

PHYSICIAN OFFICE PRACTICE TOOLKIT

This toolkit has been developed to assist physicians and practice managers in addressing potential risks within the physician office setting. It has been constructed to accommodate future tools and updates as they are developed periodically by Princeton Insurance.

In addition to the Risk Management Guidelines for the Office Practice, and reproducible forms, we also give you access to helpful tools such as patient telephone call record pads and communication posters or handouts which encourage patients to talk with you about things that are important to their care.

The Risk Management Guidelines for the Office Practice can be used to guide you through a self assessment of various aspects of your practice. They are intended to be instructional and informative and were designed to be generic in nature so that you can customize the application to meet the unique needs of your office.

The guidelines address risks in most types and sizes of practices. If you operate a single practitioner practice with no staff, you will find little need for written policies, but a practice with multiple providers and a large staff will find policies and guidelines necessary. Reading this toolkit with that commonsense approach should allow you to get the most benefit from its content.

We in the Healthcare Risk Services Department are confident that you will find the guidelines to be an asset to you in the development of your office policies and procedures. Sample forms and other resources for simplifying common office processes are found in the *Forms* section. You will find links throughout the document that will take you to appropriately related sections of the toolkit or to other supporting materials, such as Princeton's Risk Review Online articles and *Reducing Risk* documents.

Resources used in the compilation of these guidelines may not be included within each topic section. We have, instead, listed them on a page entitled *Helpful Links for Office Practices*. This is not an exhaustive list, but it contains frequently referenced authorities.

We welcome your questions and any thoughts you may have to make this toolkit even more valuable. Please feel free to call our Healthcare Risk Services Department at our toll-free number 1-866-Rx 4 Risk (794-7475) to speak directly with a Healthcare Risk Consultant.

The guidelines are neither intended to provide legal advice, nor to serve as a professional standard. The contents are only for purposes of information and education.

Healthcare law is complex and highly regulated. The law changes frequently and because these changes can be significant you should always check with appropriate professionals to stay fully abreast of the current laws that impact the delivery of healthcare services.

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RISK MANAGEMENT

Risk Management Defined

Risk Management is a common sense, systematic approach to managing the unexpected results or adverse effects of the many and varied risks associated with providing patient care in an office practice setting. The purpose of a risk management program is to establish and maintain processes that identify, help correct and prevent conditions that could result in injury (to patients, visitors, doctors and/or employees) or financial loss to the practice.

A written risk management plan for your practice is essential to provide a structure for procedures that support:

- timely identification and evaluation of risk issues
- formulation of corrective and preventive actions to eliminate or reduce the identified risks
- follow-up of the effectiveness of corrective actions

An effective risk management plan for your practice can help improve or enhance your clinical patient care and reduce your liability exposure. The commitment and efforts of all physicians and staff to quality patient care and patient satisfaction is essential.

Risk Areas in a Physician Office

Risk management in the physician office focuses on effective communication, direct patient care activities with the potential for liability for inappropriate or incorrectly performed care and office policies and procedures which, when not established or not followed, can result in patient dissatisfaction or an adverse or unanticipated outcome.

The following are some of the categories of risks that are typically addressed in a risk management program for a physician practice:

- patient care
- medical and other licensed staff credentialing
- human resources
- office safety
- communication/information management
- financial risks

Goals for a Risk Management Program

An effective risk management program is guided by ongoing, meaningful, and measurable goals and objectives. The practice's governing body or physician director approves the goals that are also used to evaluate the program at least once a year. Goals for a risk management program typically support the following efforts:

- provide for the safe delivery of health care within reasonable financial and resource limits
- facilitate the timely identification and resolution of risks in an effort to reduce or prevent the potential for injury or loss
- foster effective communication for patient care and safety
- continually improve the ongoing delivery of healthcare services
- utilize internal controls to reduce financial losses associated with professional and general liability claims, and decrease the frequency and severity of those claims

The following sections are examples of risk management activities in an office practice setting.

Adverse Events – Reporting and Investigation

When an unexpected event happens in the office, which either injures or potentially injures a patient or visitor, the practice should investigate it. In small practices this may be a rather informal process, yet it can lead to changes in office processes so that similar events are minimized or prevented. If the event is serious in nature it should be treated as the practice would treat a claim.

Information regarding [reporting](#) and [investigating events](#) can be found in Princeton's Reducing Risk documents on these subjects. A [Sample Event/Complaint Report](#) and [instructions for completing an event/complaint report](#) are included in the toolkit for your use.

Billing and Collection Practices

Sound policies and procedures for billing and collection practices are necessary to minimize risks of loss and avoid problems with your office's billing and collection policies. The following practices are suggested:

- Identify billing situations that require physician review and, possibly, special arrangements for payment or write-off.
- In order to avoid the appearance of an "admission of negligence," do not agree to a request to waive or reduce a fee because of complications that the patient perceives to be the result of the doctor's actions, until you have obtained the advice of legal counsel or Princeton Insurance. Similarly, you should consider very carefully whether to send a bill to a patient who has already experienced an adverse event since this may incite a patient to litigate.
- Carefully monitor your office billing procedures.
- Require approval of a designated individual such as the directing physician before an overdue account is referred for collection. Additionally, you may consider having a policy of not sending accounts for collection.
- Have a HIPAA Business Associate agreement with any outside billing service or collection agency that your office uses.
- Have a private area in your office for confidential discussion of billing matters.

Discharging a Patient from Your Practice

Relationships between patients and physician practices are not always smooth. You may need to consider discharging patients from your practice because of chronic non-adherence to their treatment plan, or inappropriate behavior. They may fail to pay their bills and make no attempt at repayment; and there are other situations that may cause you to turn to the option of termination.

Termination should not be a snap decision and it is important to recognize warning signs in your patient's behavior well before you are ready to consider this option. If possible, you may be able to work with your patient and improve the situation, especially as it relates to adhering to their care plan. Recognizing warning signs is also important because it is necessary to document their behavior factually and to document any conversations you may have had with them about that behavior.

The process of termination should be done very carefully. If done inappropriately, you can leave yourself open to claims of abandonment or discrimination by your patient. NJ Board of Medical Examiner (BME) rules and possibly managed care plan contracts also apply in these situations.

Princeton Healthcare Risk Services has developed a packet of information on [discharging a patient from your practice](#). The packet includes a [sample letter](#) which you can use as a template for the situation with your patient.

