How to Use This Physician Office Risk Management Guide

This guide offers practical applications of risk management concepts in the physician office setting. Not only does it include clinical matters, it also deals with legal-regulatory issues, consent, documentation practices, communication issues, employment, the environment of care, and office based surgery. The guide concludes with steps for managing risk issues in the physician office setting.

This guide is not a substitute for specific legal advice. Moreover, it is the responsibility of the person responsible for physician office risk management to develop a practice-specific risk management program and plan, taking into consideration applicable state laws, regulations, and national clinical guidelines.

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Part One – The Risk Management Process

Risk management is well known to most physicians who have treated patients in acute care facilities. Traditionally, healthcare risk management has focused on clinical matters, including consent, patient privacy, medication errors and negligence. In reality, healthcare risk management has a much broader application, encompassing business matters throughout all health service sectors, including long-term care, ambulatory care, and physician office practices.

Risk management involves identifying and managing sources of loss involving the physician practice, its employees, patients and visitors. The term “sources of loss” include physical injury, property loss or damage and financial loss.

Physician Practice risk management involves the same types of core elements as are found in other areas of the healthcare field. These core components include:

- Risk Identification.
- Risk Prioritization.
- Risk Elimination.
- Risk Prevention.
- Risk Reduction.
- Risk Minimization.
- Risk Transfer.

Many healthcare risk management professionals see their responsibilities divided between loss prevention and loss control. The former involve measures designed to avert risk exposure; the latter focuses on managing actual or potential loss exposures. Two examples demonstrate the difference between these risk management concepts.

*Loss Prevention* - a family practice office risk manager finds a biohazard receptacle unlocked on the floor in an examining room. Inside the receptacle are blood soaked pads, IV tubing and single-use drapes stained with body fluids. Knowing that children often accompany patients to the examining room, the risk manager realizes that the unlocked biohazard receptacle is a good target for loss prevention. After the risk manager made the clinical practice manager aware of the hazard, the biohazard receptacle was immediately locked and relocated to a level inaccessible by young children. The prompt action of the risk manager prevented a serious risk potential.
**Loss Control** - A severe thunderstorm caused a power failure in the area of a multi-physician practice. Within a few minutes, the practice’s lights flickered on and administrative personnel could hear the printers recycling to the stand-by mode. About ninety minutes later, at the other end of the suite of offices, a medical technologist smelled an acrid odor. She went into the lab room and found a charred power bar. Plugged into the power bar were two small vaccine refrigerators. She unplugged the power supply and summoned help from one of the doctors in the vicinity. The physician called the office manager and told her what had been found in the lab room. The facilities manager arrived soon thereafter. “I am going to have an electrician run some tests to make certain that other equipment was not impacted by the outage. This power bar is also a surge protector and it is destroyed. Have you checked the refrigerators?” he asked. The refrigerator light did not go on when the doors were opened. The thermometer inside showed that the inside temperature was above the limit for safe storage of the vaccines. The doctor spoke with the office administrator and they agreed to remove all the vaccines. The stock was logged and placed in a box for safe destruction. The insurance company was notified. Two new vaccine refrigerators and a new power surge protector were ordered from a supplier. However, before an order was placed for resupply of the vaccines, a decision was made to wait until it was determined that the electrical supply was operating properly. The practice took appropriate steps in *loss control*. Vaccines were removed from the refrigerator, logged and safely disposed. The electrical system was checked to determine if there had been more damage than the power surge bar and the two refrigerators. The insurance carrier was put on notice and steps were taken to replace the destroyed refrigerators and power surge bar. The cost estimate of replacing the vaccines, refrigerators and power surge could be furnished quickly to the insurer so that replacement costs could be calculated for the property claim.

Notice that the two examples include more than just clinical risks. In a physician office setting, risks may well involve delivery of care. However, the risks are broader, encompassing stolen or damaged property, injury to staff, and business disruption that could cause financial loss to the practice.

Sometimes the event that gives rise to a potential compensable event may also give rise to more than one type of risk. The severe thunderstorm that destroyed the power surge supply and the refrigerators led to a business disruption. The
practice was left without a viable vaccine supply. It also involved a property loss.

The physician office is a business enterprise. As such, it is amenable to a comprehensive loss prevention and loss control program. This approach is referred to as “enterprise risk management” or ERM. In an enterprise risk management program, the goal is to identify and take appropriate action involving actual and potential sources of risk or loss. For the physician office practice, the ERM approach takes into account the following risks:

- Clinical.
- Environment of care.
- Technology.
- Staff.
- Legal and regulatory.
- Financial.

Many of the examples used in this guide reflect these risk exposures.

I. The Risk Management Process in the Physician Office Practice

The risk management process can prevent loss exposure (Risk Prevention) or it can manage risk events (Loss Control). In order to take either action, the first step in the risk management process is to identify risk exposures. Recognizing that there are limited resources to fulfill risk management responsibilities in most healthcare settings, the next step is to set priorities for managing identified risk exposures. As noted earlier, risks can be managed in a number of ways, including elimination, prevention, reduction, minimization and transfer of loss exposures. The treatment of risk is informed by information gathered from a variety of sources, including quality, performance improvement, patient satisfaction, patient safety, legal and compliance data. Based on the information available, more than one method will be applied to treat a loss exposure. Once action is taken, it is important to communicate what was done to address the risk exposure in the physician office practice. The lessons learned from the risk exposure and management of it are then communicated and used to hone office practices, policies, and communication methods.
A schematic reflects steps in physician office risk management.

In practical terms, risk identification and risk treatment account for much of the risk management program in the physician office setting. To be certain, once risks have been identified and managed, the results should be shared with care providers and administrative personnel to lessen the opportunity for similar exposures in future.

A. How to Identify Risks in the Physician Office Setting
There are a number of ways in which to identify actual and potential risk exposures in the physician office setting.

- Practice risk management rounds – risks often seen in touring the physician office practice, including:
  - Unsecured drawers and cabinets in examination rooms.
  - Equipment carts with brakes in the unlocked position.
  - Toys, newspapers, and magazines left on the floor in the waiting room area.
  - Lack of polycarbonate or shatterproof glass partition in the reception area.
  - Unsecured sharps containers.
  - Unsecured biohazard containers.
- Unsecured syringes, lancets, or vials in examination or treatment rooms.
- Equipment not cleaned, sterilized or stored per manufacturer instructions.
- Unlocked lab sample collection boxes.
- Unsecured specimen refrigerators.
- Unsecured vaccine refrigerators.
- Unsecured sample medication cabinets.
- Unsecured “back doors” to the practice.
- Inoperable smoke or CO detectors.
- Inoperable fire suppressant systems.
- Inoperable AED devices.
- Inoperable or malfunctioning clinical equipment.
- Lack of disaster management plan.
- Lack of an emergency exit plan or signage.
- Use of motorized examination tables that cannot bear the weight of morbidly obese patients in the practice.
- Use of weight scales that cannot accommodate morbidly obese patients in the practice.
- Use of blood pressure cuffs that cannot accommodate morbidly obese patients in the practice.
- Chairs in the reception, waiting area or examination rooms that cannot accommodate morbidly obese patients in the practice.
- Signage about personal responsibility for personal items.
- Signage about use of mobile phones and smart phone cameras in the practice setting.

Legal and regulatory risk reviews – risks observed in documentation reviews and risk management rounds in the practice, including:
- Non-adherence to HIPAA Privacy and security regulations.
- Non-adherence to accommodation for sign language interpretation for hearing impaired patients.
- Non-adherence to provision of language interpreters for patients who do not speak English.
- Non-accommodation of sight impaired patients who cannot read print or computer text.
- Non-adherence to state laws on privacy and confidentiality of patient information.
- Non-adherence to state laws on HIV testing and/or reporting.
- Non-adherence to state laws on reporting child, spousal or elder abuse.
- Non-adherence to billing and coding requirements.
- Non-adherence to applicable laws on self-referral, kickbacks and false claims.
- Unauthorized release of patient information to third parties.
- Failure to review or inadequate review of practice contracts reviews.
- Failure to have patient transfer agreements in place.
- Failure to have a record retention schedule for clinical and non-clinical data in place.
- Failure to have record storage procedures in place to protect PHI and/or meet legal requirements regarding retention of records.
- Record migration to electronic format.
- Undefined policies and procedures with regard to record access.
- Improper patient record destruction that does not adequately protect PHI or comply with applicable record retention regulations.
- Failure to have procedures in place that speak to eDiscovery and legal holds plan for electronic records.
- Failure to have procedures in place for responding to receipt of summons or legal complaint.

➤ Clinical care risks, including:
  - Missed diagnosis.
  - Misdiagnosis.
  - Delay in care.
  - Negligent, improper or contraindicated care rendered
  - Prescribing wrong medication.
  - Prescribing wrong dose of medication.
  - Administering medications incorrectly.

➤ Clinical care follow-up risks, including:
  - Appointment logs/schedules reflecting missed appointments.
  - Missed appointments with no follow-up or rescheduling.
  - Unanticipated admission to acute care facility.
  - Laboratory test results – lack of follow-up with the patient.
  - Diagnostic imaging results – lack of follow-up with the patient.
  - Specialist reports-lack of follow-up with the patient.
Renewing prescriptions without seeing the patient –
examination required by clinical protocol.

Patient complaints – service, worsening condition, lack of
response to call, request for medical records.

Quality indicators/Performance indicators – reflecting clinical
problems.

Failure to follow-up on inquiries from community pharmacist
regarding prescribed medication.

Practice-based falls/injuries.

Clinical document risk reviews, including:

Medical record reviews – reflecting absence of required
information, incomplete medical history documentation,
unsigned consents for office-based procedures, lack of response
to laboratory, diagnostic imaging or specialist reports requiring
follow up; unanswered patient inquiries.

Discharge summaries and plans from hospitals – reflecting
change in medication or treatment plan with no action taken by
the physician practice, such as scheduling an appointment to
see the PCP.

Patient-oriented clinical information brochures that are not rated
for health literacy.

Provision of multiple types of patient-oriented information that
including data that is inconsistent from one document to
another.

Failure to document the title of the document and version
number or publication date in the medical record.

Failure to retain “retired” versions of patient-oriented
information as part of the record retention plan.

Failure to complete electronic medical record in accordance with
practice requirements.

Use of text-style language and abbreviations in the hard copy or
electronic medical record.

Failure to notate action, the date, time, and name of clinical
care provider regarding laboratory tests, diagnostic imaging or
specialist consultants’ reports in the medical record.

Communication system risks, including:

Telephone log reviews.

Secure website patient-care provider communication system
reviews.
- Computer system security.
- Back-up systems testing.
- Encryption.
- Passwords.
- Social media access and use.
- Website management.
- Mobile devices, including tablets and smart phones.
- Emergency contact with law enforcement and fire department.

➤ Employment and clinical personnel risk reviews, including:
  - Job descriptions.
  - Licensure.
  - Certifications.
  - Background checks.
  - Vaccination and PPD testing.
  - Scope of practice adherence.
  - Personnel file reviews.
  - Locums.
  - Agency personnel.

➤ Financial risks review, including:
  - Medicare payment schedules.
  - Medicaid payment schedules.
  - TRICARE payment schedules.
  - Private payer payment schedules.
  - Quality audits by private payers.
  - Insurance coverage reviews.

Risks may be identified in other ways. For example, a staff person may leave an anonymous note on the office risk manager’s desk or someone might call and leave a telephone message. Still others might send a cryptic email message. At other times, a risk may be identified in a conversation with a colleague. The point is that there are structured ways in which to identify risks in the physician office practice and more informal processes may lead to recognition of potential exposures.
B. How to Set Priorities in Office Practice Risk Management

Serious risk exposure requires a prompt response. A patient fall in an examining room, an allergic reaction to a vaccine, or disruptive, menacing behavior by a patient’s spouse all necessitates immediate action. The extent of the response should be in proportion to the evolving risk exposure. If the fall involved a 75-year-old patient who was unconscious and bleeding from a laceration above the right ear, the immediate response would be to provide first aid and call 911 for emergency transport to a nearby acute care facility.

In the case of the vaccine reaction, one would expect a clinical provider to evaluate the severity of the reaction and to provide an appropriate level of care. In some instances, the response may be to administer epinephrine, provide an antihistamine and monitor the patient until stabilized. However, if the patient’s reaction was more severe, a call to 911 would be appropriate, recognizing that oxygen as well as epinephrine and other medications may need to be administered until EMTs arrive to transport the patient to acute care.

The response to the disruptive, menacing person should be to de-escalate the situation, making certain that he or she is kept from instruments, chairs, or lamps that could be used as weapons. Speaking calmly and inviting the person to go to a quiet, secure location within the site may be prudent, since the change in location deprives the disruptive individual from access to others who could be harmed if disruptive behavior turns into violent activity. At the same time, staff can contact security or law enforcement for assistance.

In non-urgent situations that do not require an immediate response, some straightforward considerations help set risk management priorities. These include the following:

- **Likely frequency of the risk exposure** – How often is the risk exposure anticipated to occur in the physician office setting?
- **Likely severity of the risk exposure** – What type of injuries or harm are expected to arise from the risk exposure?
- **Ability to eliminate or prevent the risk exposure** – Is there anything that the practice can do to eliminate or to prevent identified risk exposures?
- **Cost of risk** – How much must be spent to eliminate or to prevent the risk exposure? What is the anticipated cost of either defending or settling a claim involving the identified risk exposure? Are there derivative consequences that will incur additional costs, such as regulatory scrutiny, professional disciplinary action, contractual disputes with private payers or reputation damage and lost market
share? Using this approach, the leadership of a physician practice may decide to suspend provision of some clinical services because the severity of risk and the inability to eliminate or prevent an untoward occurrence is outweighed by another pressing, low-risk service line. However, in a family practice, determining that there is a persistent challenge with proper hand washing by certified medical assistants might be a priority because it is a frequent risk with potentially severe consequences. Further, it is the type of risk that can be eliminated or prevented and the cost of doing so is quite low.

In acute care and other institutional facilities, additional factors may help set risk management priorities. The type of risks found in those settings may establish risk priorities that are different than those in the physician office practice. Similarly, the availability of risk management personnel, and the influence of legal and regulatory requirements may differentiate risk priorities in different healthcare delivery settings.

C. The Importance of Communicating Risk Information
Effective communication is a core element of a successful office practice risk management program. There are two general types of risk communication. The first involves “internal communication” between administrative and clinical personnel in the physician office practice. Making personnel aware of potential risk exposures and the process for handling such situations can help avert or contain loss exposure. For example, a practice leader notifies staff to follow the tornado evacuation plan after receiving an alert that a tornado has been spotted five miles from town and heading in the general direction of the medical practice. Having practiced the evacuation plan, staff members realize that this is not a drill and they quickly and calmly get patients to the basement of the medical office building.

The second type encompasses “external communication” for such matters as mandatory reporting of known or suspected child abuse, putting insurance carriers on notice in the event of a potential compensatory event, and contacting emergency response authorities such as the local EMS service, law enforcement or fire department. Depending upon applicable state law, there can be a broad range of external reporting obligations that include notification of known or
suspected elder or spouse abuse, gunshot wounds, or identified communicable disease.

There are other types of situations that trigger external risk communication. Workers compensation claims are a good example in this regard. Others may be instances of breach of protected health information through a stolen hard drive, or theft of medical equipment or controlled substances. Depending upon the nature of the event, external communication may be with regulatory or law enforcement officials.

Some situations may require both internal and external communications. Consider the following example:

Finding that as many as 100 patients may have been exposed to known pathogens due to improperly cleaned endoscopic equipment necessitates internal communication with clinical leadership as well as implementation of a so-called "look back – call back" program. In such a process, at-risk patients are identified through a chart review. A letter is then sent via certified mail notifying the patients that they may have been exposed to an infectious agent and that they need to make an appointment promptly to see the care provider. Telephone follow-up is completed within five business days with those who do not respond to the letter. When telephone communication is used, the caller asks for the patient and explains to the patient what was in the letter. If the caller does not reach the patient, the person answering the phone is asked when and where the caller could speak with the individual. If this information is not forthcoming, the caller may leave a call-back telephone number. The conversation is documented in a telephone call log and the medical record, including the time and date and the number dialed. The name of the caller — someone designated to handle the calls by the practice leader — is also recorded in the log. Staff authorities responsible for management of public health matters would also be part of the external call process. The liability insurance carrier of the practice would also be put on formal notice.

The person responsible for the practice’s risk management program should help design the internal and external communications requirements. Input should be obtained from legal counsel as well. From a practical standpoint, it is useful for these individuals to develop a communication-reporting tool that describes:

- Who should be contacted.
- Who should make the contact.
How to communicate – by phone, intranet, or in-person.
When to make a communication.
What to include in the communication.
What to document and where regarding the communication.

D. The Risk Manager for the Office Practice
For most physician practices, it is unlikely that there will be a full-time risk manager. Instead, the responsibilities of the risk manager will part of a multi-functional job involving quality, patient relations, patient safety, and regulatory compliance. This multifunctional responsibility places considerable pressure on the designated individual. It also means that in the physician office practice, colleagues and associates must be poised to serve as “deputy” risk managers in terms of identifying and managing risk exposures.

What are the necessary skills sets to serve as the physician office risk manager? The requisite skills include the following:
- Good observational abilities.
- The ability to communicate clearly in one-to-one situations and in group settings.
- Good writing skills.
- The ability to exercise good problem-solving techniques.
- The ability to evaluate and manage the response to a potential compensatory event.

In some physician practices, the person responsible for risk management will have related roles in claims management and insurance purchasing. Working with the insurance company or a third-party administrator (TPA), the physician office risk manager may help facilitate collection of and securing of equipment that is believed to have been involved in a potential compensatory event. Further, the office-based risk manager may play a key role in helping to decide what types of insurance coverage is needed for professional liability, property, business disruption, cyber risk, employment practices, etc.

The person responsible for physician office-based risk management services should have access to educational programs as well as resource tools. Such information can help the risk manager fulfill his or her responsibilities for the physician office practice.
E. Common Clinical Care Risk Exposures in the Physician Practice Setting

Whether it is a large multi-specialty group or a small physician office setting, there are a number of common clinical care risk exposures. Although the physician office risk manager should not focus just on these exposures, preemptive action may thwart several types of potential compensatory events.

Common clinical risk exposures include:

- **Missed diagnosis** – a patient comes to the family care practice with complaints of indigestion, pressure in the upper right quadrant, and fatigue. The problem started 10 days earlier. The physician assistant diagnoses gall bladder disease and refers the patient to a GI specialist. Two days later, the patient experienced a massive myocardial infarction requiring emergency triple bypass surgery. The medical record in the family practice reveals that at no time did the physician assistant consider the possibility of a cardiac problem. The patient never had an electrocardiogram at the family care practice.

- **Misdiagnosis** – A three year-old child was seen by a care provider in a pediatric practice. The presenting complaint was temperature, a sore throat, a persistent cough and temperature. Three other children in the same preschool had been diagnosed with croup. The care provider told the parents to place a cool air humidifier in the child’s room and to administer saline nasal drops to break up any mucous congestion. Three hours later, the child was rushed to a hospital emergency department with severe breathing problems and was admitted for treatment. The child had been misdiagnosed with croup. In fact, she had epiglottitis.

- **Delay in care** – a newborn was discharged to home with jaundice and an elevated Bilirubin level. The pediatrician did not think the laboratory values warranted use of phototherapy. However, a visiting nurse was scheduled to see the baby at home. The nurse observed that the infant was lethargic and not feeding well. The baby was scheduled to see the pediatrician in two days. The visiting nurse told the mother to keep an eye on the infant and if the baby’s condition became worse, to call the pediatrician. Later that day the mother called the pediatrician’s office three times over the course of six hours.
During the first two calls she spoke with a nurse who told her that the baby’s response was not unusual. On the third call, a different nurse spoke with the mother and realized that the baby’s condition had worsened and needed immediate care. She told the mother to take the child to the emergency department. The baby’s condition was life-threatening. She was flown to a pediatric hospital for treatment. Unfortunately, the delay in care made it impossible to save the child.

- Failure to follow-up on worrisome laboratory tests or diagnostic imaging results – A patient on warfarin therapy had an INR blood test that revealed that he needed to reduce his dose immediately. The blood study was done in the lab down the hall from the cardiology practice. Even though the test result was reported immediately to the cardiology practice, the temporary medical technician failed to inform the cardiologist and the same medical technician did not enter the information into the patient’s medical record until the next afternoon. Seven days later, a hospitalist called the cardiologist to tell him that the patient had been admitted to the hospital with severe abdominal pain and internal bleeding. The hospitalist wanted to know why the patient had been placed on such a high dose of warfarin. The cardiologist reviewed the patient’s record and found the problem. He had never seen the lab report per office practice. It appeared that the internal bleeding could have been averted had the warfarin dose been adjusted earlier.

- Failure to follow-up on consultant’s reports that recommend further testing or treatment – a radiologist’s report sent to a family medicine practice contained a recommendation for more in-depth diagnostic testing to rule out lung cancer. The family medicine doctor never saw the report as it was received while she was on vacation. Six months later, the patient came to see the family medical doctor complaining of difficulty breathing, becoming fatigued after walking a flight of stairs, and a persistent cough. The family medical doctor reviewed the patient’s record and saw for the first time the consultant’s report and recommendation. By the time the follow-up diagnostic tests were completed, the lung cancer had spread and become inoperable.

- Failure to follow-up on missed appointments – a patient with a history of bipolar disorder, self-abuse and violence towards his spouse had been what was considered a model patient, keeping appointments, following the prescribed medication regimen, and participating in regularly therapy sessions with a clinical psychologist. The situation
changed when the patient missed three scheduled appointments with the clinical psychologist and failed to keep a scheduled session with the psychiatrist who prescribed anti-depressant and anti-anxiety medication. The psychologist and psychiatrist worked as a team in the same practice. Although both realized that there had been a change, with the patient missing several appointments, no effort was made to find out why there had been such a behavioral change. No wellness follow-up calls were made to the telephone number provided by the patient and no letters were sent to the individual’s residence. Two weeks later, the psychiatrist in the local hospital behavioral unit called the practice and spoke with the clinical psychologist. He told him that the patient had been admitted for evaluation and treatment. He had tried to strangle his spouse and then slashed two police officers with a knife when they tried to arrest him. The patient had stopped taking his medication. The inpatient psychiatrist said, “You knew this fellow had violent propensities. Why didn’t you try to find out what had happened when he missed all those appointments?”

- Prescribing or renewing prescription medication without seeing the patient – A 26-year-old woman on oral contraceptive medication spoke with the nurse practitioner in the obstetric practice. She explained that it was really difficult for her to come in for a check-up in order to get a renewal of her contraceptive prescription. “Just call it in to the pharmacy or send it electronically. I promise when it is going to run out next time I will make an appointment,” she said. The nurse practitioner said, “Well, it is not a good idea. This is the third time you have asked us to do the same thing. You need an evaluation first. We have not seen you in a year. I will send electronically a two-week prescription refill to the pharmacy. Unbeknownst to the nurse practitioner, the patient had been having pains in her right calf. Three days later, the patient was found unconscious by her husband. She had suffered a stroke due to a deep vein thrombosis, resulting in a left-sided paralysis.

- Medication error – A neurologist sent electronically a prescription to a local pharmacy for a patient suffering from the residual effects of a longstanding neurological problem. The drug ordered was a generic version of a brand-name pharmaceutical and it was relatively new. It contained an ingredient to which the patient was known to be allergic. However, the neurologist did not know that the allergy-producing ingredient was in the compound. The software used to detect
medication allergies at the pharmacy had not been updated to include the new generic version of the drug. The woman took the loading dose of the generic preparation and experienced a severe allergic reaction requiring hospitalization.

There are many types of clinical risk exposures in a physician office practice. The goal of the risk management program should be to avoid such occurrences.

There are a number of core policies and procedures that should be in a physician office risk management policy and procedure manual. The content should include pertinent clinical, administrative, employment, disaster management, financial and regulatory policies and procedures. A sample list of such policies and procedures includes the following:

- Patient intake and reception
  - Advice of Beneficiary Notice (ABN) Medicare.
  - Advice of beneficiary notice regarding third party payers.
  - HIPAA Acknowledgement.
  - Authorized third-party communication (spouse, parent, significant other, etc.).
  - Practice signage.
  - Practice website.
  - Practice brochure.
  - Expectation about hours of operation and closure for weather events and holidays.
  - Scope of practice.
  - Accepted ways for communication in the practice with patients (landline, cell phone, text messaging, secure email site or written correspondence).
  - Prohibition on emailing care providers in the practice.
  - Personnel delivering services in the practice.
  - Presence of medical students, residents or nursing students.
  - Policy on mandatory reporting to state authorities.

- Patients’ Rights and Responsibilities
  - Rights and responsibilities statement.
  - Use of medical interpreters.
Use of sign language interpreters.
- Appointments.
- Responding to test and consultant report notifications.
- Prescription practices – e-prescribing.
- Prescription practices – telephone renewal of prescriptions.
- Appointment cancellation.
- Missed appointments.
- Consent.
- Third-party consents.
- Refusal of consent.
- Use of chaperones.
- Financial responsibility.
- Use of cell phones and smart phones in the practice.
- Non-adherence to care plan.
- Termination of provider-patient relationship.

#### Clinical Care
- Scope of authorized tests and treatments in the practice.
- Use of pre-signed prescription pads prohibited.
- Personnel authorized to communicate with community pharmacies, consultants, laboratories, or diagnostic imaging centers.
- Use of black box warning medication – consent, patient instruction and teach-back.
- Home care instructions for patients and familial care providers.
- Patient health information brochures, pamphlets and information sheets – consistent information with version number documented in the patient record; health literacy.
- AED.
- Emergency Kit.
- Transfer plan to acute care facility.
- Look back-call back.

#### Personnel and Employment Practices
- Job descriptions.
- Mandatory training – privacy, confidentiality, and boundary issues, HIPAA, personal use of practice equipment, etc...
- Scope of practice, including use of midlevel providers with and without supervision.
- Hiring process – including background checks.
- Health screening for personnel.
- Certifications.
- Licensure.
- Agency personnel.
- Locum tenens.
- Students shadowing care providers in the practice.
- Temporary personnel.
- Confidentiality agreement – all personnel, agency staff and students.
- OSHA requirements under applicable state law.
- Gloving and disposal of used gloves.
- Vaccination policy for staff.
- Working while sick.
- Vacation scheduling.
- Key person continuity.
- Use of social media by personnel – authorized and unauthorized practices.
- Termination of employees.

➤ Environment of Care

- Safety.
- Security.
- Americans with Disabilities Act (ADA) accommodation for morbidly obese patients – motorized examination tables, weight scales, blood pressure cuffs, chairs, toilets, doorways and wheelchairs.
- Security of pharmaceuticals, syringes and other devices used in the practice.
- Infection Control.
- Use and disposal of sharps.
- Use and disposal of biohazards.
- Storage collection for lab pick-up.
- Cleaning and sterilizing equipment.
- Hand washing.
- Panic button.
- Physical security in reception and intake actions.
- Managing disruptive individuals in the practice.
- Response to emergencies in the practice – falls, allergic reactions, cardiac arrest, seizures, etc.
- Disaster management – plan, drills, for storms, fire, disruptive or menacing individuals and safe evacuation.
Red tag waste – bagging, securing, and disposal.

Documentation and Information Systems
  - Contents of legal health record for the practice.
  - Use of electronic platforms.
  - Scanning of hard copy into electronic forms.
  - Password policies – frequent change; immediate “stop” after termination of employee or agency personnel.
  - Record access.
  - Record use.
  - Record retention.
  - Legal holds.
  - eDiscovery.
  - HIPAA Privacy and Security.
  - Restrictions on use of unencrypted email.
  - Remote back-up systems.
  - Penetration testing.
  - Breach notification.
  - Use and maintenance of practice website.
  - Sharing of quality indicator data with third parties and use of such information on third party websites.

Potential Compensatory Events - Legal-Regulatory
  - Contract negotiation and management.
  - Identifying and managing potential compensatory events.
  - Response upon receipt of formal summons or complaint – medical malpractice, state board disciplinary proceeding, federal or state fraud and abuse control unit, demand for records or computer hard drives; CMS RACs inquiries).
  - Managing allegations of physical abuse or neglect.
  - Managing allegations of personal property or practice theft, loss or damage.
  - Notification of insurance carriers – including all layers in an insurance program; captive manager or RRG; workers compensation process.
  - Mandatory reporting – for example, child abuse, spousal or elder abuse and, in some states, gunshot or stab wounds, and certain communicable diseases such as TB, HIV/AIDS; contact tracing notification for STDs.

Insurance and Business Management
Insurance coverages – professional liability, business disruption, equipment, property, workers compensation, cyber risk earthquake (in areas prone to earthquakes), flood (in recognized flood zones), personal lines and key person coverage.

- Use of Third-Party Administrators (TPAs).
- Management of MMSEA III reporting.
- Continuity of service plan.
- Media management.

Financial
- Risk financing.
- Claims processing – including payment data by Medicare, Medicaid or private payers.

Some practices will need additional risk management-oriented policies and procedures. These include practices providing diagnostic imaging, radiation therapy, and office-based surgical services. Several states have specific laws and regulations or guidelines that focus on radiological and office-based surgical practices that should be considered in designing physician practice risk management policies and procedures. A sample list of risk management policies and procedures for such enhanced services include:

- **Patient Selection – Office-Based Surgery**
  - Patient selection/Pre-operative screening.
  - Consent for office-based surgery.
  - Staff scope of practice.
  - Use of contracted services – anesthesia and first assistant.
  - Patient monitoring.
  - Surgical time out.
  - Discharge planning with teach-back.
  - Accompanied patient requirements – no discharge to a taxi or bus service, confirmation of designated driver.
  - Emergency management.
  - Transfer agreement plan.

- **Diagnostic Imaging – office-based practice**
  - Staffing.
  - Scope of practice.
  - Infection control and maintenance of equipment.
o Encryption and PACS requirements.
 o Patient screening – pregnancy, ferrous metal, claustrophobia.
 o Pediatric patients – who can be in the CT room; pediatric sedation for MRI.
 o Use of contrast dye – allergies, contraindications.
 o Emergency management.
 o Transfer agreement plan.

➢ Radiation Therapy – office-based practices
 o Staffing.
 o Scope of practice.
 o Infection control and maintenance of equipment.
 o Equipment and dosing calibration.
 o Encryption.
 o Consent.
 o Clinical trials – protocols, consent, adverse event reporting.
 o Notification – under dosing or overdosing.
Part Two – Applied Risk Management in the Physician Practice Setting

II. Patients’ Rights and Responsibilities in the Physician Practice Setting

A. Setting Patient Expectations
Recognize that the reception and intake of patients plays a pivotal role in setting expectations about the physician office practice. It is also an opportunity to fulfill regulatory requirements dealing with patient health information, responsibility for payment, and the scope of services furnished in the physician office practice. At the same time, reception and intake provides an opportunity to make patients aware of who may be providing services to them when receiving treatment.

Risk Exposures:
- Regulatory non-compliance.
- Breach of contract.
- Negligent delay in care.

Risk Management Strategies
Utilize reception and patient intake opportunities to provide a clear message about the services provided by the physician office practice and to specifically define the role and responsibility of patients. Risk management strategies for this purpose include the following:
- Determine if patients require the services of a language interpreter, including sign language interpretation.
- Provide qualified individuals to serve as language interpreters, whether in-person, by telephone or via Internet-based services.
- Follow applicable HIPAA Privacy acknowledgement procedures, making certain that patients have an opportunity to read the acknowledgement or have qualified individuals do so.
- Follow applicable Advice of Beneficiary Notice or “ABN” requirements for Medicare patients that notify them of their responsibilities if services are not included in the Medicare Program.
- Follow similar practices for “ABN” information for private payers, including Medicare “Gap” payers.
- Obtain written authorizations for:
  - Emergency contacts.
o Sharing information with designated individuals, noting their relationships, if any, with patients.
o Sharing information with other physician practices and care providers.
o Inclusion and opt-out by patients under applicable state law for Health Information Exchanges or HIEs.

➢ Provide patients with clear notices regarding the requirement to make mandatory reports under applicable state law for:
o Known or suspected child abuse or neglect.
o Known or suspected elder abuse and neglect.
o Known or suspected spousal abuse and neglect.
o Gunshot or stab wounds.
o Certain communicable diseases.
o Serious threats of self-abuse or harm to other individuals.

➢ Develop a consistent message regarding “Patients’ Rights and Responsibilities” in the physician office practice brochures, website or social media pages, or in telephone messages, regarding:
o Hours of operation.
o Weather-related closings notification process.
o Call-back timeframe.
o Prohibition (or “rules”?/) on the use of email messaging with care providers.
o Use of cell phones or smart phones in the practice, including taking photos or videos of the patient, practice, staff or visitors.
o Cancellation policy – typically no less than 24 hours prior to a scheduled appointment and notification that untimely cancellations will result in a financial charge if applicable (list the amount).
o Scope of practice and services, including care providers who examine and treat patients.
o The right of patients to refuse participation of medical students, medical residents, nursing students or others in observing or participating in their care.
o Patients’ access to their medical records, including any fee for providing copies of such records.
o The right of care providers or patients to ask those accompanying patients to the practice to step outside examination rooms. [See strategy for use of chaperones.]
o Unacceptable behavior in the waiting room and treatment areas.
o Termination of the care provider-patient relationship for:
- Disruptive or threatening behavior.
- Repetitive missed appointments.
- Non-adherence to agreed-upon care plan.
  - Patient satisfaction surveys.
  - Patient complaints.
- Verify that information about the practice is field-tested to meet recognized parameters for health literacy.
- Verify that information about the practice in printed format is minimally set at 12-point font and ideally larger for those with low vision.
- Verify that there is a process in place to have the information read to patients with low health literacy or visual impairment.
- Verify that the information is made available to patients in a language they can comprehend.
- Include in the attestation signed by the patient regarding HIPAA and billing a statement confirming that he or she has received information about the scope of the practice, hours of operation, and patients’ rights and responsibilities.

