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Risk Management Strategies for the Outpatient Setting

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Enterprise Risk Management

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Introduction to Enterprise Risk Management

Healthcare continues to evolve, creating predictable and unpredictable risks that are most effectively addressed on an enterprise-wide basis. By taking a global view of liability, healthcare leaders are better positioned to fulfill organizational mandates and attain strategic objectives, while promoting patient safety, minimizing loss and protecting organizational reputation.

The Enterprise Risk Management (ERM) model provides a process to identify complex and interconnected activities across the outpatient setting that affect one another positively or negatively. The ERM framework can be adopted and designed to fit any size and type healthcare organization and modified to address the unique characteristics and needs within outpatient settings.

A critical step toward implementing the ERM model is to adopt a clear and concise definition of ERM. This definition will communicate to the organization the purpose and commitment of leadership to the ERM process.

ERM represents a continuous process applied across the outpatient setting and is influenced by staff conduct at every level. In a solo practice, the provider is responsible for developing and facilitating a risk-conscious culture among staff. In an outpatient setting, the medical director and practice manager collaborate to educate staff members on the ERM process and implement an integrated risk management program. For the ERM process to be effective, all staff members in the outpatient setting must be aware of what ERM encompasses and demonstrate a commitment to its implementation.

The ERM process includes the following major components:

- **Risk identification**, i.e., detecting exposures within each of the risk domains, a process that typically includes staff interviews.
- **Prioritization and scoring of risks**, i.e., analyzing the likelihood, causes and consequences of specific exposures. The potential severity of each risk is multiplied by its probability to determine the "risk score."
- **Risk response**, i.e., developing and implementing an action plan to avoid, accept, reduce, segregate, and/or risk transfer, as defined below:
    - **Risk avoidance** denotes actions that prevent the risk from occurring such as eliminating a service or procedure.
    - **Risk acceptance** means assuming responsibility for any loss associated with an identified risk. Risks with minimal effect are customarily accepted.
    - **Risk reduction** involves activities to reduce the likelihood of a risk from occurring such as universal protocols, infection control practices, or equipment maintenance programs. Other risk reduction activities involve reducing the probability or severity, through process and system design, without eliminating the service or activity.
    - **Risk segregation** involves moving assets across multiple locations, offices, or units to reduce the likelihood of a loss of supplies, equipment, or records stored in one location.
    - **Risk transfer** refers to covering potential losses by transferring risk to a commercial insurance policy or by retaining risk through alternative mechanisms such as high deductibles, self-insured retentions, surety bonds or trust fund accounts.
- **Control and monitoring**, i.e., measuring the effectiveness of selected risk responses.

The ERM process is dynamic, involving several steps that may occur simultaneously. It serves as a useful framework for organizing risk management activities.

Mapping Risks

The first step in creating a risk management program is to classify and assess organizational risks. The following chart lists risk categories common to many healthcare settings. Risks in these categories reflect absent, inadequate or failed internal processes or systems to control the risk. There is flexibility in the specific activities assigned to each category and should be modified to complement your organizational structure. Examples of specific functions, issues, requirements and risks that fall within the various categories are provided below.

Common Risk Categories and Descriptions

Operational	Operational risks are derived from an organization's core activities: provider credentialing, research activities, professional medical services, performance improvement, risk management, appointment tracking, environment of care, emergency preparedness, policy and procedure development process.
Legal/regulatory	Legal and regulatory risks emanate from federal and state requirements, licensure/certification, reimbursement rules, fraud/abuse, compliance, contracts, patient rights, informed consent, HIPAA privacy and confidentiality provisions, Clinical Laboratory Improvements Act (CLIA) regulations, patient termination, contract management, closing or leaving a practice.
Clinical	Clinical risks involve the delivery of care to patients such as adverse events, evidence based standards of care, safety protocols, universal precautions, preventive care/screening, medication/pain management, referrals/ consultations, drug/device recalls, patient education.
Strategic	Strategic planning involves an organization's ability to grow and evolve its brand and reputation. Examples include joint ventures, marketing activities, clinical service expansion, mergers and acquisitions, capital needs, and enterprise risk management.
Financial	Financial risks reflect an organization's ability to earn, raise and access capital. These risks include insurance denial of care, billing and collections, Medicare/Medicaid reimbursement, credit rating, assets and liabilities.
Human Capital	Human capital risks relate to workforce management, hiring practices, recruitment, retention, employment practices, scope of practice, background checks, competency assessments, in-service education.
Technology	Technology risks are associated with computer hardware/software, storage/retrieval of information, digital health, wearable technology/sensors, cyber exposures, electronic health records, data privacy and security, email, social media, facsimile, texting, telephone and other remote consultation.
Hazards/business interruption	Hazard risks relate to predictable risks associated within and outside the building. These include construction/ renovation, earthquake, fires, tornado, hurricane/floods, facility management, plant age, parking (e.g., lot lighting, condition, security), securing valuables.

Adapted from American Society for Health Care Risk Management, Enterprise Risk Management: Implementing ERM, 2020

Prioritization and Scoring Risks

Risk-taking is inherent to healthcare organizations. Using an objective process to evaluate the scope and magnitude of risk will enhance the organization's ability to prioritize efforts and allocation of resources involving risk mitigation. Risks can be ranked by assigning numerical scores to the "likelihood" and "impact" the risk has on the organization. An optional third measurement is "velocity".

Likelihood is the frequency or probability the event or risk will occur.

Impact is the severity or patient injury value, often expressed in financial terms or dollar value, of the outcome should the risk occur.

Likelihood x Impact = Risk Score

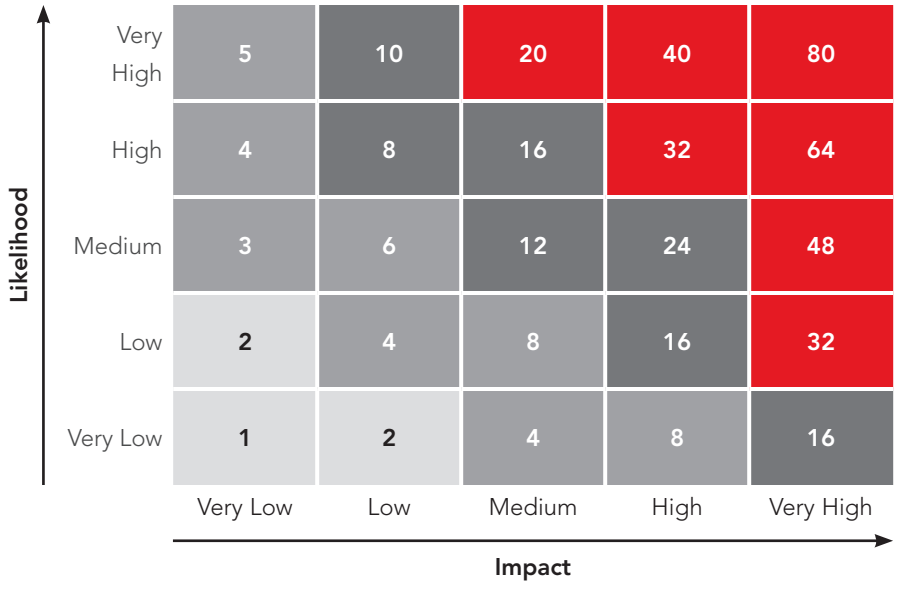
Velocity refers to the speed in which you have time to take action or "time to impact" before the outcome is realized. This is an optional measurement to enhance the risk score.

Likelihood + Velocity x Impact = Risk Score

Ranking risks using a numeric system has flexibility to evaluate an organization's tolerance, or appetite, for risk. Risks that are highly likely to occur with an outcome of minimal consequence to a patient or the organization, such as lost patient clothing, would have a low score (Likelihood of 5 x Impact of 1 = 5). In contrast, a risk with potential likelihood of occurring with major consequences to patient(s) and/or facility, a facility in the path of a tornado, would have a higher score (Likelihood of 3 x Impact of 5 = 15). In these examples, the facility would be guided by the risk scores and focus risk management efforts toward the more catastrophic event. Including the velocity, or time the organization has to the point of impact, will further enhance this risk scoring process.

Once the risk has been scored and prioritized, decisions around how to treat the risk must be determined: risk avoidance, risk acceptance, risk reduction, risk transfer.

Risk Heat Map



Reference: Enterprise Risk Management: Implementing ERM, ASHRM 2020

Responding to Risk

Managing risk involves using the information provided through adverse event reports, survey findings and other feedback mechanisms to support these four basic initiatives:

Prevention encompasses proactive risk awareness and safety programs for patients, staff, providers, family members and visitors. The goal is to ensure that all parties are aware of the risks and know how to protect themselves and others.

Correction requires implementation of post-incident remedial actions to minimize the impact of the event and prevent future similar occurrences. The corrective measures must be documented, monitored and audited to assess their effectiveness.

Documentation is critical to effective legal defense in the event of a professional liability claim. Healthcare information records must be accurate and comprehensive. In addition, all institutional policies and procedures – including those that no longer apply or have been modified – should be carefully archived.

Education involves engaging staff through relevant, practical and meaningful in-service seminars given at orientation at least annually thereafter, and following any significant adverse event that requires an immediate change in systems or processes to prevent recurrence. Education should include both an overview of the risk management process and a detailed description of other key topics. The educational sessions should clearly explain what constitutes an adverse event, how they should be reported, and why thorough and objective incident documentation is of critical importance.

Evaluating the ERM Program

All ERM programs must be routinely evaluated and updated. As healthcare reform and other legislative and regulatory initiatives continue to transform the industry, new and unpredictable risks will emerge. Healthcare leaders responsible for risk management must remain attentive to their own unique risk situation, as well as the broader political, economic and social developments affecting the healthcare field. Any changes in the program should be promptly communicated to staff members.

Sample Risk Management Plan

Organization Name: _____

Business Address: _____ **City, St, Zip:** _____

Telephone Number: _____ **Facsimile Number:** _____

Website Address: _____ **Email Address:** _____

Mission Statement

Enter organization's mission: _____

_____

_____

Purpose

The purpose of the risk management program is to provide the organization with a comprehensive framework designed to strategically identify, manage and mitigate risk in order to enhance patient safety and maximize value protection.

The risk management plan is a primary tool for implementing the organization's overall risk management program. It represents a foundation for implementation of the organization's risk management program through dissemination of detailed information regarding purpose, scope and objectives to all clinical providers and staff.

The focus of the risk management plan is to provide an ongoing, comprehensive, and systematic approach to reducing risk exposures. Enterprise-wide risks encompass issues that may be categorized as operational, clinical, strategic, financial, human capital, legal/regulatory, technology, and hazards. Risk management activities include identifying, investigating, analyzing, and evaluating risks. Follow-up activities may include taking action to address the identified risks through the development and implementation of appropriate risk reduction initiatives. These initiatives and responses can include risk avoidance, risk prevention, risk reduction, segregation of risk, and/or risk transfer.

Authority and Role of the Risk Manager

The risk manager is empowered by the governing body to implement the functions and activities of the risk management program in collaboration with administrative and clinical leadership. The governing body has overall responsibility for the effectiveness of the program and for providing the necessary resources. Routine written and verbal communications regarding risk management activities that may affect the organization's finances should be provided to the governing body.

The risk manager is responsible for creating, implementing, and evaluating the outcome of the risk management plan. These activities should be coordinated with quality/performance improvement, infection prevention, organizational/patient safety and environment of care management. A job description delineating the risk manager's role should be approved by the governing body.

The risk management program is formally addressed through designated committees, such as the risk management committee, safety committee, and quality/performance improvement committee.

Scope

Under the direction of the risk manager, the risk management program provides for collaboration among all departments, services, and patient care professionals within the organization. The risk management program focuses on policies, procedures and protocols to address events that may create business-related liability, professional liability, general liability, workers' compensation and motor vehicle liability exposures. The identification, investigation and management of accidents, injuries and other potentially compensable events are a primary organizational responsibility under the risk management plan. The risk manager and others who are delegated to participate in the various components of managing adverse events occurring with patients, staff, visitors and organizational assets direct this process.

Risk management will collaborate with and educate leaders within the following departments in order to promote quality care in a safe environment and protect the organization's resources:

- Administration
- Allied Health and Adjunct Professional Services
- Billing Services
- Business Development and Marketing
- Clinical and Ancillary Services
- Data/Health Information and Privacy Management
- Employee Health
- Human Resources
- Infection Prevention
- Legal Services
- Biomedical Engineering
- Medical Staff, if applicable
- Medical Staff Credentialing, if applicable
- Patient Relations
- Quality Improvement
- Patient Safety
- Safety Management/Environment of Care
- Security Management
- Utilization Management

Objectives of the Risk Management Program

The objectives of the risk management program include, but are not limited to the following:

- **Promoting the quality of patient care** and establishing key performance measures in collaboration with quality/performance improvement activities.
- **Identifying opportunities for improving patient safety** through analysis and trending of incidents and near misses.
- **Utilizing the results of timely incident investigation** to guide open communication and disclosure discussions with patients/families.
- **Evaluating systems and processes** that can adversely affect administrative and clinical operations leading to adverse events.
- **Protection of the organization's assets** by minimizing the frequency and severity of untoward events and legal claims.
- **Reducing the impact of losses** through insurance or other risk transfer mechanisms.
- **Enhancing patient satisfaction** and responsiveness to complaints.
- **Supporting a culture of safety** that promotes awareness and empowers staff to identify risk-related issues.
- **Enhancing environmental safety** for patients, visitors and staff.
- **Educating stakeholders on emerging and known risk exposures** and risk reduction initiatives.
- **Meeting accreditation requirements** of relevant organizations.
- **Complying with state-specific scope of practice,** applicable state and federal laws, regulations and standards.

Specific Components

The risk management program will include the following components:

Event/Incident/Occurrence reporting. Event reporting provides a systematic, organization-wide program of reporting risk exposures to identify report, track, and trend patterns of actual, potential and near miss events with the potential for causing adverse patient outcomes or other injuries to people, property or other assets of the organization. The goal of the program should be to reduce or ameliorate preventable injuries and property damage, while also minimizing the financial severity of claims.

The risk manager reports analysis of event data and recommends actions to the quality/performance improvement department and the department(s) involved in the events for follow-up action.

Sentinel events, as well as other significant incidents as specified by state or federal regulations, must be reported to governmental and/or accrediting agencies through delineated methods in compliance with the requirements of these regulatory entities. The reporting responsibility should be delegated to the risk manager or compliance department/officer, noting the established guidelines and required time frames for reporting.

Reporting risk management activities as part of the quality/performance improvement process. Recognizing that the effectiveness of risk management activities is contingent upon collaboration and integration with the quality/performance improvement activities, the risk manager will work with quality/performance improvement staff to coordinate activities between the two disciplines. This collaboration will enhance the identification and resolution of risk and quality issues.

Educational activities. The risk manager will provide or facilitate orientation programs for all new employees, volunteers and contracted staff and annually to all employees. The educational programs will focus on promoting awareness of risk exposures and current risk prevention activities. In-service and training programs should be provided as identified through the ongoing monitoring, tracking and trending of events, and/or as requested by a staff member within the organization. Ongoing education should be provided on a routine basis in order to inform staff about proactive preventative measures for common risk exposures, as well as strategies to enhance defensibility in the event of a claim in the areas of documentation and communication techniques.

Management of patient and family complaints/grievances. The organization will have a formal written process for managing patient and family complaints/grievances in compliance with federal regulations and accreditation requirements. This process should delineate response to and resolution of patient and family complaints. It also should include time frames for responding, the chain-of-command used for problem-resolution, and documentation of the activities involved.

Patient satisfaction. The organization will measure patient satisfaction and respond to issues identified in patient satisfaction surveys. The risk manager will monitor complaints and report findings related to quality/performance improvement. Of equal importance is risk management's direct participation in resolution of complaints, as appropriate.

Claim Management

In some organizations, claims management is a function outside of the risk management program and may have a separate staff with unique policies, procedures and protocols.

If the claim management function is included in the risk management plan, it should be comprised of the following elements, among others that may be adapted to your organization:

- **Reporting potentially compensable events, unexpected outcomes or patient complaints** to the involved department manager, the insurer, as appropriate, in conformity with the policy provisions, and the organization's risk manager.
- **Conducting investigation and interviews** following potentially compensable events.
- **Documenting activities and correspondence** related to the investigation of the event.
- **Protecting and preserving the patient healthcare information record** and/or other documents and evidence for potential future litigation.
- **Organizing, managing and maintaining claim files.**
- **Limiting access to claim files** to individuals as authorized under the direct supervision of the risk manager.
- **Coordinating interactions with the defense team** and providing input regarding the strategy for each claim.
- **Reporting claim management activity** to the quality/performance improvement committee and appropriate organizational leaders.
- **Participating in establishing the defense/settlement posture.**
- **Resolving claims** within established limits of authority.
- **Maintaining confidentiality and security** of protected documents.
- **Reviewing, evaluating and accepting legal services** as appropriate.
- **Timely forwarding of subpoenas, summons and complaints** to legal counsel.

Reports to the Governing Body

The risk manager will provide reports to the governing body periodically, and, at a minimum, on an annual basis. The report should summarize activities, achievements, and on-going risk management issues that have occurred since the prior report.

Ad hoc communications should be initiated with the governing body pertaining to sentinel events, significant changes in claim reserves, claims that are scheduled for trial, events that may result in adverse publicity or media attention, and severe patient injuries deemed highly probable to result in litigation.

The final annual risk management report should include all of the above parameters along with recommendations for risk control activities and identified resource needs for the upcoming fiscal year.

Protection of Risk Management Information Included in the Quality/Performance Improvement Program

Risk management data and information collected should be maintained as a component of the organization's quality/performance improvement program and reported to the quality/performance improvement committee and/or designated subcommittees. This structure may result in findings being considered privileged and confidential and should be distributed outside of the quality/performance improvement process solely at the direction of and with the written consent of legal counsel.

Review of the Risk Management Plan

The risk management plan will be reviewed, updated, and approved annually, or as needed. Dated signatures and titles from designated and authorized parties should be obtained at the time of the approval.

Annual Evaluation of the Risk Management Program

The risk management program will be evaluated by the governing body annually. Recommendations for enhancements are incorporated into the program prior to final approval.

Signature and Title: _____ Date: _____

Signature and Title: _____ Date: _____

Signature and Title: _____ Date: _____

Self-assessment Checklist: Enterprise Risk Management

This resource is designed to help evaluate customary risk control policies and procedures. For additional risk control tools and information on a wide and evolving range of topics, visit www.cna.com.

Risk Control Measures	Present? Yes/No	Comments
Stategic Risk		
Promotional/marketing materials (e.g. advertisements, brochures, websites, telephone directory listings) are reviewed to ensure that they do not include contain inappropriate language or inaccurate descriptions, and convey no unreasonable expectations.		
The organization has a formal risk management plan that:		
• Declares the organization's risk control goals.		
• Describes the scope, components and methods of the risk control program.		
• Delegates responsibilities for implementation and enforcement.		
• Demonstrates leadership commitment.		
• Mandates confidentiality and immunity from retaliation for staff members who report sensitive information.		
Human Capital Risk		
A pre-employment screening process is created and implemented that includes the following documented elements:		
• Drug screen.		
• Background investigation, which includes criminal record, Office of Inspector General (OIG) and sex abuse registries for all states where the applicant has lived or worked, as well as credit history, if relevant and legally permissible.		
• Reference verification and documentation.		
Every position has a written job description delineating specific responsibilities and required competencies.		
All staff members undergo a formal office orientation program, which covers the following topics, among others:		
• The practice's mission and vision.		
• Performance expectations and evaluation process.		
• Equipment use and other basic operations.		
• Appropriate professional appearance and behavior.		
Employees read their job description and sign an acknowledgment.		
Human resources policies and procedures are in writing, and are reviewed on a routine basis to ensure compliance with applicable federal, state and local legal requirements, such as:		
• Americans with Disabilities Act (ADA) requirements.		
• HIPAA privacy regulations.		
• Equal Employment Opportunity Commission (EEOC) and other anti-discrimination laws.		

Risk Control Measures	Present? Yes/No	Comments
Clinical Risk		
Formal written policies and procedures exist, addressing the following clinical issues, among others:		
• Medication management.		
• Hand-off communication.		
• Patient identification.		
• Time-out procedures.		
• Infection prevention.		
• Disclosure of unanticipated outcomes.		
• Medical device safety.		
• Fall prevention and mitigation.		
• Informed consent and refusal.		
• Patient scheduling and after-hours care.		
• Proper professional boundaries.		
• Test result management.		
• Referral processes for patients requiring a specialist.		
• Drug and medical device recall.		
A written, individualized plan of care is developed for each patient and updated as necessary.		
Staff members participate in annual programs on patient safety, as well as risk management, customer and community relations, confidentiality and compliance.		
Operational Risk		
There is a designated risk manager on staff, with well-delineated responsibilities.		
A system is in place for identifying and tracking medication errors and other untoward incidents.		
A system has been implemented for identifying and tracking quality issues and patient complaints.		
Administrative, operational and disaster preparedness practices are governed by written policies and procedures, which are approved by leadership and shared with all physicians and staff.		
Staff are trained in telephone etiquette, which includes dealing with angry or dissatisfied patients in a tactful, respectful and non-confrontational manner.		
A designated staff member responds to complaints from patients, family members and visitors.		
The risk manager is promptly notified of all complaints from patients, family members or visitors.		
All communication regarding patient complaints is reviewed by the risk manager and documented in case of later legal or regulatory action.		

Risk Control Measures	Present? Yes/No	Comments
Technology Risk		
Formal written policies and procedures exist and implemented regarding the following areas, among others:		
• Healthcare record management.		
• Confidentiality and release of medical information.		
• Maintenance of the healthcare record, including release authorization, retention time and storage security measures.		
• Social media.		
• Faxing of confidential information.		
• Electronic health records.		
• Use of electronic media.		
• Administration of cybersecurity.		
• Use of telehealth.		
Legal/Regulatory Risk		
Written, regularly reviewed policies and procedures address the following areas, among others:		
• Process for handling and taking action on legal and regulatory notices.		
• Process for notification of insurance carrier.		
• Process for mandatory and voluntary external reporting of adverse events and near misses.		
• HIPAA-related patient confidentiality practices and notifications.		
• Billing regulations, both federal and state.		
• Clinical Laboratory Improvements Act (CLIA) regulations.		
• Contractual agreements containing hold harmless and/or indemnification clauses.		
• Termination of the patient-provider relationship.		

Risk Control Measures	Present? Yes/No	Comments
Financial Risk		
Legal contracts are reviewed by legal counsel and other authorized parties prior to execution, then reviewed and renewed annually.		
The following contractual and financial areas, among others, are governed by written policies:		
• Insurance denials.		
• Patient billing and collections.		
• Medicare/Medicaid billing.		
• Managing payments and accounts.		
Hazards		
A hazard vulnerability assessment has been conducted.		
Disaster planning includes identification of back-up resources in the event of a major service disruption.		
An emergency response plan has been developed that outlines the necessary steps to be taken and the responsibilities of the individuals involved.		

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Risk Management Strategies for the Outpatient Setting

Operational Risks

Contents

Adverse Events

A culture of safety is inherently important to the success of a risk management program. Establishing a positive work environment and promoting transparency empowers staff to report adverse events and to be a part of the solution in preventing recurrences. Success also requires a collaborative team approach that includes all providers, staff and managers through encouraging reporting and open dialogue to implement actions to prevent recurrence.

Responding to Adverse Events

The Institute for Healthcare Improvement (IHI) defines an "adverse event" as an "unintended physical injury resulting from or contributed to by medical care (including absence of indicated medical treatment), that requires additional monitoring, treatment, or hospitalization, or that results in death." The Agency for Healthcare Research and Quality has additional information on defining adverse events, near misses and errors. These events may either be preventable medical errors or non-preventable occurrences. Most, but not all, adverse events and/or medical errors that occur in an outpatient setting are related to clinical diagnosis errors, clinical procedure injuries, laboratory test reporting, or medication errors.

Care must be taken to minimize the likelihood of negative outcomes and to prepare providers and staff to respond appropriately if an adverse event occurs.

Proactive risk reduction strategies, such as clinical and operational policy management, use of effective communication techniques and diagnostic test result tracking, among other strategies, may reduce the likelihood of unanticipated clinical events. However, once an adverse event has occurred, prompt identification and management is imperative to limit the impact.

The first priority should be patient stabilization and ensuring prompt emergency treatment, if indicated. Transparent communication with the patient and family regarding the event and subsequent treatment plans enhances trust, minimizing misunderstandings that often lead to litigious actions.

Many states have issued mandatory adverse event reporting requirements with specific definitions of reportable events, and timeframes for reporting, follow-up and investigation. The specific reporting requirements vary by state. In addition, mandatory reporting to state licensure boards vary by state and also should be considered when an adverse event arises. Failure to comply with these mandatory reporting requirements can result in adverse regulatory action against the healthcare entity and involved providers.

Post-event interventions, including trending and analyzing incidents, as well as implementing necessary process, system, and policy changes, should be performed by practice administrators/managers and clinical leaders.

Ongoing training and preparation are critical to loss reduction. Staff members should be aware of:

- How to reduce the risk of events.
- To whom events should be reported.
- How events should be reported, and how quickly.
- Who should communicate with the patient regarding the facts of the event.

After immediate medical care is provided to the patient, the following risk management steps should be taken:

- **Notify** administrative and clinical leadership.
- **Secure any equipment,** medications or supplies involved in the event and remove them from service.
- **Have a provider review the medical facts with the patient** as soon as possible after the event.
- **Postpone sending the patient's bill for services** until the event has been investigated.

Adverse event reports are the most common method for reporting and recording untoward events and near-misses. Near misses are events that, if not interrupted, have the potential to cause harm. The standardized format of the adverse event report enables staff members to clearly, concisely and consistently document anything they witness that deviates from routine care.

Reports

The adverse event report is designed to:

- **Capture** relevant, objective information regarding the event and surrounding circumstances.
- **Notify** management of a potentially serious or actionable situation.
- **Provide** information to management to determine if the situation requires mandatory external reporting requirements to state or licensure boards, the FDA and others.
- **Facilitate analysis** of data to track and trend adverse events and near-misses. By tracking incidents according to the type of event, time of day and department, organizations can identify where and when problems tend to originate, as well as underlying issues, such as staffing levels, training gaps or communication lapses. Incidents should be categorized by both ***frequency*** (i.e. the number of times an event occurs) and ***severity*** (i.e. the event's seriousness and potential impact).

Adverse event reports should include:

- Identity of the party who witnessed or was first to become aware of the event.
- Factual and objective information regarding the event.
- Time and location of the event.
- Names and contact information of any witnesses.
- Description of the patient's condition after the event.

Although a computerized adverse event reporting system permits ease in trending, paper reporting systems also may be utilized. Irrespective of the reporting method, adverse event reports should include factual, objective information regarding the event, including the patient's statement in quotes, if the patient is cognitively able to report what happened. The report should NOT include statements regarding blame or admissions of liability.

When the adverse event report is completed, the report should be reviewed by the individual responsible for receiving and managing the adverse event reporting process, as well as administrative and clinical leadership.

Investigation

An investigation should be initiated as soon as possible after the event, ideally prior to the end of the work day. Conducting the investigation immediately following the event preserves accuracy, as memories fade and perceptions of details vary over time. The scope of the investigation may depend upon the incident type and event severity. The individual responsible for receiving and managing adverse event reports should conduct the initial investigation and determine next steps.

For serious events, a root cause analysis (RCA) team may be assembled. Such a team will include providers, nursing, ancillary staff and practice/clinical managers. This team should continually ask "why" when analyzing the human, process and systems failures that led to the adverse event until all contributing factors are known. For less serious matters, discussion with those who first became aware of the event may suffice. In either situation, the information obtained should identify factors that led to the event so that actions may be implemented to prevent a recurrence.

The investigation should be performed under the auspices of the performance/quality improvement plan, which may help protect the adverse event report and subsequent investigation materials from legal discovery. However, discoverability of adverse events and investigation information varies among states. Investigative findings should be documented on a separate form specifically used for performance improvement activities.

Follow-Up

Educational programs for staff should be ongoing and include information regarding patient safety, adverse event reporting criteria, report completion, the investigative process, and patient safety enhancements as an outcome of the process. Education for those responsible for the investigative process should include the importance of investigative objectivity, witness interviewing skills, use of open-ended questions, and keen listening skills.

Documentation

Care must be exercised when documenting an adverse event in the patient healthcare information record. Factual and objective clinical information, patient treatment, patient response to treatment and follow-up plans, if applicable, should be documented. Reference to an adverse event report, or copies of the adverse event report, should not be included in the healthcare information record.

Adverse Event Policy and Procedure

Detailed written policies outlining the adverse event reporting process should be in place to address the following:

- Definition of an adverse event and near-miss.
- Individual responsible for completing adverse event reports.
- Internal management and administrative notification requirements.
- Details to be included in the adverse event report.
- Documentation in the patient healthcare information record.
- Timeframes for internal and external reporting.
- Individual responsible for external reporting, i.e. state, licensing board, FDA and others.
- Sequestering of equipment and/or supplies if they are suspected of contributing to the adverse event.
- Adverse event report review and signatures.
- Investigation process and timeframes.
- Monitoring compliance with the adverse event reporting process.
- Development of an action plan, responsibility, process, and timeframes.
- Monitoring the effectiveness of the action plan.
- Security, storage and retention of adverse event report form.

Communicating with Patients and Families Following an Adverse Event

As trust is the cornerstone of a therapeutic relationship, it is imperative that providers are skilled in how to communicate transparently with patients in all aspects of care, especially during times of crisis following an adverse event. Offering provider workshops on effective communication and difficult patient conversations may enhance their communication skills. Administrative and clinical leadership should be consulted before any discussions with the patient or family occur in order to ensure a balanced, objective approach is taken.

When an adverse event has occurred, the patient's primary provider should communicate directly with the patient, or the patient's designated healthcare proxy. If possible, communicate in person, preferably in a quiet, comfortable setting. Every effort should be made to accommodate the patient and family regarding place and time. When additional information becomes available, schedule a follow-up meeting with the patient and/or family.

Emphasize facts during the discussion, focusing on what happened and how it may affect the patient's prognosis, if this is known. Be honest with the patient, and do not speculate about the causes of the event. Express empathy without assigning blame or criticizing the care or response of other providers. Be prepared to answer questions about what steps will be taken to prevent such events in the future.

Consult with legal counsel regarding the provisions of the state's disclosure law, as well as any laws addressing apologies to patients and admission of liability.

Sample Adverse Event Report Form

This privileged and confidential incident report is intended for use by legal counsel, in accordance with risk management/quality assurance and peer review activities. This report should not be included in the patient healthcare information record.

