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Risk Management Strategies for the Outpatient Setting

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Clinical and Patient Safety Risks

Contents

Creating and maintaining a culture of patient safety can be challenging and should be a high priority for healthcare organizations. Leadership, clinical and nonclinical staff, providers, patients and visitors have a role in patient safety. Key responsibilities include patient identification, handoff communication, infection control, medication management, test results management, medical device safety as well as responding to clinical emergencies.

Patient Identification

Identifying the correct patient for the correct medication, procedure/treatment represents the first step in all patient safety measures. Avoiding misidentification is more critical in the electronic healthcare environment due to the multitude of linked internal and external databases such as laboratory, radiology and health information networks. Patient misidentification and associated incorrect documentation in the patient healthcare information record or other linked systems may have a cascade effect that can be difficult to overcome. Studies have demonstrated that patient misidentification occurs in all healthcare settings. These errors cost healthcare providers and facilities millions of dollars annually in professional malpractice claims and denied insurance claims.

Because correct patient identification is integral to patient safety, outpatient healthcare facilities should establish acceptable and reliable patient identifiers which match the correct service(s) or treatment(s) with the correct person. A patient identifier is "information directly associated with an individual that reliably identifies the individual as the person for whom the service or treatment is intended." To prevent instances of misidentification and near-misses, two identifiers must be standardized within each healthcare setting, and used by all staff at every patient encounter. The patient and/or the patient's representative should be actively engaged in the identification process. The following do's and don'ts may be used to define appropriate and inappropriate identifiers:

Do	Don't
Verify patient's full name	Use a patient's room number
Confirm patient's date of birth	Assume a patient is the individual whom you think
Use medical identification (ID) number	Select a patient's name from a list of names
Verify patient's telephone numbers	State the patient's name rather than asking the patient to state their name
Use patient's Social Security number	Rely on the patient to correct staff if the patient is called the incorrect name.
Review patient's photo Identification	Match a patient with a diagnosis/procedure

Patient Identification Resources

- **The Joint Commission (TJC).** While an outpatient organization may not be accredited, the TJC offers examples of what would or would not be acceptable patient identifiers.

- **Through the ECRI Institute,** the Partnership for Health IT Patient Safety was established to support the ongoing work on patient identification in order to gain a better understanding of the problems and prevalence of patient identification errors in clinical settings.

- **Patient Safety Network.** Patient Identification Errors: A Systems Challenge.

Hand-off Communication

Communication and teamwork are critical elements of patient safety. Ineffective communication, both with patients and other members of the healthcare team, has been linked to medical errors, patient harm and professional liability claims.

Miscommunications between providers during transitions of care (i.e. hand-offs) create special risks, as gaps or omissions in the transfer of vital clinical information may result in potential delays in diagnosis, misdiagnosis, or treatment errors. Time constraints, lack of standardized processes, distractions and interruptions are among the contributing factors that can lead to communication breakdowns. Effective provider-patient communication processes are also important in ensuring safe and effective transfers of clinical information. Providers and staff should be cognizant of their communication style with patients and engage in active listening while patients present their health concerns.

Potential areas of risk specific to the outpatient healthcare setting include, but are not limited to, lapses in reporting test results or treatment plans to patients, omissions of critical information in handoffs involving on-call coverage, and incomplete exchange of clinical information from the outpatient setting through hospital admissions and discharges. Specialty-specific risks, for example, include hand-offs between radiologists and ordering physicians, hand-offs from hospitalists to primary care providers and communications involving referrals to specialists.

Implementing the following patient safety strategies, among other actions, may help to improve communication among providers and reduce patient harm:

- **Develop a standardized process** that can be leveraged for acute care transfers, referrals and on-call coverage purposes. Face-to-face communication is preferable, as it provides the opportunity for the sender and receiver to ask clarifying questions and to discuss potential issues. Alternatively, if a face-to-face meeting is not possible, consider video conferencing or a telephonic exchange and ask for critical information to be read back.

- **Consider using evidence-based communication tools** such as SBAR (**S**ituation, **B**ackground, **A**ssessment, and **R**ecommendation) and I-PASS (**I**llness severity, **P**atient summary, **A**ction list, **S**ituation awareness and contingency planning, **S**ynthesis by receiver).

- **Conduct handoff discussions between providers** in an environment that is free of distractions, and ensure that the following information is addressed:

  - Provider contact information.
  - Details regarding the patient's condition, including anticipated complications.
  - Severity of condition and urgency regarding plan of care.
  - Contingency plan and timeframes.
  - Allergies and current medications.
  - Significant and pending diagnostic laboratory and imaging results.
  - Opportunity for clarifying questions.

- **Engage patients and families in handoff discussions between office staff and providers.** In addition to keeping patients informed, this process also promotes effective communication between providers during office visits.

- **Encourage patients to write down their questions/concerns** prior to the office visit.

- **Use templates, lists or the electronic medical record in order to readily access key data** such as medications, allergies, history of present illness and laboratory and imaging results during handoff discussions.

- **Provide ongoing education for providers and staff.** Conduct role-playing sessions to identify opportunities for improving communications with patients and other members of the healthcare team.

Creating an awareness of the importance of effective communication during office visits, procedures and transitions of care will help to enhance patient safety in all healthcare settings.

Responding to Emergency Medical Situations

Emergency medical situations can involve patients, staff or visitors. If a medical emergency occurs, appropriate responses may range from calling 911 to performing CPR to attempting more complex medical interventions, depending upon staff competencies and the setting. The following steps can enable staff to respond more effectively to a medical emergency:

- **Encourage staff to achieve and maintain certification in CPR,** and permit any certified staff member to initiate CPR, if indicated.

- **Instruct staff members to contact a provider in the office immediately if they believe a medical emergency is occurring,** implement the internal emergency process, call 911 as directed and remain on the scene until emergency personnel arrive.

- **Inspect the automated external defibrillators (AEDs) and/or emergency crash cart on a daily basis** and maintain inspection logs, if applicable.

- **Provide, and document, training for staff** who are responsible for the use of emergency equipment and medications.

- **Retain inspection and preventive maintenance records** for all emergency equipment.

- **Conduct emergency drills on a routine basis.** These drills include situations such as cardiac arrest, anaphylaxis, choking and falls.

Ambulatory Surgery and Office-Based Procedures/Surgery

The expansion in the number and type of surgical services being performed in the outpatient setting has resulted in an increase in exposures. Each state defines office-based surgeries and procedures differently.

Ambulatory and office-based procedures/surgeries may require moderate or deep sedation. The Federation of State Medical Boards provides a link to each state's statutes, regulations and policies for ambulatory and office-based surgeries. Leaders and providers of an outpatient facility must understand and comply with governing state requirements. The American College of Surgeons (ACS) provides ten core principles of patient safety that providers may utilize when considering whether to offer procedures and/or surgeries in an office or ambulatory surgery setting.

Implementing and utilizing a comprehensive checklist may be an effective tool to reduce patient safety risks associated with ambulatory surgeries and office-based procedures. The Association of periOperative Registered Nurses (AORN), and the World Health Organization (WHO) provide checklists that can be customized to meet a facility's needs. These checklists may be designed for use in all types of settings and offer guidance for pre-procedure/pre-surgical check in, sign in, time out, sign out and discharge. During each stage of the procedure/surgical process, clinical staff should always use open-ended questions to encourage active participation from all members of the surgical team. In addition to the suggested items on the checklists referenced above, the following items are required:

- **A formal pre-procedure/pre-surgical check-in process in the pre-operative area.** This interactive process between clinical staff and the patient and/or patient's representative includes the verification of the patient's identity, confirmation of the procedure/surgery, as well as the provider who will perform the procedure/surgery. During this process, a clinical staff member confirms the presence of a recent history and physical, pre-anesthesia and nursing assessment and relevant diagnostic and radiologic test results.

- **A formal sign-in process on the day of the procedure/surgery.** The sign-in process is performed prior to administering anesthesia or medications which can alter a patient's cognitive abilities. As with the pre-procedure/pre-surgical process, the sign-in process is an interactive process between clinical staff and/or the patient or patient's representative. During this process, the clinical staff and, as appropriate, a representative from anesthesia confirm the procedure/surgery being performed and verify the surgical site(s), any medication or latex allergies and acknowledge the completion of the informed consent process. At this time, the surgical site is marked by the provider performing the procedure/surgery.

- **A formal time-out process is performed prior to skin incision.** This is a crucial patient safety step and all other activities should be suspended during the time-out process so that every person involved with the procedure/surgery can participate. Verbal confirmation of the patient's identity, procedure, incision site and completed consent(s) is performed with active team participation.