**Case Example:**
Vinny Stanza, a 23-year-old plumbing supply clerk developed a cough that would not go away. At first he thought it was an allergy, but it persisted for a few months. When he started to have night sweats and chills and he coughed up blood-tinged sputum, he went to see his primary care provider, Dr. Lipton. Vinny was seen by Ted Belles, a Physician Assistant in the practice. “You do not smoke and you do not use recreational drugs, is that correct?” asked Mr. Belles. “Yes, that is right,” Vinny said. “Has anyone at work had the same type of symptoms?” asked Mr. Belles. “Yeah, this kid who worked with us for a short time over the summer — a college kid— he spoke funny English, you know. He was originally from Costa Rica,” Vinny said. After completing a physical examination Mr. Belles said, “I am going to order a chest x-ray and I am going to do a TB test. It is a little patch test. You will come back and I will review the results with you. I just want to make certain that we have a good idea of what is happening with this cough,” said Mr. Belles. Vinny agreed to have the chest x-ray done in three days when he had some time off. He arranged with Mr. Belles to review the patch prior to the x-ray. When Vinny came back, the patch test revealed that he has tuberculosis. “Okay, this tells us a lot, Vinny. We need to get you to the right level of care and there will be further testing, including chest x-rays. I will also notify the state Department of Health,” Mr. Belles said. “Wait a minute. You are reporting me to the state? You must be joking,” Vinny said.
“No Vinny. I am not joking. This is serious stuff. We are required to do so. It is not to punish you; it is to help contain the spread of the disease,” said Mr. Belles. He continued, “In fact, it is right here in the practice brochure that you received some time ago about our obligation to report certain communicable diseases to the state. Right now I think we need to focus on what you need to help get you back to health.”

Applying Risk Management Strategies:
- Establish clear expectations about patients’ rights and responsibilities, utilizing a consistent message in practice brochures, on websites and social media pages.
- Use the patient attestation statement to confirm receipt of information about patients’ rights and responsibilities.
- Make certain patients have an opportunity to read information about patients’ rights and responsibilities and provide accommodation for those with low health literacy, language interpretation needs, or low vision.
- Reiterate specific expectations set forth in patients’ rights and responsibilities information, particularly when patients challenge actions that care providers are obliged to take, such as mandatory reporting of a communicable disease to state public health authorities.

B. Care Provider-Patient Communications
The range of communication tools available today can present challenges for the physician office practice. Text-only phones, so-called “throw away” one-way cell phones, traditional cell phones, traditional landline phones, social media and email may be used by some patients. Determining how the practice will communicate with patients can help avoid missed receipt and miscommunication of important information. At the same time, some practices are using new technology that places responsibility on patients to check back for test results and follow-up instructions. These technologies include providing patients with a toll-free telephone number and patient PIN number or a secure website that requires entry of a username and password. The care provider can leave a detailed voice message on the secure telephone service or detailed information on the secure website. In each instance, once the patient accesses the information, it is date- and time-stamped, making it virtually impossible for patients to later say that they did not know about test results or the need for follow up. Yet another option is to obtain from the patient at intake and
reception permission to leave specific information on a voice-mail system or to speak with a designated individual at the patient’s preferred phone number.

**Risk Exposures:**
- Delay in care.
- Delay in follow-up required due to communication breakdowns about lab, diagnostic imaging or consultations reports.
- Patient complaints.

**Risk Management Strategies:**
- As part of patients’ rights and responsibilities information provided at intake and reception, identify the way(s) in which providers should communicate with the patient.
- Make it clear that patients using one-way cell phones or throw-away cell phones will not receive communication from the practice on those phones.
- Make it clear to patients with text message-only cell phones that the only information provided will be to contact the provider’s office for information.
- Document in the medical record when text message-only information is sent to patients, including the date, time, and text-phone number.
- Obtain permission to leave voicemail messages on the telephone number provided by the patient, noting that the message will be “This is the [Name of Practice] calling for [Name of Patient]. Please call the office at [Practice phone number] for further information.
- Document in the medical record when voicemail messages are left on the number provided by patients, including the date, time, and phone number.
- Obtain permission to speak with designated individuals to leave a message for the patient to call the practice for further information.
- Document in the medical record when messages are left with designated individuals, including the person’s name, the date, time, and phone number.
- Consider use of a secure telephone number that patients can dial and use a PIN number to retrieve messages from care providers regarding their test results and required follow-up. Ensure that this system date and time-stamps access by the patient.
- Consider use of a secure website that patients can enter with a username and PIN to retrieve messages from care providers regarding their test
results and required follow-up. Ensure that this system date and time-stamps access by the patient.

- During intake and reception at each visit, ask patients if the way in which they wish to receive communication has changed, including new telephone numbers. Document any changes in the medical record.

**Case Example:**
Twenty-six-year-old Roxanna Mason had given up her expensive cell phone plan and changed to a text-only program. However, she kept the same telephone number. When she went to her family physician for a check-up, she was asked, “Has any of your contact information changed, including your telephone number?” She replied, “No.” Ms. Mason had declined to provide names of individuals for emergency contact. She had a family history of early onset cardiovascular disease. When the family physician received Ms. Mason’s laboratory report, she was alarmed to see a demonstrable change in the LDL and triglyceride levels. The LDL was now 250 mg/dL and the triglyceride level was 375 mg/dL. “Please call Ms. Mason and tell her we need her back for follow-up,” the family doctor said to the LPN. The LPN tried several times to leave a voice-mail message on the number provided by Ms. Mason. Each time, she received a pre-recorded message, “This number is no longer in service.” The LPN told the family practitioner and a letter (return receipt requested and postal mail) was sent to Ms. Mason telling her it was urgent that she contact the family practitioner regarding her recent laboratory results. A copy of the letter and return receipt confirmation was entered into the patient’s medical record. The patient called five days later. It was at this point that the practice learned that Ms. Mason had switched to a text-only phone plan.

**Applying Risk Management Strategies:**
- Ask the right drill-down questions to get a precise understanding about telephone communication methods with patients, including if the telephone used is text-only, a one-way cell phone or a “throw away” cell phone.
- Ask specific questions about changes in telephone communication, and in particular, a switch to a text-only cell phone, a one-way cell phone or a “throw away” cell phone as well as any change in telephone number.
- When resorting to sending a letter to a patient with whom the practice cannot establish telephone communication, consider sending the correspondence by certified mail with return receipt, especially when the nature of the correspondence involves important clinical information.
- Document in the medical record the method of delivery used for written communication in lieu of telephone communication.
- Consider use of a secure telephone message system or a secure website from which patients are obliged to retrieve information about their test results or follow-up information.

C. Use Of Chaperones In The Physician Office Practice
Traditionally, chaperones have attended clinical examinations of female patients by male care providers. Today, however, it is not uncommon to find chaperones for female care providers conducting examinations of male patients. It is also a recognized practice for care providers of either gender to complete examinations of older children and adolescents with a chaperone present, even when a parent is not present. Although having a chaperone attend an examination serves to provide a level of protection against allegations of unauthorized or unwelcome touching of the patient, there are times when patients do not want another person present. They may wish to discuss intimate matters with the care provider and the presence of another individual thwarts such discussion. Many care providers feel it is prudent to give patients a choice about the presence of a chaperone. Others take a different approach, making it clear in patients’ rights and responsibilities information that a chaperone will be present during any physical examination.

Risk Exposures:
- Allegations of inappropriate touching, sexual molestation or assault.
- Professional licensure action.
- Patient complaints.

Risk Management Strategies:
- Establish a policy for the practice on the use of chaperones, identifying who may fulfill this role.
- Provide orientation and training for those identified to serve as chaperones.
- Incorporate into patients’ rights and responsibilities information that chaperones are used during clinical examinations, noting if there are exceptions, for example, when parents are present during clinical examinations in lieu of a staff member serving as a chaperone.
Recognize that some patients may decline to have a chaperone present. Educate staff about possible cultural and religious practices that may present a barrier to agreeing to have a chaperone present or what type of chaperone is acceptable. Determine if this is acceptable in the practice.

Document when a patient declines to have a chaperone present.

Document the name and role of the chaperone who does attend clinical examinations with patients.

Offer patients the opportunity to discuss sensitive or intimate matters privately in the office setting, rather than while disrobed in the clinical examination setting.

Case Example:
Twelve-year-old Dennis Belcamp came to the practice complaining of pain in the groin area. He had been lifting weights in the basement when he felt a sudden burning pain. He also noticed a lump in his groin the next morning. He told his parents what had happened and Mrs. Belcamp got Dennis an appointment with Dr. Mark Nichols, a pediatrician in the River Pediatrics Practice. Dr. Nichols first met with Mrs. Belcamp and Dennis and learned what had brought them to the office. “Okay Dennis, you need to take off everything from the waist down and put on this gown. It ties in the back. You can keep your socks on Dennis. I will be back in a few minutes to examine you,” said Dr. Nichols. Dennis said, “Mom, you have to leave.” Mrs. Belcamp was surprised. Dr. Nichols intervened and said, “Mrs. Belcamp, Dennis is an adolescent now. I think we ought to respect his request. I will have a chaperone in the room. Dennis, this means that one of the nurses will be in the room with us, but she will not be viewing your private parts. Okay?” Dennis agreed. After the examination Dr. Nichols asked Dennis to get dressed. “I will come back in after you put on your clothes and I am going to ask your mother to join us.” Dennis agreed. The doctor told them that Dennis had a hernia and that he needed to be seen by a pediatric surgeon for a surgical consultation. He explained to Dennis and his mother what the surgeon might recommend. He gave the Belcamp the names of three surgeons to consider. After they left the office, Dr. Nichols dictated a note in the medical record, including the name of the chaperone who attended and the recommendation to see one of the three pediatric surgeons suggested to the Belcamps.

Applying Risk Management Strategies:

Provide information about the practice chaperone policy in patients’ rights and responsibilities information.
➢ Provide a process for discussing with parents of older children and adolescents the use of a chaperone during clinical examinations in lieu of having a parent present.
➢ Listen to the pediatric patient’s request not to have a parent present.
➢ Provide an opportunity for the pediatric patient and parent to discuss findings and recommendations after the clinical examination has been completed.
➢ Document the use of the chaperone and the name of the person fulfilling this role.
➢ Document how the situation is handled when a pediatric patient requests the parent to leave when disrobing and during the clinical examination.

D. Termination Of The Care Provider-Patient Relationship
Sometimes it is not possible to have an effective care provider-patient relationship. Patients refuse to keep appointments, refuse to undergo agreed upon tests or see specialists. At other times patients ignore agreed upon care plan requirements such as dietary changes and medication regimen adherence (including pain medications). Steps can be taken to try to rectify such unacceptable behavior. Sometimes, however, it is not possible to resolve the matter and the most prudent step is to terminate the care provider-patient relationship. There can also be situations where there is physical confrontation, verbal abuse, intimidation, threatened violence or actual acts of violence by patients or their family members. In such instances, a summary termination of the relationship is warranted. Knowing how to manage the termination is important in order to avoid allegations of patient abandonment.

Risk Exposures:
➢ Legal action for abandonment.
➢ Professional license action.
➢ Patient complaints.
➢ Adverse publicity.

Risk Management Strategies:
Expectation setting and effective communication skills may help avert the need to terminate patients for non-adherence. Information about patients’ rights and responsibilities should make it clear that the practice will terminate the care provider-patient relationship when patient behavior or non-compliance with
agreed upon treatment plans indicates that it is time for the individual to seek treatment elsewhere. Should termination become necessary, it is important to give the non-adherent patient notice, to suggest the names of other practices that may be willing to take on new patients, to maintain availability to see the care provider during the notice period, and to make available to the successor care provider medical record information. For situations in which there is a summary termination, there is no need to provide advance notice. The patient should receive written information giving the reason for the abrupt termination from the practice. In particular, the following strategies may provide useful:

- Establish expectations for the successful care provider-patient relationship in patients’ rights and responsibilities information, early in the relationship.
- Make clear to patients what will serve as the basis for terminating the care provider-patient relationship, including a pattern of missed appointments, short-notice cancellations, non-adherence to agreed-upon tests or treatment or violation of written agreements such as controlled substance pain management contracts.
- Consider using a step-wise approach, first giving the non-adherence patient notice that current behavior is unacceptable and that the care provider wants to discuss the situation with the patient. Note that this is a counseling-style session that should then be documented.
- Provide the patient with a written summary of agreed-upon changes subsequent to the counseling session. Include in the written summary what the consequences may be if there is non-adherence.
- Consider use of a case manager from the patient’s health plan and/or a social worker in the physician practice to help resolve non-adherence to agreed-upon changes from the first counseling session.
- Document the results of the second session, noting the names and positions of the participants and agreed-upon changes.
- Provide the patient with a written summary of this second notice, the agreed-upon changes, and specifically that if there is continued non-adherence, termination will be necessary.
- Send termination for continued non-adherence letters via certified or registered mail, with return receipt requested. Recognize that a courier may be used with delivery confirmation. Note in the termination letter that the patient has thirty days from the date of the correspondence to find a new care provider. During that time, the current care provider will continue to furnish medically necessary care. Consider providing the names of other care providers in the community who may be willing to accept new patients. Offer to provide a copy of the patient’s record to the
new care provider. A copy of the letter should be kept in the patient’s record.

- Send a notice of summary termination via certified or registered mail, with return receipt requested when a patient or family member is verbally abusive to staff, to visitors, or threatens physical harm or causes physical harm to individuals or property in the practice. A courier may be used with delivery confirmation. Tell the patient to seek care elsewhere and that medical record information may be requested in writing to be sent to a successor care provider. Make clear in the letter that the patient or family member should not come to the office. A copy of the letter should be placed in the patient’s record.

**Case Example:**
Dr. Aiden was a popular internal medicine specialist in town. He was known for taking his time with his patients and answering their questions. Twelve months ago, a new patient entered the practice, Trent Williamson. Mr. Williamson was not a forthcoming individual. Mr. Williamson had a history of hypertension and cigar smoking. Although Dr. Aiden had tried three different types of anti-hypertensive medication with Mr. Williamson, none of the pharmaceuticals had resulted in getting the patient’s blood pressure within normal limits. “Are you certain that you have been taking your medication the way you were instructed to do so?” asked Dr. Aiden. Mr. Williamson nodded in the affirmative. “Have you cut back on the salty food, the beer, and the cigars?” asked Dr. Aiden. Mr. Williamson said, “Yes. What seems to be the problem?” Dr. Aiden explained that it was highly unusual to see the patient’s blood pressure go up when taking such powerful medication. He also explained the health risks associated with not following the medication and dietary plan. “I will want to see you more frequently over the next few months. We might need a consultation with a specialist for further evaluation,” said Dr. Aiden. Mr. Williamson missed three of the five scheduled follow-up appointments. He was called by the office to see if anything was wrong. Each time Mr. Williamson told the receptionist, “No. Just kind of busy.” When he did come in for an appointment, Mr. Williamson’s blood pressure was higher than his last visit. He had an odor of cigar smoke on his clothing and his breath smelled of alcohol. The receptionist said, “Mr. Williamson, it is our policy in the practice to charge the regular co-pay for missed appointments unless we have received a cancellation within 24 hours. Since you did not give us notification, you would be charged the regular co-pay for the three missed appointments and today’s visit. The total is $100.00. How would you like to pay it Mr. Williamson?” Angry, Mr. Williamson said, “This is robbery.
You tell that Dr. Aiden that he can go to hell. I am done with the lot of you.” Mr. Williamson took the pen he had been using to complete the intake reception form and threw it at the intake window and he left the office. The scene was witnessed by three other patients in the waiting area who admitted later to the practice manager that it had been very disturbing. Dr. Aiden sent a letter of summary termination to Mr. Williamson. In the letter, he pointed out the threatening behavior was unacceptable, and that his behavior was witnessed by several patients who were very upset by it. The letter stated in part, “Your actions were contrary to the Patients’ Rights and Responsibilities acknowledgement that you signed when you first came to this practice a year ago. Please arrange for another care provider to treat you. Do not come to our office again.” The letter was sent via courier and the practice leader received an electronic delivery confirmation.

**Applying Risk Management Strategies:**

- Provide patients at intake and reception information about the consequences of abusive, threatening or violent behavior.
- Include in the Patients’ Rights and Responsibilities acknowledgement, notice of the possibility of summary termination for abusive, threatening or violent behavior.
- Recognize that sometimes non-adherence on the part of a patient can escalate without warning to abusive, threatening or violent behavior.
- Send a letter of summary termination from the practice to the patient using certified or registered mail with return receipt requested. Alternately, use a courier service with delivery confirmation.
III. Consent To Treatment

A. Basic Elements of Consent
Consent to treatment is part of the foundation of the care provider-patient relationship. Premised on a two-way conversation in which the care provider and patient share relevant information, the discussion should culminate in an agreed-upon care plan. Prior to the care provider-patient consent communication process, it is useful to identify special communication needs, such as the use of sign language or foreign language interpreters. Consent to treatment is not a written form. Rather, it is the agreed-upon action steps that will be followed by the care provider and the patient. In some instances, it may be “watchful waiting” for patients with a slightly elevated PSA level. In other instances, it may be an order for diagnostic imaging. On the part of the patient it may be to adhere to a new diet and exercise plan. The medical record should reflect the discussion and the agreed-upon plan of action. In some situations, however, a consent form may be used to memorialize the conversation. This is particularly so in jurisdictions that require consent documents and for invasive office-based procedures or prescribing high-risk drugs. It is also important for care providers to complete an informed refusal of recommended or alternate tests or treatment.

Risk Exposures:
- Negligent consent litigation.
- Battery litigation.
- Unprofessional conduct allegations under state licensure board requirements.

Risk Management Strategies:
Successful consent processes begin with identifying and managing specific communication needs. Asking the right drill-down questions to obtain a complete medical history can help the care provider develop a patient-centered care plan. Setting expectations is another key matter. Having completed the consent process, the care provider should do a “systems check,” asking patients questions to confirm understanding of the agreed-upon care plan and also to assess expectations of care. If patients verbalize inaccurate information or
unrealistic expectations, further discussion is warranted. The consent communication process should be documented in accordance with applicable state law and the practice policy and procedure. Specific risk management strategies for consent include a number of steps:

- Identify and manage specific patient communication requirements, including:
  - Sign language interpretation.
  - Foreign language interpretation.
  - Voice volume and tone for hearing impaired individuals.
  - Large print font for low-vision individuals who will be asked to review printed material. Alternately, consider a high-power vision device. Recognize that patients with especially poor visual acuity should not be asked to use assistive vision devices to see graphs, photographs, charts, or text. Verbalization of descriptive information should be considered as an option.
  - Low health literacy accommodation may include use of photographs and diagrams or verbalization of descriptive information. Note that low health literacy for printed material may be an indicator to assess grade-level comprehension skills for written information read verbatim to the patient.

- Ask drill-down questions to obtain accurate patient history. Instead of asking, “Do you take medication?” pose the question as “Beside prescription medication, do you use any over-the-counter products such as aspirin, Tylenol, vitamins, herbal or natural supplements?”

- Follow applicable state law in obtaining patient consent to treatment.

- At a minimum, recognize that the consent communication should include:
  - An explanation for recommended tests or treatment.
  - A description of recommended tests or treatment.
  - A description of probable benefits and probable risks of recommended tests or treatment.
  - A description of diagnostic or treatment alternatives, including the probable benefits and probable risks of such options.
  - An explanation of the probable consequences of declining recommended and alternative tests or treatment.
  - Provide responsive answers to patient’s questions.

- Ask questions of the patient to make certain that there is a clear understanding of information shared during the consent communication process. Note that this is sometimes called the “Teach Back” process.
Complete an informed refusal process when a patient decides not to pursue either recommended or alternate forms of tests or treatment.

Confirm patient understanding of agreed-upon tests or treatment, asking the patient to verbalize his or her understanding of the tests or treatment and the anticipated outcomes of care.

Document the consent communication process in the medical record.

Ask legal counsel to provide information regarding state law requirements for tests or treatment that require a written consent form. Make certain that such consent documentation is completed when required to do so.

Ask the patient sign a consent document for in-office surgical procedures.

Ask the patient to sign a consent document for use of high-risk procedures or therapies.

Consider use of a patient information tool that provides information about side effects or risks of agreed-upon medication therapy as well as pertinent warnings about possible food-drug and drug-drug interactions and the risks of abruptly stopping prescribed medication.

Recognize that sometimes patients are not able to make their own treatment decisions and that a duly authorized legal representative or legal guardian may do so for the patient.

Involve to the extent possible the decisionally incapable patient in the consent communication process, in order to obtain relevant history information and to evaluate the practicality of a treatment plan involving medication and dietary adherence.

Involve to the extent possible young children in the consent process for their treatment, in order to obtain pertinent history as well as acceptance and participation in the agreed-upon care plan.

Document in the medical record when a legal guardian or parent is the decision-maker and the degree to which the patient was involved in the consent communication process.

Encourage with patient permission when indicated the involvement of a spouse or partner in the consent communication process, recognizing that such individuals may provide useful clinical information and help identify the likelihood of treatment plan adherence.

Document in the medical record when a spouse or partner is authorized by the patient to participate in the consent communication process. Indicate the degree to which the spouse or partner took part in the discussion.

Note in the medical record if decisional tools were used in the consent communication process.
Note in the medical record if the patient was provided with written information about the agreed upon test or treatment, including the title and version number of the tool.

Note in the medical record if the patient was provided with a list of trusted websites to review as part of the consent communication process, including the website addresses.

Document in the medical record any follow-up discussion regarding written or website information used as part of the consent communication process.

**Case Example:**

Gloria Suarez, a 53-year-old administrative assistant was referred to an endocrinologist for management of hypothyroidism and diabetes. As a new patient, she was asked to complete a medical history form. One of the questions on the form asked: “Are you allergic to any medications?” Ms Suarez checked off the “no” box. When she met with the endocrinologist, she was asked, “I see that you indicated on your history form that you have no known allergies. Is that correct?” Ms. Suarez replied, “Yes.” The doctor continued, “Okay. One of the items that are not on the medical history form involves certain types of sensitivities and intolerances to ingredients found in foods and some medication. So, please tell me if you have any sensitivities or intolerance to wheat, gluten, or the sugar in milk called lactose?” Ms. Suarez replied, “Oh yes, doctor. I am lactose intolerant. I try to avoid anything with milk or milk products because it really upsets my stomach.” The endocrinologist responded, “This is very helpful. Some of the generic medications include lactose to hold the tablets together. For patients who are very sensitive to lactose, we avoid prescribing such medication and it gives us a good argument to fight health plans that want us to prescribe the generic version of the medicine. You need to know, however, that the brand name medication is going to be more costly. If that is going be a financial challenge for you, we should discuss alternatives. Also, knowing that you are that sensitive to lactose, we need to discuss what we are going to do for you in terms of maintaining your calcium level while taking prescription thyroid medication.” After Ms. Suarez left the office the endocrinologist spoke with her team about modifying the patient history form. “If I hadn’t asked Ms. Suarez about sensitivities and intolerances, I might have prescribed a generic thyroid medication that exacerbated her lactose intolerance. We need to ask specific questions that go beyond allergies. We need to ask about lactose, gluten and wheat. Jane, you are great at this type of thing. Please come up with a draft revision for us.”
Applying Risk Management Strategies:

- Use good tools to obtain relevant patient history information, including items about food sensitivities and intolerances that may lead to inappropriate care plans and patient non-adherence with treatment.
- Encourage care providers to ask drill-down questions about medical history information that could impact diagnostic testing and medication regimens.
- Stress with care providers the importance of using the consent communication process – including the component dealing with medical history – to set patient expectations and to develop appropriate diagnostic and clinical care plans.
- Consider use of a patient history inventory tool that is used by care providers as part of the clinical intake to identify risk factors that are not addressed on documentation completed by patients.

B. Exceptions To The Rules Of Consent:

There are a number of well-known exceptions to the rules of consent. These include:

- Medicolegal emergency.
- Impracticality of consent.
- Therapeutic privilege.
- Compulsory treatment.
- Refusal to be informed.

A *medicolegal emergency* involves a life-threatening or health-threatening event in which the patient is unable to participate in a consent communication process. The situation is so dire that there is no time to seek an authorization from someone who is authorized in law to act as a surrogate to make decisions on behalf of the patient. In other words, the patient requires *immediate* treatment. In such circumstances, the law implies consent to those tests or treatment that are necessary in order to resolve the life-threatening or health-threatening event.

*Impracticality of consent* is very similar to the medicolegal emergency in that the patient presents with a life-threatening or health-threatening event that requires *immediate* treatment. The difference is that the patient is cognitive and can
participate in a consent communication. However, the time required to do so could exacerbate the patient’s situation resulting in a life-threatening or health-threatening event. Patients who present in shock from a food allergy or a bee sting or a heart attack in progress are examples of this exception. In such cases, the care provider asks relevant questions and that proceeds to treatment. The care provider keeps the patient informed of steps being taken to address the life-threatening or health-threatening event.

Therapeutic privilege is a rarely used exception. The care provider has a condition that warrants a diagnostic procedure or treatment. If, however, the patient was informed of the reason for the diagnostic test or treatment, the care provider must have a legitimate concern that revealing this information to the patient could cause serious and potentially irrevocable psychological harm to the individual. In such cases, the care provider should obtain a consultation from a behavioral health care provider who is not otherwise involved in the patients’ care. If the consultant is in agreement, that some aspects of the diagnostic test or treatment should not be revealed to the patient, he or she should document their opinion in the medical record. The care provider would then have a consent communication with the patient, leaving out those aspects that are apt to cause serious and potentially irrevocable psychological harm to the patient. The consent process would be documented in the medical record, noting what was discussed with the patient and what aspects were not disclosed using the therapeutic exception. Sometimes it is acceptable to share the non-disclosed information with the patient subsequent to tests or treatment. Much depends upon the recommendation of the behavioral health consultant and the observations of the care provider. Any post-testing or post-treatment discussions with the patient about the use of the therapeutic exception should be documented in the medical record.

Compulsory treatment involves either court-ordered or legislatively mandated care. Examples include involuntary admission to a psychiatric facility for treatment with psychotropic medication, and administration of antibiotics to a patient under a public health hold for treatment of an STD, particularly where the individual is the vector for an outbreak of the disease. It is unlikely that this exception would be used in the physician-office setting. Although the care provider is compelled to provide a well-defined medical treatment, he or she is not precluded from using an effective consent communication regarding medical history, previous treatments for a disease, allergies and potential drug-drug interactions. Not only might the discussion garner some degree of cooperation
with many patients under compulsory treatment, the conversation may lead to a more precise, patient safe care plan. Knowing that the patient fared poorly in the past on a type of neuroleptic medication, the care provider might prescribe a different drug.

The refusal to be informed is another recognized exception to the rules of consent. Sometimes patients want to proceed with a diagnostic test or treatment but do not want to be informed about the potential benefits, risks and alternatives. Absent a quality consent communication, the care provider cannot gauge patient expectation or the likelihood of adherence to a treatment plan. Although the patient may wish to proceed on this basis, it does not mean that the care provider must accede to the patient’s wishes. In such circumstances it is useful to delve into why the patient does not want to be informed and to learn if there are other ways in which to convey pertinent information. Use of videos, patient-to-patient or peer-to-peer conversations and interactive computer modules may be used to facilitate the discussion. If the patient remains adamant that he or she does not want to be informed, the care provider may respectfully decline to proceed on that basis and offer the opportunity to see other qualified care providers. Some practices will furnish a list of two or three names of other care providers who may be willing to take the patient on this basis. It is prudent to document in the medical record the conversations and the offer of other informational tools.

**Risk Exposures:**
- Negligent consent litigation.
- Battery litigation.
- Unprofessional conduct allegations under state licensure board requirements.
- Patient complaints.

**Risk Management Strategies:**
Successful use of one of the consent exceptions requires a careful analysis of the facts and circumstances to make certain that there is a basis for applying a variance to the rules of consent. Also required is a clear understanding of the definition of and application of the exception under applicable state law. Specific strategies include:
- Develop and implement a consent policy and procedure for the practice, including use of exceptions recognized under state law.
Ask legal counsel to provide guidance on applicable state consent law requirements and exceptions.

Offer orientation and training to clinical personnel on the use of the consent policy and procedure, including the exceptions recognized under state law.

Evaluate each patient’s circumstance before proceeding to utilize an exception to the rules of consent.

Document in the medical record the rationale for using the exception.

**Case Example:**

Odessa Smallwood was looking for a cure for her Parkinson’s disease. Medication therapy had not worked and her symptoms were becoming worse. She had heard from a friend that Mountain Neurological Associates was doing an innovative procedure that could “cure” her condition. She met with Dr. Frederick Chance, one of the neurosurgeons in the practice who was doing a procedure that involved inserting probes in the brain of the patient, evoking a potential and then using the information to ablate the affected area in the patient’s brain. The patient had to be awake during the procedure and talking so that the team could tell if they were getting too close to sensitive areas of the brain. Hence, it was important for the patient to understand what to expect and that she had a role in the operation. “I understand from the nurse practitioner that you do not want any details about the procedure. Is that correct?” asked Dr. Chance. Ms. Smallwood replied, “It is, doctor. All I want is for you to do it and get me back to normal.” Dr. Chance said, “Ms. Smallwood. I cannot guarantee that you will be back to normal. Much depends upon what we find once we are in the procedure. And, unlike a lot of other surgical procedures, you will play a key role in it. Thus, I want to discuss with you what is involved, what are the likely benefits and risks and also other treatment options. May we discuss it now?” Ms. Smallwood replied, “No. I don’t want to know anything about it. Just do it.” Dr. Chance said, “Do you think it might be more comfortable for you to read up on the procedure and what you have to do? Maybe talk to a patient who has been through the procedure?” Ms. Smallwood said, “No, like I said just do it.” Dr. Chance stood up and said, “Ms. Smallwood, unfortunately, I cannot treat you on your terms. It would not make the operation safe. Tell you what, the offer still stands. If you would like to think about it, we can meet again and I will be happy to explain what is involved or I can get you information to read. I even can ask a patient of mine to talk with you. There is no rush. Give it some thought and let me know what you decide, please. It was nice to meet you. Good bye.” Dr. Chance then documented the conversation in the patient record,
noting why he could not utilize the refusal to be informed exception: “This patient flatly refused to discuss with me what is involved in the procedure, the potential benefits and risks and treatment alternatives. She refused to discuss her role in the procedure. The patient has an inordinate expectation of outcome and achieving restoration to normal without us knowing how much can be accomplished through deep brain ablation therapy. I have offered her some options, including a revisit to discuss the procedure and her role in it, literature on the topic and the opportunity to discuss the ablation with a patient who has had the intervention. She will let us know if she wishes to proceed with a follow-up discussion.”

Applying Risk Management Strategies:
- Evaluate the circumstances of the case to decide if a recognized consent exception may be utilized.
- Document in the medical record the rationale for applying a consent exception.
- Document in the medical record when a consent exception could not be applied.

C. Minors And Consent To Treatment
Consent to treatment involving minors requires careful review of applicable state law and regulation. Although the basic premise is that children under the age of majority do not have the legal capacity or authority to consent to treatment, some states have carved out certain exceptions. For example, some jurisdictions have “age of consent” legislation giving minors of a certain age the prerogative to consent to treatment for child abuse, substance abuse, mental health care, and sexually transmitted disease. Indeed, one state may have different age of consent provisions for specific matters such as substance abuse or sexually transmitted disease. Going further, some states have carved out age of consent laws for minors to donate blood without an authorization from a parent or guardian. Beyond the specific age of consent laws, several jurisdictions recognize what is termed the “emancipated minor” exception. The criteria vary from state-to-state. However many of these law require a minor to be living independently and financially of his or her parents, and they may be a member of the armed forces, married or have become a parent himself. Most of these laws grant the minor meeting the emancipation criteria the ability to consent to
treatment for themselves and their offspring. Other laws restrict the ability to consent to the emancipated minor.

There are two types of laws that can prove challenging for care providers. One set of the age of consent laws gives care providers the prerogative to notify the minor’s parents or guardian regarding the provision of services. If notification would jeopardize the well-being of the minor, the care provider should refrain from contacting the parent or guardian in such cases. The other challenging set of laws involves minors and consent to reproductive services, including contraception and abortion. Given the nuances of case law and legislation on these topics, it is important secure specific legal advice with respect to minors and reproductive matters.

Should a care provider identify a child meeting state notification requirements for suspected or known abuse or neglect, there is no requirement to obtain consent to report such findings. This is a statutory duty to warn that should be made promptly.

Care providers have much leeway in their practices for handling difficult parental-minor consent communication disputes. One of the more common situations occurs when a child requests that the care provider not inform his or her parent of the reason for an office visit. The request usually involves a “rules-based” violation, such as an injury arising from an activity banned by the parent. Care providers should remind the minor that the parents will find out about the office visit through the statement of benefit sent to the parents by a health insurer. Counseling the child how to discuss the matter with the parent is often useful, and sometimes, care providers will speak with the parent with a view to facilitating a discussion with the minor. It may be more challenging in other situations, however, when the child says, “Please do not tell my father why I am here. He will beat me up.” However, given the nature of the child’s condition, parental or guardian consent may be required for treatment. For the care provider, the task is to determine if the child is exaggerating a rules-based violation or reporting a case of possible child abuse or neglect.

Practical issues abound involving minors and consent to treatment. For example, a grandmother brings her six-year-old grandson to the practice for treatment. The child’s parent is working. May the family physician accept the authorization of the child’s grandmother to order expensive diagnostic tests or a referral to a specialist? If the child is living with the grandparents while the parent is
incarcerated or deployed overseas or on a business trip abroad, may the grandparents consent to surgical treatment on the child? If the parents are divorced and the custodial parent is unavailable, may the other parent authorize treatment for the child? What should be done if a parent wants a 10-year-old child to be vaccinated with Gardasil but the child is adamant that she does not want the vaccine? Would the care provider’s response be any different if the situation involved a painful treatment that a 15-year-old patient does not want to undergo, preferring instead to try something less intrusive but also less likely to achieve a desired outcome?