Instructions

Complete an adverse event report form within 24 hours of any unusual or unexpected occurrence that is not consistent with the routine operation of the practice or the routine care of the patient. Examples of when a form should be completed include, but are not limited to:

- Delay or complication in diagnosis or treatment.
- Equipment or instrument malfunction.
- Patient fall observed.
- Foreign body retained or missing from an operative site.
- Lack of consent or inadequate informed consent.
- Lost belongings.
- Adverse medication reaction.
- Self-inflicted injury.
- Problem with transfer.
- Violation of patient's rights.

Consult a risk manager/supervisor/administrator if you have questions regarding when or how to complete this form.

Any staff member who discovers or is involved in an adverse event should complete the form and forward it to the administrative department responsible for risk management within 24 hours.

When completing the form:

1. Write clearly, using a ballpoint pen.
2. Clearly indicate the following:
    a. Facility name.
    b. Patient name.
    c. Time of event.
    d. Date of event.
    e. Type of event.
    f. Assessment.
    g. Other requested information.
3. Provide specific information when the "other" category is checked.
4. Be brief and objective.

Immediately notify a supervisor/administrator/physician of any injury and/or life-threatening adverse event.

Background information

Name of healthcare facility: _____

Individual affected: _____

☐ Inpatient ☐ Outpatient ☐ Visitor ☐ Staff ☐ Other (specify) _____

Individual's address: _____

Individual's date of birth (mm/dd/yyyy): _____/_____/_____ Sex: ☐ Male ☐ Female

If individual is a patient:

Healthcare information record number: _____

Attending physician: _____

Primary diagnosis: _____

Service: _____

Referring provider notified (if individual is not a patient): _____

Was next of kin notified? ☐ Yes ☐ No If no, why not? _____

Date and time of event

Date (mm/dd/yyyy): _____/_____/_____ Time: _____:_____ ☐ AM ☐ PM

Location of event

☐ Treatment room ☐ Bathroom ☐ Corridor ☐ Waiting room ☐ Sidewalk/parking lot

☐ Other (i.e., floor, unit, ward, etc.) _____

Type of event

Event type: ☐ Near miss ☐ Actual harm ☐ Other (specify) _____

Medication administration: ☐ Dosage ☐ IV flow rate ☐ Labeling ☐ Omission ☐ Patient misidentification ☐ Reaction

☐ Wrong medication ☐ Wrong IV solution ☐ Other (specify) _____

Fall/found on floor: ☐ Alleged fall ☐ Found on floor/sidewalk ☐ History of falls ☐ Staff lowered patient to floor

☐ Other (specify) _____

Conditions at time of fall (check all that apply): ☐ Wet floor ☐ Dry floor ☐ Obstructed/cluttered space ☐ Poor lighting

☐ Other (specify) _____

Patient rights: ☐ Alleged molestation/rape ☐ Assault by staff member ☐ Assault by other ☐ Improper consent

☐ No consent ☐ Property damaged/lost ☐ Dentures damaged/lost ☐ Patient instructions ☐ Transfer

☐ Verbal/written complaint ☐ Other (specify) _____

Patient behavior: ☐ Against medical advice (AMA) ☐ Attempted suicide ☐ Self-inflicted injury ☐ Elopement

☐ Refused treatment ☐ Other (specify) _____

Diagnosis-related: ☐ Delay in diagnosis ☐ Improper test performed ☐ Physician not available/delayed ☐ Specimen lost

☐ Test ordered – not performed ☐ Other (specify) _____

Other events: ☐ Beverage spill ☐ Fire ☐ Incorrect diet ☐ Other (specify) _____

Equipment/instrument

☐ Unavailable ☐ Defective ☐ Improper use by: ☐ Staff ☐ Patient ☐ Other (specify) _____

Type: _____

Manufacturer's name: _____

Model number: _____

Control number: _____

Removed from service: ☐ Yes ☐ No Date removed (mm/dd/yyyy): _____/_____/_____

WARNING: If the event involves an equipment malfunction, DO NOT RELEASE THIS EQUIPMENT from your supervision without approval from the risk manager/administrator.

Burns (if applicable)

Is the patient able to perceive temperature? ☐ Yes ☐ No

Was patient's skin assessed prior to, during and after treatment? ☐ Yes ☐ No

Was heat/cold source properly padded and timed? ☐ Yes ☐ No

Did patient complain of burning sensation or pain during treatment? ☐ Yes ☐ No

Assessment

Pre-event status of individual: ☐ Oriented ☐ Disoriented

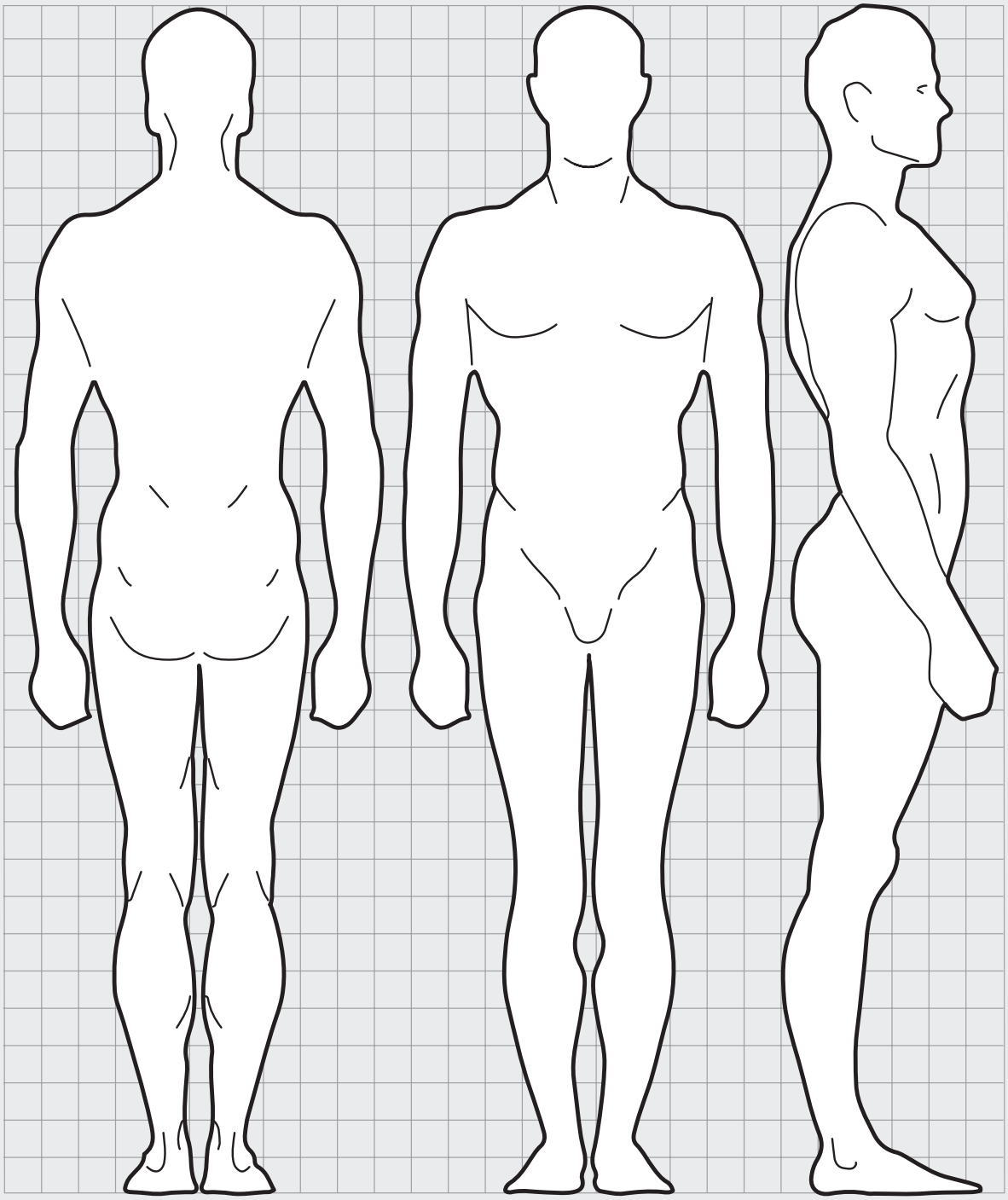
Check all that apply, illustrating on the diagram the position/place of injury, if any:

☐ No apparent injury ☐ Abrasion/contusion ☐ Anaphylaxis ☐ Burn

☐ Concussion ☐ Death ☐ Extravasation/infiltration ☐ Foreign body ☐ Fracture ☐ Hearing/visual impairment

☐ Hematoma ☐ Hemorrhage ☐ Infection ☐ Injury to/loss of organ infiltration ☐ Laceration ☐ Loss of consciousness

☐ Loss of limb ☐ Perforation ☐ Pneumothorax ☐ Rash/hives ☐ Spinal cord injury ☐ Other (specify)



Description of event

Describe the event and context in which it occurred. Record facts only, not opinions.

_____

_____

_____

Follow-up

Examining physician's name: _____

Specialty: _____ Date of examination (mm/dd/yyyy): _____/_____/_____

X-ray: ☐ Yes ☐ No ☐ Refused

If yes, specify X-ray type and pertinent findings. _____

Treatment: ☐ Yes ☐ No ☐ Refused

If yes, describe treatment. _____

Emergency department referral/transfer: ☐ Yes ☐ No ☐ Refused

If yes, indicate destination and method of transfer (e.g., wheelchair, stretcher, ambulance, helicopter, etc.).____

Report completed by

Name (print): _____ Title: _____

Signature: _____ Report date (mm/dd/yyyy): _____/_____/_____

Report reviewed by

Name (print): _____ Title: _____

Signature: _____ Review date (mm/dd/yyyy): _____/_____/_____

Witnesses

List the individuals who witnessed the event.

Name: _____ Phone number: _____

Address: _____

Name: _____ Phone number: _____

Address: _____

This sample form is for illustrative purposes only. As each practice presents unique situations, and statutes may vary by state, it is recommended that you consult with your attorney prior to use of this or similar forms in your practice.

Quality Improvement Fundamentals

Most inefficiencies and errors in healthcare settings are the result of failures in processes related to communication, the appropriate use of clinical protocols, healthcare information record documentation, scheduling and patient education. These failures can be more easily identified and corrected in settings that work to empower staff. Staff should understand that they are accountable for the processes they implement. Managers should provide staff with the resources necessary to fulfill their duties and grant them the authority to address issues that arise.

Culture of Safety

The safety culture of an organization represents a combination of attitudes and behaviors designed to promote patient safety. Creating a culture of safety is an essential component in the reduction and prevention of patient harm and improving the quality of care and services.

Key elements demonstrating an organization's commitment to a culture of safety include:

- Recognition of the high risk nature of patient care and a commitment to consistently providing safe care.
- Maintaining an environment where staff feel comfortable in reporting and discussing errors and near-misses without fear of reprisal.
- Establishing zero tolerance and requiring individual accountability for reckless behavior versus human error regardless of the existence of harm or severity of harm.
- Collaboration/teamwork across ranks and disciplines to find solutions to patient safety concerns.
- Commitment of resources responsive to patient safety initiatives.
- Analysis of system, process and human factors that contribute to errors, near misses, unexpected outcomes, and patient complaints.

Variations in the perception of safety may exist among staff, which is often due to variations in how patient safety events have been managed across the organization. Leaders and managers should be cognizant of the issues that staff encounter and understand what guides their behavior.

The first step in achieving a culture of safety is to survey providers and staff through the use of a standardized tool. AHRQ's Survey on Patient Safety Culture™ (SOPS®)and the Safety Attitudes Questionnaire.

Perception by staff of an inferior safety culture has been linked to increased error rates. Results from the AHRQ perception survey on safety culture measure responses around teamwork training, executive walk rounds, establishing safety teams, and use of structured communication.

Structured communication is a systematic approach to communication that focuses on organizing and controlling the flow of information so that information communicated is more accessible, prompt, appropriate and meaningful. Standardized communication strategies also assist the recipient of the information in taking or directing action to be taken. Examples of structured communication techniques are:

- Situation-Background-Assessment-Recommendation (SBAR)
- Illness-Patient Summary-Action List-Situation Awareness/ Contingency Planning-Synthesis by Reviewer (IPASS)

Basics of Quality Improvement

Quality improvement is the framework to systematically monitor and evaluate processes and systems that impact patient care in order to standardize practice and reduce variation, thereby increasing the probability of achieving the desired outcome. Quality improvement:

- Is internally driven, empowering all employees to participate in achieving improvements
- Focuses on improving systems and processes
- Proactively prevents problems and errors by monitoring and improving processes
- Continuously aspires to improve quality

Risk management and quality improvement are aligned in their focus on safety and positive outcomes. Continuous reporting and monitoring of adverse events facilitates the identification of process and system failures that cause or contribute to negative outcomes, thereby enabling preventative action to be taken before serious adverse events occur.

A suggested framework for quality improvement is the Plan Do Study Act (PDSA) model developed by W. Edwards Deming This cyclical process is designed to determine whether the planned change leads to improvement. The model can be used on large and small scale projects and will facilitate the creation of successful improvement plans.

PDSA Cycle

Plan

Plan the pilot test by defining the problem and designing a solution. Predict what will happen and why. Develop a plan to test the change (solution). Who? What? When? Where? What data must be collected?

Do

Test the plan on a small scale. Collect data. Document problems and unexpected outcomes, including successes. Begin analysis of the data.

Study

Analyze the data and determine where adjustments to the plan are needed. Re-test. Collect data and analyze again until the desired outcome is achieved. Finally, continue to test the plan on a larger scale to confirm that the plan performs as designed.

Act

Once the plan has been tested and proven to be effective in resolving the process or system issue, take action to implement the plan on a facility-wide basis. Ongoing monitoring will reveal if and where additional revisions are needed.

Data Collection and Monitoring

Data on key clinical and operational processes should be systematically collected and analyzed to identify potential failures that may lead to patient injury or adverse outcomes. Data collection may include manual review of healthcare information record documentation or computer data collection measured against established benchmarks or expected standards. Direct observation of processes may provide insight on behavioral variations and workarounds, thus revealing weaknesses and failures that should be addressed to achieve an effective and efficient approach.

Establishing key performance metrics provides opportunity for data collection, monitoring and improvement of processes, systems, and decrease in variation among staff in implementing tasks, such as the following:

Process measures

- Medication reconciliation discrepancies
- Ordered tests that are not performed
- Unreported and/or undocumented test results
- Misplaced or mislabeled specimens
- Lack of follow-up on significant missed appointments
- Excessive patient wait times
- Monitoring compliance with infection control measures and handwashing procedures
- Failure to perform time-out procedures
- Errors in surgical instrument/sponge counts

Outcome measures

- Patient satisfaction surveys
- Adverse drug reactions
- Patient or visitor accidents
- Facility acquired infection rates
- Surgical complication rates
- Retained foreign body post procedures
- Mortality rates

Accreditation

Voluntary accreditation of an outpatient facility and/or office-based surgical practice (OBS) by an independent third party is typically viewed by state medical boards and patients as a sign of commitment to quality and patient safety. In order to achieve accreditation, outpatient facilities and/or provider practices must participate in ongoing self-evaluation, peer review and education. The outpatient facility and/or practice also typically commits to an onsite survey by the accrediting body at a cadence determined by the accrediting body.

Several states either require or encourage accreditation for settings where conscious or deep sedation/analgesia and general anesthesia are provided. In some states, accreditation may serve as a substitute for a state-mandated and administered inspection.

Each state determines acceptable accrediting bodies and whether accreditation may be used in lieu of a mandatory state inspection. The Joint Commission provides examples of state reliance on accreditation and certification. Several states permit only accredited office settings to provide higher levels of anesthesia.

Some of the most commonly recognized accrediting bodies for outpatient settings and provider practices include:

- Accreditation Association for Ambulatory Health Care (AAAHC).
- Accreditation Commission for Health Care (ACHC).
- QUAD A
- The Joint Commission (TJC).
- National Committee for Quality Assurance (NCQA).
- National Dialysis Accreditation Commission (NDAC).

Healthcare Information Management

The paper or electronic patient healthcare information record serves two major purposes: communicating information within and outside the practice, and creating a written history in the event of later questions or challenges. It serves as a place for objective documentation of all phases of medical treatment, including the assessment, planning of care, laboratory and diagnostic testing, procedures performed and medication provided. It also provides a place to document the patient's response to treatment and changes in their condition.

Because complete, accurate and legible health records are integral to the provision of quality care and for risk management purposes, every organization should have a written documentation policy and all staff members should be trained in proper documentation practices. The policy should address, among other issues, patient confidentiality and the release and retention of patient healthcare information records.

Healthcare Information Record Completion

Timely completion of the healthcare information record is required to ensure its accuracy and completeness. Although record systems, organizational procedures and staffing levels vary with each outpatient setting or facility, establishing policies and procedures on timely documentation will support service quality, patient safety, appropriate reimbursement, and effective risk management. Guidance for provider documentation from the Centers for Medicare and Medicaid (CMS) recommends documentation of services provided to a patient should "occur as soon as practicable to maintain an accurate medical record."

Although there is no specific and universally required timeframe, professional organizations, private medical insurers, patient safety organizations and other stakeholders often recommend or suggest that completing documentation within 24 to 48 hours of services is "timely" and "practicable." On occasion, 48 hours may not be feasible due to circumstances beyond a provider's control. However, these should be rare events, rather than standard practice.

Patient Healthcare Information Record Contents

The patient healthcare information record should include a comprehensive picture of the patient's entire course of treatment. At a minimum, the record should include:

- Identifiable patient information.
- An accurate and current problem list.
- A medication list updated at every patient visit.
- A listing of food, medication and environmental allergies, highly visible in the front of the file.
- Laboratory and diagnostic test results.
- Advance directives.
- Consents and authorizations.

In addition, the record should include a comprehensive history and physical that addresses:

- The chief complaint(s).
- A review of symptoms.
- Past medical history.
- Screening and/or diagnostic test results with associated analysis and treatment recommendations.
- Family history.

At a minimum, the following facts, events and interactions should be documented:

- **A current summary of the patient's condition** including, but not limited to, presenting problems, clinical findings, assessment, treatment plan and the outcome of the prescribed treatment.
- **Any and all advice and instructions** provided to the patient.
- **Patient education provided, both spoken and written,** noting the educational resources that were given and the patient's ability to comprehend.
- **Instructions for a return visit** to the office for follow-up testing, treatment or consultation.
- **Referrals to other providers,** tests or therapies.
- **Missed or canceled appointments,** including efforts to contact the patient.
- **Receipt of test results and subsequent actions taken,** as well as referral procedures and consultations, which should be signed or initialed by the provider before filing.
- **Discussions with patients regarding abnormal test results,** including recommendations for treatment and the patient's response.

- **Informed consent discussion** or informed refusal of treatment.
- **Prescription refills,** including the name of the pharmacy.
- **Documentation of medications administered, prescribed or distributed,** including sample medications, with corresponding discussion of potential side effects and other instructions.

General Documentation Guidelines

The following general documentation principles can help providers maintain a consistent, professional patient healthcare information record:

- **Ensure that notes are legible,** include the date and time of entry and are signed.
- **Remember that some entries may require countersignatures** (e.g., authenticating a physician assistant's note).
- **Avoid subjective comments** about the patient or other healthcare providers.
- **Correct errors in a paper record by drawing a single line through the entry to be changed.** Sign and date the correction and make a notation to indicate the reason for the change.
- **Do not remove, delete or obliterate notes.** Removing, altering or destroying any part of a record may suggest an intention to purposely conceal an error or obscure the facts.
- **Document actions and patient discussions as soon as possible after the event.** Late entries should include the date and time of the entry, along with the statement, "late entry for ___ " (i.e., the date the entry should have been made).
- **When dictating notes, include all vital information,** including date of dictation and transcription.
- **Sign transcriptions** and write the date of the approval or review.
- **Never alter a record or write a late entry** after a professional liability claim has been filed.
- **Develop a list of approved abbreviations** for use in documentation. Review and revise the list as necessary, and at least annually.
- **If using a form, complete every field.** Do not leave any lines blank

Electronic Healthcare Records

Electronic healthcare records (EHRs) have positively impacted patient safety, clinical teamwork and operational efficiency. The effectiveness of EHRs depends upon many human and technical factors. The risk of error and other unintended consequences is especially acute during the period of transition from a familiar paper-based record to a new, multi-purpose electronic system.

If a provider or outpatient facility plans to implement or replace an EHR system, consider the potential benefits of "certified health IT." This certification program represents an important element in helping to ensure that the nation's health IT infrastructure becomes a connected and interoperable tool, rather than a disjointed set of stand-alone systems. Access further information on the HealthIT.gov website and consult with qualified IT professionals.

Irrespective of the medium for storing the patient's healthcare information record, basic risk management principles apply. The record must be comprehensive and accurate, and the patient's privacy must be protected. Use of EHR technology makes effective security and confidentiality measures even more critical.

The following measures may help reduce liability risks associated with EHR use:

- **Require providers to review, edit and approve dictated information** in a timely manner.
- **Mandate that documentation by "scribes" be authenticated** by individual providers.
- **Establish a patient identification integrity program** that monitors error rates and duplicate records.
- **Ensure that key patient identifiers are accurate,** in order to effectively link records within and across systems.
- **Determine what changes can be made in records,** as well as who can make them, when they can be made, and how they are tracked and monitored.
- **Implement measures to minimize the possibility of human error,** such as reviewing input data for accuracy, visually confirming bar-coded or other program code entries, and performing documented audits.
- **Limit connections to other computer systems,** to the extent possible.

- **Establish the following electronic security strategies:**
  - Ensure compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule requirement for covered entities by performing a security risk assessment.
  - Include the privacy officer in discussions whenever new services, technology or new users are added.
  - Require different passwords for all laptops, desktops and portable devices.
  - Encrypt confidential data on all devices and portable media.
  - Have privacy and security officers review and approve social media sites.
  - Develop an auditing system for practice records.
  - Ensure that laptops are never left in unattended areas.
  - Control the use of personal mobile devices.
  - Develop and maintain an equipment inventory log.
  - Ensure that all laptops have cable locks or lockable docking stations.
  - Change passwords on a routine basis.
  - Do not permit sharing of passwords or the taping of passwords to the computer, screen or keyboard.
  - Utilize strong passwords for all remote access applications.

Downtime, Scanning and Workarounds

No EHR or computer system is fail-safe. If IT problems or power outages occur, providers and support personnel may not have access to the EHR for hours, days or longer. Develop and implement policies and procedures to help address system downtime or outages due to weather events or other emergency scenarios. Cloud-based systems and/or back-up may be one approach. Consult with IT professionals and EHR vendors to help assess solutions that will prevent or minimize documentation gaps in the EHR.

Whether during the transition to an EHR or with established systems, scanning of paper documents will be necessary. Scanning frequency will depend upon many factors, including the EHR's capabilities and interoperability. Ensure and validate that scanned documents may be catalogued, filed and retrieved, similar to native electronic documents and records.

Clinical users will seek creative ways to work around an EHR system if its functions lack flexibility or fail to reflect and support actual clinical practice. Left unmonitored, such improvisations can seriously undermine patient safety. To avoid this hazard, EHR implementation plans must balance user needs and preferences with patient safety considerations.

Hybrid Records and Transition to EHR

Many providers utilize "hybrid" records, which encompass both paper and digital records, during the transitional period, while reviewing and meshing the EHR system with existing work practices.

During this hybrid phase, it is important to assess staff members' computer skills and readiness in order to navigate between paper and electronic formats. Lack of transitional planning and training can result in confusion, resistance and errors, potentially leading to breakdown even before the system is fully implemented.

To simplify the transition, consider the following risk management interventions:

- **Determine the components of the patient healthcare information record that will remain in paper form during the transition,** and devise policies to protect and preserve data maintained in a hybrid state.
- **Identify areas of potential duplication across paper and electronic systems,** and reduce or eliminate potentially confusing redundancies, especially in the high-risk areas of medication prescription and administration, allergy notation, and follow-up on laboratory and diagnostic reports.
- **Establish written parameters for the use of paper notes in the hybrid record** in order to reduce the risk of missing or inconsistent electronic documentation.
- **Ensure that staff members possess necessary IT competencies before proceeding with EHR implementation.** Consider evaluating skills of staff members and documenting results.
- **Acknowledge the increased workload implications of a newly implemented EHR system,** and provide appropriate support in the form of a call center, additional hands-on training and/or reduced patient loads for clinicians during the transition period. If necessary, assign additional IT staff to clinical settings to assist.
- **Pilot new EHR modules i**n order to identify glitches, make corrections, and increase staff members' proficiency and sense of ownership.
- **Encourage EHR users to provide comments, suggestions and other input on an ongoing basis.** Document follow-up on all verbal and written suggestions and complaints.
- **Consider scheduling regular staff forums to educate staff about EHR and sound communication practices,** as well as to encourage questions and discussion.

- **Monitor system interfaces for changes in user behavior.** If a common workaround is detected, instruct clinicians to utilize recommended procedures until the risks and benefits of the alternative method are thoroughly understood and the workaround is either approved or prohibited. In addition, analyze problematic clinical processes to better understand why end-users believe that they are compelled to circumvent standard procedures.
- **Retain vendor guidebooks, resources, protocols and programs for reference** in the event of a professional liability claim involving system design or utilization.

Access additional resources and information on EHR transition on the HealthIT.gov website.

Copy and Paste Practices

Clinicians commonly use copy-paste and copy-forward functions to document information within EHR systems. The practice – often referred to as "cloning" – involves selecting some or all of a prior note and replicating it in another entry in the EHR, or repeatedly copying forward a prior notation to create a series of entries. When appropriately utilized in accordance with standardized guidelines, this practice can save time for busy providers without compromising care. However, reflexive use of such shortcuts may result in serious patient mishaps, as well as violation of HIPAA privacy rules, federal and payer audit requirements, and fraud and abuse regulations.

Cloning also may adversely affect the ability to defend professional liability claims by raising questions about the record's credibility. As a consequence, costly forensic analysis may be required in order to refute allegations of negligent dissemination of erroneous information. The misuse of copy-paste and copy-forward functions creates vulnerabilities when patients receive care from multiple healthcare providers who primarily rely upon the EHR to communicate patient diagnostics and treatment plans. In the absence of direct communication between treating providers, erroneous or outdated information may be mistaken as truthful. Such information may influence clinical decision-making and potentially expose providers to claims based upon delayed diagnosis, failure to diagnose and misdiagnosis.

Consider the following risk management recommendations, among others:

- Incorporate regulatory and industry standards regarding the proper use of copy-paste and related functionalities into IT governing policies, EHR documentation guidelines and training programs. (See ECRI Institute's "Copy/Paste: Prevalence, Problems, and Best Practices.")
- Avoid repetitive copying and pasting when documenting high risk items, such as laboratory results, radiology reports and drug formulations.
- Review and update any shared information found elsewhere in the EHR before pasting it into current entries, especially problem lists, diagnoses, allergies, current medications and relevant medical history care across the continuum.
- Expressly prohibit the following risk-prone functions:
  - Copying-pasting text from another clinician's note without accurate attribution, which may constitute medical plagiarism and lead to allegations of billing fraud.
  - Deleting original source text or data and inserting it elsewhere in the record, thus altering the initial entry and compromising documentation integrity.
  - Carrying forward information – such as prior medical history or diagnostic results – that is readily available elsewhere in the EHR, creating clutter and that may adversely affect the readability and usefulness of the record.
- Monitor the copy-paste conduct of providers and institute corrective action when the following "red flags" are observed:
  - Copying of outdated and/or redundant information.
  - Inconsistent progress notation.
  - Unnecessarily long progress notes (AKA "note bloat").
  - Notes that cannot easily be authenticated, dated or attributed to an original author.
- Measure the level of compliance with copy-paste protocols for clinicians who create notes in the EHR, and include findings in the annual performance review process.
- Consider disabling the EHR system's copy-paste function if inappropriate copying and pasting of entries becomes a chronic problem.

Template Documentation

EHR vendors offer various tools – including template documentation and population via default – designed to make writing notes easier, while minimizing the hazards of duplication.

Templates feature predefined text options targeted to specific conditions and procedures, while populating via default involves one-click data entry to indicate normal status.

When using these forms of documentation, commonly referred to as documentation by exception (DBE), entry of negative or out-of-the-ordinary findings must be entered separately. EHR templates create a high risk for "cloned" documentation. Moreover, failure to enter negative or extraordinary findings may lead to allegations of deficient care and may be difficult to defend in the event of litigation.

Consider the following actions to strengthen EHR practices:

- **Assess whether vendor-developed templates adequately support recommended work practices.** If they do not, adjust them to accurately reflect current protocols, standards and regulations.
- **Include a variety of input controls** to facilitate the capture of all relevant findings, both normal and abnormal. Possibilities include right-left-bilateral confirmation, positive/negative notation, and multiple-choice text and number features.
- **Incorporate voice recognition and text-entry tools** in order to document subjective observations to support template use and permit patient-specific variability.
- **Create a section within templates for relevant past medical history, positive findings on exams and answers to "red flag" questions.** For example, on a strep throat template, include prominent prompts for fever, headache, rash, and a history of heart valve or kidney problems.
- **Perform quality audits to track incidence of "scribing,"** i.e., the overwriting of one practitioner's authenticating notes by another. Audits also should identify clutter-prone templates and DBE practices (e.g., when routine patient encounters produce more than one or two pages of documentation).
- **Prohibit staff from tampering with the EHR audit trail capability.** Explain that the function is necessary and that tampering with the audit trail (metadata) may result in serious legal consequences for both the individual and the organization in the event of a claim or lawsuit.

Patient Problem List Maintenance

Accurate patient problem lists are essential to effectively manage patient populations and to provide care across multiple sites. However, keeping problem list data relevant and up-to-date can present challenges due to the large number of disciplines and services – ranging from IT, medical staff and nursing to billing, quality management and clinical departments – involved in the compilation process.

Because of the many contributors, problem lists tend to accumulate a wide variety of symptoms, health factors, diagnoses and ICD code descriptors. If not reviewed and updated on a routine basis, lists may become pervaded with obsolete and irrelevant information, potentially compromising quality and continuity of care.

To avoid this situation, clearly define the purpose and scope of the problem list, focusing on these critical functions, among others:

- **Facilitating continuity of care** between patient visits.
- **Recording medical conditions** for treatment and reporting purposes.
- **Coordinating communication during patient transitions** between settings and care providers.

