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Risk Management Strategies
for the Physician Office

HEALTHCARE

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Risk Management and Performance Improvement

Introduction to Enterprise Risk Management

Historically, physician practice risk management programs have focused on limiting exposure to insurable clinical losses. Today's environment, however, requires a more comprehensive and strategic approach, which is known as enterprise risk management (ERM).

ERM has been effective in every kind of organization, ranging from manufacturing and transportation companies to global financial services firms and not-for-profit entities. It is equally relevant to physician office practices and other healthcare facilities, where the risks are especially complex, interconnected and potentially damaging.

In the ERM model, risks are categorized into domains or spheres of activity that affect one another positively or negatively. For example, consider the case of a well-trained medical secretary (human resources practices), who implements an effective follow-up system for timely receipt of laboratory reports (operational procedures), in order to facilitate a prompt diagnosis (clinical outcome). The ERM process emphasizes the connections between these domains and shows how effective risk control translates not only into better treatment outcomes and fewer lawsuits, but also enhanced patient satisfaction and community relations. This creates an upward cycle of increasing patient volume and revenue growth, strengthening the practice in clinical, financial and reputational terms.

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

The ERM process includes the following major components:

- *Risk identification*, i.e., detecting exposures within each of the risk domains, a process that typically includes staff interviews.
- *Prioritization and scoring of risks*, i.e., analyzing the likelihood, causes and consequences of specific exposures. The potential severity of each risk is multiplied by its probability to determine the "risk score."
- *Risk response*, i.e., developing and implementing an action plan to avoid, accept, reduce and/or finance risks, as defined below:
  - *Risk avoidance* denotes eliminating a service or activity in order to preclude associated risks.
  - *Risk acceptance* means assuming responsibility for any loss associated with an identified risk. Risks with minimal effect on the practice are generally accepted.
  - *Risk reduction* involves limiting the probability or severity of a risk without eliminating the service or activity.
  - *Risk financing* refers to covering potential losses by transferring risk via commercial insurance policies or by retaining risk through such mechanisms as high deductibles, self-insured retentions, surety bonds or trust fund accounts.
- *Control and monitoring*, i.e., measuring the effectiveness of selected risk responses.

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

Identifying Risks

Risk cannot be properly addressed until a system is implemented for tracking and recording unusual occurrences.

Incident report forms are the most common method for describing untoward events. Their standardized format enables staff members to document in a clear, concise and consistent manner anything they witness that deviates from routine care. The incident report form is designed to:

- *Capture relevant, objective information* regarding the event and surrounding circumstances.
- *Notify management* of a potentially serious or actionable situation.
- *Facilitate entry of relevant information* in a computer database that tracks and trends adverse events.

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 the underlying issues, such as staffing levels, training gaps or communication lapses. Incidents should be categorized both by *frequency* (i.e., the number of times an event occurs) and *severity* (i.e., the event's seriousness and potential impact).

In addition, clear and detailed policies should be established answering the following questions:

- Who is authorized to complete an incident report form?
- What details should be included in every incident report form?
- How soon after the incident should the incident report form be completed?
- Who is required to review the incident report form upon its completion?
- How is compliance with the incident reporting process monitored?
- Who is responsible for following up on the event?
- Who is responsible for monitoring the effectiveness of the response?
- How is a completed incident report form secured?
- How long are incident reports retained?

Every incident report should include:

- *Factual information* regarding the event.
- *Time and location* of the incident.
- *Names and contact information* of any witnesses.
- *Description of the patient's condition* after the event.

Clinical information regarding the event should be documented in the patient healthcare information record. However, the patient record should not refer to the separate incident report and no copies of the report should be made, in order to protect confidentiality.

Satisfaction surveys constitute an important means of identifying and defusing service and communication issues that, if unaddressed, could result in legal action. Surveys should be brief, comprising no more than 10 multiple-choice questions with space for comments. Surveys should be given to patients in waiting rooms or mailed to them. As with incident reports, survey results should be carefully 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., Are the office and grounds safely accessible, or do you encounter physical obstacles?)
- *Atmosphere and attitude* (e.g., Are staff members friendly and helpful?)
- *Communication* (e.g., Are 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?)

Survey employees and practitioners as well as patients, asking them for their opinions on a regular basis. This procedure creates a channel of constructive communication, serving both to warn of impending problems and to bolster loyalty and morale.

Complaints are a critical form of input, requiring both individualized response and tracking. The organizational risk 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 read complaints* and communicate with the aggrieved party?
- *Who is responsible for monitoring follow-up* and resolution of complaints?
- *How and when are staff members informed* that a complaint has been made?

Mapping Risks

The first step in creating a risk management program is to classify and assess organizational exposures. The following chart lists risk categories common to many healthcare settings, as well as some of the specific functions, issues, requirements and risks that fall within the various categories:

COMMON RISK CATEGORIES AND ISSUES	
Strategic planning	Marketing, expansion, mergers and acquisitions, additional medical specialties, capital needs, enterprise risk management.
Human resources	Employment practices liability, scope of practice, credentialing, background checks, competency assessments, in-service education.
Clinical risk	Standard of care, infection control, preventive care/screening, medication/pain management, referrals/consultations, drug/device recalls, patient education.
Hazards/business interruption	Facility management, plant age, parking (e.g., lot lighting, condition, security), securing valuables, construction/renovation, natural disasters.
Operational risk	Incident reporting, policies and procedures, performance improvement, scheduling and waiting times, missed appointments, patient tracking and follow-up, environment of care, fire safety, emergency preparedness, security, physical plant and surroundings.
Information technology	Electronic health records, data privacy and security, email, social media, facsimile, texting, telephone and other remote consultation.
Legal/regulatory	Patient rights, informed consent, HIPAA privacy and confidentiality provisions, Clinical Laboratory Improvements Act (CLIA) regulations, patient termination, contract management, closing or leaving a practice.
Financial	Insurance denial of care, billing and collections, Medicare/Medicaid reimbursement.

(Adapted from ***ASHRM Pearls***, Enterprise Risk Management: The Foundation, *2013 Edition.)*

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 the underlying issues, such as staffing levels, training gaps or communication lapses.

Responding to Risk

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

Prevention encompasses proactive risk awareness and safety programs for patients, staff, providers, family members and visitors. The goal is to ensure that everyone is aware of the most common risks and knows how to protect themselves and others.

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

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

Education involves engaging staff through relevant, practical and meaningful in-service seminars given at orientation and at least annually thereafter. Training should include both an overview of the risk management process and a detailed description of other key topics. The educational sessions should clearly explain what constitutes an incident, how incidents should be reported, and why thorough and objective incident documentation is of critical importance.

Evaluating the ERM Program

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

Physicians must remain attentive to their own unique risk situation, as well as the broader political, economic and social developments affecting the healthcare field.

Sample Risk Management Plan

Mission Statement

Enter organization's mission: _____

_____

_____

Focus

The focus of the risk management program is to provide an ongoing, comprehensive and systematic approach to reducing risk exposures and protecting the assets of the organization. Risk management activities include, first of all, identifying, investigating, analyzing and evaluating risks, and then selecting and implementing the most advantageous methods of correcting, reducing, managing or eliminating these risks.

Scope

The program encompasses all healthcare professionals and ancillary staff. It includes events that may result in any form of loss, including professional, property and general liability, workers compensation claims and motor vehicle exposures. Risk management is integrated with claim management, as well as the following departments:

- Administration
- Allied health professionals
- Ancillary services
- Billing
- Data/health information management
- Employee health
- Human resources
- Infection control
- Medical equipment
- Medication/therapeutics
- Nursing
- Patient relations
- Performance improvement
- Safety management/environment of care
- Security

Objectives

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

- *Promoting the quality of patient care* and coordinating with performance improvement efforts.
- *Minimizing frequency and severity* of untoward events and legal claims.
- *Enhancing patient satisfaction* and responsiveness to complaints.
- *Supporting a non-punitive culture* that promotes risk awareness and empowers staff to identify safety-related issues.
- *Improving environmental safety* for patients, employees and visitors.
- *Reducing the impact of losses* through insurance or other risk transfer mechanisms.
- *Evaluating systems within the practice* that can contribute to medical error or injury.
- *Educating stakeholders on risk exposures* and risk reduction initiatives.
- *Meeting accreditation requirements* of relevant organizations.
- *Complying with all applicable laws, regulations and standards*, whether federal, state or local.

Authority and Role of the Risk Manager (or Designated Individual)

The risk manager's precise role within the organization is specified in the job description. In general, the risk manager is empowered by practice owners to:

- Create and implement a proactive risk management program.
- Enhance compliance with applicable federal, state and local statutes and regulations.
- Meet the standards of relevant accrediting organizations.
- Evaluate program effectiveness and outcomes.

These activities are coordinated with the performance improvement plan and the Risk Management, Safety and Performance Improvement Committees, if applicable.

Specific Components

The program includes the following elements, among others:

Event/incident reporting. The event/incident reporting system serves to identify, report, track, and trend patterns of events with the potential for causing adverse patient outcomes, other injuries to persons or damage to property. It is designed to reduce both the likelihood and potential financial severity of claims. The risk manager is responsible for tracking events and producing incident reports. Trends are reported via the performance improvement process to the healthcare providers or areas involved in the events for follow-up action.

Coordination of risk management and performance improvement activities. Recognizing the affinities between risk management and performance improvement, the risk manager works closely and cooperatively with performance improvement staff. This collaboration is critical to successfully identifying and resolving risk and quality issues.

Education and training. The risk manager provides or facilitates orientation programs for all new employees and contracted staff, as well as a separate annual educational program designed to heighten awareness of risk exposures and risk prevention activities. Other in-service and training programs may be provided as needed.

Management of patient and family complaints/grievances. The practice establishes and implements a written program for managing, responding to and resolving patient and family complaints/grievances. It should address such issues as response protocols, time frames, chain of command and documentation.

Patient satisfaction. The practice measures patient satisfaction and responds to issues identified in patient satisfaction surveys. The risk manager monitors complaints noted on patient satisfaction surveys, works to resolve issues, and reports sentinel events and recurring issues identified in surveys to performance improvement staff.

Claim Management

The claim management program performs the following functions, among others:

- *Reporting potentially compensable events* via supervisory channels and the risk manager.
- *Conducting the initial investigation* following a potentially compensable event.
- *Documenting investigational activities* and correspondence related to the event.
- *Ensuring the integrity of the patient healthcare information record* and/or other pertinent documents, data and information, reflecting the nature of the event.
- *Organizing claim files* and coordinating activities with the defense team.
- *Reporting activity status* through appropriate channels.

Quarterly Report to the Board of Directors

The risk manager provides a quarterly report to the governing body covering risk management activities, achievements, ongoing risk management issues and recommendations for future risk control activities.

Confidentiality Statement

All data and information collected and maintained as part of the risk management program are utilized solely within the quality improvement process. All findings are considered to be privileged and confidential information to be distributed only at the direction and with the written consent of legal counsel.

Review of the Risk Management Plan

The risk management plan is reviewed, updated and approved annually, or as needed.

Annual Evaluation of the Risk Management Program

The program is evaluated by the governing body annually and signed off on by leaders.

Signature as needed: _____ Date: _____

Signature as needed: _____ Date: _____

Signature as needed: _____ Date: _____

Self-assessment Checklist: Enterprise Risk Management

This resource is designed to help physicians evaluate basic risk control 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
STRATEGIC RISK		
Promotional/marketing materials (e.g. advertisements, brochures, websites, telephone directory listings) are reviewed to ensure that they contain no inappropriate language or inaccurate descriptions, and convey no unreasonable expectations.		
The organization has a formal written risk management plan that:		
- Declares the organization's risk control goals.		
- Describes the scope, components and methods of the risk control program.		
- Delegates responsibilities for implementation and enforcement.		
- Demonstrates leadership commitment.		
- Delivers guarantees of confidentiality and immunity from retaliation to staff members who report sensitive information.		
HUMAN RESOURCES RISK		
There is a pre-employment screening process that includes the following documented elements:		
- Drug screen.		
- Background investigation, which includes criminal record, Office of Inspector General (OIG) and sex abuse registries for all states where the applicant has lived or worked, as well as credit history, if relevant and legally permissible.		
- Reference verification and documentation.		
Every position has a written job description, listing specific responsibilities and required competencies.		
All staff members undergo a formal office orientation program, which covers the following topics, among others:		
- The practice's mission and vision.		
- Performance expectations and evaluation process.		
- Equipment use and other basic operations.		
- Appropriate professional appearance and behavior.		
Employees read their job description and sign an acknowledgment.		
Human resources policies and procedures are in writing, and are reviewed on a routine basis to ensure compliance with pertinent federal, state and local legal requirements, such as:		
- Americans with Disabilities Act (ADA) requirements.		
- HIPAA privacy regulations.		
- Equal Employment Opportunity Commission (EEOC) and other anti-discrimination laws.		

RISK CONTROL MEASURES	PRESENT? YES/NO	COMMENTS
CLINICAL RISK		
Formal written policies and procedures exist, addressing the following clinical issues, among others:		
- Medication management.		
- Disclosure of unanticipated outcomes.		
- Medical device safety.		
- Prevention of falls and infections.		
- Informed consent and refusal.		
- Patient scheduling and after-hours care.		
- Proper professional boundaries.		
- Test result management.		
- Referral processes for patients requiring a specialist.		
A written, individualized plan of care is developed for each patient and updated as necessary.		
Staff members participate in annual programs on patient safety, as well as risk management, customer and community relations, confidentiality and compliance.		
OPERATIONAL RISK		
There is a designated risk manager on staff, with well-delineated responsibilities.		
A system is in place for identifying and tracking medication errors and other untoward incidents.		
A system has been implemented for identifying and tracking performance issues and patient complaints.		
Administrative, operational and disaster preparedness practices are governed by written policies and procedures, which are approved by leadership and shared with all physicians and staff.		
CUSTOMER SATISFACTION RISK		
Staff are trained in telephone etiquette, which includes dealing with angry or dissatisfied patients in a tactful, respectful and non-confrontational manner.		
A designated staff member handles complaints from patients, family members and visitors.		
The risk manager is promptly notified of all complaints from patients, family members or visitors.		
All communication regarding patient complaints is reviewed by the risk manager and documented in case of later legal action.		

RISK CONTROL MEASURES	PRESENT? YES/NO	COMMENTS
INFORMATION TECHNOLOGY RISK		
Formal, written policies and procedures are in place regarding the following areas, among others:		
- Healthcare record management.		
- Confidentiality and release of medical information.		
- Maintenance of the healthcare record, including release authorization, retention time and storage security measures.		
- Social media.		
- Faxing of confidential information.		
- Electronic health records.		
- Use of electronic media.		
LEGAL/REGULATORY RISK		
Written, regularly reviewed policies and procedures address the following areas, among others:		
- HIPAA-related patient confidentiality practices and notifications.		
- Billing regulations, both federal and state.		
- Clinical Laboratory Improvements Act (CLIA) regulations.		
- Contractual agreements containing hold harmless and/or indemnification clauses.		
- Termination of the patient-physician relationship.		
FINANCIAL RISK		
Legal contracts are vetted prior to execution, then reviewed and renewed annually.		
The following contractual and financial areas, among others, are governed by written policies:		
- Insurance denials.		
- Patient billing and collections.		
- Medicare/Medicaid billing.		
- Managing payments and accounts.		

Unanticipated Adverse Events

Responding to Adverse Events

Every medical practice is exposed to the risk of a patient experiencing an unanticipated outcome due to a procedure, treatment, test or medication. Care must be taken to minimize the likelihood of such outcomes and to prepare staff to respond appropriately if an adverse event occurs.

The practice can effectively reduce the impact of unanticipated occurrences by:

- Defining and identifying the potential for adverse events.
- Recognizing an event when it occurs.
- Responding with rapid, effective emergency care.
- Providing appropriate post-event intervention, including tracking, trending and analyzing incidents, as well as making necessary policy changes in response.