- **A formal sign-out process is performed prior to the patient leaving the operating/procedure room.** This process includes the completion of sponge, sharp and instrument counts, as well as the identification and labeling of any specimens.

Before a patient can be safely admitted to the post-anesthesia care unit (PACU), a formal hand-off communication should be performed by the operating room or anesthesia staff with the PACU staff.

While in the post-anesthesia recovery stage following a procedure/surgery, a patient is closely monitored to ensure hemodynamic stability and manageable pain level. A formal discharge process should be established and closely followed to assure a safe post-procedure/post-surgical discharge. The American Society of Anesthesiology and Surgery provides standards and practice parameters for the safe provision of anesthesia and sedation in an ambulatory or office based setting.

Resources

- **The AORN Comprehensive Surgical Checklist** can be downloaded and customized to meet a facility's needs. The checklist includes key safety checks as outlined in the World Health Organization (WHO) Surgical Safety Checklist and The Joint Commission.

- **The WHO safer surgery checklist time out procedure revisited: Strategies to optimize compliance and safety**

- **Agency for Healthcare Research and Quality (AHRQ).** The Inside of a Time Out

- **American College of Surgeons (ACS)** revised Statement on Safe Surgery Checklists, and Ensuring Correct Patient, Correct Site, and Correct Procedure Surgery

- **AHRQ.** Wrong-Site, Wrong-Procedure, and Wrong-Patient Surgery

- **Anesthesia Key.** What criteria should be used for discharge after outpatient surgery.

Transfer and Emergency Response

Healthcare facilities that perform outpatient procedures and/or surgeries are at higher risk for adverse events and emergencies. Therefore, staff should be capable of managing all adverse events or emergencies that may occur during or following a procedure or surgery. Such activities include providing emergency care and safe patient transfer. Implement the following safeguards to assist staff in responding to medical emergencies or complications:

• **At least one licensed healthcare provider who is currently certified in advanced resuscitative techniques,** as appropriate for the patient age group (e.g., Advanced Cardiovascular Life Support [ACLS], Pediatric Advanced Life Support [PALS] or Advanced Pediatric Life Support [APLS]), is present, or immediately available, until the patient has been stabilized and met the criteria for discharge or transfer. Age and size appropriate resuscitative equipment should be available throughout the procedure and recovery.

• **All office staff are conversant with the transfer policy** to ensure safe and timely patient transfers to an appropriate higher level of care.

• **A plan that includes:**

  • A proven accessible route for stretcher transport of the patient out of the outpatient setting;

  • Arrangements for emergency medical services and appropriate escort of the patient to the hospital;

  • A policy requiring that resuscitative equipment be evaluated for functionality according to state and manufacturer requirements and recommendations. Records of such evaluations should be maintained by the facility as governed by state record retention requirements; and

  • Where required, a compliance process to notify the regulatory or state regulatory agency of an adverse event as specified.

AHRQ has developed a national standard for team training called _TeamSTEPPS®_, Team Strategies and Tools to Enhance Performance and Patient Safety. This evidence-based program focuses on communication, leadership, situational awareness and teamwork. This team training can represent a useful tool to prepare staff to effectively and efficiently respond to emergencies and strengthen hand-off communication during patient transfer.

Infection Control and Prevention

Transmission of viral and bacterial pathogens is an ever-present safety threat, especially in a healthcare environment. Infection prevention also represents a regulatory issue that is monitored by various governing bodies. Federal and state governing bodies, such as the Occupational Safety and Health Administration (OSHA), may conduct an inspection of an outpatient facility without advance notice. Outpatient facilities should always be prepared for an unannounced or for-cause inspection. Preparation includes current policies and procedures, staff education and training.

Outpatient practice settings should develop an infection prevention plan that is written clearly, updated annually and created with staff input. All staff should have access to review the plan during orientation, annually and as needed thereafter. In addition, staff members should receive ongoing education about how infections are transmitted and what they can do to prevent the spread.

The information that follows is excerpted from the website of the Centers for Disease Control and Prevention (CDC).

Modes of Transmission

Knowing and understanding the modes of transmission of infectious agents is a vital part of an infection prevention and control program. Some infectious agents spread via multiple routes, and not all infectious agents are transmitted from person to person. The most common modes of transmission in a healthcare setting include:

• Direct contact (e.g., contaminated hands, equipment or high touch surfaces).

• Droplets and Airborne (e.g., cough, sneeze, droplets generated from talking).

• Bloodborne (e.g., needlestick, contact of a mucous membrane or non-intact skin with blood, tissue or other bodily fluids).

Standard Precautions

Standard Precautions reflect the minimum infection prevention practices in any setting where healthcare is delivered and apply to all patient care, regardless of suspected or confirmed infection status of the patient. These practices are designed to both protect healthcare providers and prevent them from spreading infections among patients. Standard Precautions include:

• Hand hygiene.

• Personal protective equipment (e.g., gloves, gowns, masks).

• Safe injection practices.

• Safe handling of potentially contaminated equipment or surfaces in the patient environment.

• Respiratory hygiene/cough etiquette.

Hand Hygiene

Good hand hygiene, including the use of an alcohol-based hand rub (ABHR) and washing hands with soap and water, is critical to reducing the spread of infections in ambulatory care settings. The use of an ABHR as the primary mode of hand hygiene in healthcare settings is recommended by the CDC and the World Health Organization because of its effectiveness against a broad spectrum of epidemiologically important pathogens. In addition, compared with soap and water, the use of ABHR in healthcare settings can enhance infection control by permitting hand hygiene, while reducing both time required and skin irritation. However, soap and water should be used whenever hands are visibly soiled or after caring for patients with known or suspected infectious diarrhea.

Hand hygiene should be performed:

• **Before touching a patient,** even if gloves will be worn.

• **Before exiting the care area** and after touching the patient or anything in the patient's immediate environment.

• **After contact with blood,** wound dressings, or bodily fluids or excretions.

• **Prior to performing an aseptic task,** such as placing an IV or preparing an injection.

• **During patient care if hands will be moving from a contaminated-body site to a clean-body site.**

• **After glove removal,** once gloves have been disposed of.

Complete guidance on how and when hand hygiene should be performed, including recommendations regarding surgical hand antisepsis and artificial nails, can be found in the <u>"Guideline for Hand Hygiene in Healthcare Settings."</u>

Environmental Infection Control

Healthcare facilities and provider practices should establish policies and procedures for routine cleaning and disinfection of environmental surfaces as part of the infection prevention plan. The focus should be placed on those surfaces in proximity to the patient and those that are frequently touched.

For best results, select EPA-registered disinfectants or detergents/disinfectants labeled for use in healthcare. Follow manufacturer's recommendations regarding the amount, dilution, contact time, safe use and disposal of such products.

Respiratory Hygiene/Cough Etiquette

Respiratory hygiene/cough etiquette represents an important element of standard precautions. It must be implemented throughout the organization, and especially at patients' and visitors' first point of contact within the organization. These measures apply to patients and visitors who enter the outpatient setting with a cough, congestion, rhinorrhea, increased production of respiratory secretions or other signs of illness.

The effort to contain potentially infectious respiratory secretions should begin upon entering the facility and continue throughout the duration of the visit. Strategies include:

• **Offering masks to coughing and otherwise symptomatic persons** upon entry to the facility.

• **Posting signs at entrances with instructions to anyone with symptoms of respiratory infection to follow basic hygienic practices,** including covering their mouths/noses when coughing or sneezing and using and properly disposing of tissues.

• **Performing hand hygiene** after hands have been in contact with respiratory secretions.

• **Providing tissues** and no-touch receptacles for their disposal.

• **Encouraging persons with symptoms of respiratory infections to sit as far from others as possible** or in a separate waiting area, if one is available.

• **Educating staff on the importance of containing the respiratory secretions of patients** who have signs and symptoms of a respiratory infection.

Bloodborne Pathogens

Bloodborne pathogens include any microorganism that may be transmitted by contact with the blood or bodily fluids of an infected individual. Common pathogens of major concern are human immunodeficiency virus (HIV) as well as the Hepatitis B (HBV) and C (HBC) viruses.