Merging or Closing a Practice

As a business, your practice may face changes which will require careful planning and management. A small practice may decide to merge with another, or several other practices for a sense of security and economies of scale as healthcare continues to change and reimbursements remain uncertain.

Other practices may decide to close, or the physician may decide to leave the practice, turning it over to another physician.

Whether you have months to plan this decision, or it is forced on you in a more abrupt fashion by circumstances you do not control, there are steps that should be taken for the sake of the business and your patients.

Whether merging or closing, business decisions will be made regarding the effective date of the change, and other issues regarding staff, policies, and assets. It is important to know and follow the BME regulations for these changes. Your business attorney should also work with you to make sure that the transition protects both the business and the people involved.

Notifications will be made in either situation too. Employees, vendors, and patients are to be made aware of the change. Decisions will need to be made regarding medical records.

More information on [ceasing to practice, or leaving a practice](#) can be found in Princeton's Reducing Risk documents.

Patients Who Do Not Adhere to Their Treatment Plans

A patient who does not follow their treatment plan can be frustrating to their caregiver, a potential danger to themselves, and a potential liability threat for the practice. Avoiding non-adherence begins with good communication between the patient and the physician, establishing a sense of trust between them.

Shared decision making can also help prevent or minimize non-adherence to the care plan. If the patient is involved in decisions on their care, and understands their care plan, they are less likely to stray from it.

When a patient does stop following their plan, communication with them is also important. They may start missing appointments, stop taking medications (or take them incorrectly), or begin to treat themselves (with over-the-counter [OTC] medications or home remedies). However their non-adherence manifests itself, it is important to make an opportunity to speak with the patient. If the patient is missing appointments and finally shows up, that is an opportunity to talk with them about the missed appointments.

When communicating with a non-adherent patient:

- review the care plan and what they have recently been doing (within or outside of the care plan's boundaries)
- attempt to find out the patient's reason for this behavior (are they unable to pay for their medication, or is something else preventing them from adhering to the plan)
- ascertain whether the patient lacks understanding of their condition or of your instructions
- discuss with the patient the consequences of continuing the non-adherent behavior
- look for clues regarding those things that do motivate your patient and find ways (if possible) to use them in your discussions and in the care plan itself

If the patient continues to demonstrate non-adherent patterns of behavior, you can:

- give them a written summary of the care plan and the consequences of their current behavior, have them sign and date their copy and a copy for their medical record
- [discharge them from your practice](#)

A Reducing Risk document focuses on [patients who don't return for follow up](#). These patients are not adhering to their treatment plan and they need to be tracked carefully in the practice's follow-up systems. Their failure to return should be documented in their chart and they should be contacted; that contact should also be documented in the record.

Risk Financing

Risk financing is a management plan to develop the sources and allocation of funds that a practice or organization would need to recover from a loss (e.g., accidental property, net income, liability, and personnel losses). The elements of risk financing are:

- identifying risks – those situations, policies, or practices that could result in financial loss (risk exposure)
- examining alternative risk financing techniques, such as purchasing insurance
- selecting the most appropriate technique(s) for risk financing
- implementing the selected risk financing technique(s)
- monitoring and improving the risk financing program

The process of risk financing encompasses a variety of issues including adequacy of insurance coverage (professional liability, property & casualty, workers' compensation, etc.), rights and obligations under managed care contracts, and mechanisms to evaluate and address the potential for loss in new ventures – to name a few. Your practice's risk financing program should be developed and regularly assessed in conjunction with advice from knowledgeable professionals. These professionals include legal counsel, financial specialists (accountant, financial advisor), and insurance specialists (broker, or agent).

Treating Minors

The New Jersey legislature has given most of the rights of adulthood to persons 18 years old and older. This includes the right to consent to medical and surgical treatment, as well as the right to sue. In most situations, minors (children under the age of 18) cannot be cared for without the consent of their parents or legal guardians.

- cases of emergency, where the child must be treated to save its life or to save it from potentially serious harm

- minors who are married
- minors seeking certain sexual-related care
 - abortion (subject in most cases to parental notification)
 - pregnancy-related care
 - sexual assault (a child of at least thirteen years of age may consent to treatment and parents or legal guardians must be notified immediately unless the physician feels it is not in the patient's best interest N.J.S.A. 9:17A-4)
 - venereal disease (child must be at least thirteen to consent)
 - drug/alcohol use or abuse treatment

More detail on [treatment of minors](#) can be found in a Risk Review article on that subject.

Family practice and pediatric offices often see minors who are accompanied by someone other than their parent or legal guardian. They may come in for a routine visit with an older sibling or with a babysitter. Some offices find it helpful to add space on the office's initial intake form for the parents or legal guardians to name those people they authorize to consent for urgent care for their child if they are not present. In this way, the practice can attempt to reach the parents for all requests for consent, but they also have the parent's written consent to allow another person to consent.

COMMUNICATING WITH PATIENTS AND OTHER PROVIDERS

Patient dissatisfaction with the physician-patient relationship is frequently part of the issues that lead to claims. Some of the underlying issues that contribute to patient dissatisfaction are:

- situations in which patients are confused by information and instructions for treatment
- unmet expectations for treatment outcome
- how they were treated by the physician and office staff

All of these factors closely relate to the patient's perception of the quality of the service they receive in a physician's office, and they all involve communication. Other communication-related claims develop out of inadequate, or lack of communication between care providers.

A majority of Princeton's claims involve one or more component/s of inadequate or absent communication.

Office Culture

It is said that much of communication is non-verbal, and what takes place in and around your office can speak volumes. How are patients treated when they call to schedule their appointment? Is the sign out front easy to find, or is it overgrown with bushes and vines? How does the front desk staff member greet the patient? Is the waiting room cramped and crowded, with a blaring television or music? These are just a few of the things that shape your patient's first impressions; and they are made even before the patient meets with the physician.

Physicians, staff, and even your office space combine to create a culture which you can mold suiting your needs and those of your patients. To improve patient safety and reduce the likelihood of claims your practice should work to create a culture of patient-centered service.

Creating and maintaining a service-oriented office culture focused on providing quality patient care and a high level of service is an important strategy for reducing your risk of a malpractice claim. A focus on customer service also is the foundation for your practice's efforts to engage patients in shared responsibility for their health care.