Thorough preparation and ongoing training 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.

The first priority is to provide immediate medical care to the patient and notify the physician. The following risk management measures should be implemented afterward:

- *Secure any equipment*, medications or supplies involved in the event.
- *Have a physician review the medical facts with the patient* as soon as possible after the event.
- *Document all actions taken in the patient healthcare information record.* Do not document any conclusions in the incident report or record that are not based on objective, factual information.
- *Postpone sending the patient's bill for services* until the event is resolved.

Incident/Adverse Event Reporting and Notification

Incident report forms assist in the uniform reporting of unanticipated events. Forms should:

- Record only objective, factual information.
- Not place blame on any individual, operating system or medical device.

Incident report forms are most effective when completed by the individual who witnesses or first becomes aware of the event. They should be completed in a legible, objective and thorough manner, with all witnesses to the event interviewed promptly. In addition, no lines in the form should be left blank. Upon completion, the form should be reviewed and approved by the practice manager or the designated physician.

Providers must exercise care when documenting an event in the patient healthcare information record. The occurrence itself should be recorded in a factual and objective manner, incorporating any medical steps that were taken to minimize negative consequences to the patient. The incident report itself, however, should never be filed or mentioned in the patient healthcare information record.

As part of the quality/performance improvement process, incidents should be investigated as soon as possible, with a focus on why the event occurred and what, if anything, could have been done to prevent it. Findings should be documented on a separate form and should not be noted in the patient healthcare information record. Incident/event reporting should be performed under the auspices of the performance/quality improvement plan, which may help protect against discovery and/or admissibility in a court of law, depending upon jurisdiction.

If a life-threatening or permanently disabling event occurs, notify the insurer either directly or through your insurance agent or broker.

Communicating with Patients and Families

To ensure continuity, the patient's primary care physician and/or the treating physician should communicate directly with the patient following any adverse event. Another individual may be designated as the primary contact with the family.

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.

The healthcare provider should consider the full breadth of the patient's/family's needs after an unanticipated event and offer empathy, comfort and support. Patients and their families deserve to know what happened, feel the physician's concern and learn what the practice is doing to prevent the event from recurring.

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. The professional liability carrier also may offer risk control materials in this area.

Device-related Incidents

Injuries associated with the use of a medical device may have liability implications for the physician and the practice. In order to better defend such cases, it is important to preserve as much documentation and other evidence as possible related to the adverse event. For this reason, consider implementing the following office protocols:

- *Immediately stop using any equipment whenever there is concern* regarding its safety or functionality.
- *Save all data in the memory of the device* at the time of the adverse event.
- *Do not change any device settings* or attempt to restart the device.
- *Photograph the setting/control panel* with the settings as they were during the serious event.
- *Sequester the device* until it has been inspected and cleared for use by a qualified, independent biomedical engineer. In the event of a serious injury or death, or any circumstance that may lead to litigation, neither the device nor related accessories should be released to the manufacturer or any outside party until they have been independently tested.
- *Save and preserve all disposables used during the treatment/test*, including wrappers and packaging.
- *Record all device-related occurrences on incident report forms* and forward them to the appropriate individual for review and corrective action, if needed.
- *Retain accurate preventive maintenance and repair records* for each medical device or product.
- *Sequester the user's manual* for the device in question.
- *Maintain a copy of all user and clinical policies and procedures* related to the specific treatment/test and device in question.
- *Comply with medical device reporting requirements*, as mandated by federal and state agencies.

Sample Incident 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 incident 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 occurrence 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 incident.
    d. Date of incident.
    e. Type of incident.
    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 incident.

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 incident

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

Location of incident

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

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

Sample Incident Report Form (continued)

Type of incident

Incident 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 incidents: ☐ 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 incident 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-incident status of individual: ☐ Oriented ☐ Disoriented

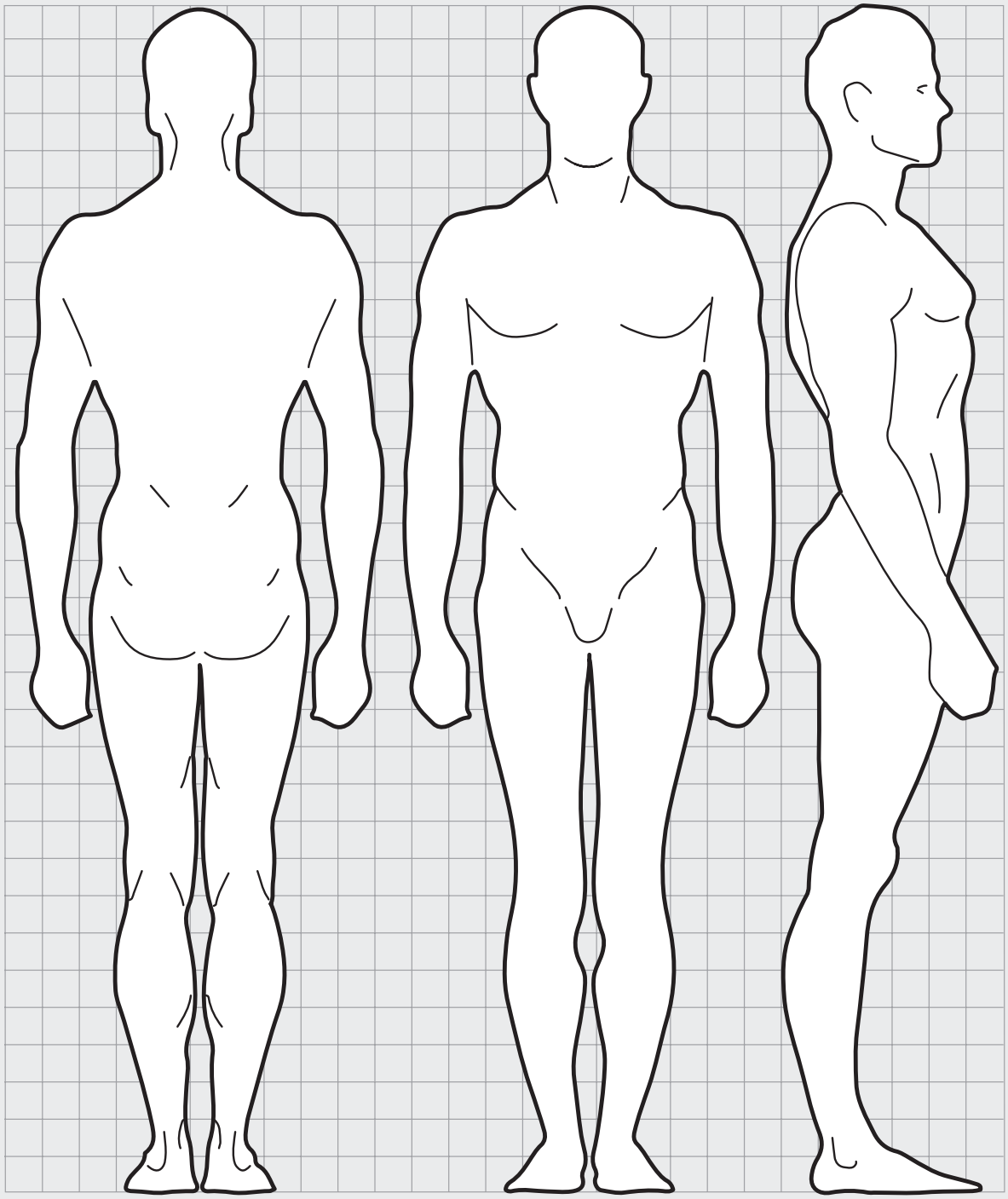
Check all that apply, illustrating on the diagram the position/place of injury, if any:

☐ 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 incident

Describe the incident 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 incident.

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.

Policy and Procedure Manual

Every medical practice should have a policy/procedure manual. Formal policies and procedures protect patients, employees and the organization by describing processes, setting limits, and helping staff members understand their duties and organizational expectations.

Written policies and procedures are also important in defending against allegations of negligence. When compiling or evaluating the practice's policy/procedure manual, consider the following suggestions:

- *Address major human resources issues*, such as disruptive behavior, harassment and other unacceptable conduct, as well as expectations regarding professionalism, patient confidentiality, dress, safety awareness and incident 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 physicians, 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 a policy manual* in printed or electronic form, and ensure that copies are readily available for reference by staff and physicians.
- *Give staff the opportunity to review the manual upon hire* and inform them of any changes in the manual.
- *Archive policies that have been revised or withdrawn* for reference in the event of litigation.

Policy Drafting Guidelines

Written policy should express an organization's official position on significant operational issues in a straightforward, understandable manner. To ensure compliance, statements must reflect the commitment and support of the governing board, administration and medical leadership, if applicable.

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 information likely to change*. To help ensure accuracy over time, omit individual names and specific titles. Should circumstances arise that are not directly addressed by written policies and procedures, advise staff members to consult with relevant departmental leadership.
- *Adhere to a template*. The template should divide the information into logical sections, organized by descriptive headings. Adjust the template as necessary, while retaining the basic structure.
- *Identify and address litigation-prone areas*. Written policies designed to reduce liability by preventing resident/patient injury are critical to effective risk control. Recurring problems in an organization's litigation history should be identified and procedures crafted that embody best practice standards.

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.
- *Section, department or 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 is to 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*, as well as accreditation and regulatory 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, department or unit manager, executive leader, medical and nursing director, governing board, and chair of the policy and procedure review committee, if applicable.
- *State the schedule* for the review and revision process, emphasizing deadlines.
- *Contain a signature block* to document approval.

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 inculcated among 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 the governing board,* 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.

Contracts

Contract Management Principles

Contractual agreements with outside entities provide a measure of flexibility to physician 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 an eye to protecting the practice's interests. 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.

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.
- Time frames.
- Costs and payment terms.
- Insurance requirements.
- 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 clinicians 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 practitioners' 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?		

Performance Improvement Fundamentals

Most inefficiencies and errors in physician practice settings are the result of failures in such processes as the use of clinical protocols, healthcare record documentation, scheduling and patient education. These failures can be more easily identified and corrected in practices that work to empower staff. Employees should understand that they are accountable for the processes they implement, while managers should provide staff with the resources necessary to fulfill their duties and grant them the authority to address issues that arise.

Basics of Performance Improvement

Performance improvement involves developing and monitoring quantifiable indicators designed to measure outcomes, identify problems and establish new parameters for improved performance. In the physician practice setting, important quality indicators include, but are not limited to, the following:

- Adverse drug reactions.
- Medication reconciliation discrepancies.
- Patient or visitor accidents.
- Ordered tests that go unperformed.
- Unreported or undocumented test results.
- Misplaced or mislabeled specimens.
- Lack of follow-up on significant missed appointments.
- Inadequate documentation of patient education.
- Excessive patient waiting times.

When an indicator is triggered, the next steps are to analyze the process, identify performance failures and quality of care issues, and implement process improvements. The process flowchart, a pictorial diagram of all steps in a designated sequence, is an important diagnostic tool to understand and address process gaps and weaknesses. For example, if excessive waiting times are recognized as a trend, a process flowchart tracing a patient's experience from entry to the office through departure can help detect avoidable delays and suggest possible solutions.

Patient satisfaction surveys are another key means of determining whether patient needs are being met and identifying areas for improvement. For additional information on satisfaction surveys, see page 12.

Accreditation

Voluntary accreditation of office-based surgical practices (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, physician practices must participate in ongoing self-evaluation, peer review and education. The practice also typically commits to an on-site survey by the accrediting body once every three years.

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 substitute for a state-mandated and administered inspection.

OBS accreditation is available through several accrediting bodies. Each state determines what accrediting bodies are acceptable and whether accreditation may be used in lieu of a mandatory state inspection; see here for examples of state reliance on accreditation and certification by The Joint Commission. Several states permit only accredited office settings to provide higher levels of anesthesia.

The most commonly recognized accrediting bodies for OBS practices are:

- Accreditation Association for Ambulatory Health Care (AAAHC).
- American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF).
- Healthcare Facilities Accreditation Program/American Osteopathic Association (HFAP/AOA).
- Institute for Medical Quality (IMQ).
- The Joint Commission.

Patient Relations

Physician-Patient Relationship

Establishment of the Physician-Patient Relationship

Determining whether a physician-patient relationship exists is an important issue in medical malpractice litigation, as physicians may be held liable even when they believe that they do not have a relationship with a patient.

The legal existence of the relationship is a question of fact specific to each individual case. Any one of the following factors can indicate that a physician-patient relationship exists:

- A contract is in place between the doctor and patient.
- A history is taken and/or physical examination is performed.
- An entry is made into the patient healthcare information record.
- A bill for services is sent and/or paid.
- A specific opinion is provided.
- The patient receives care from the physician.

Abandonment Allegations

Whenever a physician accepts or renders care to a patient, a physician-patient relationship is forged that continues for as long as the patient's condition requires attention. The relationship can be ended only by mutual agreement or a legally acceptable notice of termination. If the relationship is ended without proper notification, the physician 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 physician's failure to continue to perform his or her professional duty.

All patients must be treated equally. A physician 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 any patient who does not comply with office policies or treatment recommendations, as long as the reasons for doing so are fair and the process adequately documented.

An emphatic caveat: If a patient of record in need of emergent care is denied treatment simply because the patient owes money, the physician may become liable to an allegation of abandonment.

Certain patients may be more likely to allege abandonment than others. Risk factors include the following:

- Poor clinical outcomes.
- Unmet expectations.
- Billing disputes.
- Argumentative or stubborn personality.
- Litigious personal history.
- Inadequate compliance with postoperative care recommendations.
- Failure to schedule and/or keep follow-up appointments.

Billing and Collections

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

Physician Termination of the Physician-Patient Relationship

Prior to terminating a patient, 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 physician-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.
  - 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 physician or 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 health records to the subsequent physician.
  - A form authorizing release of medical information to the subsequent physician.
- *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 communication 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 39-42. 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 individual situation.

Document the reasons for terminating the relationship, as well as any efforts made to resolve conflicts or misunderstandings, in the patient healthcare information record.

Sample Termination Letter 1: Refusal to Accept Recommendations

Breakdowns in communication often result in the need to terminate a physician-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 _____ without first [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.

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

I will be available to see you for any emergency 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 physician as soon as possible. You can find information regarding area physicians 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 physician or a physician who specializes in _____ (called a "_____"). Failure to seek medical care may result in a serious deterioration of your condition, which may result in _____ and/or _____.

I will send a copy of your healthcare record and X-rays to you or your new physician upon receiving your signed, written request to that effect. Please allow _____ days from receipt of your request for duplication and mailing. However, I will be pleased to speak with your new physician by telephone at any time.

Sincerely,

Dr. Physician

cc: Patient File

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.

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 physician 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 with you 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 would like 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 reevaluated as soon as possible. It is recommended that you promptly schedule and keep an appointment with your new physician. Failure to seek care could result in a serious deterioration of your condition, which may result in _____ and/or _____.

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

You can find information regarding area physicians 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 physician upon receiving your signed request to that effect. Please allow _____ days from receipt of your request for duplication and mailing.

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,

Dr. Physician

cc: Patient File

Sample Termination Letter 3: Inactive Patient

Many medical offices have records of inactive patients – i.e., patients that doctors have not seen or treated in years, but with whom there has been no formal termination of the physician-patient relationship. While many of these patients may have sought care from another physician, 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 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 physician. Failure to seek care may result in a serious deterioration of your condition, which 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 practice's connection with you to have ended. 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 can find information regarding area physicians 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 physician 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,

Dr. Physician

cc: Patient File

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

While it is absolutely necessary to inform patients that the physician-patient relationship is being terminated, the precise reason for the decision to cease providing care need not be disclosed. In certain cases, the physician may wish to be tactful and remain silent regarding the reasons for the decision, if they are of a private nature or could potentially create further conflict with the patient. Irrespective of the reason, send a letter to the patient indicating that the physician-patient relationship is being terminated and 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 physician. Our physician-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 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 physician 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 can find information regarding area physicians 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 physician 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 physician by telephone at any time.