Consent to treatment with minors often involves communication challenges. Remembering that the child is the patient, enlisting his or her cooperation and input can help resolve many situations. Setting reasonable expectations about responsibility for treatment choices is also useful for care providers.

**Risk Exposures:**

- Negligent consent litigation.
- Battery litigation.
- Unprofessional conduct allegations under state licensure board requirements.
- Patient complaints.

**Risk Management Strategies**

Recognizing that minors and consent to treatment often turns on state-specific laws and setting reasonable expectations, there are some practical strategies to consider for the physician office practice, including:

- Ask legal counsel to provide guidance on state-specific consent laws regarding minors and consent to treatment that should be incorporated into the practice consent policy and procedure.
- Ask legal counsel to update the guidance on an annual basis.
- Provide education for all care providers in the practice on consent to treatment and how to document treatment authorizations, refusals and specific issues such as age of consent and emancipated minor requirements.
- Include in care provider education, the importance of expectation setting with parents and guardians regarding consent to treatment matters involving minors.
- Anticipate in policy and procedure development, practical consent situations such as non-custodial parents, grandparents, older siblings,
babysitters or family friends bringing a minor patient to the practice for treatment.

- Provide practice personnel with a practical framework for responding to minors who request that a parent or guardian not be informed of treatment.
- Incorporate in the practice brochure, signage, and the practice website information that makes clear that known or suspected child abuse or neglect must be reported to state authorities.

**Case Example:**
Seven-year-old Stephanie Johnson was brought to the Hinden Pediatric Practice by Susan Layson, a close friend of the Johnson family. Stephanie’s parents had gone to Switzerland for a business meeting and vacation. They were not expected to return for another five days. Stephanie had a history of asthma that in the past required hospitalization. Two days after her parents left, Stephanie developed a cold and she began to wheeze and cough. Ms. Layson had been instructed by the Johnsons how to do peak flow readings and how to administer Stephanie’s medications. She had been told that if the peak flow readings went below a certain level and Stephanie’s symptoms became pronounced to take her to the doctor. The Hinden Pediatric Practice had “walk in” hour appointments set aside during the day specifically for children with chronic conditions. Ms. Layson and Stephanie met with Nancy Curio, a nurse practitioner in the practice. “I do not think we have met before, Ms. Layson. Are you related to Stephanie?” asked Ms. Curio. Ms. Layson explained the situation and gave Ms. Curio a letter signed by Mr. and Ms. Johnson authorizing Ms. Layson to serve as a temporary guardian for Stephanie and her brother Joseph while the Johnsons were away for a business trip and vacation in Switzerland. The document read in part that “this authorizes Ms. Layson to consent to medical treatment on behalf of Stephanie and Joseph during our absence.” Ms. Curio read the authorization and said, “I will make a copy of the document and place it in Stephanie’s medical record.” After examining Stephanie, Ms. Curio said, “You made a good judgment call to bring Stephanie in now. She will need a change in medication and we will have to monitor her closely so we can avoid another hospitalization. I will go over with you what needs to be changed in her care plan. Before you leave today, I shall give you written instructions. Please be certain to let the Johnsons know about these changes and the need to bring Stephanie back in for a follow-up visit because once this flare-up is resolved, the medication plan will need to be modified. And, Ms. Stephanie, you have
a big role to play, too. You and I are going to work together to make you better for when your mommy and daddy get home in a few days. In fact, I have a fun activity we are going to do together. It is called 'teach me' and if you do well, you will get a prize at the end.”

**Applying Risk Management Strategies:**
- Set clear expectations with parents and guardians regarding minors being brought to the practice for treatment by other individuals.
- Require a written document authorizing another adult to make treatment decisions on behalf of the child.
- Maintain a copy of the treatment authorization in the patient’s medical record as well as any treatment plan furnished to the adult acting on behalf of the child.
- Complete a teach-back of the care plan with the adult acting on behalf of the child, noting that the individual demonstrated an understanding of how to monitor the child and administer medication.
- To the extent possible, complete a teach-back of changes in the care plan with the child.

**D. Handling Specific Consent Issues In The Physician Office Practice**
Physician practices often encounter specific consent challenges, such as adults without decisional capacity and patients refusing tests or treatment. In some circumstances, physician practices need to examine closely the requirements for consent and the prescription of some medications. Specialty practices conducting risk-prone diagnostic testing and office-based surgical procedures should also pay attention to specific consent requirements. With infants and children, vaccinations completed in the office also merit specific consent communication.

*Patients with Questionable Decisional Capacity* – Adults with developmental challenges and those with confusion or dementia may not be able to make treatment decisions. If the patient has a duly authorized legal representative responsible for making treatment decisions, it is to this person the care provider should turn for consent communications. However, whether it is a person with Downs Syndrome, some level of executive-function dementia, or under a legal guardianship for which someone is appointed to make treatment choices, there is still room for the care provider to engage the patient in the consent process.
From such communication the care provider might learn information about sensitivities to medication, the need for someone to assist with medication administration, etc. Such information can help in care planning and also it may be useful in care plan adherence. The key is to obtain the informed consent of a patient who is legally and mentally able to take part in the decision-making process. For those with questionable decisional capacity and for whom there is no legal representative; care should be exercised. For example, in the early stages of cognitive confusion, a frank discussion is warranted with the patient, encouraging him or her to appoint or designate a surrogate decision-maker. Once documented in writing, the care provider can then involve the designee in treatment decision-making. Family members who are not designated to act on behalf of the patient may mean well, but unless they have the authority to participate in the decision-making process, there is a risk of family conflicts and disagreements. The prudent approach is to identify and work with the legally authorized surrogate.

Refusal of Treatment - Just as there is a need to complete a consent process authorizing treatment, it is important to secure an informed refusal of recommended tests or treatment. For the physician practice, this means that the person caring for the patient makes certain that the patient understands what has been recommended in terms of tests or treatment, the probable benefits and probable risks, alternatives and attendant probable benefits or probable risks and the consequences of refusing recommended and alternative tests or treatment. A teach-back process is important; asking relevant questions to make certain that the patient understands the choices and consequences of declining tests or treatment. Rather than asking, “You understand that you are refusing treatment?” It is better to ask probative questions such as “Tell me in your own words what has been recommended and what are the probable or possible consequences of your decision to refuse the [test] or [treatment.]?” Another option is to say, “I am curious. Why have you chosen not to proceed with the test/treatment?” If the response indicates that the patient will have transportation issues, that insurance will not cover the test, or that the drug recommended is too expensive, then the opportunity may be present to find ways in which to accommodate such challenges. In essence, it was not a refusal of a test or treatment. It was a determination based on social or financial needs that might be averted through use of community resources (transportation) or using a cost-effective medication therapy. As with consent to treatment, a refusal should be documented in the medical record.
Black Box Drugs and Other High-Risk Medications – Some of the medications prescribed or used with patients require completion of a consent process. Patients should be apprised of the indications for such medication, how it is supposed to be used, the probable benefits and probable risks, alternative medications, if any, and the probable benefits and probable risks associated with such options, and the consequences of refusing such treatment or not adhering to the medication regimen. Examples include so-called “Black Box” warning drugs that bear a black border around the label indicating the high-risk nature of the medication. This Black Box warning is required by the FDA. The FDA has also published guidance on how to evaluate the use of such medications and what to discuss with patients. There are other medications that are high-risk that merit consent discussions with the patient. These include prescription medication that can cause serious harm if stopped abruptly or that could provoke thoughts of suicide or self-abuse. Medications that could cause temporary or permanent harm such as tardive dyskinesia, or that could impair motor function or operating motorized equipment also require a careful consent communication. Medications that can impact diet or that come with a warning about drug-drug interactions necessitate clear information. Also, medications that can cause bleeding and that may need to be stopped for diagnostic tests or surgery warrant careful communication. Care providers should document the consent communication in the medical record with respect to Black Box warning drugs and high-risk medications.

Consent to Office-Based Diagnostic Testing – Many practices conduct diagnostic testing that can prove risk-prone. It is important to discuss with patients the indications for the test, the probable benefits and risks, test alternatives, and related probable benefits and risks, and the consequences of declining suggested or alternate testing. Cardiac stress testing is a good example. Patients who present with signs of angina should know that cardiac stress testing could exacerbate angina and, in some situations, require hospitalization for immediate treatment. If the feeder hospitals have outpatient cardiac stress testing facilities, such patients may be more comfortable having the diagnostic work done in that setting rather than a physician office. Such information should be shared with the patient as part of the communication process. The discussion and the patient decision should be documented in the medical record.

Consent to Office-Based Surgical Procedures – Any type of surgical procedure done in the physician office practice warrants completion of a consent process. Several states have regulations or guidelines for office-based surgery that specify
requirements for consent. Also, physician office surgery practices that have been accredited for such services should look to the accreditation standards with regard to consent requirements. As with any surgical procedure, the patient should be made aware of the indications for the operation, what is involved in the procedure, the probable benefits and probable risks, treatment alternatives and the probable benefits and probable risks associated with such options, and the consequences of refusing both recommended and alternate forms of care. In addition, the patient should be informed about the opportunity to have the procedure done in an ambulatory care or acute care facility. If sedation is to be utilized or the surgery will impede the person’s ability to ambulate or drive, this too should be made clear as part of the consent process so that arrangements can be made for transportation to his or her place of residence. The risks of infection, potential disfigurement, disability or death should be made clear along with the risk that in some instances it may be necessary to transfer the patient to an acute care facility due to reactions to anesthesia or complications that occur during the office-based procedure. Many recommend that such consent communication be formalized in a signed treatment authorization. A copy of the authorization would be incorporated into the patient record.

_Vaccination of Infants and Minors_- Vaccinating infants and minors warrants an informed consent communication with the parent or legal guardian. It is sometimes misunderstood that Vaccine Information Statements or VIS available for free from CDC replaces the need for an informed consent process. The VIS are informational tools that are useful in helping parents understand the need for vaccination and possible side effects, risks, and how to respond to a serious problem after the vaccination. However, it is not a replacement for a consent communication that may reveal risk factors that mitigate against administering certain vaccines. Once the consent process is completed, the authorization that was provided to the parent or guardian should be noted in the medical record along with the title of the VIS document, the version or date of the document, and the language in which it was printed.

_Risk Exposures:_

- Negligent consent litigation.
- Battery litigation.
- Unprofessional conduct allegations under state licensure board requirements.
- Patient complaints.
Risk Management Strategies:

- Include in the consent policy and procedure for the physician office practice specific guidance for managing treatment authorizations for:
  - Patients with questionable decisional capacity.
  - Surrogate decision-makers making treatment decisions for patients without decisional-capacity limitations (legal guardian or duly authorized legal representative).
  - Black Box warning or high-risk medications.
  - Office-based diagnostic testing.
  - Office-based surgery/procedures.
  - Vaccination of infants and minors.

- Make certain that treatment authorizations are recorded in the medical record.

- Make certain that for surgical procedures completed in the physician office practice, applicable state requirements and accreditation standards are met for consent and signed surgical authorizations.

- Maintain a copy of VIS documents provided to parents or guardians of patients and in the medical record note the title, version or date number, and the language of the VIS tool provided to parents or guardians.

Case Example:
A 53-year-old patient with rheumatoid arthritis was prescribed Humira after other medications failed to quell some of the health problems brought about by the disease. The patient was counseled about the probable benefits and probable risks associated with the Black Box warning drug. The patient was apprised of alternative treatment options as well. Specific warnings were shared with the patient about the serious consequences of fungal infection when taking this drug. The patient completed a teach-back with the rheumatologist and signed a consent document authorizing use of the medication. The document was placed in the patient record along with a note about the teach-back process. Six months later, the patient developed a serious lung infection that required hospitalization. It turned out to be a fungal infection contracted while on a tour of Costa Rica. The patient recovered, but was angry with the rheumatologist for giving him such a powerful drug. The doctor then reminded him of their conversation, the consent document and the drug use information tool he had been given when he first started using the medication. The patient calmed down and said, “Yes, you did warn me.” A different medication was then prescribed to treat the patient’s condition.
Applying Risk Management Strategies:

- Complete a consent process for use of Black Box or high-risk medication.
- Complete a teach-back process to confirm patient understanding about the benefits, risks, and safe use of such medication.
- Document the consent communication and teach-back process in the patient record.
- Consider having the patient sign a consent document for use of Black Box and high-risk medication.
- Incorporate into the medical record information tools or instruction sheets provided to the patient regarding safe use of Black Boxed or high-risk drugs.
- Use the document to counsel the patient subsequent to appearance of side effects related to the medication.
- Document the conversation regarding the occurrence of side effects and follow-up care, including any change in medication regimen.

E. Responsibility For Obtaining And Documenting Consent

Responsibility for obtaining a patient’s consent to treatment belongs to the care provider who is to treat the patient. A care provider may ask a staff member to obtain pertinent medical history information or to explain what is involved in a test or treatment. However, the care provider is responsible for the consent process. If the person who is obtaining the medical history or who is explaining a test or treatment does not do so effectively and as a result, there is a lack of informed consent or provision of inappropriate treatment; the responsibility for the situation will come back to the care provider. Hence, it is not prudent to delegate the consent process or parts of it to other individuals in the physician office setting.

The consent communication should be documented in the medical record. In some instance the consent communication may be incorporated into a consent form signed by the patient. This is particularly important when required by state law, or the authorization is for office-based surgery, administration of risk-prone test, or ordering high-risk or Black Box medications. Legal counsel should be consulted for guidance on state law on this topic.

Consent documentation should never be signed until the treatment authorization communication has been completed.
Risk Exposures:
- Negligent consent litigation.
- Battery litigation.
- Unprofessional conduct allegations under state licensure board requirements.
- Patient complaints.

Risk Management Strategies:
The consent process is more than obtaining a patient’s signature on a standard form. It is a communication process that can help promote patient safety and facilitate good risk management practices. It is important to establish in the clinical practice clear guidance regarding responsibility for the consent process and how to properly document a treatment decision. Risk management strategies for this purpose include the following:
- Incorporate in the physician office practice consent policy and procedure a clear statement that the care provider providing treatment for a patient is responsible for completing the consent process.
- Delineate what, if any, components of the consent communication process can be completed by clinical personnel in the practice such as history-taking or explaining treatment.
- Recognize that even if a component of the consent communication process is shared with clinical personnel in the practice, the care provider is responsible for the completion of the treatment authorization.
- NEVER ask a patient or a duly authorized legal representative to sign a consent document prior to completion of the consent process.
- Provide education for care providers and clinical personnel on the fundamentals of consent communication as well as their respective roles and responsibilities for obtaining a treatment authorization.
- Identify in a policy and procedure how the treatment authorization is to be documented, whether as an entry in the medical record or using a consent form, or both.
- Ask legal counsel to provide specific guidance on state law and office-based consent documentation requirements, including surgical procedures completed in the physician practice.
- Ask legal counsel to provide specific guidance on state-mandated consent forms that are procedure-specific.
Update consent policy and procedure on an annual basis and provide care providers and clinical personnel with education on any changes made in the consent communication and documentation process.

As part of a medical record quality review, determine if there are variances from consent policy and procedure and implement appropriate actions to achieve adherence, such as one-on-one education or focused in-service training.

**Case Example:**
Lenore Hansone came into the multispecialty practice for a cystoscopy procedure. The physician who performed the test worked collaboratively with a nurse practitioner who completed thorough history-taking and also provided patients with a general explanation of the procedure. Thereafter, the physician reviewed the history with the nurse practitioner. The doctor met with Ms. Hansone and reviewed her medical history, asking questions to confirm details about medications and surgeries. The care provider then explained the indications for the cystoscopy in her case and the probable benefits and probable risks as well as diagnostic options. Also discussed was the likely consequence of declining either recommended or alternate diagnostic evaluation for her condition. The care provider then asked some “teach-back” questions to confirm the patient’s understanding of the cystoscopy. Satisfied that Ms. Hansone understood what was involved in the diagnostic procedure, the care provider asked if she had any questions. “No. But I must say I am pleased with how you and the nurse practitioner worked together to explain to me what I should expect in the test,” said Ms. Hansone. The care provider thanked her for her feedback and gave her a consent document to sign for the procedure. Once signed, the form was entered into the patient’s medical record and the test was performed without any complications.

**Applying Risk Management Strategies:**

- Follow established policy and procedure for securing a patient’s authorization for office-based diagnostic procedures.
- Recognize that the care provider doing the test or treatment is responsible for obtaining the patient’s consent.
- Note that in collaborative working relationships with other clinical personnel the care provider remains accountable for completing the consent process.
- Document the diagnostic test consent, following established policy and procedure in the physician office practice.
**IV. Documentation in the Physician Practice Setting**

A patient’s medical record and personal health information (PHI) plays an extremely important and multifaceted role in the physician office setting. Consider the attributes of the medical record documentation system in the physician office setting:

- it presents a chronological account of the patient’s medical story – history, diagnosis, the clinical decision process and treatment rationale, treatment, and the outcome of that treatment;
- it is the primary communication tool between providers and other members of the healthcare team involved in a patient’s care and therefore is critical to continuity of care;
- it serves as evidence of a physician’s compliance (or lack of compliance) with established standards of care, laws, regulations, and accreditation requirements;
- it can demonstrate a measure or lack of quality or performance when assessed by quality assurance or utilization review personnel, peer review committees, and even state licensing bodies;
- it can be a valuable source of data for benchmarking and outcome of care analysis;
- it is the foundation of all third-party reimbursement and, as such, must support all third-party claims filed for care rendered; and
- It is the legal record of the patient’s care.

When completed in a timely and accurate manner, the patient medical record can be dispositive of potential liability claims. Further, the well-documented patient medical record can prove very useful when resolving disputes with payers.

As discussed in this chapter, documentation practices are undergoing change from a hard-copy format to an electronic system. There are common risk management challenges seen in physician office practice medical documentation systems. Further, there are regulatory requirements that must be met in terms of using and disseminating protected patient information. From a loss control and loss prevention standpoint, there are important systems safeguards to consider, including documentation retention and storage, record destruction,
electronic back-up and recovery processes as well as release of information to patients.

A. Overview: From Paper Records to EHR, EMR, PHR, and HIE
Nationwide, healthcare systems and providers are increasingly moving from traditional paper-based medical records to an electronic format. Sometimes the information is practice-specific and refers to the platform as an electronic medical record or “EMR.”

Those electronic systems that are designed to share patient information along the continuum of care are often referred to as electronic health records or “EHRs”.

Patient information that is provided to patients on a flash drive or that the patient maintains through a secure patient website is often described as a personal health record or “PHR.”

A Health Information Exchange or “HIE” is a system that facilitates interoperable access to a patient’s health information. It means that a primary care provider can share pertinent, office-based information from the patient’s EHR with a hospital, a specialist and others in the HIE. Similarly, the HIE permits rapid transmission of patient information – such as discharge summaries – from a hospital to a primary care provider. Many states have specific requirements for participation in an HIE. The Federal Shared Savings Program that created Medicare Accountable Care Organizations or “ACOs” also includes specific requirements for Medicare beneficiary participation in an HIE. In practical terms, physician office practices should consult legal counsel regarding specific state requirements for participating in an HIE.

EMRs and EHRs have associated benefits and, at the same time, present challenges for physicians’ practices. Many medical offices are in transition – between 100% paper records and 100% electronic – which in itself can present problems when some patient data is stored electronically and other information is maintained in hard-copy files. Wherever the practice is along that continuum, the basic elements of good documentation apply and are essential to the provision of high-quality, safe patient care.
Moving to an EMR or EHR is not a guarantee of “good documentation” or an automatic improvement over paper records; rather, if documentation bad habits were present in a traditional paper medical record system, it is likely that they will be carried over to an electronic system. For example, while an EHR system removes the issue of illegible record entries due to poor physician handwriting, it has new potential risks that arise when poor typing skills or hasty data entry result in a care provider typing the wrong key on the keyboard. In an EMR or EHR, a “typo” can have serious patient safety ramifications. However, an EHR system with a basic computerized physician order entry (CPOE) feature can eliminate the majority of legibility issues and standardize order formats. In addition, EHR systems that incorporate clinical decision-support features such as automatic “alerts” about drug-drug interactions, patient allergies, outstanding test results, or test results that require a change in treatment have obvious risk management and patient safety potential.

B. Content of the Physician Practice Medical Record
The need for physicians to document their care of patients and, further, maintain those documents, is mandated by federal and state laws, regulations and statutes, as well as accreditation bodies, third-party payers, professional organizations, and others. Specific content – what makes up a “medical record” – is often guided or defined by these requirements.

Generally speaking, the patient record in a physician practice setting should include, at a minimum:

- A separate up-to-date problem list documenting significant illnesses and medical conditions.
- An up-to-date medication list that includes prescription drugs, over-the-counter medications, vitamins and nutritional supplements (including herbal and alternative therapies).
- Prominently and consistently displayed medication allergies/adverse reactions (if the patient has no known allergies, that fact should be clearly noted in the record).
- Patient demographics, including name, address, date of birth, marital status, and the name of any legally authorized representative/next of kin, employer, contact information (home and work phone numbers for patient and designated contact/next of kin).
Medical History, including:
   - Past surgeries.
   - Significant illnesses and conditions.
   - Past significant trauma.
   - Relevant family history.
   - Well-documented physical examination and review of systems.
   - Documentation of the presence of preexisting medical devices (e.g., indwelling catheter, central line, pacemaker, etc.), when and where the device was inserted, present condition, etc.
   - Current complaint/illness/condition/reason for treatment.

Social History, including use of tobacco, alcohol, illegal substances.

Immunization Record for children and adults.

Any special language or communication need (e.g., interpreter for non-English speaking patients, aids for hearing or sight-impaired patients, etc.)

Any advanced directives.

Clinically, the record should also include:
   - Initial diagnosis, diagnostic impression(s) or conditions(s).
   - Any diagnoses or conditions established during the patient’s course of care, treatment, and services.
   - Any medications ordered or prescribed, or administered, including the strength, dose, frequency and route.
   - Treatment goals, plan of care, and revisions to the plan of care.
   - Results of diagnostic and therapeutic tests and procedures.
   - Results of all consultations with other physicians/healthcare facilities.
   - The patient’s response to care, treatment and services.

Documentation of any and all communication between the practice, the physician, and the patient or patient’s family members (phone calls, e-mails, texts, etc.), including time received, information provided, action required or taken by practice staff or physician(s), medical advice rendered, etc.

Documentation of any patient information provided after normal office hours by other providers/consultants such as ED physicians or on-call specialists from a local hospital or other providers in the community; this includes information provided in phone calls, answering service messages, emails, texts, or whatever. Specific information as to date and time received, etc., should always be recorded as well.
Every practice will have its own patient record system and formats. Consistency among all practice providers is important. Any physician or ancillary health care provider should be able to pick up any patient’s record and easily find the information needed in a consistent location. Missing or misplaced patient information can result in treatment delays, errors and inefficiencies of care.

**Risk Exposures:**
- Medication Errors.
- Disruption in Continuity of Care.
- Communication Breakdown between providers.
- Delayed Diagnosis or Treatment / Misdiagnosis.
- Patient Injury / Death.
- Breach of Patient Confidentiality/HIPAA Violations (see Section C).
  - Protection of PHI, HIPAA, and HITECH).
- Fraud and Abuse Issues when Records don’t support claims for reimbursement.

**Risk Management Strategies:**
From a risk management perspective, good documentation practices include the following:
- Document the patient’s complete medical history and the findings – both positive and negative – of the systems physical evaluation.
- Maintain and update a medication list in a consistent and prominent place in the patient’s chart – whether paper or electronic – with medication allergies or an absence of allergies noted prominently.
- Document legibly (if done manually). If electronic records are used, record entries should be reviewed prior to sign-off for accuracy and correctness.
- Make any necessary record additions or corrections in accordance with the practice’s policy, again, depending on whether a paper-based or electronic system is used. If paper, the recognized correction method is to cross out the error with a single line; note “Error,” initial and date, and add the correct notation. An EHR will have a specified error correction method (may vary from system to system) that should be followed exactly.
- Avoid the use of abbreviations and symbols in the medical record to prevent interpretation errors.
- Complete each blank or checkbox found in record forms to indicate that the category or question was addressed. If completion of all fields is not required or not applicable to the patient, then a N/A (or whatever is
customary procedure at the practice) should be entered. No block or field (in an EHR) should be left blank.

- Review and authenticate any transcribed records to verify that what was dictated was accurately transcribed. Don’t skip the reviewing step. A signature or initials on a transcribed report or record indicates that what was transcribed or entered is correct.
- Make sure to always sign off on all orders and patient encounter notes when using an EHR system and sign off in a way that will be evident to others viewing the record. Recognize that it is essential to **review before signing off**.
- Always respond promptly to any system prompt or alert and take the appropriate action to address the problem and resolve it. These alerts are in the system for the patient’s protection as well as the benefit of the healthcare providers involved in the patient’s care. They should never be ignored or bypassed.
- The EHR system’s audit trail will demonstrate a detailed record of all activity, including who was “in” the record and when (including log in/out), edits and deletions and that alerts were active, even if they are bypassed.

**Case Example:**
Otis Medler was seen at the family practice office by Anthony Thomas, MD. Mr. Medler complained of pain in his lower to middle back and left shoulder. He denied having engaged in any activity that might have caused the ailment. “I am a couch potato,” said Mr. Medler. Dr. Thomas decided to follow a conservative plan of rest and use of NSAIDs. He told Mr. Medler to call him in five days if the pain did not ease up from rest and taking two Aleves each day. Dr. Thomas was new to the practice. He wrote a note indicating that “Pt. to call me in 5 days if still in pain. Believe it is a muscle strain. May need diagnostic imaging if pain does not abate.” Three days later, Mr. Medler was rushed to the hospital and pronounced dead on arrival. An autopsy revealed that he had suffered a massive heart attack. A lawsuit was filed for medical malpractice against Dr. Thomas for failure to meet the applicable standard of care in diagnosing a back ailment instead of considering the possibility of a serious cardiac ailment. Defense counsel reviewed the record and said, “Dr. Thomas you told me you had ruled out cardiac involvement. But, did you document the rule out in the patient record?” Dr. Thomas said, “No. Sorry. I am accustomed to just documenting the diagnosis and treatment plan, not the rule out.”
Applying Risk Management Strategies:

- Good documentation practices apply to all members of the healthcare team in all clinical settings—without exception.
- The importance of a well-documented record to a patient’s diagnosis, treatment, treatment outcome, and overall well-being cannot be overemphasized.
- The medical record takes on yet another vitally important role should a medical malpractice action be brought against a physician or practice. Documentation can be the deciding factor in the determination of whether a case is defensible or not. As the old adage says, “If it’s not in the record, it didn’t happen.”
- Make sure your documentation is timely, complete, objective, and accurately reflects the care you rendered.

C. Common Documentation Problems in Patient Records

There are a number of documentation practices that can create problems in physician office patient records. Although some are related to hard copy or paper documentations, some of the challenges can be found in electronic systems. Some common challenges include:

- Incomplete or sparse entries that do not convey a clear or accurate description of patient care.
- Illegible records due to poor handwriting.
- Documentation “jousting” between physicians or between physicians and clinical staff.
- Inclusion of inappropriate, derogatory, or subjective information in the record.
- Alteration of a medical record, after litigation has been filed.
- Use of abbreviations, acronyms, and symbols that can jeopardize patient safety.
- Delayed or out-of-sequence entries in the patient record.
- Late entries and addendums that appears self-serving, particularly if the information is provided after a potential compensatory event.
- Medicare, Medicaid, TRICARE or private insurer claims for services rendered that don’t match the documented patient care. Serious legal and regulatory consequences are possible for a physician practice in such cases.
Filing of laboratory, diagnostic imaging, or consultant reports *without* it being read by the ordering physician or a designated member of the practice staff or without action have been taken on the information. Note: if a care provider does not document date, time, and action, such information may be seen as a failure to follow required standards of care.

While EMRs and EHRs can eliminate some of the more common risks, errors, and liability associated with patient record documentation, electronic systems can bring associated problems, for example:

- Decimal point placement when typing in medication doses.
- Clicking / checking off the wrong box in a list of existing conditions.
- Auto-completion of fields left blank by a clinician.
- “Copy and paste” documentation.
- Lack of clear physician sign off and signature verification or auto-authentication that eliminates the need for physician review of an entry.
- Problems with patient identification when patients have similar or the same names.
- After-the-fact alterations or deletions of electronic entries.
- Failure to heed built-in system prompts and alerts regarding drug-drug interactions, known allergies, outstanding test results, etc. and/or attempts to bypass or work-around the system’s warnings.

There are also risks associated with non-compatibility and system failures that arise when several different electronic systems co-exist in one medical practice. For example incompatibility between the practice’s clinical information system and its claims and billing systems may preclude smooth transmission of patient data. All systems have to speak the same “language” so that data is transmitted completely and correctly. If physician practices have more than one office or are tied into a network of physician offices, IT compatibility issues may be even greater. A practice has to ensure that its computers are communicating efficiently, accurately, and promptly with other systems and data bases that play an integral part in the care process. Even more problems can occur in physician practices where some patient information is stored or transmitted on paper and some electronically – these situations can be extremely frustrating for physicians and staff looking for specific patient information and can be potentially dangerous from a patient safety perspective.
It is important to engage key stakeholders in the design of the physician office EMR or EHR. Key stakeholders should include clinical, administrative, and IT specialists as well as legal counsel and the individuals responsible for corporate compliance and risk management. The case introducing this section demonstrated the importance of having physician involvement and input in a practice’s EHR system and knowledge of compliance with its policies and procedures regarding documentation. A similar approach should be considered subsequent to activating the EMR or EHR system. End users may also provide useful information to help minimize risk exposures while helping to create a documentation system that supports quality, patient safety and regulatory compliance.

When completed in a timely and accurate manner, the patient medical record can be dispositive of potential liability claims. Further, the well-documented patient medical record can prove very useful when resolving disputes with payers, and can help care providers defend against unprofessional conduct allegations before a board of medical licensure.

**Risk Exposures:**
- Medical malpractice.
- Unprofessional conduct involving medical licensure.
- Loss of revenue.

**Risk Management Strategies:**
It is important that the physician office practice develop and adhere to a consistent approach for documentation in the patient medical record. This is true for those practices that continue to use hard-copy records and those that are moving into or have made the move to an electronic medical record format. In terms of specific risk management strategies consider the following:
- Orient all administrative and clinical personnel to the documentation requirements for the patient medical record.
- Make certain that temporary personnel and locum tenens physicians are oriented to the documentation requirements for the patient medical record.
- When changes are introduce to the format or content of patient medical record documentation in the practice, make certain that critical information is included for easy access, including the patient problems list, medication, known allergies and sensitivities and consulting specialists.
➢ Orient administrative and clinical personnel to changes in medical record format or content.
➢ Conduct regular audits of patient medical records to make certain that core elements are completed.
➢ Address areas of non-adherence with medical record documentation requirements.

**Case Example:**
Virginia Slater is a 68-year-old patient in a busy Internal Medicine practice. She was primarily seen by one physician, Dr. Thomas, but when necessary is seen by any of Dr. Thomas’ partners. She has a history of several chronic medical conditions including hypertension, cardiovascular disease, and hypercholesterolemia for which Dr. Thomas had prescribed a beta-blocker and a statin.

Because she was a long-time patient of the practice, her chart was rather thick. When the practice began the transition from paper-to-electronic medical records, in order to get the EHR system up and running as quickly as possible, the decision was made by the office manager and IT consultant to have only the most recent six months of the paper records scanned into the new EHR system, along with the problem list. The justification was to save time and get the practice online sooner. The consultant noted that with a thick chart it would take hours to scan in all the pages. However, it was agreed that eventually, the rest of a thick patient record material would be scanned in by using agency temps after regular office hours.

Dr. Vincent, a partner of Dr. Thomas, was asked by an LPN to take a call about Mrs. Slater because Dr. Thomas was out of the office. “She’s apparently been in an MVA, is unconscious, and has been taken to the ED. The ED nurse needs some info on her.” Dr. Vincent took the call and quickly pulled up the Mrs. Slater’s electronic medical record. The ED nurse asked for pertinent history and meds. Dr. Vincent related the info from the problem list and that Mrs. Slater was on Toprol XL 100 mg/day, Zocor 20 mg/day, and ASA 81 mg/day. Mrs. Slater had obvious skeletal injuries and the ED physician suspected a fracture dislocation of the femoral head and possible acetabular or pelvic fracture(s) and ordered a stat contrast CT of the abdomen and pelvis. Shortly after the contrast medium was injected, Mrs. Slater experienced a severe anaphylactic reaction including ventricular tachycardia, hypotension, and seizure. A code was called and appropriate resuscitative measures were taken. Mrs. Slater never regained
consciousness and subsequently died several days later in the hospital from complications of her multi-system trauma.

Investigation of this case revealed that Mrs. Slater had a known, severe allergy to contrast media. Unfortunately, that information was not passed on to the ED because the incomplete electronic record did not include the information about a severe allergy to contrast media. Because the practice physicians were not involved in the medical record system conversion – having delegated all responsibility to the office manager and IT consultant, the clinical ramifications of the decision to start with an incomplete electronic record were not raised or discussed prior to the “go live” date. Patients’ allergy information was not included on the practice’s problem list and actually was on a separate page; that sheet, however, was not among those chosen to be scanned into the electronic record initially.

**Applying Risk Management Strategies:**
- Involve clinical leadership in the decision-making process regarding changes in format or content of an electronic medical record that will include scanned pages from previous hard-copy patient medical records.
- Avoid selective or delayed scanned document upload into the electronic medical record to avoid disruptions in continuity of care or creating potential patient safety issues, as demonstrated by the case above.
- Make certain that critical information needed for continuity of care is easily found in the EMR display, including the patient problem list, medications, known allergies and sensitivities and consulting specialists.
- Provide administrative and clinical personnel with practical training on the use of the electronic medical record.