Promoting a service mind-set in a physician's office requires:

- physician leadership involvement to convey the message that the practice is committed to service excellence
- a Mission Statement that reflects the importance of patient satisfaction
- protocols that outline expected behaviors and mechanisms to achieve the mission (e.g., maintaining patient confidentiality, use of patient satisfaction surveys, how to handle complaints, etc.)
- involvement of all staff in setting priorities and attaining improvement in your practice's level of service

Making a Positive Impression

Techniques that enhance communications with your patients and convey a positive impression include the following:

Remember Common Courtesies

- be certain that your front desk staff greets your patients in a friendly manner upon entering your office
- require your answering service to follow the same rules of courtesy that you expect from your staff
- knock before entering an exam room
- make immediate eye contact
- greet the patient and introduce yourself
- address patients by their title (e.g., Mr., Ms., and Mrs.) and last name, unless given permission by patients to call them by their first name

Making and keeping eye contact is becoming even more crucial as healthcare moves into an age of electronic records and caregivers are tempted to focus on computer monitors instead of the patient in front of them. It has always been important to interact with the patient and avoid focusing on the chart in your hands. For those physicians and staff who are learning to work with laptops, or keyboards and monitors, this can be a bigger challenge.

If you are working with electronic health records it is important to remember that the patient is the focus of your attention. The monitor and the keyboard should only require occasional glances, and the monitor should be positioned so that looking at it allows you to keep looking at your patient. It should not cause you to turn your back on your patient.

Listen

- listen to your patients and let them speak without interrupting them
- repeat key information back to the patient after they have concluded their description of their chief complaint or reason for the visit
- determine what the patient hopes to get from the visit

Ensure Understanding

- involve the patient's family and significant others in the discussion (with patient permission)
- be considerate – restate information as needed
- use simple words and explain medical terms
- allow time for questions
- ensure that the dialogue is comprehensive enough to give patients a full understanding of their condition and the treatment plan
- pose open-ended questions to ascertain whether the patient understands
- be mindful that there is a wide spectrum of health literacy that is independent of a person's age, education, and economic status
- ask the patient to explain their understanding of the conversation to you so that you can be sure they are comprehending the situation and the proposed treatment plan
- consider cultural beliefs and practices that may influence your interactions
- have a mechanism available to provide medically knowledgeable interpreters for those patients who need them (this includes those patients who are hearing impaired)

Follow Through

- Patients, particularly the elderly or those on a complicated medical regimen, should be sent home with a brief written summary of their visit (this summary can be in the form of a pre-printed check-off sheet, requiring the physician to simply fill in reminders of what was discussed, such as changes in medications or returns to the office). Visit Summaries are also discussed in the Communication Tools segment of this section of the toolkit.
- Patients should be given instructions to call the office for results of tests if they have not heard from the office in a specific amount of time (this action does not represent an adequate method of patient notification of test results, but is intended to serve as a safety net, should your normal protocol of actively calling patients with results fails)

Mastering communication skills such as these serve not only to make a positive impression, but they can significantly improve patient trust and adherence to their treatment plan. This in turn improves patient safety. When trust is established between a physician and patient, as well as between the patient and the practice, the patient is more likely to be forthcoming with information that they may have withheld in other circumstances. Being fully aware of the patient's status allows the physician to make better informed care decisions, and fewer (if any) diagnostic errors.

Structured communication that includes attention to common courtesies, listening, and ensuring understanding don't necessarily take more time to accomplish, rather these skills can help to focus the patient visit and can reduce, and possibly eliminate those "afterthought" or "doorknob" questions that patients have. These skills can empower patients to be active participants in their care.

Patient Satisfaction

Actions that demonstrate a commitment to patient satisfaction in a physician office practice include:

- courteous treatment of all patients at all times without exception – in-person and on the telephone
- developing a telephone menu for automated call answering which is "user friendly"
- timely access to appointments and medical advice as needed
- providing adequate time for each patient visit to allow patient to effectively communicate their reason for the visit without feeling rushed
- monitoring of patient wait times with frequent updates to patients regarding delays, and the option to reschedule when a delay is longer than 30 minutes
- respecting patients' modesty, dignity and confidentiality
- continuously soliciting feedback on patient satisfaction during their visits (simple questions like: is that OK with you? are you comfortable? can give a patient an opportunity to give necessary and timely feedback which the practice can use)
- addressing patient complaints promptly on a case-by-case basis
- analyzing any trends in patient complaints and applying corrective actions to improve service
- rewarding staff for good customer service

[Patient Satisfaction Surveys](#)

Patient surveys are a valuable and more formal tool used to ascertain a patient's perception of the services provided by the medical practice. They are an invaluable means for improving communication between the health care provider and the patient. A survey is most useful if it is conducted at least annually.

One method of surveying a practice's patient population is by utilizing a mailed survey. Not all practices are able to take on that expense. Therefore, another effective method of distributing the survey is to hand them out at the reception desk, encouraging the patient to drop the anonymous, completed questionnaire in a designated box before leaving. Please note, however, that a survey handed out in the office has a potential weakness. There can be a general tendency to hand the survey to people who are friendlier and to avoid those patients who are upset. If using a survey in the office it must be distributed consistently to all patients.

A full survey is a formal collection of data and its results are to be compiled mathematically. An example patient [Satisfaction Survey](#) along with general instructions for its use and scoring can be found in the Forms section of this toolkit. This information is based on material from the Bureau of Primary Health Care, which is part of HHS' Health Resources and Services Administration.

Once the results are compiled, it is suggested that the practice manager provide an opportunity to review the results with the entire staff. Continually gauging patients' likes and dislikes will help improve the overall practice and reduce the risk of litigation.

An annual survey is typically conducted for a day or a week and, therefore, samples a limited portion of your patient population. To augment this result, mini-surveys can be done periodically throughout the year to address single issues and get a more varied survey sample. These mini-surveys can be used to ask single questions about specific issues the practice wishes to target for possible change, such as the phone menu or use of television vs. radio in the waiting room.

The practice can also survey its own staff to get their viewpoint on how they treat patients. This is a good reminder to each staff member of the behaviors they are encouraged to model. A form for [self-evaluation of staff behavior](#) is found in the Forms section of this toolkit.