The following measures can help ensure that problem lists do not engender problems:

- **Create a written procedure for developing, updating and reconciling problem lists** in the following medical situations, among others:
  - Primary care: at the end of each episode of care and annually, at a minimum.
  - Specialty care: at the end of each episode of care.
  - Responsible provider: upon discharge from an inpatient or outpatient setting.
- **Authorize only selected individuals to make or change entries in patient problem lists,** and instruct them to use an approved standard vocabulary for problem list notation.
- **Strictly prohibit the use of problem lists as a source of billing data,** a tool for revenue management or a substitute for a final diagnosis list in discharge summaries.
- **Establish timeliness requirements for problem list entries and audit activities.** See Qualis Health's resource "Standardizing the Problem List in the Ambulatory Electronic Health Record to Improve Patient Care."

Every covered entity/provider that is subject to regulations promulgated under HIPAA and the Health Information Technology for Economic and Clinical Health (HITECH) Act is expected to know and comply with its requirements.

HIPAA, a federal law, serves as the "floor" for patient information security. In states with privacy requirements that are more stringent than HIPAA, state law prevails, whereas HIPAA preempts state law in states where HIPAA is more stringent. Therefore, one must be aware of applicable state privacy requirements in order to determine whether state or federal laws or regulations apply.

HIPAA protects the privacy of all personal health records and other individually identifiable health information used or disclosed by a covered entity in any form – electronic, paper or oral. It also confers significant rights upon patients to control how their protected health information (PHI) is used. The law guarantees patient access to health records, requires patient consent before information is released in most routine situations and provides recourse to patients whose privacy protections are violated.

Under HIPAA, healthcare providers must present a written explanation or notice of both the privacy policies of the practice and the privacy rights of the patient. The notice must be supplied to patients during their first office visit and to individuals who request the information. Also, a copy must be made available in the patient waiting area.

Providers also must make a good faith effort to ensure that patients acknowledge receipt of the privacy notice when they begin receiving care. Signed acknowledgments of receipt should be retained in the patient healthcare information record. **Model notice of privacy practices** are available for download from U.S. government sources.

With advances in technology, including the ubiquitous availability and use of smart phones, the recording of image, audio and video in healthcare settings has become a primary concern for the privacy and security of PHI. Recordings (still images, audio or video files) captured in the outpatient setting may or may not include or represent PHI and may or may not be a part of the healthcare information record. In addition, the ease with which recordings may be created, saved and or posted online represents a significant potential to violate the privacy and rights of patients and providers alike.

Outpatient facilities and providers should develop policies and procedures to address and clarify when such recordings:

- may be captured by providers and other staff;
- may be captured by patients, parents or guardians of the patient;
- must be included in the patient healthcare information record.

In all cases, policies must consider and comply with state and federal law. Consult with legal counsel and other experts to address this complex issue.

HIPAA and HITECH are complex laws, and violations can have serious consequences. If questions arise, consider consulting with an attorney who is conversant with both state and federal health-care privacy laws and regulations. Compliance resources also may be obtained from many professional organizations. HealthIT.gov offers an extensive amount of information, tools, templates and educational materials to assist providers with training and compliance.

Electronic Communications in Healthcare

Electronic communications with patients is common practice in healthcare today. Although such communications may be convenient and efficient, they frequently involve patient care information or other PHI. The risk of inadvertent PHI disclosure must be recognized and mitigated. Healthcare organizations must ensure that security and privacy measures are no less robust than for internal communications and storage of PHI. To minimize electronic communication security risks, practices should establish written policies and procedures on appropriate use and ensure that such communications relating to patient care are captured in the healthcare information record.

Although facsimile (fax) transmissions are used less often than email and text messaging, this form of electronic communication is still commonplace. Consider the following issues for fax communications, among others:

- Where the fax machine is located.
- Who has access to the machine.
- What information is on the standard cover sheet (e.g., a confidentiality statement).
- Who monitors incoming transmissions and delivers them to the appropriate person.
- What safeguards exist to protect patient information.
- What procedures exist to handle misdirected facsimile transmissions.
- Whether faxed patient authorizations and signatures are acceptable (e.g., healthcare information record release forms).
- What process is utilized to ensure that faxed documents have been received by the patient or third party.

The speed and convenience of electronic mail (email) and text messaging have led to extensive use of these electronic communication methods throughout healthcare. Email may be preferred for business communications, more lengthy messages and exchange of file attachments. However, both email and text messaging are ideal for answering health questions and discussion of relatively simple matters with patients and other providers. As a result, workplace emailing or text messaging may violate privacy and security requirements imposed under HIPAA and the HITECH Act, as inadvertent transmission of PHI to an unauthorized third party may occur.

Privacy issues also arise when clinicians answer patient email and text messages from an unsecured location, such as home computers, tablets or smartphones, as any PHI would be maintained by the Internet provider and cannot be considered protected. Therefore, the use of HIPAA-compliant encrypted email systems and other methods to protect electronic patient-provider communication is strongly recommended. One common method is the use of a secure portal for exchange of PHI.

Email and text messages also have liability implications. Increasingly, plaintiff attorneys are requesting disclosure of relevant messages during the discovery process of malpractice litigation. For this reason, and because patient care-related messages constitute a form of progress note, each message received and the reply sent should be included in the patient healthcare information record. How this occurs, or the steps necessary to ensure complete documentation, may vary according to the EHR system.

Another option to examine for secure healthcare communications is "Direct Secure Messaging," launched as part of a public-private partnership to facilitate secure point-to-point communications between healthcare providers. Additional details on this topic may be accessed on the HealthIT.gov website.

Remaining current on privacy issues is imperative, especially as electronic communications and EHR systems evolve. Developing and maintaining effective policies and procedures, training staff on an ongoing basis, and evaluating the risks and benefits of communicating electronically with patients will keep privacy practices current.

Record Retention, Storage and Destruction

Record storage, retention and destruction are essential components of a complete healthcare information management program. Policies and procedures should be created and implemented in order to ensure consistency and legal/regulatory compliance with federal HIPAA and any state requirements. Whether a patient is in the midst of care or has moved to another practice, the healthcare information record must be appropriately maintained and retained in a form that permits clinical care and treatment continuity and also complies with federal and/or state privacy, security and legal requirements until the records may be purged and destroyed. Privacy and security concerns also arise when records are to be purged and destroyed.

EHRs and decreasing costs for high capacity digital storage solutions make long-term storage more feasible than with paper records. Paper and/or electronic healthcare records should be maintained beyond the statute of limitations for any legal and/or administrative liability exposures.

State professional liability statute of limitations prescribe the period of time within which a lawsuit can be filed giving the injured party time to assess the situation. However, the statute of limitations for filing medical malpractice actions varies from state to state, and many states create exceptions for minors, mentally disabled/impaired adults, or those who are incarcerated.

Even in cases not involving minors or mentally disabled/impaired adults, other circumstances may result in the statute of limitations being suspended, or "tolled," permitting plaintiffs to have their cases heard many years after the legal window of opportunity was believed to have closed.

Most states also have enacted record retention statutes which require retaining records for a minimum number of years. (Certain states do not expressly address the issue of medical record retention.) Such laws may be part of various state professional practice acts or other legislation, and often far exceed the timeframes of the statute of limitations. Consult state licensing board regulations for specific requirements.

Professional associations may be another source of up-to-date information regarding record retention requirements. Note, however, that some state record retention requirements may be significantly shorter than the retention period recommended by insurers or attorneys from the perspective of protecting the provider's legal interests.

In states without record retention laws, consult an attorney familiar with healthcare law for a recommendation. Attorneys also may base the recommendations on rulings from legal cases involving record keeping issues, as well as state statute of limitations requirements. To summarize a few key points:

- If permanent retention is not practical, maintain patient records for at least the minimum amount of time required by state professional practice acts or statutes. In most states, 12 to 15 years for adult records is sufficient.
- Note that HIPAA requires that patient consents for disclosure and use of PHI be retained for six years from the date it was last in effect.
- For electronic records, consider implementation of certified health IT systems. Also consider future storage capacity needs, the long-term viability of the EHR vendor, potential obsolescence of systems and the vendor's plans for backward/forward compatibility as technology and standards change and evolve.
- Appropriate and secure system back-ups and/or data mirroring must be in place.

In addition to vendors specializing in the secure destruction of health information records, many public resources exist to help identify important considerations. Among these are a fact sheet on the disposal of PHI from the U.S. Department of Health and Human Services.

Key points to consider for health information destruction include:

- Implement appropriate administrative, technical and physical safeguards to protect the privacy of PHI that will be destroyed, whether in paper or electronic form.
- Prohibit the disposal of PHI in public receptacles such as dumpsters or trash receptacles.
- Render paper records essentially unreadable and indecipherable, such that they cannot be reconstructed.
- Utilize acceptable destruction methods such as purging (degaussing or exposing the media to a strong magnetic field) or physical destruction (disintegration, pulverization, melting, incineration or shredding).
- Ensure destruction is performed by qualified vendors (business associate under HIPAA) that comply with legal and regulatory requirements in the destruction of PHI.

Release of the Healthcare Information Record

The HIPAA Privacy and Security Omnibus Final Rule clarified and strengthened various existing requirements under the HIPAA Privacy Rule, HIPAA Security Rule, and the HITECH Act breach notification provisions.

The HIPAA Privacy Rule states that specific patient consent for the use and disclosure of a patient's PHI is not required for purposes of ***treatment, payment*** or ***healthcare operations*** (e.g., quality improvement and assessment, accreditation, credentialing, case management activities).

However, the Omnibus Final Rule also:

- **Extends the Privacy and Security Rules** to a covered entity's business associates and contractors.
- **Establishes new limitations on the use of PHI** for marketing purposes.
- **Expands patient rights to request/receive copies of health records** in electronic format.
- **Strengthens patients' ability to prevent disclosure of information to health** insurance plans.

Apart from these conditions, all staff should be cognizant that, absent a court order, patient information must not be released to anyone without the patient's written consent. This prohibition includes releasing records to spouses, parents of adult children, children of aged parents, siblings, work associates, and, in some situations, insurance companies and governmental agencies (e.g., state medical board investigators). In addition, attorneys representing patients are required to have written patient authorization to obtain a copy of their client's healthcare information.

The release of information in the context of referrals to or consultations with other healthcare providers would probably be construed as treatment as defined above. However, it is important to note that state laws pertaining to the release of confidential patient information may be more stringent than federal HIPAA requirements. In those states, authorization may be required. It is prudent to obtain express patient authorization for disclosure whenever one is uncertain or uncomfortable about sending copies of medical records.

Providers may request that patients provide written authorization to obtain a copy of their own healthcare information record. However, unless required by state law, patients may refuse to do so. Irrespective of the circumstances, ensure that all requests and the provision of record copies to the patient or third parties are documented in the healthcare information record.

In addition, the Omnibus Final Rule permits disclosure of PHI without patient authorization under four circumstances:

1. Pursuant to legal process or as otherwise required by law.
2. To locate or identify a material witness, missing person, suspect or fugitive.
3. Under specified conditions regarding a crime victim.
4. If a covered entity believes PHI constitutes evidence of a crime committed on its premises.

Thus, PHI may be disclosed without patient consent under court order, subpoena, in medical malpractice litigation, under mandatory reporting laws or in connection with governmental audits. For example, by filing a medical malpractice lawsuit, the patient has waived disclosure prohibitions. If any concerns arise regarding the release of records, consult an attorney conversant with healthcare law.

The following additional information and suggestions may help reduce liability associated with the release of confidential patient information:

- **Although the patient has the legal right of access to all information in the record, it is the provider who owns the healthcare record** and all associated diagnostic information.
- **Never release original records,** only copies or duplicated digital files.
- **Respond to patient requests for healthcare records in a reasonable time and manner.** Refusing to transfer records due to unpaid healthcare bills is a violation of the law in most states. While the federal government requires that healthcare providers act within 30 days after receiving a request for records, some states call for a more rapid response. Check with an attorney or the state board of medicine to determine applicable requirements.
- **Do not overcharge for copying medical records.** If unsure of a reasonable charge, ask a copying or duplicating service. Note that some states have adopted specific requirements and limitations on such charges. Consult an attorney or state licensing board to confirm state-specific rules.
- **Document the request and the date that the copied records were sent or picked up** in the patient healthcare information record. Failure to make such a notation may raise issues if a lawsuit is filed, and a copy of the patient record contains information differing from what is on file in the office.
- **Ensure that records that are released by mail are sent certified and registered mail** with a required return receipt. The certified mailing receipt and return receipt should be placed in the patient's healthcare information record.

- **Release only the records that are specifically requested.** The outpatient facility's internal procedure should include confirmation with the provider or other appropriate authority of the records to be sent before mailing paper records or sending electronic records. Verify that all relevant information – and only relevant information – is included.
- **Assign a specific individual or department to process information release requests,** including associated documentation.
- **Retain signed authorization forms in the patient's healthcare information record,** with a note specifying what information was released and to whom. The form should include:
  - The name of the releasing office and the receiving facility.
  - The patient's full name, address and date of birth.
  - The extent or nature of the information to be released, with specific reference to treatment date, event or condition.
  - The date the consent was signed and the date the authorization will expire.
  - The notarized signature of the patient or legal representative.

Whether released in paper or electronic format, the provider is responsible for protecting the privacy and security of the healthcare information record.

Privacy and security for paper records must be maintained until the records are given directly to the patient or authorized third party or, alternatively, until records are sent by fax, mail or courier service.

The security of electronic records and files must be protected (typically by appropriate encryption technology) during the delivery process, such as when sending by email, making records available for viewing on-line or download by the patient or third party, or when records are stored on flash drives or other portable media.

Consent for Electronic Information Exchange

As more providers and healthcare organizations transition their healthcare information records to EHRs, real-time information exchange will be realized more widely in the healthcare environment. This process is labeled "electronic health information exchange" (eHIE). In many cases, this exchange is facilitated by third-party organizations, called a health information exchange organization (HIE).

Broader access and exchange of PHI and other health information among providers and healthcare organizations may provide a range of benefits, including:

- A reduction in medical and medication errors
- Elimination of unnecessary and/or redundant communication processes and paperwork, improving efficiency
- Improved public health data and reporting
- Better provider access to decision support tools and information
- A reduction in healthcare-related costs
- Improved healthcare quality and patient outcomes

Although the transition to EHRs and improved access to health information has many potential benefits, no system is perfect. New processes require due diligence in order to address and mitigate potential risks. Remaining current on electronic information laws and regulations, consulting with information technology companies and consultants knowledgeable in the exchange of health information, and seeking legal counsel, when necessary, are all important aspects of due diligence.

As eHIE increases, patients must be able to understand and trust how their PHI is being used and shared. Information shared with an HIE goes beyond a simple provider-to-provider request for a patient's past healthcare information records. A "consent decision" by the patient about the sharing of one's health information should be "meaningful consent" to allow for an informed decision, similar to informed consent for a medical procedure.

Full information on this topic is beyond the scope of this document. A comprehensive resource is available on the HealthIT.gov website. The content includes (in part):

- Meaningful consent resources
- Patient engagement information and educational tools (eConsent Toolkit, eConsent Trial Project and more)
- Technology-based eConsent methods and tools
- Information and resources on federal and state health information law and policy

Self-Assessment Checklist: Documenting Patient Healthcare Information

This resource is designed to help providers evaluate healthcare documentation policies and procedures. For additional risk control tools and information on a wide and growing range of topics, visit the CNA website.

Risk Control Measures	Present? Yes/No	Comments
Information System		
Are formal procedures established and implemented for compiling patient healthcare information, as well as for handling and accessing patient records?		
Is the filing system logical, making it easy to locate and hard to misplace patient healthcare information records?		
Are computerized records backed up daily, and is backup information stored off-site?		
Does the record-keeping system deter staff from making unauthorized entries in patient healthcare information records?		
Is a system in place for training new employees in office record-keeping methods?		
Record Confidentiality		
Are patient healthcare information records managed in a confidential manner, in compliance with federal and state laws?		
Is confidential information released to third parties only after obtaining written authorization from the patient?		
Are all patient authorizations included in the record (e.g., release of records, signature on file, etc.)?		
Is HIPAA compliance documented in the patient record?		
Do staff members refrain from placing confidential patient information (including health alert stickers) on the covers of patient files so that protected health information will not be inadvertently disclosed to other patients?		
Access to Information		
Are patients given access to all data in their healthcare information record?		
Does the practice have a written record release policy, and are staff members trained to comply with it?		
Is there a standard copying charge for patient healthcare information records?		
Record Retention and Record Purging		
Are patient records retained for a set period, which is at least as long as the statute of limitations for malpractice or record retention requirement within the state, whichever is longer?		
Are records of after-hours calls and telephone logs and diaries retained for an established period of time?		
Is there a system for storing inactive patient records and archiving retired policies and procedures?		

Risk Control Measures	Present? Yes/No	Comments
Record Review and Quality Assurance		
Does the office have a system in place for record review/quality assurance, and are record audits performed on a regular basis?		
Are record audit findings discussed with staff, including such areas as:		
• Patient ledger?		
• Referral forms?		
• Consultation letters?		
• Recall cards?		
• Patient correspondence?		
• Telephone communications?		
Record-Keeping Practices		
Is there an individual record for each patient containing all healthcare related documents?		
Is the patient's name on every page of the record?		
Is the date recorded in full (month/day/year)?		
Is information recorded contemporaneously during patient visits?		
Are entries legible and written in dark ink?		
Are entries factual, objective and clear?		
Are entries comprehensive, addressing who, what, when, where and why?		
Do providers and staff use appropriate terminology and maintain a professional tone?		
Are records free of disparaging or subjective comments or abbreviations about the patient and/or providers?		
Are no blank lines left in the patient healthcare information record?		
Do providers and staff sign or initial each entry they make in the patient healthcare information record, and do they also note the date and time?		
Are there protocols governing late entries, and are such entries contemporaneously signed and dated?		
Are quotation marks used when appropriate, e.g., when noting verbatim patient complaints and comments?		
Based solely on written records, is it possible to determine what treatment the patient has received and why it was necessary?		
Are procedures in place to ensure that electronic communications related to patient care are included in the healthcare information record?		

Risk Control Measures	Present? Yes/No	Comments
Patients' Personal Information		
Is there a comprehensive personal information section in the patient healthcare information record?		
Is this information up-to-date and checked at each visit?		
Does the practice maintain current emergency contact information, including cellular telephone numbers?		
Is there written documentation of guardianship for minors, especially in cases of minors with divorced parents?		
Health History		
Is a comprehensive medical history taken on every new patient?		
Are the patient's current medications and over-the-counter remedies documented and checked for potential interactions (e.g., by contacting the patient's pharmacist, if needed) before additional drugs are prescribed?		
Is there a system to alert providers of important medical conditions or other healthcare complications?		
Is critical medical information prominently displayed inside the record?		
Is the patient's medical history updated and reviewed at every treatment or consultation visit?		
Informed Consent and Informed Refusal		
Do providers and staff know the required elements of informed consent, as well as informed refusal?		
Do providers know when an informed consent discussion is necessary, as well as the special circumstances in which it may be omitted?		
Is informed consent documented in the patient healthcare information record as soon as it is obtained?		
Are written informed consent forms utilized, and if so, do they …		
• Have a patient-friendly title?		
• Describe the nature of the proposed treatment and any associated risks?		
• List alternative treatments?		
• Note potential complications?		
• Use lay language and minimize the use of medical jargon?		
• Allow for customization, as necessary?		
When possible, do providers give the informed consent form to the patient prior to the beginning of treatment so the patient has time to think about the decision?		
Is the signed informed consent form placed in the healthcare information record, and is a copy given to the patient?		

Risk Control Measures	Present? Yes/No	Comments
Do providers also have a face-to-face discussion with the patient, giving him/her as much time as needed to ask questions?		
Do providers answer all questions to the patient's satisfaction?		
If a patient declines recommendations, is this refusal documented in the healthcare information record?		
Are the risks and potential consequences of refusal to follow recommendations explained to reluctant patients in writing and documented in the healthcare information record?		
Is a Refusal to Consent to Treatment/Procedure Form used in situations where the patient does not consent to the recommended treatment or procedure?		
Progress Notes		
Is every visit documented in the patient record?		
Is the following information noted at every visit:		
• Date in full (month/day/year) of examination or treatment?		
• Review of medical history?		
• Chief patient complaint?		
• Clinical findings and observations, both normal and abnormal?		
• Diagnosis?		
• Receipt of informed consent?		
• Referral, if necessary?		
• Prescriptions and medications?		
• Postoperative and follow-up instructions?		
• Plans for next visit?		
Does the patient healthcare information record note the rationale for not following a previously documented plan of care and other important medical decisions?		
Are canceled appointments and no-shows documented in the patient healthcare information record?		
Are patient satisfaction and dissatisfaction documented, including specific complaints and concerns?		
Are instances of noncompliance documented, as well as discussions with patients regarding consequent risks?		
Are treatment complications documented, as well as unusual occurrences and corrective actions taken?		
Are all pertinent discussions documented, whether in person or by telephone?		
Are all referrals to specialists and consultants documented in the patient healthcare information record?		
Is the patient given written postoperative instructions, which reflect the specific procedure and the patient's condition, and are these instructions documented?		

Risk Control Measures	Present? Yes/No	Comments
Abbreviations and Symbols		
Are abbreviations and symbols used in the patient healthcare information record?		
If so, are they the standard pharmacology abbreviations and symbols endorsed by the American Medical Association?		
If other, nonstandard abbreviations and symbols are used in clinical records, is there a formal policy and list to ensure practice-wide consistency to reduce the likelihood of miscommunication and errors?		
Is the same abbreviation or symbol consistently used for the same item, and are abbreviations and symbols never used for more than one item?		
Correcting the Healthcare Record		
Are patient healthcare information records corrected properly, i.e., by initialing the revision and without obliterating the earlier, incorrect information?		
Are changes to the plan of care made in the next available space in the record, rather than in the margin or the body of a previous entry, and dated contemporaneously?		
Consultations		
Are telephone consultations documented in the patient healthcare information record, noting both the consultant's name and the information received?		
Is a copy retained of all written consultations with other healthcare providers?		
Referrals		
Are written referral forms used and a copy retained in the patient healthcare information record?		
Does the referral form minimally include the following information:		
• Patient name?		
• The diagnostics offered to the specialist, and the date they were collected?		
• The primary diagnosis?		
• The treatment completed to date?		
• The treatment the specialist is expected to complete?		
• The information needed from the specialist?		
Is a follow-up call made to all consulting providers?		
Do staff members check with patients to determine if referral recommendations were followed?		
Is the patient informed of potential consequences of refusing to follow through on a referral, and is this action documented in the patient healthcare information record?		
Is a written referral form required from all outside providers who refer patients to one's practice?		

Risk Control Measures	Present? Yes/No	Comments
Telephone Calls		
Are providers alerted to after-hours calls from patients needing emergency care or information?		
Are all attempts to contact a patient by telephone noted, including the number called and message left?		
Do providers and staff document all patient-related information received via telephone, whether or not the call is received in the office?		
Electronic Health Records		
If patient care plans, medical histories or other patient data are stored on a computer, are the following measures in place?		
• An adequate backup system, which is updated at regular intervals?		
• A method to detect alteration or deletion of patient information?		
• A method for accessing the patient information before, during and after treatment?		
Are the software and operating system current and in compliance with healthcare information security requirements?		
Have a security risk analysis and "gap analysis" been conducted, and have the results been documented?		
If participating in electronic health information exchange (eHIE), have policies, procedures and training been implemented to ensure compliance and to obtain patient's eConsent?		
Documentation of Follow-up Visits		
Is there a system in place for documenting follow-up appointment reminders, with visit notifications recorded in the patient healthcare information record or in a follow-up visit log?		
Are canceled and missed follow-up appointments monitored and noted in the patient healthcare information record?		
Is there a written policy addressing patients who miss scheduled follow-up appointments on a routine basis?		
Insurance		
Is there an established office procedure for completing insurance forms and communicating with health plans?		
Are insurance forms reviewed for accuracy before they are sent to the insurance company?		
Does the provider's original signature appear on all insurance forms filed on behalf of a patient?		

Policy and Procedure Manual

Written policies and procedures serve as an operating framework within which essential clinical and administrative tasks can be accomplished in a systematic and consistent manner. The term "policy" refers to the governing principles that reflect an organization's mission, philosophy and goals, while the term "procedure" denotes the measures required to implement the policy. Every policy should be accompanied by a procedure, and every outpatient healthcare facility should have a policy/procedure manual addressing both clinical and operational processes. Formal policies and procedures protect patients, employees and the organization by providing guidance for decision-making, internal processes, and compliance with laws and regulation.

Incorporate language into all policy and procedure manuals reflecting that the intent is for them to be utilized as guidelines. An example disclaimer may state, "The policies, procedures and forms in the manual are intended as guidelines. It is recognized that situations can be unique. Staff are expected to use established practice and sound judgment in making decisions during their daily activities."

In addition to reducing practice variation, well-written, concise policies also serve the following purposes:

- **Communicating roles and responsibilities to all staff** and providing guidance on standard practices.
- **Enhancing continuity of care** by promoting a consistent approach.
- **Serving as a written reference** for regulatory agencies and accrediting bodies.
- **Establishing clear lines of authority** and facilitating delegation of responsibility.
- **Instituting defined, objective parameters** for evaluating employee performance.
- **Facilitating orientation of new employees** and education of current staff about changes.
- **Strengthening leadership by fostering compliance** with directives.

In addition to promoting patient safety, written policies may help defend allegations of negligence by demonstrating an adherence to the standard of care. However, policies also may become a potential source of liability exposure or a challenge to the defense of a claim if they are not aligned with current operational and clinical practices and/or are not consistently followed. Clinical leaders and providers should remain vigilant in monitoring compliance and maintain documentation of all staff training, including orientation of new employees, as well as ongoing educational programs.

Policies should be realistic with respect to available resources, such as staffing and finances, and should be reviewed, at a minimum, on an annual basis. When reviewing existing or developing new policies, clinical leaders and administrators should conduct an assessment of the current suite of policies. A review of specialty-specific standards and relevant federal and state statutory and regulatory requirements, which may require consultation with legal counsel, also should be undertaken. Networking with colleagues in similar specialty practices may be beneficial in policy development as well. In addition, a team approach is recommended to ensure that policies support and reinforce best practices and that staff are able to comply. The use of templates may assist in ensuring that your policies are consistent and include appropriate content, such as the effective, revision/approval dates and designated owners of the process. For ease of access, new and revised policies should be stored electronically. When developing or evaluating policies and procedures, consider the following suggestions:

- **Begin by creating a policy/procedure** to explain the scope and process. Include sufficient detail to serve as a "how-to" guide for proposing, developing, approving, updating and retiring policies/procedures. This procedure typically will include a policy/procedure template.
- **Address human resources issues, such as disruptive behavior, harassment and other unacceptable conduct,** as well as expectations regarding professionalism, patient confidentiality, dress, safety awareness and adverse event reporting.
- **Insert a general statement regarding compliance** with federal, state and local statutes and regulations.
- **State clearly that policies regarding professional behavior apply equally to all**, including providers, employees and vendors.
- **Examine written policies and procedures for consistency with actual practices** and adjust, as necessary.
- **Ensure that policies and procedures are dated, signed and approved** by the designated manager and a physician-officer of the practice.
- **Include a cover page on the policy manual that displays proof of annual review,** approval date and table of contents for easy reference. The manual should be regarded as an evolving document that is regularly reviewed and revised.
- **Provide all employees with access to a policy manual** that is readily available, in printed or electronic form.
- **Include a review of all policies in orientation of new employees.** Provide ongoing education for all staff whenever new policies are created and inform them of any changes in the manual.
- **Archive policies that have been revised or withdrawn,** as policies in effect at the time of an adverse event will be requested during litigation of a professional liability claim.

Written policies should express an organization's official position on significant operational and clinical issues in a straightforward, understandable manner. To ensure compliance, statements must reflect the commitment and support of leadership. The following tips can help promote the drafting of practical, user-friendly policy statements:

- **Write at a non-expert level.** Instruct policy drafters to consider the needs of novice employees, and to remember that an effective policy provides instruction as well as direction to readers.
- **Use clear and concise language.** When it comes to policy development, less is more. By avoiding technical jargon and excessive complexity, organizations can expand the policy's potential readership and help maximize compliance. Statements should be clear and to the point, utilizing bullet points or numbered lists when possible.
- **Choose words with care.** Precise terminology gives force to the statement. For example, words such as *shall* or must indicate a requirement, whereas *should* or *may* imply that other options exist, or that a step may be bypassed altogether.
- **Do not include individual's names and specific titles, since they are subject to change.** If circumstances arise that are not directly addressed by written policies and procedures, advise staff members to consult with relevant departmental leadership.
- **Utilize information from adverse event trending and root cause analysis** to ensure that updated policies reflect noted opportunities for improvement. Recurring problems in an organization's litigation history should be identified and policies formulated encompassing best practice standards.

The Role of Policies and Procedures in Professional Liability Litigation

Allegations of noncompliance with written policies and procedures are often included within professional liability lawsuits, especially those involving inadequate training and/or substandard care. Policy statements may be requested during the discovery phase of a trial in order to determine whether an organization has adhered to its articulated practice guidelines.

In such a situation, an organization's best defense is to prove that the care in question was undertaken in good faith compliance with established procedure. Documentation of the policies and procedures authorized at the time of the adverse event, and of staff training in following these established practices, will aid in the defense of a lawsuit. If it is revealed that written policies were not delineated and implemented with staff, then the organization's legal position will be more difficult to defend.

At a minimum, organizations should be prepared to produce documentation that the policy in question was:

- **Approved by executive leadership** and, where appropriate, the medical director.
- **Included in staff orientation** and professional development programs, and its importance explained to attendees.
- **Implemented and effective** at the time of the incident.
- **Incorporated into staff handbooks** and other organizational manuals.
- **Reviewed and revised** on a scheduled basis.

Answering a plaintiff's discovery request for policy and procedure statements with a simple objection may be viewed by the court as stonewalling. Courts rarely permit discovery of all policies. In most cases, the defendant is expected to provide an index of pertinent policy manuals, from which the plaintiff requests selected documents. The defendant organization bears the burden of proving that a request for written policies and procedures is unreasonable. Responding that an obsolete policy can no longer be produced weakens the defense position.

To prevent such situations, ensure that outdated or modified policies are properly archived, preferably in a computerized system. Organizations should be able to retrieve the following information in a timely manner:

- **Dates** when the policies and procedures were created and/or revised.
- **Location** of outdated policies.
- **Names** of those requesting policy revision or elimination.
- **Reasons** for policy revision or elimination.