**D. Legal and Regulatory Requirements for Patient Health Information**
A physician’s duty to protect patient information goes back to the days of Hippocrates and is part of the Hippocratic Oath taken by every new physician:

> *Whatsoever things I see or hear concerning the life of men, in my attendance on the sick or even apart therefrom, which ought not be noised abroad, I will keep silence thereon, counting such things to be as sacred secrets.*

*Oath of Hippocrates, 4th Century, B.C.E.*
Confidentiality is a critically important part of the physician-patient relationship. A patient has a right to expect and trust that his or her medical information will be protected by the physician. The duty and expectation of confidentiality also extends to the physician office staff. It is a legal obligation framed in state law and Federal law.

Maintaining patient confidentiality can be a problem area for physician office practices. A staff member's release of patient information is not always done maliciously, but rather more in the line of gossip. “Did you hear who’s pregnant?” or “Isn’t it too bad about Mary Jones’ breast cancer?” or “I saw Harriet Brady was in for a face lift last week.” These are all examples of a deliberate PHI breach, punishable under laws like HIPAA an HITECH. The duty of confidentiality is something that should be taught to every member of the practice staff without exception, as part of initial staff orientation and reinforced often through regular staff meetings or in-services.

In addition, confidentiality should be addressed in the practice policies and procedures so there is no question on the part of any staff member as to what is expected in this regard. And with the policies should go specific ramifications of non-compliance with those policies; e.g., a warning on first offense; followed by immediate dismissal if the employee again breaches a patient’s confidentiality. Some practices adhere to a “zero-tolerance” policy making any unauthorized disclosure of PHI grounds for immediate dismissal from the practice.

Of particular importance to the physician office practice are federal requirements regarding protected health information (HIPAA) and data breach and security (HITECH). Also, there are specific rules governing civil litigation that permit attorneys to engage in discovery of electronic data. These e-discovery rules can be found in several states. At the federal level there are specific provisions as well. From a practical standpoint, the e-discovery rules demonstrate the importance of working closely with IT in designing the EMR or EHR for the physician office practice. This means having in place a plan that identifies where electronic data is stored, how it can be accessed, and what parts of the patient record should not be shared absent legal guidance to do so.

**HIPAA** - The Health Insurance Portability and Accountability Act of 1996 or HIPAA, as it commonly known, was enacted with the goal of improving and standardizing electronic healthcare records; its key components addressed e-record transactions, unique identifiers for providers, patients, insurers, and
employers, privacy, and security. It is the privacy and security components that have the most far-reaching effects on all levels of the healthcare industry – particularly how patient health information (PHI) in any form is created, maintained, and disseminated.

HIPAA applies to all healthcare providers – hospitals, clinics, physicians, physician offices – grouping them all under the name of “covered entities.” Physician office practices will be most affected by HIPAA’s Security and Privacy provisions. The Security provisions provide guidance to organizations and providers on how to protect the integrity and confidentiality of medical information collected from patients through risk identification and assessment and subsequent implementation of security measures to reduce those risks. The four areas that are addressed in the Security section are:

1. Administrative safeguards – e.g., formal security policies and procedures, data back-up and recovery plans, staff training, gap analysis (comparison of existing security standards to the HIPAA standards to identify “gaps” and develop an action plan to close those gaps).
2. Physical safeguards – e.g., limiting physical access to the facility’s record storage areas and IT department, protecting data and data back-up, and other physical safeguards PHI from unauthorized access
3. Technical security measures – e.g., measures that limit access to PHI, system audit controls, individual user password protection, data protection from alteration or destruction, PHI disclosure consents
4. Technical security mechanisms – e.g., protection for data transmitted or communicated over networks, such as alarm systems, audit trails, encryption mechanisms, user identity verification.

The physician practice must have appropriate security measures and systems in place for HIPAA compliance in this regard. Any employee or contracted physician working in the practice will be expected to abide by the practice’s policies and procedures in this regard so as not to jeopardize the privacy and protection of patient information or the practice’s compliance.

The Privacy Rule has the largest impact on healthcare facilities and providers. It protects individually identifiable health information by defining and limiting the circumstances under which PHI may be used or disclosed by a covered entity; i.e., PHI may be used or disclosed for treatment, payment, or other healthcare-
related purposes as allowed under the Privacy Rule, or with the expressed written consent of the patient (or his/her personal representative). As defined by HIPAA, treatment is “the provision, coordination, or management of health care and related services among health care providers or by a health care provider with a third party, consultation between health care providers regarding a patient, or the referral of a patient from one health care provider to another.”

HIPAA Privacy protection extends to all forms of individually identifiable health information that has been maintained or transmitted by a covered entity, whether communicated electronically, on paper, or orally. Individually identifiable health information is further defined as information, including demographic data that relates to:

- The individual's past, present, or future physical or mental health or condition,
- The provision of health care to the individual, or
- The past, present, or future payment for the provision of health care to the individual, and
- Identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual (e.g., name, address, birth date, and Social Security number).

All covered entities are required to provide and display a Notice of Privacy Practices (NPP). The notice must be in plain language, prominently posted in the facility and on the facility's Web site. It also must be made available to any person who requests it and must describe:

- How the covered entity may use and disclose protected health information about an individual.
- The individual's rights with respect to the information and how the individual may exercise these rights, including how the individual may complain to the covered entity.
- The covered entity's legal duties with respect to the information, including a statement that the covered entity is required by law to maintain the privacy of protected health information.
- Whom individuals can contact for further information about the covered entity's privacy policies.

Any disclosures of PHI must be consistent with the covered entity’s practices as outlined on its Notice of Privacy Practices. HHS’ Office for Civil Rights is responsible for enforcing the Privacy and Security Rules. Enforcement of the Privacy Rule for most HIPAA covered entities.

**HITECH** - The Health Information Technology for Economic and Clinical Health (HITECH) Act (Title XIII) is a section of the American Recovery and Reinvestment Act (ARRA) of 2009. It is notable for creating financial incentives to stimulate the adoption of EHRs by healthcare providers, with the ultimate goal being interoperability to improve health information transfer and exchange, thereby facilitating medical treatment and improving the quality of care.

HITECH addresses the privacy and security risks associated with the electronic transmission of health information, calling for strengthened civil and criminal enforcement and harsher penalties for privacy and security breaches — the first significant amendments to HIPAA’s Privacy and Security sections since its enactment.

These include but are not limited to:
- Expanded security breach notification requirements that include notification of the affected patients and HHS notification in certain situations.
- Penalties for HIPAA violations have been increased, are tiered, and can range anywhere from $100 to $50,000 per violation, depending on the nature and extent of the violation and the nature and extent of the harm resulting from the breach.
- Expanded requirements for Business Associates.
- Expanded requirements regarding disclosure accounting.
- Patients may now request electronic copies of their PHI if the covered entity uses or maintains the PHI in electronic form (i.e., EHR). The patient may direct the electronic copy to be sent to him- or herself or to another entity or person.
- Increased restrictions on use of PHI for marketing and fundraising.
Requires covered entities to comply with patient-directed restrictions on disclosure of his or her health operations-related PHI if:
- the patient restricts disclosure to a health plan for payment or health operation purposes;
- the restriction is not related to information needed to carry out treatment; and
- if the restriction deals with information related to a treatment or service that has already been paid for by the patient (i.e., "out-of-pocket").

All covered providers must continue to comply with the HIPAA requirements as amended by ARRA or their specific state law – whichever is more restrictive.

[NOTE that this information is based on the HITECH Interim Final Rule that became effective on September 23, 2009, and remains in effect until the effective date of the breach notification final rule, which has not yet been released.]

**E-Discovery Rule** - The Federal Rules of Civil Procedure make it possible for parties in a lawsuit to request and use electronic data. Similar changes were made in a number of states. These rules set forth the process guiding discovery of electronic information or e-discovery.

In essence, the Federal -Discovery Rule:
- Established electronically stored information (ESI) as a separate and distinct class of discoverable information.
- Requires counsel for both parties – plaintiff and defendant – to have mandatory “meet-and-confer” sessions to specifically address e-discovery issues within 120 days of the filing of litigation, and at least 21 days prior to the scheduling conference.
- Specific discussion should include the form of data production, data preservation, and privilege waiver.
- Recognizes that some ESI may not be “reasonably inaccessible” because of undue burden or cost to either party and clarifies the obligation to produce same. However, “reasonably inaccessible” information may subsequently be determined to be discoverable and made available by court order and under court supervision if the requesting party can demonstrate good cause.

As noted many states have a similar process in place for e-discovery. For the physician office practice, the e-discovery Rule will affect anyone involved in the
practice’s patient medical information retention, release, and destruction processes. It is important to ensure that there are formal policies and procedures in place to ensure compliance with the E-Discovery Rule’s new requirements applicable to electronically stored PHI related to litigation. Development of such policies may involve outside legal, PHI, and IT expertise so that there is a consensus as to what should be included as ESI, what form(s) data to be released should take, what is or is not “unreasonably accessible” for the practice’s various sources of information, and who should administer and coordinate such efforts. Final policies and procedures should be disseminated to appropriate staff and enforced strictly to ensure that every request for PHI—whether hard-copy format or electronic—receives consistent and compliant attention and response.

Compiling a list of what constitutes the “e” in e-discovery can be quite expansive in a physician practice. Consider the following:

- Patients’ electronic health records (EHR).
- Voice-mail messages.
- Electronic appointment calendars.
- Electronic diagnostic information, including fetal monitoring strips, electroencephalograms (EEGs), electrocardiograms (ECGs), MRIs, and CT scans whether stored as part of an EMR or stored on separate servers.
- Web site information.
- Paper documents that have been scanned into an electronic format.
- Email messages and electronically attached documents.
- Electronic media used in training patients and family caregivers.
- Electronic consent forms.
- Electronic signatures.
- Electronic information on a personal digital assistant (PDA).
- Material created or stored on a digital camera or voice recording device.

The items listed above are only some of the more obvious examples. It is prudent for the employee(s) who are assigned to handle subpoenas for records involved in litigation to understand the e-discovery requirements and to know what information is stored electronically in the practice, how it is formatted, how it can be retrieved, etc.
Risk Exposures:
- Breach in Patient Confidentiality.
- HIPAA / HITECH non-compliance.
- Reputation of provider and Facility.
- Financial penalties to all providers involved in breach.

Risk Management Strategies:
- There are a number of legal and regulatory requirements that help shape the content and uses of the patient medical record in the physician office practice. Since these legal and regulatory requirements also include potential exposures, it is important to develop practical strategies to avoid such risk, including the following:
  - Work with administrative and clinical leadership, legal counsel, the practice compliance officer, and IT to develop a practical framework for the physician office medical record.
  - Take into consideration the requirements of state law and regulation.
  - Make certain that the design and use of the medical record is compliant with HIPAA Privacy and Safety, HITECH, and both federal and state e-discovery requirements.
  - Make certain that all personnel in the practice – including temporary staff, agency personnel and locum tenens – know how to comply with HIPAA Privacy requirements.
  - Implement a process to identify and address HITECH breach issues.
  - Work with IT and legal counsel to identify and electronically tag for e-discovery, EMR and EHR information and other electronic documentation that is subject to federal and state e-discovery. Include in this process what should be tagged for legal holds, meaning that it should not be shared absent legal counsel indicating one should do so.

Case Study:
Manny Nunez was a patient of the Britta Cardiology Group. He was receiving treatment for atrial flutter that included medication. When asked if he would like to permit his spouse, Theresa, to receive information from the Britta Group in his absence or in case of an urgent situation, he said, “No. I do not want to alarm her about my condition. She gets anxious very easily.” The intake receptionist for the Britta Cardiology Group started to enter Manny’s response when she was distracted by a small child screaming in the waiting area. Thinking that she had completed the intake registration, the receptionist hit the save button. The
software for the intake form had as a default the “Yes” category for spousal notification in urgent situations. Two months later, after receiving a warning about certain doses of the medication prescribed for Manny, Dr. Ray, his cardiologist, asked a certified medical technician to call Mr. Nunez and tell him that it was urgent that he cut the dose in half and make an appointment for a follow-up visit. The certified medical technician called Mr. Nunez and Theresa answered the phone. “Mrs. Nunez, I am calling on behalf of Dr. Ray, your husband’s cardiologist. May I speak with your husband, please?” she asked. Theresa Nunez replied, “No. he is on a business trip. Is there something wrong? What should I tell him if he calls?” In response the certified medical technician said, “Tell him to reduce the dose of his atrial flutter medicine immediately and to call us as soon as possible to schedule an appointment.” Mrs. Nunez called her husband on his cell phone. “What is going on? Why didn’t you tell me you are sick? What is wrong with your heart? Are you having serious problems? Your doctor’s office just called and left a message. It was about your medication for atrial flutter.” Mr. Nunez was very angry. He told his wife to calm down and that there was nothing to worry about. He then called Dr. Ray and told him what had happened. “I am going to going to move to another cardiologist where I can be certain that ‘No’ means ‘No’ in giving out my information,” said Mr. Nunez.

Applying Risk Management Strategies:

- Make certain that personnel possess the competencies to handle medical record documentation successfully, notwithstanding the challenges of background noise, telephones ringing and requests from colleagues for information. Encourage them to focus on task completion before responding to telephone calls or requests.
- Do not create default settings on electronic records that may create misunderstandings or set the stage for rules-based non-adherence such as delineating who may be contacted in the absence of the patient or in an urgent situation.
- Reinforce the importance of avoiding inadvertent disclosure of patient information.
- Provide orientation and annual mandatory training for administrative and clinical personnel regarding the physician office practice’s privacy policies and procedures.
- Ask patients or their legally authorized representative to complete a form or otherwise provide information about disclosure of PHI in all healthcare settings. The patient or authorized representative should provide the
names and contact information of those family members or friends to whom information may be given. This information should be documented in the record.

- Physicians and staff should be aware of patients’ wishes with regard to release of their medical information and respect those wishes as documented.
- Set expectations with patients regarding mandatory disclosure of protected health information in accordance with applicable law. (For example, child abuse, elder abuse, etc.)
- Avoid non-private areas as the location for discussions with patients and authorized representatives. Never discuss patient care in public areas, even in front of other employees or providers. If the information heard specifically identified the patient by name, that disclosure was unauthorized. While these are not malicious or criminal releases of PHI, they are breaches in patient confidentiality and can result in litigation and HIPAA penalties.
- Consider PHI security when using portable electronic devices such as cell phones, PDAs, smart phones, e-notebooks, laptops, and the like to discuss or transmit PHI. These bring with them their own set of risks with regard to inadvertent release if these devices are not used securely. Ensure that there are policies on the use of these devices as well as how to use these devices securely so as not to compromise patient confidentiality and privacy. (See Section D).
- All staff should know what to do or who to contact when a breach of PHI is discovered. Prompt action is important and policies and procedures should be in place so that breach notification measures are implemented in a timely fashion.
- Consider PHI security when using portable electronic devices such as cell phones, PDAs, smart phones, e-notebooks, laptops, and the like to discuss or transmit PHI. Provide staff with contact information to report known or suspected breaches of PHI requirements.
- Require contractors and vendors that have access to PHI, to provide prompt notification of a data breach.
E. Transmission of PHI on smart phones, PDAs, tablets, and other electronic devices

Unauthorized access to PHI is a risk management concern stemming from the transmission and exchange of patient data on “smart” phones, PDAs, tablets, e-notebooks, and other electronic devices. PHI is at risk when it is stored on a smart phone, tablet, laptop, or any other portable electronic device and that device is lost, misplaced or stolen. Although the devices may be the target of thieves who wish to resell such equipment, a serious concern involves hackers who are interested in the data stored on these electronic tools. Health care records are increasingly the target of identity thieves because the files contain demographic information such as phone, address, names of relatives, and, possibly the most desired piece of data, the social security number.

Security is a key risk management concern with the array of electronic devices used in the transmission of patient data. This includes unencrypted network transmission, Bluetooth networks, and WiFi access. In addition to performing the usual phone duties, Smart phones can synchronize data to and from the physician practice PC, a physician’s home PC to the office, from the PC at the hospital back to the office allowing physicians to check email, get consults and referrals anywhere, have the entire PDR at his or her fingertips, take, receive and send photographs, and receive and send text messages. These transmissions through the Ethernet can speed the timely transfer of critical patient information from provider to provider or facility to facility – reducing treatment and diagnosis delays and errors but also can breach patient confidentiality and inadvertently release PHI if not used and maintained securely. When using these electronic devices for communication, discussion, storage, or transmission of PHI, particularly in public places care providers should be aware of each the limitations of security for these tools and vulnerability to attackers trolling for personal information.

**Risk Exposures:**
- Breach in Patient Confidentiality.
- HIPAA / HITECH non-compliance.
- Reputation of provider and Facility.
- Financial penalties to all providers involved in breach.

**Risk Management Strategies:**
The practice should have an IT security policy regarding use of such devices both in the office and off-site. IT experts can provide guidance in developing policies on how the practice staff can and cannot use these devices securely so as not to
compromise patient privacy. A good IT Security Policy for the physician practice would include:

- Guidelines on downloading PHI to hand-held encrypted electronic devices.
- Guidelines and education on maintaining security of hand-held devices.
- Guidance on transmission and storage methods of any type of PHI on a portable electronic device or drive.
- Standards on EHR security and data encryption.
- Guidelines on staff use of these devices for personal communications during work hours from the office.
- Guidelines on electronic communication of PHI between providers, emphasizing such data transmission must be accomplished on secure networks and communication should not take place to or from non-work-related email addresses or networks.
- Guidance on the use of electronic or text communication between physician and patients.

**NOTE:** Electronic and text communication between care providers and patients is discouraged due to concerns about electronic security and hacking as well as the potentials for misunderstanding an electronic or text communication. Similarly, delays in care can occur if there is a long lag time between a patient sending a text or email communication and the care provider having the time to respond to it.

Recognize that many physician office practices now use secure web portals to facilitate communication between patients and care providers. Patients are given a website address and PIN to enter the secure website to leave messages for care providers. Similarly, care providers can leave messages for patients in this way, including test results, the need for follow-up visits, etc. Using the secure web portal means setting a clear expectation with patients about the “ground rules” for e-communication including:

- How to use the secure web portal.
- Refraining from sending unencrypted email or text messages via regular email accounts.
- What should be included in the web portal message.
- No text-messaging style, “shorthand” should be used in a message.
- The timeframe for a response to a secure message.
- Informing the patient that any messages written in the secure website portal will become a part of the patient’s permanent medical record in the practice.
Informing the patient that email communication will be provided the same level of protection from unauthorized disclosure as any other part of her medical record.

A key component is to include a warning on the secure web portal specifically advising patients when they should NOT communicate electronically, e.g., in an emergency situation when a delayed response time could put the patient’s health and well-being in jeopardy. The warning may also be posted in the office and in the patient intake acknowledgement documents. Many practices also use a specific patient-provider electronic communication agreement form that serves as an educational and reinforcing document to demonstrate what the patient can expect from the practice and its physicians in this regard, what is expected of him or her in return, and that she agrees with and will abide by the terms of the agreement.

For the practice, it is equally important that care providers follow a secure web portal patient communication protocol in terms of frequency of checking for messages and responding to questions from patients. A useful aspect of the protocol is a reminder that when a patient or a care provider enters information via the secure web portal, the entry is captured in terms of user, time and date. This can help facilitate continuity of care, especially with regard to patients needing to obtain follow-up care.

**Case Example:**
Melinda Sands signed up to use the secure web portal of the Vincent GI Practice. She was given written instructions on how to use the system and she was asked to demonstrate how to use it as well. She signed a patient user agreement, acknowledging that it was her responsibility to use the secure web portal to check for test results, medication changes, and follow-up appointments. Ms. Sands had Crohn’s Disease and was recovering from a flare-up for which she was hospitalized. Dr. Vincenti, reviewed the discharge report from the hospital. He was displeased that the medication list did not include a key prescription used by the patient. Moreover, he was concerned about changes in the dose of two other drugs. He used the secure web portal messaging system to tell Ms. Sands to modify the drug regimen. When there was no activity indicating that Ms. Sands had read the message, Dr. Vincenti telephoned the patient. “Oh, thank you for calling me Dr. Vincenti. My computer is in the shop for repairs. I am supposed to pick it up tomorrow. I am sorry that I did not get the email message. Yes, I will make the adjustments to the medication,” said Ms. Sands.
Applying Risk Management Strategies:
- Educate patients on the use of email and text communication.
- Make certain that a secure web portal for messaging between patients and care providers includes date- and time-stamping on posting and retrieving messages.
- Set a “tickler” alert so that the care provider who uploads a secure message that is not retrieved can take appropriate measures, including telephoning the patient.
- Document the follow-up telephone call in the patient medical record.
- Reinforce with patients the importance of letting the practice know when they are unable to retrieve or send messages via the secure web portal system.

F. E-Prescribing
E-prescribing is increasingly the norm, especially with CMS incentivizing the use of e-prescribing under its Medicare Quality Reporting Incentive Programs. In the CMS program Electronic Prescribing (eRx) is defined as:

The transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan either directly or through an intermediary, including an eRx network. Electronic prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser. Durable Medical Equipment (DME) and over-the-counter medications may be electronically prescribed for the purpose of this measure. (Faxes initiated from the eligible professional’s office do not qualify as electronic prescribing). ¹

Aside from financial incentives tied to specifications for a qualified eRx system under the CMS program, there are practical risk management considerations involving use of this technology.

Risk Exposures:
- Medical malpractice.

¹ Medicare E-Prescribing Incentive Program: Group Practice Reporting Option. CMS Website: https://www.cms.gov/ERxIncentive/07_Group_Practice_Reporting_Option.asp#TopOfPage
Risk Management Strategies:
There are several ways in which legal and regulatory exposures can be avoided in using an e-prescribing system. These strategies include:

- Aligning the E-Prescribing system with the requirements set forth by CMS for eRx.
- Make certain that the e-prescribing system has a function that captures successful transmission, time, and date of an electronic prescription.
- Training care providers how to use the e-prescribing system.
- Using patient safety defaults built into the e-prescribing system to identify wrong dose; wrong drug (for this patient); drug-drug interaction and food-drug interactions that must be avoided when prescribing the drug.
- Insist on care providers following the patient safety defaults and, when a decision is made not to do so, to document the reasons for taking such action. For example, an off-label use of a medication.
- Insist on Business Associate Agreements with vendors who supply the e-prescribing software and also require vendors to provide alerts to any known or suspected breach potentials in the software.
- Work with IT to develop security parameters for the e-prescribing System.
- Obtain legal and compliance advice to make certain that the system will meet CMS and state requirements.

Case Example:
Deborah Timmons, PA-C was new to the GMW Medical Group. She had only had a brief exposure to e-prescribing at her last job. She was given a quick orientation on the system by the IT manager. All seemed to be going well with Ms. Timmons becoming an effective member of the GMW Medical Group. On one occasion, however, Ms. Timmons wanted to change the dose of an antibiotic for a patient. The system would not let Ms. Timmons do so. Ms. Timmons called the IT manager and said, “I need some help here. This program won’t let me send the prescription.” The IT manager came to the work station and reviewed with Ms. Timmons what the steps she had taken to the point that the order could not be processed. “I see what happened. You were trying to override the dose calculated on the patient’s weight parameter. You cannot do it unless you provide the variance explanation first. This is how you do it,” said the IT manager.

Applying Risk Management Strategies:
- Provide clinical personnel with training on common challenges that may occur with an e-prescribing system.
Discourage personnel from trying to override defaults other than in the manner approved for documenting a variance.

Encourage personnel to seek assistance from a knowledgeable person in the physician office practice or from an approved help line to address difficulties in using the e-prescribing system.

G. Record Retention and Destruction

Record retention considerations involve both clinical and business information. Many states have laws delineating record retention periods for clinical, tax, and business records. The same is true at the Federal level. For example, record retention periods can be found for the Internal Revenue Service, for HIPAA Administrative Simplification Rules, and other purposes.

Due to liability exposure for medical malpractice, the statute of limitation or timeframe in which one may be subject to litigation, also factors into calculating a record retention period. For physician practices involved with infants, children, and developmentally disabled individuals, the statute of limitation may be much longer for the record of those groups of patients than for other patients.

Contracts can also help to establish the retention period.

The record retention issue may not be a major factor with the move to EMR and EHR. However, as with paper record storage, there are monetary costs to consider.

A related issue is destruction of archival record information that is no longer required to be maintained for legal, regulatory or clinical purposes. There are national guidelines and recommendations regarding record destruction. These include recommendations from the American Health Information Management Association (AHIMA). Care should be exercised to segregate those records that are needed or may be needed in litigation, as well as regulatory issues such as responding to a RACs inquiry or tax matter.

Risk Management Exposures:

- Non-compliance with applicable state and federal laws and regulations.
- Breach of contract.
- Medical malpractice.
Risk Management Strategies:
There are a number of factors that should be considered in developing a risk management strategy for record retention. Consider the following:

- The types of records to be stored in hard copy or electronic format.
- The content of retained records: business, tax, or clinical information.
- Storage of electronic clinical data on servers maintained by the clinical practice or related healthcare entities (For example: PACS images, ECGs, EEGs, and fetal monitoring tracings).
- Storage of hard-copy clinical data in boxes separate from related and stored patient records, such as x-ray films, EEGs, ECGs, and fetal monitoring tracings.
- Legal requirements (limitation periods) for record storage set by applicable state and federal laws and regulations, including HIPAA and the federal Privacy Act of 1974.
- Work with IT, billing, coding, administrative and clinical personnel to standardize an indexing system for archiving records.
- Make certain that the indexing system applies to both hard copy and electronic records.
- Population-specific laws and regulations that extend the limitation period and record retention timeframe.
- Contracts that set record retention periods.
- Develop with legal counsel an agreement with outsourced storage facilities (paper and electronic) that addresses:
  - Access to archived material.
  - Cost of accessing archived data.
  - Facility specifications for storage of hard copy and electronic record information, including temperature, humidity, fire suppression, and physical security.
  - Right of first refusal to accept a change of ownership or management of the outsourced storage facility.
  - Insurance coverage requirements.
- Make certain that hard copy active records are stored in a secure manner.
- Make certain that active electronic records are backed up off-site in a secure manner.
- Designate individuals in the physician office practice who are responsible for maintaining the integrity of the record retention schedule.
Work with IT, billing, coding, administrative and clinical personnel as well as legal counsel to develop a record destruction process. Note this process is particularly important with respect to hard-copy documentation.

Establish the method for record disposal (e.g., shredding or burning), including whether an employee of the practice or a vendor will dispose of records no longer required to be retained.

Establish a policy for purging records that should be removed and destroyed.

Ask legal counsel to review agreements with vendors who are hired to dispose of records, including the method to be used, transport of records to be destroyed, and insurance coverages for failure to meet standards for safe destruction of records.

Maintain a Record Destruction Log that includes specifics on which records have been destroyed, when, where, how, and by whom; the log should include the patient’s name, date of birth, date of last visit, and format (e.g., paper, CD-ROM, microfiche, etc.) as well.

Case Example:
A three-physician internal medicine practice was located in an area known for severe storms and tornadoes. The practice was in the process of selecting a vendor from whom to purchase an EMR system. The practice kept archival records of billing and coding information off-site at a local document storage center. However, due to the cost of storing archival hard-copy clinical records at the same facility, a decision had been made to keep the “old” patient records in the basement of the medical office building. The decision proved unwise after a strong tornado devastated the medical building. The records stored in the basement of the medical building were lost. People residing some five miles away told a local media outlet that they had found all kinds of medical records of their neighbors strewn across their backyards.

Applying Risk Management Strategies:
- Follow guidelines and advice of legal counsel on record retention.
- Consider safety and security of archival records to guard against theft, damage and destruction.
- Look to national standards and guidelines for safe and effective destruction of records that no longer need to be retained for legal, regulatory or clinical purposes. See, the summary of guidelines from AHIMA, below.
- Destroy records so there is no possibility of reconstruction of information.
Develop methods to destroy computerized data permanently and irreversibly.

Reassess destruction methods annually.

- Document the destruction as follows:
  - Date of Destruction.
  - Method of Destruction.
  - Description of disposed series, and
  - Inclusive dates covered.

Obtain from the vendor who will be destroying the records:

- A Business Association Agreement for HIPAA compliance.
- A certificate of destruction.
- Signatures of authorized representative of the vendor.
- A statement that the records were destroyed in the normal course of business.

Make sure the destruction contract includes method of destruction and time to elapse between acquisition and destruction.

Establish safeguards for confidentiality.

Indemnify your practice from loss due to unauthorized disclosure

Provide proof of destruction.

H. Record Back-Up And Recovery Process

All practices should have processes, guidelines and procedures in place whereby all data stored electronically is routinely backed up to prevent problems that could result in data loss or system interruptions and for prompt data recovery should a loss or interruption occur. This Backup and Recovery Plan is part of a larger Business Continuity Plan. The Recovery Processes are the steps that are required to restore the system and return the practice to normal day-to-day operations and healthcare delivery. This means having a paper-based documentation process in place to use during the time electronic record systems are inoperable and a procedure for uploading hard-copy information once the electronic system is restored.

Risk Management Exposures:

- Negligence.
- Business disruption.
- Lost revenue.
- Diminished market share.
Risk Management Strategies:
A successful Backup and Recovery Plan includes several strategies such as the following:

- A schedule for all periodic backups of the practice’s data systems, labeling all files, and storage information of the backup files (off-site storage is obviously preferable);
- Identifying trained practice personnel responsible for the regularly scheduled backup process;
- Acceptable Downtime – how much IT system downtime the practice can accommodate without compromising operational efficiency and the delivery of the usual level of patient care;
- A process for shifting to hard-copy documentation during down times and then uploading paper-based information once the electronic record system is back online.
- A List of Critical Systems – if there is more than one system in the practice (e.g., a billing system, an EHR system, etc.), which is most critical? Which one should be brought back online first? Which has the highest recovery priority based on factors like effect on the health and safety of staff, patients, and visitors; any legal implications or liability it exposes; confidentiality of PHI and the practice’s business information; the risk to corporate confidentiality, and replacement costs.
- Key personnel and their individual or group tasks and/or roles in the Recovery Process are identified.

Case Example:
The Sphere Pediatric Group went completely “paperless” in 2010. The system included a local server and a remote location back-up system. After a large substation exploded, the Sphere Pediatric Group lost power. It was learned that power would not be restored for at least 10 to 12 hours since new electric equipment had to be brought in from another part of the state. The practice had a short-term back-up power supply that would last for about 6 hours. The electronic record system was not on the list of equipment powered by the back-up system. Dr. Ted Sphere and the practice manager called a staff meeting and decided to cancel all patient appointments after 3 pm. For those patients who were to be seen that day, paper records would be used and those responsible for EMR recovery would then upload the documents once the system was back online.
Applying Risk Management Strategies:

- Anticipate disruptions in access to or use of electronic records.
- Implement a Back-up and Recovery plan for business and clinical record information.
- Make certain that practice personnel are trained on steps to follow when there is a disruption in the use of or access to electronic record systems.
- Follow procedures for bringing electronic record systems online, including the use of backup and recovery of records.
- Follow procedures for uploading hard-copy records generated during situations in which there is a disruption in access to or use of electronic records.

I. Release Of Patient Health Information

It is generally accepted that a physician and/or physician practice is the legal owner of medical records generated during the care and treatment of patients. However, most states recognize a patient's right to access to his or her own records. A physician’s office must comply with a patient request to view his or her own medical record (or to authorize someone other than the patient to have access to the record on behalf of the patient). However, first and foremost, the practice, its physicians, and its staff have a duty to protect patient confidentiality and protect the information contained in a patient’s medical record from inadvertent or unauthorized disclosure. For that reason, it is important that physician practices develop and implement protective policies and procedures to ensure confidentiality of patient health information.

If the patient indicates that he or she wants his or her records, the appropriate medical record release form should be completed and signed by the patient or his or her representative (e.g., a parent or legal guardian in the case of a minor patient, someone holding power of attorney for the patient, the executor of a deceased patient’s estate, etc.). Some states require more than one signed authorization, for example, if the patient is authorizing release of general records and mental health records, or records containing HIV/AIDS information. Practices should be aware of the specific authorization to release records required in their states and tailor their forms accordingly.

Once the appropriate release has been signed, the patient should be given a copy – never the original – of his or her record in a timely fashion. Note that, generally, the HIPAA Privacy Rule requires a covered entity to provide a patient
with a copy of his or her medical record in the format requested by the patient within 30 days of the patient’s request, or in cases where the patient records are not stored on-site by the covered entity, no later than 60 days of the patient’s request. Generally speaking, it is good policy to never allow any original medical records to leave the premises. If the patient requests a copy of his or her own record either for transfer to another health care provider or for personal purposes, most states permit health care entities to charge a “reasonable” copying fee. A patient’s record should never be “held hostage” by a health care facility or physician’s office in an attempt to recoup outstanding charges (e.g., “We won't release your records to you until your account is settled”).

There are notable exceptions in several states in which patient medical record information may be released without the patient's expressed permission; for example, in workers' compensation cases, for court-ordered treatment, and when communication of information is required by statute as with cases of infectious diseases, venereal diseases, gunshot wounds, suspected child abuse, etc. However, such exceptions only apply to general medical records. Many states provide an added level of protection to information related to documentation of mental health treatment and to drug or alcohol rehabilitation, HIV/AIDS, and pregnancy in a minor patient. Record release policies, procedures, and forms should follow applicable state law in this regard.

**Risk Management Exposures:**
- Breach of applicable state law on disclosure and release of patient health information.
- Breach of HIPAA Privacy requirements.
- Adverse publicity.
- Litigation.

**Risk Management Strategies:**
There are a number of practical strategies to consider for release of patient health information, including the following:
- Orient all administrative, clinical and temporary staff to the requirements for safeguarding patient health information under HIPAA and state law.
- Establish a standard process for managing release of patient health information and records.
- Designate specifically trained personnel to manage release of patient records.
Make certain that specific authorizations for release of patient records involving HIV status, pregnancy of a minor, mental health treatment, and others noted in state law are handled in accordance with legislative and regulatory requirements. Flag those records that contain information requiring a separate authorization to release in some consistent and noticeable way to prevent their inadvertent release in response to a general record request.

Encourage personnel to seek assistance from the practice manager when there is any doubt about the authenticity of a request for access to or release of patient health information and records.

Make certain that the practice manager has access to legal counsel to address situations involving the propriety of releasing patient health information.