Patient Triage

Scheduling patient appointments – based on assessed patient needs – in a timely manner is another opportunity to generate a positive perception of your office. Scheduling should adhere to standard written procedures that utilize the following criteria, modified as necessary to fit your practice:

- **Emergency Care** – life-threatening condition that requires immediate referral to an emergency room
- **Urgent Care** – conditions that require medical attention the same day
- **Routine Care** – conditions that are not urgent but require a timely appointment in the near future
- **Preventive Care** – physical examinations and similar services that require a visit within a reasonable period of time
- **Walk-Ins** – if walk-in patients are routinely accepted, regular patient scheduling must be amended to accommodate interruptions in visit flow.

Effective Telephone Communication

Telephone communication is a routine but significant component of every physician practice. Everyone in your office should be instructed to regard telephone calls as an opportunity to provide patients with good service and to obtain important information. A patient's first and lasting impression of your practice is often from a telephone call.

Phone Set Up

- train all office staff in telephone etiquette, including handling an angry or dissatisfied patient; the attitude of the person who answers the telephone will set the first impression of your office
- a caller should always have the option of speaking with a person
- try to answer the telephone by the third ring and monitor calls that are put on hold; allow callers to speak first, and ask for and get permission to place them on hold
- if your office is equipped with an automatic call distribution system, limit the menu selections to four or five at most; the first message should always be, "if this is an emergency, dial 911 or go to the nearest emergency room immediately"
- conduct telephone conversations out of the hearing of patients to protect the caller's privacy
- install additional phone lines if all lines are frequently in use or chronically busy

Giving & Receiving Medical Information

- Obtain the caller's phone number and confirm identifying patient information.
- When a return call is required, ask the caller what time he or she will be available, and give an approximate time for the return call. Then, make return calls as promised. This conveys a message to patients that you care and are respectful of their time and concerns.
- Develop a Telephone Advice Protocol Manual for nursing and other staff authorized to give telephone advice that addresses areas such as handling routine questions and doing telephone assessments and triage. Monitor staff compliance with the protocol.
- Instruct staff to consult a physician or other designated clinician whenever they have concerns or questions regarding their telephone assessment or advice. Respond promptly and positively when staff seek guidance.
- Develop a policy and procedure for handling phoned-in lab reports that include how "panic values" are to be relayed to the physician.
- The practitioner who orders a test should be the person who calls the patient to communicate sensitive results.
- To reduce the chance of miscommunication when calling in a prescription or giving treatment instructions, ask the person with whom you are speaking to repeat what you said, and then you repeat it once more.

Handling Prescription Refill Requests

- Protocols for handling requests for prescription refills should include review of the patient's chart, physician/prescriber approval and documentation in the chart of the request and refill.

What to Document

- [Document every telephone communication](#) with a patient or family member, including date, time, caller's name, complaint, and advice/prescription given. Also document all telephone calls with other providers. Consider use of duplicate telephone message pads, and maintain one copy chronologically in the patient's medical record. Princeton will provide, at [request](#), patient telephone call record pads for after-hours calls; these notes peel off the original pad and stick to the chart sheet, providing a complete record for continuity of care and minimization of liability.
- Date and document the medical record when you call a patient and must leave a message with a family member or on a recording device, or if there is no answer.
- Maintain appointment books and [telephone logs](#) with entries written in black or blue ink. Entries should never be erased or obliterated with erasure fluid. When making a change, write a single line through the information already entered, and record the change below. Keep old appointment books and telephone logs for as long as you maintain medical records.

Answering Service

- Use a reliable answering service during off-hours. Place test calls regularly to assess the quality of the service. Provide the service with an emergency number in the event that the physician on call cannot be reached.
- If you do not use an answering service, have a process in place to promptly retrieve and respond to off-hours calls.

Monitor Trends

- Consider keeping a log of categories of calls received such as scheduling, test results, prescription refills, etc., as a way to identify trends possibly needing revision or improvement in your system for managing telephone communications.

Communicating Test Results is Critical

When tests, consults, or referrals are ordered, the practice should inform the patient of the results of the tests or exams. This includes notifying them of both abnormal and normal findings, and documenting that notification in their medical record. This exercise of notification is part of a continuum of tracking the test from order to notification and documentation. Tracking is discussed in more detail in this toolkit's [Tracking and Follow-Up section](#).

Failure to follow up on test or consult results leads to claims. In Princeton's experience, this is a persistent problem which can only be improved by a determined approach to the process of ensuring that information is communicated to the patient. It is suggested that all test results be consistently handled by being:

- routed to the physician who ordered the test
- reviewed and appropriately signed off by that physician (i.e. initialed and dated)
- shared with the patient on a timely basis
- documented in the patient record

Each practice should establish what 'timely' means to them and their patients, but in general it means that "panic" or critical values require immediate notification (usually by the physician themselves). The definition of what constitutes 'panic' or 'critical' should also be established by

the office and that sometimes may be in part determined by a specific patient's condition. It most definitely will not only be what a lab labels as panic or critical. To be specific, a patient whose normal potassium level is above normal (as patients with kidney disease may be) will have a different level for a critical value, but it will be very important to respond quickly if the patient reaches their personal panic value.

In keeping with that same example, other values which are abnormal for the patient may require a phone call within 24 to 48 hours. This phone call might request a return to the office, a medication adjustment, or another test for confirmation of the initial results. The difference between the two reactions is not subtle; patients with true critical values may be in potentially life threatening situations needing immediate follow up, but other abnormal values require a quick response instead of an immediate reaction.

Notifying the patient of their test results on their next visit can be effective if the results are within normal limits and if the visit is scheduled within a few weeks of the first visit. If the circumstances are different, however, it is appropriate that the patient be notified by phone or mail that their tests or consult report were negative. This reassures the patient, completes the practice's responsibility regarding timely notification, and improves patient satisfaction.

All notifications, whether by phone, in person, or by mail, should be documented in the patient's medical record. If the notification was by mail, a copy of the letter to the patient, filed in the chart, is sufficient.

As a safety practice, it is appropriate to tell patients to call the office if they have not been notified of their test results after a few weeks. This backup measure can be helpful in catching any missed notifications; it also keeps the patient involved in, and a responsible party in, their own care.