Sample Policy and Procedure Template

By developing a policy template, organizations can facilitate the drafting process, streamline review and approval phases, and produce a more useful document. Templates should include the following elements, among others:

Header

The header section should include:

- **Title** of the policy (which should be brief and descriptive).
- **Number** of the policy.
- **Unit** responsible for drafting the policy and the area(s) to which the policy applies.
- **Status** of the policy.
- **Date** on which the policy was approved, reviewed and/or revised.

Purpose

The purpose section should summarize the policy's objectives and note why it was developed.

Definitions

The definitions section is a reference tool that explains technical terms for the benefit of novice readers.

Policy

The policy section should:

- **State the governing principle, position or belief** that guides the procedure.
- **Establish legal and ethical criteria** for assessing appropriateness of policy decisions.
- **Provide a framework** for the policy and procedure, including intended outcomes.

Procedure

The procedure section should:

- **Describe the process** clearly and accurately.
- **Identify the participants** and their responsibilities.
- **Provide step-by-step instructions** on how the policy must be implemented.
- **List materials and documents** necessary to implement the policy and procedure.
- **Refer to preexisting guidelines or protocols** for accomplishing the task.

Related Policies and Forms

The related policy section should:

- **List companion policy statements** that help clarify the issues.
- **Refer to federal and state laws and regulations,** as well as accreditation and professional association standards.
- **Direct the reader to standardized and/or electronic forms** associated with the policy statement.

Review

The review section should:

- **List necessary reviewers,** including, but not limited to clinical executive leaders, medical and nursing director, governing board, if applicable, and manager of the policy and procedure review process, if applicable.
- **State the schedule for the review and revision process,** emphasizing deadlines.
- **Include a signature block to document approval.**

Contracts

Contract Management Principles

Contractual agreements with outside entities provide a measure of flexibility to outpatient facilities and practice owners, but they also pose certain risks that must be addressed.

As most contracts have liability implications, they must be carefully drafted and reviewed with a focus on protecting the interests of the organization. A centralized contract development process brings all necessary parties to the table, strengthening negotiating capabilities and reducing the potential for misunderstandings. The process involves three major phases: negotiation, drafting and review. Legal counsel should be involved in all three phases.

Phase 1: Negotiation. Identify any provisions that require in-depth research and legal review. Certain areas of healthcare contracting, such as provider agreements and outsourcing of information management, are subject to state and federal oversight and regulation. Written policy and procedures should delineate areas that require extensive due diligence.

Phase 2: Drafting. Avoid using sample contract documents, as reliance on generic templates may produce unintended legal consequences. Customize a format to accurately address the following items:

- Scope of work.
- Goods or services to be provided.
- Obligations of contracting parties.
- Performance expectations.
- Quality requirements.
- Timeframes.
- Costs and payment terms.
- Insurance requirements.
- Confidentiality provisions.
- Consequences of breach of contract.
- Termination provisions.

Phase 3: Review. Consider taking a tiered approach to the review process, differentiating between routine contracts (e.g., those under $10,000) and those that may entail a significantly higher level of financial, regulatory or legal exposure. Such higher risk contracts include employment agreements, information technology contracts and physician service arrangements. This strategy facilitates fast track approvals while accommodating a more in-depth review when necessary.

Self-assessment Checklist: Contract Management

The following questions are designed to help healthcare business owners evaluate their contract management policies and procedures. For additional risk control tools and information on a wide and growing range of topics, visit www.cna.com.

Risk Control Measures	Present? Yes/No	Comments
Business		
Are both parties' expectations clearly expressed within the contract?		
Does the contract include a termination provision, both for and without cause?		
Are all post-termination obligations – such as returning intellectual property or keeping identifiable patient information confidential – clearly stated and acceptable to both parties?		
Does the contract specify the renewal arrangement – i.e., whether renewal is automatic or must be agreed upon by both parties?		
Are patient satisfaction levels and other contractually specified quality indicators reviewed on an ongoing basis?		
Is there a "disruption of business interest" clause, i.e., a stipulation that the party responsible for any interruption of business must reimburse the other party for lost earnings?		
Can reimbursement arrangements be administered – i.e., can the organization give or receive something of value in exchange for business paid for by Medicare or other government programs in conformity with federal and state laws and regulations?		
Financial		
Are payment methods and risk-sharing issues expressly addressed within the contract?		
Does the agreement protect against the potential consequences of criminal actions committed by the other party, such as Medicare fraud or abuse?		
Is disclosure of negotiated rates prohibited by contractual provision?		
Is there an opt-out clause to protect against payer insolvency?		
Clinical		
Is there a reasonably restrictive non-compete clause for providers who terminate services with the practice?		
Are the contract's credentialing procedures for contracted healthcare professionals consistent with applicable laws, as well as organizational policy?		
Are contracted personnel required to participate in facility committees, such as risk management, safety, quality and clinical service?		
Does the contract address patient confidentiality and healthcare information access and disclosure in a manner consistent with HIPAA and other state and federal laws?		
Does the contract cover peer review, as well as other performance review processes?		

Risk Control Measures	Present? Yes/No	Comments
Insurance		
Does the contract specify the type and minimum limits of coverage to be carried by each party?		
Is "tail" coverage required for parties carrying claims-made liability insurance?		
Does the contract discuss coverage for self-insured parties, requiring that such parties meet state requirements for the duration of the contract?		
Is a hold harmless provision included in the contract to minimize vicarious liability?		
Does the contract limit indemnification to the extent of insurance coverage?		
Is the practice named as a certificate holder with respect to providers' professional liability carrier?		
Does the contract require written notice of changes in insurance coverage?		
Does the contract address joint cooperation in the event of a claim, if such a provision is applicable?		
Does the contract involve performance of administrative duties, and if so, are associated exposures covered by the practice's directors and officers insurance policy?		
Legal		
Do the parties signing the contract have the authority to make decisions on behalf of their business, and does the contractor have the appropriate legal structure to contract with others?		
Have all necessary documents and references been obtained and carefully reviewed?		
Is the contract wording plain and unambiguous, as well as specific and well-defined?		
Are contractual obligations explicit, comprehensible and reasonable?		
Are both parties permitted to negotiate changes in the contract prior to execution?		
Does the contract contain guidelines for dispute resolution, and are these guidelines mutually acceptable?		

Patient Relationship Challenges

Patient Education, Health Literacy, and Managing Expectations

Patient education is an essential element in improving health outcomes. However, in our multicultural society, ensuring that all patients understand their medical situation and needs can be a challenge.

The U.S. Department of Health and Human Services defines "health literacy" as "the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions." A significant portion of the adult population in the United States has a low level of health literacy. This problem can affect compliance with treatment and preventive care recommendations, potentially leading to harmful or even life-threatening situations. Health literacy thus represents a key patient safety issue.

Low health literacy also may lead to unrealistic patient expectations. What patients know, or think they know, about the medical treatment affects their expectations of providers, staff and treatment outcomes. The distance between a patient's expectations and the provider's ability to meet those expectations (actual performance) may be referred to as a "malpractice gap." Various strategies may be considered to address and attempt to close the malpractice gap. Ultimately, the provider and/or other clinical staff must determine each patient's level of understanding and educate patients, to the extent necessary, to reduce the risk of patient dissatisfaction and malpractice claims. Several strategies to consider include the following:

- Ask patients and determine their expectations about the proposed treatment and treatment outcomes.
- Discuss the patient's expectations of the provider and staff.
- Explain expectations of the patient and their importance to treatment success.
- Regularly re-assess patient expectations, especially for situations involving chronic conditions or long-term/multi-step treatment scenarios, considering whether expectations have shifted or become unrealistic.
- Use brochures, articles, websites, videos and other appropriate educational tools to enhance understanding.

Improved health literacy and management of patient expectations enhances treatment outcomes and also serves to fortify informed consent and other risk management processes. Knowledgeable patients who understand and accept treatment risks and possess reasonable treatment expectations are more likely to comply with recommendations and are less likely to sue.

The following resources can aid providers in their role as educators and communicators:

- Fundamentals of Communicating Health Risks
- Health Literacy Basics
- Health Literacy Universal Precautions Toolkit
- The Patient Education Materials Assessment Tool (PEMAT)
- U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, Health Literacy.

Patient Communication Strategies

Trust and respect are the foundation of the provider-patient relationship, and they must be earned from the first encounter and continuously fostered. Trust and respect depend upon effective communication, which involves more than talking to patients. It also encompasses careful and empathic listening, awareness of gestures, posture and other forms of nonverbal communication, and attention to the level of information presented. By consistently utilizing strong communication skills, providers and staff can create a positive impression of their practice and maintain healthy rapport with patients.

Deficiencies in communication are often a factor in a patient's decision to initiate legal action against a provider following an adverse event. Communication challenges may include poor listening skills, such as interrupting others in mid-sentence, finishing their sentences or changing the subject abruptly. Another common issue is inappropriate body language, such as fidgeting, glancing around the room, looking at one's phone or watch, or otherwise exhibiting impatience. Other negative nonverbal traits include a lack of eye contact, poor posture, inattentive or irritated facial expression, or crossed arms or legs, which may appear defensive to the patient.

Fortunately, sound communication skills- including the critical nonverbal aspect of communication – can be learned and improved through practice. Learning new communication skills and practicing will enhance interpersonal behavior in ways that can increase patient satisfaction and decrease the risk of claims. In addition, the communication strategies on the following pages are designed to help organizations and providers initiate and maintain constructive relationships with patients.

Provider-Patient Communications

- Sit down after entering the examination room.
- Greet the patient by name while establishing eye contact.
- Remove physical barriers, such as furniture or computers.
- Display open and relaxed body language, avoiding signs of impatience.
- Ask patients to describe the one issue causing them the greatest concern, in order to narrow the discussion.
- Focus on the concerns that seem the most clinically urgent and can realistically be addressed during the visit.
- Use open-ended questions, such as "What can I do for you today?" and "How are you feeling?" to encourage patients to describe concerns and symptoms.
- Explain clearly and succinctly the medical diagnosis, as well as treatment options and follow-up recommendations.
- Avoid interrupting the patient and limit one's own talking.
- Tune out distractions and concentrate intently on what the speaker is saying.
- Clarify key points by asking questions and paraphrasing patient comments.
- Focus on both the verbal and nonverbal messages conveyed by the patient.
- Make use of other informational tools such as videos, brochures, photos and models.
- Ask patients to restate important information in their own words.
- Hold all patient discussions in a private area to maintain confidentiality.
- End encounters on a helpful and concerned note by asking the patient, "is there anything else I can do for you today?"

Staff-Patient Communications

A professional communication style should be consistent throughout the outpatient setting and be reflected in every patient and staff encounter. Such communication creates a professional tone conveying to staff and patients the organization's culture of respect.

- Emphasize the importance of a positive communication style that demonstrates respect and concern for patients.
- Provide staff members with ongoing training in effective communication strategies and monitor patient-staff interactions.
- Create an effective triage process for patient telephone calls. The triage system should ensure timely, efficient and polite responses to the patient's questions.
- Permit swift access to the provider in emergency situations.
- Ensure that scheduling systems minimize appointment waiting time, i.e., the period between a request for an appointment and its occurrence, as well as office waiting time.
- Have staff notify waiting patients as soon as possible if the provider is running late, and offer to reschedule appointments, if necessary.
- Remind staff to maintain confidentiality throughout the office by not holding patient care discussions in hallways, patient waiting rooms and other common areas.

Communications with Noncompliant Patients

- Review the recommended plan of care with patients and confirm that they agree to the plan and understand their responsibilities.
- Discuss possible barriers to compliance and treatment recommendations.
- Document all efforts made to communicate the need for compliance in the healthcare information record.
- Provide a written description of the potential consequences of noncompliance. Request that patients sign the document, then give them a copy of it and place the original in the patient healthcare information record.
- Assess the risk involved in continuing to provide care to chronically noncompliant patients. In some cases, it may be necessary to terminate the provider-patient relationship.

Communications with Dissatisfied Patients

- Watch for verbal and nonverbal signs of anger, dissatisfaction and frustration.
- Provide a private area for discussion, away from other patients.
- Acknowledge the patient's feelings of dissatisfaction and show that concerns are taken seriously.
- Ask the patient to clarify the issues, then restate them in one's own words.
- While listening, maintain a nonjudgmental attitude, indicated by a neutral tone of voice and open body language.
- Enlist angry patients in the problem-solving process by asking them for their ideas on how to resolve the issue.
- End the discussion with a mutual understanding of actions that will be taken to address the patient's concern and a timeframe for further discussion, if needed.
- Do not mention police or security to a hostile patient or visitor. Instead, immediately request assistance using a prearranged distress signal if patients or visitors use profanity, make threatening comments, state that they are about to lose control, appear extremely tense or angry, or seem to be under the influence of alcohol or drugs.
- Without alarming the patient, exit the room and summon help if the situation escalates (e.g. "You've certainly raised some tough questions. I'll consult my colleagues to see what I can do.")
- Dial 911 to report threats of violence, using a telephone that is out of the hostile person's sight and hearing.
- Objectively and carefully document events (e.g. "The patient's face was flushed and hands were clenched," rather than "The patient appeared to be angry.")

For more information, refer to OSHA's Guidelines for Preventing Workplace Violence for Health Care & Social Service Workers.

Patient Complaints

In healthcare, "patient complaint" is a general term used to describe an expression of dissatisfaction from a patient or family member regarding their treatment or service. Complaints represent an invaluable source of risk control information, requiring both an individualized response and a process to proactively identify trends. The goal of complaint management is to promote patient satisfaction, identify potential patient safety gaps, and reduce the likelihood of litigation. Although complaint management may occasionally be thought of as a "nuisance," especially with frivolous matters, addressing complaints affords providers an opportunity to gain patients' trust. It also permits identification of potential patient safety issues in order to prevent future occurrences.

The Centers for Medicare & Medicaid (CMS) publishes requirements in the Conditions of Participation (CoPs) for healthcare organizations related to the handling of patient complaints and grievances. Accreditation organizations such as The Joint Commission (TJC) and Accreditation Association for Ambulatory Health Care (AAAHC) also have accreditation requirements for responding to patient complaints and grievances.

Although these requirements may not apply to all outpatient healthcare settings, it is recommended that providers and outpatient facilities develop and implement a comprehensive complaint management process in order to enhance patient satisfaction and communication, and to serve as an important adjunct to their overall patient safety and risk mitigation program.

The Importance of Staff in Managing Patient Complaints

The ability of staff to help manage patient satisfaction issues is critical to an effective patient safety and risk management program. Medical assistants, nurses, administrative assistants and others represent the public face of the organization, the first representatives to whom the patient will speak by phone or meet in person. Patients' first impressions can have a profound effect on the healthcare organization.

A written protocol for managing, responding to and resolving patient and family complaints should include:

- Patient/family complaint submission process
- Internal complaint review process
- Review and response timeframe or deadlines
- Chain of command and communication methods
- Complaint submission, review and response documentation

The complaint management program should address the following procedural questions:

- Who is notified after a complaint is received?
- How are complaints logged, processed, categorized and filed?
- Who is assigned to receive complaints and communicate with the aggrieved party? (It is important to assign this role to an empathic individual with effective communication skills. Regardless of their skillset, initial and ongoing training in conflict resolution and effective communication is strongly recommended.)
- How and when are staff members informed of new complaints?
- Who is responsible for monitoring the review and follow-up process, and complaint resolution?

Patient dissatisfaction is a significant factor in professional liability claims. With multiple patient contacts in a variety of interactions, staff has a profound ability to improve patient satisfaction and reduce the likelihood of a professional liability claim.

Satisfaction Surveys

Satisfaction surveys constitute an important means of identifying and defusing service and communication issues that may result in complaints or legal action, if unaddressed.

Surveys should be brief, comprised of multiple-choice questions, including space for comments. Surveys should be given to patients in waiting rooms or mailed to them. Electronic surveys also may be made available on the organization's website, patient portal or via portable electronic devices such as tablets. As with adverse event reports, survey results should be tracked and analyzed to identify patterns and trends. Consider including the following topics and questions in the patient survey:

- **Convenience** (e.g., Are the hours of operation convenient for you?)
- **After-hours assistance** (e.g., Were you able to obtain clear information about emergency services when the office was closed?)
- **Physical environment** (e.g., Do you find the waiting and treatment areas clean and comfortable?)
- **Accessibility** (e.g., Were the office and grounds safely accessible, or did you encounter physical obstacles?)
- **Atmosphere and attitude** (e.g., Were staff members friendly and helpful?)
- **Communication** (e.g., Were your questions answered promptly and courteously?)
- **Referrals** (e.g., If you needed to see other providers or obtain specialty care, were you assisted in making appointments?)

Professional Boundaries

Healthcare providers assume a position of trust and authority with their patients, frequently becoming familiar with the most intimate and sensitive aspects of their lives. Care should be taken to ensure that these relationships do not become too personal, leading to an erosion of boundaries, confusion of roles, and/or incidents of abusive or exploitive behavior.

Each state board formulates its own policies regarding professional boundaries and sexual misconduct. Providers are responsible for being conversant with state laws and other guidelines governing their practice.

Allegations of improper relationships constitute a significant risk for providers, indicating failure to:

- Adhere to the relevant professional code of ethics.
- Maintain sound social and sexual boundaries with the patient.
- Act within the established scope of practice.
- Seek supervision and assistance when ethical questions arise.
- Transfer the patient to another practitioner if conflicting roles have developed.
- Communicate appropriately in social media forums.

Improper use of social media has become an increasingly common vehicle for boundary-related occurrences and claims, as such outlets can potentially blur the line between professional and personal communication. Websites and social media tools should be utilized prudently. Message content should be limited to routine information, such as educational resources, office hours, practice-related news, and appointment or other care reminders. Providers should adopt conservative privacy settings for their social media accounts and decline "friend" requests from current or former patients.

Not all transgressions are rooted in provider behavior. Patients can also behave in an inappropriate, boundary-threatening manner, such as:

- **Referring to a provider by his/her first name,** despite requests not to do so.
- **Asking personal questions of a provider** that are irrelevant to the course of treatment.
- **Displaying undue affection** toward a provider.
- **Attempting to socialize with a provider** outside of the provider-patient relationship.
- **Giving gifts** that are expensive or highly personal.
- **Using sexually explicit language** unnecessarily or provocatively, or otherwise trying to seduce a provider.
- **Physically or verbally abusing a provider** or threatening bodily harm.

These transgressions should be immediately addressed with the patient, restating the need for appropriate boundaries.

While not all boundary issues are equally serious, they tend to impair the objectivity and judgment of both parties, thereby potentially skewing expectations and/or affecting health outcomes. In extreme circumstances, boundary violations lead to verbal, emotional, physical, financial, or sexual misconduct, requiring direct, swift and proportionate intervention.

Sexual Abuse and Molestation

Allegations of sexual abuse and molestation (SAM) may result in criminal prosecution, professional liability claims and professional license sanctions. A written policy outlining the commitment of the outpatient healthcare organization to sexual abuse prevention should be created and implemented. The policy should address the process for identification and management of "at risk" providers and staff who display boundary issues. Such issues may include offering gifts or lending money to patients, having close physical contact outside of the necessary examination, and altering the times/locations of patient visits. The written policy should clearly define what constitutes inappropriate behavior and designate a "zero tolerance" position. Adverse event reports should be completed for concerns regarding inappropriate behavior involving any healthcare provider or other team member.

The SAM prevention policy should outline how reports of suspected SAM should be handled, including designating a staff member(s) to investigate reported events and outlining criteria for when law enforcement must be contacted. A culture of safety within the outpatient setting will ensure that staff feel empowered to report suspicious behaviors without fear of retaliation. All staff, providers, management and volunteers should be trained annually regarding the policy. Diligent inquiry regarding sexual molestation and abuse history should be included in all pre-employment screening, as a prior history may negatively impact the defense of a sexual abuse allegation.

The SAM prevention program also should include a chaperone policy. Consistent use of chaperones can help protect patients from sexual abuse/molestation and healthcare providers from exposure to allegations of sexual abuse/molestation. Chaperone policies should be reviewed by legal counsel annually, as regulations may change and will vary by state and jurisdiction. For example, several states have implemented legal mandates for the presence of medical chaperones during sensitive physical examinations. Providers should inform patients that they are entitled to have a chaperone present for any physical examination and strongly advise or require the presence of a chaperone during examinations of the breasts, genitalia, or rectum. Patients should be informed about the availability of chaperones verbally and in written admission materials.

Chaperones should be members of the practice who undergo stringent background checks and receive ongoing training on their role and expectations as a chaperone and patient advocate. The chaperone policy should address special circumstances such as chaperone unavailability, cultural considerations, sensitive situations involving patients who lack decision-making capacity and pediatrics. The American Academy of Pediatrics recommends that chaperones attend "sensitive care" examinations of adolescents and young adults. A parent or guardian should be present during exams of infants, toddlers and young children. In cases of suspected parental abuse, an office chaperone should be present.

Patient-provider communications regarding the offering of chaperones and of the presence of a chaperone during an exam should be consistently documented in the healthcare information record. Documentation should include whether a chaperone was present, the name and title of the chaperone, any postponement of care related to the unavailability of a chaperone and patient declination of the offer to have a chaperone.

SAM prevention training should be provided to all staff and providers annually. This training and education should include definitions of boundary violations, sexual abuse and molestation and examples of reportable suspicious or "at risk" behaviors.

The SAM prevention policy should provide staff with internal reporting requirements and procedures in the event of an actual or suspected incidence of sexual abuse/molestation. The policy should include support of staff who report in good faith and protection from retaliation.

The internal reporting process should include options for anonymous reporting, and reporting options to address situations where the suspected abuser is in a position of authority over the reporter.

An internal investigation process should be developed, identifying those responsible for investigating, evaluating, and external reporting to law enforcement and regulatory agencies. Senior leadership should assume responsibility by guiding the investigation process.

A robust SAM prevention program may help to prevent professional liability claims, potential criminal ramifications and pervasive reputational harm for your organization.

Abandonment Allegations

Whenever a provider-patient relationship is established, that relationship continues for as long as the patient's condition requires attention. The relationship may be terminated by the patient, mutual agreement, or by the provider. If the relationship is ended without proper notification, the provider may face allegations of patient abandonment. Abandonment allegations are based upon the patient's belief that he or she has suffered an injury due to the provider's failure to continue to perform his or her professional duty.

All patients must be treated equally. A provider cannot legally deny treatment to or dismiss a patient from the practice solely on the basis of disability, race, color, creed, ethnicity, gender or age. However, it is acceptable to dismiss a patient for reasons such as non-compliance with office policies or treatment. The reason for termination must be fair and equitable, and the process must be appropriately documented.

Notably, if a patient in need of emergent care is denied treatment simply because the patient has not paid their bills to the practice/provider, the provider may become liable to an allegation of abandonment.

Certain situations have a greater likelihood of leading to allegations of abandonment. Risk factors include the following:

- Poor clinical outcomes.
- Unmet expectations.
- Billing disputes.
- Failure to schedule and/or keep follow-up appointments.

Termination of the Provider-Patient Relationship

Prior to terminating a provider-patient relationship, review any applicable provider contract guidelines regarding termination policies and consider seeking legal counsel. The following guidelines can help minimize the risks associated with terminating the provider-patient relationship:

- **Document the reasons for terminating the relationship,** as well as any efforts made to resolve conflicts or misunderstandings, in the patient healthcare information record.
- **Terminate the relationship by sending a certified letter requesting return receipt.** A copy of the letter also should be sent via first-class mail in the event that the patient is not available to accept certified letters.
- **Include the following information in the termination letter:**
  - A clear statement that the relationship is being terminated.
  - The date on which the relationship will end, giving at least 30 days' notice. Be cognizant of state law and regulations, since states may establish specific notice requirements.
  - A statement that emergency care will be provided to the patient until the stated date of termination.
  - An offer to refer the patient to another provider or to help locate another practitioner of the same medical specialty.
  - An assessment of the patient's current health status and description of any required care.
  - An offer to forward a copy of the patient's healthcare information record to the subsequent provider.
  - A form authorizing release of medical information to the subsequent provider.
- **Keep a copy of the letter and return receipt** in the patient's healthcare information record.
- **Document in the record that the letter was sent,** noting the date.
- **Document any subsequent communications with the patient,** whether in writing, by telephone or in person.

Sample Termination Letters

Examples of patient termination scenarios and corresponding sample letters follow on pages 45-48. These letters represent common situations and are not intended to be comprehensive, to constitute legal advice, or to determine what should or should not be written to a specific patient when a relationship has ended. These sample letters are intended to assist in the development of individualized letters, based upon one's knowledge of the patient and the specific situation.

Billing and Collections

Billing and collections processes can significantly affect the provider-patient relationship, potentially causing additional concerns to escalate into legal action. A patient's account information should never be sent to collections before the provider has considered any mitigating circumstances regarding the patient's ability to pay and the possible impact of the collections process on a potentially dissatisfied patient.

No Surprises Act

Providers and organizations must understand requirements under the Consolidated Appropriations Act of 2021, also referred to as the "No Surprises Act." This Act restricts surprise billing and establishes an independent dispute process. The requirement details are beyond the scope of this manual.

The rules and requirements generally apply to healthcare services provided to individuals enrolled in group health plans, group/individual health insurance coverage, and Federal Employee Health Benefits plans. The requirements for transparency of healthcare costs and the requirements related to the patient-provider dispute resolution process also apply to uninsured consumers. However, the Act requirements do not apply to all consumers. Those with coverage through Medicaid, Medicare, Indian Health Services, Veterans Affairs Health Care, or Tricare have other medical billing protections in place.

The "Requirements Related to Surprise Billing" Part 1 and Part 2 address a number of topics including:

- Restricting surprise billing from out-of-network providers at in-network facilities, and air ambulance services from out-of-network providers.
- Establishing a dispute resolution process for out-of-network payment amounts between providers/facilities and health plans.
- Requiring good-faith estimates of medical items or services for uninsured/self-paying consumers.
- Establishing a patient-provider dispute resolution process for uninsured/self-paying consumers associated with payments due to a provider or facility.
- Providing an appeal process involving certain health plan decisions.

Access the CMS website for comprehensive information, including an overview of rules and fact sheets.

Self-assessment Checklist: Provider-Patient Relationship and Effective Communication

This resource is designed to help providers evaluate policies and procedures relating to patient communication and professional boundaries. For additional risk control tools and information on a range of other risk management-related topics, visit the CNA website.

Risk Control Guidelines	Present? Yes/No	Comments
Patient Communication		
Do providers clearly convey the severity of the problem and the risks of failing to implement instructions? For example, *"Your wound must be cleaned three times a day in the first week after surgery, in order to avoid hard-to-treat infections and permanent scarring. What questions do you have about dressing changes?"*		
Do providers explain to patients that they must take some responsibility for the outcome of their care or treatment? For example, *"We both want you to benefit from physical therapy, but I'm not sure you fully support our current approach."*		
Do providers relate personally to patients in order to build a stronger therapeutic partnership? For example, *"Tell me, what can I do differently to better help you meet your personal health goals?"*		
Are providers and staff trained to communicate with difficult patients, using live workshops and role-playing scenarios?		
Setting Patient Goals		
Are patients encouraged to identify goals and preferences on their own, before the provider offers suggestions? For example, *"Let's talk about the various treatment options, and then decide what is suitable for you."*		
Do patient encounters begin with a discussion of the patient's personal concerns, rather than a recap of laboratory or diagnostic workups? For example, *"First, tell me what concerns you most, and then we'll discuss test results."*		
Does each encounter end with the patient verbalizing at least one self-management goal in a clear and specific manner? For example, *"I will monitor blood glucose levels before meals and at bedtime between now and my next appointment."*		

Risk Control Guidelines	Present? Yes/No	Comments
Patient Education		
Are barriers to communication assessed and documented in the patient healthcare information record, including low health literacy, cognitive impairment and limited English proficiency?		
Are qualified and credentialed interpreters available when required?		
Is the "teach-back" technique used to ensure understanding of proposed treatments, services and procedures – e.g., not only asking patients if they have any questions about their medications, but also requesting that they describe in their own words how to take them?		
Is use of the teach-back technique documented in the patient healthcare information record?		
Are patients asked to explain in everyday language the medical information they have been given, including:		
• Diagnosis or health problem?		
• Recommended treatment or procedure?		
• Risks and benefits of the recommended treatment or procedure, as well as alternatives to it?		
• Patient responsibilities associated with the recommended treatment?		
Are patients asked to repeat back critical instructions, and is their response noted in the patient healthcare information record? For example, *"It is important that we remain on the same page regarding your recovery. Can you tell me in your own words what an infected wound looks like and what you would do if you saw signs of infection?"*		
Barriers to Compliance		
Are underlying factors affecting compliance explored with patients in a nonjudgmental manner? For example, *"It sounds as if you may be concerned about the medication's possible side effects. Is that why you have not taken it as prescribed?"*		
Do providers strive to achieve a mutually acceptable plan of care with hesitant patients, using the following strategies:		
• Identifying and recognizing specific patient concerns, such as the out-of-pocket costs of a surgical procedure?		
• Identifying practical or logistical difficulties that may hinder compliance, such as lack of reliable transportation to and from the practice?		
• Encouraging patients to get a second opinion, if desired?		
• Taking the time to explain the potential consequences of failing to comply with recommendations?		
Are open-ended questions used to assess a patient's resistance to change? For example, *"How do you think your life would be different if you stopped smoking?"*		
Are patients asked if they have a means of contacting healthcare providers in the event they cannot make an appointment or pick up a medication?		
Is there an assessment of the patient's capacity to perform essential tasks, such as changing dressings or picking up prescriptions?		

Risk Control Guidelines	Present? Yes/No	Comments
Patient Management		
Do patient healthcare information records note the individuals upon whom patients rely to meet their general healthcare needs (e.g., spouse, relatives, paid caregivers, friends, etc.)?		
Are written protocols established and implemented for patient management issues, including:		
• Effective pain management, including prescriber responsibility to mitigate the risk of drug diversion, misuse, non-medical use and/or addiction?		
• Appointment or procedure cancellations?		
• Unacceptable behavior, such as belligerent voicemail messages, yelling or cursing at staff?		
• After-hours patient management?		
• Refusal to consent to recommended treatment?		
• Noncompliance with recommendations regarding medications or lifestyle changes?		
• Patient termination?		
Are patients reminded of upcoming appointments, including referrals and laboratory visits, and are reminders documented in the patient healthcare information record?		
Are electronic alerts used to remind patients with a history of noncompliance about screening and monitoring requirements?		
Are blind or otherwise impaired patients informed of subscription services that, via wireless devices, deliver reminders to take medications or perform other self-care activities?		
Are follow-up and referral appointments scheduled and entered in the computer system before patients leave the facility?		
Does written policy require documentation of no-shows, as well as appropriate follow-up?		
Is there a written policy for terminating the provider-patient relationship if the patient is chronically noncompliant?		
Professional Boundaries		
Are activities with patients that fall outside of accepted medical or mental health practices carefully avoided (e.g., agreeing to meet them at social events or communicating with them on a social media site outside the parameters of a professional relationship)?		
Do providers read the state medical practice act at least once a year to strengthen their awareness of the legal and ethical scope of practice?		
Is there ongoing peer review and performance evaluations of all healthcare providers' competencies, focusing on clinical conduct, ethical awareness, and rapport with colleagues and patients?		

