Risk Management Strategies for the Physician Office
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Introduction to Enterprise Risk Management (ERM)

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

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

The Committee of Sponsoring Organizations of the Treadway Commission (COSO), a private-sector organization dedicated to the establishment of more effective, efficient and ethical business operations, defines ERM as “(a) process, effected by an entity’s board of directors, management and other personnel, applied in a strategy setting and across the enterprise, designed to identify potential events that may affect the entity, manage risks within its risk appetite and provide reasonable assurance regarding the achievement of entity objectives.” (See “Enterprise Risk Management – Integrated Framework,” at http://www.coso.org/Publications/ERM/COSO_ERM_ExecutiveSummary.pdf.)

Diagram 1–Enterprise Risk Management Framework
(adapted from the American Society of Healthcare Risk Management ERM model)

In the ERM model, risks are categorized into domains or spheres of activity that affect each other positively or negatively, as shown in Diagram 1.
For example, consider the case of a well-trained medical secretary (human capital), who implements an effective follow-up system for timely receipt of laboratory reports (operational risk), which ultimately facilitates a timely diagnosis (clinical outcome). The ERM process centers on the financial component of an organization because risk takes the form of potential loss of capital. Positive clinical outcomes translate into enhanced patient and community relations, resulting in an upward cycle of increasing patient volume and revenue growth.

ERM is a continuous process that is applied across the physician practice and influenced by staff behavior 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 should 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 a risk manager.

**The Enterprise Risk Management Process**

The ERM process includes the following major components:

- **Risk identification** – This involves discerning practice risks within each of the risk domains, a process that typically includes staff interviews.

- **Prioritization and scoring of risks** – This involves analyzing the likelihood, causes and consequences of specific risks, both quantitatively and qualitatively. The potential severity of each risk is multiplied by its probability to determine the "risk score."

- **Risk response** – This involves developing and implementing an action plan to avoid, accept, reduce 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 a minimal effect on the physician practice are generally accepted.
  - **Risk reduction** entails limiting the probability or severity of a risk without eliminating the service or activity.
  - **Risk financing** refers to covering potential losses via risk transfer, such as commercial insurance, or risk retention, such as deductibles, self-insured retentions or trust fund accounts.

Physicians and staff are equally accountable for implementation of the risk response program.

- **Control and monitoring** – This involves measuring the effectiveness of the risk responses.

The ERM process is dynamic, with several steps that may occur simultaneously. It serves as a useful framework for organizing a medical practice's risk management activities.
**Identifying Risks**

Diagram 2 provides examples of specific risks for a physician practice in each of the risk domains. These domains help categorize specific risks and make the assessment process more manageable and comprehensive.

**Diagram 2 – Identification of Risks**

<table>
<thead>
<tr>
<th>Risk Domain</th>
<th>Examples of Potential Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strategic</td>
<td>Marketing; Expansions and acquisitions; Additional medical specialties</td>
</tr>
<tr>
<td>Human Capital</td>
<td>Physician extenders; Scope of practice; Credentialing; Background checks; Competency assessments; In-service education</td>
</tr>
<tr>
<td>Clinical Risk</td>
<td>Standards of care; Preventive care/Screening; Medication management; Referrals and consultations; Patient education</td>
</tr>
<tr>
<td>Customer and Community Relations</td>
<td>Physician-patient relationship; Patient complaints; Patient satisfaction survey and subsequent actions taken; Disclosure of unanticipated events; Office physical plant</td>
</tr>
<tr>
<td>Operational Risk</td>
<td>Event reporting; Policies and procedures; Performance improvement; Patient scheduling; Patient waiting time; Missed appointments; Patient tracking and follow-up; Environment of care; Fire safety and emergency preparedness; Security</td>
</tr>
<tr>
<td>Technology</td>
<td>Medical devices; Electronic communication, including e-mail, fax, telephone consultation and electronic medical records</td>
</tr>
<tr>
<td>Legal/Regulatory</td>
<td>Patient rights; Informed consent; Patient confidentiality/ HIPAA; Clinical Laboratory Improvement Amendments (CLIA); Patient termination; Contract management; Closing or leaving a practice</td>
</tr>
<tr>
<td>Financial</td>
<td>Insurance denial of care; Billing and collections</td>
</tr>
</tbody>
</table>

**Scoring Risks**

For the purposes of risk “scoring,” we may rate severity and probability on a scale of one to 10, with ultimate risk scores ranging from one to 100. Medication management, for example, is considered a high-risk process in the physician practice, with a severity rating of eight. Because medication reconciliation has not been implemented in our hypothetical practice, the probability of errors is rated as a 10, with a total risk score of 80. Medication management thus represents a significant clinical risk.

Referrals from a general practitioner are facilitated in a timely manner, as the medical secretary contacts the specialist’s office and schedules the appointment. The probability of a patient not being seen on time is minimal, and is thus scored as a one. When a patient is not seen in a timely manner, a delayed diagnosis may result, with a risk rating of eight. The total score for this clinical risk is eight times one, or eight.
Assume that our hypothetical practice has recently installed an electronic medical record system, but not all staff members are trained in its use. The probability of delays in documentation due to lack of experience with the technology is rated as a 10. The severity of the risk is also rated as a 10, as information regarding follow-up care may not be documented in a timely manner. Thus, the total risk score for delayed documentation of clinical care is 100. The installation of the system and the consequent initial exposure are technical and human capital risks. The new system also produces clinical and legal/regulatory risks, as lack of timely documentation may compromise legal defense in the event of litigation.

**Responding to Risks**

The risk scores for the above situations are 80, 8 and 100. The risks are now prioritized, with the highest-scoring risks addressed first.

The physician practice could avoid the documentation risk (risk score 100) by postponing implementation of its electronic medical record system, but this is not a long-term solution. A more prudent measure is to educate staff thoroughly on using the new record system, which will prevent delays in documentation and facilitate continuity of care. This risk response will help decrease human capital, technology, clinical and legal/regulatory risks.

The medication management risk (risk score 80) can be reduced by implementing an effective medication reconciliation policy that detects and prevents potential errors.

The low-level referral risk is accepted, as the practice has already adopted a system for managing specialty consultant appointments.

**Monitoring and Evaluating the ERM Program**

Controls must be monitored to determine whether they are succeeding in reducing the level of risk. For example, the medication reconciliation policy in the above hypothetical scenario would be scrutinized to ensure that the volume of medication errors is decreasing. Audits or surveys are another way to evaluate the effectiveness of ERM risk responses. A documentation audit can determine whether training staff in the use of the new electronic medical record system has proven effective.

You can evaluate the effectiveness of the ERM program as a whole by assessing the risks within each domain and scoring these risks. The process is ongoing, as different risk responses are implemented, evaluated and modified over time.
Performance Improvement, Accreditation and Patient Safety

Performance Improvement

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

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
- neglecting to perform ordered tests
- failure to report or document test results
- misplaced or mislabeled specimens
- omitting follow-up on significant missed appointments
- inadequate documentation of patient education
- excessive waiting times

When an indicator is triggered, the next steps are to analyze the process, identify performance failures and quality of care issues, and suggest process improvements. The process flowchart, a pictorial diagram of all steps in a designated sequence, is an important diagnostic tool. By using a flowchart to identify process failures and redesign faulty processes, you can minimize the possibility of future errors or problems. 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.

Comprehensive performance improvement efforts utilize patient satisfaction surveys to determine whether patient needs are being met and identify areas for improvement. Measures of patient satisfaction include, but are not limited to, the following:

- availability of the physician or other provider
- cleanliness and organization of the office
- confidentiality of medical information
- costs and fees
- helpfulness of the staff
- patient education
- waiting times
Accreditation

Accreditation can benefit a physician practice by encouraging self-scrutiny, providing objective feedback, and demonstrating to patients and managed care organizations that it meets national standards of quality, performance improvement and safety.

The accreditation process involves undergoing a voluntary survey by a non-profit organization that evaluates the quality of patient care and services delivered in the office practice against national accreditation standards. The process has three main stages:

1. **The practice evaluates itself against the accreditation standards** and decides prior to the survey what improvements should be made.

2. **The practice participates in an on-site survey** conducted by the accreditation organization.

3. **The practice obtains the survey findings** and any recommendations for improvement. If the practice meets the standards, it receives accreditation status, which can then be publicized.

The survey process is repeated every one to three years to maintain accreditation. Surveys may be unannounced.

Two major accreditation organizations that accredit physician practices and other ambulatory facilities are the Joint Commission, at [http://www.jointcommission.org/AccreditationPrograms/AmbulatoryCare/](http://www.jointcommission.org/AccreditationPrograms/AmbulatoryCare/), and the Accreditation Association for Ambulatory Health Care (AAAHC), at [www.aaahc.org](http://www.aaahc.org).

The Joint Commission surveys use “patient tracer” methodology, which involves tracking the patient's progress from the point of entry to post-discharge follow-up efforts. These surveys observe or review the following items, among others:

- direct patient care
- environment of care
- monitoring of medication processes
- open clinical records (i.e., records of current patients)
- patient education at various points, as applicable
- performance improvement discussions with staff
- practice policies
- staff skills and attitudes

AAAHC surveys examine practice performance against core standards in the following areas:

- administration
- clinical records and health information
- facilities and environment
- governance
- patient rights
- quality management and improvement
- quality of care provided
Patient Safety

Quality and loss-reduction initiatives can succeed only when supported by a practice-wide culture of safety. To create such a culture, physician practices must embrace the concept of transparency, in which patients and families are informed of unanticipated outcomes, professionals are encouraged to report errors in a non-punitive environment, and emphasis is placed on analyzing systems rather than blaming individuals.

Every practitioner and employee in the physician practice must be committed to the goal of patient safety as expressed by the Hippocratic injunction of “First, do no harm.” Teamwork and communication play a major role in reducing error, as does the willingness to share information freely and learn from mistakes. A culture of safety strives to decrease patient harm by increasing accountability at all levels.

The Joint Commission has established a series of National Patient Safety Goals for Ambulatory Care designed to promote specific improvements in patient safety. These goals, summarized below, are critical to any practice seeking to improve its overall level of safety, whether or not it is accredited:

- Improve the accuracy of patient identification.
- Improve the effectiveness of communication among caregivers.
- Improve the safety of using medications.
- Reduce the risk of healthcare-associated infections.
- Accurately and completely reconcile medications across the continuum of care.
- Reduce the risk of surgical fires.
- Encourage patients’ active involvement in their own care as a patient safety strategy.¹

For detailed information regarding these safety goals, visit www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/default. The goals are updated annually.