Email Communications

Both patients and physicians may feel that email is a helpful alternative to missed phone calls or voice messaging. It has the advantage of flexibility (it can be sent or accessed at any hour), speed (test results can be sent much quicker), documentation (it provides a written record of every communication), and information (it can be used to provide readers links to resources the practice feels important for them).

But email has risks. Patient privacy and confidentiality can be breached; this includes possible violations of HIPAA. Email can be intercepted, misdirected, or forwarded. Practices can be accused of not sending responses to a patient's email, or test results, in a timely manner because email can be its own proof. It provides a record of what was sent and, conversely, what was not sent; and all email records are timed and dated. Deleted emails can be recovered so a practice cannot maintain that they sent something and then delete records of the email. Emails are also subject to discovery in malpractice cases.

If a physician or practice decides to use email as a form of communication with patients, steps should be taken in preparation for implementation, developing guidelines for acceptable and unacceptable use. **Please note. It can be deceptively easy to move from simply making appointments online to dispensing medical advice and diagnosing online. The latter two activities represent an unacceptable risk level. We are, therefore, providing you the following suggestions:**

- the practice should develop a policy regarding email, specifying uses and limits, allowable content of messages (no anger, sarcasm, criticism, or remarks that could be interpreted as such, or any other negative values)
- the practice should develop a policy regarding email, specifying restrictions on patient-identifiable information being sent to anyone besides the patient or their designee
- HIPAA regulations require encryption (such as password protection) for all email which transmits patient PHI (protected health information)
- patients should be informed of permissible uses such as prescription refill requests and appointment scheduling requests or reminders
- patients should be informed that email is not the appropriate format for relaying questions of a serious nature, since there could be a delay in receiving or checking the emails and these questions need to be answered more quickly
- patients should be informed of inappropriate uses such as relaying sensitive information (HIV, behavioral health information, etc.); specifically, the patients should not be sending this information or discussing this information via email
- to keep emails private (since patient emails to the practice are usually not encrypted) patients should be informed of appropriate set-up of their emails (they should put a category in the subject line and their name and patient ID number should be put in the body of the email for extra privacy)
- patients should be informed whenever their treating physician is unavailable, the name of the covering physician, and informed that their email may not be addressed until after their treating physician returns
- the practice should determine a reasonable turnaround time for resolution of email messages from patients and should communicate that expectation in an automatic reply acknowledging receipt of the message
- the automatic reply should also direct patients to call 911 or go directly to an emergency department if their situation is an emergency
- patients should be informed that all matters that need to be addressed more quickly than the email turnaround time would allow, should be handled by other forms of communication (specifically they should call if they need a quicker response)
- if the practice intends to engage in email dialogs with patients, or to send information to patients via email, the practice should develop a consent form for use of practice/patient email (this form would be used to obtain the patient's written consent to email them) and the signed form should be placed in the patient's medical record
- if group mailings are sent patient names should be blind copied so that no recipient can read the names of other recipients
- the practice policy should also include keeping email software up to date, maintained, and regularly backed up on secure storage devices such off-site secure servers (for disaster recovery)
- specific patient emails, appropriate to the care of the patient, should be printed out and included in the patient's record (if using paper charts), or copied into the patient's electronic medical record

Shared Decisions, the Dialog of Consent

Informed consent is often equated with invasive procedures, yet patients and providers engage in consent discussions every day in all types of situations. For example, a dialog regarding the pros and cons about changing a patient's medication regimen can be an exercise in shared decision making.

The U.S. Preventive Service Task Force (USPSTF), part of the Agency for Healthcare Research and Quality (AHRQ) defines shared decision-making as a process involving the clinician and the patient “in which the patient:

- understands the risk or seriousness of the disease or condition to be prevented
- understands the preventive service, including the risks, benefits, alternatives, and uncertainties
- has weighted his or her values regarding the potential benefits and harms associated with the service
- has engaged in decision making at a level at which he or she desires and feels comfortable

This process has the goal of an “informed and joint decision.”

The task force also describes informed decision-making as the “individual’s overall process of gathering relevant health information from both his or her clinician, and from other clinical and non clinical sources, with or without independent clarification of values.”ⁱ

Making patients part of their own health care treatment plan decisions can empower them and also make them more responsible for their own health. Each practice, therefore, should incorporate basic shared decision making communication techniques into its processes. In procedure based practices and practices that utilize high risk medications or other treatments, these communication techniques can be expanded to include a consent form. In all practices, the decision whether to use a shared decision or informed consent discussions should be based on whether the proposed treatment is:

- a surgical or invasive diagnostic procedure
- any treatment where the risk of complication is common
- any treatment where the risk would have grave consequences (such as with high-risk drugs, some immunizations, etc.)

This type of dialog becomes even more important as patients experiment on their own with personal empowerment for their health decisions. They ask for, and sometimes demand, tests or medications that they have heard about, and that they believe will be important to their diagnosis and treatment. As a clinician, the physician may believe the requested test or drug may be unnecessary, or even detrimental. In these situations a shared decision making process helps both patient and practitioner come to a conclusion that can maintain patient safety and quality care.

Shared decision making and [informed consent](#) are points on the same timeline. They are not mutually exclusive. In shared decision making the patient is given information, sometimes through brochures and videos along with discussions with the physician, and then makes their decision after weighing their options. Shared decision making is, in effect, that fundamental basis upon which true informed consent is based. A patient who has a consent form in their hand, and is asked to sign, should have been given the opportunity to dialog at length with the physician, and review brochures, videos, or other educational materials as available and appropriate. The decision made in informed consent should be a process, shared with the physician.

More information on shared decision making can be found in a [Risk Review article](#) on the topic.

Communication Tools

Your practice can incorporate a number of tools and processes into your routine which enhance communication with your patients and within the practice team. Some of the tools are Patient Agendas, Practice Brochures, Websites, and Visit Summaries. Team Huddles enhance team communication.

Patient Agendas

A [patient agenda](#) is an effective tool for helping to keep an office visit focused on what prompted the patient to come in. It can help to ensure that all of the patient's expectations for that visit are met. It can be especially effective for those patients who have longer lists of complaints each time they come in, or for those patients who tend to forget something important while they are with the physician, thereby necessitating a call to the office one or more times with extra questions. Having an agenda filled out by a patient with a long list of issues allows the physician and patient to pick the top two or three issues that can be covered in the current visit, and when appropriate perhaps make a second visit to address the rest.

