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Risk Management Strategies for the Outpatient Setting

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Operational Risks

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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

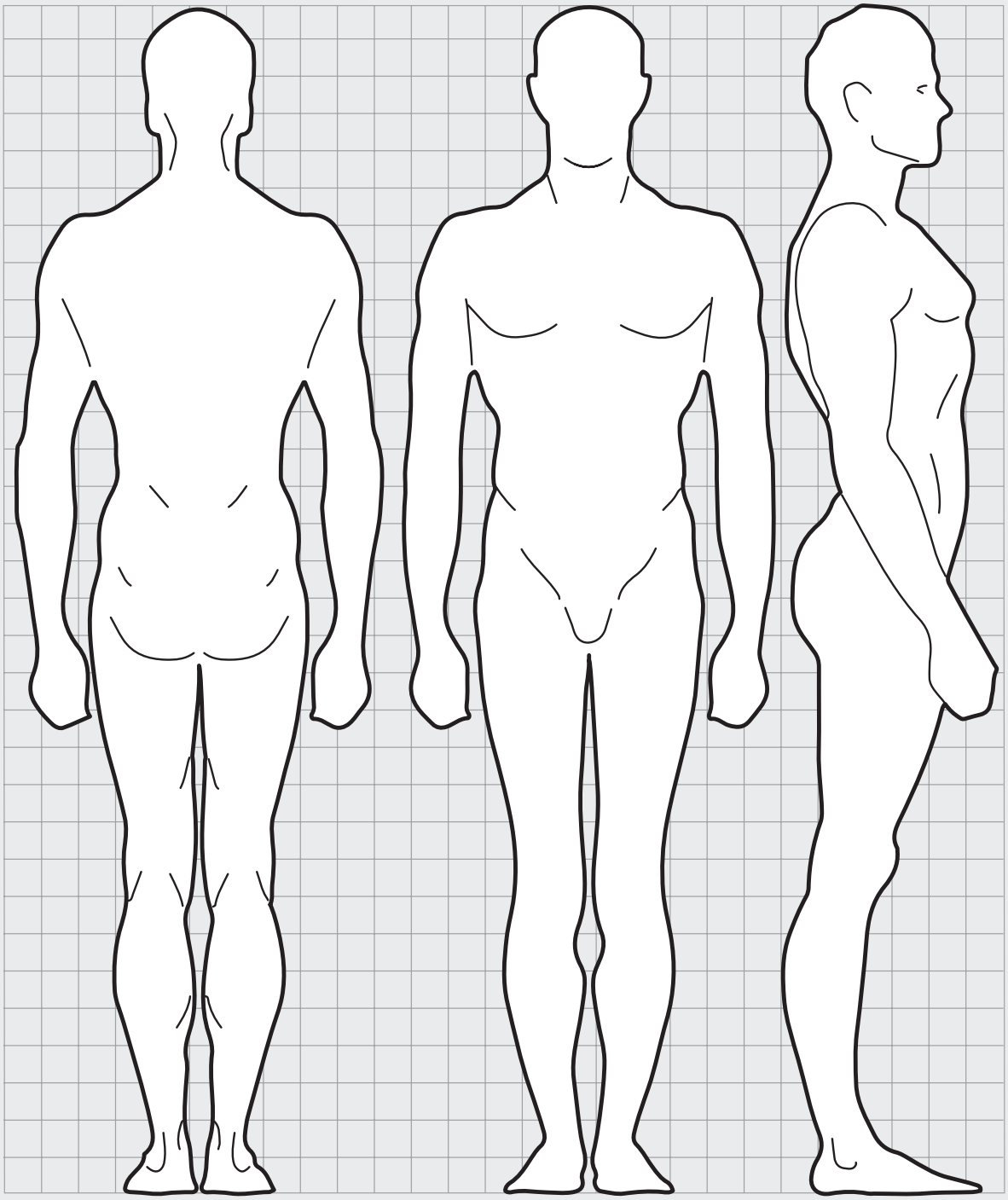
Check all that apply, illustrating on the diagram the position/place of injury, if any:

☐ 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

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

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