OSHA issued the <u>Bloodborne Pathogens Standard</u> to protect workers (29 CFR 1910.1030), which includes the federal <u>Needlestick Safety and Prevention Act</u>. This protection applies to all employers of one or more employees with occupational exposure (e.g., reasonably anticipated skin, eye, mucous membrane or parenteral contact with blood or other potentially infectious materials resulting from the performance of the employee's duties).The standard requires employers, including outpatient healthcare organizations, to select safer needle devices and to involve employees in identifying and selecting these devices.

The Bloodborne Pathogens Standard requires employers to develop a written exposure control plan for employees whose duties may result in contact with blood, bodily fluids or other potentially infectious substances. The standard includes the following requirements, among others:

- **Adopting engineering and work practice controls** and using appropriate personal protective equipment.

- **Drafting a written exposure control plan,** to be updated annually.

- **Implementing universal precautions** to prevent infection.

- **Maintaining a log of employee injuries** from contaminated sharps.

- **Offering medical follow-up** after a potential exposure.

- **Properly containing and disposing of all regulated waste** to minimize contamination.

- **Providing Hepatitis B vaccine** to exposed employees at no cost.

- **Selecting safer, better-engineered needles and sharps** and using them whenever possible.

- **Training employees on an ongoing basis** in established safety practices.

- **Labeling or color-coding sharps disposal boxes** and containers designed to hold regulated waste, contaminated laundry and certain specimens.

General needlestick precautions include using safety products that do not require recapping, removing, breaking or otherwise manipulating needles by hand. Sharps should be disposed of in containers that are closable, leak-proof, puncture-resistant, and properly labeled and/or color-coded. In addition, single-use sharps products should never be reused.

Staff response to needlestick and splash exposures should be prompt, thorough and consistent. Key measures include first aid, baseline serology and thorough incident documentation. It is also necessary to obtain patient consent to test for bloodborne pathogens.

Personal Protective Equipment

Proper use of gloves, masks, gowns, face shields and protective eyewear can reduce transmission of a variety of infectious pathogens in the outpatient setting. OSHA requires employers to determine if personal protective equipment (PPE) is necessary to protect workers from exposure to hazards and, if so, to mandate the use of PPE.

Gloving should be required whenever there is a reasonable chance of contact with blood, bodily fluids, secretions or excretions, or with any items contaminated by these fluids. The employer should ensure that gloves in the appropriate sizes are issued to employees or are readily accessible at the worksite.

Hypoallergenic gloves, glove liners, powderless gloves or similar alternatives should be readily accessible to employees who are allergic to conventional gloves. Providers and staff should be reminded to wear gloves when touching contaminated objects, but not to touch items such as doorknobs, telephones, equipment, computer terminals or keyboards with soiled gloved hands.

Gowns or plastic aprons are necessary whenever staff clothing is vulnerable to soiling by secretions, excretions, blood or bodily fluids.

Sterilization

In general, equipment that contacts mucous membranes requires high level disinfection, whereas instruments that penetrate skin or mucosal membranes must be sterilized. The effectiveness of disinfection depends upon the type and concentration of disinfectant, elapsed contact time and microbial resistance. Document sterility and store all sterilized or disinfected equipment where it will not become contaminated. Follow the manufacturer's instructions, as well as established guidelines of professional organizations, when using reprocessed medical instruments or equipment.

Waste Management

Medical waste may include dressings, needles, sharps and bodily fluid samples. Written policies should define infectious waste and establish safe procedures for separating, labeling, storing and transporting. Staff should be trained to handle potentially dangerous waste, manage spills and respond to inadvertent exposures in compliance with federal OSHA standards, as well as state and local regulations.

Employee Health

Do not permit staff members who are coughing or sneezing, or have lesions, weeping dermatitis or open sores, to have direct contact with patients or handle patient care equipment until their condition improves.

In addition, create an employee health program to track and document vaccinations and tuberculin skin testing, as well as to manage any staff-acquired communicable diseases. The program should include accurate and up-to-date health records for each employee, which are maintained separately from the personnel file. These employee health records should be retained during the employment period and afterward for the period required by state statute(s).

Resources

- Centers for Disease Control (CDC).
- Accreditation Association for Ambulatory Health Care (AAAHC).
- Quad A - American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF).
- Association for Professionals in Infection Control and Epidemiology, Inc (APIC).
- The Joint Commission.
- National Institute for Occupational Safety and Health (NIOSH).
- Occupational Safety and Health Administration (OSHA).
- World Health Organization (WHO).

Medication Management

The process of prescribing, dispensing and administering medications presents a high level of potential risk in every type of healthcare setting. Medication-related errors in the outpatient setting may arise from a number of causes, including illegibility, transcription oversights, incorrectly prescribed medication or dosage, medication side effects and polypharmacy.

Establishing Safe Medication Procedures

To reduce risk, every outpatient setting should adopt a sound medication management policy and monitor staff compliance. The following guidelines may assist organizations in crafting and evaluating their medication management procedures:

- **Adopt a "zero tolerance" policy for illegibility.** Use electronic entry or print in block letters.

- **Delineate the medications that require laboratory monitoring** and use a system to alert staff when a laboratory test should be ordered.

- **Follow proper** vaccination administration protocols and provide comprehensive, competency-based training on vaccination administration.

- **Devise internal processes to monitor, track and correct medication errors,** and evaluate and update these processes on a routine basis.

- **Do not prescribe medications over the telephone for a new, non-recurring problem/complaint** without first examining the patient.

- **Ensure that documentation guidelines include indications for use of medications** and instructions given to the patient. Note and archive any patient information handouts.

- **Establish a medication list for every patient.** Lists should be reviewed and reconciled at each patient visit.

- **Implement a process for reviewing current medications** each time drugs are ordered, administered or dispensed.

- **Limit verbal orders to emergencies,** and ensure that all authorized prescribers or delegates sign or initial verbal orders within a prescribed timeframe.

- **Prohibit the use of abbreviations when documenting the name of a medication,** as well as dosage, route or frequency.

- **Provide a complete list of medications to subsequent providers**, such as consultants or specialists.

- **Permit providers to refill only those medications that they have originally prescribed.** All others should be refilled only after a visit.

- **Follow state and federal pharmacy regulations** when accepting and dispensing sample medications to patients.

- **Implement detailed policies and procedures** addressing screening for drug interactions, duplicate therapy, allergies, contraindications, storage, maintaining an inventory log, handling recalls, discarding expired medication with drug destruction log, and medication sample security.

Medication Alerts and Clinical Decision Support

In the computerized clinical environment, various types of clinical decision support systems are employed to generate alerts that can strengthen medication safety. Although automated alerts may represent an effective means to improve medication safety, consideration should be given to the potential impact of alert fatigue.

According to the Agency for Healthcare Research and Quality (AHRQ), the term "alert fatigue" describes how busy healthcare providers become desensitized to safety alerts. As a result, they may bypass, override, ignore or otherwise fail to respond appropriately to warnings, potentially leading to patient harm. Alert fatigue is caused by an excess of alerts and/or warnings in the clinical environment. This unintended consequence has become a significant hazard in many healthcare settings. Consider these steps to help address this safety issue (adapted from the AHRQ resource):

- **Reduce or eliminate clinically inconsequential alerts.** Removing/deleting insignificant alarms should be performed using a structured review process, restricting individuals from making such changes.

- **Tailor alerts to the outpatient setting and patient characteristics.**

- **Tier alerts according to severity.** Warnings may be presented in different forms, in order to direct providers to alerts that are more clinically consequential.

- **Apply human factors principles when designing alerts** – selecting the format, content, legibility and color of alerts.

- **Assess the clinical support system for clinically insignificant and false positive alerts,** and take action to minimize alert fatigue.

- **Review all system reports on alerts** to determine alerts that are overridden and the reasons for the overrides.

- **Require that providers document the rationale for overriding a serious alert,** such as exceeding a maximum dose, or a serious drug interaction.

High-Alert Medication Management

Although alert fatigue is a concern, certain "high-alert medications" require special attention due to their heightened risk of causing significant patient harm. Providers may access a listing for "High-Alert Medications in Community/Ambulatory Settings" on the Institute for Safe Medication Practices website for further information. High-alert medication lists are also available for acute and long-term care settings.

Awareness is helpful, but implementation of risk management strategies is necessary to address the risks associated with high-alert medications. Many strategies apply to the pharmacy and pharmacists, if these services are provided in the outpatient organization. These strategies include the following, among others:

- **Have easy access to updated medication information,** and check these sources whenever a question arises.

- **Use a secondary labeling system for high-alert medications,** as well as automated alerts.

- **Standardize the process of ordering high-alert medications,** as well as storing, preparing and administering them.

- **Limit access to high-alert medications** to staff that are appropriately trained.