¹ “2009 Ambulatory Care National Patient Safety Goals.” Copyright 2009, the Joint Commission.
Medical Record Management

Medical records are vital to the delivery of patient care. The medical record serves as objective evidence of the care plan, laboratory and diagnostic testing, procedures performed and medication provided during the patient’s treatment, as well as other vital information. Complete, accurate and legible documentation is a risk management strategy of paramount importance.

The practice must have a written policy governing documentation issues, and all staff members must be trained in proper documentation practices. The policy should address, among other issues, confidentiality and maintenance of the medical record, including its release, retention and storage.

The following strategies can help you minimize liability exposures related to medical record management.

Organizing the Medical Record

Every practice should have a standard format for the medical record. The patient’s name should be on every page in the medical record, in case a page is misfiled or inadvertently removed. A second identifier, such as address or birth date, can prevent confusion between patients with common or similar names. Records should be securely bound in order to prevent the loss of important demographic or medical information. Lost records impair continuity of care, jeopardize the defensibility of claims and may suggest the possibility of a conspiracy or cover-up.

Each patient should have an individual medical record. The medical records of family members should not be combined into one record.

The medical record should reflect a complete picture of the patient and his or her entire course of treatment. At a minimum, the record should include

- individually 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, posted conspicuously
- laboratory and diagnostic tests
- 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
- positive findings
- pertinent negative findings
- family history
Documentation in the Medical Record

The following general principles of documentation can help you maintain a consistent, professional medical 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 purposely conceal an error in patient care.

- **Document your actions and patient discussions as soon as possible after the event**. Late entries should be labeled as such.

- **When dictating notes, include all vital information**, such as the date of dictation, the date of transcription, and a signature and 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 blanks.

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** provided to the patient

- **Patient education efforts**, oral and written, with a description of the patient’s ability to comprehend and repeat the information provided

- **Instructions** for a return visit

- **Referrals to other providers** or for tests or therapy

- **Missed or cancelled appointments**, including efforts to contact the patient

- **Receipt and subsequent actions** involving test results, referral results, procedures and consultations, 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
**Telephone Protocol**

Telephone inquiries compose a significant portion of a physician’s office practice. On occasion, these calls become so routine that the need to properly document them, follow established protocols and practice basic telephone etiquette may be overlooked.

**Documentation.** Staff members sometimes assume that patients always fully understand what was communicated during a telephone call, but this assumption may not be correct. From a risk management perspective, it is important to clearly and objectively document the following items in the patient record:

- **date and time** of every call
- **all calls made to report abnormal test results** and any follow-up instructions given to patients
- **discussions that include patients’ medical symptoms**, medical advice and prescriptions provided
- **calls that include any disagreements** regarding medical treatment
- **patient’s response to follow-up instructions** or medical advice given
- **name of the individual** who spoke with the patient

**Telephone etiquette and protocols.** As telephone skills have a direct impact on patient satisfaction, consider establishing the following policies, among others, to help improve physician-patient relationships:

- answer telephones within a designated number of rings
- establish a maximum holding time, including time spent awaiting physicians
- designate a time during each day to return patient telephone calls

Your office telephone should be a time-saver and a problem-solver, not a source of risk. Ensure that you and your staff treat telephone calls no differently than face-to-face interactions, with due attention paid to documentation, follow-up and basic courtesy. In order to reduce liability associated with telephone calls, consider the following risk management practices:

- **Establish clear timeframes** for responding to patients’ telephone calls. These timeframes should correspond directly to the nature of the call.
- **Give staff members proper training and clear protocols** regarding how to respond to patients when a physician is not available. This training should be reinforced on an ongoing basis.
- **Provide 24-hour access to physicians** through the use of a reliable answering service during off-hours. Routinely monitor the quality and courtesy of the answering service.
- **Place a list of emergency numbers next to each telephone.** The list should include hospital emergency services, poison control centers, crisis prevention hot lines, and a list of on-call or covering physicians.
- **Develop protocols regarding follow-up telephone calls to patients** after medical interventions or if there is a cause for concern.
- **Ensure that there is a sufficient number of incoming and outgoing telephone lines** to accommodate your patient population.
Medical Record Retention

Ideally, medical records would be kept forever. As that is not always possible, the following issues should be considered when establishing a medical records retention policy:

- Seek legal counsel regarding state requirements, including the statute of limitations applying to medical professional liability causes of action, as well as any applicable federal laws, regulations or medical society guidelines relating to record retention.

- Consider the age of your patients, noting that claims relating to minors may emerge many years after treatment.

- Identify the patient care, research and teaching needs of outside organizations that request access to your medical records.

- Weigh the cost of archiving and microfilming records against the potential risk of destroying them.

- Establish a regular schedule for medical records destruction that is governed by written policies and procedures, if applicable.

- Institute a policy for permanently listing all records that have been destroyed.

Release of Medical Information

Although the information contained in the medical record belongs to the patient, the physical record itself belongs to the medical practice, under most state laws and regulations. Therefore, medical practices must devise policies to control the release of copies of medical records and protect the privacy of patients. As all medical record contents are confidential, a completed and signed authorization is required for information releases, except as required by law. Release of information should be carried out in accordance with all applicable accrediting and regulatory agency requirements, as well as written office practice policy.

A specified individual or department should be responsible for processing information release requests. The signed authorization form should be retained 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
- the name of the facility that is to receive the information
- 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 on which authorization will expire
- the date the consent was signed
- the patient’s or legal representative’s notarized signature

Maintain original medical records in the possession of the practice. If the original records (such as x-rays) must leave the office for an authorized reason, they should be conveyed to or from reviewers via bonded courier services, rather than having patients assume responsibility for transporting them.
**Faxing Medical Information**

The American Health Information Management Association (AHIMA) recommends the use of facsimile transmissions only when the need for immediate patient care makes mail-delivered copies impractical. AHIMA further recommends that routine disclosure of information to insurance companies, attorneys or other legitimate recipients should be effected through mail or messenger service.

At a minimum, facsimile transmission policies should address:

- 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 will monitor incoming transmissions and deliver them to the appropriate individual
- what safeguards are in place to protect patient information
- what procedure exists to handle misdirected facsimile transmissions
- whether faxed authorization and release forms are acceptable
- what process is in place to ensure that faxed documents have been received

**E-mail and the Medical Record**

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 taking care of routine office business.

Because a patient care-related e-mail constitutes a form of progress note, each e-mail message received should be printed in full and included in the patient care record, along with the reply. Increasingly, plaintiff's attorneys are requesting disclosure of relevant e-mail messages during the discovery process of malpractice lawsuits. Evaluate the risks and benefits of using e-mail for these types of communications before adopting this practice.

The risk of liability associated with e-mail communication may be reduced by establishing sound written policies and procedures. Your practice policy should address a variety of issues, including, but not limited to, the following:

- what constitutes appropriate e-mail use, as well as inappropriate use
- how e-mail messages should be formatted, stored and archived, electronically and as hard copies
- when e-mail must be checked to ensure timely receipt of messages
- what instructions will be contained in the signature block or automatic reply message (e.g., instructions for managing lapsed response times, out-of-office referrals and patient emergencies)
- how to safeguard patient privacy and ensure staff discretion
- what identifiers will be required for e-mail (e.g., date of birth or mother's maiden name)
- how to obtain and document patient consent for e-mail communication, including an explanation of the risks and limitations associated with the use of e-mail
- how patients will be identified as appropriate for e-mail correspondence (e.g., whether patients own a computer, know how to use e-mail and have visited the physician's office within a specified period of time)
- who has authority to access the e-mail system, and who is responsible for printing and distributing e-mail messages
- what e-mailed information must become part of a patient's medical record, and what can be omitted
- what disciplinary action will be taken if staff members fail to comply with practice policies
- how to document responses to telephone calls via e-mail or telephone calls made in response to e-mails in the medical record

When clinicians answer patient e-mail messages from an unsecured location, such as home computers, privacy issues arise. Protected health information (PHI) contained in e-mail messages sent or received from an unsecured location would be maintained by the Internet provider, and therefore, would not be protected.

The HIPAA Security Rule, 45CFR Parts 160 and 164 et.seq., provides guidelines for the appropriate level of security to ensure protection of electronically transmitted PHI. The e-mail management system should be able to track disclosures, as required by HIPAA. Also, the practice should update current confidentiality policies to address e-mail security issues and develop quality indicators to monitor and evaluate e-mail correspondence.

**Electronic Medical Records**

Regardless of the medium for storing the patient's medical record, these basic risk management principles apply: The record must be accurate and the patient's privacy must be protected. The widespread use of electronic medical record technology makes the issues of security and confidentiality even more compelling.

If your practice uses computerized medical records, these measures can help reduce some of the associated liability risks:

- **Establish audit trails**, so that access to each record is tracked by the system.
- **Provide mechanisms for minimizing 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** as much as possible.
- **Utilize proven anti-virus software** and regularly check for “bugs.”
- **Require software companies to indemnify** against sabotage efforts.
- **Ensure that your practice has adequate backup and emergency capabilities** in the event of a hardware or software failure or a disaster.
- **Routinely monitor security systems** and upgrade as appropriate.
While medical records exist primarily to promote continuity of patient care, they also represent one of the most important objective defense tools in the event of a malpractice allegation. Every practice should review and revise its record management policies on a routine basis to ensure that records are as complete, accurate, secure and well-organized as possible.

**Electronic Discovery**

Electronic discovery (e-discovery) involves requests for data and records created and maintained in electronic media. Information systems that contribute to the legal record, and data and records maintained in electronic form, may become a critical part of the evidence used in legal proceedings.

On December 1, 2006, changes to the Federal Rules of Civil Procedure were enacted addressing e-discovery. (See [http://www.uscourts.gov/rules/EDiscovery_w_Notes.pdf](http://www.uscourts.gov/rules/EDiscovery_w_Notes.pdf).)

Although these changes address e-discovery in federal lawsuits, they potentially could affect healthcare organizations in the near future. Discovery request procedures incorporating e-discovery often involve analysis of hard drives, servers, and other electronic devices and media. These methods can demonstrate when a document was accessed, who examined it and whether any alterations were made from its original format.