Practice Brochures/Websites

Not all practices will decide to develop their own brochure or website, but they can be effective tools. Brochures and websites are a great way to introduce and orient patients to your practice. While they are not a substitute for effective communication, brochures and websites can provide patients with information ranging from your care philosophy and core values to practical office matters, such as scheduling appointments and office hours.

Brochures and websites can help you showcase your services and accomplishments. However, they should never promise perfect results or contain unnecessary superlatives describing physician skills.

Visit Summaries

A practice may consider offering an [information sheet](#) that summarizes the most important points of the patient's visit and explains what he or she needs to do after leaving your office. This can be valuable in achieving patient adherence to agreed-upon treatment and follow-up. In today's hectic environment, a summary of the office visit can be invaluable. It's also particularly useful for parents of pediatric patients as well as primary care or specialty practice patients who may be confused or have memory loss. It can be helpful for older patients whose children cannot attend the visit, but want to know what was discussed and what the care plan is. It enables the patient to leave knowing they have a reference for what was discussed and what the plan is for further action.

To simplify doing visit summaries, the practice can use a standard format with checkboxes and space to write brief notes. Those practices with EHR systems may already have the capability to print a visit summary embedded in their software.

Team Huddles

The quality of patient care, as well as the efficiency of the office practice, relies on a well-designed framework to facilitate communication. Team huddles can be a very effective framework for enhancing communication within the team so that everyone has a better idea of what the day will bring. Team huddles, or briefings, are utilized by crew members of airlines to

assure safety and efficiency. Everyone is made aware of the plan, any alternations to the plan and their roles and responsibilities.

In an office practice, a team huddle may take different forms. Staff may gather at the end of the day, when all charts have been pulled for the next day. During this brief meeting the group goes over the plan for the next day, anticipating as many needs as possible in advance. In other situations, this type of huddle may occur before patients arrive in the morning. In large practices it could be divided up into huddles which include individual physicians and their staff. These meetings are always brief and simply orient all members of a particular team to their plan for the day. It brings focus to the task at hand and the mission of the day, which is good patient care.

Posters

At Princeton Insurance, we encourage physicians to build a partnership with their patients by helping them to take a more active role in their care. When patients ask questions and seek to understand their doctor's point of view, they are more likely to arrive at an agreed-upon understanding of their condition and treatment. Ultimately, this partnership can reduce the likelihood of medical errors and miscommunication.

In the past, much of the responsibility to ensure that effective communication takes place between physicians and their patients has fallen squarely on physicians. Princeton's approach seeks to get patients more involved, ultimately helping them begin to take more responsibility for their own health.

In conjunction with the various techniques referenced in this Princeton Insurance Physician Office Practice Tool Kit, physicians can foster a partnership with their patients by encouraging dialogue between themselves and their patients.

Patient communication tools, developed by Princeton, may be used in several ways to accomplish this goal. They are available in both English and Spanish.

Communication posters may be placed in your waiting room and in each exam room for patients to reference while they are waiting for you.

Click below to view posters in your browser:

- [11"x17" color Communication poster](#)
- [8.5"x11" color Communication poster](#)

[Click here to order posters for your office.](#) These posters are free of charge, when ordered appropriate to the size of the practice. You may also contact our Risk Resource Line at 1-866-Rx4-Risk (1-866-794-7475) to order.

Handouts

You may provide patients with a two-page patient communication handout (which can be copied as one double-sided page) as they arrive at the front desk to sign in. Your staff can instruct patients to review the information on the handout and encourage them to make sure the physician addresses their questions before their appointment is over.

Click below to view downloadable **handouts** in your browser:

- [8.5"x11" color Communication handout](#)

- [8.5"x11" black & white Communication handout](#)

Also available in Spanish:

- [11"x17" color Communication poster in Spanish](#)
- [8.5"x11" color Communication poster in Spanish](#)
- [8.5"x11" color Communication handout in Spanish](#) to download
- [8.5"x11" black & white Communication handout in Spanish](#) to download

All of the above tools can be downloaded to your computer after opening the file by right clicking on the file name and selecting the "Save Target As" option.

Please note: These downloads require Adobe Acrobat reader. This Adobe Acrobat software, which comes standard with almost all new computers, can be downloaded for free at www.adobe.com/products/acrobat .

Communicating Under Stress

Though attempts are made to keep communication between practice, patient, and family members as stress-free as possible, medical care can be a tense area for all parties. The following are a few of the situations you may encounter in which you will find communication more stressful.

In all of these situations, communication should be kept non-confrontational. This is not easy to do when a patient or family member is upset, but confrontation may be minimized if:

- the possibility of confrontation is considered and planned for
- the patient and family are treated with honesty, respect, kindness, and an attempt at understanding them
- practice staff and physicians do not become defensive

Anger and Violence

Though it does not happen frequently, office practices may be required to respond to patient or family anger. The anger may be expressed in a variety of ways, through letters, phone calls, or direct confrontation and/or threats. Now that there are websites which encourage patient review of physicians and their practices, there can also be angry postings on the internet.

Responding to patient/family anger resembles the steps listed in the section on Patient Complaints. However, responding to patient anger may require more preparation on the part of physicians and staff. To be prepared to handle anger, and possible violence, the practice should have a policy in place that:

- includes a zero-tolerance policy for violence (including verbal and non-verbal threats, sexual misbehavior, and any form of bullying)
- defines the difference between anger and violence, or potentially violent situations
- covers not only patients and visitors, but also covers all staff and physicians
- encourages prompt reporting of any incidents in a non-punitive environment
- defines security for the practice, both inside and on the grounds
- commits to the safety of staff, physicians, and all others who may be present (other patients and family members)

Consideration should be given to establishing emergency signals or codes to be used by staff and physicians if a patient is violent or in danger of becoming so, or in situations where the patient is using verbal, sexual or other bullying behavior.