- **Implement verification redundancies,** such as manual independent and automated double-checks, as appropriate.

- **For additional pharmacy recommendations,** access ISMP's Medication Safety Self Assessment® for Community/ Ambulatory Pharmacy.

Prescription Management

The management of new and renewal prescription orders in healthcare settings is complex, especially when orders involve controlled substances. Electronic prescribing can streamline workflow, and strengthen medication safety when prescribing controlled substances. Centers for Medicare and Medicaid Services (CMS) requires electronic prescribing for controlled substances (EPCS) for all Schedule II, III, IV, and V controlled substances covered through Medicare Part D. In addition, regulatory action for compliance with EPCS is being taken at the state level. Further comments on EPCS appear later in the Medication Management section.

Outpatient facilities and providers must remain current on state e-prescribing requirements for all prescriptions. These general prescription safety guidelines should be followed:

- **Permit only designated staff members to call in prescriptions** to pharmacies.

- **Document all new prescriptions called in to pharmacies,** including the name of the pharmacy and the pharmacist who received the order.

- **Require that prescription orders be read back,** and document this step.

- **Retain a copy of faxed or emailed prescription orders** in the healthcare information record.

- **Perform medication reconciliation at every office visit.**

- **Keep prescription pads in a secured location** away from patients and staff.

- **Prohibit use of pre-signed and post-dated prescription forms,** which can lead to theft, abuse and/or licensing board actions.

- **Report any lost or stolen prescription pads** to local pharmacies, hospitals and the Drug Enforcement Agency.

Prescription Drug Monitoring Programs (PDMPs)

According to the Center for Disease Control and Prevention (CDC) website, a prescription drug monitoring program (PDMP) "is an electronic database that tracks controlled substance prescriptions, now available in all states and Puerto Rico. PDMPs can provide health authorities with timely information about prescribing and patient behaviors that contribute to the epidemic and facilitate a nimble and targeted response."

All providers should be aware of PDMPs and their importance in helping mitigate risks related to drug diversion and misuse of prescription drugs. Providers who prescribe controlled substances must understand and comply with applicable state and federal laws and regulations and also understand that such requirements may include registration and use of PDMPs. These requirements vary widely depending upon the state, provider type and professional scope of practice. Depending upon the state, requirements may be promulgated under various authorities, including state pharmacy regulations and professional practice acts.

Compiling factual information about the patient's complete controlled substance medication history will help providers to prescribe when appropriate, and to resist prescribing when it's not, notwithstanding patient pressure. PDMPs are an important tool in the battle against substance use disorders and prescription drug diversion that may alert providers to potentially lifesaving information and interventions. Providers may consult the PDMP Training and Technical Assistance Center for state PDMP program summaries and contact information, as well as a listing of educational opportunities and upcoming meetings and conventions. Providers should note that suspected fraudulent activity should be reported to the Drug Enforcement Administration (DEA) or local law enforcement.

Off-label Use of Medications

In the United States, medications are approved for market by the Food and Drug Administration (FDA) for specific approved indications. Regulatory requirements and the drug approval process provide a base of evidence to promote and support safe medication use.

Off-label use of medications refers to the use of approved drugs for unapproved indications. Prescribing providers may determine that a medication may be beneficial for conditions other than those approved by the FDA, based upon research results published in professional literature. For example, the use of tricyclic antidepressants, approved for depression, may be used on an off-label basis to treat neuropathic pain.

Although a common and often beneficial practice, off-label use can present certain risks to patients, providers and facilities. Negative patient outcomes may result in professional liability claims against providers and/or facilities alleging negligence, failure to obtain informed consent, and imprudent off-label prescribing.

Off-label use of FDA-approved medications and devices is an ethically and legally accepted practice. However, the attendant risks must be understood and carefully managed. Providers should proceed with caution and due diligence to mitigate the risk of professional liability malpractice allegations. Prescribers should consider the following actions, among others:

- **Review, understand and comply with requirements and/or professional guidelines for off-label medication use** that are promulgated by state licensing boards and/or professional organizations associated with the provider's scope of practice.

- **Ensure that off-label uses are supported by reputable peer-reviewed literature** and reflect the recommendations of national drug compendia, guidelines of professional organizations and industry consensus statements, where available.

- **Critically review the evidence supporting the proposed off-label use.** Consider the type of studies, their validity and bias, according to accepted evidence-based medicine methods.

- **Understand the medication's pharmacology,** adverse effect profile and existing contraindications in detail, according to the approved labeling.

- **Consider the potential benefits for the individual patient.** Evaluate medications with approved indications for the patient's condition and why there is a need to deviate from that course of action.

- **If you proceed, discuss the findings with the patient and obtain the patient's informed consent.** Disclose that the use is "off-label" and that risks may be unknown. Inform the patient of the benefits and risks versus "on-label" treatment options, if any.

- **Comprehensively document the process,** including your risk assessment, the clinical rationale and the informed consent process.

While the details are beyond the scope of this manual, providers also should understand how off-label, investigative and emergency medication uses differ. The following resources provide additional information related to these three topics.

- CNA InBrief, Off-label Product Use: Basic Risk Management Considerations

- FDA guidance, Off-Label' and Investigational Use of Marketed Drugs, Biologics, and Medical Devices

- FDA information sheet, Emergency Use of an Investigational Drug or Biologic

Medication Storage and Disposal

- **Adhere to applicable state and federal regulatory standards** for ordering, storing, dispensing and discarding controlled substances and other medications.

- **Follow proper vaccination storage and handling practices** to ensure effectiveness.

- **Avoid possible drug diversion by performing a weekly reconciliation of stock medications,** i.e., comparing drugs dispensed to patients against remaining stock.

- **Minimize use of multi-dose vials.** According to the CDC, multi-dose vials should be dedicated to a single patient whenever possible. If multi-dose vials must be used for more than one patient, they should not be kept or accessed in the immediate patient treatment area, as this could lead to contamination and infection of subsequent patients. If a multi-dose vial is brought near the patient treatment area, it should be dedicated to that patient alone and discarded after use.

- **Limit access to medications** to appropriate staff members.

- **Monitor expiration dates of medications** and use a reverse distribution system to dispose of expired or otherwise unwanted drugs.

- **Reconcile the inventory of controlled substances every day,** and include the signatures of two licensed professionals who performed the task. All administered and discarded doses should be accounted for in writing.

- **Store only necessary pharmaceuticals,** keeping them in a locked cabinet away from patient and staff access. Controlled substances should be double-locked.

- **Dispose of expired medications safely.** Disposing of drugs via the wastewater system (e.g., sink or toilet) is discouraged, as such disposal may have adverse environmental consequences. Comply with all state/local directives for safe medication disposal.

- **Exercise care when discarding any portion of a controlled substance.** The disposal should be witnessed by two staff members who then sign off on the process. Comply with federal and state requirements for disposal of controlled substances.

- **Outpatient facilities may wish to consider engaging a vendor that provides** medication disposal services that comply with regulatory guidance.

Medication Administration and Documentation

- **Consider prohibiting administration of certain categories of medications** (e.g., allergy injections) when an appropriate provider is not on the premises.

- **Advise patients to remain at the facility for a specified time after the administration of any medication,** in the event of an adverse reaction.

- **Encourage staff members to question medication orders that appear incomplete,** confusing or illegible.

- **Permit only qualified employees to administer medications,** based upon statutory requirements for licensing, training and/or clinical experience.

- **If non-pharmacist providers dispense medications, they must understand and comply with state requirements,** which may be equivalent to those required of a pharmacy/pharmacist. This includes the dispensing of sample medications.

- **Store sample medications safely and securely,** following all applicable state and federal regulations.

- **Enter all dispensed samples into a dispensing log** to facilitate patient notification in the event of a drug recall. The log should include patient name, authorizing provider name, drug name, dose, lot number and date dispensed. Access further information, recommendations and a checklist on drug and device recalls in CNA's InBrief article, Device and Drug Recalls: Enhancing Preparedness, Reducing Risk.

- **Maintain current drug reference materials in the office** for use by staff and providers.

- **Implement a documented annual medication proficiency exam** and related competency training for employees.

- **Document all vital information in the patient healthcare information record immediately after administration.** Include the name of the drug, dose, frequency, route, number of doses dispensed, and special instructions or advice, e.g., "Patient was advised that drug may cause drowsiness."

- **Instruct staff to administer only drugs that they have personally drawn up or prepared**, in order to minimize miscommunication and consequent errors.