Make certain that the practice’s policies and procedure address record release, including third-party access and the fees charged to patients for copies of their records.

Case Example:
Liz Nettles was helping her 83-year-old aunt move to Florida. She said that the elderly woman was to move into an assisted-living facility. Ms. Nettles wanted to get a copy of her aunt’s medical records to take with them to Florida. “I cannot act on your request,” said the office manager. “But I need that information,” insisted Ms. Nettles. “I will be happy to assist you once I have a signed release from your aunt. We have a specific form for this purpose that meets state requirements. However, it must be signed by her or, if she is under a legal guardianship for medical decision-making, by her duly authorized legal representative. Please understand this requirement is designed to protect the confidentiality of the patient’s information,” said the office manager.

Applying Risk Management Strategies:
- Follow established policy and procedure for the release of patient health information and records.
- Never release original patient records; instead provide a copy.
- Be prepared to address third-party requests for patient record information.
- Require a signed release for patient records from either the patient or a duly authorized legal representative.
- Recognize that there are situations in which patient record information may be released pursuant to state law requirements.
J. Policies And Procedures In The Physician Practice
A formal, up-to-date Policies and Procedures Manual (electronic or paper) is a valuable tool for the practice and its professional, clinical, and administrative staffs. It allows the practice to operate consistently and efficiently and compliantly with regard to state and federal rules and regulations that affect patient care; medical records/PHI storage, protection, release; employment issues including interviewing and hiring, orientation, benefits and compensation, absences and vacations, disciplinary actions and dismissal; Confidentiality Statements; Patient Rights, Americans with Disabilities Act (ADA) and antidiscrimination requirements and practices; Equal Employment Opportunity Commission (EEOC) requirements; OSHA regulations with regard to staff safety, infection control, hazardous materials, etc. In addition, it is the primary resource tool for the practice or employer to communicate with its employees with regard to what the practice will do and provide for them in the course of employment and what is expected of them in return. As suggested in this Risk Management Manual, it should include scheduling guidelines, telephone answering guidelines and triage, patient calls for prescription refills or to speak to a physician, documentation issues, office emergencies, patient complaints, disruptive behavior, etc.

It should be noted, however, that practice policy and procedures may be viewed as setting a standard of care. Thus, if there is a departure from an established policy and procedure and there is injury to a patient, the stage may be set for negligence litigation. Further, the failure to keep policies and procedures current may be seen as following outdated practices. This is as true for clinical policies and procedures as it is for those dealing with billing, coding, and employment practices.

Risk Management Exposures:
- Negligence litigation.
- Employment practices liability exposure.
- Regulatory non-compliance.
Risk Management Strategies:
There are some practical steps to consider in developing and implementing policies and procedures for a physician office practice. These risk management strategies include the following:

- Develop and use a standard template for all policies and procedures in the physician office practice.
- Make certain that the content is easy to understand and apply.
- Field-test policies and procedures with colleagues. If there is uncertainty in how to apply the content or it is subject to varying interpretations, revise the content accordingly.
- Orient new colleagues and temporary personnel on how to apply policies and procedures.
- Make certain that colleagues have an identified “go to” person when there is any doubt in applying policies and procedures.
- Number each policy and procedure and include the origination date, date of review (at least annually), and a signature block for the person authorizing the policy and procedure.
- Do not include references to state or federal legislation, regulations, or guidelines case law or accreditation standards as these references frequently change and may not be accessible to staff.
- Include a “redirect” indicator to superseded or replaced policies and procedures.
- Maintain a copy of expired or retired policies and procedures in accordance with the documentation retention schedule established for the practice.
- Provide orientation on new or revised policies and procedures.
- Encourage all personnel to exercise professional judgment in the use of policies and procedures.

Case Example:
Marge Tollie took over responsibilities for coding and billing for the Brooder Medical Group. A large, multi-specialty group, Brooder had transitioned to an electronic documentation system three months prior to hiring Ms. Tollie. In reviewing policies and procedures for coding and billing, Ms. Tollie noticed references to outdated industry standards. She looked more closely and realized that many of the policies had been scanned into the electronic system. Approximately 50% of the documents had not been reviewed for three years -- at least that was the implication drawn from the last review date. Ms. Tollie discussed it with the practice manager. “Oh yes. Good thing you saw it. I was
meaning to tell you about it, Marge. Your predecessor sort of let it go, thinking the issue would be handled when we went electronic. Let me know if you need any assistance in revising the policies and procedures. Feel free to speak with the outside accounting firm too, if you have any questions,” said the practice manager.

**Applying Risk Management Strategies:**

- Complete at a minimum an annual review of policies and procedures to make certain that the content is current.
- Make certain that the review is documented by including a review date and the signature of the reviewer.
- When moving to an electronic platform, make certain that policies and procedures are not just scanned into the system. Instead, make certain that the content can be modified and that it is searchable.
- Maintain archival copies of retired policies and procedures in accordance with the document retention schedule for the physician office practice.
V. Communication with Specialists, Hospitalists, Pharmacies, Labs and Diagnostic Centers

Physicians, particularly those in Family Practice, Primary Care and Internal Medicine, routinely find the need to consult with another physician, usually a specialist or subspecialist for diagnostic or treatment recommendations or assistance, diagnostic testing, specialized care, and the like. The process sounds simple enough – one physician asking another for assistance in caring for one patient. From a risk management and professional liability claims perspectives, however, communication breakdowns during the referral and consultation process frequently lead to patient injury and subsequent litigation. The breakdown of information flow can occur anywhere along the consultation continuum – between physician and patient, physician and consultant, patient and consultant, or consultant and referring physician – for a variety of reasons. This section will look at the consultation process and look at steps that can be taken to prevent communications breakdowns so that all involved get the intended benefit(s) of the consultation.

The first step in the process is for a physician, particularly those in Family Practice, Primary Care and Internal Medicine, to recognize the need for a consultation or referral. All physicians have a duty to consult whenever he or she is lacking the training, knowledge or expertise necessary to diagnose or treat a patient’s condition. In addition, there will be circumstances that warrant or may benefit from a consultation for a second opinion. Once the need for a consultation has been determined, the referring physician should find the consultant/specialist who is most competent to handle the patient’s medical problem or condition.

It is at this point in the process that the risk of communication breakdowns first arises. To assure patient compliance with the recommendation for consultation, the referring physician must convey to the patient the purpose, importance, and necessity behind the decision to refer. The urgency of the situation should also be conveyed: “I’ll have one of my staff make the consult appointment for you before you leave the office today so that we can get you in to see Dr. Young as soon as possible” vs. “I’d like you to see Dr. Young about this before next year’s annual physical with me.” The patient should leave with an understanding of
why the consult is necessary, what the referring physician hopes to learn from it and, to the extent possible, the probable outcome of the referral (e.g., additional diagnostic testing, hospital admission, surgery, etc.).

There are other types of communication that impact the delivery of patient care. These include discussions with and written correspondence from specialists, hospitalists and on-call providers. Keeping track of these important communications is essential for maintaining continuity of care. One of the more vulnerable communication areas involves late or missing reports expected from diagnostic imaging centers, clinical laboratories or specialists. Sometimes this information can be written in a vague or unclear manner necessitating follow-up communication prior to initiating treatment or recommending an intervention procedure.

Physician office practices can anticipate their own share of calls seeking clarification, particularly from pharmacies filling prescriptions for patients. Such inquiries need to be handled promptly, making certain that potential food-drug, drug-drug, sensitivity or allergies identified on the pharmacy e-Alert system is reconciled with data in office record system.

**A. Patient authorization**

At the point that the provider feels that a “consultation” for diagnosis or treatment is warranted, the patient has to agree to or refuse the recommended consult. Part of the discussion should include setting clear expectations about the timeframe for an appointment with the consultant and also, the need to check with the patient’s health insurer to see if a prior authorization is needed. If the care provider is “out-of-network,” the patient should understand that there could be a higher co-pay for such services. These are matters that the patient should discuss with his or her health insurer. Care providers should be prepared for patients asking for a consult with an in-network specialist.

If the patient refuses despite the referring physician's discussion of why the consult is needed, documentation of the refusal in the patient chart is very important. That note should include the details of the consultation that were provided to the patient, the patient’s perceived or stated understanding of the ramifications of not complying with the consultation recommendation and the fact that, despite all that, the patient still elected to refuse consultation. In some
instances, care providers may ask the patient to sign a document attesting to the fact that the patient declined the consultation.

**Risk Management Exposures:**
- Negligence.
- Lack of informed refusal of a consultation.
- Patient complaints.

**Risk Management Strategies:**
To facilitate a patient authorization for a consultation to a specialist or for diagnostic testing, there are some practical strategies to consider:
- Explain the reasons for the recommended diagnostic test or referral for a consultation by a specialist.
- Ask the patient to verify with his or her health insurer if the recommended diagnostic facility or specialist is within “network.”
- Ask the patient to confirm with his or her health insurer if there is a higher co-pay for out-of-network diagnostic centers or specialists since this may be a factor in the patient’s decision whether to authorize the referral.
- Consider in-network providers for the referral.
- Be poised to have a frank discussion about co-pay costs for expensive diagnostic test referrals and the possible options to such procedures.
- Make certain the patient understands the consequences of refusing recommended and alternative diagnostic procedures.
- Make certain the patient understands the consequences of declining a referral to a specialist.
- Document the patient’s refusal of the referral for diagnostic testing or a specialist consult. Check with legal counsel if the preferred manner is to ask the patient to sign a refusal document.
- Obtain the patient’s or legal guardian’s written authorization for release and transmission of relevant patient health information to the identified diagnostic center or specialist.

**Case Example:**
Karen Henning had a history of recurrent sinus infections. Her primary care provider was concerned that the pattern was indicative of a more complex problem. She wanted to refer Ms. Henning to a well-respected ENT specialist at the academic medical center. “Is he covered? I mean, is he in my insurance plan? I cannot afford to pay those high co-pays for doctors who are not in my network,” said Ms. Henning. The primary care provider said, “Please call your
health insurer now. I have a private area in the office where you can place the call. If this specialist is not in the network, I will help identify another ENT provider for you who is,” said the primary care provider. Ms. Henning made the call and learned that the specialist was in network. “That is great news, Ms. Henning. Before you leave today, please sign the release form allowing me to send electronically your relevant health information to the specialist. I will be looking forward to seeing his report,” said the primary care provider.

Applying Risk Management Strategies:

- Set clear expectations for recommending a referral to a specialist or to undergo diagnostic testing.
- Make certain the patient understand the potential for higher co-pays for out-of-network providers.
- Give the patient the opportunity to confirm that a recommended specialist or diagnostic center is within network.
- Be prepared to recommend an in-network specialist or diagnostic center.
- Ask the patient or his or her legal guardian to sign a release authorizing transmission of pertinent health information to the specialist or diagnostic center.

B. Consult Content Requirements

The referral process should be completed in a timely manner. Once the patient has signed the record release, relevant information should be sent to the consulting physician. Many practices include a letter with the consultation request that outlines the reason for the diagnostic work or specialist visit. Some have template letters available in which the care provider or an administrative person can type in the reason for the consultation. In urgent situations, the care provider may elect to speak with the specialist or the clinician at the diagnostic center. A copy of the referral or a summary of urgent call request should be included in the patient record.

The referring physician, the patient, and the specialist should have a clear understanding regarding the consultation. Is the referral for an evaluation or to manage the patient’s specialty needs? If it is the latter, what information will be shared with the referring physician to assure continuity of care? In complex situations in which more than one referral physician is involved in the care of the patient who will be the accountable care provider for managing the patient’s
comprehensive medical needs? These questions should be addressed as part of the consultation process.

**Risk Exposures:**
- Negligent referral for consultation.
- Negligent delay in making a referral to a specialist.
- Negligent delay in referring the patient for diagnostic services.
- Patient complaints.

**Risk Management Strategies**
There are several practical measures to consider for consultation referral requirements, including the following:
- Determine that the specialist or diagnostic center can provide the necessary service within a reasonable time period and in a geographic area accessible to the patient.
- With record information authorized for release by the patient include a request letter outlining the reason for the referral and the deliverable expected in response.
- Utilize a telephone referral process for urgent cases and document in the patient record, the date, time, and person with whom the conversation took place. Include a summary of the conversation, especially the expectation of seeing the patient or completing diagnostic tests and receipt of report.
- Make clear whether the consultation with a specialist is for recommendation or for actual, ongoing care of the patient’s condition.
- Have office personnel confirm receipt of the referral letter and clinical information with the specialist or diagnostic center. Include the confirmation in the patient record.
- Work with the treating specialist or specialists to identify who will be the care provider responsible for coordination of patient care, making certain that all care providers receive regular updated information to assure continuity of care.

**Case Example:**
Stan Morrow was considered a complex Type II diabetes patient. He had CHF, coronary artery disease, renal failure, peripheral neuropathy and glaucoma. Although his cardiac issues were under control, his renal failure and neuropathy were not. Mr. Morrow was under the care of several specialists, but he always insisted on seeing his primary care provider, Cindy Nance, DO. “I trust you. I
want you to be my quarterback. I have had too many problems with repeated blood tests, medications that clash with what I am already taking, and I just do not feel comfortable. Can you help me Dr. Nance?” he asked. Dr. Nance said she would do what she could to assist him. She contacted the other care providers and shared the patient’s concerns. She offered to be what Mr. Morrow called, “the quarterback.” As she said to her colleagues, “After all, I referred Mr. Morrow to you all. It is the least that I can do.” All the care providers agreed.

Applying Risk Management Strategies:

- Develop a process for referral to specialists and diagnostic centers.
- Make certain that there is a cover letter or document that accompanies patient health information send to the specialist or diagnostic center that outlines expectations.
- Document urgent requests for consultation in the medical record.
- Develop a coordinated approach for complex patient cases in which one care provider manages.

C. Follow-up on Diagnostic and Specialist Reports

All aspects of the consultation / referral process should be discussed and confirmed by all parties. For instance, the referring physician cannot assume that the patient was seen by the consultant. “No news is good news” does not apply with regard to referred patients or consultation results. At the same time, the consultant cannot assume that the referring physician will automatically be copied on test results, treatment decisions, discharge summaries, etc. Follow-up mechanisms should be in place to insure that the patient completed scheduled appointments with the consultant and that test results, treatment decisions, and consult/referral outcomes were communicated to the respective parties.

Many practices use calendar “tickler systems” to trigger office staff to verify that tests or consultations have been completed and received. This process is sometimes in hard-copy format and, with EMR and EHR systems, an “e” reminder prompts confirmation. The results may be captured in a “test results log” in the patient record or “consultation report log.” Whether in hard-copy or electronic format, the log typically includes:

- A list of all tests ordered.
- The date when the test results are received.
- The date when the ordering care provider reviewed the results.
- The follow-up, if any, ordered by the physician.
- The date and format in which the patient was notified of the results and any follow-up instructions.

A similar process is used with respect to diagnostic imaging and specialist reports.

As noted in another section of this manual, some practices have “closed the loop” on patient notification by using a secure message system. One type involves a secure website or web portal. The patient is given the website address and a PIN number to retrieve his or her unique information, including test or consult results and follow-up instructions. Another process relies upon a toll-free telephone number system. The patient is given the telephone number and a PIN number. Once into the system, the patient hears a recorded message that will review test results and follow-up instructions. Once the patient has entered the website or dialed into the secure phone number, the system date and time stamps completion of the notification. Such information can be entered into the patient hard-copy record, EMR or EHR.

The key is to avoid ineffective tracking processes that could lead to delays in diagnosis or care or result in patient injury.

**Risk Management Exposures:**

- Negligent delay in care
- Medical malpractice
- Adverse publicity
- Professional licensure action
- Loss of Market Share.

**Risk Management Strategies:**

Follow-up on diagnostic tests and specialist reports are an important aspect of a well-managed physician practice. Such measures should include processes for tracking late or missing reports and also include a framework for receipt of critical test results. Practical strategies to consider for this purpose include the following:

- Implement a practical policy, procedure, and process for follow-up on diagnostic and specialist reports.
- Make certain that the system is consistent with the documentation methods used in the practice, including hard-copy or electronic records.
- Include in the process notification methods for patients regarding test results, specialist reports, and recommended follow-up.
- Build into the process a framework for critical test result notification to the ordering care provider and patient.
- Consider efficient, secure patient notification systems such as web-based portal or toll-free notification retrieval that place responsibility on the patient to obtain information.
- Make certain that patient-driven retrieval systems include date and time-stamping to indicate that the patient did obtain test results and follow-up instructions.
- Build into the patient-driven retrieval system a tickler that alerts office personnel when a patient has not obtained test results or follow-up instructions.
- Incorporate a process for telephone and/or mailed correspondence when there is no response to a patient notification, including correspondence sent return receipt with confirmation through the U.S. Postal Service or via courier.
- Obtain during the patient intake process an authorization for how to notify patients of test results, specialist reports, and follow-up instructions, including with whom information may be shared for this purpose, consistent with HIPAA Privacy requirements and applicable state law.
- Make certain that the patient understands his or her responsibility to notify the ordering physician if a choice is made not to undergo testing or completing the consultation with a specialist.
- Make certain that patients are oriented to and agree to use the electronic notification system.
- Maintain a process for telephone and written notification for patients who elect not to use the electronic process.
- Orient staff how to manage the tickler process for situations in which test results or specialist reports are not received by a specific date.
- Make certain that the ordering care provider reviews test results and specialist reports and documents that the review has been completed including the date and any follow-up action. The care providers signature or e-signature should be included in the notation.
- Recognize that there are different modalities for tracking tests and specialist reports including hard-copy and electronic logs and entries in the patient record.
Design the process such that test results and specialist reports cannot be entered into the patient record absent a dated, review, action indication and signature.

Incorporate into the process a mechanism for tracking late or missing reports.

Consider the following examples for recording patient notification of test results and instructions for follow-up.

12/14/11, 2:15PM – Dr. Jones reviewed mammogram report. Patient called re: negative mammography report. Appointment given for repeat screening mammogram in one year. Patient states she understands information and will keep annual appt.

J.Smith, RN

12/18/11, 9:15AM – Patient called re: receipt of mammogram results. No answer. Message left on answering machine asking that she call the office during normal office hours to get the results.

J.Smith, RN

12/20/11, 2:45PM – Patient called again re: mammogram results. No answer. Message left again asking her to call the office for the results.

J.Smith, RN

Case Example:
Sharon Crowley, a 42-year-old female, made an appointment to be seen by her family practitioner, Dr. Chang, after finding a lump in the right breast during her monthly self-exam. At the time of his examination, Dr. Chang could not palpate the lump in the upper outer quadrant of the breast where Ms. Crowley said she had felt it. He simply recommended a screening mammogram and the office staff made the appointment at a local imaging center. After the mammogram, the Radiology Center told Ms. Crowley that the report would be going directly to Dr. Chang. After not hearing from Dr. Chang for almost a month, Ms. Crowley called the practice office to inquire about her test results, and was told that they were not in her record so “Dr. Chang must have the report in his office”. The medical assistant said she would look for the report next chance she had, but said “I’m sure it’s okay or Dr. Chang would have been in touch with you by now if there
had been a problem. If you don’t hear from us that means your mammogram was negative.” Several months passed without any contact between Dr. Chang and Ms. Crowley, who had come to assume her mammogram was fine. At the time of her next annual visit, Dr. Chang asked her if she ever had the mammogram he had ordered the year before because he did not have a report in her record. When he found out she had, the imaging center was contacted and faxed over a copy of the report. The radiologist’s report noted a 2 mm. mass in the patient’s right breast, upper outer quadrant that was suspicious for malignancy. The radiologist went on to recommend a surgical referral for biopsy. Ultrasonic exam of the breast was also mentioned as potentially helpful, but because of the characteristics of the mass, the radiologist felt the patient would be better served by an immediate surgical referral.

Dr. Chang told this information to Ms. Crowley, downplaying the impact of the lost report and 12-month delay in referring her to a surgeon. Ms. Crowley was naturally angry and upset and said she would find a surgeon herself, which she did. Because a year had passed since the first mammogram, the surgeon ordered another mammogram. The mass had more than doubled in size since the first study, now measuring approximate 4.2 mm. The patient was scheduled for surgical biopsy which was positive for malignancy – Grade 3 Invasive Ductal Carcinoma. PET/CT studies showed metastatic spread to the liver. Her breast cancer was treated with total mastectomy, followed by aggressive chemotherapy. Despite treatment, Ms. Crowley developed additional metastatic lesions in the bones of her pelvis and femur. She subsequently died from her disease, approximately two years after diagnosis, which occurred 13 months after the original mammography study.

The patient’s husband and two children sued Dr. Chang for delayed diagnosis of breast cancer resulting in death of a 42-year-old woman. The physician practice was also a named defendant in the litigation because of the failure of the practice to have appropriate diagnostic test follow-up procedures in place that could have prevented the diagnostic delay and given Ms. Crowley a better chance of surviving her disease.

**Applying Risk Management Strategies:**

- Build into the test result and consultation report process redundant systems to avoid missing or late reports.
- Build into the test result and consultation report process mechanisms to confirm receipt of and action on test results and specialist report recommendations.
Encourage staff to recognize that when a patient calls about anticipated test results or specialist report recommendations that this should signal a need for prompt follow-up.

Complete regular medical record audits to determine if patient hard-copy or EHR or EMR do not include anticipated test results or reports from specialists.

D. Follow-up for ambiguous or unclear reports

To get the most value from a consultation, it is imperative that both sides – the referring physician and the consultant – communicate well. Both have information that is important to the other and, ultimately, to the patient. If the referring physician’s consultation request is unclear or the patient records provided do not provide information essential to the consultant, it is incumbent upon the consultant to contact the referring physician and obtain that information.

Likewise, if the consultant’s ultimate report and recommendations back to the referring physician are unclear, ambiguous, or is not responsive to the information that the referring physician was seeking in the consultation, the referring physician should contact the consultant and ask for clarification or additional information.

Risk Management Exposures:

- Delay in care.
- Missed diagnosis.
- Misdiagnosis.
- Negligence Litigation.

Risk Management Strategies:

- Setting expectations at the outset can help avoid receipt of ambiguous or unclear consultant reports. Strategies in this regard include the following:
- Develop a standard letter template to send to specialists that describes in specific detail the reason for the consultation and what is anticipated from the consultant.
- Include in the letter a framework for the degree of detail requested from the consultant.
➤ Make clear in the letter what information is being included for consideration in the consultation. Offer to provide such additional details as necessary as long as this level of specificity has been authorized by the patient’s release.

➤ Implement a process for following up on what is considered ambiguous or unclear statements in the report. Insist on a written addendum to clarify such matters.

➤ Include the request for the consultation and the report results—including follow-up addendums—in the patient record.

➤ Document in the medical record any clarification received in telephone conversations with the consultant, noting the date and time of the communication.

**Case Example:**
Dr. England requested a consultation with Neal James, MD, a urologist. He sent to Dr. James information about 54-year-old Mark Trovel. Over the preceding six years, Mr. Trovel had experienced rising PSA levels and BPH. The request asked that Dr. James “rule out possible CA.” It did not include important information such as that the patient had a strong family history of prostate cancer, including three brothers, the patient’s father, grandfather, and two great-uncles. The request letter did not indicate that the patient had experienced a positive response with BPH medication and that he was on Plavix after receiving two urinary tract stents a year earlier. Dr. James telephoned Dr. England and said, “I just examined Mr. Trovel. Your letter did not indicate some important information. Yes, I do my own history, but golly if I had not probed more deeply, I might have recommended a prostate biopsy. This fellow is on Plavix and baby aspirin. That will need to be stopped for at least a week if I have to take biopsy samples. And the PSA levels are not that elevated. Why did you refer him to me? Why not “watchful waiting” for this man? Are there additional concerns that I should know about so I do not unduly alarm this man?”

**Applying Risk Management Strategies:**
➤ Provide sufficient medical and medication history to facilitate the consultation by the specialist.

➤ Work with local feeder network specialists to ascertain the degree and type of background information needed by specialists for consultations.

➤ Be poised to field telephone follow-up from specialists providing consultations for patients.
Document telephone communication with specialists regarding patients referred for consultation.

E. On-call Practices
The practice should have policies and procedure in place that address the individual on-call physician’s specific coverage responsibilities. This may be for coverage of another practice, or as part of a specialty on-call rotation for hospital emergency department patients. The failure to respond in a timely manner or to meet applicable standards while serving in an on-call capacity may have serious repercussions.

Risk Management Exposures:
- Medical malpractice
- Delay in care
- Violation of medical staff bylaws, rules and regulations resulting in corrective action

Risk Management Strategies:
Recognizing the scope of responsibility involved in serving in an on-call capacity, there are some strategies to consider in a protocol shared with other medical practices in the area, including the following:
- An agreed-upon answering service.
- Primary and secondary communication systems to contact the on-call provider, including landline, cell phone, pager and text messaging systems that are field-tested for reliability.
- Timeframe for responding to patient requests relayed by the answering service.
- Documenting information obtained from and provided to the patient, including the date and time of the call, the person with whom the care provider was speaking, and a summary describing the instructions or recommendation given to the caller.
- The process to securely relay the information to the patient’s regular physician or physician practice.
- Planned scheduled for on-call physician rotation in the community or hospital.
- Process to confirm that the scheduled provider will be able to fulfill the on-call responsibility.
- Designation on the schedule of a back-up on-call provider.
- Confirmation of the availability of the back-up on-call provider to avoid gaps in coverage.
- Maintain an emergency telephone line for the practice that provides 24/7/365 access by emergency department physicians or hospitalists who may need to obtain important information on a mutual patient.

Case Example:
An ED in a community hospital received a middle-aged male patient via ambulance at 10:45PM. The patient was a passenger on a commuter train and, at the scheduled stop nearest to the hospital, lost consciousness and collapsed. 911 was called from the station and an emergency response team arrived quickly. On questioning, other passengers told the EMTs that the man was traveling alone, but had mentioned to another passenger that he had a “killer” headache shortly before collapsing into the aisle. The EMTs reported that the man had regained consciousness in the ambulance en route to the hospital, and again had complained of a severe headache. The ED physician ordered a STAT CT, which was positive for a cerebral hemorrhage, confirming the need for immediate surgery to relieve the increasing intracranial pressure from the bleed. The OR was called and told to prepare to receive the patient. However, repeated ED staff attempts to contact the neurosurgeon on-call were unsuccessful -- a message repeatedly told the caller that “the phone you are calling is not in service at this time.” It soon became obvious that the cell phone was not going to work -- either the physician had turned off her cell phone or that she was out of range of in a dead zone. The ED finally called the practice number, which was an after-hours answering service and the answer service was eventually able to track down the physician and relay the need to get to the hospital STAT!
Unfortunately, the physician was not aware that she was on call that night and was an hour-and-a-half out of town. The answering service contacted the practice manager who managed to find another neurosurgeon at home and able to get to the hospital relatively quickly. Notwithstanding the delay in trying to reach the on-call physician, the patient had a good surgical outcome and recovery.

Applying Risk Management Strategies:
- Always have a back-up communication system in place when the on-call physician cannot be reached.
➢ Make available to feeder hospitals and on-call practices an emergency contact number for 24/7/365 access to a provider in the physician office group.
➢ Test the primary and back-up communication systems frequently to make certain landlines, cell phones, and pagers are operating correctly.
➢ Remind on-call providers to charge their cell phone and pagers and to set the devices to a loud, audible ring tone.

F. Communication with Hospitalists
An increasing number of hospitals and health systems have moved to a hospitalist model of care for all in-patients. Hospital-based physicians – the hospitalist – manage and coordinate all aspects of inpatient medical care, including admission, consultations, transfer, and discharge. Ongoing communication with the patient’s primary care physician and other consultants is critically important for continuity of care and even patient satisfaction.

Studies have shown that communication (or a lack thereof) between primary care physicians (PCP) and hospitalists can have a significant impact on the success or failure of a transition in care and the outcome of care. The hospitalist has the disadvantage of having no prior physician-patient relationship with the newly admitted patient and, therefore, a lack of past clinical information that could be invaluable in treating the patient.

At any transition of care point, in any setting, there is a need for effective and timely transmission of information from one provider to another. If a PCP refers a patient for admission, it is the PCP who is the information provider to the hospitalist before or at admission. Once the patient is admitted, however, it is the hospitalist who takes over as communicator – to the patient, the patient’s family, and other providers involved in the patient’s in-hospital care and, at discharge, the patient’s PCP. It is incumbent on all providers to make themselves available for ongoing communication and consultation about their patients. Otherwise, risk exposures increase for both patients and providers.

Risk Exposures:
➢ Disruption in Continuity of Care.
➢ Delayed treatment or diagnosis due to lack of essential information.
➢ Unnecessary duplication of medical or diagnostic tests / efforts.
- Drug-drug interactions or other medication errors.
- Patient “lost” to follow-up or delayed follow-up post-discharge.

**Risk Management Strategies:**
A majority of the risks exposures can be mitigated by the development of good professional relationships and two-way communication between hospitalists and the primary care providers in the community who may refer patients for admission to the Hospital Medicine service.

- Consistently follow a mutually agreed-upon communication method with the hospitalists; e.g., phone, fax, secure e-mail, or, if absolutely necessary, by regular mail.
- Adhere to defined communication contact points during a patient’s hospital stay (i.e., when the hospitalist will ALWAYS contact the patient’s primary care provider and vice versa): e.g., within $x$ hours of admission, within $x$ hours / $x$ days of discharge, or when patient status / diagnosis changes, etc.
- Define deliverables: e.g., a primary care provider referring a patient for admission will provide the hospitalist with:
  - Past medical history.
  - Pre-admission treatment.
  - Medication list (including allergies).
  - Ongoing specialty consultations.
  - Family and social concerns.
  - Advance directives.
  - In return, the hospitalist will send the primary care provider a timely, completed discharge summary.
- Documentation and communication of treating physician’s contact information: Many physicians have started giving their patients a wallet-sized card that contains his or her name, practice contact information, and office hours. Such cards can be very useful to patients and their families should hospitalization be required when the patients are out-of-town, on vacation, etc., and will increase the likelihood that the primary care provider will be contacted and informed about his patient’s hospitalization or that he or she will be copied on the patient’s discharge summary.

**Case Example:**
A 68-year-old woman was admitted to the Hospitalist Service at the Graysen Community Hospital. The woman had presented with a fever and productive
cough and x-rays revealed pneumonia in the right lung. The patient told Wayne Head, DO that she obtained medical services at the Grange Health Clinic located outside of town. “At Grange, I see two or three different doctors and physicians assistants. I think the one who told me to go home and drink lots of fluids and take Tylenol was Lindsey Nance. She is the new physician assistant,” said the patient. Dr. Head replied, “Okay before I start prescribing any medications for you, I want to be certain that I have your permission to contact the Grange Health Clinic and obtain your health information. You signed an authorization in the emergency department, but I like to check with my patients first.” The patient smiled and said, “Thank you. Sure, go ahead and call them.” Dr. Head first sent through a secure email the patient’s authorization for release of her records. He then called Ms. Nance at the Grange Health Clinic. He provided the diagnosis and learned that the patient had a history of recurrent bronchitis and pneumonia. “I am the third person here at Grange to encourage her to be vaccinated against pneumonia. She is also stubborn. She will not see the pulmonologist at the hospital clinic. I think she is afraid that she might have COPD. She has tried to stop smoking several times, but it has not been successful,” said Ms. Nance. Dr. Head thanked her for the information and told her that the patient discharge report would be sent to Grange electronically.

**Applying Risk Management Strategies:**

- Understand as a community care provider that the hospitalist does not have the benefit of an established care provider-patient relationship.
- Develop in the practice a process for and an expectation about what information will be shared with the hospitalist.
- Make certain that there is an authorization to discuss the patient’s health needs with the hospitalist.
- As a care provider in the community, provide timely information to the hospitalist to facilitate patient care.
- Recognize that there should be a process for sharing information, including the hospitalist furnishing in a timely manner the patient’s discharge summary and care plan.
VI. Environment of Care

From a risk management perspective the environment of care in the physician office practice is of paramount concern. A safe environment is one component. Another involves security matters, especially disaster plans and evacuation methods and management of emergency situations that occur in the office setting. The office environment of care is subject to state law and federal requirements, including occupational safety under rules from the Occupational Safety and Health Administration or “OSHA.” Infection prevention is another important aspect for physician practices as is the maintenance of equipment. Interestingly, risk management strategies can help eliminate, prevent, and reduce many potential environment of care exposures.

A. Safe Premises

It is a responsibility of an office practice to take measures to ensure the safety of patients, visitors and staff. In general, that means the practice area should be clean and clutter free. Patient areas should be designed for a free flow of “traffic,” complying with Americans with Disabilities Act (ADA) specifications to ensure barrier-free, unimpeded access to the practice services. In addition, the Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor mandates that appropriate measures should be followed in terms of general cleanliness, prevention of needle sticks, and infection prevention to protect physicians, staff, patients and visitors from the transmission of diseases.

In the physician practice setting, patient and staff safety should not be a concern only for management but, rather, an everyday, ongoing concern involving everyone who works in the medical group. Every employee, every member of the staff – administrative or clinical – should be alert for anything that could jeopardize the health and safety of a patient, a visitor, or a fellow-practice employee – a burned out light-bulb in the practice foyer, a wet floor from a leak, a full “sharps” container, drops of blood on the floor of a procedure room, an empty hand sanitizer dispenser, etc. In addition, staff should be empowered to do what is necessary to correct the safety problem and/or encouraged to bring it to the attention of management without delay.
Risk Exposures:
- Patient injury.
- Staff injury.
- Visitor injury.
- Regulatory non-compliance.
- Adverse publicity.
- Reduced market share.
- Reduced revenue.