Angry behavior carried out through letters, phone calls, and other media such as web postings can be addressed in ways specific to the approach taken by the patient or family. The practice's policy may include instructions that:

- angry letters should be responded to verbally whenever possible, since it is easy to misinterpret what a person has written, and it may be impossible to understand until you have a chance to discuss the situation with them
- angry phone calls can be handled by the physician, who may be able to clarify with the caller the reason for their emotion
- abusive calls, or calls which become abusive, may be politely terminated
- web postings may be nullified or reduced in intensity by positive reviews; at this time there are no other workable measures to counteract this type of complaint

Angry or disruptive behavior on office premises requires a different approach. The practice's policy may define responses to these patients and visitors in a different manner because the goal will be the protection of staff, physicians, and other patients/visitors. The policy may include instructions such as:

- patients or visitors who become abusive or disruptive in the office may be escorted to a private area in which to discuss their complaints so that others are not upset by their behavior and so that they may be calmed
- a disruptive person who is asked to go to a quieter part of the office can only go there of their own free will, they cannot be coerced or physically moved in that direction
- this part of the policy can also include information on:
 - keeping the disruptive person at least two to three arms length distance from any staff member or physician
 - always making sure that there is a safe exit for staff (that is, the disruptive person should never be placed between staff and the door)
 - there are no potential weapons (sharp, heavy objects) in the room
 - using a firm tone of voice, and no defensive behavior or speech
 - promising the offender that they will be escorted from the office if they cannot amend their behavior

If it is believed that the disruptive person is too much of a threat to be brought back into a more private area, they can be asked to leave the practice premises with an explanation that their current behavior is not allowed by practice policy. Also, if it is believed that the disruptive person remains a threat (lurking in the parking lot, cruising up and down the street, or in any way indicating that physicians and staff will not be safe when they leave) local police may be notified of the situation.

In all cases involving angry patients, whether or not they become violent and threatening, the practice may consider [discharging the patient from the practice](#).

If a decision is made to try to work with this patient, it is appropriate to write a clear and simply worded statement describing the behaviors they have manifested, and that will not be accepted in the future by the practice. The statement can also review the consequences of further disruptive behavior. The physician may review this statement with the patient and the patient

can sign and date it. A copy of the statement can then be sent home with the patient, while the original remains in the patient's medical record along with documentation of their behavior and discussions with them about it.

Disclosing Difficult Information/Apoloizing

Unanticipated or adverse events can happen in the course of care, and when they do the patient and/or family should be told about them. Each practice should have a policy for handling this type of situation. The policy should address what an adverse event is; what will be disclosed; when, who, how, and where the disclosure should take place.

An adverse event is any event that:

- causes injury to the patient
- causes (leads to) the patient's death
- causes the treatment plan to change unexpectedly (even minor things)

The event should be disclosed when the event is discovered, or as soon as possible afterwards. In the practice setting this may mean that the patient may be required to return to the office for the discussion.

The physician involved and/or the patient's treating physician (if they are not the same person) should be present. In most cases only the treating physician will be there, but if a partner is involved in the event, they should also be present. Some practices may wish to have a managing partner present in all such discussions.

The exception to this would occur in situations where the involved physician is emotionally distraught. In circumstances such as these it may be advisable to have a group discussion, bringing in another physician from the practice and possibly a staff member that the patient or family is comfortable with.

The actual disclosure conversation:

- shares only the facts that are known
- uses clear language, words that the patient/family understand, and communicates with them very simply (at approximately a fifth grade level)
- is honest and caring
- does not speculate as to cause, responsibility or blame
- asks the patient/family open-ended questions such as "How can we assist you?"
- promises to keep the patient/family informed of any future pertinent information which may become available
- is held (if at all possible) in a quiet, comfortable setting (in a practice this might be in the physician's office with the physician sitting with the patient/family, not behind the desk)

Apologies have their place in healthcare. For instance, if you were detained and your patients had to wait an extra fifteen minutes in the waiting room, it is simple courtesy to apologize when you see them. Doing something as simple as this can help reduce tensions and ill will in your patient; this can ultimately increase patient satisfaction.

In the same way, an apology may be appropriate after an adverse event; however, it is best if this apology is more carefully thought out than the prior example. When a patient has suffered an adverse event, the exact cause of that event is often not clear until after an extensive

investigation. Therefore, it may be appropriate to express regret for what the patient has actually suffered (inconvenience, pain, anxiety, etc). On the other hand, saying that you are sorry that you (or someone else) made a mistake may turn out to be incorrect because the investigation may show that a process error led to the event.

In all cases of disclosure and/or apology it is necessary to document in the patient's medical record that the conversation took place, what the patient was told, the patient's response, and the agreed upon plan between the patient and the practice.

Patient Complaints

Patients do not always complain. As noted in the patient satisfaction section, patient's feedback can be solicited at any time during any visit. In this way, practice staff and physicians may discover something that could be improved, something that is bothering that or other patients. Doing this may forestall future complaints, or loss of patients due to their dissatisfaction with the practice.

In spite of efforts at prevention, the practice, or individuals in it, may receive complaints. The practice staff and physicians, therefore, can:

- have a policy prepared in advance which details how the practice will respond to a complaint
- make sure all staff and physicians are familiar with the policy since patients may complain to anyone in the practice
- listen carefully and respectfully to each complaint
- ask for clarification, if necessary, only after the complainant has finished their initial complaint
- apologize for the inconvenience or frustration experienced
- offer a workable solution (if it is appropriate for the practice and within the respondents power to accomplish)
- promise that the practice will take a close look at the problem to identify possible solutions, and implement them (if this is required)
- thank the complainant for taking the time, and making the effort to share this with the practice

Patients Who Record Conversations with You

You may encounter situations in which patients ask for permission to tape their conversations with you. More information on this can be found in a [Risk Review Online article](#).

Other times, you may find that they already have taped you surreptitiously. This situation is addressed in an additional [Risk Review article](#).

Communicating With Other Providers

A majority of Princeton's cases are rooted in communication breakdowns, whether between physicians and patients/families or among the physician and other providers of care. In the practice setting, management of a patient's care depends on good communication between the various parties involved in the patient's care. Phones, faxes, emails, written reports, and the occasional 'hallway consult' all are vehicles used to accomplish this task.

[Consults and Referrals](#)

While often a time-consuming and inadequately reimbursed process, referrals necessitate the need for diligent communication and coordination of care across multiple settings and providers. Consultations must be performed following a systematic process and in a timely manner to maintain continuity of care, enhance patient care and satisfaction, and to help prevent serious adverse consequences that would impact all those involved in the care, especially the patient.

Direct communication helps to establish clear responsibility for monitoring or follow up and avoids the false reliance of one physician upon the other that the patient is being followed. Failure in communication between the primary care physician (PCP) and the specialist as to who will monitor and follow up with the patient on a continuing basis is a common source of liability exposure.