I wish you every success with your future medical care.

Sincerely,

Dr. Physician

cc: Patient File

Effective Patient Communication Strategies

Mutual trust and respect are the foundation of the physician-patient relationship, and they must be developed from the first encounter and continuously reinforced. Trust and respect depend in turn 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, physicians can create a positive first impression of their practice and maintain a healthy rapport with patients.

Deficiencies in communication are sometimes a factor in a patient's decision to initiate legal action against a provider following an adverse outcome. Communication problems 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 watch or the clock, or otherwise exhibiting impatience. Other negative nonverbal traits include lack of eye contact, poor posture, inattentive or irritated facial expression, or crossed arms or legs, which may appear defensive to the patient.

Fortunately, good communication skills – including the critical nonverbal aspect of communication – can be learned and improved through practice. Professionals can be trained to alter their interpersonal behavior in ways that can increase patient satisfaction and decrease the risk of claims. The following communication strategies are designed to help medical practices and providers initiate and maintain a sound relationship with patients.

Physician/Provider Communication with Patients

- *Sit down* when 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 verbal and nonverbal messages* conveyed by the patient.
- *Make use of other informational tools*, such as DVDs, brochures/pamphlets, 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 Communication with Patients

- *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. (See page 97 for more information on telephone triage.)
- *Permit swift access to the physician* 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.

Communication with Noncompliant Patients

- *Review the recommended care plan with patients* and confirm that they agree to the plan and understand their responsibilities.
- *Discuss possible barriers to compliance* with treatment recommendations.
- *Document all efforts made to communicate the need for compliance* in the healthcare record.
- *Provide a written description of the potential harmful 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 suspend or terminate the physician-patient relationship. (See pages 38-42.)

Communication with Angry Patients

- *Watch for verbal and nonverbal signs of anger*, dissatisfaction and frustration.
- *Provide a private area for discussion*, away from other patients.
- *Acknowledge patient anger or dissatisfaction* and show that these 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 issues.
- *End the discussion with a mutual understanding of actions that will be taken* to address the patient's concerns.
- *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 sexual comments, state that they are about to lose control, appear extremely tense or angry, or seem under the influence of alcohol or drugs. (See "Violence Prevention," pages 115-118.)
- *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 describe events* – e.g., "The patient's face was flushed and his 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."

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. Sometimes these relationships become too personal, leading to an erosion of boundaries, confusion of roles, and/or incidents of abusive or exploitative behavior.

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

Allegations of improper relationships constitute a significant risk for physicians, 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 after conflicting roles have developed.
- Communicate appropriately in social media forums.

To avoid reputational harm and potentially costly and hard-to-defend claims, physicians must ensure that proper boundaries are maintained at all times between themselves, their employees and their patients.

Most healthcare specialties have a code of ethics that clarifies behavioral boundaries. These guidelines embody basic legal and professional standards, serving to ensure that the physician-patient relationship exists to serve the patient's needs rather than the practitioner's. Examples of potential issues may take many forms, as when a physician:

- *Assumes a dual role*, e.g., socializing with a patient under treatment.
- *Extracts inappropriate professional fees* or otherwise takes advantage of a patient.
- *Relates to a patient inappropriately*, e.g., in a flirtatious or overly familiar manner.
- *Exchanges gifts of significant value* with a patient.
- *Becomes a business partner* with a continuing patient.
- *Uses social media to connect with a patient* outside of the parameters of a professional relationship.

Improper use of social media has become an increasingly common trigger 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, with message content generally limited to routine information, such as educational resources, office hours, practice-related news, and appointment and other care reminders. Physicians 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 too can behave in an inappropriate, boundary-threatening manner, such as:

- *Referring to a physician by his/her first name*, despite requests.
- *Asking personal questions of a physician* that are irrelevant to the therapy.
- *Displaying undue affection* toward a physician.
- *Attempting to socialize with a physician* outside of the physician-patient relationship.
- *Giving gifts* that are expensive or highly personal.
- *Using sexually explicit language* unnecessarily or provocatively, or otherwise trying to seduce a physician.
- *Physically or verbally abusing a physician* or threatening bodily harm.

These transgressions should be immediately pointed out to the patient, and the need for appropriate boundaries restated.

While not all boundary issues are equally serious, as a rule they tend to impair the objectivity and judgment of both parties, thereby potentially skewing expectations and/or affecting health outcomes. The worst-case scenario is when boundary violations lead to verbal, emotional, physical, financial or sexual misconduct, requiring direct, swift and proportionate intervention.

A breach of boundaries can have devastating consequences for both patient and physician. By implementing and enforcing sound policies, physician practices can prevent initial ethical lapses, which ultimately may develop into serious violations and associated liability exposure.

Self-assessment Checklist: Physician-Patient Relationship

This resource is designed to help physicians 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 at www.cna.com.

RISK CONTROL GUIDELINES	PRESENT? YES/NO	COMMENTS
PATIENT COMMUNICATION		
Do physicians clearly convey the severity of the problem and the risks of not carrying out 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 non-judgmental 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 not complying with recommendations?		
Are open-ended questions used to assess patients' 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 whom patients rely upon 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:		
- Narcotic use and general pain management in drug-seeking patients?		
- Appointment or procedure cancellations?		
- Unacceptable behavior, such as belligerent voice-mail 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 care 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 physicians 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?		

Personnel

Human Resources

Personnel-related Policies and Procedures

Sound personnel/human resources policies are essential to good patient care, helping ensure that the practice employs competent staff who provide services within their licensing or certification. Such policies can therefore help practices better comply with pertinent federal, state and local legal requirements.

Every practice also requires an effective credentialing process for independent providers if it hires or contracts with physicians, midwives, nurse practitioners or other licensed professionals. The following guidelines can help minimize risk when hiring and managing employees or contracting with independent health-care practitioners.

Job Description

Prior to hiring a new employee, draft an accurate and complete job description, encompassing the essential duties and physical demands of the position, as well as required education/training, experience, knowledge and skills. Stated requirements should be reasonable and reflect actual job functions.

Application

Require applicants to complete, sign and date a detailed application, which includes:

- Full legal name.
- Addresses for past 10 years.
- Educational background.
- Detailed employment history, including reasons for leaving or considering leaving the most recent job and explanations for gaps in employment.
- Availability for work.
- Driving record, if relevant.
- Statement that applicant can perform the essential functions of the job, with or without accommodation.
- Response to question as to whether the applicant has worked at or applied to the organization previously.
- References, both personal and professional.
- Non-discrimination statement compliant with the Equal Employment Opportunity Commission (EEOC) and the Americans with Disabilities Act.
- Statement certifying that answers submitted are correct, including notification that any false information will lead to rejection of the applicant or termination if the falsehood is discovered subsequent to hiring.

Conversely, do *not* include questions designed to elicit information that may lead to allegations of discrimination, such as:

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

On another form, obtain applicants' written consent to confirm their stated job and educational history, contact references and conduct a criminal background check. Applicants also should sign a statement acknowledging that they understand that employment is contingent upon successful completion of a drug test and/or criminal background check, as well as confirmation of credentials/licensure. (Note that in some states, it is unlawful to ask about an applicant's arrest or conviction record on the application. EEOC guidance recommends caution when inquiring about conviction records, as such a query may have a disparate impact on certain protected classes.)

Background Check

Inquiries should be thoroughly and consistently implemented and documented, verifying education, licensure, credentials and references. Criminal background checks should query both conviction history and sex offender status. Credit checks should be conducted only if they are relevant to the position and are not prohibited by state or municipal law.

Exercise caution when screening prospective employees based upon criminal record or credit history. EEOC guidance discourages automatic rejection due to a criminal conviction, instead suggesting that employers individually assess each applicant to ensure that exclusions are job-related and consistent with business necessity. EEOC guidance also discourages use of credit information in hiring decisions. Criminal background and credit checks are a complex issue requiring consultation with an attorney conversant with these aspects of employment practices law.

Drug Testing

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

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

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

Orientation and Verification of Skills and Competencies

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

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

Upon hire and annually thereafter, assess employees' knowledge, skills and competencies, and document findings in personnel files.

Continuing Education and Performance Review

Continuing education (CE) and other ongoing training opportunities should be aligned with license/certification requirements, and CE credits and annual performance appraisals should be documented and stored in personnel files.

Credentialing Physicians and Other Independently Licensed Healthcare Practitioners

Physicians and other independently licensed healthcare practitioners may be brought into the group as employees, through a contractual arrangement or as a member of the group's medical staff.

Employed and all other independently licensed healthcare practitioners also must be credentialed. A signed collaborative agreement between the practitioner and supervising physician should be included as part of the credentialing process, in accordance with state laws. In addition, a credentials file should be created for all physicians and other independent licensed healthcare practitioners, containing documentation of:

- Current license.
- Privileging for or assignment of clinical services, consistent with the scope of licensing and/or certification.
- Periodic review of quality of services provided.
- Training and experience.
- Education.
- Certificate of insurance.

Orientation should include basic information about the practice, organizational mission and vision, clinical practice standards, work schedules, emergency protocols and behavioral expectations.

Self-assessment Checklist: Human Resources Practices

This resource is designed to help physician practices evaluate their human resources policies and procedures. For additional risk control tools and information, visit www.cna.com.

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

RISK CONTROL STRATEGIES	PRESENT? YES/NO	COMMENTS
Employment policies are clearly conveyed to new staff members during the orientation process and are regularly reviewed by supervisors. Issues to discuss include:		
- Code of conduct.		
- Acceptable business and professional practices.		
- Disciplinary measures and warnings.		
- Workplace health and safety issues.		
- Conflict of interest.		
- Whistleblower protections.		
- Employee non-solicitation and outside employment rules.		
- Contract worker rules and regulations.		
- Equal opportunity and diversity policies.		
- Dress code.		
- Compensation, benefits, hours of operation, paid time off, holidays, and personal and professional leaves.		
- Smoking policies.		
- Absenteeism and tardiness rules.		
- Cell phone, internet, email and social media rules and limits.		
- Concealed weapons policy.		
- Harassment definition and prohibition.		
- Drug testing.		
- Exit interviews.		
Performance appraisals are conducted annually, with findings acknowledged in writing by the supervisor and employee.		
A "tickler system" is established to track due dates for appraisals and licensure recertification.		
Exit interviews are conducted whenever staff members voluntarily end their employment.		

Scope of Practice and Supervision of Non-physician Providers

The increasing integration of nurse practitioners (NPs) and physician assistants (PAs) into a wide variety of inpatient and outpatient settings has enhanced efficiency and increased patient access to care. Depending upon state scope of practice regulations and position descriptions, these tasks often include prescribing medications, ordering diagnostic tests and taking after-hours calls. However, the relationship between physicians and these highly trained and skilled professionals presents certain complexities, and establishing a safe and effective collaboration requires careful attention to such issues as communication, documentation and extent of practice.

Depending upon state practice regulations, both NPs and PAs are permitted to diagnose clinical conditions and write prescriptions. NPs, however, may have independent practice authority under state law, whereas PAs always perform their duties under the supervision of a physician. A number of states also require a practice agreement between the physician and the advanced practice provider.

As the healthcare industry evolves, NPs and PAs likely will assume a more prominent position, and delegation of clinical tasks will become a more critical issue.

Practice Agreements

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

A sample NP practice agreement from the Maryland Board of Nursing, which can be adapted to meet jurisdictional requirements, is available here.

A PA practice agreement template from the American Association of Physician Assistants website is available here.

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

Delegation Considerations

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

A sample prescriptive authority agreement, which can be downloaded as a separate document, is on pages 57-58.

Performance Evaluation and Record Review

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

In some jurisdictions, frequency of performance reviews is specified by state law. Otherwise, as a general guideline, quality and record reviews should be conducted during the probationary period, every six months afterwards, and as part of the annual performance review or re-credentialing process. Record review techniques will vary based upon the practitioner's scope of delegated duties, degree of experience and training, and assigned patient load.

Sample Quality/Record Review Form for Advanced Practitioners

This template can be used to document regularly scheduled patient healthcare information record reviews and meetings between supervising/collaborating physicians and advanced practitioners. Quality reviews should occur on a monthly basis for the first six months following hire, then every six months thereafter.

1. Clinical case: _____

_____

_____

2. Review of history: _____

_____

_____

3. Review of physical assessment: _____

_____

_____

4. Differential diagnosis, plan and disposition: _____

_____

_____

5. Recommendations for improvement: _____

_____

_____

6. Improvement plan and time line: _____

_____

_____

Nurse practitioner/physician assistant signature: _____ Date: _____

Primary supervising physician signature: _____ Date: _____

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.

Sample Prescriptive Authority Agreement for Advanced Practitioners

PART I: Background Data

Name of supervising or collaborating physician: _____

License number: _____

Address: _____

Name of alternate physician, if applicable: _____

License number: _____

Address: _____

Name of nurse practitioner (NP) or physician assistant (PA) to whom prescriptive authority is being delegated: _____

License number: _____

Address: _____

Practice area (e.g., pediatrics, primary care, OB-GYN, internal medicine): _____

Practice location(s)/unit(s): _____

PART II: Prescriptive Parameters

The following types or categories of drugs and devices may be prescribed:

☐ All nonschedule drugs, other than the following: _____

☐ All medical devices and biologicals, other than the following: _____

_____

☐ All respiratory therapies, orthotics and prosthetics, other than the following: _____

_____

☐ All schedule II controlled substances for inpatients or emergency department patients being treated for:
☐ Pain ☐ Sedation ☐ Seizures ☐ Anesthesia (for emergency procedures)

☐ All schedule III-V controlled substances, other than the following: _____

☐ Limitations on schedule III-V controlled substances:
☐ Thirty-day or less supply.
☐ No refills without prior consultation with the supervising or collaborating physician.
☐ Prescriptions for patients under 2 years of age require prior consultation with supervising or collaborating physician.