Risk Management Strategies:
A central theme in environment of care risk management is critical thinking and situational awareness. In addition, there are some strategies to consider to encourage development and maintenance of a safe environment of care, including the following:

- Implement a safety plan for the practice that includes both the interior and exterior of the practice.
- Designate individuals in the practice to complete routine “walk arounds” to identify potential risks and hazards that could jeopardize the health and welfare of staff, patients, or visitors, and to take corrective, preventive measures to ensure their safety.
- Complete walk-arounds of common areas, stairwells, and exterior areas, such as the parking lot, walkways and steps leading into the practice.
- Encourage personnel to get assistance to correct identified hazardous conditions, such as icy sidewalks, loose handrails, cracked pavements, or lights that are not working.
- Consider use of a safe premises checklist to be completed, dated, and signed by those doing the walk arounds and completion of improvements or repairs.

Case Example:
Rhonda Stevens, CMT was responsible for practice “walk arounds” every third week. Ms. Stevens did her tour prior to the office opening for patients on Monday. On this occasion, Ms. Stevens inspected the patient restroom. She followed the safe premises checklist. When she tested the grab bars on either side of the toilet, she noticed that the right-side grab bar wobbled. Ms. Stevens determined that a bolt was missing and that the situation created a safety issue. Ms. Stevens alerted the practice manager and recommended that a sign be posted on the restroom door noting it was “Out of Service” and directing patients to use a different restroom at the other end of the hallway. “Great job Rhonda.
Please get the sign up and I will let the facilities manager know we need that grab bar repaired as soon as possible,” said the practice manager.

Applying Risk Management Strategies:
- Have designated individuals complete environment of care “walk arounds” on a regular basis.
- Provide a checklist to facilitate a thorough environment of care inspection.
- Encourage staff completing the walk arounds to exercise critical thinking and situational awareness.
- Encourage them to develop practical solutions to address identified risks in the environment of care.

Safety in the Reception and Patient Waiting Areas
Inside the office, the reception area should be well-lit, have adequate seating for waiting patients and their family members, and have clear, unobstructed pathways allowing for easy accessibility for all patients, but especially those in wheelchairs, using walkers, canes, etc. Furniture should be well maintained and clean, kept uncluttered and be placed out of “traffic” areas. Given the fact that youngsters may leave toys or books in traffic areas, it is important to regularly check for safety risks in the reception and patient waiting areas.

Risk Exposures:
- Patient and visitor injury.
- Staff injury.
- General liability claims.
- Workers compensation claims.
- Adverse publicity.

Risk Management Strategies:
Practical measures can help prevent or reduce safety risks in medical office reception and patient waiting areas. Some strategies to consider include the following:
- Develop a safe design plan for the medical office reception and patient waiting areas.
- Take into consideration traffic flow, including patients who use walkers, canes, wheelchairs or crutches.
- Take into consideration the impact of baby strollers in the traffic flow pattern.
Consider the patient population served by the practice and evaluate the need for chairs that accommodate obese patients.

- Look at the height of chair seating and consider how easily patients can sit down or stand up.
- Evaluate where coat closet or coat racks will be placed along with stands and rubber or plastic mats to collect water from boots or umbrellas.
- Make certain that any floor mats are flush to the floor and do not bunch up or curl up.
- Place children’s books and toys in a corner area away from traffic flow.

**Case Example:**
The Reid Family Medical Group served patients from 3 to 85 years of age. It was a busy practice. The patient population had increased over the last two years with the addition of a new 55-and-up condominium complex in town. Many of the 60 to 75-year-old patients in the new complex had serious health issues. Over 50% of them had serious knee and hip problems and relied on walkers or canes for ambulation. Still others were morbidly obese. After one 300-pound patient had difficulty getting out of a chair in the waiting room and nearly fell, the practice manager decided something had to be done. She checked with a medical office designer who provided suggestions for revising the seating to accommodate the needs of patients. “I think this will solve the problem for you,” she said.

**Applying Risk Management Strategies:**
- Monitor the needs of the patient population to determine if the design and traffic flow in reception and waiting areas is appropriate.
- Obtain advice from office design consultants to help make modifications to accommodate identified shifts in the needs of the patient population.

**Safety in Treatment and Examination Rooms**
Treatment and examination rooms are areas in the physician practice that can be the focal point of numerous safety concerns. Equipment, carts, cabinets, and drawers as well as waste receptacles may be the source of harm. Taking appropriate measures, however, can create a safe environment in treatment and examination rooms.
Risk Exposures:
- Injury to patients.
- Injury to individuals accompanying the patients.
- Injury to staff.

Risk Management Strategies:
Treatment and examination rooms can be a source of serious injury. Building upon the idea of an interior walk-around and safety check, staff can take steps to avert injury, including the following:
- Complete regular walk-arounds in examination and treatment rooms.
- Prior to bringing a patient to a treatment or examination room, ask staff to complete a safety check, looking for sources of potential injury such as:
  - Equipment or carts with brakes that are unlocked.
  - Medication or equipment carts with drawers that are unlocked.
  - Cabinets that are unlocked.
  - Medication or equipment left on countertop areas.
  - Liquids on the floor.
  - Waste receptacles that overflowing.
  - Biohazard waste receptacles that are unsecured.
  - Unsecured sharps containers.
- Make certain that any safety issues are resolved prior to permitting patients or those accompanying the individual to enter the treatment or examination room.
- Provide regular in-service training for office staff to reinforce safe practices in the set up and use of patient treatment and examination areas.
- Encourage staff to identify and resolve safety concerns in patient treatment and examination areas.

Case Example:
Over the weekend, a contractor had completed repainting the newly redesigned patient treatment rooms in the office of Internal Medicine Associates. had recently undergone a redesign and repainting of its patient care areas, On Monday morning, Mia Saunders, a 35-year-old female patient was being seen in the office for a routine check-up of her mitral valve prolapse. The medical assistant put her in one of the newly remodeled exam rooms to wait for Dr. Shaw. Because her babysitter was ill, she had brought her 26-month-old son with her to her appointment. While waiting to see the doctor, Mrs. Saunders was paging through a magazine while her son was crawling around the floor of
the exam room playing with his truck. When he suddenly cried out, she looked up and saw him with his right arm completely inserted into the top slot of a red "sharps" container that was sitting on the floor. A passing nurse heard the child crying and came in to assess the situation. She determined that the child was more scared than actually stuck in the box, and she and his mother were able to calm him down and enable him to take his arm out of the box.

Neither the nurse nor Mrs. Saunders could find any evidence that the child had been stuck by the disposed needles in the sharps box. When Dr. Shaw came into the room, the situation was explained to him and he too examined the child and could find no sign of a needle stick. In actuality, it seemed improbable that the child’s arm was long enough to have reached the level of the discarded needles in the box. However, because it was impossible to completely rule it out, Dr. Shaw decided that the child should be routinely tested for HIV, Hepatitis and other blood borne infectious diseases, for the next several years, at the practice’s expense.

The child’s parents sued Dr. Shaw and the practice corporation, alleging negligence in failing to provide a safe environment for patients; infliction of emotional distress to Mrs. Saunders who witnessed the incident and to both Mr. and Mrs. Saunders, who had to live with the possibility that their child may have contracted a life-threatening infectious disease from his contact with the discarded needles.

In the case described above, the medical assistant who escorted Mrs. Saunders and her son to the exam room should have automatically scanned the room when she entered for any issues that could compromise patient or staff safety. She should have noticed the bright red “sharps” container on the floor and either removed it from the floor or escorted Mrs. Saunders to another examination room. In a practice where safety is given high priority, where everyone is involved in keeping the practice, its patients, and its staff safe and sound, incidents like the one described in the case would never happen.

**Applying Risk Management Strategies:**
- Complete a thorough safety check of patient treatment and examination areas following renovations, construction, or painting.
- Ask staff to verify that all equipment is properly installed, locked, and secured in patient treatment and examination rooms.
- Ask staff who finds rooms with equipment improperly positioned, unlocked or not installed properly to alert the practice manager with a view to working with colleagues to reiterate maintaining a safe environment of care.
- Encourage staff to exercise good judgment to create a secure environment of care in patient treatment and examination rooms.
- Encourage staff to use properly maintained examination and treatment rooms in lieu of assigned areas that are not ready to receive patients.
- Make certain that sharps containers are placed at a height inaccessible to young children.
- Make certain that biohazard receptacles are locked in treatment and examination areas.

B. Security Considerations
Security is an important consideration for medical offices. Because criminals perceive physician offices as a place to obtain drugs or medication, it is important to put in place appropriate security measures. Taking appropriate measures is important for patients, visitors, and office staff.

Risk Management Exposures:
- Injury to patients, visitors and staff.
- Property damage to patients, visitors, staff and the practice.
- Theft from patients, visitors, staff and the practice.
- Workers compensation claims from staff.
- General liability claims from patients and visitors.
- Adverse publicity.
- Loss of market share.

Risk Management Strategies:
Security measures and guidelines exist for medical office buildings and practices. The types of measures implemented may depend on whether the practice is located in a medical office building that provides security or whether the physician group is in a self-contained building that it leases or owns. Practical strategies to consider include the following:
- Consider a security consultation from an expert in healthcare security.
- Develop a security plan for the practice.
• Establish a relationship with local law enforcement and meet with the community service officer for regular updates on specific security risks in the area.
• Offer staff training on how to manage criminal activity in the practice.
• Install shatter-proof and bullet-proof partitions at the reception desk that prevent an assailant from climbing over the counter or grabbing reception personnel.
• Install Closed Circuit TV (CCTV) around the building.
• Install lighting along walkways and parking areas on the exterior of the building.
• Install lighting inside interior walkways and stairwells.
• Remove bushes, trees, trash dumpsters and bins around the exterior of the building that could be used as hiding places for would-be criminals.
• Secure ground level doors and windows.
• Install a silent panic alert that dials local police.
• Secure pharmaceuticals in locked cabinets.
• Secure equipment, including laptops, desktop, and tablet devices.
• Restrict after-hours access to the practice without specific security for staff.
• Install a security alarm system that dials directly to a reputable security firm when there is a break-in or tampering with locked and alarmed doors.
• Post signage in the patient reception and waiting areas encouraging patients and visitors not to leave valuables visible in their vehicles and to secure the doors to their vehicles.
• During orientation and on a regular basis, remind office personnel not to leave valuables visible in their vehicles and to lock the doors to their vehicles.
• Ask staff to report suspicious behavior that may signal a security issue, including drug-seeking behavior or threats.

Case Example:
Alexandra Deal noticed a change outside her medical office. The sidewall of an adjacent building was painted with markings. This was followed a few days later with markings painted on two power line poles. She also noticed old model cars driving up and down in front of the medical office around dusk. As the practice manager for Nephrology Partners she decided it was time to call Gene Towers, the community area police officer. Gene drove over to the practice within 30 minutes and reviewed the markings. “This is signage used by a local drug gang that is trying to establish itself in the area. The cars that you saw fit the
description of some of the gang leaders. Alexandra, I am concerned. I am going to increase patrols in the area. I think you should consider increasing your security measures. Get a security guard and put in very bright lighting. Make certain that the back entries are kept locked at all times. Test the panic button at least once each week. And, please, do not leave anyone alone at close of office hours. Always exit together,” said Officer Towers. He continued, “I am not trying to alarm you, but the reality is there is a problem developing in the area.”

**Applying Risk Management Strategies:**

- Review and revise the office practice security plan as needed.
- Reiterate with staff the importance of security in and around the office practice.
- Exercise situational awareness, looking for changes on the exterior of the practice that appear unusual or disconcerting from a security perspective.
- Contact local law enforcement when there is a concern about the potential for criminal activity.

C. **Emergency Preparedness /Evacuation plan**

Physician office practices should be poised to address emergency situations, including natural disasters, man-made events, and the impact of epidemics. Sometimes, however, an emergency situation can occur in the physician office practice necessitating prompt action. From a risk management standpoint, anticipating such exigencies is important for medical offices.

**Disasters**

Like any public workplace, a medical office practice is should have an emergency action plan. The Occupational and Safety Administration (OSHA) has requirements for making employees know about the plan. OSHA requirements notwithstanding from a risk management perspective such a plan should be in writing, readily accessible to all staff. Further, administrative and clinical personnel should be familiar with implementing the emergency plan in a disaster.

**Risk Exposures:**

- Injury to patients, visitors, and staff.
- Destruction of or damage to equipment.
- Business disruption.
- Damage to or loss of clinical records and practice documentation.
**Risk Management Strategies:**

There are many aspects to a well-developed emergency response action plan. Several components may be found in OSHA regulations and others are based on practical risk management strategies, including:

- Implementing an emergency action plan that is compliant with OSHA requirements.
- Implementing procedures that guide reporting of emergency situations.
- Posting of primary and alternate emergency evacuation routes from the physician office. Note that elevators may be inoperative during an emergency evacuation and therefore should not be considered as either a primary or alternate mechanism for evacuation.
- Signage that indicates emergency evacuation exits.
- Signage for tornado shelters in the medical office building.
- Training for office personnel on managing various emergency situations, including safe evacuation of staff, patients and visitors in the event of a fire, fire alarm, tornado warning, earthquake, or other exigencies. This should include:
  - A procedure for evacuating patients in the practice who require continuous oxygen supplementation.
  - A procedure for evacuating patients in the practice who are not ambulatory or require assistance with ambulation.
  - A procedure for accounting for employees, patients, and visitors after evacuation.
  - Designated, trained staff members to manage the evacuation and care and attention of patients and staff subsequent to leaving the office.
- Development and implementation of a post-emergency or disaster recovery plan that includes:
  - Restoration of telephone lines or use of back-up telephone systems.
  - Damage assessment.
  - Insurance carrier notification, including workers compensation carriers for injured employees.
  - Restoration of records from remote back-up servers once computer systems are back online.
  - Location of temporary facilities if damage to the office makes the current building space unusable.
  - Equipment repair or replacement.
o  Arrangements for patient continuity of care in situations in which there will be a time delay in reopening the practice.

o  Debrief with staff on lessons learned and improvements in the future for possible emergency situations.

o  Counseling services for staff as needed.

**Case Example:**
The Wysten Medical Group was located in a three-story medical office building. On a cold January afternoon a visitor to another practice decided to smoke a cigarette at the bottom of the south doorway. When he saw someone coming towards the door, he flicked the lit cigarette from his hand. The cigarette landed on top of a collection of old newspapers and magazines left for recycling pick up the next day. The visitor took the nearby elevator to the second floor. The person entering the building did not notice the cigarette. Approximately fifteen minutes later, the fire alarm sounded throughout the building. The scent of burning paper was evident throughout the building. There were 12 people in the Wysten Medical Group office, including seven staff and five patients. As the designated emergency action plan coordinator, the practice manager checked the primary and secondary exit routes. An acrid smoky haze obscured the secondary exit. In a calm but firm manner, the practice manager got everyone out of the office safety down the front stairs. She completed a head count of staff and patients. Fire department crews quickly doused the blaze in the stairwell while those who had been in the medical office building were taken across the parking lot to the lobby of another building. Once inside, two physicians and a nurse from the Wysten Group checked with their patients to make certain that they were not ill or hurt and they provided assistance to patients and staff from other medical groups in their building. Thankfully, no one was injured. Because the building was filled with smoke, the fire chief ordered that no one return to their offices until the air quality was considered safe. The next day staff was allowed to return to the office. Service technicians were called to make certain that all equipment was working properly. The insurance carrier was put on notice and a claim was prepared for business interruption. Dr. Wysten congratulated the practice manager for her handling of the situation and said, “I am so glad that you insisted on those drills several weeks ago. I think it made a difference for our staff.”

**Applying Risk Management Strategies:**

➢  Have a practical emergency action plan in place.
Orient staff to the emergency action plan and how to evacuate the office safely.
Run practice drills to make certain staff understand how to implement the office evacuation plan.
After an emergency situation that could potentially damage or destroy equipment, have certified technicians determine if the equipment is operating properly.
Put appropriate insurance carriers on notice.
Document information required for a business disruption claim.

Medical Emergencies in the Office
In any healthcare setting, the likelihood of an acute, clinical emergency occurring at anytime must be considered. Should a patient, a patient’s family member, visitor or staff member to the office suffer an acute episode while in the practice setting, staff should be trained and ready, with the appropriate equipment to handle that emergency – whether by appropriately treating the patient or by initiating emergency transport to the nearest emergency department in a timely fashion for treatment.
Common medical emergencies in a physician office setting include respiratory distress (asthma), anaphylaxis, shock, seizure, and cardiac arrest. However, the patient population of a practice and the specialties of the physicians practicing there will greatly influence what types of medical emergency would be likely.

Risk Exposures:
- Medical negligence.
- Delay in Care.
- Adverse publicity.
- Diminished markets share.

Risk Management Strategies:
Anticipating that medical emergencies may occur in the physician office setting is prudent from a risk management perspective. Some strategies to consider for this purpose include the following:
- Have a plan in place to respond to medical emergencies in the practice.
- Provide all staff – clinical and non-clinical – with initial orientation and annual training and mock drills regarding their respective roles and responsibilities in the event of a medical emergency in the physician office practice.
Have clearly posted the telephone numbers to access commercial and volunteer emergency medical services.

Have a transfer plan in place for transport of patients to an acute care facility should a medical emergency occur in the practice.

Consider the type of medical emergencies that may occur in the physician office setting. Recognize that what might occur in a cardiology practice may be different than those medical emergencies that take place in a pediatric group practice.

Have in place the equipment and supplies needed to respond to medical emergencies, including but not limited to a crash cart, AED devices, epinephrine, and a well stocked emergency kit.

Recognize that pediatric practices should have the right type of emergency equipment to use with infants and children. By the same token consider what is needed to respond to an emergency situation in an internal medicine practice that has a significant number of morbidly obese patients.

Obtain input from clinical leadership regarding what should be available to respond to an emergency situation in the practice and consider the following:

- Oropharyngeal airways (pediatric and adult).
- Oxygen and masks.
- AMBU bag (bag valve mask).
- Blood pressure cuffs.
- Supplies for starting an IV line.
- Resuscitation equipment.
- Drugs often used in medical emergencies, such as epinephrine, lidocaine, aspirin, insulin, and atropine; asthma rescue drugs; diazepam, and IV fluids.
- Blood glucose meters and strips.
- Cardiac monitoring devices if not already in the practice.
- Protective equipment for staff such as gloves, masks, and eye protection should also be available.

Make the emergency response supplies scalable to anticipated need. For example, a practice in a very rural location 50 miles from the nearest ED and medical center has to be prepared for a longer resuscitation period and possibly more intensive care for a patient while waiting for an emergency response team to arrive.

Make certain office staff both clinical and non-clinical is certified in CPR and Basic Life Support (BLS).
Make certain that physicians, physician assistants, nurse practitioners and registered nurses are certified in Advance Life Support (ALS) and Advanced Cardiac Life Support (ACLS) and that pediatric practices have staff certified in Pediatric Advance Life Support (PALS).

Make certain that during office hours that BLS or ALS certified staff is available to respond to a medical emergency.

Require recertification for all BLS, ALS, ACLS and PALS certified staff.

Offer refresher and training drills for office personnel on responding to medical emergencies in the practice.

Keep the medical emergency supplies and equipment in an accessible location.

Make certain that medical emergency supplies and equipment are properly labeled so that the contents are not accessed and used for routine care purposes.

Designate individuals in the practice who are responsible for maintaining all medical emergency supplies and equipment.

At least quarterly, complete a review of medical emergency supplies and equipment to make certain that nothing in the kit is beyond usable expiration dates and that equipment is functioning properly. Note that after use in an emergency situation, supplies should be restocked and equipment checked to make certain it is in working condition.

Examine guidelines and resources from recognized national professional groups to help guide development of an medical emergency response plan for the office practice, including, the American Heart Association, the American College of Emergency Physicians (ACEP), the American Society of Internal Medicine (ASIM), the American Academy of Family Practice (AAFP), and the American Academy of Pediatrics (AAP).

Case Example:
Dr. Harrold had just finished removing a tube from the left ear of Jenny Mayes when the examining door opened suddenly. “We need you up front STAT! Medical emergency,” said the medical technician. Dr. Harrold turned to the patient and said, “Wait here. I will be back as soon as I can.” In the waiting room a man was lying unconscious on his back. A nurse and a PA in the ENT Associates Practice were completing an evaluation. “Pulse is weak and irregular. BP is real low. He has blood running from a cut on the right side of his head. EMTs are en route. ETA 20 minutes,” said the PA. Dr. Harrold turned to the people in the waiting area and said, “Ladies and gentlemen, this is a medical emergency. We need your cooperation. This area has to be cleared to assist this
person. Please go downstairs to the lobby and we shall let you know when it is time to return to the office. We do not know how long it will take, so if you wish to reschedule, please call the office after 2 pm. We regret any inconvenience.” Dr. Harrold then asked the office manager and receptionist to clear the rest of the office and reschedule patient appointments. After the last visitor left, the door was locked. It took less than two minutes to clear the area. Meantime, Dr. Harrold’s colleague and the PA set up an IV line and, given the patient’s labored breathing; a decision was made to intubate the patient and to follow Advance Life Support measures. The EMTs arrived within 15 minutes and took the man to the local hospital. It was learned that he was a returning patient of the other ENT in the practice. The ED physician called to let Dr. Harrold’s colleague know that the patient had sustained an 8 cm gash to his head when he fell. “Looks like he had a heart attack. The cardiology folks are working on him now,” said the ED physician. Call-backs were made to all the patients who had been escorted out and to those who had not returned after the “all clear” was given in the lobby. Each patient was thanked for his or her cooperation and given a rescheduled appointment.

Applying Risk Management Strategies:

- Maintain a well-equipped and well-stocked emergency kit.
- Complete refresher training for all members of the practice regarding managing a medical emergency.
- Ask non-clinical and administrative personnel to move other patients and visitors away from the medical emergency situation.
- Use good patient relations and service recovery procedures to handle disruptions caused by an emergency medical situation in the practice.
- Notify appropriate insurance carriers regarding a potential compensatory event with regard to the patient collapsing and cutting his head.
- Debrief after an office-based medical emergency and review how the situation was addressed, what went well and what could be learned for the future.
- Have a debriefing session with all the staff as some may be quite upset by a medical emergency in the office setting.

D. OSHA Regulations

The Occupational Safety and Health Administration has published regulations and standards that apply to medical office employees. In addition, 26 states
administer their own occupational safety and health programs that are required to be “at least as effective” as the Federal program. Compliance with the rules is important since non-adherence can mean the imposition of fines.

The Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor has several standards applicable to medical offices to ensure the safety and health of their employees. These include:

- The Blood borne Pathogens Standard.
- The Hazard Communication or “Employee Right to Know” Standard.
- The Ionizing Radiation Standard.
- Exit Routes Standards.
- Electrical Standards.
- Emergency Action Plan Standards.

OSHA has published a useful guidance document that is easily obtained at no cost. Entitled, Medical & Dental Offices, A Guide to Compliance with OSHA Standards [OSHA 3187-09R, 2003], it can be found at: http://www.osha.gov/Publications/OSHA3187/osha3187.html.

Another important document is the OSHA Poster or the state equivalent that must be displayed in the workplace where employees can see it. [OSHA Publication 3165. It can be obtained at www.osha.gov. The poster explains worker rights to a safe workplace and how to file a complaint.

Risk Exposures:

- Non-compliance with OSHA or state equivalent regulations and standards.
- Fines for non-compliance with OSHA or state equivalent regulations and standards.
- Regulatory inspections in response to complaints.
- Adverse publicity.

Risk Management Strategies:

OSHA and state equivalent regulations provide a compliance-driven approach to worker safety, an important aspect of office practice risk management. Some practical strategies to implement the requirements include the following:

- Post OSHA Worker Safety or state equivalent notices in the medical office.
- Provide orientation and regular in-service training for practical personnel on the OSHA requirements.
Maintain appropriate documentation to substantiate compliance with OSHA standards or state equivalent requirements.

Be poised to report work-related fatalities or hospitalizations of three or more employees in a single episode.

Be prepared to manage OSHA inspections and investigations.

Utilize the tools made available by OSHA on its website to facilitate development of and implementation of a worker safety program for the office that meets applicable OSHA or state equivalent standards. Go to: Compliance Assistance Quick Start: Health Care Industry: http://www.osha.gov/dcsp/compliance_assistance/quickstarts/health_care/index_hc.html

Recognize that these tools help promote worker safety as well as patients.

Case Example:
Amy Tearney was a new hire in the Chandler Medical Group. Ms. Tearney had worked for a healthcare temporary staffing agency for a year as a certified medical technician. During her second week in the practice, a nurse noticed that Ms. Tearney was not following the Bloodborne Safety Standard. “Amy, are you familiar with the steps we are to follow for bloodborne pathogens?” the nurse asked. “Yes, of course,” she replied. “Then why are you not following the standards?” asked the nurse. “Oh, I am. I am doing what I was taught to do at my old worksite,” she replied. The nurse said, “Here, let me bring you up to speed with what we have to do in the Chandler Medical Group. I am responsible for OSHA bloodborne training for everyone in the practice. I was out last week and I thought my colleague had gone over this material in your orientation. Not to worry. Let us spend some time together now.” The nurse later learned that her colleague had assumed that since Amy had worked for another medical practice it was not necessary to go over the details on the bloodborne pathogen standard.

Applying Risk Management Strategies:

Require all new hires to receive the same level of training on OSHA or state equivalent standards.

Never assume that a person who worked in another medical office has the requisite understanding of OSHA or state equivalent standards.
E. Infection Control and Prevention

Infection control and prevention is an important risk management issue in the physician office. Minimizing the risk of patients or staff acquiring and/or transmitting an infection requires good infection control practices and procedures coupled with staff and patient education.

Risk Exposures:
- Physician office practice-acquired infections.
- Negligence.

Risk Management Strategies:

Infection control and prevention depends upon adherence to recognized practices that are intended to thwart transmission of infections. Some practical strategies in this regard include the following:

- Implement an infection control and prevention plan that is tailored to the needs of the medical practice.
- Utilize safe sharps and needles in the practice.
- Use approved sharps containers, biohazard waste receptacles and contaminated laundry receptacles.
- Use a secure box for specimen collections.
- Locate sharps containers, biohazard waste receptacles, and contaminated laundry receptacles in safe “child proof” locations or heights.
- Insist on staff using appropriate personal protective equipment, such as gloves and face and eye shields.
- Encourage staff to receive Hepatitis B vaccinations.
- Encourage staff to have routine blood tests for Hepatitis B immunization levels.
- Require staff to completed recognized immunization schedules for measles, mumps rubella, varicella and influenza.
- Consult with legal counsel if such immunizations can be made a condition of employment and what exceptions should be permitted for other than health reasons.
- Follow established guidelines for disposal of sharps containers, biohazard receptacles and cleansing of contaminated laundry.
Follow manufacturer, FDA and national guidelines on cleaning and sterilizing equipment used in the diagnosis and treatment of patients.

Institute hand hygiene protocols for all employees, considering as a guideline the World Health Organization’s “Your Five Moments to Hand Hygiene” and other resources at http://www.who.int/gpsc/5may/en/.

Provide patients and visitors with antibacterial hand cleanser dispensers in the waiting room and reception area, making certain to post signage that encourages them to use the dispensers.

Post signage in the waiting area reminding patients and visitors of respiratory etiquette.

Consider separate waiting areas for patients who are coming to the practice for treatment of respiratory or flu-like symptoms.

Consider scheduling patients who are coming to the practice for treatment of respiratory or flu-like symptoms for the later part of the day so that there is a reduced likelihood of transmission of respiratory infections to others in the waiting areas.

Provide orientation to all employees on infection control and prevention measures to be followed in the practice.

Offer regular in-service training on infection control and prevention measures.

Require personnel responsible for cleaning or sterilizing equipment to regularly check FDA and manufacturer websites for updated infection control guidelines in the cleansing, sterilizing and storage of equipment used in the diagnosis or treatment of patients.

Clean examination rooms between patients.

Work with the cleaning service for the practice to establish requirements for cleaning procedures that reduces the risk of disease transmission.

**Case Example:**
Dr. Risorio went into the equipment room thinking he might find the size scope that he needed for a patient coming in for a procedure that afternoon. What he saw in the equipment room disturbed him. He found scopes that had not been cleaned left next to other equipment that had been disinfected. Dr. Risorio called the nurse responsible for clinical services to meet with him. She too, was surprised by what Dr. Risorio had found. There were several new sterilized scopes available for the afternoon procedures. The nurse learned that a temporary employee had agreed to assist the staff member who was responsible
for sterilizing and disinfecting equipment. She did not appreciate the risk created by leaving the dirty scopes near the disinfected equipment.

**Applying Risk Management Strategies:**
- Follow established protocols and guidelines for the sterilization, disinfecting, and cleaning of all equipment used in the diagnosis and treatment of patients.
- Assigned specifically trained personnel to manage the sterilization, disinfection, and cleaning of equipment.
- Do not permit delegation of such responsibilities to anyone who has not received appropriate training for this purpose.

**F. Planned Maintenance of Equipment**
It is the responsibility of the practice to see that all equipment is in good working order and will function properly when used by a physician or other health care provider in the delivery of patient care, and that staff are properly trained in the use of equipment and devices. A process for regular examination and maintenance of such equipment can help diminish the risk of equipment malfunctioning and harming staff and patients.

**Risk Exposures:**
- Equipment failures or malfunctions.
- Equipment failures or malfunctions that result in patient injury.
- Equipment failures or malfunctions that injury staff.
- Litigation.
- Workers compensation claims can result in injuries to staff and patients.

**Risk Management Strategies:**
There are a number of practical measures to consider in terms of planned maintenance of equipment and handling identified equipment-related issues, including the following:
- Develop a plan for planned maintenance of equipment.
- Recognize that the maintenance schedule may be established by the manufacturer or in national guidelines.
- Carefully examine equipment warranties, equipment purchase orders and lease agreements to determine if the documents specify who may complete planned maintenance of equipment.
➤ Use approved biomedical or technical firms to complete planned maintenance of equipment that cannot be completed by individuals employed by the practice.
➤ Make certain practice personnel designed to complete planned maintenance of equipment receive necessary training for this purpose.
➤ Maintain an inventory log of equipment that includes:
  o Serial Number.
  o Purchase or lease date.
  o Purchase price or lease price.
  o Warranty period.
  o Required planned maintenance schedule.
  o Service performed by office personnel.
  o Service performed by outside vendors for specific equipment.
  o Service performed and list of equipment components replaced.
  o Service date.
➤ During orientation and in regular in-service training remind staff never to use or to attempt to repair equipment that is not working properly. Instead, insist upon staff notifying the practical manager or her designee so that service can be obtained on such equipment.
➤ Remove from service any equipment that is not working properly and that has or is believed to have been involved in injury to a staff member or a patient.
➤ Do not return to service any equipment that was or is believed to have been involved in injury to a staff member or a patient until it has been determined to be safe for use by a qualified biomedical engineer or certified technician.
➤ Contact appropriate insurance carriers and follow instructions from claims management or legal counsel on the storage of equipment believed to have been involved in a potential compensatory event or possible workers compensation claim.
➤ Consider leasing alternate equipment while owned devices are under repair or stored due to possible involvement in a potential compensatory event or workers compensation claim.
➤ Exercise contractual options under a lease agreement for substitution of a temporary or replacement equipment while leased devices are under repair or stored due to possible involvement in a potential compensatory event or workers compensation claim.
➤ Offer in-service training for personnel on any upgrades and changes in functionality occasioned by planned maintenance of equipment.
Case Example:
London Internal Medicine Associates leased a number of pieces of diagnostic equipment, including three state-of-the-art electrocardiogram machines. All clinical personnel had been trained on the way to use the new machines. Approximately six months after the new electrocardiogram devices were installed, an indicator light glowed red indicating it was time for planned maintenance on one of the machines. The equipment had been leased and the lease included a two-year service agreement with a third-party biomedical engineering firm. A biomedical engineer came to the office, serviced the equipment, and was about to leave when the office manager said, “I need to know what you did today on the machines.” The biomedical engineer replied, jokingly, “Oh, just the usual stuff, you know, changed the oil, rotated the tires, that sort of thing.” The office manager smiled and said, “Nice try. Please give me a written statement of what you did in this planned service call.” The biomedical engineer complied.

Applying Risk Management Strategies:
- Obtain planned maintenance on equipment in accordance with the duty cycle on devices.
- Make certain that the person performing planned maintenance on medical device equipment is qualified to do so.
- Document the date of the service and obtain from the service provider a statement of work to incorporate into the practice equipment inventory log.
- Recognize that the state of work may prove important if there is any dispute regarding proper maintenance of medical device equipment.
VII. Employment Practices in the Physician Office Setting

There is an established process among human resource professionals that guides much of the employment practices found in healthcare and physician office settings. Along with federal and state laws following established employment practices can help develop a staff of highly motivated and well-qualified individuals to serve the needs of patients.

This section highlights key aspects of employment practices, including the employee handbook, job advertising, screening and hiring procedures, job descriptions tied to scope of practice laws, orientation and training, use of agency personnel, and contingency planning.

A. Employee Handbook

Many medical offices have employee handbooks that are linked to administrative policies and procedures. Others have employee guidelines. The handbook is a useful tool since it sets out relevant processes from hiring to termination. It sets expectations for staff and it makes clear the consequences of deviating from recognized policies, procedures, and processes in the physician office.

Once hired, an employee should be asked to review the content of the handbook. He or she should be given the opportunity to ask questions and thereafter, the individual should sign an acknowledgement or attestation that the content of the handbook is understood and that he or she agrees to abide by the terms of the handbook.

Risk Exposures:

- Employment practices liability exposure.
- Negligent hiring.
- Vicarious liability based on the legal concept of respondent superior, the employer being responsible for the errors or omissions of the employee.
**Risk Management Strategies:**
Several practice matters can be addressed in an employee handbook. These include such strategies as the following:

- Work with knowledgeable legal counsel to develop an employee handbook or guideline set appropriate to the physician office practice setting.
- Make clear in the handbook and on job applications that any statement regarding training, background, certification or experience is automatic grounds for termination.
- Provide clear direction for chain of command when a staff member in the practice has questions about or disagrees with management of patient care, coding and billing, or administrative matters.
- Incorporate into the handbook information that addresses:
  - Clinical competencies.
  - Orientation and in-service training.
  - Maintaining clinical competencies and certification.
  - Staff vaccinations and exceptions.
  - Annual TB testing.
  - Hepatitis B blood titers screening.
  - Expectations for personal grooming and hygiene.
  - Timeliness.
  - Acceptable behaviors.
  - Approved uses of office equipment.
  - Unauthorized uses of office telecommunications, computers and Internet services.
  - Scope of practice parameters.
  - Use of social media in the office practice.
  - Patient privacy.
  - Patient confidentiality.
  - Complaints.
  - Complaint management.
  - Sick leave.
  - Family leave.
  - Workers compensation.
  - Performance evaluation.
  - Progressive discipline.
  - Termination.
- Annual review and revision as needed to the content of the employee handbook.
- Retain copies of retired versions of the employee handbook.
Provide employees with in-service programming on changes to the employee handbook.