Sample Termination Letter 1: Refusal to Accept Recommendations

Communication breakdowns may result in the need to terminate a provider-patient relationship. In the case below, the patient refuses to accept treatment recommendations. Other communication problems include patients who have unrealistic expectations, pose unreasonable demands or simply make staff members uncomfortable. In such situations, it is prudent to send a letter to the patient indicating that the relationship is being terminated, outlining treatment needs and explaining how to find a new provider.

Dear Patient,

Over the course of your recent visits, I have frequently stated my objection to proceeding with _____ due to the need for [treating/controlling/addressing] _____. Although we have spent substantial time discussing your condition and treatment plan, you have stated that you do not wish to pursue the recommended course of action.

Although you have the right to reject my recommendation, I believe that [pursuing the treatment sequence you desire OR proceeding without addressing _____] does not fulfill the requirements of accepted medical practice. Based upon your choice not to proceed as recommended, I must cease serving as your provider. Please consider this letter as formal notice of this decision.

I will be available to see you for any urgent needs that you may have for the next 30 days, provided that you contact my office to schedule an appointment.

You must seek the care of another provider as soon as possible. You can find information regarding area providers in the telephone directory or online, or by contacting your health plan or the local medical society/association referral service.

You should select either a primary care provider or a provider who specializes in _____ (known as a "_____"). Failure to seek medical care may result in a serious deterioration of your condition, which may result in _____ and/or _____.

A form authorizing release of medical information must be signed by you so that we can release your medical information to your new provider. Please allow _____ days from receipt of your request for duplication and mailing. I will be pleased to speak with your new provider by telephone at any time.

Sincerely,

Your Provider cc: Patient File

Sample Termination Letter 2: Missed Appointments

In this example, the patient has missed multiple appointments. She has been advised by telephone and in writing of the consequences of further missed appointments, yet the patient fails again to keep the scheduled appointment. The provider determines that it is in the best interest of the patient and the practice that the relationship be terminated. A letter such as the following may be appropriate:

Dear Patient,

Over the past four months, we have made great progress in treating _____. Unfortunately, further progress continues to be hampered by your repeated failure to keep scheduled appointments. Although we have previously discussed the impact of missed appointments both on your health and on our ability to serve other patients, another appointment was missed on [provide exact date].

As much as we wish to continue to provide care, we cannot do so under these circumstances. Therefore, this letter is being sent to inform you that we must terminate the relationship between our practice and you

As of your last visit, our records indicate that you still require the following medical care:_____. Your condition should be re-evaluated as soon as possible. It is recommended that you promptly schedule and keep an appointment with your new provider. Failure to seek care may result in a serious deterioration of your condition, which also may result in _____ and/or_____.

As it may take time to locate a new provider, we will be available for the next 30 days to care for any urgent problems you may experience. If necessary, please contact our office to schedule an appointment.

You can find information regarding area providers in the telephone directory or online, or by contacting your health plan or the local medical society/association referral service. We will forward a copy of your healthcare information records to you or to your new provider upon receiving your signed request to that effect. Please allow _____ days from receipt of your request for duplication and mailing. I will be pleased to speak with your new provider by telephone at any time.

If we do not hear from you in the next 30 days, we will assume that you have sought medical care from another practice.

Sincerely,

Your Provider cc: Patient File

Sample Termination Letter 3: Inactive Patient

Many medical offices have records of inactive patients – i.e., patients that providers have not seen or treated in years, but with whom there has been no formal termination of the provider-patient relationship. Although many of these patients may have sought care from another provider, those that have not may still be considered a patient of record, even if they have not responded to recall requests. Depending upon the patient's medical history and health status, it may be prudent to contact the patient and discuss whether to continue or formally terminate the relationship. This protocol reflects both patient safety and risk management considerations.

Dear Patient,

It has been a long time since your last visit to our office. We have tried to contact you by telephone, mail and email, but you have not yet responded. Our records indicate that your medical condition is one for which frequent monitoring is required. For this reason, we are concerned that your safety may be at risk.

We hope that you have sought medical care elsewhere since your last visit to our office. If not, we strongly suggest that you make an appointment as soon as possible with us or another provider. Failure to seek care may result in a serious deterioration of your condition, which also may result in _____ and/or _____.

We would be pleased to resume providing medical care to you. Please contact our office, and we will schedule another appointment for you. If we do not hear from you within the next 30 days, we will assume that you are being treated elsewhere and will consider our provider-patient relationship with you to have terminated. We would appreciate receiving a call from you regarding your decision, so that we will know whether to keep your records in our inactive file or return them to active status.

If you decide not to return to our office for care, you may find information regarding area providers in the telephone directory or online, or by contacting your health plan or the local medical society/association referral service. We will forward a copy of your healthcare records to you or to your new provider upon receiving your signed, written request to that effect. Please allow _____ days from receipt of your request for duplication and mailing. Thank you for your attention to this matter.

Sincerely,

Your Provider cc: Patient File

Sample Termination Letter 4: Generic Letter (No Reason Given)

While it is absolutely necessary to inform patients that the provider-patient relationship is being terminated, the precise reason for the decision to cease providing care need not be disclosed. In certain cases, the provider may wish to be tactful and remain silent regarding the reasons for the decision – especially if such reasons are of a private nature or may potentially create further conflict with the patient. Irrespective of the reason, send a letter to the patient indicating that the provider-patient relationship is being terminated, clearly outlining continuing treatment needs.

Dear Patient,

I am writing to inform you that, after careful consideration, I have decided to discontinue serving as your provider. Our provider-patient relationship will end 30 days from the date of this letter.

Based on our records, your current medical conditions include _____, _____ and _____. We are also monitoring your [blood count/specific diagnostic test/etc.]. Past results indicate that you may be developing _____, which may require _____. Therefore, for your own safety, it is important that you locate, pursue and follow up with a new provider as soon as possible.

I will be available to see you for the next 30 days for urgent medical issues, provided that you contact my office in advance to schedule an appointment.

Again, I encourage you to seek regular medical care as soon as possible. You may find information regarding area providers in the telephone directory or online, or by contacting your health plan or the local medical society/association referral service.

I will mail a copy of your healthcare record free of charge to you or your new provider after receiving from you a written and signed request to that effect. Please include the address to which you would like the records sent. Please allow _____ days from receipt of your request for duplication and mailing. I will be pleased to speak with your new provider by telephone at any time.

I wish you every success with your future medical care.

Sincerely,

Your Provider cc: Patient File

Risk Management Strategies for the Outpatient Setting

Legal and Regulatory Risks

Contents

Definitions

A few basic definitions are provided to ensure a baseline understanding of the terminology utilized in the following sections.

Potential compensable event (PCE) is characterized by an unanticipated adverse event or medical error causing an injury or clinical sequelae. Indications of a formal claim may or may not be present. However, based upon the nature of the incident, injury and litigious patient/family communications, there is a likelihood that a claim will be initiated.

Incident typically refers to an event that is not in alignment with customary operations and/or policies and procedures of the outpatient healthcare setting and is reported through internal channels. The event may or may not be associated with a patient injury. An incident also may be associated with a medical board complaint, an unanticipated adverse event or a request for medical records.

Claim is a verbal or written demand for compensation based upon an alleged error or omission resulting in injury or damage and may be filed as a lawsuit or pre-suit notification. A demand may be made in writing, in person, or by telephone, facsimile or email. It may be asserted informally in the form of a letter or telephone call (often directly from the patient), or formally submitted as a filed legal action. Claims may be asserted by the patient, the patient's guardian or a family member with appropriate legal authority.

A **subpoena** is a court order issued by attorneys, government agencies or courts requiring an individual to appear in court, or other legal and regulatory proceedings, and testify. A subpoena also may require document production.

A **lawsuit** is a civil legal action initiated by filing a complaint within the judicial system. Lawsuits are governed by the rules of civil procedure. When a lawsuit is filed by a patient, a Summons and Complaint will be filed with the court and delivered by the designated authority to the named parties or the defense attorney, if one has already been assigned.

Professional Liability Claims: Prevention and Management

Not all unanticipated adverse events result in a claim or a lawsuit. Prompt, proactive management of these events enhances patient safety and may reduce the likelihood that a claim will be initiated. Providers and staff should collaborate with risk managers and become active participants in preventing claims, while simultaneously enhancing defensibility in the event a lawsuit is filed.

The role of the risk manager and clinical leaders in preventing and/or managing claims varies among outpatient healthcare settings. However, customary risk management activities relating to claim management include, but are not limited to, the following:

- Reporting PCEs to regulatory bodies and insurers, as required.
- Conducting the initial investigation following a PCE.
- Documenting investigational activities and correspondence related to the event.
- Ensuring the integrity of the patient healthcare information record and securing other pertinent documents, equipment and information associated with the event.
- Organizing claim files and coordinating activities with insurers and the defense team.
- Reporting potential and actual claim activity to professional liability insurers through appropriate channels.
- Trending and analyzing the organization's adverse event and claim data to support the development of risk management initiatives and prevent future occurrences.
- Benchmarking and reviewing industry liability trends. CNA publishes claim reports that provide additional information and detail on professional liability claims and licensing board actions focusing on healthcare practitioners including dentists, pharmacists, nurses, nurse practitioners, physical therapists, and counselors.

Although we cannot predict with certainty when an adverse event or medical error will result in a claim, the following are often precipitating factors:

- Diagnostic error coupled with serious harm and/or adverse financial impact.
- Anger or distrust.
- Retaliation for billing disputes and collection actions.
- Lack of communication with provider(s) regarding outcome and future care.
- Unrealistic expectations regarding treatment outcomes.
- Inaccessibility of provider(s) after an adverse event.
- Altruistic reasons, i.e., "I don't want it to happen to someone else."

Identification of the above risk factors, including proactive risk management techniques, may help to reduce the likelihood that a patient will pursue a claim. For example, training providers on how to effectively communicate with patients and families after an unanticipated adverse event may help to reduce a patient's anger and distrust towards providers.

Occasionally, providers may become so distraught about a medical error or serious adverse event that they isolate themselves from the patient and family. This reaction results in emotional distress for the provider and also creates a chasm in the provider-patient relationship, often leading to the pursuit of legal action as a last resort. Peer support programs may help providers resist the instinctive "flight" response. In addition, coaching sessions may be offered to help providers navigate difficult disclosure conversations.

Medical Malpractice

Malpractice is a type of negligence. It is often referred to "professional negligence." Malpractice claims in the outpatient healthcare setting are often related to a failure or delay in diagnosis, improper management of test results and referrals or improper performance of a procedure. Communication issues and a lack of clear expectations regarding treatment outcomes also may influence a patient's decision to file a claim or lawsuit.

Parties to a malpractice lawsuit involve the following:

- Plaintiff(s) – parties who initiate a lawsuit in a court. Such parties may include a patient, family member or third party.
- Defendant(s)–the parties against whom a claim or charge is brought in a court.
- Witness(es)-individuals who provide additional information regarding the case and sequence of events, including experts, consultants, staff, and organizational leaders, among others.

In order to prevail in a medical malpractice lawsuit, all of the following 4 requirements are met:

1. The provider owed a duty to the patient.
2. There was a breach of duty (standard of care).
3. An injury was sustained.
4. There was a direct causation between the breach and the injury sustained.

Establishment of the Provider-Patient Relationship

Determining if a provider owes a duty to the patient depends upon whether a provider-patient relationship exists. Providers may be held liable even if they believe no provider-patient relationship was established. It is incorrect to assume that an individual is not a "patient of record" if the patient was only seen on one or two occasions or never accepted a treatment plan. Irrespective of the circumstances under which it is created, including location of provider or duration of the contact, a provider-patient relationship may be deemed to have been formed. For example, a provider may offer professional information or opinion establishing a provider-patient relationship, even when the communication occurs outside of a professional practice setting. If the patient suffers an injury as a result, the provider may be held liable.

The legal existence of the relationship is a question of the facts specific to each individual case. Any of the following factors may indicate that a provider-patient relationship exists:

- A contract is executed between the provider and patient.
- A history is taken and/or physical examination is performed.
- An entry is made into the patient healthcare information record.
- A bill for services is sent.
- A medical consultation was provided.
- The patient receives care from the provider.

Standard of Care

A medical malpractice lawsuit is based upon allegations that a provider failed to properly fulfill the "standard of care." Standard of care violations relate to the professional conduct of a reasonable provider in the same jurisdiction with similar credentials. This judgment will be based upon the standard that existed at the time the care was rendered.

In a malpractice lawsuit, the standard of care is articulated through the testimony of expert witnesses. Expert witnesses are professionals with background and training similar to the defendant, typically from the same practice community, who give their opinion to the court regarding the allegations in the complaint. Expert witnesses retained by the plaintiff opine as to why the defendant's care failed to meet the standard, and that the failure was the direct cause of the injury. Defense attorneys also will retain expert witnesses to refute the plaintiff's allegations.

Another factor to consider when determining the standard of care is educational curricula, including what is taught both in medical and other healthcare professional schools, as well as continuing education courses. If a provider uses unapproved procedures, materials, or techniques, whether the standard of care was fulfilled may be scrupulously analyzed.

Resolution of Claims and Lawsuits

Claims and lawsuits may be resolved, by a settlement between the parties, through mediation or arbitration, by a jury verdict at trial, or by the plaintiff's voluntarily dismissal of the lawsuit against one or more defendants. It may take years before a malpractice suit reaches trial. Insurance policies vary with respect to the management of settlement decisions. There may be a consent to settle clause, which requires that an insurer obtain its insured's consent before settling a claim. In non-consent to settle policies, the insurer collaborates with the involved provider(s), but ultimately has the final decision making authority regarding settlement determinations. An insurer's decision to settle a claim or lawsuit is based upon several factors, including the assessment and apportionment of liability, estimated likelihood of prevailing at trial, as well as an assessment of how the witnesses will appear during testimony before a jury.

Managing Claims and Other Legal Notices

Diligent management of actual and anticipated claims and/or lawsuits can reduce the potential severity of the matter. Attempting to manage claims and other legal notices independently will be counterproductive to the defense. The professional liability insurer must be notified immediately, and defense counsel assigned, so that they may respond on behalf of the outpatient center and/or involved provider. Designation of a staff member of the outpatient setting to handle legal notices will ensure prompt notification to insurers and seamless coordination of required responses.

Upon receipt of notification from a patient asserting a claim of injury, or when a summons and complaint or subpoena has been received, the following steps should be taken:

- Immediately report the matter to the professional liability insurer of the outpatient facility and/or provider(s) involved in the situation.
- Secure all medical records, equipment and evidence that may be important to the defense of the case.
- Do not discuss the facts of the case with the patient or any party other than the professional liability insurer and the attorney representing the outpatient facility and/or involved provider(s).
- Respond immediately to requests for information by the insurance carrier and attorney representing the outpatient facility or provider(s).
- Refer all inquiries for information involving the case to the attorney representing the outpatient facility or provider(s).
- Copy and retain the summons and complaint, subpoena and attorney letter(s) for your records.
- Maintain signed and dated copies of all employment contracts.

Reporting to Your Professional Liability Insurance Carrier

Professional liability insurance policies include provisions to guide insureds on how and when to report potential compensable events (PCEs), claims and lawsuits in order to comply with the policy terms and conditions, and initiate a prompt investigation. Refer to your claim professional or broker for specific details regarding the protocol for claim reporting. In situations where a formal claim notice has not been received, but there is reason to believe that that a claim will be initiated, such as when an attorney's request for records is received or the patient verbally indicates dissatisfaction with care or the plan to file a claim, the insurer or broker should be notified. The insurer will evaluate coverage, initiate an investigation and assign a defense attorney, if indicated.

Typically, a written summary is included in the initial report addressing details of the PCE, claim or lawsuit including, but not limited to, the following:

- How, when and where the adverse event took place;
- The names and addresses of any injured persons or witnesses; and
- The nature and location of any injury or damage arising out of the occurrence.

In addition to the initial report of a claim, pertinent documents, including policies and healthcare information records, are typically included in the initial notification.

Subpoenas

In the context of a medical malpractice lawsuit, a plaintiff attorney may issue subpoenas to named defendants or other treating providers who are not named in the lawsuit, but may be utilized as witnesses. The subpoena is a court order requiring providers or the outpatient facility to submit evidence in court and/or to produce documents, such as paper copies of the electronic health-care information record or policies in effect at the time that care was rendered.

Subpoenas are delivered in person or by certified mail. Deadlines for responding to subpoenas and penalties for non-compliance with the subpoena apply. It is imperative that you consult with legal counsel and your professional liability insurer immediately upon receipt of a subpoena so that they may respond on your behalf. Attempting to manage these requests on your own may be counterproductive in defending your case, if you are a named party, or may potentially result in you or your facility being named in the lawsuit

State Licensing Board Matters

For state licensing board matters, such as licensure restrictions, disciplinary matters, or complaints filed by patients or others, consult your professional liability insurer and/or legal counsel to obtain guidance prior to initiating a response. Matters such as these often emanate from allegations of professional misconduct, fraudulent billing or scope of practice violations. It is important to emphasize the benefits of concise, objective documentation in the healthcare information record, as this may help to avoid a lengthy licensing board investigation. Insurance coverage for legal expenses related to state licensing board complaints varies depending upon the insurer, policy, exposures, and jurisdiction, among other factors. Many professional liability insurance policies will provide defense coverage related to these matters.

Managing the Risks of Vicarious Liability

Healthcare organizations or provider-owned outpatient facilities and practices may be held vicariously liable for the negligence of employees acting within their scope of practice. The following suggestions may help to minimize vicarious liability risks:

- Review your professional liability insurance policy to determine whether it includes vicarious liability coverage.
- Require a certificate of insurance from all independent contractors.
- Ask independent contractors sharing space to sign a hold harmless/indemnification provision, which minimizes exposure against any losses arising from their activities. As these clauses are varied and complex, consult with legal counsel before initiating or signing any contracts.

Apparent (Ostensible) Agency

Vicarious liability is not limited to liability resulting from the actions of employees. It also may arise from the actions of individuals with whom the provider has, *or appears to have*, a supervisory relationship. Vicarious liability involves the legal theory of apparent agency, also referred to as ostensible agency. The theory of apparent agency applies, for example, to independent contractors (IC). An outpatient healthcare organization or physician group practice may be held liable for the acts of independent contractors if the patient believes that the independent contractor was acting as an employee of the organization or practice.

Therefore, an important liability consideration is whether the patient had a clear understanding of the independent status of the IC. If the patient perceived that the contracted provider was associated with the healthcare organization or group practice, the IC may be deemed to be an "apparent agent." For healthcare business owners, well-drafted contracts relating to independent contractors, as well as ensuring clear role delineation and provider employment status, may help mitigate liability in lawsuits claiming vicarious liability.

National Practitioner Data Bank

The National Practitioner Data Bank (NPDB) or "the Data Bank" was created by the *Health Care Quality Improvement Act of 1986* and operates within the U.S. Department of Health and Human Services. It's important for healthcare providers to be aware of its role.

The Data Bank was created to serve as a flagging system to facilitate a review of healthcare practitioners' professional credentials. The information contained in the Data Bank is used by healthcare entities, state licensing boards and professional societies, in connection with information from other sources, for decisions involving clinical privileges and credentialing, employment, affiliation, or licensure. Healthcare providers, entities, and suppliers are permitted to self-query and/or dispute information reported to the NPDB. Refer to the NPDB guidebook for a complete list of providers who are authorized to query.

Each insurance company or other entity that makes a malpractice payment for the benefit of a practitioner must submit a report if the payment meets certain criteria. The companies also are required to send these reports to state licensing boards. Each state licensing board also establishes its own reporting requirements.

Informed Consent

Informed consent (IC) is a two-way educational and communication process that provides patients with sufficient information to make a reasoned decision regarding proposed treatment. The consent must be given without coercion or fraud, based upon the patient's reasonably accurate and complete understanding of what will take place. The IC process is a legal and ethical obligation, serving to enhance decision-making and protect both parties.

Although some practitioners may consider the informed consent process burdensome and time-consuming, it is critical to effective risk management. Providers who ignore the wishes of a patient and proceed with treatment without the necessary consent may be subject to malpractice litigation, whether or not the treatment was in the best interest of the patient in the provider's professional opinion. If the treatment can be characterized as an unauthorized touching of the patient, the provider also may have committed the criminal offense of battery.

Most patients have a reasonable idea of procedures that occur during routine examinations or treatment. Thus, patients are sometimes considered to give implied permission for treatment when they visit an office for routine care. Implied consent, however, is limited as a legal defense.

Fundamentals of Informed Consent

The informed consent process involves two primary components:

- **Discussion**, including disclosure and patient education.
- **Documentation in the healthcare information record**, which typically includes the use of a written informed consent form.

The informed consent discussion represents the first step in managing patient expectations, thus reducing the possibility of a misunderstanding and a consequent lawsuit. In addition, documentation of the informed consent process provides the best defense against a patient's assertion that the proposed treatment, other options and the potential for complications were not adequately explained.

Many claims of professional negligence are accompanied by an allegation of lack of informed consent. In such an action, patients may assert that, if they had known in advance that an adverse outcome was possible, they would not have agreed to the treatment. Rarely do claims solely allege lack of informed consent, without other claimed damages.

In many lawsuits, the provider met the standard of care, but the patient was dissatisfied with the outcome, often due to a lack of communication. A sound informed consent process can enhance patient management and education, thus reducing risk.

Informed consent is a process, not a specific document. The process requires a verbal component, irrespective of whether a written form is used. In most jurisdictions, a patient can give an oral informed consent. However, informed consent requirements vary among states, and a written form may be required in addition to discussion with the patient. Whether the patient's permission is spoken or written, the goal of the informed consent process remains the same: to ensure that the patient has an adequate understanding of the proposed treatment, including its risks and alternatives, as well as the consequences of no treatment, prior to giving consent.

Although laws and regulations vary, most states require that patients be given sufficient information on three major subjects:

1. **Nature of the proposed treatment**, including the need for treatment, its anticipated benefits and the prognosis.
2. **Alternatives to the proposed treatment** including an explanation of the risk and benefits associated with the alternatives, as well as reasons that the recommended care is preferable to other options, such as specialty referral or no treatment.
3. **Foreseeable risks**, including potential complications of the proposed treatment and the risks of refusing it. Similar to the discussion of alternative treatments, the list of foreseeable risks need not be all-inclusive, but it should reflect the patient's condition and overall health status.

In addition, if medical residents, interns, fellows or medical supply vendors will be present at and/or participating in a proposed surgery or procedure, their presence and roles should be disclosed to the patient, including in the IC discussion and documented in the patient healthcare information record.

Following the educational component of the consent discussion, patients should be asked whether they have any questions about the proposed treatment or any other information given to them. The patient then states his/her desire to either pursue or decline the proposed treatment. Questions and answers and the patient's decision should be noted in the patient healthcare information record.

The provider who will perform the treatment or procedure must conduct the IC discussion – it cannot be delegated. Nurses and other healthcare staff may witness a patient's signature on a consent form, but they are not permitted to conduct the informed consent discussion. IC rules vary as they pertain to nurse practitioners, certified nurse midwives, certified registered nurse anesthetists and other non-physician providers. Refer to state statutes and regulations, as well as professional licensing board guidelines, ethical opinions, and healthcare legal counsel for specific guidance on the IC process in these cases.

Informed Consent Tips

The following strategies can help enhance the informed consent process:

- **Tailor discussions** to the needs and level of understanding for each patient.
- **Use basic, uncomplicated language** that the patient can understand, defining any technical terms that must be used.
- **Consider the complexity of the proposed treatment and the degree of risk** when conducting the informed consent discussion with the patient.
- **Focus on the educational opportunity that IC provides.** Use brochures, as well as pamphlets, models and other educational resources, as needed.
- **Give the patient opportunities to ask questions**, and answer as clearly and comprehensively as possible.
- **Ask the patient to "teach-back" and describe the proposed plan of treatment** in his or her own words.
- **Encourage the patient to have a family member present in the room** during the IC discussion to make the patient feel more at ease.
- **Have a staff member present during the IC discussion** to serve as witness.
- **Be aware that in most cases, minors must obtain the consent of a parent or legal guardian** prior to beginning treatment. Many states allow for an exception to obtaining parent or legal guardian consent when the minor is seeking treatment for sexually transmitted disease, pregnancy, and birth control. An emancipated minor can also seek treatment without the consent of parental or legal guardian.
- **Always ask the patient, "Do you have any questions about the information you have been given or about the proposed treatment?"** and document the answer.
- **If necessary, use a qualified interpreter**, noting their name, address and telephone number in the patient healthcare information record. Interpretive services can be for language as well as communication barriers including, but not limited to, hearing and visual impairments. Family members and friends should not serve as interpreters unless the clinical situation is emergent and a qualified translator in unavailable. In that event, document the reason for using a family member/friend and the patient's consent to do so.
- **Consider translating standard consent forms** into commonly spoken foreign languages in the area serviced.
- **Proceed only after obtaining the patient's approval**. Any treatment rendered without the patient's consent may result in malpractice allegations or charges of battery.

Informed Refusal

Every adult patient with decision-making capacity has the legal right to decline treatment recommendations. At the same time, the physician or other healthcare provider is responsible for clearly explaining the reasons for pursuing the recommended course of care, as well as the potential consequences of not doing so. Patients who experience serious injury after refusing care may later assert that their provider was negligent in failing to fully disclose the risks of forgoing treatment. The patient may further assert that if the risks of refusal had been properly and completely explained by the provider, he or she would have consented to the procedure or treatment.

The following risk control measures, adapted to the unique needs and circumstances of individual practices or facilities, can help healthcare providers and organizations reduce liability exposures relating to refusal of treatment:

- Create a standard informed refusal form that accompanies and documents the provider-patient discussion. (See sample form provided in this section, which should be modified as necessary.)
- Inform the patient that refusal of treatment may affect progression and treatment of other medical conditions, and note this discussion in the patient healthcare information record.
- Continue to examine and treat the patient for the duration of the provider-patient relationship, periodically noting in the healthcare information record that the patient continues to decline the recommended treatment and is aware of continued risks associated with this refusal.

Documenting informed refusal. Refusals of care increase liability exposures, which can be minimized by comprehensively documenting the informed refusal process and emphasizing that the patient understood and acknowledged the risks of rejecting the recommended care.

Techniques for documenting informed refusals are similar to, but surpass, those for informed consent. After discussing the potential consequences of refusal with the patient, write a comprehensive progress note and document the refusal using a written form, which should be incorporated into the patient healthcare information record.

Progress notes should document:

- Those present during the discussion.
- The treatment discussed.
- The risks of not following treatment recommendations, listing the specific risks presented.
- The brochures and other educational resources provided.
- The questions asked and answers given by both parties.
- The patient's refusal of the recommended care.
- The patient's reasons for refusal.
- The fact that the patient continues to refuse the recommended treatment.

Using an informed refusal form. Few patients remember all that they were told during the informed consent/refusal discussion, making written forms a valuable reminder. A written form also helps manage patient expectations, provides further documentation of the disclosure of information and may deter negligence claims. The informed refusal documentation process is not designed to persuade reluctant patients to accept necessary and recommended treatment. It serves as an additional communication process to ensure the patient understands the risks they are accepting with their refusal of the recommended treatment or procedure.

Obtaining Informed Consent Under Special Circumstances

Under certain circumstances – such as when the patient is a minor, is cognitively impaired or is undergoing a life-threatening emergency – the process of obtaining informed consent (IC) becomes more complex. In such situations, risk management representatives and legal counsel should be consulted regarding relevant state statutes and regulations. Their input should be documented in the patient's healthcare information record, including other relevant medical and treatment details.

Pediatric patients. Before rendering treatment to an unemancipated minor, providers must first obtain the IC of a parent or legal guardian. Adult siblings, grandparents and other adult caretakers are generally authorized to provide consent only if they have been granted legal guardianship by the court. If a parent or legal guardian cannot be contacted by telephone, determine the degree of urgency as indicated by presenting signs and symptoms, and then decide whether to proceed immediately or defer treatment until consent can be obtained. Document the factors considered in the patient healthcare information record.

Adolescents. Minors cannot consent to their own treatment unless they are emancipated. Laws vary across the United States on what constitutes emancipation and there is little guidance provided from federal law. Therefore, you must be aware of state specific guidance on criteria to be an emancipated minor. In general, emancipated minors are considered those who serve active duty in the military, minors who are married, or minors living independently from their parents and managing their own financial affairs. If an unemancipated adolescent presents for care and is unaccompanied by a parent or legal guardian, the following steps can help minimize potential liability exposure:

- **Make a reasonable effort to contact a parent or legal guardian.** Document all such attempts – whether made by telephone, text message, email or other means – in the patient healthcare information record.
- **If a parent or legal guardian cannot be contacted immediately, defer routine treatment** until a parent or guardian has been informed of the patient's situation and has authorized care.
- **If immediate intervention is imperative due to traumatic injury or other emergent conditions, provide necessary care to the patient** while continuing efforts to contact the parent or guardian. The patient healthcare information record should include the rationale for proceeding with emergency care, as well as ongoing efforts to obtain authorization.

Cognitively impaired patients. For patients to grant their informed consent to or refusal of treatment, they must have the capacity to comprehend the relevant issues. Therefore, if there is reason to doubt a patient's decision-making ability, the provider must assess his or her capacity in this area. Patients who can respond cogently to the following three requests are generally considered capable of giving consent to medical treatment:

- **Describe the reason for your visit/admission to the facility,** including major symptoms and concerns.
- **In your own words, repeat back what we have discussed** about your condition and treatment needs.
- **Tell me a little about yourself,** such as your age, birth date, address and name of an emergency contact person.

Emergency situations. The majority of states recognize special circumstances where delaying treatment in order to obtain IC may be detrimental, such as an emergency situation when the patient is unable to give consent and efforts to contact a family member or guardian have been unsuccessful. In addition, the IC process can be modified if, in the provider's judgment, full disclosure of risks would have a serious adverse effect on the patient or the thera-peutic process. For example, a depressed patient who may potentially become actively suicidal if given too much information during a mental health crisis represents a situation in which the IC process may be modified.