PART III: Instructions

Process and rules for communicating information regarding patient care to the supervising/collaborating physician (e.g., direct or telephonic consultation, reporting format, required response time, follow-up): _____

_____

Specific instructions for certain drugs or drug classes: _____

_____

Follow-up monitoring requirements for specific drugs or classifications of drugs: _____

_____

Protocol for handling patient emergencies: _____

_____

Protocol for physician/pharmacist consultation and referral of patients: _____

_____

PART IV: Quality Assurance (QA)

Prescriptive-authority QA measures (e.g., chart review frequency, number/percentage of charts to be reviewed): _____

_____

Method of documenting quality review: _____

_____

Frequency of meetings with supervising or collaborating physician: ☐ Monthly ☐ Quarterly ☐ Other (specify below)

_____

PART V: Documents

Title of QA plan and date of last review: _____

Names of applicable clinical practice protocols and date of last review: _____

_____

PART VI: Signatures

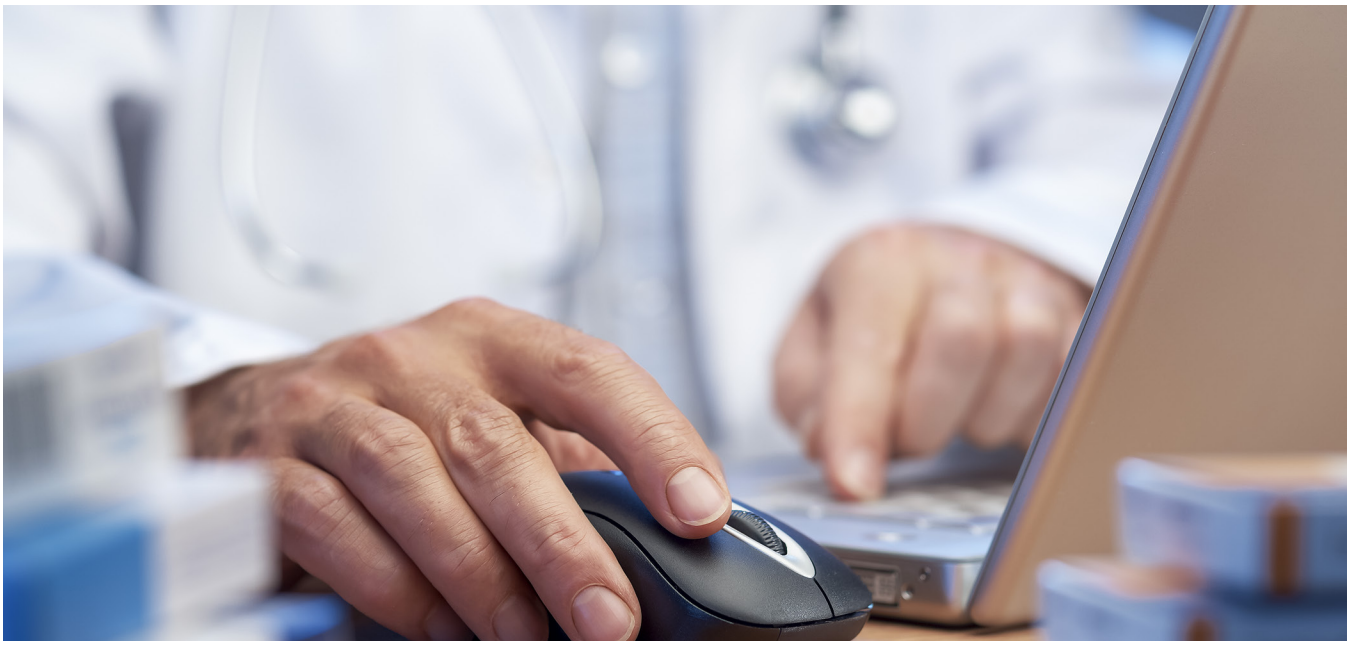
The NP or PA listed below acknowledges that he or she:

1. Holds an active license to practice in [name of state] and is in good standing in this state.
2. Is not currently prohibited by the State Board of Nursing or the Physician Assistant Board from executing a prescriptive authority agreement.
3. Has disclosed to the undersigned physician any prior disciplinary actions by the State Board of Nursing or the Physician Assistant Board.

Signature of supervising or collaborating physician: _____

Signature of NP or PA: _____ Date of agreement: _____

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.



Records Management

Health Records

The paper or electronic patient healthcare information record serves two major purposes: communicating information both within and outside the practice, and creating a written history in the event of later questions or challenges. It serves as objective documentation of all phases of medical treatment, including the care plan, laboratory and diagnostic testing, procedures performed and medication provided.

Because complete, accurate and legible health records are such an essential risk management measure, every practice needs a written policy governing documentation issues, 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.

The following strategies can help practices minimize liability exposures related to record management:

Patient Healthcare Information Record Contents

The patient healthcare information record should contain a complete 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 each 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 contain a complete 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 pamphlet title(s) and the patient's ability to comprehend the information given.
- *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 receipt of results of referral procedures and consultations, which should be signed or initialed by the physician 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 and pharmacist.
- *Documentation of medications administered or distributed,* including sample medications, with corresponding discussion of potential side effects and other instructions.
- *Termination of the physician-patient relationship*, where applicable.

General Documentation Guidelines

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

- *Ensure that notes are legible*, are written and signed in ink, and include the date and time of entry.
- *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 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 erase or obliterate notes in any way.* Erasing or using correction fluid or black markers on notes may suggest an attempt to purposefully conceal an error in patient care.
- *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*, such as date of dictation and transcription.
- *Sign note transcriptions* and write the date of approval or review.
- *Never alter a record or write a late entry* after a 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 revolutionized the practice of medicine, creating the potential for significant improvements in patient safety, clinical teamwork and operational efficiency. However, the effectiveness of EHRs depends upon many factors, both technical and human. 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.

Regardless of the medium for storing the patient's healthcare information record, basic risk management principles apply. The record must be thorough 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 can help reduce liability risks associated with EHR use:

- *Establish a policy regarding electronic copying, cutting and pasting.* To this end, consider limiting or deactivating the copy, cut and paste function of the electronic health record software. (For guidelines, see AHIMA's "Auditing Copy and Paste.")
- *Avoid repetitive copying and pasting when documenting high-risk items*, such as laboratory results, radiology reports and drug formulations.
- *Review and update information found elsewhere in the EHR before pasting it into current entries*, especially problem lists, diagnoses, allergies, current medications and history.
- *Expressly prohibit copying and pasting text from another clinician's note without proper attribution*, which may constitute medical plagiarism and lead to allegations of billing fraud.
- *Do not delete original source text or data and insert it elsewhere in the record*, thus altering the initial entry and compromising documentation integrity.
- *Discourage staff from "carrying forward" information* (such as prior medical history or diagnostic results) that is readily available elsewhere in the EHR, as this creates clutter and may adversely affect the record's reliability and usefulness.
- *Require providers to review, edit and approve dictated information* in a timely manner.
- *Mandate that documentation by "scribes" be authenticated* by individual physicians.

- *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*:
  - Include the privacy officer in discussions whenever new departments are added or new technology is implemented.
  - Require different passwords for all laptops, desktops and portable devices.
  - Encrypt confidential data on all devices.
  - 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 regular 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.

Hybrid Records

Many providers utilize "hybrid" records – part paper, part digital – 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' basic computer skills and readiness to navigate between paper and electronic formats. Lack of transitional planning and training can result in confusion 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. To learn more about the impact of hybrid records on the legal requirements of healthcare record management, see AHIMA's "EHR as the Business and Legal Records of Healthcare Organizations."
- *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 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 staff members' skills 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.

Transitional Measures

Consider the following interventions to reduce liability while making the transition to EHRs:

- *Pilot new EHR modules*, in 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 feel 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.

Copy and Paste Practices

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 notation, providers must enter negative or out-of-the-ordinary findings manually, a practice known as documentation by exception (DBE). Both options carry a high risk for "cloned" documentation, which can render the record of a 70-year-old patient similar in content and appearance to that of a 20-year-old. Such generic records can lead to allegations of deficient care and may be difficult to defend in the event of litigation.

Consider the following interventions:

- *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* to document subjective observations and to help locate specific EHR entries in the event a malpractice action is filed years after the date of care.
- *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 to two pages of documentation).
- *Prohibit staff from tampering with the EHR audit trail capability*. Explain that the function is necessary and does not significantly slow down the system.

Patient Problem List Maintenance

Accurate patient problem lists are essential to effectively manage patient populations and provide care across multiple sites. However, keeping problem list data relevant and up-to-date can be a challenge due to the large number of disciplines and services – ranging from health 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 riddled with obsolete and irrelevant information, potentially compromising quality and continuity of care.

To avoid this situation, it is important to 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 become a problem:

- *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.
  - Internists and specialists: at the end of each episode of care.
  - Attending physicians: 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 AHIMA's "Problem List Guidance in the EHR" and also "Standardizing the Problem List in the Ambulatory Electronic Health Record to Improve Patient Care," from Qualis Health.

For additional information, see AHIMA's sample policy and procedure template.

HIPAA Compliance

Every physician is expected to know and follow the privacy regulations promulgated under HIPAA and the HITECH Act.

HIPAA, a federal law, serves as the "floor" for patient information security. In states with privacy requirements that are stricter 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 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 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 practice's privacy policies and the privacy rights of patients. 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. Privacy notice templates that incorporate new requirements under the Omnibus Final Rule (see page 66) can be downloaded from the HHS website.

HIPAA and HITECH are complex laws, and violations can have serious consequences. If questions arise, consider consulting with an attorney or requesting HIPAA/HITECH compliance resources from the American Medical Association or other professional associations.

Release of the Healthcare Information Record

In 2013, the HIPAA Privacy and Security Omnibus Final Rule was promulgated and published by the U.S. Department of Health and Human Services (HHS). The Omnibus Final Rule clarified and strengthened various existing requirements under HIPAA Privacy, HIPAA Security, and the Health Information Technology for Economic and Clinical Health (HITECH) Act breach notification provisions. Several new requirements were added, as well as a more active enforcement initiative for privacy/security breaches and legal/regulatory compliance.

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

The Omnibus Final Rule …

- *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 personnel must understand 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). Even attorneys representing patients are required to have written patient authorization to obtain a copy of the record.

The release of information in the context of referrals to or consultations with other healthcare providers would likely 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, meaning that authorization may be required in these circumstances. It is good practice to obtain specific patient authorization for disclosure whenever one is uncertain or uncomfortable about sending copies of medical records.

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 cases, 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, consider first contacting an attorney.

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

- *Remember that while the patient has the legal right of access to all information in the record, it is the physician who owns the healthcare record* and all associated diagnostic information.
- *Never release original records or radiographs*, only copies.
- *Respond to patient requests for healthcare records in a reasonable time and manner.* Refusing to transfer records because of unpaid physician/medical 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 quicker 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 what constitutes 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 the state board to confirm state-specific rules.
- *Document the request and the date the copy was sent or picked up* in the patient healthcare information record. Failure to make such a notation could prove embarrassing later if a lawsuit is filed, and a copy of the patient record surfaces containing information that differs from what is on file in the office.
- *File all original patient authorizations in the record.* If records are sent by post, utilize certified, registered mail with a required return receipt, which should be placed in the patient's records. If records are picked up by the patient, ask that he or she sign and date a receipt.
- *Release only the records specifically requested.* Have staff members check with the physician before mailing paper records or sending electronic records to 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 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.

Electronic Discovery

Electronic discovery (e-discovery) involves requests for electronic data and records within the context of a legal proceeding. E-discovery request procedures often include analysis of hard drives, servers, and other electronic devices and media, in order to reveal when a document was accessed, who examined it and whether any alterations were made from its original format.

Discovery may involve standard portions of the electronic health record, as well as:

- *Metadata*, i.e., hidden files that may be used to authenticate entries and other information.
- *Clinical decision support data*, including system alerts, prompts, reminders and similar tools.
- *Email records* from all relevant parties.
- *Data on mobile devices and storage media*, including photos and videos stored on smartphones and tablets.

Based on CNA's experience with claims involving computerized patient records, we know that it can be a challenge to compile all pertinent claim-related records. As the patient's records may be found in a number of electronic "buckets," the process is sometimes much more involved than clicking one "print" button or copying one or two computer files.

If the record becomes part of the defense of a malpractice claim, the physician must attest that the printouts or electronic files represent a true, complete and accurate account of the patient's treatment. It is critical, therefore, to be conversant with the EHR system design, and the types of data that may be requested/required during the claim or legal discovery process.

In addition, every practice should have e-discovery guidelines covering retention and legal hold, including strict retention and deletion policies and procedures. These can protect the practice from allegations of destruction of evidence, while allowing for routine disposal of unnecessary documents.

Finally, ensure that operating policies, procedures and systems are regularly updated to comply with evolving regulations governing electronic records. By including e-discovery in periodic compliance reviews and activities, organizations can monitor performance and practices in this area.

Emailing Protected Health Information

Electronic mail has become an integral part of many physician practices. Its speed and convenience make it an ideal medium for answering general health questions, discussing relatively simple matters with other providers and transacting routine office business.

However, workplace emailing or text messaging may violate privacy and security requirements imposed under HIPAA and the HITECH Act, as it could lead to inadvertent transmission of PHI to an unauthorized third party. Privacy issues also arise when clinicians answer patient email messages from an unsecured location, such as home computers 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 recommended for all physician practices.

Email also has liability implications. Increasingly, plaintiff's attorneys are requesting disclosure of relevant email messages during the discovery process of malpractice litigation. For this reason, and because patient care-related emails constitute a form of progress note, each message received and reply sent should be printed out in full and included in the patient healthcare information record.

HIPAA enforcement activities are escalating, and every practice is at risk of improperly disclosing PHI. It is vital to remain current on privacy issues, create effective policies and procedures, train staff on an ongoing basis, and weigh the risks and benefits of communicating electronically with patients.

Faxing Protected Health Information

Patient information can be legally transmitted by fax. However, such a practice creates the risk of inadvertent disclosure of PHI. To minimize these risks, practices should establish a written facsimile transmission policy, which addresses the following issues, 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 authorization and release forms are acceptable.
- What process is utilized to ensure that faxed documents have been received.

Privacy issues arise when clinicians answer patient email messages from an unsecured location, such as home computers or smartphones, as any PHI would be maintained by the Internet provider and cannot be considered protected.

Self-Assessment Checklist: Documenting Patient Healthcare Information

This resource is designed to help physicians evaluate basic policies and procedures regarding documentation of patient care. 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
INFORMATION SYSTEM		
Is there a formal procedures 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 handled in a confidential manner, in compliance with federal and state laws?		
Is confidential information released 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 state statute of limitations for malpractice or record retention requirement, whichever is longer?		
Are records of after-hours calls and telephone logs and diaries stored for a set period of time?		
Is there a system for storing inactive patient records and archiving old 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 a separate record for each patient, containing the originals of all patient 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 prior physicians?		
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?		
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?		

RISK CONTROL MEASURES	PRESENT? YES/NO	COMMENTS
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 calling 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 basic 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?		
- List alternative treatments?		
- Note potential complications?		
- Use the simplest language possible?		
- Allow for customization as necessary?		
When possible, do physicians 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?		
Do physicians also have a face-to-face discussion with the patient, giving him/her as much time as needed to ask questions?		
Do physicians 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?		

RISK CONTROL MEASURES	PRESENT? YES/NO	COMMENTS
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?		
Is 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?		
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 and 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., 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?		

RISK CONTROL MEASURES	PRESENT? YES/NO	COMMENTS
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 physician's 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?		
TELEPHONE CALLS		
Are physicians alerted to after-hours calls from patients needing emergency care or information?		
Are all attempts to reach 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 health-care information security requirements?		
Have a security risk analysis and "gap analysis" been conducted, and have the results been documented?		

RISK CONTROL MEASURES	PRESENT? YES/NO	COMMENTS
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 physician's original signature appear on all insurance forms filed on behalf of a patient?		

Clinical Risks

Evidence-based Practice

In today's evolving practice environment, physicians must stay abreast not just of the latest information on treatment and patient management, but also of the applicable standard of care. The professional obligation to remain current involves awareness, evaluation and application of current knowledge – i.e., taking an evidence-based approach to clinical practice.

Staying up-to-date with medical knowledge, standards and best practices requires a well-defined procedure to search for the most current guidelines and warnings from recognized organizations and websites. In addition to actively searching for clinical guidelines, physicians should utilize so-called "push" technology to receive automatic updates from key medical sources. A strategy combining both of these elements will reduce the possibility of overlooking important data and findings.

Evidence-based practice and clinical guidelines are designed to enhance patient outcomes by strengthening the clinical decision-making process. Applying guidelines involves informing patients of the benefits and risks associated with accepting or rejecting the recommendations. It is therefore vitally important to document the rationale for decisions, especially if they deviate from an established guideline.

Remember that a combination of poor communication, preventable misunderstandings and an inadequate informed consent process is often at the heart of healthcare professional liability claims. Regular review of communication skills and methods is thus a key risk management measure for all physicians and medical practices. (See pages 43-44.) Well-honed communication skills are of particular importance when implementing guidelines that are more complex, vague or general in nature, or that represent a significant change in current practice.

Informed Consent

Informed consent is the process of providing patients with sufficient information to make a reasoned decision regarding proposed treatment. The consent must be given without coercion or fraud, based upon the patient's reasonably accurate and complete understanding of what will take place.

Physicians who ignore the wishes of a patient and proceed with treatment without the necessary consent may be subject to malpractice litigation, whether or not the treatment was in the best interest of the patient in the physician's professional opinion. If the treatment can be characterized as an unauthorized touching of the patient, the physician also may have committed the criminal offense of battery.