Every practice should prepare for e-discovery by developing guidelines for retention and legal hold. This includes formally notifying staff of the necessity of maintaining electronic documents, as well as providing a repository for protocols governing record preservation and destruction. Strict retention and deletion policies and procedures will help support your rationale for routine destruction of certain documents.

If you are linked to a hospital’s electronic medical record system, establish open communication channels with the health information management (HIM) staff. HIM professionals knowledgeable about information technology can assist in aligning office practice policies with those of the hospital. By collaborating with hospital staff, you can achieve consistency in practice standards.

Ensure that the individuals in your practice responsible for information management are involved in developing and updating operating policies, procedures and systems to comply with the ever-changing regulations governing electronic records. To help ensure ongoing monitoring and evaluation, include e-discovery in periodic compliance reviews and activities.
Patient Relations and Effective Communication

The relationship with your patients starts with their first contact with the practice, which is often a telephone call with office staff. By recognizing the importance of these first encounters and implementing patient-friendly communication practices, you can create a positive initial impression of your practice. In addition, the quality of early staff contacts may influence whether the patient’s relationship with your practice develops in a cooperative or antagonistic direction.

Strong communication skills on the part of the physician are essential to establishing a healthy rapport with patients. Deficiencies in physician-patient communication are frequently a key factor in a patient’s decision to initiate legal action against a provider following an adverse outcome. Fortunately, good communication skills can be learned and improved through practice. Professionals can be trained to alter their interpersonal behaviors in ways that will both increase patient satisfaction and decrease the risk of claims against the provider.

The following strategies are designed to help your practice initiate and maintain a sound relationship with patients.

Staff Communication with Patients

- **Emphasize the importance of a 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.
- **Maintain a system for telephone access to the physician/provider** in emergency situations.
- **Ensure that scheduling systems minimize appointment waiting time,** which represents the period between a request for an appointment and its occurrence.
- **Ensure that scheduling systems minimize office waiting time,** which refers to the interval between the scheduled time of the appointment and the physician-patient encounter.
- **Notify patients when there is likely to be a delay of longer than 15 minutes** between the scheduled appointment time and the expected time of the physician-patient encounter.
- **Maintain confidentiality throughout the office.** Avoid patient care discussions in hallways, the patient waiting room and other common areas.
Physician/Provider Communication with Patients

- **Greet the patient by name.** It is especially important to meet new patients when they are fully clothed.

- **Sit down, maintain eye contact, and remove physical barriers between you and the patient.** Research demonstrates that the simple act of sitting while speaking with patients affects their perception of how much time they have spent with you.

- **Display open and relaxed body language.** If you have doubts about your body language, ask staff members to evaluate the impression you make.

- **Explain the flow of the visit to patients,** including when there will be time to discuss their questions.

- **Ask patients to describe which of their issues is most pressing** or causing the greatest concern.

- **Continue to ask if there are additional issues** until the patient says no.

- **Discuss which of their concerns you believe are most clinically urgent** and can realistically be addressed during the visit.

- **Validate patients’ expressed beliefs,** fears, concerns, symptoms and pain.

- **Use open-ended questions** to encourage patients to describe concerns and symptoms.

- **Explain and provide education regarding the medical diagnosis,** treatment options and follow-up recommendations. (See “Informed Consent,” page 58.)

- **Ask patients to repeat back what you have told them** in their own words.

- **Maintain a non-judgmental, respectful demeanor** with patients and their families.

- **Avoid patronizing, demeaning and/or critical comments** when talking with patients and families, and be aware of your tone of voice.

- **Hold all patient discussions in a private area** to maintain confidentiality.

Communication with Noncompliant Patients

- **Review the recommended care plan with patients** and ensure that they agree to the plan and understand their responsibilities.

- **Discuss possible barriers to compliance** with the recommendations contained in the care plan.

- **Document in the medical record all efforts made to communicate the need for compliance** and to assist the patient in following the recommended care plan.

- **Provide a written description of the potential harmful consequences of non-compliance.** Request that patients sign the document, then give them a copy and include the original in the medical record.

- **Assess the risk involved in continuing to provide services to the patient if noncompliance persists.** In some cases, it may be necessary to suspend or terminate the physician-patient relationship. (See page 22.)

- **Refer to managed care contracts or provider agreements** and determine if any provisions address working with noncompliant patients.
Communication with Angry Patients

- Watch for verbal and nonverbal signs of dissatisfaction and frustration. Be aware that anger, dissatisfaction and frustration can be expressed in many ways.
- Provide a private area for discussion, away from other patients.
- Acknowledge patients’ anger or dissatisfaction and let them know that their concerns are being heard. Explain that your intention is to discuss and address their concerns.
- After patients have vented their anger, respond to the content of the message. Identify those issues that can be readily resolved.
- Ask for clarification of the issues as needed.
- Be aware of your response. While listening, maintain a non-judgmental attitude, neutral tone of voice and open body language.
- Use self-disclosure when appropriate to indicate that you have had similar experiences and can relate to the patient’s issues.
- Enlist disgruntled patients in the problem-solving process and ask them for their ideas on how to resolve the issues.
- End the discussion with a mutual understanding of what will be done to address and/or resolve the patient’s concerns.

(See “Violence Prevention,” page 34.)

Physician Termination of the Physician-Patient Relationship

Whenever you accept or render care to a patient, a physician-patient relationship is created that continues for as long as the patient’s condition requires attention. The relationship can only be ended by mutual agreement or a legally acceptable notice of termination. If you end the relationship improperly, you may face charges of abandonment.

Prior to initiating the process, review any applicable managed care contract guidelines regarding termination policies. It is advisable to seek legal counsel. The following guidelines can help minimize the risks associated with terminating the physician-patient relationship:

- Document reasons for terminating the relationship in the patient’s medical record, as well as efforts made to avoid ending the relationship.
- Terminate the relationship by sending a certified letter requesting return receipt. A copy of the letter also should be sent via regular 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
  - an offer to refer the patient to another physician or help locate another practitioner of the same medical specialty, either through the state/county medical society or a hospital physician referral service
- an offer to provide the patient with emergency care until the stated date of termination
- an assessment of the current status of the patient’s health and any required care
- an offer to forward a copy of the patient’s medical records to the subsequent physician
- a form authorizing release of medical information to the subsequent physician
- Maintain a copy of the letter and mail receipt in the patient’s medical 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.

**Patient Termination of the Physician-Patient Relationship**

Even if a patient has not contacted you in years, do not assume the relationship has ended. An allegation of abandonment can emerge years after the last physician-patient communication. The following actions are recommended if your patient decides to terminate the physician-patient relationship:

- Retain all patient records indefinitely, whether or not the relationship has been formally terminated.
- Document the patient’s decision in the medical record.
- Advise the patient in writing of any incomplete treatment plans and recommend continuation of any unfinished treatment.
- Offer to forward a copy of the patient’s records to the subsequent provider upon receipt of a signed authorization to release information.

**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 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 discontented patient.
Incident Reporting and Communicating
Patient Outcomes and Unanticipated Events

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

Your practice can effectively reduce the impact of unanticipated events by
- identifying the potential for events
- recognizing an event when it does occur
- responding with quick, effective emergency care
- providing appropriate post-event intervention

Thorough preparation and ongoing training are the keys to loss reduction. Staff members should be aware of
- how to reduce the risk of events
- how and to whom they should report such events
- what the timeframe is for reporting events
- who will communicate with the patient regarding the facts of the event

Incident/Event Reporting Policy

Develop an incident/event reporting policy and procedure that takes, at a minimum, the following requirements into account:
- defining incidents/events in order to determine what is reportable
- handling incidents/events from inception to closure
- investigating incidents/events, which includes, among other measures, placing investigative notes in separate risk/quality management files, conducting medical record reviews promptly and interviewing witnesses
- completing the report form legibly, objectively and fully, which includes writing Not Applicable (N/A) where appropriate, rather than leaving blank spaces
- reporting incidents/events in a timely manner, and routing them correctly
- protecting incident reports against discovery via correct reporting procedures

By addressing these items in ongoing staff education programs, you encourage prompt reporting and timely investigation, which will help prevent similar events from occurring in the future.

Incident/event reporting should be performed under the auspices of the performance/quality improvement plan, which will assist in protection from discovery and/or admissibility in a court of law. Ensure that incidents/events are tracked and trended to identify opportunities to improve processes and systems.

Review applicable state laws regarding protection from discoverability and ensure that the reporting form highlights the following statements:
- Objective Information Only
- Confidential and Privileged Communication
- Quality Initiative – Not to Be Included in the Medical Record
**Documentation and Notification**

Incident report forms assist in the uniform reporting of unanticipated events. Forms should
- be brief and to the point
- 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 first becomes aware of or witnesses the event. Upon completion, the form should be reviewed and approved by the practice manager or the designated physician. Physicians also may complete incident reports when they become aware of an unanticipated event.

Medical record documentation of an event must be handled with care. The occurrence itself should be recorded in a factual and objective manner, incorporating any medical steps that were taken to minimize adverse effects. Incident reports themselves, however, should never be filed in the medical record. Do not document in the medical record that an incident report was completed.

As part of the quality/performance improvement process, an investigation of the incident should take place as soon as possible subsequently. Attempt to ascertain why the event occurred and what, if anything, could have been done to prevent it. Document the findings on an investigation form that is separate from the incident report form. The investigation should not be recorded in the medical record.

If an unanticipated event occurs in the hospital setting, the practitioner should notify the other members of the practice, as well as the practice manager/administrator or the risk manager. If there is a call from a patient or attorney, staff should refer the call to the practice manager, risk manager or physician.

If an event of life-threatening or permanently disabling nature occurs, notify your insurance carrier either directly or through your insurance agent or broker. If the insurance company already has the information at hand, it will be better prepared to take the necessary steps to protect you and your practice against a potential claim.

**When an Unanticipated Event Occurs**

The first priority is to provide immediate medical care to the patient and notify the physician. Afterwards, implement these general risk management strategies:
- **Require that the physician review the medical facts with the patient** as soon as possible after the event.
- **Secure any equipment, medications or supplies** involved in the event.
- **Document all actions taken in the medical record.** Do not document any conclusions in the incident report or medical record which are not based on objective, factual information.
- **Postpone sending the patient’s bill for services** until the event is resolved.
Communicating with Patients and Family

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

If possible, communicate in person, preferably in a quiet, comfortable setting. Use the telephone if necessary, but avoid e-mail. Every effort should be made to accommodate the patient and family regarding place and time. If additional information becomes available, schedule a follow-up meeting.