Case Example:
Larry Dexter was hired to manage the billing and coding section of an orthopedic practice. Mr. Dexter came with a strong background in billing and coding and good recommendations. After reading the employee handbook, Mr. Dexter signed the attestation acknowledging receipt of the document and that he had read and agreed to all the terms of the handbook. About seven months after he was hired, Mr. Dexter was found scanning child pornography websites on a medical office computer. “It was my lunch hour, so what is the problem?” he said to the practice administrator. “Larry, you are summarily terminated. The employee handbook clearly states that use of office computers to access unauthorized website, including any erotic or pornographic websites, is strictly prohibited and will result in summary termination. You signed the acknowledgement when you started seven months ago. I will escort you to collect your belongings from the billing and coding office. Please give me your keys to the office,” said the practice administrator.

Applying Risk Management Strategies:
- Set expectations for employee behavior in the employee handbook.
- Define what is unacceptable practice in the handbook.
- Enforce the employee handbook disciplinary and termination procedures in a consistent manner.
- Document in the employee personnel file disciplinary and termination actions taken consistent with the employee handbook and administrative policies and procedures of the physician office practice.

B. Job Advertising
Good employment practice includes the use of well-worded job descriptions in employment advertising. Care must be taken to avoid any suggestion of discriminatory practices in job advertising. Similarly, the advertisement should provide an accurate description of what is expected of applicants and what is involved in the physician office practice position.

Risk Exposures:
- Discriminatory advertising practices.
Regulatory scrutiny.
Deceptive advertising claims.

Risk Management Strategies:
Employment advertisements should be well-written and consistent with state and federal laws that bar discriminatory employment advertising and hiring practices. Some practice strategies to consider include:

- Develop accurate job ads that convey what is involved in the position and required and preferred qualifications.
- Include language that makes clear that the physician office follows all applicable federal and state laws dealing with anti-discrimination in hiring practices.
- Before posting the advertisement, ask someone who was not involved in the development of the ad to review it and to determine if it conveys the intended message about the open job position and requisite qualifications to apply.
- Revise the content until the ad conveys intended information.

Case Example:
A general surgery practice wanted to hire a registered nurse fluent in Portuguese to assist in post-operative wound management and suture removal. The practice had seen a large increase in the Portuguese service population and it thought it would be a good idea to hire a nurse who spoke Portuguese to handle the position. The job description stated in part, “The registered nurse must be licensed in this state. The registered nurse must be fluent in spoken and written Portuguese in order to work effectively with the practice’s patient population.” Jorge Mello, RN, applied for the job, but he was not hired. Mr. Mello was annoyed. “Why did I not get the job? Was it because of my gender?” he asked the practice manager. She replied, “Not at all. The advertisement made it very clear that the successful applicant had to be fluent in spoken and written Portuguese. You are not completely fluent in spoken Portuguese and you are not able to read the language. You do not meet the qualifications stated in the advertisement.”

Applying Risk Management Strategies:
- Follow the job qualifications stated in posted employment ads for the practice.
- Make certain that the wording of the job ads is clear and leaves no room for interpretation in the qualifications for the position.
C. Screening and Hiring Procedures
Many physician office practices ask job seekers to complete a detailed employment application. The information is used to screen out those who do not possess necessary training and qualifications. Job seekers should be apprised of the steps in the hiring process, from submitting an application, through background checks and confirming information supplied on the application form, to an offer of employment. Setting a reasonable expectation about timeframe is important as it demonstrates respect for job seekers.

Risk Exposures:
- Unlawful hiring practices.
- Discriminatory hiring practices.
- Litigation.

Risk Management Strategies:
Effective screening of job applicants and following established hiring practices could help a physician office avoid liability risk exposures. Some practical strategies to consider include the following:
- Use a job application form that requests needed information to identify qualified individuals for possible employment.
- Make clear to all applicants their responsibility to provide accurate and timely information and that any falsehoods or misrepresentations on the application or during the hiring process will terminate consideration as a job applicant.
- Set expectations about the timeframe for the job screening and hiring process.
- Provide specific information about the required qualifications for the position so that job seekers can determine if they meet the specifications.
- Ask for at least three references from individuals who are not relatives of the applicant. In the application process, obtain written authorization to ask references to confirm information provided by the applicant regarding background, training, and experience to fulfill the position.
- Ask if the job seeker if he or she needs any reasonable accommodation to fulfill the requirements of the position, noting that by providing such information it is not an automatic disqualifier from consideration for the job.
- Ask if the job seeker has had any criminal convictions and if the answer is “yes” to supply details about the criminal convictions. Note that absent state law barring someone with such a criminal background from serving...
in the job, the information will be evaluated along with other factors about the job seeker’s ability to fulfill the responsibilities of the position.

- Make certain the application and tests for bon fide occupational qualifications for the job are consistent, such as ability to lift weights of a certain amount in a practice that services bariatric patients or specific data entry processing speeds and accuracy for billing and coding clerical positions.

**Case Example:**
Tanya Collette completed a job application for a position as a scheduler for a large urban pediatric practice. The job had multiple components, including scheduling tests for patients with diagnostic imaging centers, completing patient referrals to specialists, and serving as a substitute for patient registration. On the application form, Ms. Collette said she needed a reasonable accommodation. She noted that she had poor eyesight in her left eye and even with special eyeglasses, the vision in her right eye was 20/60. “As long as I can enlarge the content on screen, I should be able to complete online forms. Ms. Collette had a very nice resume and good references. The practice leader used the enhancement function on the office computer for the scheduling program to determine if Ms. Collette could visualize the content. “Oh yes. I can see it just fine. In fact the font size does not need to be that large. Shall I demonstrate how I can complete it?” asked Ms. Collette. After demonstrating her ability to use the software, Ms. Collette was offered the position.

**Applying Risk Management Strategies:**

- Follow a consistent approach with job application review and reference-checking.
- Address on a case-by-case basis requests for accommodation, following in such instances guidelines from state and federal regulators for determining if the specific accommodation challenges can be met in each situation.
- Document the findings for each reasonable accommodation situation.
D. Job Descriptions Tied To Scope Of Practice Laws
All administrative, clerical and clinical position in the practice should have a specific job description that outlines the tasks and responsibilities of the job. With regard to clinical positions, job descriptions should be based on scope of practice outlined in state laws and regulations. Scope of practice rules are often issued by state boards of medicine or nursing. Asking someone to exceed his or her job description or to go beyond state scope of practice laws is a risk-prone activity.

Risk Exposures:
- Violation of applicable scope of practice regulations.
- Non-adherence to job descriptions.
- Negligence.
- Vicarious liability.

Risk Management Strategies:
Developing well-written job descriptions requires careful thought about the duties to be fulfilled by an employee. For clinical personnel, it is important to make certain that these duties are within the scope of practice recognized under applicable state law. Some practical strategies for this purpose include the following:
- Develop a template for job descriptions in the practice.
- Make certain that the job descriptions are consistent with applicable state and federal legal and regulatory requirements.
- Obtain scope of practice information for those professional groups for whom such information is available either in state legislation or from a regulatory body such as the state board of medicine, nursing, etc.
- Work with legal counsel to confirm that job descriptions intended for use in the practice are consistent with scope of practice requirements.
- Ask legal counsel to notify the physician office practice manager annually of any changes in state legislation or regulations that modify scope of practice requirements.
- Update job descriptions when there have been modifications to related scope of practice requirements.
- Reinforce with care providers the importance of staying within a person’s scope of practice and job description when working with him or her in the delivery of care.
Case Example:
Darryl Cummings, CMA, was asked by Dr. Notte to “consent the patient” for a skin biopsy. Mr. Cummings knew from his job description that he was prohibited from participating in the consent process for any patient. Mr. Cummings tried to talk with Dr. Notte about his request, but the physician told him, “Just handle it, Darryl.” Mr. Cummings conferred with the clinical leader for the CMAs, Ms. Weldon, RN, MSN. “You did the right thing Darryl. I will confer with Dr. Notte,” she said. Ms. Weldon took Dr. Notte aside and said, “Doctor, did Darryl misunderstand you? Did you want him to ‘consent the patient’ for a skin biopsy?” The doctor replied, “Yes, that is correct. It is no big deal.” Ms. Weldon replied calmly, “Well, Dr. Notte, it is a big deal. You are asking one of my CMAs to exceed the scope of his job description and the parameters of his certification. I think you had better manage the consent for this patient, and we can discuss who manages consent procedures later today.”

Applying Risk Management Strategies:
- Develop and follow job descriptions in terms of roles and responsibilities of employees.
- Make certain that clinical personnel stay within the scope of practice or certification for his or her professional designation.
- Provide orientation and, in appropriate situations, one-to-one counseling when physicians ask clinical personnel to go beyond recognized job or scope of practice parameters.
- Encourage clinical personnel to seek assistance when asked to exceed job or scope of practice parameters.

E. Orientation and Training
An important risk management consideration for all physician office practices is orientation and regular in-service training for administrative, clerical and clinical personnel. Recognizing that orientation education and in-service training can help prevent or reduce risk exposures, it is useful to develop content that is oriented to the adult learner. The failure to do so could translate into billing and coding errors, harm to staff, and patient injury.
Risk Exposures:
- Inadequate physician practice orientation education.
- Inadequate physician office in-service training.
- Injury to staff.
- Injury to patients.
- Clerical, billing and coding errors.

Risk Management Strategies:
Orientation education and in-service training need not be boring or offered solely on an in-person basis. Rather, the information can be presented in a manner that is informative and easy to apply to work in the physician office setting.

Strategies to consider for this purpose include the following:
- Identify orientation modules and programs that all staff must complete on such topics as HIPAA Privacy, sexual harassment, and related topics.
- Consider use of online orientation modules for this purpose that includes post-orientation testing.
- Document successful passing scores in individual personnel files.
- Offer annual refresher modules on mandatory topics with related testing and recording of scores.
- Develop orientation modules for administrative, clerical and clinical responsibilities.
- Consider use of web-based orientation modules with testing for some administrative and clerical responsibilities.
- Designate one or two individuals to provider administrative and clerical orientation education for some topics or for all content in lieu of web-based training.
- Designate one or two individuals to provide clinical orientation education.
- Include demonstrated competencies testing for individuals completing orientation education.
- Provide additional orientation for those colleagues who do successfully complete clinical orientation competencies testing.
- Consider use of web-based orientation programs for some clinical topics such as needlestick injury prevention.
- Offer on a scheduled or on an as-needed basis in-service training on new equipment, new processes, new procedures, etc.
- Require colleagues to attend in-service training on new clinical equipment, clinical procedures or practices.
- Offer annual refreshers on resuscitation procedures, disaster evacuation, etc.
➢ Complete unannounced mock drills for medical emergencies in the office practice.
➢ Never assume that a person new to the practice or someone who is
  returning after an extended absence is oriented to the use of
  administrative, clerical or clinical equipment, software or completing
  specific procedures.

Case Example:
Yvonne Moreau was perceived as one of the most reliable coding and billing
clerks in the Stevenson Poly Practice. All seven offices called Ms. Moreau for
advice. While Yvonne was on medical leave, the practice installed an updated
software package for coding and billing. Although Yvonne had been consulted
about purchasing it, she missed all the in-service training provided by the
software company. When Ms. Moreau returned to work she encountered several
difficulties in using the new software. She called a counterpart at another office
and asked for help. “Yvonne, I think you should have the same day-long
program we had while you were out on leave. Ask Jen Powers, the practice
administrator. I am sure it can be arranged for you,” her colleague replied. Ms.
Powers readily agreed and arrange for the in-service program.

Applying Risk Management Strategies:
➢ Provide all staff with pertinent orientation and in-service training.
➢ Make certain that those who are unable to attend orientation or in-service
  training have the opportunity to complete a “make-up” program prior to
  using new equipment, software or carrying out new or revised clinical
  responsibilities.

F. Use of Agency Personnel
Staffing agencies often provide physician office practices with temporary
personnel. The role and responsibilities of these individuals may involve
administrative or clerical work. However, it is not uncommon to find agency
personnel fulfilling the role and responsibilities of certified medical technicians,
nurses, nurse practitioners, and physician assistants. Locum tenens physicians
may be assigned by medical staffing agencies to work on temporary assignment
in physician office practices as well. Because patients view these individuals as
part and parcel of the physician office practice, any errors or omissions on the
part of agency personnel may be ascribed to the medical group. This is due to
the fact that such temporary personnel are seen as the agents of the practice. To guard against liability, the practice should utilize good contracting methods and set specific requirements for the activities of agency personnel.

**Risk Exposures:**
- Ostensible agency.
- Apparent agency.
- Litigation.
- Adverse publicity.
- Loss of market share.

**Risk Management Strategies:**
Successful relationships can be developed with staffing agencies. From the vantage point of the physician office practice, there are several strategies to consider including the following:
- Work with legal counsel to develop a template contract for use with staffing agencies.
- In lieu of a template contract, work with legal counsel to develop specific language to include and to exclude from agreements provided by staffing agencies.
- Address the issue of background checks, verification of active licensure, professional liability insurance coverage, and orientation to mandatory rules and regulations, including HIPAA privacy, sexual harassment, bloodborne pathogens, universal precautions, etc.
- Insist upon use of certified staffing agencies.
- Require specific limits of insurance coverage and also language to hold harmless and to indemnify the medical practices for legal expenses and judgments involving errors or omissions on the part of the staffing agency or its assigned personnel.
- Include the prerogative to insist upon replacement of assigned personnel.
- Require the staffing agency to notify the medical practice of any investigations, complaints or litigation involving assigned personnel.
- Require the staffing agency to notify the medical practice of any civil or criminal investigations involving the entity or loss of certification.
- Build in the right to terminate the staffing agency contract.
- Build in the prerogative to utilize more than one certified staffing agency.
Case Example:
The Excellar Staffing Agency had a five-year agreement with Nuance Medical Associates to provide temporary personnel to fill roles and responsibilities as medical technicians and physician assistants. All seemed to be going well until the local media carried an exclusive that Ivan Jorege, a physician assistant, had been picked up by state police on charges of impersonating a licensed physician assistant. It was discovered that Mr. Jorege was not a physician assistant. He had stolen the identity of a recently retired PA. The man holding himself out to be Mr. Jorege was really Itmar Jundersen. He was wanted on several other charges in nearby states. The practice administrator for Nuance Medical Group was horrified because “Mr. Jorege” had been assigned to work in the practice by Excellar Staffing. He had been working in the practice for three weeks. One of the patients called to ask, “Is that man the police arrested working in your practice? He looks so familiar. I think he is the one who treated me the other day.” The practice administrator called the Excellar Staffing Agency to tell the president of the firm that Excellar would be held accountable for the situation. The practice administrator contacted legal counsel and the insurance carrier to notify them of the situation. A decision was made to terminate the Excellar contract and to file suit for breach of contract.

Applying Risk Management Strategies:
- Execute well-crafted contracts with reputable staffing agencies.
- Build in the prerogative to terminate such agreements in appropriate situations. Make certain that staffing agency agreements include hold harmless and indemnification provisions favorable to the physician office practice.

G. Contingency Staff Planning
As in other types of healthcare settings, physician office practices should anticipate staffing issues. Contingency plans should be in place for vacation periods, maternity leave, medical leave, and active duty call-ups of personnel by the armed services or in exigencies, DMAT mobilization. From a practice perspective, continuity of care should be the focal point. As such, having a staffing contingency plan in place is an important risk management consideration.

Risk Exposures:
- Discontinuity in delivery of patient care.
- Delays in patient care.
- Loss of market share.
- Reduced revenue.

**Risk Management Strategies:**

Having in place a contingency plan for staffing purposes is useful to address a range of situations. Agency staffing resources, locum tenens, and doubling patient load for a short period of time, may be part of the plan of action. However, there are some practical strategies to consider in a staffing contingency plan, including the following:

- Identify possible resources to address staff contingency situations, including staffing agencies and locum tenens.
- Consider the types of staffing contingencies that may impact the practice, including planned vacations, staff medical leaves, maternity leaves, family leaves, and regular two-week training and active duty call-ups for reservists and National Guardsmen who work in the practice.
- Identify staff that may be mobilized as part of a DMAT unit.
- Think about ways in which essential functions of the practice can be maintained and whether or not it is prudent to refer patients to other practices for ongoing care.
- Determine if it is prudent to obtain locum tenens.
- Determine what if any staffing is required to fulfill on a temporary basis administrative or clerical positions.
- Orient temporary staff from staffing agencies to their roles and responsibilities.
- Make certain that all pre-screening and job qualifications have been completed by the staffing agency.
- Have a program in place for refresher training for returning employees.
- For clinical personnel, including physicians, make certain that they receive refresher training and complete where required a licensure board-mandated re-entry program.
- Make certain that returning employees meet requisite health requirements to fulfill their duties in the practice.
- Work with the insurance agent or broker for the medical group to determine if key person insurance coverage is warranted to address costs associated with finding a permanent or temporary replacement for a key individual in the practice.
**Case Example:**
Tomas Fernandez, NP, went bungee jumping with some friends over a long holiday weekend. Tomas was injured when his safety strap snapped. He fractured his right wrist and dislocated his right elbow. Although he did not require surgery, Mr. Fernandez was unable to return to work for six weeks. The other NP in the practice was going on maternity leave in three weeks. A decision was made to ask a staffing agency to supply two nurse practitioners. They would be oriented to their duties in the practice by the NP who was going out on maternity leave.

**Applying Risk Management Strategies:**
- Develop a staffing contingency plan for the practice that anticipates personnel needs for administrative, clerical and clinical responsibilities.
- Make prudent choices about temporary staffing in order to maintain continuity of care, service, and the business aspect of the practice.
- Work with reputable, certified staffing agencies when a decision is made to address a staffing contingency issue.
- Provide orientation for temporary agency personnel to acquaint them with office policies, procedures, and practice routines.
VIII. Managing Problems in the Physician Practice Setting

A. Recognizing Problems, Complaints and Potential Compensatory Events

It is well understood that risk management encourages an early response to patient complaints, problems that impede delivery of patient services and potential compensatory events. Sometimes too, patient complaints or problems in service delivery may be an indicator of serious systemic or clinical problems that need prompt attention. The failure to take appropriate action can result in serious repercussions, including adverse publicity, poor patient satisfaction scores, and litigation.

Risk Exposures:
- Failure to act on identified service problems or patient complaints to the practice resulting in formal complaints to health insurers.
- Failure to act on identified service problems or patient complaints to the practice resulting in formal complaints to state medical boards.
- Formal complaints by patients to state ombudsmen or Medicaid programs.
- Formal beneficiary complaints filed with Medicare.
- Possible legal-regulatory investigations by state and federal payers.
- Litigation for substandard care when the practice knew or ought to have known that there was a departure from recognized standards of care that could result in reasonably foreseeable injury or death.
- Adverse publicity.
- Loss of healthcare plan credential or certification.
- Diminished market share.
- Loss of revenue.

Risk Management Strategies:
Using a good “early warning” system and a customer-oriented service recovery program can help avert complaints lodged with the practice fulminating into formal complaints with health plans or insurers, state and federal regulators, or litigation. Strategies for this purpose include the following:
Consider use of an in-house patient complaint system that allows for reporting of problems or complaints from patients or their familial care providers.

- Daily check the complaint system, whether it be in hard-copy format, voice mail, or information posted on completion of an office visit on a form or an electronic tablet.
- Encourage reception, billing, and clinical personnel to “speak up” and report to the practice manager patient complaints that they cannot resolve at their respective levels.
- Review monthly reports from reception, billing, and clinical personnel regarding patient problems or complaints that were resolved without intervention by the practice manager. Use this information to determine if there is a need to change policy, procedure, practice routines or staff education.
- Use a prompt response approach to service problems or complaints, including telephone calls and revisits with the practice manager and care provider.
- Develop good service recovery correspondence to send to patients who encountered problems or made justifiable complaints.
- Follow good risk management practices for identified potential compensatory events. [See Section X.B.].

**Case Example:**

June Waldron had heard from several patients that something was just not “right” with the new medical technician who worked with Dr. Nettie. Ms. Waldron used to work with that part of the practice, but due to a maternity leave and an illness, she had been reassigned to work with another physician. When patients saw her, some would take Ms. Waldron aside and say, “Wish you were back working with Dr. Nettie” or “Where did they find that guy who is working with Dr. Nettie?” Ms. Waldron told the practice manager who said, “Thanks, June. Please give me the names of the patients who spoke with you. I will put them on my list for patient satisfaction calls that I do each week to see if we need to make improvements. Some of these calls are to randomly selected patients, and others come about because of concerns or problems voiced to staff. I will take it from here.” Ms. Waldron gave her a list of five patients who had made similar statements about the new medical technician. The practice manager called each patient individually to say that she was completing a practice patient satisfaction survey. After asking about timeliness of their appointments, cleanliness of the examination room, and satisfaction with the treatment provided by the care provider she said, “Please share with me any insights, suggestions, complaints, problems or staff compliments were most
“Four of the five of them gave Dr. Nettie high praise for the amount of time he took with each of them and his way of explaining things to him. They all gave Ms. Waldron high marks, with one saying, “She is just like my daughter. I think she is wonderful.” But all five patients said basically the same thing about the new medical technician: “You have a problem in the practice. There is something wrong with that new medical technician. He is rude, abrupt, and rough. He does not listen to what I tell him.” Each one noted that when asked if they had any health concerns or issues that the doctor should know about, he never recorded these items on the record. In fact, all of them noted that had Dr. Nettie not mentioned, “I see you have no new health concerns or issues,” some of their health complaints might have been ignored. In three instances, the health “complaints” caused Dr. Nettie to make important changes in medication and in another a referral to a specialist. The practice administrator thanked the patients for their input. She then met with the new medical technician. She told him that she had received numerous complaints and expressions of concern from patients about the way he treated them. She also asked if he recorded patient health concerns and issues in the record for Dr. Nettie to review prior to seeing patients. “Nope. Don’t bother with it. Doing that recording is a hassle. Besides asking patients about that stuff is the doctor’s job, not mine,” said the new medical technician. It did not seem to trouble him that practice routine required such documentation. He remained adamant that it was the doctor who handles it. The practice administrator spoke with Dr. Nettie. “Ahh. I thought the guy was a little rough around the edges. I should have told you that some patients complained to me about him. I just thought he was learning the ropes. Golly, if I had relied on the record and not asked the patients about their health concerns, we could have had serious problems,” said Dr. Nettie. Based on the information gathered a decision was made to terminate the new medical technician. He was within his probationary period. His record reflected he had been counseled twice before early on in the “new hire” phase about poor documentation practices. A thank you letter was sent by the practice administrator to each of the patients who participated in the telephone survey. “In our medical practice we value input from our patients. It helps us learn how we can make improvements. Thank you!”

**Applying Risk Management Strategies:**

- Make certain that all personnel and care providers “speak up” when they hear concerns or complaints from patients.
Encourage patients and their familial care providers to complete patient satisfaction surveys that are designed to identify good practices and opportunities for improvement.

Act promptly to evaluate the basis for patient dissatisfaction, concerns or problems.

Take action that is commensurate with the level of patient dissatisfaction, concerns or problems.

Let patients know that the practice appreciates their candid concerns, complaints and suggestions.

Recognize staff members who are identified for providing patients with quality service.

B. Investigating And Managing Potential Compensatory Events

Reports of adverse events and potential compensatory events in the physician office setting signal the need for a prompt response. The initial step should be to manage the situation. A patient may have received the wrong prescription or gone home and had a bad response to a new dose of regularly prescribed medication. The result may be that the patient is rushed to hospital and a family member calls the practice to make the care provider aware of the situation. In other instances, the event may take place on the premises of the medical practice. In either type of situation, the first step is to make that that anyone who was or who may have been harmed receives an appropriate level of response.

The fact that there was an untoward event does not mean that it occurred as a consequence of a breach of a standard of care on the part of the physician office practice or the care provider. However, once aware of a potential compensable event, it is important investigate the situation. Typically, this step begins after the injured or harmed individual has been stabilized, treated, or transferred to an appropriate level of care.

The investigation will include interviews, and also securing equipment, syringes, medications, and test devices that may have been implicated in the event. It is important to secure the medical record as well. If the practice is using a hard-copy system, the record may be placed in a secure location after a copy is made up to the point of the occurrence. In this way, no one can go back and modify the record. However, the copy can be used for continuity of care. If the record
is electronic, the IT manager for the physician office will be asked to initiate measures to safeguard the record against deletion and changes. A legal hold policy may come into action too, to safeguard the integrity of the electronic record. In some instances, a copy of the electronic record may be used for continuity of care, maintaining the original record up to the time of the event in a segregated or “hold” manner.

When events take place on the premises, many risk managers will take digital photographs of the area of the occurrence. The digital photographs include software that permits the user to time stamp the photographs as well as securing the images to prevent so-called “photo-shopping” the content.

Various notifications may take place as part of the management of a potential compensatory event. This process is discussed in the next session of this document. [See X.C., Notification Requirements]

Prompt and early management of potential compensatory events has many benefits. First, it may allow the physician practice to pre-empt possible litigation and resulting adverse publicity. Second, it sends a strong message to other patients that the administrative and clinical leadership of the physician practice truly care about them, a point of reassurance for them. Third, an early response may also permit the practice to contain the scope of what might otherwise be a much more serious and expensive compensatory event. Finally, when the occurrence has been managed and the results are collected from the investigation, the practice can take from it “lessons learned” to help avert similar events in future. Physician office policy, procedure and practice routines may be modified or the configuration of the environment of care may be redesigned. In some instances, a decision may be made to stop providing certain services because the potential risks are too severe for the practice.

**Risk Exposures:**

- Litigation.
- Legal-Regulatory Review.
- Adverse Publicity.
- Diminished staff morale.
- Increased staff turnover.
- Loss of market share.
- Reduced revenue.
**Risk Management Strategies:**
Physician office practices should have a practical plan in place for responding to a potential compensatory event (PCE), focusing first on the needs of the individual who is the subject of the event. This is true for events that take place outside the office setting and those occurring within the confines of the office. The next step is to investigate the event with a view to resolving what may be a potentially compensable occurrence and to improve processes and systems to avert similar occurrences in future. Some practical strategies include:

- Incorporate in the practice risk management policy and procedure guidance on how to manage:
  - An in-office potential compensatory event.
  - An out-of-office potential compensatory event.

- Include in the guidance:
  - Immediate attention and assistance for the injured or harmed individual, including transfer to acute care.
  - Securing the area of the in-office event and collecting syringes, tools, devices, or equipment that may have been involved in the event.
  - Taking digital photos of the area in which the event took place and securing the digital photographs.
  - Securing the hard-copy medical record, making a copy that can be used for continuity of care.
  - Securing the electronic medical record and using an electronic copy for continuity of care.
  - Safeguarding the original electronic record from deletions or changes through processes put in place by the IT manager or HER system vendor.
  - Completing interviews.

- Evaluating the occurrence by asking:
  - When did the event occur? (Day of the week; time of the day)
  - Where (specific and descriptive) did the event occur?
  - What transpired?
  - What was supposed to transpire? (Variance from policy? Procedure? Practice routine?)
  - Who was present?
  - Who was supposed to be present?
  - Did the event involve diagnostic testing by staff? Self-assessments at home by the patient or family member?
o Did the event involve medication administration? By staff? By the patient or family at home?

o Was the medication a sample provided by the physician office?

o Was the medication a prescription filled at a community pharmacy? Ask for: (a) name of pharmacy; (b) pharmacist; (c) medication name on the label; (d) dose and (e) instructions.

o Was the medication a mail-order prescription? If so, follow the process above but instead of the name of the retail pharmacy, obtain the name of the mail-order pharmacy.

➢ Determine if the patient or family were responsible for home management of equipment, such as a CPAP or nebulizer that may have been involved in the event.

➢ Determine if home health agency personnel, durable medical equipment vendors, family care givers may have been involved in the occurrence, including Meals-on-Wheels, Home Visitors, or home cleaning firms.

➢ Evaluate the medical record to see if it points to triggers for or explanations for the PCE.

➢ Obtain outside expert review of any medical equipment that may have been involved in the occurrence to make certain that a recognized approach is used that will not void equipment warranties. Note: It is prudent to ask legal advice on this matter, particularly from a defense attorney assigned to the case by the professional liability insurance carrier.

➢ Identify the causes of the event to the extent that is practical to do so.

➢ Consider use of a root cause analysis and develop feasible action plans to address untoward events or occurrences.

➢ Recognize that any action steps that involve modification to policy, procedure, or practice routines should go through the physician office review process as well as inclusion in staff in-service education.

➢ Be certain to make appropriate notifications in a timely manner to insurance carriers and when required or indicated, to law enforcement and state agencies.

➢ Make certain that a “hold” is placed on submitting claims for patient services.

➢ Notify billing and coding, whether done inside the physician office or through an outsource entity, of the “hold” and when it may be released.

➢ Be poised to respond to media inquiries, identifying a spokesperson for the physician office practice.
NOTE: For employee-related occurrences:
- Recognize that the format for the management of the event and the investigation will be different for employee-related occurrences as such matters will trigger workers compensation requirements and potential OSHA requirements.
- Recognize that employees should receive prompt medical attention as the subject of a potential compensatory event.

Case Example:
Thirty-three-year-old Stephanie Wilde brought her four-year-old daughter with her to the Anderson Orthopedics Group. Ms. Wilde was scheduled to have an evaluation of her right elbow. An avid tennis player, Ms. Wilde reported that her elbow had become quite sore and stiff. Ms. Wilde asked to use the ladies room while waiting to see Dr. Tanton, an orthopedist in the practice. “Certainly. It is down on the left, third door,” said the receptionist. “Oh, could you keep an eye on my daughter while I am in the ladies room?” asked Ms. Wilde. The receptionist nodded as she picked up the telephone to answer a call. Ms. Wilde had to wait because the ladies room was occupied. When she returned to the reception area, she did not see her daughter. She asked the receptionist, “Where is my daughter?” The receptionist replied, “She was here a minute ago. Maybe you should ask the other people in the waiting area.” In a loud voice, Ms. Wilde said, “Excuse me. Has anyone seen a little girl leave the office? It is my daughter.” A woman spoke up and said, “She was playing with a doll right over there near the door the last time I saw her.” Panic set in and Ms. Wilde turned back to the reception area. “You said you would keep an eye on her. Now she is gone. This is ALL your fault. Help me! Please help find her,” shouted Ms. Wilde. At this point, the practice manager heard the shouting and asked Ms. Wilde to come back to her office. She remained calm and asked her what happened. “Okay, I will alert building security and the local police. Give me a description so that I can share it with them. Meanwhile, our staff will start a search of our office and notify the four other medical practices in the building and the pharmacy on the first floor. I know that you have got to be terribly upset. Let’s try to stay focus and find her. My name is Nancy Rey, but please call me Nancy,” she said. Three hours elapsed when Ms. Rey received a telephone call from the local police. The little girl had been found in a park two miles away. Someone had given her a ride to the park and when she did not obey the driver, he spanked her and pushed out of the car. The little girl was bruised and had several cuts on her leg and arm. The little girl also had a broken wrist and forearm on the right side. She was very frightened. Ms. Wilde was
very happy to be reunited with her daughter. She thanked Nancy Rey for her help and the police. “But Nancy, you have a problem with that receptionist. This would not have happened had she kept an eye on my little girl,” said Ms. Wilde. Ms. Rey notified the practice leadership of the event. “This is a definite potential compensable event,” she said. The insurance carrier was notified. Realizing that many of the people in the waiting room were very upset, she put in place an immediate plan to address their fears and concerns. Ms. Rey called Ms. Wilde to check on the little girl and to see if Ms. Wilde or her daughter needed anything. “My baby is going to need surgery to fix her arm and wrist. They want to keep her in the hospital after the operation,” she said. Ms. Rey replied, “Do you need me to make any phone calls? I hope you will not find it intrusive, but I would like to be with you while your little girl undergoes the operation. I don’t want you to be alone. I also want to make certain that if she is kept overnight that you get a “rooming-in” arrangement so that you can be with her.” Ms. Wilde accepted Ms. Rey’s assistance. The little girl was in and out of surgery quickly and the prognosis was very positive. Ms. Wilde then returned to the office to start her investigation. She took photographs of the area and completed interviews. The receptionist was from a staffing agency. She did not realize that the practice had a policy not to accept responsibility for child left unattended in the reception area. In fact, there was a sign on wall obscured by a coat rack that said “Please watch your children.” Two staff were traumatized by the event. They had nightmares and persistent headaches. “Nancy, what if we found her stuck in a closet or dead in the building. We have children the same age. We cannot get over it,” the two staff members told Ms. Rey. Arrangements were made for the staff to receive one-on-one counseling and, if need be, follow-up therapy. The action plan was reviewed with the workers’ compensation carrier that had been notified the day of the event. Ms. Rey received a statement of claim from a well-known plaintiff’s attorney representing Ms. Wilde and her daughter. The claim was for negligence, post-traumatic stress, and a request for $3.5 million in damages. Ms. Rey referred the matter to defense counsel retained by the insurance carrier. She gave him her insights into the matter and he said, “Let me see if I can get this one settled quickly. Mom has a lot of responsibility here, Nancy. That staffing agency should also put some money on the table,” said the attorney. The staffing agency was put on notice that they would be named as a third-party defendant. The temporary receptionist was removed from the practice by the staffing agency. The sign was moved to a location where all visitors could see it. An all-staff education program was completed on lessons learned from the event. Just when Ms. Rey thought everything was settling down, a television crew appeared to do an interview.
**Applying Risk Management Strategies:**

- Address immediate risk issues when a potential compensatory event is identified.
- Set priorities in managing potential compensatory events.
- Make use of ancillary resources in appropriate situations, such as law enforcement or building security.
- Provide notification to practice leadership and insurance carriers.
- Maintain good communication with and be supportive of those who are affected by the event.
- Gather information that will be important for the internal investigation, including interviews, photographs and other information.
- Work with defense counsel to resolve statements of claim to reduce the risk of litigation and adverse publicity.
- Develop and implement a corrective action plan to avoid similar situations in future.
- Ask the identified spokesperson for the practice to respond to the media.