Special cases such as these may present a high degree of both stress and risk for healthcare providers. For this reason, facilities and practices should hold regular training sessions about the IC process, with attention paid to consent issues involving patients who are minors, are cognitively impaired and/or are experiencing a life-threatening emergency.

Informed Consent Documentation and E-consent

The patient's informed consent must be documented in the healthcare information record, including evidence that the patient understands and agrees to the proposed treatment. A written description of the informed consent discussion, signed and dated by the patient, effectively demonstrates that the process has been completed. Consult state laws and regulations to determine whether a written informed consent document is required, but even if it is not mandatory, a written form serves as valuable documentation of the consent process.

Irrespective of whether a written informed consent form is used, write a progress note that reflects the specific consent process for the patient, including questions asked and answers given, staff and/or family members present, educational materials provided, and whether the patient agreed to or declined the recommended treatment.

Sample Discussion and Consent for Treatment/Procedure Form

Patient's name: *(Last, First, Middle initial)* _____ Date of birth: _____

I am being provided with this information and consent form so I may better understand the treatment/procedure recommended for me. Before beginning treatment/procedure, I wish to be provided with sufficient information, presented in a form that I can understand, to make a well-informed decision regarding my proposed treatment/procedure.

I understand that I may ask any questions I wish, and that it is better to ask them before treatment/procedure begins than to wonder about these issues after treatment/procedure.

Nature of the Recommended Treatment/Procedure

It has been recommended that I have the following treatment/procedure: _____

_____

This recommendation is based upon physical examination(s), diagnostic test results and my doctor's knowledge of my medical history.

My needs and desires have also been taken into consideration. The treatment/procedure is necessary due to _____

_____

The intended benefit(s) resulting from this treatment/procedure is (are): _____

_____

The prognosis, or likelihood of treatment/procedure success, is: _____

_____

Alternative Treatment/Procedure

The treatment/procedure recommended for me was chosen because it is believed to best suit my needs. I understand that alternative methods or treatment/procedure options include: _____

☐ No other reasonable treatment/procedure options exist for my condition.

_____ I have had an opportunity to ask questions about these alternatives and any other treatment/procedure that I have heard or thought about, including: _____

Patient's initials

_____

Risks of the Recommended Treatment/Procedure

I understand that no treatment/procedure is completely risk-free and that my provider will take reasonable steps to limit any complications. I am aware that some treatment/procedure effects and complications tend to occur with regularity. These include:_____

_____

_____ I have had an opportunity to ask questions about these and any other risks about which I have heard or thought.

Patient's initials

(continued)

Acknowledgment

I have provided as accurate and complete a medical and personal history as possible, including antibiotics or other medications I am currently taking, as well as those to which I am allergic. I will follow any and all treatment/procedure and post-treatment/procedure instructions as explained to me and will permit the recommended diagnostic procedures.

I realize that notwithstanding the possible complications and risks, my recommended treatment/procedure is necessary. I am aware that the practice of medicine is not an exact science, and I acknowledge that no guarantees, warranties or representations have been made to me concerning the results of the treatment/procedure.

I, _____, have received information about the proposed treatment/procedure. I have discussed my treatment/procedure with _____ (specify provider), and have been given an opportunity to ask questions and have them fully answered. I understand the nature of the recommended treatment/procedure, alternative options and the risks of the recommended treatment/procedure.

My signature below indicates that I understand the risks and wish to proceed with the recommended treatment/procedure.

Signature of patient or guardian: _____ Date: _____

Signature of treating provider: _____ Date: _____

Signature of witness: _____ Date: _____

This sample form is for illustrative purposes only. Your clinical treatments/procedures and risks may be different from those described. We encourage you to modify this form to suit your individual practice and patient needs. As each practice presents unique situations and statutes may vary by state, we recommend that you consult with your attorney prior to use of this or similar forms in your practice.

Sample Refusal of Treatment/Procedure Form

Instructions

This form should be signed by the patient or authorized party if he/she refuses any surgical procedure or medical treatment recommended by his/her physician or provider. If the patient or authorized party not only refuses the treatment/procedure, but also refuses to sign this form, note this fact in the patient healthcare information record.

1. I have been advised by my physician/provider *(insert name)* _____, that the following treatment/procedure should be performed upon me *(insert name of treatment/procedure):* _____

   _____

2. Nature of the Recommended Treatment/Procedure

   This recommendation is based on physical examination(s), diagnostic test results and my physician's/provider's knowledge of my medical history. My needs and desires have also been taken into consideration. The treatment/procedure is necessary due to:

   _____

   The intended benefit(s) resulting from this treatment/procedure is (are): _____

   _____

   The prognosis, or likelihood of treatment/procedure success is: _____

   _____

   The consequences of not proceeding with the recommended treatment/procedure are: _____

   _____

3. Alternative Treatment/Procedure *(check one):*

   ☐ The treatment/procedure recommended for me was chosen because it is believed to address my medical condition. I understand that alternative treatment/procedure options include: _____

   _____

   ☐ No other reasonable treatment/procedure options exist for my condition.

4. I have read the following educational materials provided to me *(list materials, if applicable):*

   _____

5. Risks of Not Having the Recommended Treatment/Procedure:

   I understand that complications to my health may occur if I do not proceed with the recommended treatment/procedure. These complications include: _____

   I have had an opportunity to ask questions about these risks and any other risks I have heard or thought about.

6. Acknowledgment

   I, _____, have received information about the proposed treatment/procedure. I have discussed my treatment/procedure with my provider/physician and have been given an opportunity to ask questions and have them fully answered. I understand the nature of the recommended treatment/procedure, alternate treatment/procedure options, and the risks of the recommended treatment/procedure, and my refusal of care.

7. My reason for refusal is as follows: _____

(continued)

8. I personally assume the risks and consequences of my refusal, and release for myself, my heirs, executors, administrators or personal representatives those physicians/providers who have been consulted in my case as well as *(insert name of medical practice)* _____, its officers, agents and employees, from any and all liability for ill effects that may result from my refusal to consent to the performance of the proposed treatment(s)/procedure(s).

I acknowledge that I have read this document in its entirety, that I fully understand it and that all blank spaces have been either completed or crossed off prior to my signing.

I do NOT wish to proceed with the recommended treatment/procedure.

Signature of refusing patient: _____ Date: _____ Time:_____ ☐ AM ☐ PM

Signature of refusing party, if other than the patient: _____ Date: _____

Relationship to patient: _____

Signature of the physician/provider: _____ Date: _____

Signature of witness: _____ Date: _____

This sample form is for illustrative purposes only. Your clinical treatments/procedures and risks may be different from those described, We encourage you to modify this form to suit individual needs of your healthcare setting and patients. As each setting presents unique situations and statutes may vary by state, we recommend that you consult with your attorney prior to use of this or similar forms in your healthcare setting.

Risk Management Strategies for the Outpatient Setting

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 "Guideline for Hand Hygiene in Healthcare Settings."

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 Bloodborne Pathogens Standard to protect workers (29 CFR 1910.1030), which includes the federal Needlestick Safety and Prevention Act. 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		
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		
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 out-patient 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.

Risk Management Strategies for the Outpatient Setting

Strategic Risks

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Introduction to Strategic Risks

Managing strategic risks can assist an organization's leaders in making critical decisions and ensuring financial stability. Organizations are under competitive pressure from ongoing developments in the healthcare market. New entrants to the market, including retailers developing healthcare services, online pharmacies and new partnerships, may ultimately decrease the market share of traditional physician practices, outpatient facilities, urgent care facilities and clinics. These developments will increase competition and may negatively affect financial performance. Organizational leadership should routinely analyze existing competition and new entrants into the market in order to adjust their operating plans and strategic direction to mitigate associated risks accordingly.

Strategic risks may involve expansion of services, reputation management, branding, marketing, relationship and partnership management, divestitures, mergers, acquisitions and more. When determining the strategic direction, organizational leaders may consider several approaches that can be implemented individually or simultaneously. Consider the following strategic initiatives and associated risks when determining strategic direction:

Expanding Services and Capabilities

Expanding services may involve untapped or underserved markets and service lines, as well as techniques to innovate patient care delivery. Incorporating telemedicine, laboratory services and other clinical service lines are ways to expand services and capabilities. Risks to consider include general/professional liability issues associated with new services, necessary capital investments, and/or personnel issues (training, staffing, etc.).

Partnerships

Driven by a new generation of providers and technology development, creative partnerships have become an option for many organizations to achieve strategic goals and sustain or expand financial performance. Partnering with management organizations to increase provider/patient care time and focus represents one type of partnership arrangement.

Others include, but are not limited to, partnerships involving health plans, health systems and private equity firms. Risks to consider include business culture alignment, past performance in managing medical operations, compliance, safety, quality, governance, control over operations and clinical decision-making, financial/capital expense support and degree of business risk tolerance. Another consideration is the potential for partnership termination, if desired by the parties involved.

Joint Venture

Joint venture is a type of organizational structure functioning as a commercial enterprise formed by two or more separate entities for the purpose of combining resources to achieve a common purpose or goal. Joint ventures may encompass many types of arrangements. They include, but are not limited to, management services affiliations, contractual venture partnerships, clinical integration programs, co-management agreements, Management Services Organizations (MSOs), Physician-Hospital Organizations (PHOs), and Professional Services Arrangements (PSAs). Some of the risks associated with joint ventures include compliance considerations such as fraud and abuse, the federal Anti-Kickback Statute and the Stark law, and similar state laws, as well as issues related to antitrust statutes. Seeking legal counsel early in discussions pertaining to the formation of a joint venture will help to mitigate associated risks.

Mergers and Acquisitions

Expanding scale and revenue diversification has become increasingly important in the face of a weakening payor mix. For example, when a significant portion of reimbursement emanates from government insurance programs, which typically pay less than commercial insurers, analysis of this measure will affect the determination. It may generate increased interest in mergers or acquisitions in order to combine resources and improve operating efficiencies. Common conflicts that occur with mergers and acquisitions are culture clashes, stakeholder push-back, miscommunication, unexpected clinical risks, and massive staff turnover.

Divestitures

Selling non-core assets may be a strategy to concentrate and reinvest in other initiatives, and restore or maintain financial stability. Examples of divestitures may include, but are not limited to, sale or termination of services, sale or termination of marketing ventures and divesture of non-clinical services. Risks associated with divestitures include insufficient analysis of the downstream effect of organizational changes and failure to realize the planned gains.

Reputation Management

Consumers are driven by positive and negative reviews of the services they seek, including healthcare services. These reviews come by word-of-mouth, online reviews, marketing campaigns and brand strength. Reputation management is an important factor in maintaining relevance in a competitive market. Proactive reputational monitoring is more cost effective than efforts to salvage or re-build a reputation. The following are important components of reputation management:

- Communication – effective communication with employees and stakeholders.
- Patient concerns – responding to patient concerns in a timely manner and with empathy.
- Branding – or the process of shaping how the organization is perceived by others.
- Marketing – increased visibility influencing media and public opinion.
- Online presence – social media platforms, website presence, and online rating sites.
- Monitoring – plan to monitor reputation setting metrics indicating positive and negative indicators of performance.
- Crisis response plan – a plan to respond to a crisis involving the organization, providers, affiliates and others that may create pressure from the media, regulatory bodies, law enforcement and others.

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Risk Management Strategies for the Outpatient Setting

Financial Risks

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Introduction to Financial Risks

The financial strength of an organization is the cornerstone of its overall stability. Healthcare organizations are under pressure to maximize financial operating margins while maintaining quality patient care. Efforts to increase efficiency and lower costs should be monitored for any adverse downstream effect on patient care. Financial processes should be controlled to avoid operational disruptions, facilitate the achievement of strategic objectives and help to ensure the organization's future success.

Ongoing analysis of key financial metrics and well-established performance measures will identify the financial strength of the organization and provide opportunities to implement effective risk mitigation and operational improvement strategies. Analyzing key financial metrics, including their synergistic effects – both positive and negative – should enable leaders to address potential risks.

Financial Performance Metrics

- **Reimbursement and payor mix** – refers to the percentage of patients covered by public health insurance plans, such as Medicare and Medicaid, versus the percentage of patients covered by private health insurance plans. Understanding the amount paid for medical services by public and private third party payors, the timeframe within which they pay, the incentives to deliver quality of care, and accuracy of billing are important in managing the revenue stream within an organization.
- **Billing accuracy/compliance** – accurate and compliant medical billing and coding are critical to receiving the entire amount to which the organization is entitled for services rendered. Inaccurate or noncompliant billing and coding practices can create vulnerabilities to lost revenue, delay in reimbursement, denial of claims and the potential of governmental fines and penalties. The most common medical billing and coding errors include upcoding, downcoding, unbundling, and billing for services that were not rendered. These errors may lead to allegations of fraud and abuse resulting in serious consequences involving federal penalties, sanctions against an individual provider or healthcare organization from participation in federal healthcare programs, as well as monetary fines and potential criminal sanctions.
- **Revenue cycle management** – refers to the process of accurate medical billing and coding, timely submission of claims to the payor, managing incoming payments, claim adjustments and/or rebilling denials, and accurate collection of patient payments such as copayments and co-insurance.
- **Revenue enhancement** – is the process of measuring how well the revenue cycle is managed by setting specific goals at each point along the billing process. An important measure is days in accounts receivable (A/R), or the average number of days it takes to collect on outstanding payments. Other important measures include the length of time for a claim to be submitted, the percentage of payment denials and reasons, and the age of claims past 90 or 120 days from service.
- **Credit and collections** – credits can reflect overpayment by a payor which must be returned. Understanding the reason for overpayments is important in the understanding of billing accuracy. The number of delinquent accounts may reflect inaccurate billing, payor contract issues or failure to collect payments that are patient responsibilities. It is important to develop a process that requires providers to review all accounts identified for collection prior to submitting them for action. The review should consider and determine whether any care-related issues are evident that would influence the decision to proceed with collections.
- **Audits** – routine proactive audits of provider transactions, care coordination functions (referrals), billing and claims coding, and the effectiveness of the compliance program are often required and necessary to ensure efforts are established and implemented in order avoid fraud, waste and abuse allegations.
- **Access to capital** – access to capital, or additional financial support, may be required in the event of a sudden, unexpected large expense, or the intent to expand service capabilities. A financially healthy organization is in a stronger position to negotiate terms or rate of loans.
- **Budgeting** – successful management of an organization's finances requires the establishment of an annual budget reflecting income and expense. To establish an annual budget, all revenue and expenses should be categorized and tracked using the prior year's data to estimate the revenue and expenses for the subsequent year. Consideration should be given to operational changes that may affect revenue and/or expenses year-over-year such as expanding services, adding staff, investment in technology and rising costs of supplies, to name a few. Monitoring budget variances from month to month can enable organizational leaders to make adjustments, as needed, to keep the budget on track.

The following items should be considered when developing and monitoring the organization's budget:

- **Income**
  - Revenue from services rendered
  - Revenue generated from other sources (e.g. leasing space to another provider)
- **Expense**
  - Staff salaries
  - Provider salaries
  - Benefits
  - Supplies
  - Equipment
  - Contracts – cost of others under contract that support the organization and/or operations
  - Rent/mortgage
  - Insurances – professional liability, business interruption, general liability, errors and omissions, property, cyber

If necessary, consult and engage experienced financial and legal advisors to ensure implementation of required financial controls and compliance with applicable laws and regulations.

Risk Management Strategies for the Outpatient Setting

Human Capital Risks

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Human Resources

Policies and Procedures

Sound human resource policies are essential to the delivery of quality patient care, helping to ensure that the outpatient health-care setting employs competent staff who provide services within their licensure or certification. These policies also should reflect applicable federal, state and local legal requirements.

Job Description

Prior to hiring a new employee, review the job description for the position to ensure that it is accurate and complete, encompasses the essential duties and physical demands of the position, as well as required education/training, experience, knowledge and skills. Stated requirements should be job-related and reflect actual job responsibilities. If a job description does not exist, one should be drafted.

Application

Applications should not include questions on topics which may elicit information that may be protected and/or lead to allegations of discrimination, such as:

- Maiden or previous name/title.
- Citizenship or birthplace.
- Children or other family commitments.
- Race, religion or ethnicity.
- Date of birth or high school graduation date.
- Physical description or photo.
- Whether English is the primary language.
- Club or union memberships.

Background Check

Background checks should be comprehensively and consistently implemented and documented, verifying education, licensure, credentials and references. Criminal background checks should query both conviction history and sex offender status and should be performed on both a state and national level in accordance with governing laws and regulations.

Exercise caution when screening prospective employees based upon criminal record or credit history. Equal Employment Opportunity Commission (EEOC) guidance discourages blanket restrictions of applicants with criminal conviction records because they also may have a disparate impact on certain protected classes. Instead, the EEOC recommends that employers assess each applicant individually to ensure that exclusions are job-related and consistent with business necessity.

Factors such as the age of the offense, the nature of the offense in relation to the job duties of the position, and the degree to which the employee will be supervised by others may be considered in order to determine whether to disqualify an applicant based upon a criminal conviction record.

EEOC guidance also discourages the use of credit information in hiring decisions. Criminal background and credit checks are complex issues which should be discussed with an employment attorney prior to implementation.

Drug Testing

If drug testing is part of the hiring process, establish a policy addressing the following issues:

- Testing timetable.
- Positions to which testing applies.
- Specific "target" substances.
- Testing procedures.
- Consequences of a positive result.

Drug testing should be performed only after a contingent offer of employment has been tendered. As laws vary from state to state, consult with an employment attorney to ensure compliance.

Orientation

Orientation should include basic information about the practice, organizational mission and vision, clinical practice standards, work schedules, emergency protocols and behavioral expectations. It also should address such relevant issues as workplace rules, vacation time and insurance options, as well as staff responsibilities regarding patient safety and incident reporting. Orientation sessions should be tailored to the role and duties of newly hired staff, and should include:

- Review of the job description.
- Description of the performance evaluation process.
- Signed confirmation that the employee understands and accepts his/her responsibilities.

Verification of Skills and Competencies

Delegation of clinical tasks to unlicensed assistive personnel, i.e., medical assistants, technicians, patient care representatives, and others, must be consistent with state regulations, licensing boards and/or certification programs. In situations where state regulations have not been promulgated, delegation of clinical tasks must be consistent with the education, training and demonstrated clinical proficiency of the unlicensed assistive personnel.

Decisions about delegation of clinical tasks should consider whether it is safe and permissible to transfer tasks from a highly trained to a less-trained provider. Healthcare leaders should have a clear understanding of the tasks and activities that may be safely delegated, and those tasks which should not be assigned to others. As a general rule, tasks delegated to unlicensed providers should not require independent assessment or a high degree of problem-solving ability.

The following questions can help enhance the process of determining whether an activity is safe for delegation to unlicensed medical assistive personnel:

- Is there evidence-based literature demonstrating safe delegation of the clinical task?
- Does the staff have the education, training and competence to safely carry out the task?
- Is the task performed on a routine basis within the healthcare setting?
- Can the task be performed safely and guided by standing orders or directions?
- Is the task relatively simple, or does it involve making complex observations, interpretations and/or critical decisions?
- Is the task invasive, creating potentially life-threatening consequences for the patient if performed incorrectly?
- Will a licensed provider be available for consultation while the task is carried out, if applicable?

Skill competency of all healthcare staff (nurses, technicians, physical therapists, aides, and others) should be demonstrated upon hire, annually and when new tasks are added to a provider's role. Competencies should be documented in hiring records, personnel files and job performance reviews, including primary credentials, continuing education courses and the dates and results of competency testing.

Competency evaluations should focus on the following performance indicators, at a minimum:

- Basic skills and level of competence.
- Proficiency in completing the delegated task.
- Compliance with practice protocols.
- Urgency of response to unexpected situations.
- Openness of communication with the delegating provider.
- Accuracy of documentation.
- Timeliness of progress reports.
- Transparency in error reporting.
- Overall reliability and professionalism.

Continuing Education and Performance Review

Continuing education (CE) and other ongoing training opportunities should be aligned with licensure/certification requirements. CE should include relevant topics relating to patient safety i.e., professional boundary violations, sexual abuse prevention, adverse event and medical device reporting, and medical error mitigation. CE credits, annual performance appraisals and training programs should be documented and stored in personnel files.

Employee Termination

Terminating employees is a challenging component of human capital management. Disciplinary actions or termination may be necessary when employees are not complying with policies relating to conduct, clinical practice guidelines, and/or deficient performance. In order to preclude legal ramifications emanating from terminations, including violations of local, state or federal laws and regulations, healthcare organizational leaders must follow appropriate steps and comprehensively document all performance issues, disciplinary actions, and other steps taken prior to terminating an employee. Managers and clinical leaders tasked with employment matters should work closely with their human resources manager, compliance officer and/or legal counsel when addressing disciplinary or employee termination cases.

The organization should have a written policy outlining the necessary steps and required documentation for employee termination. The policy should be reviewed by legal counsel on an annual basis to ensure that it is in compliance with state and federal employment laws. The American Society for Health Care Human Resources Administration (ASHHRA) provides additional information.

Credentialing Healthcare Providers

Healthcare organizations have traditionally been held legally responsible for granting staff privileges only to competent physicians and advanced practice providers.

The need for greater organizational accountability of provider credentialing is recognized from various perspectives. The federal Medicare Conditions of Participation require healthcare organizations to examine credentials of all eligible candidates and conduct periodic appraisals of performance. State regulations also require medical staffs to verify that applicants can demonstrate their ability to perform surgical, treatment and/or other procedures competently at the time of application, and at least bi-annually thereafter.

The credentialing process consists of two phases: verification of primary qualifications pursuant to medical staff application, and the granting of specific clinical privileges based upon evaluation of competence. Successful credentialing thus requires sound initial assessment procedures, as well as access to comprehensive, reliable and practitioner-specific performance data.

The following strategies can help healthcare organizations protect patients and reduce liability risk by enhancing both major phases of the medical staff credentialing process.

1. Identify red flags when reviewing applicants' history.

- **No response to reference inquiry** from a prior medical staff, medical group, healthcare entity, training program or professional society with which the applicant has been affiliated.
- **Difficulty in verifying** general requirements, including training and education, professional liability insurance coverage and past employment.
- **Gaps in education** and/or work history.
- **Discrepancies in applicant responses** and information received from primary verification sources.
- **History of disciplinary actions** by medical staff organizations, healthcare entities, state medical boards or professional societies.
- **Non-voluntary resignation from a medical staff** at any time in the applicant's career.
- **Credible reports of problems** in the applicant's professional practice.
- **Past or pending investigative proceedings** by a state licensing board, medical staff organization or professional society.
- **Claims or investigations** of fraud, abuse and/or physician misconduct by professional review organizations or private and third-party payors, such as Medicare and Medicaid.
- **Criminal investigations, charges and/or actual convictions** of a misdemeanor or felony.
- **Jury verdicts and settlements** of professional liability claims within the past five years.

2. Thoroughly document initial findings regarding professional competence. Organizations must demonstrate through scrupulous documentation that they have objectively and thoroughly assessed practitioners' overall professional competency.

3. Implement a consistent, evidence-based evaluation program. The following measures help ensure that privileging criteria are clear, applied in a fair and non-discriminatory manner, and accommodate changes in both practice and technology:

- **Apply criteria uniformly and document all decisions.**
- **Define the practice of "core privileging" in the medical staff bylaws** – i.e. evaluation of applicants based upon a preselected group of procedures or treatments relevant to the medical specialty – and evaluate all skills independently, even if they are grouped together.
- **Draft a written protocol to guide the development of new criteria,** and require the approval of the medical executive committee and governing board before granting the privilege.
- **Document exceptions to adopted criteria,** noting the consensus of organizational leadership and the medical staff.
- **Convene an interdisciplinary team** to review any contested privileging-related decisions.

4. Collect performance data on an ongoing basis including a process to identify, investigate and address clinical practice concerns throughout the privilege period. Organizations should require a detailed assessment of practitioner-specific data, as provided by the system known as ongoing professional practice evaluation (OPPE). Incorporating such activities as periodic chart reviews, direct observation, monitoring of diagnostic and treatment techniques, and discussions with peers, OPPE provides an opportunity to obtain a more balanced view of the practitioner's strengths and weaknesses. Major OPPE criteria include:

- Involvement in adverse events and sentinel events
- Appropriateness of operations and other procedures
- Medical assessment and treatment methods
- Timeliness and accuracy of assessment and treatment
- Test and procedure request/handling

Data should be collected and analyzed systematically during quarterly reviews. This process can be performed internally, or, in cases of potential conflict, outsourced to an external peer review organization.

5. Establish and enforce evaluation parameters to protect patients and avoid the appearance of a failure to take indicated action by implementing a practitioner review system known as focused professional practice evaluation (FPPE). This process requires a delineation of both the events that trigger monitoring and the period of observation, consisting of either an established timeframe or a specified number of procedures. In addition, documentation should outline how monitoring will be performed, information compiled and evaluated, and performance issues resolved. Common assessment methods include retrospective chart reviews, simulations, external peer reviews, proctoring, and discussions with colleagues and others.

6. Ensure leadership oversight of the credentialing process.

- **Thoroughly investigate the qualifications of medical staff applicants,** focusing on education, board certification, training, licensure and medical malpractice history.
- **Review grandfathering provisions and other organizational practices** related to credentialing and appointment, and codify them in medical staff bylaws.
- **Establish an oversight committee** to ensure compliance with the process.

Resources

Medical Staff Credentialing: Eight Strategies for Safer Physician and Provider Privileging, CNA *Vantage Point*® 2019.

Scope of Practice and Supervision

The integration of advanced practice providers (APPs), such as nurse practitioners (NP) and physician assistants (PA), into a variety of outpatient settings has enhanced efficiency and increased patient access to care. Depending upon state scope of practice regulations and position descriptions, these roles often include prescribing medications, ordering diagnostic tests and taking after-hours calls. However, the relationship between physicians and APPs presents certain complexities, and establishing a safe and effective collaboration requires careful attention to such issues as communication, documentation and scope of practice.

Depending upon state practice regulations, both NPs and PAs may be permitted to diagnose clinical conditions and prescribe medications. Due to evolving state laws, APPs may have independent practice authority under state law. A number of states also require a practice agreement between the physician and the APP.

Resources

National Conference of state Legislatures (NCSL) Scope of Practice Policy.

Practice Agreements

Practice agreements are intended to clarify and strengthen the collaborative working relationship between the collaborating or supervising physician and APP. Prior to hiring, the physician should have clear criteria for duties and procedures that may be delegated, and avoid the temptation of altering a job description to suit a candidate's limitations. In an outpatient context, practice guidelines should consider the size and complexity of the patient population and the availability of a provider.

Agreements should be reviewed annually, dated and signed by both parties, and made easily accessible to the healthcare team in the event that questions arise requiring clarification

Resources

Nonphysician Providers: A Guide to Safer Delegation, CNA *Vantage Point*® 2019.

Considerations for Delegating the Authority to Prescribe Medications

Parameters for prescribing different categories of drugs – such as antibiotics, antivirals, diabetic drugs, hormones, antiasthmatics and antihypertensives – should be carefully delineated. Collaborating and/or supervising physicians should maintain a current record of the medication prescription authority delegated to APPs. Likewise, any prescription authority delegated for medical devices, diagnostic tests and procedures should be expressly noted.

For additional information on safe delegation practices please review the CNA *Vantage Point*® Scope of Practice Changes: Ten Keys to Safer Delegation.

Performance Evaluation

Annual performance review of all providers promotes quality of care and helps ensure that these providers function within the permitted scope of practice. The evaluation process should minimally cover clinical performance, documentation, patient satisfaction, patient safety and risk management awareness, as well as compliance with patient assessment and management protocols.

The following two components play an integral part in successful performance evaluation of APPs:

Performance review. A supervising or collaborating physician should be assigned to evaluate in a methodical, ongoing manner the outcomes of services provided by an APP, as well as their skill, knowledge and ethical standards. Written supervisory guidelines should focus on the following criteria, among others:

- Compliance with scope of practice, as delineated in applicable regulations, privileges granted by the organization, position descriptions and/or contracts.
- Basic skills and professional competence, which should be reviewed upon hire, at six months and annually thereafter.
- Management of patients with complex problems, including case referrals made or consultations requested with other professionals.
- Response to urgent situations, including compliance with approved emergency care guidelines.
- Narcotic/controlled substance prescribing, if applicable, and adherence to the organizational formulary.
- Compliance with the organization's policies and procedures, as well as medical staff bylaws, rules and regulations, and documentation requirements.
- Continuous availability during assigned work times, either in person or via reliable communications technology.

PA competencies are available from the National Commission on Certification of Physician Assistants. In addition, the National Organization of Nurse Practitioner Faculties outlines NP core competencies.

Resources

American Academy of Physician Assistants (AAPA)
American Association of Nurse Practitioners™ (AANP)

Patient healthcare information record reviews. As appropriate, supervising or collaborating physicians may be expected to review selected patient care records for compliance with practice directives and standards of care. In some jurisdictions, frequency of quality reviews is specified by state law. Otherwise, as a general guideline, reviews should be conducted during the probationary period, every six months afterwards, and as part of the annual review or re-credentialing process.

Record review techniques will vary depending upon the practitioner's scope of delegated duties, degree of experience and training, and assigned patient load. At a minimum, chart reviews should assess the following competencies:

- Diagnostic descriptions.
- Application of routine standing orders.
- Compliance with clinical guidelines and documentation policies and procedures.
- Explanations for any deviations from clinical guidelines or established policies and procedures.
- Issues and/or concerns including differential diagnosis, plan and disposition, as well as discussion with patient, physicians and other members of the healthcare team.
- Explanation for referrals to outside healthcare providers.
- Recommendations for care improvement.
- Discussion with the patient and significant others, including documentation of educational efforts made and indication that the patient or the patient's healthcare decision-making surrogate understands the suggested care plan.
- Timely and legible documentation.
- Entry of signatures and dates.

When necessary, record reviews should be supplemented by face-to-face discussion between reviewing physicians and APPs. APPs are anticipated to assume an increasingly meaningful role within the healthcare delivery system of the future. By specifying their range of duties, fostering a collaborative work environment, and carefully conducting and documenting performance and record reviews, organizations can obtain the full benefit of their knowledge and skills, while minimizing associated liability risk exposure.

Healthcare Industry Representatives

According to the Association of periOperative Registered Nurses (AORN), "health care industry representatives include employees of health care product companies (e.g., clinical consultants, sales representatives, technicians, repair/maintenance personnel)." Although they have a valuable role in offering technical support for providers, there are limitations to their activities in the outpatient healthcare setting. Strict credentialing guidelines should be established and implemented in order to ensure patient safety and alignment with the facilities that they are entering. While the role of the healthcare representative with specialized training may include calibration of equipment/devices under the supervision of a provider, they should not be providing direct patient care. Irrespective of the level of technical support being offered by the healthcare industry representative, all providers and staff should be trained on the safe and effective use of medical equipment and devices before it is deployed.