Ensure that discussions emphasize facts. The initial discussion should focus 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 explaining what will be done to prevent future events.

The healthcare provider should consider the full breadth of patients’/families’ 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 your state’s disclosure law, as well as any laws addressing apologies to patients and admission of liability.
Disaster Preparedness

A disaster is a state of extreme and usually unpreventable destruction due to natural or human circumstances, such as fire, flood, tornado, earthquake, hazardous material incident, biohazard event or civil disturbance. An emergency or disaster can hit anywhere at any time – including your practice setting. When a disaster occurs, physicians are responsible for the safety of those in their office. By understanding what can go wrong and making adequate preparations, you can minimize the impact on your practice if a disaster does occur.

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 you maintain order, prevent major service disruption, reduce losses and restore vital facility functions afterwards with minimal delay. It may even mean the difference between survival and failure for your practice.

This section is designed to help you prepare for a disaster, identify potential disaster-related losses and consequences, and implement general safety measures. 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 disasters, both man-made, e.g., strikes, sabotage, arson, riots, terrorism and contamination, and weather-related, e.g., hurricanes, tornadoes, wildfires, floods and blizzards. Ask yourself about the types of adverse incidents, emergencies and disasters the practice is most likely to confront, based on local conditions and history. In addition to determining the likelihood of different types of disasters, ascertain what conditions give rise to emergencies, when and how frequently they may occur, and their possible impact on your practice and the community.

Quantifying the Risks

After identifying potential sources of loss, the next step is to quantify the hazard posed by specific events. This involves plotting the likelihood (or frequency) of an occurrence against its potential consequences (or severity). After calculating the degree of risk, you can focus your efforts on those scenarios that present the greatest threat.

Gauging the probability of an event requires a clear understanding of your practice’s vulnerabilities, as well the natural and human environment in which it operates. Assign consequences to different events based upon your knowledge of organizational processes, so that potentially crippling occurrences can be distinguished from ones that can be contained. Consider your organization’s loss history, and consult with police and fire departments, government and private agencies, and other external authorities.

In addition, know what back-up processes, systems and equipment are already in place to help you withstand various emergency conditions. Finally, consider whether existing power and utility services will suffice in adverse circumstances and identify alternative sources in case of interruption.
Creating and Implementing the Plan
After immediate risks have been identified and evaluated, the next step is to craft a response structure and plan. The written plan should be thorough and precise, specifying the title of the individual assigned to each task. Request input from local authorities when designing and reviewing your disaster management plan. If possible, participate in local and regional emergency drills. These community programs will enable you to pool information and ideas with officials and neighboring facilities. They also will provide resources and contacts that may prove useful in the event of an emergency.

Chain of Command and Communication
Effective disaster response requires a chain of command that extends throughout the practice, from senior leaders to those responsible for daily operations. It is critical that staff know who is in charge in the event of a disaster. 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.
- **Assign responsibility for 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 an emergency number in strategic locations for staff to call for information.
- **Develop a system that will 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, 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.

Continuing Operations
During some disaster situations, it may be advantageous to remain in the building rather than evacuate. The following measures can help keep your facility operating:

- **Maintain a supply of appropriate weather-related materials and equipment**. These include sand and salt for ice and snow, and pumps and sandbags for floods.
- **Stockpile critical medical resources**. Identify multiple suppliers of key medicines, equipment and services.
- **Retain certain supplies on the premises in case of a disaster**. These might include
  - a basic tool kit
  - a portable radio with spare batteries
  - fire extinguishers
  - first aid kits
  - flashlights
**Plan Testing and Training**

The first level of disaster plan testing involves “table-top” exercises, in which employees review the plan’s effectiveness by talking through various disaster scenarios. The second level consists of “walk-through” drills, in which staff perform their functions using the methods and communication tools indicated in the plan, such as walkie-talkies or telephone call trees. If possible, include public agencies in “walk-through” drills.

The disaster plan should be evaluated at least annually and updated to reflect organizational changes, lessons learned and emerging exposures. By continuously refining the plan and educating staff members about their roles and responsibilities, you can significantly diminish the confusion and panic that often accompany an emergency situation.

Everyone in your practice covered by the emergency plan – including practitioners, nurses and staff members – should receive initial training and annual refresher courses on emergency procedures. Those designated as floor leaders or monitors require additional training. Schedule disaster drills on a regular basis.

**Continuity Planning and Recovery**

Despite the best precautions, there is always a possibility that your practice may be rendered inoperable by a disaster. By formulating a continuity and recovery plan, you are better positioned to restart operations as quickly as possible. The effectiveness of your continuity plan will partly determine how quickly your practice can return to full functioning after an emergency. Disaster recovery plans should include recovery priorities; procedures to contact families, public agencies, suppliers and community representatives after the disaster; and arrangements to establish alternate work locations.

Your continuity plan should include off-site storage of the following documents:

- **building plans** and blueprints
- **inventory of equipment** and other assets, either as a list or in video form
- **reconstruction plan**, along with an updated list of contractors, movers, equipment vendors and staffing agencies to facilitate rebuilding and re-opening
- **listing of financial resources** to assess your practice’s ability to withstand a disaster

Also, establish an alternative mailing address (such as your residence or a post office box) in the event the building is destroyed or damaged.
Post-disaster Response

It is important to resume your practice as quickly as possible. A sound response plan will expedite restoration of operations and systems, return of employees and, most importantly, resumption of patient treatment. After the danger has passed, you can help facilitate a swift return to operations by implementing the following recommendations:

- **Provide patients with information** regarding their treatment and records.
- **Communicate with employees** regarding the extent of the disaster and what action they should take in the short term.
- **Contact your landlord** and, if necessary, the fire department for a general assessment of the damage.
- **Inform your insurance agent or company** of the disaster.
- **Reroute mail** and telephone calls.
- **Conduct salvage operations** and keep a careful accounting of all damage-related costs.

Fire Safety

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

When creating an office fire safety program for your practice, consider adopting the following elements, among others:

- **Post the fire safety management plan**, including fire and emergency evacuation instructions, in a conspicuous place in the office.
- **Post evacuation routes** in each examination room.
- **Assign responsibility for shutting off piped gases**, such as nitrous oxide and oxygen.
- **Provide a fire safety orientation** and annual education program to all employees.
- **Conduct quarterly fire drills** and evaluate and document drill results.
- **Ensure that the building’s fire alarm systems are tested on a quarterly basis** by a reputable testing service.
- **Declare your office a smoke-free environment** and rigorously enforce no-smoking rules.
- **Report any identified safety deficiencies** involving fire doors, exit signs, emergency lighting, fire extinguishers or smoke/heat detectors to the building manager.
Information Management

No business – least of all a medical practice – can be successful without adequate records. The strength of your business and continuity plan depends to a large extent on the ability to protect clinical, personnel and financial records.

The following guidelines can reduce the risk of losing vital data due to a collapse of your information processing system:

- **Protect paper records and files** by storing them in fire-resistant/proof cabinets, remembering that documents stored in rooms with sprinklers are highly susceptible to water damage.

- **Retain copies of the following documents off-site**, ideally in a safe deposit box:
  - disaster plan/policies
  - important telephone numbers
  - IT system records, including a back-up copy of your 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.

- **Place critical data servers (if kept onsite) in their own controlled-access room**, equipped with smoke and heat detectors and minimal flammable materials. Maintain a spare server for emergency use.

- **Install and regularly update IT 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 data, patient lists, procedures, suppliers and inventory. Store backup files offsite.

- **Identify third-party IT service providers** outside of your potentially affected area and arrange for emergency services on a contingency basis.

Medical Emergencies

Medical emergencies can involve a patient or staff member in medical crisis. In either case, the practice should be ready and capable of responding effectively.

If there is a flu-like epidemic/pandemic and numerous employees call in sick, you must arrange to secure adequate temporary staffing. Options to consider include overtime, employment agencies, and floating or per diem staff. In this situation, the practice may need 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 allow any certified staff member to initiate CPR if necessary.
- Instruct staff to contact a physician in the office immediately if they believe a medical emergency is occurring.
- Explain to staff that they must call 911 immediately if requested by a physician and remain on the scene until emergency personnel arrive.
- Visually 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. Document training and proficiency in personnel files.
- Maintain inspection and preventive maintenance records for all emergency equipment in the office.
- Ensure that the automatic incoming telephone service allows patients to speak to office staff in the event of an emergency, or refers them to 911.

**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.
- Require that all examination rooms be checked 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 over to the answering service before leaving the office.
- Instruct staff members to meet at a designated location following the evacuation.

**Security**

Maintaining security during a disaster is difficult, as buildings may need to be swiftly evacuated and remain empty for a prolonged period. Protecting the lives and safety of patients and staff is of course the highest priority. However, it is also necessary to consider means 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 – especially controlled substances. You may wish to consult with police and government authorities when creating your security policies.
Resources

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

- American Health Information Management Association, at www.ahima.org
- Disaster Preparedness and Emergency Response Association, at www.disasters.org
- National Fire Protection Association’s NFPA 1600, a standard for disaster/ emergency management and business continuity planning, at www.nfpa.org
- National Oceanic and Atmospheric Administration, at www.noaa.gov
- Occupational Safety and Health Administration, at www.osha.gov (click on “Emergency Preparedness”)
- U.S. Environmental Protection Agency, which provides information on hazardous materials and the Right-to-Know Act, at www.epa.gov
- American Society for Healthcare Engineering, which provides an example of a hazard vulnerability analysis, at http://www.ashe.org/ashe_app/index.jsp
Violence Prevention

The National Institute for Occupational Safety and Health (NIOSH) defines workplace violence as “violent acts (including physical assaults and threats of assaults) directed toward persons at work or on duty.” Violence prevention is an important risk management issue for physician practices, where intense and stressful situations may occur involving patients, physicians and/or staff.

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 structure and culture of your practice, your patient demographics and the specific risks you face. After the program has been developed, inform staff members of their responsibilities and begin training them in the prevention and de-escalation of violent behavior.