- **Prominently display drug allergies on the patient record,** using colored allergy stickers or other means.

Chronic Pain Management

A comprehensive medical history, physical exam and assessment of psychosocial factors and family history are necessary for all patients suffering pain and/or anxiety, or whose symptoms and conditions may otherwise require the use of controlled substances. Reevaluate the level of pain and/or other signs and symptoms to determine the efficacy of the treatment plan at every visit.

Appropriate substance use/mental health risk assessment tools should be employed before prescribing opioids and other controlled substances. Thereafter, patients should be routinely screened. Common risk factors for substance use include, but are not limited to, family history of alcohol or other substance use, history of physical or sexual abuse, and behavioral health conditions.

Commonly used screening tools include the following:

- Diagnosis, Intractability, Risk, Efficacy (DIRE) tool.

- Opioid risk tool.

- Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R).

- Screening Instrument for Substance Abuse Potential (SISAP), which assesses the potential for misuse at every visit.

Additional screening tool information for alcohol, tobacco, and other substance use risks is available on the National Institute on Drug Abuse (NIDA) website.

In order for providers to appropriately manage patients with chronic pain, remain current on prescribing guidelines and best practices. Two key resources issued by the CDC and an interagency government task force are listed below for further information. The second resource addresses both chronic and acute pain management recommendations:

- CDC Guideline for Prescribing Opioids for Chronic Pain.

- Pain Management Best Practices Inter-agency Task Force Report.

A pain treatment agreement is a means of contractually defining the responsibilities of the patient and provider, thus potentially reducing liability while enhancing patient understanding and continuity of care. Such an agreement should address both prescription refill parameters (e.g., one physician, one pharmacy, refills only as scheduled, no early refills) and the repercussions of noncompliance, which may include discharging patients who repeatedly violate practice policies and procedures.

Once the agreement is executed, it must be strictly enforced. Violations should be clearly communicated to the patient and documented in the patient healthcare information record. Physicians have the right to determine whom they will treat, but discharging a patient in chronic pain may lead to complaints or legal action. Providers can help protect themselves against allegations of abandonment by rigorously documenting instances of noncompliance, communicating clearly and straightforwardly with patients, and establishing and consistently implementing formal policies and procedures.

Providers should seek the advice of legal counsel when drafting and updating pain agreements, and update them regularly in order to reflect changes in level of pain, health status and medication dosages.

Patient Education

Notwithstanding a myriad of patient safety initiatives, medication errors in all settings continue to occur, with serious and sometimes fatal consequences. The following patient focused recommendations can help to reduce medication related safety issues:

- **Develop a comprehensive medication education program for patients,** including general written materials, as well as specific spoken advice.

- **Retain copies of any medication-related educational materials provided to patients** in the healthcare information record.

- **Conduct and document the informed consent process whenever a new medication is prescribed** or the course of therapy changes.

- **Understand and ensure compliance with state or local requirements** that may apply for specific informed consent forms and/or other documentation when opioids, other controlled substances and/or psychotropic medications are prescribed or administered in the outpatient setting.

- **Provide educational materials to patients in a useful form,** i.e., in languages and at a reading level appropriate to the patient population.

Medication Safety: A Self-assessment Tool

Medication errors may be caused by a multitude of individuals, including ordering clinicians, dispensers, providers and patients. Preventing or mitigating errors is a complex process, requiring more than an annual review of policies and procedures. Medication safety requires an ongoing commitment to evaluate and improve everyday processes, with the goal of ensuring that patients receive the correct medication at the right time, in the right amount, via the correct route.

Consider using this self-assessment tool, which focuses on the following critical issues:

• Treatment team access to patient and clinical data.

• Safeguards for computer order entry.

• Automatic drug-dispensing systems.

• Handoff communication practices.

• Protocols for high-alert, non-standardized, and look-alike and sound-alike drugs.

• Safety parameters for medication administration devices.

Medication Safety Practice	Present (Yes/No)	Comments
Patient and medication data management		
1. A complete medication history – including current prescription medications; over-the-counter medications and supplements; alternative therapies; and alcohol, tobacco and illicit drug use – is accessible, as well as medication records from recent episodes of care.		
2. Medication profiles are readily available at the point of care in electronic or paper form, and reflect up-to-date medication orders.		
3. Medication profiles include an allergy notation, as well as a tiered severity rating to alert staff about drug intolerances.		
4. Allergy alerts are visible on all screens or pages of the patient medication administration record (MAR).		
5. Patient weight and height measurements are always recorded in metric units to avoid potential confusion.		
6. Laboratory values and diagnostic reports are easily accessible to prescribing practitioners, either through an electronic health record tracking program or conspicuous placement in paper records.		
7. Two or more patient identifiers (such as patient name, date of birth, home address and telephone number) are used for verification.		
8. Documentation occurs simultaneously with medication administration to prevent critical gaps or oversights.		

Medication Safety Practice	Present (Yes/No)	Comments
Computerized systems		
1. The system is linked to a patient's profile, in order to alert ordering practitioners about comorbid or chronic conditions.		
2. The system interfaces with a pharmacy, in order to facilitate information sharing, if applicable.		
3. Patient allergies are noted and coded in the system before medications are ordered.		
4. The system screens against patient profiles for allergies, as well as contra-indicated medications, potential interactions and inappropriate doses.		
5. The system requires practitioners to document why they are overriding an alert message regarding allergy status, maximum dose or potential drug interactions.		
6. The system incorporates precautions for look-alike and sound-alike drugs, such as placing them on different screens, showing names in boldface and/or uppercase letters, and triggering alerts for similar suffixes, such as XL, SR, ED and CD.		
7. Software does not permit error-prone notations and abbreviations (such as q1d and sub q), as well as improper use of trailing/leading zeros.		
8. Automatic drug dispensing cabinets (ADCs), where available in treatment areas, are customized with medications required for the clinical specialty only.		
9. ADCs are not stocked with potentially hazardous compounds, such as vials of neuromuscular blocking agents and undiluted electrolytes.		
10. ADCs are double-checked by staff to ensure that high-alert medications are not present, and these checks are documented.		
11. ADC security databases are updated at least annually to remove expired access codes and create new passwords.		
12. ADC override reports and blind counts are monitored and reviewed via quality and audit processes.		

Medication Safety Practice	Present (Yes/No)	Comments
Handoff communication		
1. All medication containers prepared in advance – including IV and oral syringes, vials, bowls and basins – are appropriately labeled with the name of the patient, the drug's name, strength, dose, frequency and expiration date.		
2. Unit-doses of medications remain packaged up to the point of handoff/administration, in order to facilitate a final check of the order and medication record.		
3. All handoffs of prepackaged medications are preceded by a spoken exchange of information, which includes patient and drug name, as well as the dose, route and frequency of administration.		
4. Verbal drug orders from practitioners are acceptable only during emergencies or sterile procedures, and require the receiving party to transcribe the order, read it back to the prescriber and document the read-back for verification.		
5. Potential drug side effects are clearly communicated between healthcare staff at points of transition and are documented on accompanying patient care plans and/or handoff reports.		
6. Written protocol addresses the safe use and disposal of anesthesia-related medications, requiring that syringes be prominently labeled with drug name, strength/concentration and expiration date.		
7. Patients receiving high-alert drugs via IV or epidural infusion are accompanied by a qualified nurse or licensed practitioner when transported between treatment areas, and the exchange from the accompanying staff member to the receiving staff member involves a formal documented handoff.		
8. Staff and providers responsible for the ordering, transcribing, dispensing and/or administering of medications participate in documented simulations of higher-risk situations, in order to reinforce effective communication techniques and handoff practices.		

Medication Safety Practice	Present (Yes/No)	Comments
9. Patients are included in the handoff dialogue, when possible, in order to prevent errors, reinforce their awareness of the medication regimen and enhance post-discharge compliance.		