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

Fundamentals of Informed Consent

The informed consent process involves two main components:

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

Although some practitioners may consider the informed consent process burdensome and time-consuming, it is critical to effective risk management. The informed consent discussion represents the first step in managing patient expectations, thus reducing the possibility of a misunderstanding and consequent lawsuit. In addition, documentation of the informed consent process provides the best defense against a patient's allegation that the proposed treatment, other options and the potential for injury were not adequately explained.

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

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

Informed consent is a process, not a specific document. The process requires a verbal component, regardless of whether a written form is used. In most jurisdictions, a patient can give an oral informed consent. However, informed consent requirements vary among states, and conceivably a written form may be required in addition to discussion with the patient. Whether the patient's permission is spoken or written, the goal of the informed consent process remains the same: to ensure that the patient has an adequate understanding of the proposed treatment prior to giving consent.

The doctrine of informed consent requires that the patient be given sufficient information about, and time to consider, three major subjects:

1. *Nature of the proposed treatment*, including the need for treatment, its anticipated benefits and the prognosis.
2. *Alternatives to the proposed treatment*, including specialty referral options and no treatment at all, with an explanation of why, in one's professional judgment, the recommended treatment is preferable to the alternatives.
3. *Foreseeable risks*, including potential complications of the proposed treatment and the risks of refusing it. As with the discussion of alternative treatments, the list of foreseeable risks need not be all-inclusive, but it should reflect the patient's condition and overall health status.

Following full discussion of these questions, the patient then states his/her desire to either pursue or decline the proposed treatment.

Note that the practitioner who will perform the treatment or procedure must conduct the informed consent discussion – *it cannot be delegated*. Nurses and other healthcare staff may witness a patient's signature on a consent form, but they are not permitted to conduct the informed consent discussion. Refer to state statutes for guidance on the informed consent process in relation to healthcare practitioners such as certified nurse midwives, certified registered nurse anesthetists, nurse practitioners and other non-physician providers of care.

Informed Consent Tips

The following strategies can help enhance the informed consent process:

- *Tailor discussions* to the needs and level of each patient.
- *Use basic, uncomplicated language* that the patient can understand, defining any technical terms that must be used.
- *Present the informed consent requirement as a benefit to the patient*, rather than a burden.
- *Consider the complexity of the proposed treatment and the degree of risk* when conducting the informed consent discussion with the patient.
- *Utilize brochures*, as well as pamphlets, models and other educational resources as needed.
- *Give the patient every opportunity to ask questions*, and answer them as clearly and comprehensively as possible.
- *Ask the patient to describe the proposed plan of treatment* in his or her own words.
- *Encourage the patient to have a family member present in the room* during the informed consent discussion to make the patient feel more at ease.
- *Have a staff member present during the informed consent discussion* to serve as witness.
- *Be aware that in most cases, minors must obtain the consent of a parent or guardian* prior to beginning treatment. Minors cannot consent to their own treatment unless legally declared emancipated by the court or determined to be emancipated pursuant to state law; see page 80 for more information.
- *Remember that the informed consent process is the responsibility of the physician* and cannot be delegated to staff members.
- *Always ask the patient, "Do you have any questions about the information you have been given or about the proposed treatment?"* and document the answer.
- *If necessary, use a qualified interpreter*, and include the translator's name, address and telephone number in the body of the progress note for that day. If many patients speak the same foreign language, consider having consent forms translated into that language.
- *Proceed only after getting the patient's approval*. Any treatment rendered without the patient's consent may result in malpractice allegations or even charges of battery.

Informed Consent Documentation

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

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

Informed Refusal

An informed refusal is essentially the opposite of an informed consent, in that the patient has said "no" to the procedure instead of "yes." The information presented to the patient is the same for both processes, until the patient declines the recommendation. From that moment, the physician is required to provide more information to the patient.

The patient has the legal right to decline treatment recommendations and refuse care. If this occurs, explain to the patient the consequences and foreseeable risks of refusing treatment and ask the patient's reasons for doing so. If the refusal reflects a lack of understanding, re-explain the rationale for the procedure or treatment, emphasizing the probable consequences of the refusal. If the patient again refuses to accept treatment recommendations after the risks of refusing treatment have been explained, then the patient has given an *informed refusal*.

Patients who suffer a serious injury after refusing care sometimes claim that they did not fully understand the potential consequences of such refusal and that the healthcare provider was negligent in not fully disclosing the risks of forgoing treatment. The patient may further assert that had the risks of refusal been properly and completely explained by the provider, he or she would have consented to the procedure or treatment.

For this reason, disclosure of the likely consequences of declining treatment recommendations is central to the informed refusal process. The physician who continues caring for a refusing patient must be aware of several consequent responsibilities relating to the informed refusal, which include:

- *A continued duty to examine and diagnose the patient* for the duration of the physician-patient relationship and as long as the patient continues to refuse treatment.
- *A continued duty to inform the patient about the condition and its associated risks* while the physician-patient relationship is in place, the condition exists and the patient continues to refuse treatment.
- *A heightened duty to tell the patient how refusal of treatment may affect treatment of other conditions or problems* when discussing these conditions.

The failure to fulfill these obligations has resulted in numerous *failure to diagnose* and *failure to inform* allegations.

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

Techniques for documenting informed refusals are similar to, but go beyond, those for informed consent. After discussing the potential consequences of refusal with the patient, write a comprehensive progress note and document the refusal using a written form, which should be incorporated into the patient healthcare information record. (A sample informed refusal form is on page 84.)

Progress notes should document:

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

Using an informed refusal form. Few patients remember all that they were told during the informed consent/refusal discussion, making written forms a valuable reminder. A written form also helps manage patient expectations, provides further documentation of the disclosure of information and may deter negligence claims.

Complete the Discussion and Refusal of Treatment form on page 84. Patients may reconsider when presented with a written document to sign. Although the informed refusal documentation process is not primarily designed to persuade reluctant patients to accept needed treatment, it may have this beneficial effect on some.

Of the patients who persist in refusing recommended treatment, some will sign the form and others will not. While it is preferable to have the patient's signature, other approaches to document the process may be pursued. For example, the physician may sign the form and also have the staff member who witnessed the discussion and disclosure sign it as well. If the patient will not sign, write "Patient refuses to sign this form" on the patient signature line. Regardless of whether or not the patient signed the form, place the original in the patient's healthcare information record and provide a copy to the patient. The signatures on the form, as well as the progress note, will demonstrate that a discussion took place and an informed refusal was given.

Continuing responsibilities. As noted earlier, the documentation process for informed refusal does not end after the first refusal. Continue to assess the patient's condition and health status, update the patient on changes and needed treatment, and state the patient's refusal of care in the progress note as appropriate.

Special Issues in Informed Consent

Consent for minors. As a general rule, unemancipated minors cannot consent to treatment. The informed consent of a parent or legal guardian must be obtained before treatment is rendered. Adult siblings, grandparents and other adult caretakers may not be legally authorized to provide consent unless they have been granted legal guardianship by the court. Sometimes the adult party who brought the child is not authorized to grant consent. If the parent or legal guardian cannot be contacted by telephone, consider the presenting signs and symptoms, and determine whether to proceed or defer treatment until consent can be obtained.

From a liability perspective, this is a gray area. However, considering the frequency of lack of informed consent allegations, proceeding without consent may increase risk by creating conflict between the physician and the child's parents.

By establishing and communicating an office policy on consent for both accompanied and unaccompanied minor patients, medical practices can prevent misunderstandings. If an unemancipated minor, unaccompanied by a parent or legal guardian, asks for care, the following steps can help minimize potential conflict and reduce liability exposure:

- *Determine whether, in light of the patient's presenting condition, it is in the patient's best interest to proceed with the treatment immediately*, or whether treatment can wait until a parent or legal guardian can be contacted.
- *Make a reasonable effort to contact the parent or legal guardian.* To that end, maintain up-to-date cellular telephone numbers and other contact information. Document all attempts to communicate with a parent or guardian.
- *If a parent or legal guardian cannot be contacted, defer routine treatment* until the informed consent of a parent or guardian can be obtained.
- *Generally, it is acceptable to intervene without parental consent when immediate intervention is warranted* due to traumatic injury or other truly emergent conditions.

The age of majority varies by jurisdiction, as do laws about emancipation of minors. For clarification of these issues, contact an attorney in the area who specializes in medical malpractice defense.

Diminished mental capacity. Physicians confront a range of medical, ethical and legal questions when treating patients who are mentally incapacitated due to organic condition, aging or disease. Healthcare decisions, including informed consent and refusal matters, are valid *only* when patients have the capacity to comprehend the issues at stake. It is the physician's responsibility to assess patients' decision-making capacity, which is not always an easy task.

Consider the following tenets when mental capacity is at issue:

1. All adult patients are assumed to be capable of consent unless proven otherwise.
2. Only a court can officially designate someone as legally incapacitated.
3. Emergency procedures may be completed regardless of mental capacity, provided that the urgent need for intervention is clear and well-documented.

The following questions may assist a physician in determining and documenting a patient's capacity to understand information, deliberate about choices and consent to treatment. Ask the patient to:

- *Describe the reason for the visit* to the medical office.
- *Repeat back the information* given him or her about treatment needs.
- *List basic personal information*, such as age, birth date, current address and the name of the emergency contact person.

Patients who can correctly and fully answer these questions may be considered of adequate mental capacity to proceed with the informed consent discussion and subsequent treatment. Treatment of patients who do not fully comprehend the questions or do not provide cogent answers should be deferred until mental capacity is more fully investigated.

Remote consent for minors or the cognitively impaired. Consent should be obtained by telephone or other electronic means only if the patient's legal surrogate is not otherwise available. The following guidelines can help reduce risk in this situation:

- *Clearly explain why consent was obtained in this manner* in the patient healthcare information record.
- *Ensure that consent by telephone is witnessed by a third party*, who remains on the line during the entire consent discussion between the healthcare surrogate and the practitioner.
- *Document all of the elements of the informed consent discussion*, i.e., description of the recommended procedure and its material risks and benefits, risks and benefits of alternative treatments, risks associated with treatment refusal, name of the consenting party, relationship to the patient, nature of the consent given, and date and time.
- *Have the witness time, date and countersign the entries* in the patient healthcare information record.
- *Print or scan all emails involving patient consent* and include them in the patient healthcare information record.

Exceptional situations. States generally recognize special circumstances where delaying treatment in order to obtain informed consent could be detrimental to the patient. These include emergency or life-threatening situations when the patient is unable to consent and diligent efforts to contact the appropriate family member or guardian have been unsuccessful. In addition, the informed consent process can be modified if, in the physician's medical opinion, the disclosure of risks would have a serious adverse effect on the patient or the therapeutic process.

Such exceptional situations must be well-documented in the patient's healthcare information record. Legal counsel should be sought regarding specific state statutes.

Sample Discussion and Consent for Treatment Form

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

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

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

Nature of the Recommended Treatment

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

_____

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

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

_____

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

_____

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

_____

Alternative Treatments

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

☐ No other reasonable treatment option exists for my condition.

_____ I have had an opportunity to ask questions about these alternatives and any other treatments I have heard or
Patient's initials

thought about, including: _____

_____

Risks of the Recommended Treatment

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

_____

_____

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

Acknowledgment

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

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

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

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

Signature of patient or guardian: _____ Date: _____

Signature of treating physician: _____ Date: _____

Signature of witness: _____ Date: _____

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

Sample Refusal of Treatment Form

Instructions

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

1. I have been advised by my physician/practitioner, *(insert name)* _____, that the following procedure/treatment should be performed upon me: *(insert name of procedure/treatment)* _____
2. My physician/practitioner has explained the following points to my understanding:
   a. The nature of the recommended procedure/treatment.
   b. The purpose of and need for the recommended procedure/treatment.
   c. The possible alternatives to the recommended procedure/treatment, which I similarly refuse.
   d. The probable consequences of not proceeding with the recommended procedure/treatment and/or alternatives.
3. I have read the following educational materials provided to me: *(list materials, if applicable)*

   _____

   _____
4. My reason for refusal is as follows: _____
5. I personally assume the risks and consequences of my refusal, and release myself, my heirs, executors, administrators or personal representatives, as well as the physicians who have been consulted in my case and *(insert name of medical practice)* _____, its officers, agents and employees, from any and all liability for ill effects that may result from my refusal to consent to the performance of the proposed procedure(s)/treatment(s).
6. I acknowledge that I have read this document in its entirety and that I fully understand it.

Caution: This is a release of liability – read carefully before signing.

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

If refusing party is other than patient:

Signature of refusing physician: _____ Date: _____

Signature of witness: _____ Date: _____

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

Infection Control and Prevention

Transmission of viral and bacterial pathogens is an ever-present safety threat for medical offices, physicians and their allied healthcare support staff. Infection prevention is also a regulatory issue of particular interest to the Occupational Safety and Health Administration (OSHA), which may at any time conduct inspections of physicians' offices.

Every physician's office and practice setting should develop an infection prevention plan that is written clearly, updated annually and created with maximum staff input. All staff should receive a copy of the plan and review it during orientation and at regular intervals thereafter. In addition, staff members should receive ongoing education about how infections are transmitted and what they can do to prevent their spread.

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

Modes of Transmission

According to the CDC, modes of transmission vary by type of organism. They include:

- Direct or indirect contact (e.g., Herpes simplex virus, respiratory syncytial virus, Staphylococcus aureus).
- Droplets (e.g., influenza virus, B. pertussis).
- Airborne (e.g., M. tuberculosis).
- Bloodborne (e.g., hepatitis B and C viruses and HIV, which are transmitted via percutaneous or mucous membrane exposure).

Some infectious agents spread via multiple routes, and not all infectious agents are transmitted from person to person. More information is available on this and the topics that follow at the CDC website.

Standard Precautions

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

- Hand hygiene.
- Personal protective equipment (e.g., gloves, gowns, masks).
- Safe injection practices.
- Safe handling of potentially contaminated equipment or surfaces in the patient environment.
- Respiratory hygiene/cough etiquette.

Hand Hygiene

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

Hand hygiene should be performed:

- *Before touching a patient*, even if gloves will be worn.
- *Before exiting the care area* and after touching the patient or anything in the patient's immediate environment.
- *After contact with blood*, wound dressings, or bodily fluids or excretions.
- *Prior to performing an aseptic task*, such as placing an IV or preparing an injection.
- *If hands will be moving from a contaminated-body site to a clean-body site* during patient care.
- *After glove removal*, once gloves have been disposed of.

Complete guidance on how and when hand hygiene should be performed, including recommendations regarding surgical hand antisepsis and artificial nails, can be found in the "Guideline for Hand Hygiene in Health-Care Settings."

Environmental Infection Control

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

For best results, select EPA-registered disinfectants or detergents/disinfectants with label claims for use in healthcare, and follow manufacturer's recommendations in terms of amount, dilution, contact time, safe use and disposal.

Respiratory Hygiene/Cough Etiquette

Respiratory hygiene/cough etiquette is a key element of Standard Precautions. It must be implemented throughout the practice, and especially at patients' and visitors' first point of encounter – i.e., reception. These measures apply primarily to patients and visitors with undiagnosed transmissible respiratory infections, as well as any person who enters the office with a cough, congestion, rhinorrhea, increased production of respiratory secretions or signs of illness.

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

- *Posting signs at entrances with instructions to anyone with symptoms of respiratory infection to follow basic hygienic practices*, including covering their mouths/noses when coughing or sneezing and using and properly disposing of tissues.
- *Performing hand hygiene* after hands have been in contact with respiratory secretions.
- *Offering masks to coughing and otherwise symptomatic persons* upon entry to the facility.
- *Providing tissues* and no-touch receptacles for their disposal.
- *Encouraging persons with symptoms of respiratory infections to sit as far from others as possible* or in a separate waiting area if one is available.
- *Educate staff on the importance of containing the respiratory secretions of patients* who have signs and symptoms of a respiratory infection.