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.
- 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 to assess overall progress in reducing violence.
- Outline a comprehensive security plan for the practice. This includes establishing a liaison with law enforcement agencies and others to identify ways of preventing and mitigating workplace violence.
- Ensure that adequate resources are available for the program and encourage practice leaders to develop expertise on the subject of violence prevention in the healthcare environment.
- Affirm your commitment to a supportive environment 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 and on safety-related issues.

As with any health and safety initiative, your violence prevention program requires leadership commitment to the following principles:

- employee involvement
- work-site analysis
- hazard prevention and control
- ongoing staff training
- careful record-keeping
- program evaluation

**De-escalation Tips**

Do not argue with or provoke a hostile person. (See “Communication with Angry Patients,” page 22.) Instead, focus on defusing tense situations, utilizing the following strategies:

- **Stay at least two or three arm’s 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. Do not isolate yourself with the individual.
- **Develop an emergency code** to alert other office staff that a violent person is on the premises.
- **Signal immediately for assistance** using a prearranged distress sign 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.
- **Do not mention police or security** to a hostile patient or visitor.
- **Find a way to excuse yourself from the room and summon help**, if the situation escalates (e.g., “You’ve certainly raised some tough questions. I’ll consult my supervisor to see what I can do.”).
- **Dial 911 to report serious threats of violence**, using a telephone that is out of the hostile person’s sight.

For more information, refer to the Occupational Safety and Health Administration’s (OSHA’s) “Guidelines for Preventing Workplace Violence for Health Care & Social Service Workers,” available at [http://www.osha.gov/Publications/OSHA3148/osha3148.html](http://www.osha.gov/Publications/OSHA3148/osha3148.html).
Medication Management

Prescribing, dispensing and administering medications present 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 dosage
- medication interaction
- polypharmacy prescriptions
- wrong medication for the diagnosed condition

To reduce risk, your office should adopt a sound medication management policy and monitor staff for compliance. The following guidelines can assist you in crafting and evaluating your medication management procedures.

General Principles

- Adopt a “zero tolerance” policy for illegibility. Use electronic entry or print in block letters.
- Delineate which medications 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 your 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, and keep it current.
- 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 timeframe.
- Prohibit the use of abbreviations when documenting the name of a medication, dose, route or frequency.
- Provide a complete list of medications to subsequent providers, such as consultants or specialists.

New Prescriptions

- Designate the staff members permitted to call in prescriptions to the pharmacy.
- Carefully document all new prescriptions called to a pharmacy, 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 e-mailed prescription orders in the medical record.
- Update the medication list every time a new prescription is written or a medication is discontinued.
- Lock prescription pads or store them in a safe place away from patient care and reception areas.
- Prohibit use of pre-signed and post-dated prescription forms to prevent abuse.
- Report any lost or stolen prescription pads to local pharmacies, hospitals and the Drug Enforcement Agency.

**Prescription Refills**

- Ask the pharmacist to read back the order to ensure accuracy.
- Check the date of the last visit and last refilling to determine if a new refill is warranted.
- Document patient allergies, the name of the caller if different from the patient, and the name of the pharmacy and the pharmacist.
- Provide patients with information and educational materials about drug administration, actions and side effects.
- Refill only those medications that you originally prescribed.
- Require staff to consult with a physician or other provider regarding refill requests.
- Retain faxed or e-mailed refill orders in the medical record.

**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 to remaining stock.
- Dispose of expired medications safely. Flushing drugs is discouraged, as it may have adverse environmental consequences.
- Initial and date multi-dose vials when they are opened and follow manufacturers’ advice for disposal.
- 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 your inventory of controlled substances every day and include the signatures of two licensed personnel. 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.
- Exercise care when discarding any portion of a controlled substance. The process should be witnessed by two staff members with accompanying signatures.
Medication Administration

- 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.

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

- Ensure that only qualified employees 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.

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

- Implement an annual medication proficiency exam and related competency training for employees.

- Document all vital information in the medical 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 errors.

- Prominently display drug allergies on the medical record through use of allergy stickers or other means.

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 education information that is provided to patients in the medical record.

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

- Provide educational materials to your patients in languages and at reading levels appropriate to your patient population.
Medical Device Safety

The Federal Food, Drug, and Cosmetic Act defines a “device” as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals, and which is not dependent upon being metabolized for the achievement of its primary intended purposes. 21 U.S.C. 321(h).

Medical device technology for physician practices is evolving at an unprecedented rate. Offices may have a vast array of diagnostic and patient treatment equipment, ranging from hypodermic needles to 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 information on FDA rules and programs, visit www.fda.gov.

Medical Equipment Management Process

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

- 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, regardless of ownership, including manufacturer, model and serial number
- 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
- recognizing product hazards and limitations
- training staff on the safe use of devices they are expected to operate
- using the equipment in a reasonable manner as intended by the manufacturer

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

Use of Off-label and Unapproved Devices

Physicians are permitted by federal regulation to use a legally marketed device outside its labeling to treat a patient, as long as research is not being conducted. In such cases, the FDA expects the physician to assess the potential benefits of the device and be able to clinically justify the benefits of using the device outside of the manufacturer’s labeling. Become conversant with FDA guidance documents for off-label use of medical devices.

An unapproved medical device may be used on human subjects only when the device is under clinical investigation and when used by investigators participating in a clinical trial. The FDA recognizes circumstances in which a healthcare provider may need to use an unapproved device to save the life of a patient or to prevent irreversible morbidity, when no alternative therapy exists. Consult FDA guidelines for appropriate usage.

Needlestick Safety and Prevention Act (NSPA)

The NSPA (P. L. 106-430) was signed into law in November 2000 and became effective in April of 2001. In response to the NSPA, the Occupational Safety and Health Administration (OSHA) revised the Bloodborne Pathogens Standard, in part to clarify the requirement that all private sector and federal employers with one or more employees (including physician-owned practices) select safer needle devices and involve employees in identifying and selecting these devices. The standard applies to all employees who have occupational exposure to blood or other potentially infectious bodily fluids, such as saliva, semen or vaginal secretions.

The NSPA requires employers whose staff use medical devices that are classified as sharps (e.g., hypodermic needles, scalpel blades or suture needles) to implement an Engineering Control Plan (ECP) designed to isolate or remove bloodborne pathogen hazards from the workplace. Engineering controls refer to the use of such items as sharps disposal containers, self-sheathing needles, engineered sharps injury protections and needleless systems. The employer must review all processes and procedures for potential worker exposure to blood or other potentially infectious substances.
The ECP must include an annual documented review of changes in technology and medical device safety that reduce or eliminate exposure to bloodborne pathogens. In addition, the plan must have input from non-managerial employees regarding identification, evaluation and selection of engineering controls. By regulation, the input should come from a representative sample of employees who are responsible for direct patient care and are potentially subject to exposure, and should be documented in the ECP.

According to the NSPA, “where engineering controls will reduce employee exposure either by removing, eliminating, or isolating the hazard, they must be used.” (CPL 2-2.44D) For more information, visit http://www.osha.gov/needlesticks/needlefaq.html.

**Clinical Laboratory Equipment**

Basic laboratory tests fall under 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 waives simple 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 to comply with these protocols:

- **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 confirmatory tests.
- **Adhere to proper expiration dates** and properly dispose of expired products.
- **Perform function checks or calibrations**, as well as regular instrument maintenance.

More information is available at http://www.fda.gov/cdrh/clia/.

**Radiation-emitting Devices**

Many physician practices offer diagnostic radiography and fluoroscopy, which may cause injury resulting from excess radiation. Injuries also have been reported resulting from x-ray machine components falling on the patient. All states assume responsibility for inspecting diagnostic radiographic equipment and evaluating film processing, machine performance, technologist qualifications and operator protection.

The physician must balance the radiation risk associated with each examination against the potential benefit. Exposure must be as low as possible, consistent with good diagnostic quality. Continuing education of healthcare practitioners and technicians is necessary to ensure minimal radiation exposure to patients and staff, reduce the number of retakes and obtain high-quality x-rays.
Typical problems include nonlinear outputs and machines not calibrated. The following suggestions can improve the quality of diagnostic films:

- **Certify and document the training** of your x-ray machine operator.
- **Collimate the x-ray beam** on each x-ray examination.
- **Continually review the diagnostic quality of x-ray films** to ensure high quality.
- **Ensure that your x-ray film processor is set up correctly** and is running optimally.
- **Perform routine preventive maintenance** on each x-ray machine.
- **Schedule annual calibration checks** by a hired medical physicist.
- **Update your technique chart** to reflect actual conditions and equipment used.

**Safety Recall Notices and Hazard Alerts**

Safety recall notices and hazard alerts for specific medical devices are published on an as-needed basis by both manufacturers and the FDA. A recall is an action taken to address a problem with a medical device that violates FDA requirements. Recalls occur when a medical device is defective, when it could pose a risk to health, or when it is both defective and a risk to health.

A recall may require removing the device from where it is used or sold. The device may then be inspected, repaired, adjusted, relabeled or destroyed. In most cases, the manufacturer, distributor or other responsible party recalls a medical device voluntarily. The FDA also can require a company to recall a device if the manufacturer neglects to respond properly to a product failure.

When a company recalls a medical device, it directly informs known customers of the recall and attempts to notify all other customers. The company is responsible for supplying information to help users identify the product and minimize potential health consequences.

In addition to recalls, the FDA issues “Public Health Notifications,” which describe potential hazards associated with medical devices and recommend ways to avoid or reduce the risk. To subscribe to these e-mail announcements, visit [http://www.fda.gov/cdrh/safety.html](http://www.fda.gov/cdrh/safety.html).

If you receive a recall notice or a hazard alert, follow these guidelines:

- **Post the notice** in the recall/alert log of your practice.
- **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 published on the Internet and are accessible to the public. Specific searches can be conducted at [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm).
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 regulations. 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 maintain its safety surveillance of the products it regulates. These reports are published on the Internet and can be found at www.fda.gov/medwatch.