High-alert, non-standardized and look-alike/sound-alike drugs

Medication Safety Practice	Present (Yes/No)	Comments
1. Documented procedures are implemented in order to prevent wrong dosages or concentrations of identified high-alert drugs (e.g., anti-coagulants, muscle relaxants, insulin, potassium chloride, opioids, adrenergic agents, dextrose solutions, chemotherapeutic agents).		
2. High-alert medications are accompanied by standardized orders and/or computerized safe-dosing guidelines, and are verified by two persons before administration.		
3. Pediatric medications are accompanied by standardized orders and/or computerized dosing guidelines, and are stored separate from adult dosages of the same medications.		
4. Infusions of high-alert drugs – such as IV opioids, epidural narcotic infusions and vasopressors – are standardized to a single concentration for use in the majority of cases.		
5. Dosages, formulations and concentrations of drugs on medication carts and in medication cabinets are secured and reflect emergency drug guidelines for both adult and pediatric patients.		
6. Antidotes and reversal agents for medications, as well as dosing guidelines, are available at the point of care.		
7. Appropriate measures are taken to avoid the risk of contrast-induced nephrotoxicity or allergic response, including use of nonionic contrast, adequate hydration and postponement of treatment, if necessary.		
8. Non-standardized drugs approved for therapeutic use have accompanying safety enhancements, including but not limited to parameters for use, prescription guidelines, administration checks, monitoring protocols and separate storage areas apart from other medications.		
9. Medications requiring multiple dilutions or extensive calculations are made available only when necessary, and are maintained in limited quantities for safety reasons.		
10. Clinical staff is educated about minimizing the risks associated with look-alike and sound-alike products, and their training is documented.		
11. Drugs with look-alike and sound-alike names are kept separate from each other, are not stored alphabetically with other stock medications, and have enhanced labels or other auxiliary warnings.		

Medication Safety Practice	Present (Yes/No)	Comments
12. Clinical staff is notified when medication stock is relocated or storage areas are reorganized, in order to reduce the likelihood of confusion or error.		
13. Pharmacists are available onsite or by telephone to consult with providers regarding prescribed medications.		

Medication device safety

Medication Safety Practice	Present (Yes/No)	Comments
1. Staff is educated about operating medication devices – including standard infusion pumps, "smart pumps" and ancillary equipment – and undergo documented competency testing on their safe use on a cyclical and routine basis.		
2. Smart pumps and related devices are programmed to deliver maximum-dose alerts when administering potentially hazardous medications.		
3. Only one type or model of epidural pump is utilized, and it differs noticeably in appearance from standard IV infusion pumps.		
4. The type and number of syringe pumps used to deliver medications are limited, and all pumps are clearly marked to prevent mistakes.		
5. IV and epidural infusions are prominently labeled with the intended route of administration, and dosing concentration is consistent with infusion-pump programming (e.g., mg/kg/min).		
6. Tubing for epidural infusions differs noticeably from peripheral or central venous IV access tubing and does not contain Y-connector access ports.		
7. The distal ends of all tubing are clearly labeled for patients receiving multiple solutions via different routes, such as peripheral, central venous, arterial, epidural, enteral, bladder or other access sites.		
8. Syringes containing medications intended for oral/enteral administration are incompatible with the luer-locking mechanisms of IV infusion tubing, in order to prevent potentially catastrophic accidents.		
9. Solutions intended for infusion are verified jointly by two persons, unless the facility employs smart pump technology that checks doses and verifies bar codes at the point of care.		
10. The infusion verification procedure includes patient name and ID number, as well as: • Drug and base solution. • Drug concentration and rate of infusion. • Channel of administration (for pumps that offer multiple channels). • Line attachment.		
11. Written policy prohibits the administration of IV boluses via an infusion pump, unless smart pump technology recognizes and permits programming for bolus doses.		
12. Trained technicians are available to provide prompt assistance in the event of a medication device malfunction.		

Test Results Management

By consistently reviewing and following up on outpatient test results in a timely manner, providers may both enhance patient safety and reduce potential liability. Consistency of operations, reliable backup systems, comprehensive documentation and regulatory compliance for patient access to test results are critical to effective test results management.

Clinical Laboratory Improvement Amendments (CLIA) – Implications for Outpatient Facilities

The Clinical Laboratory Improvement Amendments (CLIA) Program regulates labs testing human specimens and ensures that they provide accurate, reliable and timely patient tests irrespective of where the test is performed. The Centers for Medicare & Medicaid Services (CMS) oversees all laboratory testing (except some research) performed on humans in the United States as governed by CLIA.

Depending on the scope of services provided by the outpatient facility, CLIA may or may not apply. Facilities must meet certain federal requirements if applicable testing services are provided to patients. Under CLIA, such testing involves "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." If a facility is located in a state that has a CMS-approved laboratory program, a CLIA certificate may not be required. Facilities and/or providers must understand and comply with requirements of the applicable state program, even if exempt from CLIA.

A sound resource to help a facility or provider understand how CLIA may apply is available for download from CMS. How to Obtain a CLIA Certificate begins by stating, "Do I need to have a CLIA Certificate?" and describes the various types of certificates that may be necessary for facility/provider compliance. Although performing so-called "waived tests" might lead to the assumption that certification is not required, this is not the case. Waived tests are "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." "Waived" tests are classified as such by the Food and Drug Administration (FDA). Detailed information about waived and non-waived test systems is readily available by accessing the FDA website.

Outpatient facilities and providers may access numerous resources via the CLIA webpage and related links on CMS.gov and on the Centers for Disease Control and Prevention (CDC) "About CLIA" page on CDC.gov.

Information Blocking

Patients have the right to access their healthcare information records, and these rights have been further defined under the Office of the National Coordinator for Health Information Technology (ONC) 21st Century Cures Act (Cures Act). The final rule promotes healthcare information technology innovations and is intended to promote transparency and access to information on healthcare quality, costs, diagnosis and treatment.

Information blocking refers to a "practice that interferes with, prevents, or materially discourages access, exchange, or use of electronic health information, except as required by law or specified in an information blocking exception." Although the details of the Cures Act and "information blocking" are beyond the scope of this manual, it is important to recognize that timely access to laboratory test results is a necessary component of compliance. Outpatient facilities and providers may access information on the Cures Act and compliance through a number of sources, including qualified legal counsel, professional organizations and others. A comprehensive resource is available on the HealthIT.gov website, which includes the final rule, fact sheets, webinar information and frequently asked questions on information blocking.

Information blocking may take many forms, including various limitations on the exchange of healthcare information between providers, excessive fees charged for records or EHR connections and interfaces, or related to the use of non-standard EHR methods or technology that block the use, access to, or exchange of, medical information. With respect to laboratory test results, a delay in releasing results requested by the patient may result in a violation of information blocking rules.

Although most providers are accustomed to having the opportunity to review laboratory test results prior to releasing the information to patients, providers should anticipate that patients may access their test results before or concurrently with the provider's review, as laboratories are required to comply with access requirements of the Cures Act.

Eight types of exceptions to information blocking rules are described by the Cures Act. Although the "preventing harm" exception or a few others may apply to individual patient situations, justifying a delay in the reporting of laboratory test results, implementation of standing orders or an outpatient facility's procedure to delay the reporting of laboratory results until after provider review would likely violate the rule.

Consider the recommendations for ordering, conducting and reporting of laboratory test results included in the balance of this section and those from other appropriate advisers, professional organizations and/or legal counsel to ensure compliance with the Cures Act and/or other requirements.

Labeling Specimens

Research estimates that each year in the United States more than 160,000 adverse patient events occur as a result of laboratory specimen identification errors. Therefore, it is incumbent upon outpatient facilities to implement processes and procedures to help reduce or eliminate sources of error related to specimen labeling and laboratory testing.

Depending on the facility and the scope of its internal laboratory test program, consensus standards such as those available from the Clinical and Laboratory Standards Institute (CLSI) may prove to be useful resources. A still-in-effect 2011 standard to reduce the unacceptably high incidence of mislabeled specimens is intended to reduce human errors associated with clinical laboratory specimen labeling practices. The standard addresses formats for the required human-readable elements that must appear on the label for each specimen, the location and size of bar codes and other labeling details.

To help minimize laboratory specimen labeling errors, consider these strategies:

Patient Identification

- Implement written policies and procedures to describe patient identification practices. Ensure that procedures are reviewed and updated at least annually and staff members are properly trained and notified of changes.

- Use appropriate patient identifiers and require audible verification. Patient identification must not rely only on memory.

- Confirm the identity of both the patient and the specimen. Always check processing labels and forms against the patient's record and/or the provider's order/requisition.

- Use bar coding to generate patient identification labels and confirm patient/specimen correlation.

- Minimize staff traffic and other environmental distractions in the specimen procurement area to help prevent patient identification errors.

- Train and periodically assess staff for competency and compliance with established patient identification procedures.

Specimen Procurement

- Ensure that specimen procurement and submission policies are consistent with national standards such as those of CLIA.

- Develop written policies that require rigorous specimen documentation, including, at a minimum:

  - patient name
  - type of specimen
  - date and time of collection
  - source of specimen
  - patient history and diagnosis
  - tests/studies required

- Ensure that staff members have ready access to equipment and supplies required for collecting and labeling specimens.