**C. Notification Requirements**

When a potential compensatory event occurs in the practice, the person responsible for risk management should notify professional liability insurance carriers. If the event involved harm to a staff member, the notification would involve the workers’ compensation carrier. If the occurrence resulted from damage or destruction of property or theft, the property insurance carrier should be put on notice.

Many states have mandatory reporting or notification laws that can impact a physician office practice. Common examples include known or suspected child abuse and elder abuse. In some states, the mandatory reporting of abuse extends to spouses. Several jurisdictions have mandatory notification for such matters as patients presenting with stab wounds or gunshot wounds and also for patients who test positive for sexually transmissible diseases or STDs and also for TB.

Successful reporting requires compliance with the notification provisions spelled out in an insurance program or, in the case of state reporting, laws and regulations. Typically, the notification process is quite straightforward, including
how to file the notice and the required timeframe for doing so. The failure to follow the prescribed process can lead to a denial of coverage by an insurance carrier and, in the case of mandatory state reporting, potential fines and penalties.

**Risk Exposures:**
- Denial of insurance coverage for failure to notify the carrier of actual or potential compensable events.
- Denial of insurance coverage for not following the requirements for submitting notification.
- Fines and penalties for failure to make mandatory notifications to the state.
- Potential professional disciplinary action for failure to make mandatory notifications to the state.
- Litigation for failure to warn about identified abuse situations.

**Risk Management Strategies:**
- Develop a reporting matrix tool that identified individuals in the physician practice may use to notify insurance carriers of actual or potential compensatory events, workers’ compensation issues, and property claims.
- Provide identified personnel with education about the notification process.
- NEVER rely on one insurance carrier to notify another in the insurance program for the physician office practice.
- Make certain that care providers, clinical personnel and practice leadership are familiar with state mandatory reporting obligation and how to provide timely notice in a way that complies with applicable statutes and regulations.
- Confirm receipt of notification with insurance carriers, documenting the date and time and how the notification was provided to the insurance carriers.
- Confirm receipt of notification with state authorities under mandatory reporting laws.

**Case Example:**
Harriet Plumber, RN, Office Practice Manager for Pulmonology Specialists P. C. realized that patient Guy West never received a test notification follow-up for his diagnostic imaging study. The report from the radiologist was worrisome. The radiologist indicated that there was an ill-defined mass in the right lower lung that warranted immediate follow-up by a pulmonologist. The report was
submitted within forty-eight hours of the diagnostic imaging study. It was now four months later that Ms. Plumber found the report. She called Guy West and told him that the doctor wanted to see him. “Why? I thought everything was fine that this was just a cough. What’s up?” he asked. Ms. Plumber said, ”The doctor wants to go over the report.” Mr. West saw the pulmonologist who apologized for the delay. He arranged for Mr. West to have more precise diagnostic imaging studies. It was clear that in the four-month interval, the ill-defined area had become a larger mass and there were other areas in the lung that suggested the mass had spread. It was determined that Mr. West had an aggressive type of lung cancer and that it had spread to his left lung and his bones. “I am sorry to tell you Mr. West that you have stage IV lung cancer. I would like to discuss your care options,” said the pulmonologist. “Yeah well, it is a little late don’t you think, doctor. I mean if you had followed the radiologist’s report four months ago I might not be in this situation. I am going to see another doctor. You will hear from my lawyer,” said Mr. West. The pulmonologist asked Ms. Plumber to notify the malpractice insurance carrier that they may face a serious delay in care lawsuit. “This guy is only 45 years-old. Experts can argue, but he has a point. Four months ago this might have been a resectable tumor. Darn it! We need to fix our report management. Meantime, notify the insurer,” said the pulmonologist.

This was the first time that Ms. Plumber had to notify a professional liability insurance carrier of a potential compensable event. She was not familiar with the reporting process. She left a message simply asking for someone at the insurance company to call her. She then went on extended medical leave the next day. Ms. Plumber was out for eight weeks following a knee operation. When she returned to the office, she found a message indicating a return call from the insurance company the day of her surgery. When she called again and said she wanted to report a PCE that occurred over eight weeks earlier, the insurance company representative said, “I see that we returned your initial call the next morning, Ms. Plumber, but never heard from you or your office again.” She continued, “Under your policy, you were supposed to give us notice within five business days. This was not done and, as I understand it, you have received a formal legal complaint from the patient’s lawyer. I am sorry to tell you but this situation involves untimely notification. You are welcome to discuss the situation with my superior, but the policy is very clear on the timeframe notification. I do not think we shall defend this case due to untimely notice.” The practice received a formal denial of coverage letter from the insurance company.
Applying Risk Management Strategies:

- Follow the requirements for notification of insurance carriers.
- Follow the requirements for mandatory reporting under application state laws and regulations.
- Document confirmation of notification.

D. Terminating Employees And Contracts

The process for terminating employees is a matter of state law, employment contracts, and collective agreements. It is also impacted by employee handbooks. In some states, employees may be terminated without cause. This approach is followed in so-called “at will” states. However, if there is a true employment contract or personnel are unionized, termination of employment will be guided by these legal provisions. Sometimes, even in a physician office practice, an employee handbook goes beyond providing employer and employees “guidance;” instead, it actually forms a contract of employment. From a risk management standpoint, it is important to obtain clear legal advice on employment contracts, union agreements, and the content of employee handbooks. Legal counsel can advise on applicable state law whether or not it is an “at will” jurisdiction.

Non-employment contracts are crafted to set out the roles and responsibilities of the parties. In most instances, such contracts address deficiencies, the ability to cure substandard performance, indemnification for damages, and termination. Choice of jurisdiction, that is, the set of laws that will be applied and also the venue for litigation over disputed contract claims, is frequently found in contracts. Increasingly, contracts set forth the ability of the parties to go to arbitration rather than litigation.

In the physician office practice, it is unlikely that there will be much consideration of collective agreements with unionized personnel. This perspective may change as hospitals purchase medical practices and physician office personnel get the opportunity to join bargaining units. From a practice standpoint, physician office risk management should emphasize good employment and contractual practices.
Risk Exposures:
- Employment practices liability – failure to terminate employees in accordance with state law or employment contracts.
- Grievances under collective agreements.
- Adverse publicity.
- Reduced market share.
- Reduced revenue.

Risk Management Strategies:
- Work with legal counsel to develop clear guidelines for employment practices, from hiring through termination.
- Work with legal counsel to craft employee handbooks that are not considered contracts.
- When dealing with unionized personnel, work closely with legal counsel on developing clear guidance on termination of members of the bargaining unit in the office practice.
- Follow applicable state law and the terms and conditions of pertinent employee handbooks or contract to terminate employment.
- Ask legal counsel to provide guidance when terminating a contract, recognizing that the need to take such measures should have been spelled out clearly when negotiating the agreement [See IX.F.]

Case Example:
State law prohibited anyone convicted of aggravated assault or an armed felony from working with vulnerable populations. The law defined vulnerable populations to include the elderly, children, and developmentally challenged individuals. The Stratford Geriatric Medicine Group hired Joe Compeski, a PA, who had working successfully with older patients. Mr. Compeski went through the practice hiring process, including screening outsourced to a local human resources company. The practice manager had been told that background checks were running behind. The human resources company representative said to the practice manager, “It is your choice. It could be three weeks or nine weeks. I have no way of knowing. You can tell Mr. Compeski that his application is pending a routine background check, or you can decide to hire him.” The practice needed a well-trained PA with a background in geriatrics. Mr. Compeski looked good on paper and his two references said that everything was fine. The practice manager and clinical leader decided to hire Mr. Compeski. He was given an orientation program as a new hire that included a review of the employee handbook. One of the provisions in the handbook indicated that an
employee could be terminated without cause if, subsequent to becoming an employee of the practice, it was learned that he or she provided false information about his or her identity, criminal background, or professional disciplinary action.

Mr. Compeski was on the job for twelve weeks when the practice manager received an urgent call from the human resources company representative. “I think you will need to talk with your attorney about this one. We just got a report back from our criminal background check on Compeski. He is using an alias. His real name is Jonathan Predneski. He was released from jail four years ago after he was convicted of aggravated felonious assault on a nursing home resident.”

The practice manager alerted the clinical leadership of the group and conferred with legal counsel. Mr. Compeski was terminated on grounds of providing false information in the hiring practice. At the suggestion of legal counsel, the practice manager and the clinical leader reviewed the cases on which Mr. Compeski had provided treatment. Knowing that this was a vulnerable population group, he also recommended giving the group’s insurance carrier notice of the circumstances of the employee’s termination. The insurance company was pleased to learn that there was no evidence that any patients of the practice had been harmed by Mr. Compeski. The state board responsible for PA licensure was notified of what had transpired. An internal investigation was launched immediately to find out how Mr. Compeski had slipped through the system.

**Applying Risk Management Strategies:**

- Complete background checks prior to employing a job candidate.
- Incorporate into employee handbooks and employment contracts language that gives the employer the prerogative to terminate without cause for information learned subsequent to hiring that the individual provided false information about his or her qualifications, background, or identity.
- Report to the applicable professional licensing board that a now terminated employee had provided false information about identity, criminal background, job qualifications and identity information.
- Complete an evaluation to determine if there was any wrongdoing with regard to patients served by the terminated employee.
Provide the insurance carrier with formal notice about the potential risk exposure.

Be prepared to respond to allegations that the terminated employee assaulted or abused patients in the physician practice.

E. Continuity Of Services

Weather conditions, natural disasters, water damage, and fire and flood damage potential can cause major disruptions in the delivery of services in the physician practice. Another challenge to continuity involves the sudden departure or disability of a care provider.

Although one can purchase business disruption insurance, it is equally important to contemplate contingency planning. Both measures represent important risk management actions.

Risk Exposures:

- Business disruption.
- Delays in care.
- Irreparable damage to equipment.
- Inability to access electronic records or back-up information at remote services.
- Inability to provide care to patients.
- Lost revenue.

Risk Management Strategies:

Some think that they will never experience a prolonged or a devastating business disruption. Instead, they think that such events will happen to someone else in a different part of the country. Subsequent to serious hurricanes and tropical storms along the Gulf Coast and Eastern Seaboard and damaging earthquakes along the Pacific Coast, many acute care facilities put in place measures to help reduce the risk of natural disasters and weather-related disruptions to service continuity. At the same time, they invested in redundant infrastructure to help maintain continuity of service. Gas-powered generators are a good example. However, the plans completed in the early part of the 21st century may not have been upgraded to accommodate demands from new electronic systems, computers, servers, and, in addition, the power requirements of hospital-acquired physician office practices. Even for non-hospital-owned physician
practices, the plan developed years ago may be inadequate today. Business continuity planning goes beyond storm, fire, or natural disasters. From a risk management standpoint it should include what to do if a key person in the practice suddenly becomes disabled, dies, or leaves the practice abruptly. Risk management strategies for business continuity include the following:

- Design a comprehensive business continuity plan for the physician office practice that addresses:
  - Storm-related disruptions.
  - Natural disasters trigger disruptions.
  - Fire-related disruptions.
  - Water-related disruptions.
  - Smoke-related disruptions.
  - Power supply-related disruptions.
  - Telecommunications-related disruptions.
- Orient administrative and clinical personnel to the plan.
- Examine infrastructure back-up and redundancy to determine if it is adequate to meet the needs of the physician office practice.
- Make cost-effective enhancements to back-up and redundancy systems.
- Think about the ability to switch the base of operations to another office setting if the practice has more than one location.
- Consider a patient notification system that alerts patients to the change of location, using a recorded message on the practice’s answering machine, automatic message dialing to patients, and text messaging if the patient agreed to receive information about office closings in this manner.
- Consider posting alternate office or closing information on the medical practice website or on local television public service announcements, websites, and social media venues operated by local television, radio or newspapers.
- Develop a succession plan for the practice.
- Develop a key person replacement plan for the practice.
- Work with the insurance agent or broker for the practice to obtain appropriate insurance coverages for:
  - Business disruption.
  - Key person coverage.

**Case Example:**
An unexpected late October snowstorm dumped 15 inches of wet snow across the area. The trees had yet to shed their leaves. Branches snapped like toothpicks from the combined effect of the heavy snow and strong, gusty winds.
Electric utility and telecommunications lines were also damaged or destroyed. The Adams Medical Group had moved to an electronic medical record system approximately one year before the storm. The practice was without electrical power for seven days. Even when power was restored, the practice could not communicate with patients because the landline telephones were inoperable and the street leading to the practice had been rendered impassable by down trees and wires. A tree branch had knocked down the Internet connection for the practice. Two weeks later, the electrical, Internet, and telephone systems were restored. Practice leadership decided to install a propane-generator. A cell phone system was installed as a back-up the telephone system. A claim was filed for business disruption with the practice insurer. Patients appreciated that the practice had put a public service notice on local television and radio stations and the websites of those media sources. One patient, a telecommunications expert said,” Maybe you should think about asking patients to permit emergency text messaging and auto dialer calls. You know there are reputable consultants who can help you with contingency planning.”

**Applying Risk Management:**

- Develop a business disruption continuity plan for the physician practice.
- Review the continuity plan on an annual basis to make certain that the content addresses power supply sufficiency, telecommunications, and backing up hard-copy records once power is restored for the electronic record system.
- Make certain the continuity plan takes into account remote server access and late backup due to power outages.
- Consider in the plan messaging through public service or media outlets to alert patients regarding closures or a shift to a different office location due to a disruption.
- Make certain that the practice has a business disruption insurance plan.
- Make certain that the practice has a succession plan for key persons.
- Make certain that the practice has key person insurance coverage for situations in which key personnel become suddenly disabled, die or abruptly leave the practice.
F. Allegations Of Theft, Loss, And Destruction Of Property

It is not uncommon for physician office practices to receive complaints or allegations of theft, damage or destruction to property. Such allegations may come from a patient, a patient’s relative, or a staff member. Sometimes theft, damage or destruction involves property that belongs to the practice. Such allegations should not be treated lightly. A risk management investigation is warranted in such cases. At the same time, service recovery techniques are prudent for patient and family who are the victims of property theft, loss and destruction. Staff morale also warrants prompt action to assist them when they are the individuals whose property has been stolen, damaged or destroyed.

Risk Exposure:

- Financial responsibility for stolen, damaged or destroyed property.
- Liability claims for stolen, damaged or destroyed property.
- Disruption in clinical care and business continuity if the stolen, damaged or destroyed property involved needed medical equipment or medications.
- Reputational risk; patients and families whose property is stolen, damaged or destroyed.
- Diminished staff morale if it is practice personnel whose property was stolen, damaged or destroyed.
- Diminished market share.
- Revenue loss.

Risk Management Strategies:

A standard risk management approach is to provide warnings to patients, families and staff about safeguarding personal property. The same is true with regard to physician office property. A prompt investigation should be initiated once an allegation is received of property theft, damage or destruction. Good service recovery methods should be followed with patients and family as well as physician office staff whose property was stolen, damaged or destroyed. Risk management strategies include:

- Post warnings in the reception and treatment areas reminding patients, family members, and visitors to safeguard personal property.
- Consider posting warnings in the major language groups reflected in the patient population.
➢ Incorporate the warning about safeguarding personal property in printed and website-based Patients’ Rights and Responsibilities information and the attestation signed at intake into the practice.

➢ Seek legal advice about including exculpatory language that the practice is not responsible for the theft, damage or destruction of property of the patient, family or other practice visitors. Recognize, however, that from a service recovery perspective, it may be prudent to offer patients or family members some assistance.

➢ Build into the employee handbook, new hire orientation and in-service programs a reminder for physician office personnel to secure personal property.

➢ Remind staff to take appropriate steps to safeguard property of the physician practice.

➢ Investigate promptly allegations of theft, damage or destruction of property belonging to patients and families, physician office personnel and the practice.

➢ Notify building security and law enforcement personnel regarding theft, damage, or destruction of property that occurs on the practice premises.

➢ Utilize good service recovery strategies to assist patients and family members.

➢ Provide appropriate support for staff whose property was stolen, damaged or destroyed.

➢ Consider surveillance cameras and deterrent lighting in parking lots owned by the physician office practice.

➢ Explore available insurance coverages to address theft, damage or destruction of personal property of patients, families and staff.

➢ Make certain that the practice has in place appropriate insurance coverage for theft, damage or destruction of property belonging to the practice.

➢ Put in place an insurance plan for theft of electronic devices containing protected health information of patients or sensitive personal data of office practice employees.

➢ Make certain that the practice compliance plan addresses notification and credit rating service checking for theft of electronic devices containing protected health information of patients.

➢ Implement an insurance notification protocol for cases involving theft, damage or destruction of property, including, in relative situations, cyber risk carriers.

➢ Have a process in place to address media inquiries about property theft, damage or destruction involving patients, families, staff and the practice.
Case Example:
The Logan Medical Group owned the medical office building and adjoining parking lot. The lot was well-illuminated. Posted signs warned that the lot was for use of Logan Medical Group staff and patients only. Additionally, signage alerted those using the parking lot that it was under camera surveillance and that the practice was not responsible for theft, damage or destruction of vehicles or personal property. A security officer on the first floor of the building monitored the CCTV camera overlooking the parking lot. Dianna Faulk, RN was responsible for outreach to practice patients in skilled nursing facilities and homebound individuals. She used a tablet device to access the patient’s office record through a VPN. In a rush to get to an office meeting, Ms. Faulk forgot to take the tablet device into the building. She left it in a case that was embossed with Logan Medical Group name and logo. She locked the car with her remote key device. Two hours later she went to the vehicle to drive to her last patient appointment. When she got to her car she found that the right rear window had been smashed. She looked into her vehicle and found that her GPS device was missing, as was her dashboard radio system. On the floor next to the right passenger door beneath shards of glass she saw the tablet case. It was open and empty. Ms. Faulk raced back to the office and spoke with the office manager. Ms. Faulk was very upset. The office manager called building security and the police. It turned out that three other vehicles in the parking lot had been broken into in the same way. These vehicles belonged to patients. The surveillance camera tapes were obtained for the relevant period and provided to the police for analysis. The office manager alerted the property and cyber risk insurance carriers. Since the tablet device contained a large amount of patient health information, the process was started to deal with notification and to offer patients assistance with credit checks for a year. The IT manager locked down the system, and modified the system to prevent someone using the tablet device to enter the practice system. Later that night local police arrested two young men who had in their possession the tablet device, Ms. Falk’s GPS, and dashboard radio. One had a device used to smash out windows. The surveillance camera images had been matched against state criminal investigation databases to identify the two men. They were charged a variety of crimes. Stolen property from the other cars in the lot were retrieved, tagged, and entered as evidence. The property would be returned to the owners. The tablet device was checked to determine if the thieves had gained access to the system. The two young men had not been able to do anything more than turn on the device. Patient health information had not been penetrated by the
thieves. Ms. Faulk was counseled not to leave the tablet device or GPS in the vehicle. The “personal property” warning was reinforced with physician office personnel. As a matter of service recovery, arrangements were made for the three patients whose cars had been damaged by the thieves. They were given taxi transportation home. Only one patient asked for the practice to “step to the plate” to help pay the deductible for the damage repair to her vehicle. The Logan Medical Group also decided to have security officers make visible and frequent rounds in the parking lot.

**Applying Risk Management Strategies:**

- Respond promptly to allegations of theft, damage or destruction of property whether such assertions come from patients, families, or those working in the practice.
- Put in place signage warning patients, family members and staff that the practice is not responsible for theft, damage or destruction of their property. Recognize, however, that as part of service recovery some measures may be taken to avert reputation and market share loss.
- Notify insurance carriers in appropriate situations regarding property theft, damage or destruction, including cyber risk insurers when the theft involves patient health information.
- Follow practice compliance requirements for notifying patients about the potential of a data breach through theft and the availability of credit check services.
- Follow-up with patients when there is a resolution regarding the possibility of a data breach through theft, including determinations that such information was not accessed.
- Reinforce with office personnel safeguarding personal and practice property, including never leaving data sensitive devices or clinical equipment in unattended vehicles.
- Evaluate, and, when necessary, enhance security measures to safeguard property from theft, damage or destruction.
G. Apology And Disclosure After Acute Events
Patients should be apprised of the outcomes of tests or treatment. Whether the information involves positive outcomes or adverse events, patients should receive a clear description of findings or untoward occurrences. This concept is part of the “disclosure” process that is seen as an important way to enhance patient care and trust.

Disclosure communication involving adverse outcomes should not be done in the belief that it will either cause litigation or prevent it. Rather, it is part of the ethics of clinical practice.

Disclosure communication is not a one-time event. It may be part of an ongoing dialogue with the patient or family, especially as more details come to light about the occurrence.

Disclosure communication is part of accreditation standards for many healthcare facilities. It is also found in state laws governing the practice of medicine. Some require such disclosures. Other laws make it voluntary for the care provider to disclose and discuss adverse outcomes with the patient or family. Many jurisdictions preclude the disclosure process from being used as evidence of negligence or an admission of fault or responsibility in a variety of legal proceedings.

A related issue is apology. Some state laws include apology for untoward outcomes as being protected from being used as an admission of negligence, fault, or responsibility. Others do not. Many care providers fear saying, “I am sorry” or “I apologize” to a patient or the patient’s family. They are concerned that such expressions may be admissions of liability. However, a sincere apology and honest disclosure may help avert a lawsuit. Indeed, a bad outcome involving a potential compensatory event may be resolved through service recovery or a pre-lawsuit settlement.

Disclosure and apology discussions can be quite difficult and emotionally challenging for the care provider who was involved in the occurrence. Sometimes it is better to have the practice leader manage the discussion and follow-up with further communication by the care provider. Counseling services may be
indicated to help the care provider in such cases who is sometimes described as the “second victim.”

It is important to document all disclosure and apology discussions. Legal counsel can advise on the best approach to documenting these communications.

**Risk Exposures:**
- Non-compliance with applicable state law on disclosure.
- Ineffective disclosure communications increasing the risk of litigation.
- Failure to have disclosure communications serving as the basis for litigation.
- Failure to take care of the second victim, the care provider involved in the untoward outcome.

**Risk Management Strategies:**
There are several risk management communication approaches that have been developed to guide disclosure discussions. These resources can be found from a variety of sources. Some risk strategies include:
- Determining state law requirements on disclosure and apology, using this information to develop a practice policy on the subject.
- Hold the initial conversation with the patient and family as soon as possible, recognizing at this stage that the only information available will be focused on the outcome.
- Determine if the patient or family have specific needs, such as transportation, lodging, baby-sitting, etc.
- Set a reasonable expectation regarding when further information will become available.
- Provide follow-up factual information as it becomes available whether through in-person meetings or through telephone conversations.
- Document all disclosure communication, including the names of those present, the date and time, a summary of the information provided, questions posed and answers provided. Also note if the meeting was in person or by telephone.
- Practice what to say prior the disclosure communication.
- Do not read from a script in the course of the disclosure communication.
- Recognize that there may be times when the care provider who was involved in the untoward event should not participate in the disclosure process. Consider in such situations asking the practice leader to conduct
the discussion, noting that at a later stage the care provider will be
speaking with the patient or family.

- Make certain that language interpreters are used for those who need such
  services.
- Ask a practice staff member to take notes.
- Develop a “next steps” list with the patient and family and follow-up on it.
- Be poised to consult legal counsel when there is a demand for payments.
- Notify professional liability insurers when there the untoward outcome
  involves a potential compensatory event or there is a threat of litigation.
- Provide appropriate services for the care provider who is the second
  victim of the event.

**Case Example:**

A 41-year-old patient saw a new member of the family practice for what he
thought was a nagging head cold and sore throat. The doctor took a few
samples from his desk and gave the medication to the patient. “This will get you
started. Just be certain to use up the complete prescription. I will send it to the
pharmacy electronically. The store will be closing soon. You can pick it up
tomorrow. I have given you enough for this evening and tomorrow morning,
said. The patient thanked him and left the office. The doctor noted in the
electronic record that he had given the patient samples as a starter and
electronically sent the antibiotic prescription to the pharmacy.

The patient went home and took the first dose of the medication. Within a half-
hour he left terrible. His throat, ears and nose felt itchy. He developed welts on
his torso. Then he felt as if he could not catch his breath. He asked his wife to
call 911. Just before he lost consciousness he said to his wife, “I think there is
something wrong with the medication.” At the hospital, the man suffered a
cardiac arrest. Although he was resuscitated, he suffered permanent brain
damage. An intensivist at the hospital asked the patient’s wife if her husband
had any drug allergies. “Yes. He is terribly allergic to any drugs that contain
aspirin, sulfur, and penicillin. Why are you asking?” she said. The intensivist
replied, “That medication your husband took contained one of the ingredients to
which he is allergic. I think your husband was correct. It was the medicine that
caused the reaction.”

The patient’s wife called the office manager early the next morning. Shouting
she said, “Who is this doctor you hired? Do you know he almost killed my
husband? He is in the hospital ICU. He had a cardiac arrest from a drug-
induced allergic reaction. They say he is may have experienced some brain damage.” Then the patient’s wife hung up the phone.

The practice manager contacted the practice leader and recounted what she had heard from the wife. “Yes, and I just got a call from the intensivist. Not a good situation. Where is the new doctor? Get him to my office ASAP. Initiate the e-hold on the patient record and notify our insurer.”

The practice leader had a candid discussion with the new family physician. He learned that the young care provider was regularly dispensing medication samples even though the practice had a written policy prohibiting it. “We have had for 18 months a written policy banning dispensing of medication samples. We do not accept samples from pharmaceutical representatives. We do not have a medication samples cabinet. Too much of a hassle,” said the practice leader.

The care provider seemed unmoved. “Do you realize what happened to the patient?” asked the practice leader. He informed him about the reaction and the cardiac arrest. The care provider said, “Gee that is too bad. I was only trying to help get him started on his medication.”

The practice leader was furious. He learned that the care provider had not checked the sample against the patient’s allergy list in his electronic medical record. “You actually dispensed a sample drug without finding out if it might be contraindicated because of known allergies? What were you thinking, doctor? You are suspended from seeing other patients. Meantime, I will personally handle the disclosure session with the patient and his wife,” said the practice leader.

Later that morning, the practice leader went to the hospital and met with the patient’s wife. He explained that he was the practice leader and that he was very sorry that the woman’s husband had experienced such a serious outcome. He shared with her that thus far he had learned that the family physician had given her husband medication the night before to treat his respiratory condition. We are going to do a thorough review of what happened. I understand that you have been told that the medication contained an ingredient to which there was a known allergy. It would be helpful for me to know if your husband took any other medication or over-the-counter preparations that may have helped to trigger the reaction. We will explore that possibility, but for now, I want you to know that my colleagues and I are very sorry about this outcome. Your husband
is getting great care from a good team her at the hospital. Is there anything that you need? Transportation? Do you want me to help you notify family members? Please just let me know. Here is my direct-dial telephone number. Do not hesitate to call me night or day. I would like to meet with you tomorrow and keep you updated about what I find out as I continue my investigation. Is that acceptable? What is a good time for us to meet?” he asked. The patient’s wife burst into tears and said, “Thank you doctor. I can tell you are upset too. I just want him to get better. Yes, I could use some help. We have two kids who need transportation after school. Can you get me some assistance?” The doctor told her would do so.

A month later, following regular meetings with the patient’s wife and completion of the internal investigation, the practice leader met with the patient and his wife. He shared with them what had been learned. He told them that there was a rule in the practice prohibiting doctors from giving patients drug samples. The new family practitioner did not follow it. Also, he had learned that the family doctor had not checked the patient’s allergy list. “I regret that you have gone through this terrible situation. I apologize,” he said.

The patient made a remarkable recovery. He experienced some residual challenges. Following rehabilitation, he was able to return to employment. A pre-litigation settlement was reached with the family. And, the couple asked the practice leader if he would be willing to be their family physician. The doctor smiled and said, “Yes. But I ask one thing of you: please get a medallion or bracelet that alerts anyone who takes care of you that you have these severe drug allergies.” The patient agreed.

The family doctor who dispensed the sample drug left the practice. He was reported to the state medical board by the practice leader.

**Applying Risk Management Strategies:**

- Develop a disclosure and apology protocol for the physician office practice, making certain that it is consistent with applicable state law.
- Provide prompt notice to the professional liability insurance carrier regarding serious untoward events that are likely to be potentially compensable.
- Provide education on how to manage a disclosure and apology process.
- Meet with the patient and family as soon as possible to provide factual information, acknowledging that after there is a complete evaluation, further information will be provided to them.
- Do not speculate about what gave rise to the adverse event.
- Find out if the patient or family has any immediate needs. Maintain an open line of communication with them.
- Be empathetic and sincere.
- When the evaluation is concluded, meet with the patient or family and let them know what was determined, recognizing that it may not be possible in all cases to find out why there was an untoward or adverse outcome.
- Follow guidance from legal counsel on the way in which to document disclosure communication with the patient or family.
IX. Emerging Issues for Physician Practices: Office-Based Interventional and Surgical Procedures

A number of medical practices have decided to offer patients interventional and surgical procedures in the office setting. For these practices, the potential revenue and control of scheduling is an attractive option. For patients, it is an equally attractive alternative, especially for those who loathe the prospect of procedures offered in day-surgery units of hospitals or ambulatory surgery centers.

There are a number of risk management considerations that enter into the decision to offer interventional or surgical procedures in the office setting. The following is a list of some important risk management questions to address before moving forward with such services:

**Regulations**
- Are there state regulations that must be met to offer office-based interventional or surgical procedures?
- Does state law require office-based surgery practices to be accredited? If so, has the practice achieved accreditation for this purpose?
- Does the office and equipment meet regulatory standards?

**Environment of Care**
- Does the practice have the appropriate equipment to offer interventional or surgical procedures?
- Does the practice have the right electrical supply to support interventional or surgical procedures?
- Will equipment accommodate obese or immobile patients who require interventional or surgical procedures?
- Is there fire suppression equipment in place for intraoperative fires?
- Does the interventional, surgical or recovery area have ready access to fully stocked crash carts, AEDs, and other resuscitation tools and medication?
Staffing

- Does the practice have qualified and trained personnel to offer interventional or surgical procedures?
- Will staff have to be contracted to provide interventional or surgical procedures, including:
  - Anesthesia
  - First assistants
  - Recovery nurses
- Will staff be asked to exceed recognized scope of practice?
- Will those participating in the interventional or surgical procedure complete team orientation and training before offering interventional or surgical procedures in the office setting?

Patient selection criteria

- Are there clinical criteria to determine which patients should be excluded from office-based interventional or surgical procedures?
- Will all patients undergo a pre-operative work-up?
- Will all patients undergo an anesthesia work-up?
- Is there a “rule out” protocol for the day of the procedure due to change in medical condition?

Consent

- Is there a consent policy and procedure for interventional and surgical procedures to be offered in the office?
- Will the patient sign a consent form for interventional or surgical procedures completed in the office?
- Will the consent process and document indicate that there are alternatives to having the interventional or surgical procedure completed in the office?

Legal Considerations

- Does the practice’s lease permit interventional or surgical procedures in the office space?
- Do zoning laws permit interventional or surgical procedures in the office building?
- Has legal counsel developed appropriate agreements for contracted services?
- Has legal counsel developed appropriate agreements for leased equipment?
Has legal counsel developed appropriate agreements with contracted cleaning services consistent with recognized infection prevention standards for equipment and the interventional or surgical suite?

Has the practice confirmed which health insurers will cover interventional or surgical procedures completed in the office practice?

Has legal counsel developed an appropriate transfer agreement with a properly equipped emergency medical transport service?

**Insurance**

Has the practice consulted with an agent or broker regarding insurance needs for the interventional or surgical program?

Does existing professional liability coverage include interventional or surgical procedures completed in the office setting?

**Patient Safety**

Is there a process to postpone the intervention or surgical procedure due to inclement weather or unsafe road conditions? If so, who will notify scheduled patients and personnel?

Does the interventional or surgical procedure set include a time out protocol?

Does the interventional or surgical protocol meet recognized patient standards such as those of the National Quality Forum or any of the major ambulatory accreditation programs?

Does the interventional or surgical anesthesia plan include immediate access to a malignant hyperthermia kit?

Are anesthesia providers and post-operative recovery staff trained to recognize and respond to malignant hyperthermia in the office setting?

Are interventional, surgical and recovery staff qualified to perform cardiopulmonary resuscitation or to respond to intra-procedure and post-procedure emergencies?

Does the interventional or surgical suite meet infection prevention standards?

Has staff been trained to comply with recognized infection prevention standards appropriate for an interventional or surgical suite in the office setting?
**Discharge Planning**
- Do all patients have a responsible person available to drive them home and assist them post-procedure?
- Have post-procedure medications and supplies been ordered, delivered or picked up prior to the interventional or surgical event?
- Are patients and an accompanying responsible person (with the patient’s permission) oriented to post-procedure care, ambulation and nutrition instructions?
- Are patients provided with instructions regarding side effects or complications that require care in a hospital emergency department?
- Are patients provided with follow-up appointments?
- Are patients given a telephone number to call with post-procedure questions? Is it made clear when telephone inquiries will be answered?
- Is there a post-procedure follow-up wellness call? If so, who completes it and when?

**Documentation**
- Is there are plan for documenting pre- and post-procedure clinical information?
- What type of information will be included in the procedure clinical record?
- How long will the documentation be retained?
- Is there written permission from the patient to share the information with other care providers?
- Is there written permission from the patient to photograph or videotape the procedure? Does it delineate uses for the photograph or videotape?