Responding to Adverse Events

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 evidence as possible related to the adverse event. For this reason, consider establishing office protocols that incorporate the following guidelines:

- **Immediately stop using any equipment** whenever there is a 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 independently tested. Do not turn the device over to the manufacturer if you suspect it may have contributed to the adverse event.
- **Save and preserve all disposables**, including the wrappers and packaging for supplies and disposables used during the treatment/test.
- **Record all device-related occurrences on incident report forms**, and forward them to a designated staff member 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.
- **Maintain a copy of all user and clinical policies and procedures** related to the specific treatment/test and device in question.
Non-physician Use of Medical Devices

State law or regulation may designate certain occasions when non-physician staff may use specific devices to treat patients. For example, Idaho permits hair removal treatment using laser or intense pulsed light devices to be delegated to a properly trained individual who is directed by a physician. (See http://www.bom.state.id.us/licensees/laser.html.) Non-physician staff members may only utilize those devices that are within their scope of practice, based on 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 (if applicable) by the appropriate state healthcare professional licensing board
- comply with written office protocols when using the medical device
- participate in ongoing, well-documented continuing education for these procedures
- report all adverse incidents to the supervising physician and document them in the patient’s record
- satisfactorily complete a documented special education and training program on applicable medical devices, covering such topics as safety, proper techniques, and pre- and post-treatment care. The program should include supervised practice and clinical skill competency testing.

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

Liability Allegations

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
- improperly educating users in the operation or use of the product
- using the device incorrectly as defined by the user’s manual
- 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 the specifications of the device manufacturer
- 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, you can minimize the likelihood of adverse events while strengthening your defense in the event of a lawsuit.
Patient Education

Patient education is an essential element in improving health outcomes. However, in our multicultural society, helping patients and families understand their medical situation and needs can be a significant 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 healthcare literacy, which can affect compliance with treatment and preventive care recommendations and may lead to potentially harmful or even life-threatening mistakes.

Healthcare practitioners must have some understanding of the cultural beliefs, practices and languages of their patient population in order to better serve their patients and protect against poor health outcomes and consequent lawsuits. To reduce risk, spoken and written communication must be both culturally appropriate and simply presented.

Improving Cultural Competence

Cultural competence can be improved via educational programs designed for practitioners and staff, some of which are available online. (A variety of resources is available from the U.S. Department of Health and Human Services’ Health Resources and Services Administration, at http://www.hrsa.gov/culturalcompetence/.)

The following general guidelines can help bridge cultural divides:

- **Assess each patient individually** and do not make generalizations.
- **Choose words that show respect** for the patient’s culture as well as the individual.
- **Provide competent medical translators or readers,** as unskilled interpreters are more likely to make potentially harmful errors. Federal regulations regarding interpreters note that patients’ family and friends may be less accurate and objective in this role. The use of children as translators is discouraged.
- **Provide interpreters for the physically challenged,** such as the blind or deaf.
- **Offer teaching materials in the primary language of patients** with limited English proficiency.

Improving Communication

Instead of merely asking, “Do you understand?,” invite patients to tell you in their own words what has been discussed and decided. The following basic guidelines will further strengthen rapport:

- **Sit down,** rather than towering above patients.
- **Take the time to listen to patients** and to build trust.
- **Utilize visual models** to clarify more complex ideas.
- **Use plain language** instead of technical or medical jargon – e.g., “keeps bones strong” instead of “prevents osteoporosis.”
- **Ask open-ended questions,** rather than questions that can be answered with a simple yes or no.

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Consider utilizing “Ask Me 3,” a free tool provided by the Partnership for Clear Health Communication of the National Patient Safety Foundation, at http://www.npsf.org/. It promotes the three questions that patients should always ask their provider:
- What is my main problem?
- What do I need to do?
- Why is it important for me to do this?

**Giving Visual Instructions**
To improve communication with patients, it is a good idea to complement verbal instructions with printed information, video, audio, models, pictures and universal symbols. The following suggestions can help you improve your nonverbal communication abilities:
- **Organize information carefully**, so that the most important points are first, stand out and are repeated.
- **Ensure that teaching tools and other materials are written at the fifth-grade level** to ensure comprehension by patients. For example, use the words “give” rather than “administer,” and “birth control” instead of “contraception.”
- **Use short, clear headings**; bulleted lists instead of paragraphs; and Q&A formats when possible.
- **Request a return demonstration** when teaching a skill, such as how to change a dressing.

**Documentation**
If patient education efforts or preventive care recommendations are not adequately documented, the patient may deny having any memory of these discussions. Without a written entry, proving that these activities occurred can be difficult.

Enter a progress note in the patient’s medical record describing the information and instructions given to the patient, as well as the patient’s response and level of understanding. Document the name of any interpreters, and, if handouts are provided, place copies in the patient’s medical record. Finally, archive all printed materials, videotapes or other teaching aids that have been revised or withdrawn from use.
Infection Control and Prevention

Transmission of viral and bacterial pathogens is an ever-present safety risk for medical offices, physicians and their allied healthcare support staff. Infection control 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 establish an infection control 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. To improve patient and employee safety, ensure that staff understand how infections are transmitted and what they can do to prevent and control the spread of infection.

Infection control activities are an organization-wide function and should be considered standard operating procedure in a well-run medical practice. A sound infection control program reflects the range of procedures performed, medical specialties within the practice and patient case mix.

Modes of Transmission

Major sources of office-based and outpatient infection include:

- accidental needlesticks with contaminated needles
- contaminants harbored in toys and stuffed animals in the waiting room
- cross-contamination due to ineffective cleaning of equipment
- inadequate hand hygiene
- patient-to-patient respiratory contagions
- poor office cleaning
- reuse of disposable supplies
- staff-to-patient respiratory contagions (and vice versa)

Infection control improves when employees understand the two primary routes of bacterial and viral transmission:

- **Direct contact** includes blood, urine, stool, infectious drainage and respiratory tract secretions (e.g., MRSA, HIV, Hepatitis B and C).
- **Indirect contact** includes airborne droplets related to colds and influenza, pertussis, respiratory virus and SARS (e.g., chicken pox, measles, tuberculosis).

Environmental/Housekeeping Infection Control

Environmental surfaces (i.e., equipment or surfaces that do not come into direct contact with patients) may become contaminated, allowing microorganisms to spread through hand contact. Touching these surfaces allows the transfer of microbial agents to instruments, other environmental surfaces, and to the nose, mouth or eyes. Environmental surfaces can be divided into clinical contact surfaces (such as examination tables) and housekeeping surfaces (such as floors, walls and sinks). Because housekeeping surfaces are less likely to transmit disease, they can be decontaminated with methods that are less rigorous than those used on clinical contact surfaces and patient care items.
Barrier protection is effective for clinical contact surfaces that are difficult to clean. Barriers include clear plastic wrap, bags, sheets, tubing, and plastic-backed paper or other materials that are impervious to moisture. Because such coverings can become contaminated, they should be removed and discarded after every use.

The physical action of scrubbing with detergents and surfactants and rinsing with water removes substantial numbers of microorganisms. If a surface is not thoroughly cleaned and scrubbed prior to disinfection, the disinfection process can be compromised. General cleaning and disinfection are recommended for clinical contact surfaces and countertops at the end of daily work activities and whenever surfaces have become contaminated.

Depending on the type and degree of contamination, housekeeping surfaces should be cleaned either with detergent and water or an Environmental Protection Agency (EPA)-registered hospital disinfectant/detergent. Floors should be cleaned regularly, and spills should be attended to promptly. Unless contamination is obvious, it is unnecessary to disinfect walls, drapes and other vertical surfaces. Toys should be washed on a regular basis and whenever contamination is obvious.

Good hygiene involves minimizing contamination of cleaning solutions and tools, such as mop heads and cloths. Ensure that mops and cloths are cleaned after each use and allowed to dry before reuse, or substitute single-use, disposable mop heads and cloths. Solutions of detergents or disinfectants can become reservoirs for microorganisms, especially if they are mixed in dirty containers, stored for long periods of time or prepared incorrectly. By preparing fresh cleaning solution each day, discarding any remaining solution and allowing the container to dry, cleaning staff can reduce the threat of bacterial contamination.

**Hand Hygiene**

Hand hygiene should be performed
- before and after every encounter with patients, bodily fluids and soiled materials
- after removing gloves and using the restroom
- whenever hands are visibly soiled

Hand-washing methods can range from scrubbing with plain or anti-microbial soap under running water to the use of alcohol-based hand sanitizers and manicure sticks. Situating hand sanitizer stations in or near treatment rooms will help encourage better habits among staff and physicians. Monitor hand-washing protocols to ensure compliance with this basic but essential infection control tactic.

**Respiratory Etiquette**

Implement respiratory etiquette whenever patients with a communicable or potentially communicable disease enter your facility. Respiratory etiquette consists of warning signage, provision of tissues and waste containers, instructions on how to cough and sneeze, and use of surgical masks, if needed. Staff should wear masks, face shields and protective eyewear if there is any possibility of droplet or airborne contamination. OSHA has published specific protocols requiring the use of respirators when caring for patients with contagious airborne agents.
OSHA's tuberculosis enforcement guidelines are based on those of the Centers for Disease Control (CDC). In physicians' offices, these guidelines apply to personnel who are present during the performance of high-hazard procedures – including sputum induction and administration of aerosolized medications – on suspected or infectious patients. These medical procedures should be performed on infectious patients only if absolutely necessary. (See “Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005” at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s_cid=rr5417a1_e.)

**Bloodborne Pathogens**

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

In 1991, OSHA issued the Bloodborne Pathogens Standard, 22 CFR 1910.030, to protect workers. It was revised in 2001 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 choosing 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 (See page 50.)
- 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 in the event of an exposure incident
- 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 making use of them
- training employees in appropriate safety practices
- utilizing labels or color-coding for sharps disposal boxes and containers for 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 or color-coded. In addition, never reuse a single-use sharps product.

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

The 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.

Gloves should be available and 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 those employees who are allergic to the gloves normally provided. Wear gloves when touching contaminated objects, but do not 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 and Disinfection

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. Sterilization involves the use of an autoclave (heat or gas) or a chemical soak. 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 professional organization guidelines, when using reprocessed medical instruments or equipment.

Waste Management

Waste management practices must comply with federal OSHA standards, as well as state and local regulations. Medical waste at your office 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.

Employee Health

Implement measures to ensure that your employee health program is tracking and documenting vaccinations and tuberculin skin testing, as well as scrupulously managing any staff-acquired disease. In addition, establish and maintain an accurate medical record for each employee that is separate from the personnel file. These employee health records should be retained after employment for the duration established by state requirements.