- Implement policies requiring staff to check with patients and confirm the type of specimen to be procured.

- Label specimens immediately upon placement in a vial, container or other receptacle in the presence of the patient.

- Implement methods to automatically document the date and time of specimen collection, e.g., by means of an electronic system.

- Prohibit the use of abbreviations on requisition forms, container labels and supporting documentation.

- Incorporate appropriate warnings and appropriate safety precautions on labels (e.g., the presence of biohazardous materials).

- Identify and follow specimen rejection criteria as part of specimen procurement and handling procedures to prevent the processing of defective or doubtful specimens (e.g., in cases involving mismatched demographic data or missing clinical information)

- Document training and assess staff competency for specimen procurement, at least annually and whenever procedures change.

Ordering Tests and Receiving Results

Liability claims associated with laboratory tests ordered in the outpatient setting are generally classified under diagnosis-related allegations of negligence (e.g., failure to diagnose or delay in diagnosis) or treatment-related allegations (e.g., failure to treat, delay in treatment or premature end of treatment). In order to manage risk, increase patient satisfaction and improve quality in this critical area, implement a written policy/procedure that clarifies provider and staff responsibilities and associated processes. The policy should address all aspects of test management, including ordering tests, review of results and patient notification.

Most practices have established and implemented a system for ordering tests and sending specimens to reference laboratories. It is equally important to track test reports to ensure timely review and patient notification. Consider implementing the following practices:

- **Consider acquiring an effective test management system** that integrates with the electronic health record.

- **Utilize a test order log that is compatible with the facility's records management system.** Record the date the specimen was sent or the test that was ordered, the patient's name and unique identifier, the name of the test and the date that the specimen is expected to be received.

- **Implement an effective method to document** when the results are received or past due, requiring investigation and follow-up.

- **Place paper healthcare information records awaiting test results in a designated area.** Arrange the records in chronological order, and assign a staff member to review them daily and follow up on outstanding test results.

Reviewing Test Results

All test results should be reviewed and signed by the responsible provider prior to filing them in the patient's healthcare information record. If an electronic signature is utilized, the system should permit only one authorized user.

Results must be reviewed in a timely manner. If the ordering provider is unavailable, refer test results to another provider, in accordance with practice policy.

Critical test results received by telephone should be immediately reported to the ordering provider or, if the provider is unavailable, to another individual designated by written policy. When documenting a test-related call, consider using a form designed to capture the following information:

- Date and time of call.

- Name of individual taking the call.

- Patient's name and unique identifier.

- Test name and critical test value.

- First name, last name and location of caller/sender (e.g., John Doe, Acme Diagnostics).

- Acknowledgment that information has been read back and confirmed.

Serial Testing

Certain drugs and conditions require serial monitoring and close clinical observation. Failure to order tests at recommended intervals may compromise the patient's health and lead to a lawsuit. Consider implementing the following risk reduction measures:

- **List the drugs requiring a laboratory baseline value and periodic reassessment** (e.g., Lipitor®/liver enzymes). Review and update the list annually, or as needed, to incorporate the latest clinical guidance and list additions/deletions.

- **Identify the conditions requiring periodic reassessment** (e.g., chronic lymphatic leukemia). Review and update annually, or as needed, to incorporate the latest clinical guidance and list additions/deletions.

- **Develop and implement an alert system** to ensure that patients are notified and serial tests are ordered at appropriate intervals.

- **Engage in an informed consent discussion with the patient** regarding the drug or condition and the need for serial follow-up. Include signs and symptoms that should prompt a call to the provider.

Prior to each patient visit, review the patient healthcare information record and any information received since the last patient visit to determine if a diagnostic test should be ordered.

Notifying Patients of Test Results

Patients should be notified of all test results. The patient should not be told to assume a test result is normal if they are not notified by the practice of abnormal results.

Before leaving any messages regarding test results, obtain patients' written consent to do so. This consent form, which may be completed by patients as part of the registration process, should include an authorization on how the patient prefers to be notified of test results. The patient should sign and date the form.

Providers should not leave a message stating that test results were abnormal. Instead, the message should direct the patient to call for results. Follow-up calls should be initiated if the patient does not respond. Document all calls and whether or not the patient was successfully contacted. Identify circumstances (e.g., abnormal mammogram or PSA) requiring the use of registered mail with a return receipt if the patient cannot be contacted by telephone. Document and retain the receipt in the patient healthcare information record.

Compliance with the Cures Act by laboratories could result in the patient receiving test results before a discussion with the ordering provider. This does not replace the provider's responsibility to discuss the test results with the patient.

Documenting Notification of Test Results

Document all attempts to notify patients of test results in the patient healthcare information record, as well as follow-up treatment instructions and recommendations for preventive/screening tests, such as colonoscopies or mammograms.

In situations where the patient has not completed the recommended testing, explain the potential consequences of failing to obtain the test or procedure, and document both the discussion and the patient's response.

Medical Device Safety

Medical device technology for outpatient settings is evolving at an unprecedented pace. All types of healthcare settings are affected by this rapid expansion in technology, as evidenced by updates to existing equipment and the development of new technology. The technology, including artificial intelligence, can enhance diagnostics and treatment capabilities, streamline administrative and operational processes and engage patients in preventative care programs.

The manufacturer has the duty to design the device so that it does not cause injury when operated properly. However, the operator is responsible for ensuring that the equipment is in proper working order and used correctly, even if the equipment is leased and maintenance and repair services are contractually assigned to an outside vendor.

When using medical devices, providers are required to adhere to a wide range of regulations promulgated at the federal level by the Food and Drug Administration (FDA). For more information on FDA rules and programs, visit the agency's website.

Medical Equipment Management

Sound medical equipment management involves, at a minimum, the following elements:

- **Selecting the appropriate equipment** to satisfy clinical needs, while recognizing potential hazards and limitations of the products.

- **Establishing a process to review purchases of equipment** to ensure that new equipment is safe, appropriate for the setting and that staff are trained prior to deployment.

- **Using the equipment in a reasonable manner** as intended by the manufacturer.

- **Training staff on the safe use of devices** that they are expected to operate.

- **Creating a quality control program** for all equipment used for patient diagnosis and treatment.

- **Designing and adhering to preventive maintenance, electrical safety and calibration schedules and policies,** as recommended by the manufacturer.

- **Establishing procedures** in the event of equipment failure and for emergency preparedness.

- **Formalizing reporting processes** for medical equipment management problems, failures and user errors.

- **Implementing inspection procedures** upon receipt of new or repaired equipment.

- **Initiating a tracking system and log** for product recalls, alerts and implantable devices, if indicated.

- **Maintaining an inventory of all medical devices,** including manufacturer, model and serial number, as well as whether they are owned or leased.

- **Retaining copies of device-specific operator and user manuals** and ensuring that they are readily available to staff.

- **Performing regular safety inspections** at intervals as recommended by the manufacturer.

Review all written documents regarding the purchase and use of medical devices for language that may create liability or transfer risk solely to the user. Ensure that all such documents are reviewed by legal counsel. In addition, ensure that appropriate contracts are in place for preventive maintenance services from either the manufacturer or a qualified outside biomedical engineering firm.

Clinical Laboratory Equipment

CLIA's regulatory requirements vary according to the test type that is being performed and are categorized as waived, moderate complexity or high complexity. Moderate and high complexity tests are referred to as "non-waived" testing. CLIA exempts basic laboratory examinations and procedures from oversight if they "employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if the test is performed incorrectly."

Exempt laboratories are required to follow manufacturer's test instructions as well as the following:

- **Provide current manufacturer's instructions to staff members** involved in testing and test processing.

- **Routinely check new product inserts** for changes.

- **Perform quality control testing** and required corroborative tests.

- **Adhere to expiration dates** and properly dispose of expired products.

- **Perform function checks or calibrations**, as well as regular instrument maintenance.

Direct Access Testing

"Direct access testing" (DAT) is testing initiated by the patient without a provider order. There is an increasing trend of consumer usage of laboratory testing through direct marketing due to convenience and cost savings.

DAT testing is state-regulated, and CLIA regulations and standards do not differentiate between facilities performing DAT and facilities performing provider-ordered testing.

Point-of-Care (POC) Testing

Point-of-care (POC) testing involves performing a diagnostic test outside of a laboratory, typically at the patient's bedside. These tests are waived under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. In addition to onsite testing in outpatient healthcare settings, POC testing also may be performed at pharmacies, thereby offering greater access to care.