A written policy/procedure relating to healthcare industry representatives should be established and implemented, including the following:

- Requirements for informed consent that align with federal, state, and local laws and regulations, relating to the presence of a representative during an operative or other invasive procedure. The informed consent process should include the name of the representative and documentation of consent in the patient's healthcare information record.
- Roles and limitations for their activities while in patient care areas.
- Requirements for patient confidentiality.
- Vendor credentialing and training requirements prior to entry to the outpatient setting including, but not limited to, infection control, fire safety, bloodborne pathogens, and patient privacy and confidentiality rights. The healthcare industry representative must follow the regulations of the federal HIPAA statute and regulations, and OSHA's Bloodborne Pathogens Standards.

Independent Contractors

Determinations about whether providers are employees or independent contractors are complex and regulated by federal and state laws. For example, the Internal Revenue Service (IRS) common-law rules state that "anyone who performs services for you is your employee i*f you can control what will be done and how it will be done*." Hiring practices and classifying staff as employees or independent contractors should be developed in conjunction with legal counsel. Many outpatient healthcare organizations outsource a wide range of clinical, technical and administrative functions through the use of independent contractors to manage the following functions:

- Providers, nurses, technicians, pharmacists and other staff positions.
- Physical, occupational and respiratory staff and other therapists for patient rehabilitation.
- Laboratory, radiology, pharmaceutical and other ancillary services.
- Medical director oversight for aging services and allied health facilities, as well as home healthcare providers and medical group practices.
- Payroll, billing, purchasing, equipment maintenance and information technology support.

Outpatient healthcare organizations also may provide their services to other healthcare facilities in order to fulfill business goals and expand their reach. In either situation, it is important to have unambiguous contract terms clearly outlining services to be provided, mutual obligations under the contract, term of contract, and insurance requirements, as well as indemnification and hold harmless clauses to reduce risk exposures. Contracts with vendors and non-employed personnel often include provisions designed to protect one or both parties in the event a patient is harmed by the negligent actions of one of the parties. In the context of healthcare service contracts, an indemnification provision may refer to an agreement to compensate outside providers and vendors for costs and expenses incurred as a result of their own negligence. In contracts lacking such indemnity language, each party is held responsible for any third party claims associated with its own acts or omissions.

All contract language should be negotiated with independent contractors, drafted in consultation with legal counsel and communicated to insurers. Waiver of subrogation language is typically included in contracts, which is designed to reassure contracting service providers that neither the healthcare organization nor its insurance company will pursue recovery of damages if the contractor is found partially responsible for injury to a patient. Issues may arise if the insured signs a contract that includes a waiver of subrogation and then fails to notify the insurer, as the waiver may affect the subrogation or cooperation clause of the policy. If the outside vendor asks to be granted a subrogation waiver during contract negotiations, always notify the insurance company before complying, and request that the waiver be included in the policy form.

In addition to contractual considerations, leaders who oversee the hiring of independent contractors also must ensure that they are appropriately credentialed for the role they are assuming, carry professional liability coverage and have undergone health screening that aligns with the requirements of the organization.

Self-assessment Checklist: Human Resources Practices

This resource is designed to help leaders in outpatient healthcare settings evaluate their human resources policies and procedures. For additional risk control tools and information, visit www.cna.com.

Risk Control Strategies	Present (Yes/No)	Comments
Behavior-based questions and reliable personality profile assessment tools are used in hiring interviews to determine whether candidates possess the requisite integrity, decision-making ability and communication skills.		
A comprehensive pre-employment screening process is consistently utilized and includes the following elements, among others:		
• Drug screen.		
• Criminal background investigation, encompassing all states where the applicant has lived or worked in conformity with laws and regulations.		
• Review of Office of Inspector General and sex abuse registries.		
• Verification and documentation of references and licensure.		
• Check of credit history, if relevant and legally permissible in the jurisdiction.		
Personnel files are organized, reviewed and maintained to ensure that required documents and records are current and accessible.		
Personnel files, whether electronic or paper, are secured to protect employee privacy.		
Personnel files are continually updated and include the following documents:		
• Current professional licensure/certification.		
• Pre-employment screening documents (e.g., criminal background check, drug screen results, reference verifications).		
• Required employment documents completed by the employee (e.g., application, tax forms, contracts).		
• Position-specific skill certifications (e.g., CPR, ACLS).		
• Professional liability insurance carrier and limits of coverage, if applicable.		
• Professional liability claims history, if applicable, including a list of both pending and closed claims.		
• Reports of disciplinary licensing board actions, if any.		
• Current job description, signed by employer and supervisor.		
• Copy of photo identification card.		
• Emergency contacts.		
• Confidentiality statement, signed by employee.		
• Signed form indicating that the employee has read and understood the employment policies as delineated in the employee handbook.		
• General orientation documentation, with a signed acknowledgement by the employee and a human resources representative or supervisor.		
• Performance evaluations, signed by the employee and his/her supervisor.		

Risk Control Strategies	Present (Yes/No)	Comments
Employment policies are clearly conveyed to new staff members during the orientation process and are regularly reviewed by supervisors. Issues to discuss include:		
• Employment at will policy.		
• Code of conduct.		
• Acceptable business and professional practices.		
• Adverse event and near-miss reporting policy and process.		
• Disciplinary policies and procedures.		
• Workplace health and safety issues.		
• Conflict of interest.		
• Whistleblower protections.		
• Employee conflicts with outside employment.		
• Contract worker rules and regulations.		
• Professional boundary violations and associated internal reporting process.		
• Equal employment opportunity and diversity policies.		
• Anti-harassment policy.		
• Dress code.		
• Compensation, benefits, hours of operation, paid time off, holidays, and personal and professional leave policies.		
• Smoking policy.		
• Absenteeism and tardiness rules.		
• Artificial Intelligence, cell phone, internet, email and social media policies.		
• Concealed weapons policy.		
• Drug testing.		
• Exit interviews.		
Performance appraisals are conducted on a consistent basis, with findings acknowledged in writing by the supervisor and employee.		
A "tickler system" is established to track due dates for appraisals and licensure recertification.		
Exit interviews are conducted whenever staff members voluntarily end their employment.		

Risk Management Strategies for the Outpatient Setting

Technology and Electronic Media

Contents

Electronic Documentation

Electronic media – including email, blogs, social networking platforms, websites, texting and instant messaging have become a primary means of self-expression and communication for many individuals, including providers and other medical practice personnel. The increasing volume of online communications and instant messaging has created a new sense of connectedness – as well as a myriad of risks, including electronic discovery requests that may encompass text messages, blog entries and social media postings.

The substance of all electronic communications related to patient care – whether by phone, text, email or instant messaging should be documented in the patient's healthcare information record.

At a minimum, the following information should be included when documenting any electronic communication:

- Date and time of the discussion
- Patient's name and date of birth
- Identity of the other party (if other than the patient)
- Identity of the staff member involved in the communication
- Subject of the communication
- Advice given or other outcome and recommended follow-up

The following clinical information also should be included, among others:

- Patient's relevant medical history and allergies
- Nature of the patient's symptoms and associated complaints
- Aggravating and relieving factors

Electronic Media Exposures

The risks associated with electronic media continue to evolve and expand with increased usage. Providers should be aware that litigation discovery requests may transcend the traditional scope of patient treatment and financial records, potentially encompassing text messages, blog entries and social media postings. Consequently, providers must understand the associated exposures and create policies that recognize their benefits while minimizing the possibility of carelessness or misuse. The use of social media and electronic devices by healthcare personnel may result in the following additional risk exposures, among others:

Patient confidentiality. Workplace emailing or text messaging may violate privacy and security requirements imposed under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH), as protected health information (PHI) may be inadvertently transmitted to an unauthorized third party. If protected health information (PHI) is inadvertently revealed on organization-owned equipment or employee-owned devices, disclosure may constitute a breach of the HIPAA Privacy Rule and the Security Rule, as well as related state laws. The use of cellular telephones and smartphones to take and share photographs relating to a patient has significant privacy implications. Every healthcare setting should consider implementing a HIPAA compliance program that encompasses ongoing staff training, review of protocols and technical upgrades, including use of a HIPAA-compliant encrypted email system. A wide range of resources and tools are available to aid medical practices in this effort , including resources from the US Department of Health and Human Services and CMS.

Improper texting. Harassing, threatening or otherwise inappropriate messages posted by employees from workplace computers, texted from employer-issued mobile telephones, or employee-owned equipment can create vicarious liability exposures for the healthcare practice. In addition, improper litigation-related postings and text messages can undermine legal defense efforts.

Overuse of electronic devices. Texting and conversing on cellular telephones in patient care areas may decrease staff efficiency, leading to distraction and patient safety issues.

Network security issues. Unregulated web browsing and emailing on networked computers can introduce viruses or spyware into the system, resulting in possible data loss, theft or damage. Sharing of passwords and other security lapses can compromise confidential information, with potentially serious regulatory and liability implications.

Reputational risk from patient comments. Patients' use of electronic media, especially through blogs and online rating sites, creates reputational risk exposures for providers and practices. Many states have enacted laws that affirm the patient's legal right to offer a public opinion, even if that opinion is considered inaccurate or offensive to the provider. In general, legal cases in which providers challenge patient statements have not resulted in favorable outcomes for the providers.

Patient recruitment risks. Utilizing electronic media forums to recruit new patients or build loyalty may damage the reputation of a healthcare practice, unless the effort is managed in accordance with ethical guidelines. Risk exposures include, but are not limited to, jurisdictional issues and allegations of fraud and defamation.

Risk Management Strategies

Policies should directly address the issues raised by the proliferation of electronic media, in order to clarify rules and expectations and reduce liability exposure. These policies should clearly state that they apply to administrative, support and professional staff, as well as any contractors working for the organization.

The following strategies can help providers effectively manage the widespread use of these communication tools:

- **Create and enforce a formal policy governing personal use of networked computers,** with provisions that strictly prohibit all messages and activities of an offensive, threatening, harassing, defamatory or unprofessional nature.
- **Request that employees sign a form acknowledging that they understand the rules and the consequences of noncompliance.** Signed forms should be retained in personnel files.
- **Provide staff with written copies of electronic monitoring policies.** Explain that employers have the right to monitor email messages and other communications on practice-owned computers and that inappropriate conduct may have disciplinary consequences, up to and including termination.
- **Regulate cellular telephone use by staff members,** specifically addressing such key issues as personal telephone calls while at work, confidentiality, conversational volume and etiquette, talking while driving and utilization of the camera feature.
- **Revisit the privacy and confidentiality policies on a routine basis,** taking into consideration the risks of posted and texted messages containing PHI or other sensitive material.
- **Convey to staff the possible legal and ethical implications of the unprofessional use of email, texts and social media,** including the permanence and recoverability of deleted messages, limits of anonymity and realities of e-discovery. Clearly describe both the nature of the risks and the consequences of policy violations in the employee handbook, and reinforce the importance of sound judgment through staff training.
- **In consultation with administration and/or legal counsel,** formulate a protocol requiring written authorization from patients before discussing PHI on any electronic media or outside the patient care setting.
- **Encourage appropriate etiquette and model a mature attitude.** Remind staff members that they are viewed as ambassadors of the practice, and their posture on the internet should reflect this fact. Consider assigning mentors to coach less experienced staff in the nuances of professional conduct.
- **Regularly underscore cyber security rules and concerns,** using orientation and training sessions, posters, supervisory reminders and other means.
- **Have both legal counsel and information technology staff review all social media-related policies** for regulatory compliance and technical relevance.
- **Draft policies addressing the following important activities:** engaging e-patients, managing online discussions, conveying medical advice and general medical information, integrating electronic communications with the personal healthcare information record, and disengaging e-patients who publish derogatory statements or falsehoods about the practice.
- **Review marketing language used online to avoid inaccurate statements of services provided, avoiding use of** superlative and absolute phrases such as "best care," "highest quality" or "state of the art," as these descriptions may be quoted in lawsuits alleging breach of an express or implied warranty. In addition, social media messaging should not entice patients to expect care beyond the capabilities of the practice.
- **Adopt a HIPAA-compliant email encryption system** in order to better protect the confidentiality of sensitive information.

Social Media

Many healthcare organizations use social media for purposes of outreach, reputation management and emergency communication. They expand their networking ability by linking their practice-based websites to the following types of media platforms:

- **Social networking sites,** such as Facebook and Instagram, which promote mutual sharing of news and information, as well as marketing messages.
- **Video and photo-sharing sites,** including YouTube, Flickr, DropBox, Google Drive and OneDrive, which facilitate exchange of footage and images.
- **Micro-blogging sites,** such as Twitter, which encourage interaction via short published messages and links.
- **Weblogs,** including practice, personal and media blogs, which communicate ideas and opinions in journal format.
- **Business networks,** such as LinkedIn, which connect job seekers and potential partners to the practice or organization, and colleagues with each other.

Launching an effective social media site requires preparation, planning and attention to a number of risk management considerations. Before initiating a social media project, consider its implications from a strategic, marketing, liability and information security perspective. The following questions may help focus the planning process:

- **What is the underlying purpose** of the social media activity?
- **Does the proposed social media presence complement the business strategy?**
- **Who is the intended audience** for the site, page or profile?
- **Which topics, activities and forms of interaction will be promoted,** and which will be excluded?
- **Are adequate human and financial resources available** to maintain and update the project on an ongoing basis?
- **Which media platform, tool or application is best suited** to the intended purpose and audience?

Organizations may wish to retain a social media specialist to address these initial questions, as well as to assist in the planning and implementation of the following essential activities:

- **Establishing practical boundaries and guidelines** for electronic media use.
- **Promulgating sound operating rules and security controls** to protect against infiltration and other external threats.
- **Negotiating with vendor platforms regarding terms of use,** such as requirements for separate login pages and written notice of changes in privacy conditions.
- **Reviewing insurance policies** for potential cyber liability insurance coverage gaps and recommending portfolio changes, where necessary.

Once the site goes online, the social media consultant also can help to educate staff, patients and other users on rules and etiquette, advise on updating guidelines, assist legal counsel in reviewing and updating vendor contracts and site controls, and ensure that all social media tools have a consistent identity and appearance – including appropriate use and placement of the organization's logo.

Social Media Policies and Safety Measures

The many potential benefits of social media platforms for healthcare organizations are accompanied by an equally broad range of risk management considerations, which must be addressed by office policy. The following guidelines can help organizations retain control of this powerful tool and simultaneously minimize liability and regulatory exposure:

Incorporate social media issues into staff training. Sessions should include such key concerns as social networking protocol and expectations, parameters for use during working and non-working hours, potential legal ramifications, patient confidentiality issues and disciplinary consequences of misuse. Offer training to all employees and providers upon hire and annually thereafter, documenting session content and attendance.

Establish standard terms of use. Inform users that they are subject to the site's terms and conditions and that repeat violations will result in termination of access. The "click agreement" with users should be written in clear and unambiguous language and include these basic provisions, among others:

- **Users understand the risks associated with participating in online communication** and acknowledge that postings by providers and staff are not intended to be interpreted as a medical diagnosis or treatment.
- **Service marks and trademarks of the practice are the sole property of the organization,** and no copyrighted text, image, video or audio content may be distributed, modified, reproduced or used, in whole or in part, without prior written consent of the organization's leadership.
- **Blog postings may be edited or deleted by leadership without prior notice,** and abusive, illegal, disruptive or medically misleading communications are subject to immediate removal.
- **Disclosure of patient health information shall be governed by patient privacy policies,** as well as relevant federal and state privacy laws and regulations. Solicitation of confidential or proprietary patient information is strictly prohibited.
- **The practice is indemnified against any damages, liabilities, judgments or expenses** arising from any third-party claim involving posted material.

Prepare disclaimer statements. Sites should include the following standard disclaimers:

- **All content and information are of an unofficial nature** and are not intended to be interpreted as medical advice.
- **The views expressed are those of users** and do not necessarily represent those of the organization.
- **The sponsoring practice is not obligated to monitor chat rooms, Facebook pages, bulletin boards or other interactive areas** where visitors post their comments.

Institute strict editorial controls. Written guidelines for user-posted comments should include the following restrictions:

- **Postings cannot include specific patient data** or other confidential information.
- **No unlawful material can be posted on the site,** nor any content that could be considered obscene, defamatory, threatening, harassing or malicious.
- **No material can infringe on the rights of any third party,** including rights to intellectual property, privacy and branding.
- **Any off-topic material may be deleted,** including the promotion of outside products, services, groups or organizations.
- **The organization reserves the right to remove posts advertising commercial products,** including business solicitations, chain letters or pyramid schemes. Platform settings should disable advertisements and "pop-ups," where possible.
- **Users may not impersonate another individual** or share their identity and password.
- **Develop an incident response plan.** The written response plan should address violations of site rules, such as sharing of passwords, hacking, or posting of unauthorized patient images or other inappropriate content. At a minimum, the plan should encompass removal of objectionable material, notification of offenders, documentation and reporting of incidents, staff follow-up action and disciplinary standards, drafted in compliance with relevant employment laws and regulations.

Telehealth

The advent of the internet has reshaped many areas of life, including the practice of medicine. As the virtual realm has grown, the traditional in-person encounter between healthcare provider and the patient has become supplemented by telehealth. Telehealth (TH) refers to a broad range of remote patient care services, including clinical and non-clinical services. Videoconferencing, transmission of still images, patient portals, remote monitoring of vital signs, continuing medical education, and nursing call centers may be within the scope of telehealth.

Telemedicine (TM) is one aspect of telehealth. Telemedicine refers to delivery of clinical services provided at a distance through telecommunications in real-time. Through audio and visual technology, providers connect with patients using TM for healthcare services such as health screening, patient monitoring, counseling and education, specialty consultation, and diagnosis and treatment of disease.

Digital Health is another aspect of telehealth. Digital health includes health technology, digital tools, software and sensors to connect people and populations to manage health and wellness. Mobile health apps, electronic healthcare records, wearable devices are examples of digital health.

Forms of Telehealth

Telehealth – also known as *telemedicine, digital health, e-health* and *virtual care* – refers to healthcare services delivered remotely using advanced electronic technology. Some of the more common telehealth modalities are described below:

Form:	Definition:	Examples and uses:
Video conferencing	Live two-way interaction between patient and healthcare provider using audiovisual telecommunications technology.	• **Real-time healthcare services** and consultations for remote patients. • **Annual wellness visits** to clinics and medical offices. • **Collaborative consultation,** medical diagnosis and treatment by physicians and other providers based in different locations. • **Convenient referrals** to physically distant specialty providers. • **Emergency and critical care** in outlying locations, including prompt assessment of patients and consultation with specialists. • **Mental health services** for rural-based or underserved patients.
Store-and-forward or asynchronous video	Electronic transmission of patient health and medical data to a healthcare provider, who then treats the patient at a later time.	• **X-rays, MRIs, photos and other images** used for diagnostic purposes by primary or specialty providers. • **Prerecorded video clips** of patient examinations used to enhance the diagnostic process. • **Patient data** – including electronic health records, laboratory reports and medication management files – transmitted to specialists for use in consultations. • **Translated healthcare records** of non-English-speaking patients to facilitate provider treatment or consultation.
Monitoring and diagnostics	Electronic collection of patient data via "wearables" and "implantables," in order to enhance clinical monitoring and treatment of conditions.	• **Physiological data** – including blood pressure, heart rate, weight, and levels of oxygenation and blood sugar, among other metrics – gathered in real time. • **Comprehensive reports on chronic diseases** – e.g., diabetes, hypertension, asthma – used for data-driven decision-making and virtual patient education. • **Device-initiated alerts** to providers regarding patient noncompliance with diet recommendations, activity directives and other aspects of the treatment/care plan.
Mobile health or "mHealth"	A subset of telehealth that – using software applications designed for smartphones and other handheld communication devices – focuses on educating patients as well as connecting them electronically with their providers.	• **Personalized educational applications** that promote patient self-management of medical conditions, such as asthma and diabetes. • **Tools that integrate with electronic health records** and offer providers a more detailed view of a patient's medical history. • **Interfaces with wearable tech devices** that facilitate real-time review of patient data by members of the healthcare team. • **Automated reminders** to change surgical dressings, take medications or otherwise follow post-procedure recovery instructions.

Telemedicine (TM)

Implementation of TM as an accepted tool across the continuum of healthcare remains fluid as technology, licensing issues, costs, reimbursement, access, cybersecurity, and quality issues continue to evolve.

All providers using TM are held to the same professional practice standards as a provider practicing in the same profession or specialty, in an in-person setting. Consideration to the time of day, location, type of setting, and other variables will affect practice standards. Referral to a higher level of care is the responsibility of the provider.

Licensure and State Laws

TM licensure laws and regulations remain primarily within the purview of the individual states. The types of providers permitted to engage in telemedicine depends upon the jurisdiction. Requirements may include physicians, nurse practitioners, physician assistants, and some other licensed providers. Knowing the providers who are permitted to practice virtual care is the responsibility of the provider and facility.

Most states continue to require that providers who engage in telemedicine be licensed in the state where the patient is located. Federal and state waivers issued during a national healthcare emergency, such as a pandemic, expire and the regulations return to "pre-emergency" status. In view of the legislative volatility regarding interstate licensure, review current licensing requirements when verifying a provider's authorization to practice TM. State-by-state listing of licensure standards and policy statements are located at the Federation of State Medical Boards.

Telemedicine Training

Provider training is critical to successful implementation of TM. Training on TM can take the form of mock patient visits and practice modules designed by the software distributor. Training should be updated as new functions and upgrades are implemented.

At a minimum, training should seek to establish competency in video communication skills, documentation, understanding the scope and limitations of services provided via TM, proficiency with technology to be used and ability to troubleshoot unexpected equipment malfunctions.

Document all staff and provider training for TM. Permit only authorized providers, who have completed the required training and demonstrated an understanding of the unique issues, to provide healthcare via TM.

Establishing Provider-Patient Relationship

A patient-provider relationship can be established without a prior in-person visit or examination. Establishing a provider-patient relationship depends upon the following:

- Obtaining the patient's consent for the use of TM as the tool in which care will be delivered, and
- Verification of the patient's identity and disclosure of the provider's identity and credentials.

Document both of these steps in the patient's healthcare information record.

Standard of Care

Patient Selection – Not every patient is a suitable candidate for remote care. Formal selection criteria should be established that considers medical factors, as well as internet access and computer skills.

Consent – Obtain a verbal consent from the patient to proceed with providing healthcare via TM and document in the patient healthcare information record.

Patient verification – Confirm patient identity prior to TM encounters, in order to prevent identity theft and fraudulent insurance billing.

Documentation – All care delivered via TM must be documented in the patient's healthcare information record in accordance with the standards of documentation for in-person care. Such documentation includes patient history, review of systems, information used to make treatment decision(s), follow-up, referrals, any instructions given, and, where required, discussion with the supervising physician.

In addition, documentation should reflect that the service was provided through interactive TM technology, indicating the location of the patient and the provider, as well as the names and roles of other individuals participating in the virtual event.

Follow-up – Providers must impart patients with the means to contact the treating provider, or covering provider, for follow-up care and questions.

Prescribing medications – Providers must comply with all state and federal regulations for prescribing in the state where the patient is located and the provider is licensed to practice.

Safeguards

Privacy – All HIPAA requirements that apply to in-person encounters also apply to TM encounters. The use of healthcare specific, HIPAA compliant platforms is recommended.

Equipment and maintenance – Equipment should be suitable for diagnostic and treatment purposes, readily available when needed and fully functional during clinical encounters. Organizations should identify an individual with sufficient technical knowledge to be responsible for the maintenance and routine testing of equipment and privacy functions. User and administrator passwords should be changed every 90 days, at a minimum.

Cybersecurity – Install effective security software. Implement technical safeguards to protect electronic health information, including password-protected access to software applications, end-to-end encrypted data transmission, formal procedures for obtaining patient information during consultations and automatic log-off times.

Video conferencing from outside the secure office network – Two-way audio/visual interface platforms used outside a secure office network create additional privacy issues of which providers must be aware. When selecting and approving TM platforms for use, due diligence in evaluating the strength of the privacy and encryption capabilities is required. Install a virtual private network (VPN) with software patches and security configurations to ensure safe transmission of data and communications. Conduct periodic testing to ensure adequate bandwidth.

Selecting a TM Vendor

There are many vendors of TM/TH products and services, and selecting the safest and most suitable tools requires careful consideration of multiple factors, including system capabilities, technical specifications, compatibility with existing digital infrastructure, privacy elements and post-sale service.

When conducting due diligence in selecting a TM vendor, consider the following:

- The vendor's profile (e.g., ownership arrangement, size of workforce, domicile, years in business).
- Total funds allocated to research and development, a sign of commitment to quality and innovation.
- Proof of product compliance with HIPAA requirements, such as HITRUST Alliance certification or a similar vetting.
- Presence of certified trainers specializing in healthcare applications.
- Names of comparable healthcare clients who can provide references.
- Extent of the product's mobile compatibility, permitting providers to access information through their smartphones or other handheld devices.
- Availability of onsite and web-based training, as well as 24/7 customer support.
- Software licensing arrangements and associated user fees.
- Means of documenting patient interactions when using the product or service.
- Implementation costs, including hardware and software requirements, staff training, program maintenance and upgrades, and patient education on use of web-based portals.

When acquiring digital applications from a vendor, a user license is considered preferable to a subscription arrangement. By purchasing a software license, organizations obtain ownership of the product and exercise full control of the data. In contrast, a subscription often involves centralized data storage by the vendor, which may potentially lead to third-party interference. In either case, request that vendors sign a Business Associate Agreement to ensure that they remain legally responsible for HIPAA privacy and security regulations. Consult with legal counsel regarding contractual arrangements with vendors and applicable conditions and provisions.

Checklist: Creating a Defensible and Compliant Record of Virtual Care

Compliance Measures	Status	Action Plan
Basic Business and Operational Considerations		
A written protocol is created, which delineates acceptable uses of remote care technologies, e.g., prescription refills, appointment scheduling, assessment, patient and specialist consultation, and education, among others.		
A thorough, documented due diligence evaluation is conducted of potential telemedicine and telehealth (TM/TH) partners, especially with regard to clinical and technical compatibilities.		
A business associate agreement is signed with all TM/TH partners, pursuant to HIPAA privacy rule requirements.		
A record is maintained of TM/TH partners' contact information, including business email addresses.		
A "memorandum of agreement" is written, reviewed by legal counsel and entered into with partner sites.		
The memorandum is checked to ensure that it provides specific answers to key questions about the partnership arrangement, including the following:		
• Who provides support staff?		
• Who pays for telecommunication connections?		
• Who supplies and maintains equipment?		
• What space is available for TM/TH encounters?		
• Who manages the billing process?		
A TM/TH coordinator is designated and a job description written, assigning the coordinator responsibility for providing administrative support for consultations/referrals, program functioning and system processes.		
A written TM/TH procedure manual is developed, which addresses a broad range of clinical processes that occur before, during and after consultations.		
The procedure manual is reviewed by affiliated healthcare providers to ensure that it conforms with practice guidelines issued by national associations.		
Uniform referral and scheduling guidelines are drafted and included in partnership agreements.		
A formal policy for reserving TM/TH equipment and space is promulgated, which includes a conflict resolution protocol.		
A written protocol is instituted to guide the patient selection process, which includes specific parameters for referral to TM/TH providers, such as patients who require the following types of treatment:		
• Chronic care management.		
• Acute, uncomplicated care.		
• Medication management.		
• Pre- and post-operative care.		
• Mental health therapy.		
• Nutrition services.		
• Specialty care referral.		

Compliance Measures	Status	Action Plan
Basic Business and Operational Considerations (continued)		
A consistent patient registration process is implemented for distant site facilities.		
Formal procedures are established for patient testing and notification, including documentation of test results and follow-up measures in the patient healthcare information record.		
A procedure to escalate care in emergency situations is adopted, which includes consulting with other providers, accessing backup technology for immediate use and arranging prompt in-person intervention if necessary.		
Provider Fitness and Preparedness		
Licensure verification records are maintained for physicians, nurse practitioners, physician assistants and other designated healthcare professionals (hereafter "providers") involved in the delivery of virtual care.		
TM/TH credentialing, privileging and peer review processes are developed for providers, reflecting patient safety, jurisdictional and liability considerations.		
Roles and responsibilities related to the provision of virtual care are clearly defined by regularly updated formal policies, which are disseminated to different medical disciplines and staff levels.		
Guidelines are adopted to ensure that TM/TH services are offered only when there is a professional relationship between the provider and the patient, as defined by the following criteria, among others:		
• **Knowledge of the patient and the patient's health status** through an ongoing personal or professional relationship.		
• **A previously conducted in-person examination** of the patient.		
• **Availability for appropriate follow-up care** at medically necessary intervals.		
• **Past treatment of the patient in consultation with another professional** who has an ongoing relationship with the patient.		
• **An on-call or cross-coverage arrangement** with the patient's regular treating healthcare professional.		
Providers are formally instructed and regularly informed that the same standard of care applies to both TM/TH services and in-person care, and it is neither modified, enhanced nor reduced simply because a patient visit is conducted remotely.		
Receipt of TM/TH-related policies and procedures is acknowledged in writing by providers, who are tested on their comprehension, including how and when to do the following:		
• Schedule a consultation.		
• Arrange for a consulting room.		
• Set up necessary equipment.		
• Establish network connections.		
• Prepare and advise the patient and consulting provider, if applicable.		
• Document consultation findings.		
• Secure and back up required data.		
• Prepare reports of virtual care episodes.		