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.
Office Practice Guidelines

- Treat all bodily substances from patients as potentially infectious, and place an appropriate barrier between yourself and the substance.
- Treat any device that is visibly soiled as contaminated, even if the stain is dried. Use hygienic precautions when handling any device, even if it appears to be clean.
- Prohibit mouth pipetting or suctioning of blood or other potentially infectious materials.
- Place specimens of blood and other potentially infected material in a tightly sealed container, and carry it in an outer container.
- Provide mouthpieces, resuscitation bags or other ventilation devices wherever the need for resuscitation is likely.
- Ensure that staff adhere to the basic principles of aseptic technique for the preparation and administration of all medications.
- Do not permit eating, drinking or smoking in the office. Do not permit food or drink to be kept in or on refrigerators, freezers, shelves, cabinets, countertops or bench tops where blood or other potentially infectious materials are present.
- Do not permit employees to handle contact lenses or apply cosmetics in work areas, or to rub their eyes or other mucous membranes.
- Do not permit personnel to wear artificial nails or nail polish if they have direct contact with patients.

Online Resources

- Accreditation Association for Ambulatory Health Care (AAAHC), at www.aaahc.org
- American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), at www.aaaasf.org
- Association for Professionals in Infection Control and Epidemiology, Inc. (APIC), at www.apic.org
- Centers for Disease Control and Prevention (CDC), at www.cdc.gov
- The Joint Commission (JC), at www.jointcommission.org
- National Institute for Occupational Safety and Health (NIOSH), at www.cdc.gov/niosh
- Occupational Safety & Health Administration (OSHA), at www.osha.gov
- World Health Organization (WHO), at www.who.int/en
Continuity of Care: On-call Coverage, Hospitalists and Patient Referral

Practices must have 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. Systems that ensure access to physicians and other practitioners will help enhance continuity of care and patient satisfaction.

On-call Coverage Within the Practice

- Establish a written protocol for coverage that ensures round-the-clock access to a physician in your practice, and which 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.
- Provide on-call coverage through 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 care records and information regarding patients who may have urgent care needs.
- Select answering machines and answering services that are patient-friendly and that facilitate contact with the on-call physician without complicated instructions. Some patients may not be able to negotiate several levels of options in order to access the answering service or page the physician.
- 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.
- Determine billing procedures for services rendered by the on-call provider. If the provider is covering for managed care patients, comply with the coverage arrangements of the managed care contract.

Use of Locum Tenens

If your practice is too small to provide adequate coverage, 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 your patients’ needs and expectations.
- Obtain referrals, confirmation of status at a local hospital, quality data and patient satisfaction data as part of the process of selecting locum tenens physicians.
Consult with legal counsel in creating and executing the *locum tenens* contract, after selecting a qualified individual or group.

Draft the contract with the *locum tenens* carefully, 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 care records. The contract should also require an annual certificate of the provider’s professional liability insurance.

**Providing On-call Coverage for Another Practice**

- Consider the fit between your expertise and style of providing services and those of the other practice when committing to cover for an outside provider.

- Examine the contract carefully and ensure that it adequately addresses the quality of services provided, documentation expectations and access to patient care records, and also requires an annual certificate of professional liability insurance.

- Arrange for access to patient care records and obtain reports on patients who may have urgent care needs.

- Complete as thorough a medical history as possible whenever contacted by a patient.

- Document advice given to patients 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 of time.

- Clearly document the rationale supporting any treatment recommendations that you give, including prescriptions.

- Promptly report all patient encounters to the practitioners for whom you are providing coverage.

**Use of Hospitalists**

- Explain to patients that your practice utilizes hospitalists. Describe the credentials of and services provided by a hospitalist, and discuss with the patients whether they will see you during the hospitalization.

- Evaluate the competence and experience of hospitalists utilized by the practice, if there is a choice of providers.

- Initiate communication with the assigned hospitalist at the time of a patient’s admission and at discharge.

- Communicate specific patient safety issues when transferring care to and from a hospitalist.

- Track patient discharge to ensure follow-up communication and continuity of care.
**Referring Patients for Consultation to Other Providers**

- Discuss with the patient the reasons for consulting another physician for additional treatment and/or recommendations for a treatment plan. Include the rationale, benefits and risks associated with this option.

- Consider assisting the patient in making the appointment, based on the degree of urgency and the patient’s ability to follow through with the instructions. Patients requiring immediate attention should be assisted in order to facilitate the process.

- 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 whether the patient is following up on the consultant’s recommendations.

- Assume primary responsibility for the patient’s follow-up care unless the patient is transferred to the consultant. Specific duties include encouraging patients to complete recommended diagnostic tests, helping them understand the test results and proposing a care plan consistent with test results.
Human Resources

Sound 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 also help your practice better comply with pertinent federal, state and local legal requirements – including the Americans with Disabilities Act, 42 U.S.C. §§ 12101-12213 and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), P.L. 104-191 – and protect against allegations of discrimination.

Your practice also needs 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 you minimize risk when hiring, contracting with and managing both employees and independent healthcare practitioners.

Hiring Staff

- Create a human resources file for each applicant.
- Explain the hiring process to each applicant and ask to see a photo ID.
- Require a completed application for employment.
- Obtain a signed consent form from the applicant authorizing past employers to release information. Attach the consent form to each request for information.
- Obtain the applicant’s signature on an attestation to affirm the accuracy and completeness of the application.
- Give the applicant the opportunity to clarify answers as needed and to provide additional information.
- Ask open-ended questions that help you evaluate whether the individual will contribute to a patient-centered culture.
- Avoid asking questions that could trigger allegations of discrimination, such as applicants’ sexual preference, age, religion, marital status or nationality.
- Verify and document the following information:
  - biographical details (e.g., name, address, telephone number, Social Security number, driver’s license number)
  - current license/certification, where applicable
  - additional certifications, such as Basic Cardiac Life Support (BCLS), Advanced Cardiac Life Support (ACLS) and Cardiopulmonary Resuscitation (CPR)
  - certificate of insurance, where applicable
  - credit history, criminal history, Office of Inspector General and sex abuse registries for all states where the applicant has lived or worked
  - drug testing, as permitted by law
  - education (i.e., undergraduate/graduate/internship/residency programs attended)
  - previous relevant positions
  - references
  - membership in professional organizations
  - professional liability claims history (list of pending and closed claims)
  - reports of disciplinary board actions
- **Assure and maintain confidentiality of information** obtained for credentialing and/or hiring.

- **Obtain a written confidentiality agreement** immediately after hiring to comply with HIPAA requirements.

- **Maintain a current license/certification** for each employee, as required.

**Job Descriptions**

Each position in the physician practice should have a written job description that is competency-based. Job descriptions for licensed and certified professions should be consistent with the scope of practice defined by state boards and professional organizations, and should comply with the requirements of the Americans with Disabilities Act.

**Orientation, Continuing Education and Performance Evaluations**

Orientation should include basic information about the practice, clinical practice standards, patient confidentiality and patient courtesy. Also address such relevant issues as insurance options, vacation time, dress code and responsibilities with regard to safety, incident reporting and appropriate professional behavior.

Orientation sessions should be tailored to the role and duties of newly hired staff, including:

- review of the job description
- performance expectations and evaluation process
- signed confirmation that the employee understands his/her responsibilities

Continuing education and ongoing training opportunities should be consistent with license/certification requirements. All personnel files should contain evidence of continuing education credits and annual performance appraisals.

**Policy/Procedure Manual**

Every medical practice should have a policy/procedure manual. Formal policies and procedures protect the patient, employees and organization by providing guidelines, setting limits and helping staff members perform their duties more effectively. They are also important in defending against allegations of negligence. When compiling or evaluating your policy/procedure manual, consider the following suggestions:

- **Address major human resources issues in the policy manual**, such as disruptive behavior, harassment and other unacceptable behavior in the workplace. Additional topics include expectations regarding professional behavior, patient confidentiality, dress code, safety 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 physicians, employees and vendors.

- **Examine written policies and procedures for consistency** with actual practices.

- **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
treated as an evolving document that is regularly reviewed and revised.

- **Provide all employees with written information** regarding policies and proce-
dures, and ensure that this information is readily available for reference by staff
and physicians.

- **Give staff the opportunity to review the manual upon hire** and after any
changes or revisions are made to the manual.

- **Archive policies that have been revised or withdrawn** for reference in the
event of litigation.

**Hiring/Contracting with and Credentialing Physicians and**
**Other Independent Licensed Healthcare Practitioners**

Physicians and other independent 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. The staff hiring guidelines outlined on pages 55 and 56 may also be useful
when bringing licensed providers into the practice.

Employed and all other independent licensed healthcare practitioners must also be creden-
tialed. 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, create a credentials file for each physician and other independent licensed health-
care practitioner that contains proof 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
Informed Consent

Patients have the right to make informed decisions regarding their healthcare and to consent to or refuse treatment or tests. The goal of the informed consent process is to achieve mutual understanding between the patient and practitioner regarding the potential outcomes, positive and negative, of the medical care to be rendered.

A medical malpractice lawsuit may be based on the allegation that the patient did not adequately understand the information provided by the physician. Your practice should have a written policy and procedure addressing all aspects of obtaining a patient’s informed consent.

Fundamentals of Informed Consent

The informed consent process consists of two equally important elements: communication and documentation. The process involves

- communicating the information that any patient in similar circumstances would reasonably wish to know.

- describing the recommended treatment or procedure clearly and simply, avoiding medical jargon and providing a qualified interpreter if necessary.

- explaining how the recommended treatment or procedure relates to the patient’s condition or diagnosis, why it is indicated and what are the risks.

- discussing reasonable alternatives, including receiving no treatment, and describing the material risks and benefits of each option. Some states specifically outline the risks that must be disclosed for each treatment/procedure.

- identifying the practitioner who will treat the patient by name and professional category.

- informing the patient if the recommended treatment is experimental, unconventional or unusually hazardous.

- ensuring that the patient understands the information provided by encouraging questions and asking the patient to describe the treatment/procedure in his/her own words. You may also wish to encourage patients to have a family member or friend present during the informed consent discussion.

Medical record documentation should convey the essence of the communication between the practitioner and patient. Documentation should be sufficiently explicit so that a third party reviewing it will be able to derive both what the patient was told and whether the patient had a reasonable understanding of the implications.

Signature Consent Requirements

Treatments/procedures that are considered to be low-risk and are within generally accepted standards of medical practice (e.g., routine chest x-ray, Pap smear and vitamin injection) do not generally require signed consent. In these instances, the informed consent discussion should be conducted between the patient and practitioner and documented in the medical record.
For non-routine and higher risk treatment/procedures, a consent form should be utilized, as described below:

- **Ensure that the form is clear and simple**, and written in the primary language of the patient.