More information about CLIA is available here .

Radiographic Safety

Providers must weigh the risks and benefits of radiography and expose patients to the lowest radiation level that is consistent with good diagnostic quality. Protecting patients and staff while obtaining useful results requires ongoing education and training of both providers and technicians. For more information, see the 2011 statement from the American College of Radiology.

Safety Recall Notices and Hazard Alerts

Medical device recalls occur when a device is defective and/or a health risk, as determined by the federal Food and Drug Administration (FDA).

According to the FDA, "A medical device recall does not always mean that you must stop using the product or return it to the company. A recall sometimes means that the medical device needs to be checked, adjusted or fixed. If an implanted device (for example, an artificial hip) is recalled, it does not always have to be explanted from patients. When an implanted device has the potential to fail unexpectedly, companies often tell doctors to contact their patients to discuss the risk of removing the device compared to the risk of leaving it in place."

The majority of "recalls" are actually safety notifications requiring no emergency measures on the part of the recipient. However, a formal process must be in place even for low-level recalls, in order to implement the indicated actions. Failure to notify patients of a recall situation after being instructed to do so by the FDA may create liability exposures for providers and healthcare organizations.

Healthcare facilities must be ready to disseminate recall-related information to providers and patients in a clear and timely manner, as well as to properly identify, track, retrieve, and return or dispose of affected items, as indicated. One of the major obstacles to an effective recall response is the presence within the facility of unauthorized or undocumented medical products, which have been obtained without the knowledge of the supply-chain team. This problem is often the result of such risky practices as manufacturers providing devices and implants on consignment, or pharmaceutical sales representatives dropping off medication samples. To ensure an accurate inventory and effective recall process, all devices, irrespective of their provenance, must be registered. A centralized inventory and recall management system, anchored by well-defined policies/procedures and a dedicated coordinator or team, can enhance patient safety, efficiency and accountability.

If a recall notice or hazard alert is received:

- **Document the notice in the** recall/alert log.

- **Immediately check all equipment**, both in use and in the inventory.

- **Discontinue use of equipment that has been reported defective or possibly harmful** until it has been repaired, replaced or deemed safe to use.

- **Respond to instructions** provided in the recall notice.

- **Complete the recall tracking log**, documenting evaluation of the product, recommendation(s) for corrective action and corrective action taken.

Recalls are posted on the Internet and are accessible to the public.

Medical Device Adverse Events and Reporting

Under the Safe Medical Devices Act (SMDA) of 1990, Pub.L. 101-535, a "device user facility" must report serious device related injuries to the manufacturer or, if the manufacturer is not known, to the FDA. The FDA has established a voluntary system for health-care providers to report serious adverse events, product quality problems or product use errors associated with a medical device. The FDA uses the data to assess the safety of the products it regulates and posts reports on the agency's Medwatch website.

Regulation

This section provides an overview of reporting adverse events involving medical devices and equipment. Detailed information can be found at 21 CFR Part 803. The Medical Device Reporting (MDR) regulation outlines the mandatory federal reporting requirements for manufacturers, importers, and device user facilities regarding device-related adverse events in which a death or serious injury has occurred. A device user facility is defined as a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility. Serious injuries must be reported to the manufacturer of the device, or to the FDA, if the medical device manufacturer is unknown. A device-related death must be reported to both the FDA and manufacturer. Both reports must be filed within 10 working days of becoming aware of the incident. In addition to reporting individual events, annual summary reports to the FDA are due every year on January 1.

Decisions as to whether the injury or death was directly related to the medical device adverse event, and/or whether the injury should be viewed as "serious,"are not always obvious. For example, needlesticks requiring medical/surgical treatment to prevent permanent injury are reportable. The expectation is that decisions regarding causation and injury severity are based upon information gleaned from detailed clinical investigations. Physician/provider offices are not subject to this regulation, but may report on a voluntary basis. It is a prudent risk management strategy for provider offices to establish a reporting program dedicated to adverse events involving medical device use. Additional information regarding reporting criteria available on the FDA website may be helpful in determining whether a device-related event is reportable.

Policy and Procedures

In order to comply with FDA regulations, device user facilities are required to establish and implement written policies and procedures to address adverse event reporting, investigation and documentation. There should also be an established process for conducting an investigation and maintaining associated documents. It is advisable to designate a staff member to oversee the MDR process, including, but not limited to, coordination of regular staff training regarding identification and reporting of adverse events related to medical devices.

Regardless of whether the adverse event was related to a flaw in the equipment or user error, or whether or not a patient injury occurred, an investigation of "near-miss" events should be conducted to prevent future occurrences.

Medical devices and equipment, including disposables, involved in an adverse event should be sequestered with the chain of custody documented. Decision-making regarding whether to return the device to the manufacturer for analysis and repair should be made in consultation with risk management, clinical leaders and legal counsel.

Documentation

The MDR regulations also require that user facilities maintain files of submitted reports to manufacturers and the FDA, i.e. Form 3500A and annual FDA report Form 3419, as well as files for adverse events that were not reported. Such files should include references to documents used to conclude that an event was not reportable. Documentation in the patient healthcare information record should include details regarding the equipment, such as manufacturer, lot and serial number and usage dates.

Adverse Events Relating to Implantable Medical Devices

Implantable medical devices may be explanted for various reasons such as infection, patient choice, expiration or product defect/malfunction. In cases of product defect or device failure/malfunction, removal of the implantable device may be reportable if the explantation was required to prevent permanent impairment. To ensure compliance with MDR regulations relating to implantable devices, policies should be established and implemented to address device tracking, alerts and recalls, adverse event reporting, 3-D implant printing and disclosure requirements relating to providers' financial relationships with device manufacturers.

Off-Label Use of Medical Devices

According to the FDA, "If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects." Although the FDA recognizes that off-label use of medical devices, drugs and products is appropriate in specific situations, and may represent the standard of practice, there are patient safety and risk management implications specific to the consent process. Liability exposures may exist when the informed consent process fails to include a discussion specific to the "off-label" usage. Patients should be informed about the use of "off-label" medical devices for their care. The informed consent discussion should include information about the approved use of the device and the associated known risks, benefits and alternatives, as well as the fact that there may be risks or complications not known regarding the "off-label" use.

Non-provider Use of Medical Devices

State law or regulation may designate occasions when non-provider staff may use specific devices to treat patients. For example, several states permit hair-removal treatment involving laser or intense pulsed light devices to be delegated to a properly trained individual who is directed by a provider.

Non-provider staff members may utilize only those devices that are within their scope of practice, based upon education and training, and must work under the supervision of a provider. To protect patients and minimize risk, non-provider staff members also must:

- **Be properly licensed** by the appropriate state healthcare professional licensing board, if applicable.

- **Comply with written office protocols** when using the medical device.

- **Satisfactorily complete a documented education and training program**, covering such topics as safety, proper technique, and pre- and post-treatment care. The program should include supervised practice and clinical skill competency testing.

- **Participate in ongoing, well-documented continuing education** for these procedures.

Document in the patient healthcare information record the activities, decision criteria and plan that the supervised non-provider must follow, as well as the devices and settings that can be used. In addition, develop guidelines addressing the methods by which all devices are to be operated and maintained. Finally, create protocols covering appropriate care and follow-up for common complications, serious injuries and emergencies.

Medical Device Liability Implications

Providers should monitor the selection, inspection and maintenance of medical office equipment and devices, as both providers and manufacturers are often named as defendants in liability actions involving medical products. The manufacturer will often try to demonstrate that it was the provider or outpatient setting that erred by:

- **Purchasing the wrong type of medical device** or equipment for the procedure.

- **Failing to reasonably inspect the product** for obvious defects.

- **Using the device incorrectly and outside the parameters** as defined by the user's manual.

- **Improperly educating users** in the operation or use of the product.

- **Neglecting to maintain or service the equipment** in a reasonable manner.

- **Modifying the device** without the express written consent of the manufacturer.

- **Utilizing unapproved disposables and supplies** that do not meet manufacturer specifications.

- **Omitting to implement upgrades** as specified by the manufacturer.

- **Overlooking a product recall** or safety notice.

A comprehensive medical equipment management process can mitigate many of the risks related to the use of medical technology. By adhering to the basic elements of the process and to applicable federal and state laws and regulations, providers can help to minimize the likelihood of adverse events while strengthening their defense in the event of a lawsuit.

For more information, please call us at 215-509-5437 or visit www.nso.com or www.hpso.com.

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