Compliance Measures	Status	Action Plan
Provider Fitness and Preparedness (continued)		
Educational and professional development requirements are specified in writing, including participation in pilot programs, as well as familiarity with clinical protocols, equipment capabilities and documentation requirements.		
Providers and staff members are tested for general computer proficiency, as well as knowledge of software applications and device features and connectivity, and records are maintained of testing results.		
Providers are trained on an ongoing basis in virtual care protocols, including proper documentation practices.		
Staff members are trained in incident reporting, and adverse TM/TH occurrences are tracked and trended for quality improvement purposes.		
Technical Safeguards		
Organizational standards and technical specifications are developed to promote safe and effective delivery of care, covering such areas as bandwidth, interoperability, verification of data transmission, equipment maintenance and on-site technical support.		
A private and secure computer network is maintained to protect patient confidentiality and the integrity of data exchanged between sites and providers.		
Equipment and software are catalogued by make, model and serial number, and are tested for functionality and interoperability prior to use.		
Warranties on all TM/TH equipment are filed for easy reference, as are all equipment maintenance records.		
A system is created to swiftly inform staff of technical glitches – such as a disconnection with a remote site during a consultation – that may affect clinical outcomes.		
Privacy and Security Provisions		
All TM/TH policies and procedures are reviewed periodically for compliance with extant regulations relating to patient privacy.		
Rules are established regarding the virtual consultation process and environment, including the following, among others:		
• **TM/TH sessions are scheduled in a suitable clinical setting** that offers both seclusion and professional amenities, when possible.		
• **Consulting spaces are identified by clearly visible signs,** indicating that a private patient session is in progress.		
• **Appropriate security measures are implemented during the transmission process,** including such critical functions as authentication, patient identification, data control and tracking, and Wi-Fi protected access.		
Measures are taken to protect the confidentiality of patient information, including the following, among others:		
• Electronic privacy safeguards, such as use of passwords and/or encryption.		
• Physical site security.		
• Securing of store-and-forward images and other patient records.		
• Confidentiality agreements for all personnel involved in TM/TH, including vendor staff.		

Compliance Measures	Status	Action Plan
Privacy and Security Provisions (continued)		
Providers are trained to comply with HIPAA, CMS, CDC and other state and federal regulations and guidelines relating to protection of patient privacy and confidentiality.		
A policy is adopted prohibiting use of personal email accounts for the exchange of protected patient health information, and mandating use of network-based accounts or secure, facility-approved messaging applications.		
Clinical Documentation and Recordkeeping		
A standard method of collecting and storing TM/TH information is implemented at both originating and distant sites, if applicable.		
TM/TH documentation formats are standardized and integrated with electronic patient health information records.		
Virtual care encounters are thoroughly documented, including, but not limited to, the following information:		
• Patient name and identification number.		
• Originating facility's name.		
• Distant facility's name, if applicable.		
• Registration information (i.e., patient identification number and provider assignment) at distant site, if applicable.		
• Date of service.		
• Referring provider's name, if applicable.		
• TM/TH provider's name.		
• Type of evaluation to be performed.		
• Informed consent form and signature.		
• Diagnosis/impression of providers.		
• Recommendations for further treatment.		
A formal process is established for obtaining and documenting patients' informed consent for TM/TH services, encompassing the following information, per the Federation of State Medical Boards:		
• Patient identification, including name and date of birth.		
• Names, credentials, organizational affiliations and locations of physician and/or other healthcare professionals involved in the visit.		
• Name and description of the recommended procedure.		
• Potential benefits and risks of the procedure.		
• Possible alternatives, including no treatment.		
• Risks of declining the treatment/service.		
• Confirmation that patient understands and accepts remote care delivery mode.		
• Contingency plans in the event of technical problems during the procedure.		
• Explanation of how care is to be documented and accessed.		
• Security, privacy and confidentiality measures to be employed, as well as extent of risk to privacy notwithstanding such safeguards.		
• Names of those responsible for ongoing care.		
• Reiteration of the right to revoke consent or refuse treatment at any time.		
• Consent of patient to forward patient-identifiable data to a third party.		

Compliance Measures	Status	Action Plan
Quality Improvement		
A formal TM/TH quality improvement program and review process is implemented, which tracks the following quality of care indicators, among others:		
• Equipment or connectivity failures.		
• Number of attempted and completed visits.		
• Average waiting times.		
• Patient and provider satisfaction with virtual patient encounters.		
• Patient or provider complaints related to virtual visits.		
Outcome metrics are decided upon to monitor and assess the clinical quality and efficiency of virtual care encounters, including the following:		
• Patient complication and morbidity rates.		
• Provider compliance with performance criteria, including productivity and patient satisfaction levels.		
• Diagnostic accuracy.		
• Adherence to evidence-based clinical protocols.		
• Referral rates.		
• Cost per case.		
• Delays in accessing consultations, referrals or specialty practitioners.		
Outcome findings are reported to the Quality Improvement Committee (QIC) on an ongoing basis.		
Written guidelines are developed for auditing TM/TH practitioners and sharing internal review information – including virtual care-related adverse events – with established quality improvement and risk management programs.		
TM/TH-related policies, procedures and staff training efforts are reviewed every six to 12 months, with revisions based upon incident report findings and assessment of the program's overall safety, effectiveness and efficiency.		
Regular equipment testing and maintenance is performed and documented, including post-installation testing and pre-session calibration, as well as ongoing quality checks of audio, video and data transmission capabilities.		
Routine audits of equipment and software functionality are conducted, and reports are prepared for the QIC.		

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Risk Management Strategies for the Outpatient Setting

Hazard Risks

Contents

Disaster Preparedness

The goal of disaster planning is to protect patients, visitors, staff, physical property and financial assets in the event of an emergency situation. Effective disaster planning can help outpatient healthcare facilities maintain order, prevent major service disruption, reduce losses and restore vital facility functions with minimal delay. It may also affect the success of future business continuity for the facility.

Although it may be tempting to postpone analyzing future risks and focus on more immediate concerns, the key to successful disaster management is to plan ahead. Proactive planning by healthcare facilities may help mitigate the following risk exposures, among others:

- **Negligence for failing to maintain an up-to-date emergency response plan** and/or prepare for emergencies through staff training and simulation exercises.
- **Professional liability, when healthcare providers are physically and emotionally exhausted,** creating vulnerability to clinical errors.
- **Unauthorized scope of practice,** when providers transcend legally prescribed practice parameters under the stress of delivering emergency care.
- **Breach of privacy and confidentiality** for failing to protect patient/resident privacy and confidentiality during emergencies.
- **Inappropriate emergency use authorization,** when healthcare facilities and providers disregard important conditions related to these temporary issuances.
- **Discriminatory allocation of resources,** when healthcare settings lack a legitimate process for determining appropriate and reasonable use of limited resources.
- **Regulatory violations** for failing to comply with federal and state emergency preparedness mandates; accommodate patients/residents with disabilities, as prescribed by the Americans with Disabilities Act; or permit access to treatment pursuant to the Emergency Medical Treatment and Active Labor Act, among other sources of noncompliance.
- **Premises liability,** when patients and staff are left to shelter in place despite structural indications for facility evacuation.

Mitigation of risks associated with disaster preparedness extends beyond policy development, requiring a continuous process of review, testing and improvement. This section serves as a tool to help outpatient healthcare facilities and providers develop a range of emergency management initiatives in response to regulatory expectations, industry guidelines and professional risk management recommendations. Because no two facilities or outpatient practice settings are identical, the information included here should be adjusted to the type, size and complexity of a setting or practice. By tailoring risk initiatives to the nature and scope of operations, healthcare settings and providers may respond to a crisis with practical, realistic and efficient measures. For additional information regarding emergency planning and disaster preparedness, please see the CNA Special Resource – Emergency Planning: A Risk Management Guide for Healthcare Facilities and Providers.

Federal and state statutes provide a degree of immunity to facilities and providers during emergency conditions. However, failure to prepare for crisis situations can nullify those protections. The Centers for Medicare & Medicaid Services (CMS) Emergency Preparedness Rule *requires* 17 types of healthcare providers, suppliers and facilities to have a written emergency management plan to guide their response to natural and man-made disasters.

The four basic components of emergency readiness outlined in the CMS regulations will be discussed in this section:

1. an annual risk assessment utilizing an "all hazards" approach;
2. response-related policies and procedures;
3. communication plans; and
4. a training program.

This information applies to all types of outpatient healthcare settings, irrespective of whether or not the setting is governed by the CMS regulatory requirements.

Identifying Risks

The first step in preparing for disaster-related risks is to identify and prioritize potential foreseeable events, both man-made (e.g., active shooter, violent crime, sabotage, arson, riots, terrorism and contamination) and weather-related (e .g ., hurricanes, tornadoes, wildfires, floods and blizzards). A team-based, systematic approach to conducting a gap analysis will broaden the scope of the assessment and provide a comprehensive risk analysis.

Quantifying Risks

After identifying potential sources of loss, the next step is to quantify the hazard posed by specific events. This process involves ascertaining the likelihood (frequency) of an occurrence against its potential impact (severity). It may be determined that it is no longer safe to shelter in place, and an evacuation is required. Use of a risk matrix, such as the widely recognized Kaiser Permanente HVA tool, enables the crisis management team to identify exposures and prioritize resources.

Gauging the probability and potential impact of an event requires a clear understanding of the vulnerabilities of the facility, as well the environment in which it operates. This evaluation involves reviewing the loss history, as well as consulting with local emergency management agencies and first responders, government and private agencies, and other external authorities.

It also involves knowing the available backup processes, systems and equipment in the event of an emergency, including power sources and other utilities.

Creating a Response Plan

After immediate risks have been identified and evaluated, the next step is to develop a response plan. An emergency response plan should be based upon the results of the risk assessment and incorporate disaster response and recovery protocols. The plan should be specific and include the titles of the individuals assigned to tasks. When designing the response plan, request input and active involvement of local authorities and first responders, as partnerships formed during the planning and drafting phases can become useful during an actual emergency.

The following tasks, among others, should be addressed in the emergency response plan:

- Emergency notification
- Incident command
- Media relations
- Crisis staffing
- Phone contact procedures
- Resource procurement
- Healthcare information record maintenance
- Care site establishment
- Bed utilization
- Surge capacity/diversion
- Shelter availability
- Evacuation and patient tracking
- Transfer arrangements
- Child care for staff
- Mortuary services
- Supply chain management
- Utility outages

The plan should include detailed instructions for managing outages involving critical systems, such as electricity, IT, natural gas, water, sewage and ventilation/heating/air conditioning. The National Fire Prevention Association (NFPA) Standard 110 outlines performance requirements for emergency and standby power systems in healthcare settings, including weekly and monthly inspections of emergency generator systems.

During times of crisis, supply chain operations can be adversely affected by inefficient distribution networks, inadequate inventory space, outdated manual processes and data systems that cannot track real-time supply levels, among other deficiencies. As part of the emergency management planning process, measures should be taken to help prevent or mitigate shortages and supply chain breakdowns that may adversely affect patient care and safety.

Policies and Procedures

Policies and procedures should reflect the emergency response plan and include steps for designating a command center, establishing communication procedures, maintaining security, and developing patient evacuation and tracking protocols, as well as drafting measures to safeguard the healthcare information record.

Chain of Command and Communication

If disaster strikes, staff must know who is in charge. Effective emergency preparedness requires a clear chain of command that extends from senior leadership to every level of staff. By creating an incident command center, healthcare facilities and office practices can ensure that necessary tasks – such as information gathering, staff coordination and debriefing – are completed in a prompt and efficient manner.

Whether an emergency requires evacuating a setting, initiating a lockdown, diverting patients or establishing a controlled external perimeter, promptness, clarity and accuracy of communication is critical to maximizing safety and minimizing loss.

The following guidelines can minimize confusion during and immediately following an emergency situation:

- **Designate a disaster coordinator,** who has responsibility for declaring the disaster, mobilizing the response and keeping everyone informed.
- **Clearly define roles and duties of staff members,** including contacting government agencies, neighboring healthcare facilities, emergency aid providers and other outside entities.
- **Maintain a list of providers and staff, by title, in the chain of command that are to be contacted in case of an emergency,** and post the list in strategic locations.
- **Develop a system to track all patients, staff and visitors** who may have been in the facility at the time of the disaster.

- **Arrange an alternative means of communicating** information to key internal and external audiences, such as cellular telephone "trees," electronic mail "blasts," text messaging, online portals, satellite telephones and two-way radios.
- **Develop a listing of preferred vendors and alternative suppliers that details their** contact information, including primary and emergency telephone numbers.
- **Maintain electronic and hard copy contact information** for key stakeholders, including fire and police departments, ambulance services, utility companies, contractors, insurance companies and relevant government agencies.
- **Establish an emergency hotline to relay** urgent instructions and safety messages to employees, and also to summon appropriate on-call personnel if the incident occurs after business hours.

Sheltering in Place

Certain emergencies – such as a contained hazardous materials release, armed intruder situation or inclement weather – may require patients and staff to shelter in place. Identify areas of lower risk within the premises depending upon the type of emergency at hand and move patients and staff to safer zones. As part of the emergency planning process, supplies needed for sheltering in place should be stored in advance. For example, water, durable food, emergency medications, portable radios, first aid kits, eating utensils, blankets, flashlights, batteries and other basic supplies should be stockpiled. Continually assess the safety of sheltering-in-place arrangements and be prepared to order an evacuation if it becomes the safer option.

Evacuation Procedures

Depending upon circumstances, it may be determined that it is no longer safe to shelter in place, and an evacuation is required. The decision to evacuate requires consideration of several factors, including the urgency of the threat, the type of damage sustained and the capability of staff and providers to meet the medical needs of patients. Immediate threats to life, such as a fire or explosion, will require emergent evacuation. Other situations may permit a planned and phased evacuation. When selecting an evacuation site, leaders must consider both the short- and long-term needs of patients. In a large scale disaster, patients may be evacuated to multiple, widely dispersed sites. It is essential to know where patients and staff are located, both during the crisis and afterward.

Plan ahead for appropriate transportation needs during an evacuation, and select the safest mode based upon the acuity needs of patients. Draft an emergency transfer protocol, emphasizing the need for staff to properly monitor patients enroute, irrespective of the mode of transportation. Prior to transport, print out the patients' baseline history and medication administration record, if applicable, and provide these documents to the accepting facility/location.

The following measures can help reduce panic and ensure an orderly evacuation:

- **Prepare detailed diagrams of the facility and surrounding area,** showing all critical access and escape routes.
- **Check all patient care areas** to ensure that no patients are left behind. Instruct staff to close doors behind them as a sign that the room is empty.
- **Implement a voicemail system** during the period of evacuation in order to convey ongoing evacuation details to families of patients, relay information to staff, and provide daily updates on the status of evacuation.
- **Instruct staff members to meet at a designated location** following the evacuation.

Plan Testing and Training

Disaster drills should be scheduled on a regular basis. Evacuation techniques and the response plan, in its totality, should be evaluated at least annually and updated to reflect organizational changes, lessons learned from drills and emerging exposures. Training should be mandatory for all staff and providers, temporary/contracted employees and volunteers upon hire, and as required by CMS and other regulatory bodies. Training sessions should include a review of emergency-related policies. Document all training events, drills and other exercises, including dates and names of attendees. For those facilities falling within the CMS rule, the first level of testing involves "tabletop" exercises, in which team members review the plan's effectiveness by analyzing various disaster scenarios. The second level consists of "walk-through" drills, in which responders perform their functions using the methods and communication tools indicated in the plan.

Continuity Planning and Recovery

Despite the best precautions, there is always a possibility that the facility may be rendered inoperable by a disaster. By formulating a continuity and recovery plan, providers are better positioned to restart operations as quickly as possible. Disaster recovery plans should address communications with patients, public agencies, suppliers and community representatives after the disaster, as well as arrangements to establish alternate patient care locations, if necessary.

The business continuity plan should include procedures for safe storage of critical documents off-site, including financial and insurance documents, building blueprints, equipment inventory and reconstruction plans. An alternative mailing address should be established in the event that the building is severely damaged. Guidelines for safeguarding vital clinical and business data against potential disruption of the information processing system should also be established.

Post-disaster Information Management

The strength of the continuity plan depends, to a great extent, on the ability to protect clinical, personnel and financial documents.

The following guidelines can reduce the risk of losing vital data due to disaster, hackers or computer glitches:

- **Store paper records and files in fire-resistant/proof cabinets,** remembering that documents kept in rooms with sprinklers are highly susceptible to water damage.
- **Keep copies of the following documents off-site,** ideally in a safe deposit box:
  - Disaster response plan.
  - Essential telephone numbers.
  - IT system records, including a backup copy of the computer's basic operating system, boot files and essential software.
  - Insurance policies.
  - Lease.
  - List of assets.
  - Mailing list of current patients.
- **Physically separate telecommunication network devices** to reduce the likelihood of a single-point failure.
- **Install and regularly update protective devices and software,** including anti-virus software, electronic firewalls and surge protectors.
- **Back up data on a regular basis,** including accounting and payroll records, employee information, patient lists, procedures, suppliers and inventory.
- **Store backup files off-site** in a secured location.
- **Identify third-party IT service providers** outside of the potentially affected area and arrange for emergency services on a contingency basis.

Post-disaster Response

A sound response plan will expedite restoration of operations and systems, the return of staff and, most importantly, resumption of patient care. After the immediate danger has passed, it is necessary to take the following steps, among others:

- **Provide patients with vital information** regarding their treatment and records.
- **Communicate with staff regarding the extent of the disaster** and the timetable for reopening the facility.
- **Contact the landlord and, if necessary, the county building inspector and/or the fire department** for a general assessment of the damage.
- **Inform the insurance agent or company** of the disaster.
- **Reroute mail and telephone calls** as needed.
- **Conduct salvage operations** and maintain a careful accounting record of all damage-related costs.

Fire Safety

Every building must comply with the structure and fire protection rules set forth in the National Fire Protection Association Life Safety Code. The standards in the code apply to various types of buildings. Contact the local fire marshal for information regarding applicable fire safety standards.

Outpatient healthcare settings should have a fire safety plan, including emergency evacuation instructions, posted in a conspicuous place. The plan should include the following actions, at a minimum:

- **Posting of evacuation routes** in each examination room.
- **Assignment of responsibility for shutting off piped gases,** such as nitrous oxide and oxygen.
- **Providing a fire safety orientation** and annual education program to all staff and providers.
- **Holding quarterly fire drills,** as well as evaluating and documenting drill results.
- **Ensuring that the building's fire alarm system is tested on a quarterly basis** by a reputable testing service.
- **Declaring the office a smoke-free environment** and rigorously enforcing no-smoking rules.
- **Reporting any identified safety deficiencies** involving fire doors, exit signs, emergency lighting, fire extinguishers or smoke/heat detectors to the building manager.

For more information, see the sample fire safety plan on page 9-7.

Medical Emergencies

Medical emergencies can involve patients, staff or visitors. Widespread public health emergencies, such as pandemics, may affect clinical and operational systems within outpatient healthcare settings and result in potential staffing issues, supply shortages and the need to utilize telemedicine or cancel elective appointments and procedures. Management of public health emergencies such as pandemics is outside of the scope of this manual. Additional information can be found in the CNA Special Resource entitled COVID-19: Achieving Recovery Through Risk Management

If a clinical emergency occurs in the office, appropriate responses range from calling 911 to performing CPR to attempting more complex medical interventions, depending upon staff competencies and the specialty of the healthcare setting. The following policies and procedures may enable staff to respond more effectively to a medical emergency:

- **Encourage staff to achieve 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,** to call 911 if told to do so, and to remain on the scene until emergency personnel arrive.
- **Inspect the emergency crash cart on a daily basis** and maintain inspection logs, if applicable.
- **Train staff in the use of emergency equipment and medications,** documenting training and proficiency in personnel files.
- **Keep inspection and preventive maintenance records** for all emergency equipment in the office.
- **Check the automatic incoming telephone service,** ensuring that it transfers patients to office staff.

Sample Fire Safety Plan

Fires are the most common emergency situation and, hence, serve as a good starting point for emergency planning efforts. During a serious fire or similar emergency, firefighters will probably take command of the facility. Therefore, it is important to develop the fire prevention and safety plan in coordination with the local fire department and emergency responders. The plan should assign responsibility for the following measures, among others:

Before:

- **Implementing and enforcing proper disposal procedures** for flammable materials.
- **Regularly inspecting the electrical system** for safety and capacity.
- **Ensuring that evacuation routes are well marked** and clear of obstructions.
- **Checking and maintaining fire protection equipment** – including extinguishers, smoke detectors, sprinklers, fire doors and alarm systems – in accordance with manufacturer recommendations.
- **Conducting fire drills** at regular intervals, followed by evaluation and recommendations.

During:

- **Declaring an emergency** and initiating the response plan.
- **Notifying the fire department** of the existence, intensity and exact location of the fire.
- **Implementing initial safety steps,** such as ensuring that fire doors have closed properly.
- **Evacuating staff, patients and visitors,** if necessary.
- **Ensuring that fire protection valves are open** and fire pumps are operating, if applicable.
- **Providing clear access for fire trucks** and other emergency vehicles.
- **Meeting arriving firefighters** and providing them with necessary information.
- **Removing or covering combustibles,** such as oxygen tanks, when possible.

After:

- **Securing the fire area** as possible.
- **Accounting for all staff and patients** by name.
- **Notifying authorities if arson is a possibility,** noting any suspicious circumstances.
- **Informing insurers as soon as possible,** and following their recovery suggestions.
- **Cleaning up excess water quickly** to reduce staining, mold and other post-fire damage.
- **Beginning salvage operations,** while taking care not to disrupt ongoing insurance or criminal investigations.
- **Debriefing staff** and evaluating emergency response protocols and plan execution.

This basic format can be followed for other types of emergencies, including tornadoes, floods, utility outages, hazardous chemical releases, wildfires, intrusions and disease outbreaks.

Security

Maintaining security following a disaster can be a challenge, as buildings may require swift evacuation and remain empty afterward for a prolonged period. While the top priority is protecting the lives and safety of patients and staff, it is also necessary to minimize property loss and damage, possibly by contracting with private security. In the event of a disaster, it may be necessary to lock down the facility or provider offices. Written security procedures should be developed in collaboration with local emergency management agencies, law enforcement and governmental agencies. These procedures should address such concerns as tracking patients and staff, preventing looting, preserving basic order and coordinating with law enforcement.

Emergency preparedness planning should be a core component of every healthcare setting's risk management program. Only by anticipating disaster and crafting an effective response can leadership and providers maintain some degree of control during an emergency; minimize injury, damage and disruption; and expedite recovery. Although facilities vary widely with respect to risk profile and patient population, the prevention-preparation-response-recovery format presented in this section may serve as an emergency planning template modifiable to the specific needs of each healthcare setting.

Resources

Disaster planning involves a wide range of regulatory issues. Begin the process by checking local laws and regulations regarding life safety and fire prevention. Other resources for disaster planning include the following websites:

- American Health Information Management Association.
- American Society for Healthcare Engineering, which provides an example of a hazard vulnerability analysis.
- Department of Homeland Security.
- The International Association for Disaster Preparedness and Response.
- Federal Emergency Management Agency.
- National Fire Protection Association's NFPA 1600, a standard for disaster/emergency management and business continuity planning.
- Occupational Safety and Health Administration.
- U.S. Environmental Protection Agency, which provides information on hazardous materials and the Right-to-Know Act, which makes state and local governments responsible for informing the public about potentially dangerous chemicals in the community.

Self-assessment Checklist: Emergency Management

The following questions are designed to help healthcare business owners evaluate disaster-related policies and procedures. For additional risk control tools and information on a wide and growing range of topics, visit www.cna.com.

Risk Control Measures	Present (Yes/No)	Comments
Risk identification and assessment		
Have all foreseeable sources of disaster been identified, reflecting both past incidents and emerging concerns?		
Have identified loss exposures been categorized, quantified and prioritized?		
Have appropriate response measures been identified, along with their projected costs?		
Has the potential impact of a disaster on vendors, suppliers and utilities been considered, in terms of recovery and rebuilding time?		
Emergency management planning and preparation		
Has an emergency operations center been designated, as well as an emergency manager?		
Have emergency communication methods (including backup systems) been identified, and is necessary equipment available?		
Is a current emergency contact list available in both hard-copy and electronic form, with names and telephone numbers clearly noted?		
Has a list of primary and alternative vendors/suppliers been drafted, including telephone numbers and websites?		
Are mutual disaster and evacuation arrangements in place with other practices and healthcare facilities?		
Have emergency evacuation procedures been developed and practiced, as well as search and evacuation techniques?		
Are there detailed drawings and maps of the facility and surrounding area, depicting access/escape routes?		
Have incident-specific procedures been developed to address identified risks?		
Are computer records and other important documents backed up and securely stored?		
Have insurance coverage, risk control and mitigation measures been upgraded as needed, to address changing conditions and emerging exposures?		
Do response plans meet the requirements of the Occupational Safety and Health Administration, the Environmental Protection Agency and other regulatory bodies?		
Have all staff members (including temporary/contracted employees) been trained in emergency procedures, and has this training been documented?		
Is the disaster recovery plan in writing and available for review?		

Risk Control Measures	Present (Yes/No)	Comments
Plan implementation and testing		
Have all parties involved with the emergency management plan received initial training, and do they undergo ongoing refresher courses?		
Have team members been trained using walk-through drills (i.e., simulation testing)?		
Have public agencies been included in walk-through drills?		
Is the plan regularly updated to reflect mistakes made and lessons learned during testing/drills?		
Disaster recovery		
Does the recovery plan encompass a wide range of disaster scenarios, both natural and man-made?		
Have recovery goals been prioritized, and does the recovery plan reflect these priorities?		
Are procedures in place to contact patient and staff families immediately after a disaster, as well as government agencies, suppliers, local media and community representatives?		
Have arrangements been made to establish alternate care locations, if necessary?		
Have all insurance options, both conventional and alternative, been fully considered, and are coverage levels sufficient for both surviving a protracted business interruption and rebuilding a severely damaged facility?		

Violence Prevention

The National Institute for Occupational Safety and Health defines workplace violence as "violent acts (including physical assaults and threats of assaults) directed toward persons at work or on duty."

Every healthcare setting is vulnerable to aggressive behavior and abuse. Therefore, this critical issue, which potentially affects patients, staff and providers, must be addressed. There are four types of healthcare workplace violence:

- Criminal intent
- Customer/Client-on-worker
- Worker-on-worker
- Personal relationship

Developing a Program

Begin the process of creating an effective violence prevention program by soliciting staff input regarding their experiences and ideas. Then, formulate clear objectives that reflect the practice structure and culture, patient demographics, and community risks and issues. After goals and strategies have been determined, inform staff members of their responsibilities and begin training them in violence prevention and de-escalation.

At a minimum, workplace violence prevention programs should incorporate the following measures:

- Analyze your workplace.
- Create a supportive environment.
- Offer communication and empathy training.
- Establish a clear workplace violence policy.
- Commit to a non-violent workplace.
- Train employees to recognize warning signs.
- Create an action plan, share it with staff, and practice implementation by conducting walk-through drills.

At a minimum, workplace violence prevention programs should incorporate the following measures:

- **Create and disseminate a zero-tolerance policy for violence,** including verbal and nonverbal threats and other forms of hostile behavior. Ensure that providers, staff members, patients and visitors are apprised of this policy.
- **Ensure that staff will not face reprisal** if they report instances of workplace violence or abuse.
- **Encourage staff to promptly report incidents** and present suggestions about reducing or eliminating risks.
- **Maintain records of incidents** in order to evaluate the measures taken and assess overall progress in reducing violence.
- **Outline a comprehensive security plan for the practice.** This plan should include working with law enforcement agencies to identify strategies for preventing and mitigating workplace violence.
- **Allocate adequate resources for the program** and encourage practice leaders to develop expertise on the subject of violence prevention in the healthcare environment.
- **Affirm the commitment of the practice to maintaining a supportive culture** that places as much emphasis on staff safety and health as it does on serving patients.
- **Periodically brief staff members and others on incidents that have occurred in the practice,** as well as on general safety- related issues.

As with other health and safety initiatives, the violence prevention program requires leadership commitment to the following principles:

- Staff involvement.
- Workplace analysis.
- Ongoing staff training.
- Careful recordkeeping.
- Program review and evaluation.

Active Shooter Situations

Shootings within healthcare settings are relatively rare, but appear to be on the rise. Although armed intrusions are unpredictable, a sound emergency response plan can help save lives and minimize civil liability for willful lack of preparedness. The following measures can significantly enhance organizational response to a potentially panic-inducing situation:

- Make the issue an organizational priority.
- Craft a written policy.
- Conduct armed intruder exercises and drills.
- Develop a communication plan.
- Collaborate with emergency responders.
- Appoint an incident commander.
- Establish a uniform response for lockdowns.
- Advise staff against confronting an active shooter.
- Be prepared for a hostage situation.
- Provide safe evacuation routes.
- Draft plans for both evacuating and sheltering in place, based upon the nature of the incident and the mobility of patients.
- Carefully consider whether to advertise that the building is "weapons-free."

De-escalation Tips

Do not argue with or provoke a hostile person. Instead, focus on defusing tense situations, utilizing the following strategies:

- **Stay at least two or three arm lengths away** from a hostile person.
- **Listen and acknowledge concern.**
- **Use a firm tone of voice,** but not a hostile or angry one.
- **Separate the hostile person from other patients,** if possible, and avoid being alone with the individual.
- **Develop an emergency code** to alert other office staff that a violent person is on the premises.

Self-assessment Checklist: Violence Prevention

The following questions are designed to help practices evaluate their policies and procedures regarding violence prevention and response. For additional risk control tools and information on a wide and growing range of topics, visit www.cna.com.

Risk Control Measures	Present (Yes/No)	Comments
Workplace Analysis		
Has a comprehensive violence and abuse analysis been performed in the facility, in order to ensure that:		
• Locking systems are in place on outer doors?		
• Unused doors are always locked?		
• Visitor access is carefully controlled?		
• Entrances and parking lots are well-illuminated?		
• Lights are regularly inspected?		
• Shrubbery is trimmed to minimize shadows?		
• Security alarm systems are carefully maintained and frequently tested?		
• Response procedures are in place for violent incidents, including assaults, bomb threats, gunfire and hostage situations?		
Community and Environmental Considerations		
Have local law enforcement and other emergency response agencies been contacted regarding area crime risks?		
Has an environmental risk assessment been performed, which considers:		
• Crime statistics of the surrounding community?		
• Past occurrences of workplace violence, as documented in medical and safety reports?		
• Instances of employees working alone?		

Risk Control Measures	Present (Yes/No)	Comments
Prevention Program		
Has a violence prevention program (VPP) been developed and implemented?		
Is there a team in place that is responsible for implementing the program and monitoring results?		
Is the VPP in writing, and does it undergo periodic review for effectiveness and relevance?		
Does the VPP clearly define the various types of violence, including verbal and psychological abuse?		
Are the policies and procedures of the VPP drafted in a clear, thorough manner, and are they realistic in view of the organization's human and financial resources?		
Does the VPP endorse one consistent procedure for reporting, investigating and documenting acts of real and threatened violence?		
Does the VPP work to avert workplace violence via human resources policies and conflict management training for staff?		
Is the VPP addressed in new hire/volunteer orientation programs, and are personnel required to acknowledge their understanding of the VPP through a written protocol?		
Is a criminal background check completed and documented for all new hires and volunteers?		
Is there a rapid response protocol for crisis situations, including evacuating the office and calling 911?		
Have staff been adequately trained in defusing conflicts and restraining out-of-control patients?		

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

Published 2/2024.

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