Bloodborne Pathogens

Bloodborne pathogens include any microorganism that may be transmitted by contact with the blood or bodily fluids of an infected individual. The pathogens of major concern are HIV and the Hepatitis B and C viruses.

In 1991, OSHA issued the Bloodborne Pathogens Standard to protect workers (*29 CFR 1910.1030*). In 2000, it was revised in response to the federal Needlestick Safety and Prevention Act, *Pub.L. 106-430*. The revised standard clarifies the need for employers, including physician-owned practices, to select safer needle devices and to involve employees in identifying and selecting these devices.

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

- *Adopting engineering and work practice controls* and using appropriate personal protective equipment.
- *Drafting a written exposure control plan*, to be updated annually.
- *Implementing universal precautions* to prevent infection.
- *Maintaining a log of employee injuries* from contaminated sharps.
- *Offering medical follow-up* after a potential exposure.
- *Properly containing and disposing of all regulated waste* to minimize contamination.
- *Providing Hepatitis B vaccine* to exposed employees at no cost.
- *Selecting safer, better-engineered needles and sharps* and using them whenever possible.
- *Training employees on an ongoing basis* in established safety practices.
- *Labeling or color-coding sharps disposal boxes* and containers designed to hold regulated waste, contaminated laundry and certain specimens.

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

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

Personal Protective Equipment

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

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

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

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

Sterilization

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

Waste Management

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

Employee Health

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

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

Online Resources

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

Medication Management

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

Establishing Safe Medication Procedures

To reduce risk, every office should adopt a sound medication management policy and monitor staff for compliance. The following general guidelines can assist practices in crafting and evaluating their medication management procedures:

- *Adopt a "zero tolerance" policy for illegibility*. Use electronic entry or print in block letters.
- *Delineate the medications that require laboratory monitoring* and use a tickler system to alert staff when a laboratory test should be ordered.
- *Devise internal processes to monitor, track and correct medication errors*, and evaluate and update these processes on a regular basis.
- *Do not prescribe medications over the telephone for a new non-recurring problem/complaint* without first examining the patient.
- *Ensure that documentation guidelines include indications for use of medications* and instructions given to the patient. Note and archive any patient information handouts.
- *Establish a medication list for every patient*. Lists should be reviewed and reconciled at each patient visit.
- *Implement a process for reviewing current medications* each time drugs are ordered, administered or dispensed.
- *Limit verbal orders to emergencies*, and ensure that physicians or other designated providers sign or initial verbal orders within a prescribed time frame.
- *Prohibit the use of abbreviations when documenting the name of a medication*, as well as dose, route or frequency.
- *Provide a complete list of medications to subsequent providers*, such as consultants or specialists.
- *Permit providers to refill just those medications that they have originally prescribed*. All others should be refilled only after a visit.

New Prescriptions

- *Permit only designated staff members to call in prescriptions* to pharmacies.
- *Carefully document all new prescriptions called in to pharmacies*, including the name of the pharmacy and the pharmacist who received the order.
- *Require that prescription orders be read back,* and document this step.
- *Retain a copy of faxed or emailed prescription orders* in the healthcare information record.
- *Perform medication reconciliation at every office visit* to protect against negative interactions.
- *Keep prescription pads in a locked storage area* away from patient care and reception areas.
- *Prohibit use of pre-signed and post-dated prescription forms*, which can lead to theft or abuse.
- *Report any lost or stolen prescription pads* to local pharmacies, hospitals and the Drug Enforcement Agency.

Medication Storage and Disposal

- *Adhere to applicable state and federal regulatory standards* for ordering, storing, dispensing and discarding controlled substances and other medications.
- *Avoid possible drug diversion by performing a weekly reconciliation of stock medications*, i.e., comparing drugs dispensed to patients against remaining stock.
- *Minimize use of multi-dose vials*. According to the CDC, multi-dose vials should be dedicated to a single patient whenever possible. If multi-dose vials must be used for more than one patient, they should not be kept or accessed in the immediate patient treatment area, as this could lead to contamination and infection of subsequent patients. If a multi-dose vial is brought near the patient treatment area, it should be dedicated to that patient alone and discarded after use.
- *Limit access to medications* to appropriate staff members.
- *Monitor expiration dates of medications* and use a reverse distribution system to dispose of expired or otherwise unwanted drugs.
- *Reconcile the inventory of controlled substances every day* and include the signatures of two licensed professionals. All administered and discarded doses should be accounted for in writing.
- *Store only necessary pharmaceuticals*, keeping them in a locked cabinet away from patient access. Controlled substances should be double-locked.

- *Dispose of expired medications safely*. Disposing of drugs via the wastewater system (e.g., sink or toilet) is discouraged, as this may have adverse environmental consequences.
- *Exercise care when discarding any portion of a controlled substance*. The disposal should be witnessed by two staff members who then sign off on the process.

Medication Administration and Documentation

- *Consider prohibiting administration of certain categories of medications* (e.g., allergy injections) when a physician is not on the premises.
- *Advise patients to remain in the office for a specified time after taking any medication*, in case of an adverse reaction.
- *Encourage staff members to question medication orders that appear incomplete*, confusing or illegible.
- *Permit only qualified employees to administer medications*, based upon statutory requirements regarding education and/or training.
- *Enter all dispensed samples into a dispensing log* to facilitate patient notification in case of a later drug recall. The log should include patient name, drug name, dose, lot number and date dispensed.
- *Store sample medications safely and securely*, following all applicable state and federal regulations.
- *Maintain current drug reference materials in the office* for use by staff and physicians.
- *Implement a documented annual medication proficiency exam* and related competency training for employees.
- *Document all vital information in the patient healthcare information record immediately after administering any drug*. Include the name of the drug, dose, frequency, route, number of doses dispensed, and special instructions or advice, e.g., "Patient advised that drug may cause drowsiness."
- *Instruct staff to administer only drugs that they have personally drawn up or prepared*, in order to minimize miscommunication and consequent errors.
- *Prominently display drug allergies on the patient record*, using colored allergy stickers or other means.

Vaccines

The protective effects of vaccines can be compromised by improper storage and handling practices. Consult the CDC for information about vaccine storage and handling.

Opioid Prescribing

As opioid use grows, public and regulatory concerns about drug addiction, misuse and diversion are increasing. More than ever before, providers risk a lawsuit or medical board investigation if they inappropriately manage patients taking opioids for chronic or recurring pain.

The following recommendations, combined with the basic principles of sound professional practice, can help providers render quality care while minimizing the risks surrounding the prescribing of controlled substances, including drug addiction, diversion, and respiratory depression or other adverse effects.

Opioid Risk Evaluation

All patients suffering pain should be given a thorough physical and have a history taken, including an assessment of psychosocial factors and family history. Reevaluate the level of pain and the efficacy of the treatment plan at every visit.

An opioid risk assessment, depression scale testing and an assessment of the risk of abuse should be completed for each patient before opioids are prescribed. Thereafter, patients should be routinely screened. Common risk factors of abuse include, but are not limited to, family history of alcohol or drug use, history of physical or sexual abuse, and psychiatric conditions.

Commonly used screening tools include the following:

- Diagnosis, Intractability, Risk, Efficacy (DIRE) tool.
- Opioid risk tool.
- Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R).
- Screening Instrument for Substance Abuse Potential (SISAP), which assesses the potential for misuse at every visit.

Other tools for identifying misuse include random urine drug screening and pill counts.

Pain Treatment Agreements

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

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

Always seek the advice of legal counsel when drafting and updating pain agreements, and remember to update them regularly so that they reflect changes in level of pain, health status and medication dosages.

Patient Education

- *Develop a comprehensive medication education program for patients*, including general written materials, as well as specific spoken advice.
- *Retain copies of any medication-related educational materials provided to patients* in the healthcare information record.
- *Conduct and document the informed consent process whenever a new medication is prescribed* or the course of therapy changes.
- *Provide educational materials to patients in a useful form*, i.e., in languages and at a reading level appropriate to the patient population.

For more information, see the lengthy and detailed "CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016." The guideline is available here at time of publication.

Providers can help protect themselves against allegations of abandonment by rigorously documenting instances of noncompliance, communicating clearly and straightforwardly with patients, and establishing and consistently implementing formal policies and procedures.

Test Results Management

By consistently reviewing and following up on outpatient test results in a timely manner, physicians can both enhance patient safety and reduce potential liability. Consistency of operations, reliable backup systems and thorough documentation are the keys to effective test results tracking and patient notification.

Tracking Diagnostic Information

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

Sending out Tests and Receiving Results

Most practices already have a system in place for sending specimens to reference laboratories and ordering tests. It is equally important to ensure that test results are reported back to the office so they can be reviewed in a timely manner. Consider implementing the following practices:

- *Utilize a paper or electronic test order log.* Record the date the specimen was sent or the test was ordered, the patient's name and unique identifier, the name of the test and the expected date of return.
- *Indicate the results of returned tests by using the designated notation* or, in a computerized system, by highlighting the entry with a color marker or color filler.
- *Consider acquiring an effective test management system*, based on the telephone, computer software or the Internet. Most electronic health records systems include a test management component.
- *Place paper health information records awaiting test results in a designated area.* Arrange the records in chronological order, and assign a staff member to review them daily and follow up on outstanding tests.

Reviewing Test Results

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

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

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

- Date and time of call.
- Name of individual taking the call.
- Patient's name and unique identifier.
- Test name and critical test value.
- First name, last name and location of caller/sender (e.g., John Doe, Acme Diagnostics).
- Acknowledgment that information has been read back and confirmed.

When handing off the results to another practitioner, document the physician/individual notified (first name, last name, credentials; e.g., John Smith, D.O. or Jane Doe, CNM), indicate that the test results are of critical importance, and note the date and time of the interaction.

Serial Testing

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

- *List the drugs requiring a laboratory baseline value and periodic reassessment* (e.g., Lipitor®/liver enzymes). Review and update the list annually.
- *Identify the conditions requiring periodic reassessment* (e.g., chronic lymphatic leukemia). Review and update annually.
- *Develop and implement an alert system* to ensure that patients are notified and serial tests are ordered at appropriate intervals.
- *Engage in an informed consent discussion with the patient* regarding the drug or condition and the need for serial follow-up. Include signs and symptoms that should prompt a call to the doctor.

Review the patient healthcare information record and any information received since the last patient visit to determine if a diagnostic test should be ordered. Failure to do so can lead to poor patient outcomes and a possible lawsuit.

Notifying Patients of Test Results

Patients should be notified of all test results. The physician should deliver significant abnormal results in person to the patient (e.g., a pathology report that has identified a malignancy). Patients should not be told to assume a test result is normal if they are not notified by the practice of abnormal results.

Before leaving any messages regarding test results, obtain patients' written consent to do so. This consent form, which may be filled out by patients as part of the registration process, should include the following statements:

- Message may be left on home telephone. (yes/no)
- Message may be left on work telephone. (yes/no)
- Message may be left on cellular telephone. (yes/no)
- Message may be left with the following individuals: (first name, last name) _____

Have the patient sign and date the form.

Do not leave a message stating that test results were abnormal. Instead, tell the patient to call for results, and make follow-up calls if patients do not respond. Identify circumstances (e.g., abnormal mammogram or PSA) requiring the use of registered mail with a return receipt if the patient cannot be contacted by telephone. Document and retain the receipt in the patient healthcare information record.

Electronic health record systems are available that permit test results to be posted and automatically retrieved by the patient, following review by the physician.

Documenting Notification of Test Results

Document all attempts to notify patients of test results in the patient healthcare information record, as well as follow-up treatment instructions and recommendations for preventive/screening tests, such as colonoscopies or mammograms. Explain the potential consequences of failing to obtain the test or procedure, and document both the discussion itself and the patient's response.

Continuity of Care

Appointment Management

Sound patient scheduling practices support continuity of patient care and help medical offices meet their business goals. Because scheduling has important risk management implications, it should be guided by written office policies and procedures tailored to the office's range of services and patient population.

Urgent Appointments

Incorporate time in the office schedule to treat walk-ins or call-ins requiring non-routine ambulatory care. In addition, consider the following guidelines:

- *Establish clear triage policies for urgent/same day appointments,* including staff-physician consultation and related documentation.
- *Instruct non-clinical staff members to consult with a nurse or physician before informing patients that their request for an urgent/same day appointment cannot be accommodated,* and to document this consultation and the rationale given.
- *Require that a physician or other qualified healthcare provider promptly evaluate all patients who present with an urgent condition,* and inform waiting patients of any delay this may cause.

Missed Appointments

Writing "no-show" or "patient canceled" and then filing the patient healthcare information record without further consideration can lead to poor health outcomes for patients and allegations of negligence against the physician.

Every practice should develop a standard procedure for following up with patients who have miss a scheduled office visit, which minimally includes the following practices:

- *Obtain consent from the patient to leave appointment reminder messages* either on an answering machine or with another person.
- *Develop a tickler system to trigger a follow-up appointment* if a patient does not call to schedule a return visit within the agreed-upon time frame (e.g., one week after surgery).
- *Notify physicians of missed appointments* and have them review the patient healthcare information record for critical concerns. This includes determining whether patients who miss appointments are awaiting test results, require follow-up care or have not completed a course of therapy.
- *Attempt to make telephone contact with every patient who misses or cancels an appointment* and document these attempts.
- *Delineate the circumstances when it is necessary to send the patient a registered letter with return receipt requested,* a first-class letter or an email following unsuccessful attempts at telephone contact.
- *Document all steps taken to contact the patient* in order to reschedule the appointment.
- *Notify the referring physician that the patient has failed to appear* for a scheduled consultation, if applicable.
- *Archive appointment books and computer records* in accordance with state statutes or regulations applying to health record retention. A history of repeated missed appointments may demonstrate that a plaintiff contributed to his or her injuries, which may help counter allegations of provider negligence.

For patients who chronically cancel appointments, or simply do not show up, send a registered letter stating that failure to keep appointments and follow advice puts them at medical risk. They should be instructed to contact the office immediately upon receipt of the letter to schedule an appointment. If a patient fails to call, consider discharging the patient from the practice. (See pages 38-42.) Document and retain the receipt.

Cancellation of Office Hours

Occasionally, office hours must be canceled by the physician due to unavoidable circumstances, such as illness, a patient emergency requiring the physician's attendance or a power failure. In these cases, the following guidelines can help the practice return to schedule quickly and minimize the risk of dropped appointments:

- *Notify patients and reschedule appointments as soon as possible*, extending sincere apologies to patients for the inconvenience.
- *Have a physician or other designated practitioner review all patient healthcare information records to determine the urgency and time frame for rescheduling*. Non-clinical staff should never reschedule patients without direction.
- *Permit patients who say they are too ill to wait to speak directly with clinical staff*, who can determine the need for emergency or alternative care.
- *Document patient contacts and new appointments* in the patient healthcare information record.
- *Develop a backup plan in the event that the office cannot reopen on the next scheduled business day*, or if a patient requires same-day care (e.g., a dialysis treatment).

Long Waiting Times

If patients experience long waiting times, apologize to them and take the following additional measures:

- *Contact affected patients who have not yet arrived at the office* if delays of more than one hour are expected. If the physician or other designated clinical staff approves, permit patients to reschedule the appointment.
- *Inform patients in the waiting room of delays* and provide periodic updates.
- *If possible, give an estimated time for seeing the physician and a reason for the delay* (e.g., the doctor was detained due to an emergency surgery). Again, permit patients to reschedule their appointment if the wait continues and the physician concurs.
- *Document rescheduled appointments* in the patient healthcare information record.

Excessive waiting is a major source of patient dissatisfaction. If the practice routinely runs behind schedule, develop and implement strategies to improve scheduling accuracy.