- **Provide an interpreter or reader** for patients who have visual or hearing impairments, or lack proficiency in written English.

- **Include an attestation statement** signed by the physician confirming that the required elements of an informed consent discussion were completed and that the patient indicated comprehension of the information provided.

- **Require that a third party serve as witness**, attesting to the patient’s and practitioner’s signatures on the consent form.

- **Consider drafting procedure-specific consent forms** for frequently performed tests and treatments.

- **Enter a progress note into the patient’s medical record**, including the date and time the informed consent discussion took place, and the names of persons present. Include the relevant aspects of the discussion and a statement that the patient accepted the risks and consented to the test/procedure.

Tests/procedures requiring a patient’s signature include, but are not limited to, the following:

- **use of sedation**, anesthesia or narcotic analgesia

- **injection of any substance into a joint space or body cavity**, including non-vascular spaces

- **aspiration of body fluids** through skin

- **removal** of skin lesions

- **any procedure that may reasonably be expected to produce significant discomfort or a risk of complications** (e.g., chemotherapy, radiation therapy, injections of contrast material)

- **electrocauterization** and laser therapy

- **transfusion** of blood or blood products

- **experimental procedures**, drugs or treatments (Review the FDA consent requirements for experimentation on human subjects.)

**When a Patient or Parent Refuses Consent**

If a patient chooses an alternative treatment or procedure, refuses treatment, or revokes prior consent, the practitioner should document the patient’s reasons, if known, and the expected outcome of the patient’s choice. Include a notation that the patient was advised of the potential consequences of the decision. Whenever possible, obtain a formal written refusal, either on a form or in a progress note, signed by the patient.

When a parent or guardian refuses a treatment on behalf of a minor, the decision should be respected, unless the practitioner believes that the minor’s health is in jeopardy. All discussions and interventions should be documented. If a conflict cannot be resolved, and where medical treatment is indicated to prevent physical or mental impairment or death, the practitioner should immediately contact appropriate state agencies.
Role of Other Staff Members
The practitioner who will perform the treatment or procedure must conduct the informed consent discussion – it cannot be delegated. Refer to state statutes for guidance on practitioners such as certified nurse midwives, certified registered nurse anesthetists, nurse practitioners and other providers of care.

Nurses and other healthcare providers may witness a patient’s signature on a consent form, but they are not permitted to carry out the informed consent discussion. Support staff should be encouraged to act as patient advocates by asking patients if they have additional questions or concerns, and by relating these to the physician for direct patient follow-up.

Exceptional Situations
States generally recognize special circumstances where delaying treatment in order to obtain informed consent could be detrimental to the patient. Some exceptional circumstances 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
- when the patient has waived his or her right to the informed consent discussion in writing
- if the disclosure of risks would have a serious adverse effect on the patient or the therapeutic process, in the physician’s medical opinion

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

When the Patient Cannot Consent
When a patient lacks decision-making capacity, the practitioner must make a reasonable inquiry as to the availability and authority of a durable power of attorney for healthcare document naming a healthcare proxy. If the patient has not designated a healthcare proxy decision maker in writing, the physician must approach family members, guardians or even the court to obtain consent. The informed consent discussion must then take place with the individual who has been granted the authority to make healthcare decisions on behalf of the patient.

Written documentation explaining why someone other than the patient consented and signed the consent form should be included in the patient’s file. Office policy also should clearly delineate who, in hierarchical order, may give consent and sign a consent form. Consult with legal counsel regarding specific state laws governing healthcare power of attorney.
Consent of Minors

Staff should be aware of state-specific statutes, laws, rules and regulations, as well as exceptions, regarding consent and treatment of minors. While most states consider 18 the age of consent, state statutes differ regarding specific situations, such as sexual or physical abuse, sexually transmitted disease, abortion and birth control. Typically, parental or guardian consent is not required if a minor is legally emancipated, living independently of a parent or guardian, legally married or a parent.

Mature minors should be included in discussions about their healthcare. In cases where a parent has agreed to a treatment for a minor child but the minor is vehemently opposed, it is advisable to contact an attorney prior to proceeding.

Consent by Telephone, Letter, E-mail or Facsimile

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 you reduce risk in this situation:

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

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

Tracking Diagnostic Information

Liability claims associated with outpatient tests ordered in the office setting are generally grouped 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 reliable system for sending specimens to reference laboratories and ordering tests. It is equally important to ensure that test results are returned to the office so they can be reviewed in a timely manner. Consider implementing the following practices:

- Place charts 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 results.

- Utilize a manual 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 using the designated notation and highlight the entry with a color marker, or color filler in a computerized system.

- Consider acquiring an effective test management system. Telephone, software and Internet-based systems are available. Most electronic medical records systems have a component for test management.

Reviewing Test Results

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

Review results in a timely manner. If the ordering practitioner is unavailable, refer test results to another physician as designated by the practice’s policy.
Critical test results received by telephone should be reported immediately to the practitioner who ordered the test, or, if unavailable, to another person designated by policy. When documenting a call, consider using a form designed to capture the following information:

- date and time
- call received by (first and last name)
- patient’s name and unique identifier
- test name and critical test value
- information read back and confirmed correct
- first name, last name and location of caller/sender
  (e.g., John Doe, Acme Diagnostics)

When handing off the results to another practitioner, document the physician/person 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 health of a patient and lead to a lawsuit. Consider implementing the following risk-reduction measures:

- **Identify a list of drugs that require a laboratory baseline value and periodic reassessment** (e.g., Lipitor/liver enzymes). Review and update annually.
- **Identify a list of conditions that require test(s) for 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. (See “Patient Education,” page 45 and “Informed Consent,” page 58.)

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

Consider the following hypothetical scenario:

> An infant is discharged from a hospital a few hours after birth, and has not been tested for phenylketonuria (PKU). The infant has an appointment with a pediatrician four days later. The doctor does not review the hospital record, which shows that the PKU was not done, and does not order the blood test. The infant is diagnosed with kernicterus at the age of 20 months. A lawsuit is settled on behalf of the plaintiff.
**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.

Obtain written consent (which may be included in the patient registration form) from patients to leave a message informing them that their test results have returned. The form should allow the patient to indicate the following:

- Message may be left on home telephone. (yes/no)
- Message may be left on work telephone. (yes/no)
- Message may be left with the following people: (first name, last name)
- Patient signature, date and time

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 you are unable to contact the patient by telephone. Document and retain the receipt in the medical record.

Electronic and telephone systems are available that allow test results to be “posted” and automatically retrieved by the patient. These systems should be approached cautiously, as people may be frustrated at having to navigate through an automated system, rather than speaking to a real person. Elderly patients and those with limited healthcare literacy, English proficiency or computer skills may have difficulty using such a system or comprehending the information they receive.

**Documentation**

All attempts to notify patients of test results should be documented in the medical record, as should follow-up treatment instructions or other advice. In addition, document all 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.
Patient Scheduling

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 your practice’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 policies regarding triage for urgent/same-day appointments. Outline procedures for staff-physician consultation regarding triage and documentation of the reasoning behind triage decisions in the clinical record.
- Ensure that non-clinical staff members consult with a nurse or physician before informing patients that their request for an urgent/same-day appointment cannot be accommodated.
- Require that a physician or other qualified provider promptly evaluate all patients who present with an urgent condition.

Missed Appointments: Canceled and No-show

Writing “no-show” or “patient canceled” and then filing the chart without further consideration can lead to a poor health outcome for the patient and allegations of negligence against the physician.

Consider the following scenario:

Your patient, a diabetic, calls and cancels his appointment. He states he has jury duty and will call to reschedule. Several months later, you have not heard from the patient, but you have heard from his attorney. A lawsuit has been filed, claiming (among other allegations) that the patient was never informed of the consequences of forgoing regularly scheduled appointments, resulting in failure to diagnose renal nephropathy.

Your practice should develop a standard procedure for following up with patients who have missed a scheduled office visit. Minimally, the procedure should include the following risk management strategies:

- Obtain consent from the patient to leave appointment reminder messages either on an answering machine or with another person. (See “Notifying Patients of Test Results,” page 64.)
- Develop a tickler system to trigger a follow-up contact if a patient does not call to schedule a return visit within the agreed-upon timeframe (e.g., one week after surgery).
- Notify the physician of missed appointments and have him or her review the medical 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.
- Require that telephone contact be attempted with every patient who misses or cancels an appointment, unless the physician documents it as unnecessary. (For example, annual physicals for patients with no chronic conditions may be exempt.)

- Delineate the circumstances when it is necessary to send the patient a registered letter following unsuccessful telephone contact (e.g., an appointment to discuss an abnormal diagnostic test). Document and retain the receipt in the medical record.

- 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.

- Record missed or canceled appointments by first-time patients (i.e., medical record not established) in the schedule book, computer record or day sheet. Do not obliterate, delete or erase no-shows or cancellations.

- Archive appointment books and computer records according to state statutes or regulations applying to medical records retention. A record of repeated missed appointments may demonstrate that a plaintiff contributed to his or her injuries, which could limit 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 call the office immediately on receipt of the letter to schedule an appointment. If a patient fails to call, consider discharging the patient from the practice. (See “Physician Termination of the Physician-Patient Relationship,” page 22.) Document and retain the receipt.

**Office Hours Canceled**

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

- Patients should be notified and rescheduled as soon as possible. Sincere apologies should be extended for the inconvenience.

- A physician or other designated practitioner should review all patient medical records to determine the urgency and timeframe for rescheduling. Non-clinical staff should never reschedule patients without direction.

- Patients who feel they are too ill to wait should speak directly with clinical staff for evaluation and direction.

- Document patient contacts and new appointments in the medical record.

- Develop a back-up plan in the event that the office cannot reopen on the next scheduled business day, or the next business day does not meet the needs of a patient (e.g., if dialysis is required).
Appointment Times Delayed

If patients experience long waiting times, extend sincere apologies 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, allow patients to reschedule the appointment.

- **Inform patients in the waiting room of delays and provide periodic updates.** If possible, give an estimated timeframe for seeing the physician and a reason for the delay (e.g., the doctor was detained due to an emergency surgery). With physician approval, allow patients to re-schedule if waits continue.

- **Document rescheduled appointments** in the medical record.

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