Telephone Practices

Documentation of Telephone Calls

Because so much important information is exchanged on the telephone, documentation of calls between patients and physicians or staff can be critical to legal defense in the event of a malpractice allegation. The following guidelines can help medical practices enhance the thoroughness and timeliness of such documentation:

- *Include in the patient's healthcare information record all calls regarding canceled appointments*, as well as medications, emergencies, referrals, consultations, etc.
- *If unable to reach the patient by telephone, document the telephone number called* and make a notation such as "No answer, left message on machine" or "Spoke with spouse, left message to call back."
- *Document after-hours telephone calls at the earliest opportunity*. Be certain to clearly indicate any directions provided to the patient and required patient or physician follow-up.

To facilitate after-hours access to care, physicians generally carry pagers or cellular telephones, or use an answering service, answering machine or voice mail. When speaking with patients after hours and without access to patient files, it is sometimes difficult to compile and document all pertinent information regarding the call.

To reduce the possibility of documentation lapses, consider using a special form, log or diary for after-hours calls. Completed forms should be placed in the patient's healthcare information record, while logs or diaries should be permanently maintained by the practice as documentation for use in case of subsequent litigation, after important notes have been transferred or attached to the patient record.

Another possibility is to immediately call the office and dictate a message on the office answering machine for later transcription, or scan notes into the patient's electronic record. If dictating a voice recording or typing a note into a smart phone, tablet device or home computer, take appropriate precautions to protect the privacy and security of the captured information, and follow office policies and procedures regarding use of personal or practice-owned mobile electronic devices. (See page 68.)

Telephone Etiquette and Protocols

The office telephone should be a time-saver and a problem-solver, rather than a source of headaches and liability exposure. As telephone skills have a direct impact on patient satisfaction, it is important that providers and staff treat telephone calls no differently than face-to-face interactions, with due attention paid to documentation, follow-up and basic courtesy. All personnel should be trained to:

- Answer telephones within a designated number of rings.
- Establish a maximum holding time, including time spent waiting for a physician.
- Designate a time during each day to return patient telephone calls.

Unreturned or inadequately responded-to patient telephone calls can have serious care and liability consequences. The following telephone protocols can help improve patient relations and minimize risk:

- *Establish clear time limits for responding to patient telephone calls*, with response times corresponding to the nature of the call.
- *Train staff members how to respond to patients when a physician is not available* and reinforce these lessons on an ongoing basis.
- *Provide 24-hour access to physicians via a reliable after-hours answering service.* Routinely monitor the service for accuracy and courtesy.
- *Place a list of emergency numbers next to each telephone*, including hospital emergency services, poison control centers, crisis prevention hotlines, and contact information for on-call or covering physicians.
- *Develop policies regarding follow-up telephone calls to patients after medical interventions* or if there is a cause for concern.
- *Ensure that the office has sufficient telephone lines* to accommodate the patient population.

Telephone Triage

Even with the advent of newer communication methods, the telephone remains an important tool for patient communication and management. Telephone triage – i.e., the use of the telephone to assess the relative urgency of patient complaints – is an important tool in terms of enhancing efficiency, educating and managing patients, and reducing risk. The following suggestions can help improve triage safety and effectiveness:

- *Develop triage protocols and algorithms with the input of practicing physicians*, and review protocols periodically to ensure that they accord with current standards of care.
- *Give the triage nurse the option of calling the patient's physician*, regardless of the patient's self-described condition.
- *Permit patients to seek treatment beyond the advice given by the triage nurse*, if they so desire.
- *Make written triage protocols available to providers* who participate in the triage program.
- *Conduct well-documented physician oversight of the triage program*, issuing regular reports to providers and staff.

Recording of Practitioner Visits

Using their smartphones, patients are capable of recording office visits, clinical exams, medical procedures and telephone calls with their healthcare practitioner. This practice has both pluses and minuses. On the one hand, a video or audio recording can enhance patient understanding and decision-making. It may also complement the clinical summary documents generated through electronic health record applications. On the other hand, recordings run the risk of compromising patient privacy if overheard by a third party or posted online, and may even serve as grounds for a lawsuit should the practitioner make compromising statements. The issue of whether to permit recordings therefore requires balancing potential privacy and liability risks with the benefits of improved patient recollection and compliance.

HIPAA privacy rules do not bar recording of encounters. However, state recording laws in some jurisdictions make it harder for patients to do so. In 12 states, both the practitioner and patient must consent to the recording, as opposed to one-party consent laws that require only the patient's acquiescence. Although some providers may prefer to prohibit the practice, it appears that patients can record medical encounters without physician consent in the majority of states.

Because patient recordings may have liability implications and can potentially undermine patient-provider trust, the subject should be addressed in written policy and made subject to the following safeguards:

- *Explicitly state a preference that patients disclose their intent to record*, if in a one-party consent state.
- *Have the patient execute a written consent form*, if in a two-party consent state.
- *Document the purpose of the recording in the patient healthcare information record*, e.g., an elderly patient with memory problems is worried about forgetting discharge instructions.
- *Negotiate concessions when possible*, such as limiting the recording time to a designated portion of the visit or permitting a trusted person to take notes during the visit.
- *Require patients to acknowledge in writing that they will limit the distribution of recordings*, in order to safeguard the privacy of the patient-provider encounter.
- *Consider terminating patients who insist on recording without the provider's consent* – but remember that such a hard-line stance risks alienating the patient.

Be sure to consult legal counsel before drafting a policy statement in regard to recording of visits, in order to ensure that it is consistent with applicable state consent and authorization requirements.

Coverage

Practices must have formal processes in place to ensure adequate communication between the primary care provider and those who care for the patient during on-call coverage and hospitalizations. Such protocols help prevent miscues, strengthen continuity of care and enhance patient satisfaction.

On-call Arrangements

- *Establish a written protocol for coverage that ensures round-the-clock access to a physician in the practice*, and facilitates mutual understanding of expectations and responsibilities for on-call coverage.
- *Maintain a formal on-call schedule* to avoid any misunderstandings that may lead to gaps in coverage.
- *Obtain on-call coverage from a physician within the same clinical discipline* and with comparable scope of practice and admitting privileges, whenever possible.
- *Ensure that the on-call provider has access to patient health records* and current information about patients who are most likely to have urgent care needs.
- *Select answering machines and answering services that are patient-friendly* and that permit contact with the on-call physician without complicated instructions.
- *Inform hospitalized patients when the primary physician will be unavailable* and explain coverage arrangements during these absences. The office staff, answering service and hospital should all have the same information and give patients the same message.
- *Report on-call patient contacts to the provider of record by the next working day or sooner*, as indicated by the patient's medical condition.
- *Delineate billing procedures* for services rendered by the on-call provider.
- *Comply with the coverage arrangements of the managed care contract* if the healthcare provider is covering for managed care patients.

Locum Tenens Contracts

If the practice is too small to provide adequate coverage utilizing its own physicians, consider contracting with a locum tenens or another practice to ensure access and continuity of care. Consider the following guidelines when selecting and negotiating with a potential locum tenens:

- *Evaluate the expertise and practice style of prospective external providers*, and consider how well these would fit with current patients' needs and expectations.
- *Obtain referrals, confirmation of status at a local hospital, quality reports and patient satisfaction data* as part of the process of selecting locum tenens physicians.
- *Draft the contract with the locum tenens in consultation with an attorney*, as sound contract provisions are critical to a successful, mutually satisfactory coverage arrangement.
- *Ensure that the contract addresses the quality of services provided*, expectations regarding documentation and access to patient healthcare information records.
- *Include insurance coverage provisions in the contract*, requiring that the locum tenens produce an annual certificate of professional liability insurance.
- *Obtain and review the professional liability loss run* of the proposed locum tenens.

Hospitalist Care

- *Explain to patients what a hospitalist is*, and inform them that if they require hospitalization, they may be admitted by and cared for by a hospitalist.
- *Brief the assigned hospitalist upon patient admission* and request a debriefing when the patient is discharged.
- *Discuss specific patient safety issues* when transferring care to and from a hospitalist.
- *Track patient discharge* to ensure proper follow-up.
- *Ensure continuity of care through provider-to-provider communication and written reports*, both at the time of the referral request and following the consultation.
- *Check follow-up measures taken* against the hospitalist's recommendations.

Providing On-call Coverage for Another Practice

- *Consider philosophical similarities and differences in practice and philosophy* before committing to cover for an outside provider.
- *Examine the contract carefully* and ensure that it adequately addresses the quality of services provided, documentation expectations, access to records, and insurance and liability considerations.
- *Arrange for access to patient healthcare information records* and obtain reports on patients who may have urgent care needs.
- *Complete as thorough a medical history as possible* when contacted by a patient.
- *Document all advice given to patients,* whether in person or over the telephone.
- *Obtain full information from patients who request new prescriptions or refills* to ensure that the prescription/refill is needed during the on-call period.
- *Clearly document the rationale supporting any treatment recommendations given*, including medications prescribed.
- *Promptly report all patient encounters* to the primary healthcare practitioner.

e-Practices

Electronic and Social Media

Documentation Issues

Electronic and social media – including email, blogs, social networking platforms, websites, texting and instant messaging – have become a primary means of self-expression and communication for many individuals, including physicians and other medical practice personnel. The increasing volume of electronic communication between patients and providers has created a stronger sense of connection, as well as new risk management issues, including documentation of the many different types of patient contacts.

The substance of all electronic communication related to patient care – whether by phone, text, email or instant messaging – should be documented. If an electronic communication cannot be saved directly into the patient healthcare information record, it should be documented in a log.

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

- Date and time of the conversation.
- Patient's name and date of birth.
- Identity of the other party (if other than the patient).
- Identity of the staff member taking the call.
- Subject of the discussion.
- Advice given and recommended follow-up.

Also be sure to include the following clinical information:

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

Other Electronic Media Exposures

The risks associated with electronic media continue to evolve and expand with increased usage. For example, physicians should be aware that litigation discovery requests may go well beyond the traditional scope of patient treatment and financial records, potentially encompassing text messages, blog entries and social media postings. Consequently, physicians must understand the exposures associated with these media and create practice policies that recognize their benefits while minimizing the possibility of carelessness or misuse. (See the Electronic Discovery section on page 67.)

The use of social media and electronic devices by medical personnel may result in the following additional risk exposures, among others:

Patient confidentiality. Workplace emailing or text messaging may violate privacy and security requirements imposed under HIPAA and the HITECH Act, as protected health information (PHI) may be inadvertently transmitted to an unauthorized third party. Every practice should consider implementing a HIPAA compliance program, featuring ongoing staff training, review of protocols and technical upgrades, including use of a HIPAA-compliant encrypted email system. A wide range of resources and tools are available to aid medical practices in this effort.

Improper texting. Harassing, threatening or otherwise inappropriate messages posted by employees from workplace computers or texted from employer-issued mobile telephones can create vicarious liability exposure for a medical practice, and improper litigation-related postings and text messages can undermine legal defense efforts.

Overuse of electronic devices. Texting and conversing on cellular telephones in patient care areas may decrease staff efficiency and lead to distraction and error, thereby endangering patients. Even the use of MP3 players and other headphone devices can create a sense of disconnection from the environment, impairing communication and slowing response time.

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

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

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

Risk Management Strategies

Medical office policies should directly address the issues raised by the proliferation of electronic media, in order to clarify rules and expectations and reduce liability exposure. The following strategies can help physicians effectively manage the widespread use of these communication tools:

- *Create and enforce a formal policy governing personal use of networked computers*, with provisions that strictly prohibit all messages and activities of an offensive, threatening, harassing, defamatory or unprofessional nature.
- *Request that employees sign a form confirming that they understand the rules and the consequences of noncompliance.* Signed forms should be retained in personnel files.
- *To maintain morale, consider installing non-networked computers for personal use* during lunch and breaks.
- *Provide staff with written copies of electronic monitoring policies.* Explain that employers have the right to monitor email messages and other communications on practice-owned computers and that inappropriate conduct may have disciplinary consequences, up to and including termination.
- *Regulate cellular telephone use by staff members*, specifically addressing such key issues as personal calls while at work, confidentiality, conversational volume and etiquette, talking while driving and utilization of the camera feature.
- *Revisit the practice's privacy and confidentiality policies on a routine basis*, taking into consideration the risks of posted and texted messages containing PHI or other sensitive material.
- *Convey to staff the possible legal and ethical implications of the careless use of email, texts and social media*, including the permanence and recoverability of deleted messages, limits of anonymity and realities of e-discovery. (See page 67.) Clearly describe both the nature of the risks and the consequences of policy violations in the employee handbook, and reinforce the importance of sound judgment through staff training.
- *Remind all personnel that, as a threshold requirement, they must receive written authorization from patients prior to discussing their cases on blogs or websites.* Postings should not include individually identifiable information.
- *Encourage appropriate etiquette and model a mature attitude.* Remind staff members that they are viewed as ambassadors of the practice, and their posture on the Internet should reflect this fact. Consider assigning mentors to coach less experienced staff in the nuances of professional conduct.
- *Regularly underscore cyber security rules and concerns*, using orientation and training sessions, posters, supervisory reminders and other means.
- *Have both legal counsel and information technology staff review all social media-related policies* for regulatory compliance and technical relevance.
- *Draft policies addressing the following important activities:* engaging e-patients, managing online conversations, conveying personal medical advice and general medical information, combining social media with personal healthcare information records, and disengaging e-patients who publish derogatory statements or falsehoods about the practice.
- *Review marketing language used on social media sites,* avoiding such superlative and absolute phrases as "best care," "highest quality" or "state of the art," as these descriptions may be quoted in lawsuits alleging breach of an express or implied warranty. In addition, social media messages should not entice patients to expect care beyond the capabilities of the practice.
- *Consider adopting a HIPAA-compliant email encryption system,* in order to better protect the confidentiality of sensitive information.

Social Media Planning Considerations

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

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

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

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

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

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

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

Social Media Policies and Safety Measures

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

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

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

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

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

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

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

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

Telemedicine

Telemedicine is the practice of electronically connecting geographically separate healthcare facilities and providers. It encompasses numerous methods and technologies, ranging from traditional store-and-forward data applications, commonly utilized in radiology and pathology, to innovative "telepresent" techniques, including robotic surgery and interactive consultation. Among other benefits, telemedicine permits …

- *Patients in underserved rural areas to enjoy improved access* to quality, state-of-the-art healthcare.
- *Physicians in large networks to collaborate more readily* via shared electronic health records, digital imagery and data files.
- *Specialty providers to communicate with (or "tele-assist") primary care physicians in diagnostic tasks*, leading to enhanced outcomes, shorter treatment periods, decreased use of unnecessary drugs and reduced costs.

The American Telemedicine Association provides a variety of protocols in this evolving area of healthcare. Additional information on protocol development is available at the Telehealth Resource Center.

Telemedicine encompasses numerous methods and technologies, ranging from traditional store-and-forward data applications, commonly used in radiology and pathology, to innovative "telepresent" techniques, including robotic surgery and interactive consultation.

Safety Culture and Emergency Readiness

Patient Safety, Education and Health Literacy

Culture of Safety

"Just culture," as described in an informative video from the Agency for Healthcare Research and Quality (AHRQ), is one key to creating a safety-centered practice. The concept, which became popular in the medical world following publication of a 2001 report by David Marx, refers to the cultivation of positive, humane values that support an open, fair and learning-oriented workplace, where individuals are encouraged to question substandard practices and ask for assistance when in doubt. Realizing a just culture requires the fostering of accountability on the part of the institutions that implement systems and processes, as well as the individuals who make choices within those systems.

Changing the culture of an organization requires dedicated leadership, tenacity and understanding. It involves acknowledging that no practice is perfect, and that adverse events must be recognized, tracked and analyzed as a precondition for learning and improvement. Developing a patient safety culture requires a willingness to consider the possible limits of one's own awareness and to critically examine office policies, practices and systems. By creating and sustaining a safe and supportive patient care environment, physicians can maximize the benefits of treatment while minimizing attendant risks.

Patient Education and Health Literacy

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 is thus a key patient safety issue.

What patients know or think they know about medical treatment affects their expectations of physicians, staff and treatment outcomes. Therefore, the physician and/or other clinical staff must determine each patient's level of understanding and educate patients to the extent necessary, using such means as brochures, articles, websites and in-office videos.

Improved health literacy not only enhances treatment outcomes, it also supports informed consent and other key risk management processes. Knowledgeable patients who understand and accept treatment risks and possess reasonable treatment expectations are more likely to comply with recommendations and less likely to sue.

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

- Health Literacy Measurement Tools, from the AHRQ, are designed to measure reading comprehension in a medical context.
- Health Literacy Universal Precautions Toolkit, from the AHRQ, can help practices remove health literacy barriers and promote understanding.
- The Patient Education Materials Assessment Tool (PEMAT), from the AHRQ, helps practitioners evaluate the comprehensibility and usefulness of patient education materials. Separate tools are available for use with print and audiovisual resources.
- "Quick Guide to Health Literacy," from the U.S. Department of Health and Human Services, offers a basic overview of health literacy concepts, plus techniques for improvement.

Medical Device Safety

Medical device technology for physician practices is evolving at an unprecedented pace. Many physician offices have a large and changing array of diagnostic and treatment equipment, ranging from basic hypodermic needles to advanced lasers.

It is the duty of the manufacturer to design the device so that it does not cause undue injury when operated properly. However, it remains the responsibility of the clinician and supervising physician to ensure that the equipment is in proper working order and used correctly, even if the physician does not own the equipment and maintenance and repair services are contractually assigned to an outside vendor.

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

Medical Equipment Management

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

- *Choosing the appropriate equipment* to satisfy clinical needs, while recognizing products' potential hazards and limitations.
- *Using the equipment in a reasonable manner* as intended by the manufacturer.
- *Training staff on the safe use of devices* that they are expected to operate.
- *Creating a quality control program* for all diagnostic equipment.
- *Designing and adhering to preventive maintenance, electrical safety and calibration schedules and policies*, as recommended by the manufacturer.
- *Establishing emergency procedures* in the event of equipment failure.
- *Formalizing reporting processes* for medical equipment management problems, failures and user errors.
- *Implementing inspection procedures* upon receipt of new or repaired equipment.
- *Initiating a tracking system and log* for product recalls and alerts.
- *Maintaining an inventory of all medical devices used within the practice*, including manufacturer, model and serial number, whether or not the practice owns the device.
- *Retaining copies of device-specific operator and user manuals* and making them readily available to staff.
- *Performing regular safety inspections* at intervals recommended by the manufacturer.

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

Needlestick Safety and Prevention Act

The Needlestick Safety and Prevention Act (the Act)(Pub. L. 106-430) was signed into law on November 6, 2000, in response to the serious problem of occupational exposure to infections from accidental sharps injuries. The law applies to all employers of one of more employees with occupational exposure (i.e., reasonably anticipated skin, eye, mucous membrane or parenteral contact with blood or other potentially infectious materials resulting from the performance of the employee's duties).

OSHA's Bloodborne Pathogens standard was modified one year later (29 CFR 1910.1030). The revised standard explains in greater detail OSHA's requirement that employers implement engineering or work practice controls (such as needleless systems or self-sheathing needles) designed to eliminate or minimize employee exposure. It also mandates additional requirements, including maintaining a sharps injury log and involving non-managerial healthcare workers when developing effective engineering and work practice controls. Finally, it requires training of employees in how to reduce exposure via appropriate engineering controls, work practices and/or personal protective equipment.

Under the law, employers are required to maintain a log of percutaneous injuries from contaminated sharps. The sharps injury log must also include, at a minimum, the type and brand of device involved in the injury (if known), the department or work area where the exposure incident occurred, and an explanation of how the incident occurred. The log must be maintained in a manner that removes personal identifiers and otherwise protects the confidentiality of the injured worker. The OSHA website contains more information.

Clinical Laboratory Equipment

Basic laboratory tests are governed by the regulatory authority of the Clinical Laboratory Improvement Amendments (CLIA). CLIA sets quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of test results, irrespective of where tests are performed. CLIA exempts basic laboratory examinations and procedures from oversight if they "employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if the test is performed incorrectly."

Exempt laboratories are required to follow manufacturers' test instructions and also to …

- *Provide current manufacturer's instructions to staff members* involved in testing and test processing.
- *Routinely check new product inserts* for changes.
- *Perform quality control testing* and required corroborative tests.
- *Adhere to expiration dates* and properly dispose of expired products.
- *Perform function checks or calibrations*, as well as regular instrument maintenance.

More information about CLIA is available here.

Radiographic Safety

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

Safety Recall Notices and Hazard Alerts

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

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

If the practice receives a recall notice or a hazard alert …

- *Post the notice* in the practice's recall/alert log.
- *Immediately check all equipment*, both in use and in the practice inventory.
- *Discontinue use of equipment that has been reported defective or possibly harmful* until it has been repaired, replaced or deemed safe to use.
- *Respond to instructions* provided in the recall notice.
- *Complete the recall tracking log*, documenting evaluation of the product, recommendation(s) for corrective action and corrective action taken.

Recalls are posted on the Internet and are accessible to the public. Searches of specific devices can be conducted here.

Serious Adverse Event Reporting

Under the Safe Medical Devices Act (SMDA) of 1990, Pub.L. 101-535, a "device user facility" must report serious device-related injuries, including needlesticks, to the manufacturer or, if the manufacturer is not known, to the FDA. A physician's office is not categorized as a device user facility, and therefore is not subject to SMDA regulation. Nevertheless, it is a prudent risk management strategy to establish a reporting program dedicated to adverse events involving medical device use.

The FDA has established a voluntary system for healthcare providers to report serious adverse events, product quality problems or product use errors associated with a medical device. The FDA uses these data to assess the safety of the products it regulates and posts reports on the agency's Medwatch website.

Non-physician Use of Medical Devices

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

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

- *Be properly licensed* by the appropriate state healthcare professional licensing board, if applicable.
- *Comply with written office protocols* when using the medical device.
- *Satisfactorily complete a documented education and training program*, covering such topics as safety, proper technique, and pre- and post-treatment care. The program should include supervised practice and clinical skill competency testing.
- *Participate in ongoing, well-documented continuing education* for these procedures.

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

Medical Device Liability Implications

Physicians should carefully monitor the selection, inspection and maintenance of medical office equipment and devices, as both physicians and manufacturers are often named as defendants in liability actions involving medical products. The manufacturer will often try to demonstrate that it was the physician or practice that erred by:

- *Purchasing the wrong type of medical device* or equipment for the procedure.
- *Failing to reasonably inspect the product* for obvious defects.
- *Using the device incorrectly* as defined by the user's manual.
- *Improperly educating users* in the operation or use of the product.
- *Neglecting to maintain or service the equipment* in a reasonable manner.
- *Modifying the device* without the express written consent of the manufacturer.
- *Utilizing unapproved disposables and supplies* that do not meet manufacturer specifications.
- *Omitting to implement upgrades* as specified by the manufacturer.
- *Overlooking a product recall* or safety notice.

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

Violence Prevention

The National Institute for Occupational Safety and Health defines workplace violence as "violent acts (including physical assaults and threats of assaults) directed toward persons at work or on duty." Every healthcare practice and facility is vulnerable to aggressive behavior and abuse, and therefore must address this critical issue, which potentially affects patients, staff and providers.

Developing a Program

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

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

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

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

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

Active Shooter Situations

Shootings within healthcare settings are relatively rare but appear to be on the rise. Although armed intrusions are unpredictable and not fully preventable, a sound emergency response plan can help save lives and minimize civil liability for willful lack of preparedness. The following measures can significantly enhance organizational response to a potentially panic-inducing situation:

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

De-escalation Tips

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

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

Although armed intrusions are unpredictable and not fully preventable, a sound emergency response plan can help save lives and minimize civil liability for willful lack of preparedness.

Self-assessment Checklist: Violence Prevention

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

RISK CONTROL MEASURES	PRESENT? YES/NO	COMMENTS
WORKPLACE ANALYSIS		
Has a comprehensive violence and abuse analysis been performed in the facility, in order to ensure that:		
- Locking systems are in place on outer doors?		
- Unused doors are always locked?		
- Visitor access is carefully controlled?		
- Entrances and parking lots are well-illuminated?		
- Lights are regularly inspected?		
- Shrubbery is trimmed to minimize shadows?		
- Security alarm systems are carefully maintained and frequently tested?		
- Response procedures are in place for violent incidents, including assaults, bomb threats, gunfire and hostage situations?		
COMMUNITY AND ENVIRONMENTAL CONSIDERATIONS		
Have local police and other agencies and organizations been contacted regarding area crime risks?		
Has an environmental risk assessment been performed, which considers:		
- Crime statistics of the surrounding community?		
- Past occurrences of workplace violence, as documented in medical and safety reports?		
- Instances of employees working alone?		

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

Disaster Preparedness

The goal of disaster planning is to protect patients, staff, physical plant and financial assets in the event of an emergency situation. Effective disaster planning can help practices maintain order, prevent major service disruption, reduce losses and restore vital facility functions with minimal delay. It may also mean the difference between survival and failure for the practice as a business.

This section is designed to help practices prepare for a disaster, identify potential disaster-related losses and consequences, and implement general safety measures, including regular assessment of insurance coverage. The key lesson is that the time to plan for disasters is now. It may be tempting to postpone preparedness planning in favor of more immediate concerns, but such delay can be fatal.

Identifying Risks

The first step in preparing for disaster-related risks is to identify and prioritize potential foreseeable events, both manmade (e.g., violent crime, sabotage, arson, riots, terrorism and contamination) and weather-related (e.g., hurricanes, tornadoes, wildfires, floods and blizzards). In addition to determining the likelihood of different types of disasters, it is necessary to ascertain what types of weather conditions give rise to emergencies, when and how frequently they typically occur, and their possible impact on the practice and the community.

Quantifying Risks

After identifying potential sources of loss, the next step is to quantify the hazard posed by specific events. This involves plotting the likelihood (i.e., frequency) of an occurrence against its potential consequences (i.e., severity).

Gauging the probability and potential impact of an event requires a clear understanding of the vulnerabilities of the practice, as well the natural and human environment in which it operates. This involves reviewing the practice's loss history, as well as consulting with police and fire departments, government and private agencies, and other external authorities.

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

Creating a Response Plan

After immediate risks have been identified and evaluated, the next step is to craft a response plan. The written plan should be thorough and precise, specifying the title of individuals assigned to each task.

Request input from local authorities when designing and reviewing the disaster management plan and, if possible, participate in local and regional emergency drills. These programs permit the sharing of information and ideas with officials and neighbors. They also offer resources and contacts that may prove useful in the event of an emergency.

Chain of Command and Communication

If disaster strikes, staff must know who is in charge. The following guidelines can minimize confusion during and immediately after an emergency situation:

- *Designate a disaster coordinator*, who has responsibility for declaring the disaster, mobilizing the response and keeping everyone informed.
- *Clearly define roles and duties of staff members,* including contacting government agencies, neighboring healthcare facilities, emergency aid providers and other outside entities.
- *Maintain a list of key personnel to be contacted in case of an emergency*, and post the list in strategic locations.
- *Develop a system to track all patients, employees and visitors* who may have been in the office at the time of the disaster.
- *Arrange alternative means of communication*, such as cellular telephones, email and social media in case land-based telephone lines become inoperable.
- *Develop a list of preferred vendors and alternative suppliers* with full contact information, including primary and emergency telephone numbers.

Evacuation Procedures

Depending upon circumstances, staff and patients may seek shelter within the facility during a disaster or require evacuation just before its onset. The disaster plan should anticipate both possibilities. The following measures can help reduce panic and ensure an orderly evacuation:

- *Prepare detailed diagrams of the facility and surrounding area*, showing all critical access and escape routes.
- *Check all examination rooms* to ensure that no patients are left behind. Instruct staff to close doors behind them as a sign that the room is empty.
- *Switch the telephones to the answering service* before leaving the office.
- *Instruct staff members to meet at a designated location* following the evacuation.

Emergency Supplies

During some disaster situations, it may be advantageous to remain in the building rather than evacuate. The following measures can help keep the office functioning:

- *Maintain a supply of appropriate weather-related materials and equipment*, including sand and salt for ice and snow, as well as pumps and sandbags for flood-prone areas.
- *Stockpile critical medical resources* and identify multiple suppliers of key medicines, equipment and services.
- *Create a disaster supply kit,* which minimally should contain basic tools (including a wrench and pliers), portable radio with spare batteries, fire extinguisher, first aid equipment and flashlight.

Plan Testing and Training

Disaster drills should be scheduled on a regular basis. Evacuation techniques and the response plan as a whole should be evaluated at least annually and updated to reflect organizational changes, lessons learned from drills and emerging exposures. By continuously refining the plan and educating staff members about their roles and responsibilities, it is possible to significantly diminish the chaos and confusion that often accompany an emergency situation.

Everyone in the practice should receive initial training and annual refresher courses on emergency procedures. Those designated as floor leaders or monitors require additional training.

Continuity Planning and Recovery

Despite the best precautions, there is always a possibility that the practice may be rendered inoperable by a disaster. By formulating a continuity and recovery plan, physicians are better positioned to restart operations as quickly as possible.

Disaster recovery plans should include a listing of recovery goals and priorities; procedures to contact families, public agencies, suppliers and community representatives after the disaster; and arrangements to establish alternate work locations if necessary. It also should list critical documents and materials that should be stored off-site, such as the following:

- *Blueprints* and related plans, if relevant.
- *Inventory of equipment* and other assets, either as a list or in video form.
- *Reconstruction plan*, including a current list of contractors, movers, equipment vendors and staffing agencies who can facilitate rebuilding and reopening.
- *Listing of financial resources and insurance policies* to help the practice bounce back from a disaster.

Also, establish an alternative practice mailing address (such as a residence or post office box) in the event the building is seriously damaged or destroyed.

Post-disaster Response

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

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

Fire Safety

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

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

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

For more information, see the sample fire safety plan on page 123.

Post-disaster Information Management

No medical practice can be successful without complete records. The strength of the continuity plan depends to a great extent on the ability to protect clinical, personnel and financial documents.

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

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

Medical Emergencies

Medical emergencies can involve patients, staff or visitors. If there is a flu-like epidemic/pandemic and numerous employees call in sick, medical practices must arrange to secure adequate temporary staffing. Options to consider include overtime, employment agencies, and floating or *per diem* staff. In this situation, it may be necessary to cancel elective appointments and procedures.

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

- *Encourage staff to achieve certification in CPR*, and permit any certified staff member to initiate CPR if indicated.
- *Instruct staff members to contact a physician in the office immediately if they believe a medical emergency is occurring*, to call 911 if told to do so and to remain on the scene until emergency personnel arrive.
- *Inspect the emergency crash cart on a daily basis* and maintain inspection logs, if applicable.
- *Train staff in the use of emergency equipment and medications*, documenting training and proficiency in personnel files.
- *Keep inspection and preventive maintenance records* for all emergency equipment in the office.
- *Check the automatic incoming telephone service*, making sure that it transfers patients to office staff or refers them to 911 in the event of an emergency.

Security

Maintaining security following a disaster can be a challenge, as buildings may require swift evacuation and remain empty afterward for a prolonged period. While the top priority is protecting the lives and safety of patients and staff, it is also necessary to minimize property loss and damage, possibly by contracting with a private security firm. Items at highest risk of loss include cash, valuables, patients' personal health information, equipment, supplies and medications. It is advisable to consult with police and government agencies when creating security policies.

Resources

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

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

Sample Fire Safety Plan

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

Before:

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

During:

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

After:

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

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

Self-assessment Checklist: Emergency Management

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

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

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