[For referring physicians](#)

When referring a patient to a specialist, be cognizant of the process:

- whenever possible, speak personally with the consultant, before the patient is seen, especially in “urgent” situations
- avoid leaving a request for a consult with an answering service; however, if absolutely necessary, be sure to follow up to ensure consultation request was received
- explain to the patient why the consult is being requested and document this discussion in the medical record
- develop a standardized [format for ordering consults](#); information should be provided, such as: relevant patient history, working diagnosis, what tests/diagnostic studies have been performed and current medications
- indicate the type of consultation being requested and notify the specialist of its urgency
- keep track of all ordered consults on a [log sheet](#) (if using a manual system) to facilitate accurate tracking

[For consulting physicians](#)

- answer a consult in a timely fashion
- speak with the PCP before and after the consult, and clearly establish who will follow the patient regarding your findings
- respond to the consult according to the type of consult requested
- explain to the patient your role in his/her care
- avoid inflammatory verbal or written remarks about previous care and treatment
- provide the patient with feedback as to your findings, their therapeutic options and whether further studies or follow-up are indicated, explaining why they are needed

Careful tracking of a patient’s care and good documentation of the same help minimize liability risk. Some information on this can be found in both Reducing Risk documents and Risk Review articles.

- a Risk Review article on [consults](#)
- tracking and follow-up of tests and consults are [discussed](#) in a Risk Review Online article

Most of these topics are addressed in more detail in other sections of this toolkit; this section will focus on hallway consults.

Hallway Consults

Informal requests for advice from one physician to another are made routinely and they can be helpful. They also pose a risk for both physicians. When involved in “hallway consults”, it is a good idea to remember the risks and requirements of your role in the discussion.

If you are requesting information:

- bear in mind that the advice you receive may be inaccurate since the person you have talked with may not have had a chance to examine your patient and/or review their records
- unless they are formally brought in as a consultant, do not record their name in your patient’s chart as the source of the advice you are following
- ask for a full “official” consult when your patient’s case is complex

If advice or information is asked of you:

- remind your colleague that your advice could be inaccurate since you only have a partial picture of the case
- suggest that a full consult may be more appropriate if the case is complex
- suggest that a full consult may be more appropriate if you are approached multiple times on the same case

More information on consults, referrals, and their follow-up can be found in this toolkit’s section on Follow-Up systems.

ⁱⁱ Sheridan, Stacey L., MD, MPH, Russell T. Harris, MD, MPH, Steven H. Woolf, MD, MPH, for the Shared Decision-Making Workgroup of the U.S. Preventive Services Task Force, *Shared Decision Making About Screening and Chemoprevention: A Suggested Approach from the U.S. Preventive Services Task Force*, American Journal of Preventive Medicine, 2004.

FOLLOW-UP SYSTEMS FOR THE PHYSICIAN OFFICE: OVERVIEW

“Failure to diagnose” claims are among the most common and more serious types of medical malpractice allegations. Frequently claims arise as a result of a detrimental delay in following a patient’s medical condition. More often than not, the physician is completely unaware that the patient failed to have the prescribed treatment, diagnostic evaluation, or recommended referral or consult, as the medical condition worsens.

The patient then sues the doctor, alleging that he/she either failed to recommend the treatment or the evaluation, or didn’t explain the risks of non adherence to the treatment recommendations. If, however, the physician can offer chart documentation that demonstrates attempts made to contact the patient and encourage compliance with the recommended follow-up and diagnostic studies, the physician’s ability to defend against such claims will be materially strengthened.

Therein lies the importance in developing and utilizing follow-up systems in the physician office. Many medical office computer programs have excellent recall and follow-up capabilities. If the system you currently utilize does not, or if the office still maintains paper records, forms such as the [Diagnostic Test Tracking Log](#) and the [Follow-up Appointment Log](#) represent some effective and efficient manual systems you may wish to investigate. One is not more reliable than the other, as each system works well. It is purely a matter of preference. All that is necessary is that you HAVE a system in place for your patient’s protection as well as your own.

Systems in your practice can benefit from careful tracking, by computer or manually. As noted above, situations often seen in claims are those which involve ordered tests and consults or referrals. Another issue which benefits from careful tracking is patients on high risk medications. The medications themselves (prescription renewals and dosage levels) and the lab tests required to monitor blood levels for certain drugs should be tracked to prevent over or under treatment. You will find more information on this type of tracking in the [Medication Safety section](#) of this toolkit.

As you evaluate your practice you will be able to identify those systems which are, in effect, lynch pins in your patient’s care; those are the processes which require tracking.

Tracking Systems

Components of an effective tracking system include the following:

- built-in redundancies such as separating charts with pending reports and keeping a log of all orders and referrals that includes the expected date that the report should be received in your office
- a mechanism to ensure that recommended referrals for tests and consults are scheduled or done in a timely manner
- a process for review of all test reports by the ordering clinician or other designated staff member such as an MA or RN
- written protocols requiring that all positive or borderline results be promptly communicated to the ordering physician or other clinician if non-physician staff review reports

- determination of critical or “panic” values that require immediate physician attention and making sure that all clinical staff are aware of the values
- reminders to patients who have not had recommended tests or consults
- patient notification of test results (abnormal and normal) by clinical staff
- instructions to patients to contact your office if they have not been notified of test results after a certain period of time following a test
- patient reminders about routine and preventive care

How to Develop Manual Tickler System

1. Obtain a card file (3.5” x 5”, 4” x 6”, or 5” x 7”) with monthly dividers.
2. When the physician indicates that a patient must follow up with diagnostic studies, be seen in consultation with a specialist, or return to the office in a specific time frame, fill out a card with the patient’s name, medical record number, telephone number and address, the type and reason for follow-up, and the year and month that the follow-up by your office is due.
3. Place this card in the file box in the slot for the month the patient needs follow-up.
4. There are two ways to complete the process: a Pre and/or a Post Initial Contact:
 - a. **Pre Contact** – If you wish to remind the patient prior to the date, then pull all cards in the month before the patients are due to return. Call or send a reminder card to them. It is important to keep the cards until the end of the month in which the patient was to return. You need to recheck these at the end of the month and notify the patients who failed to comply.
 - b. **Post Contact** – You may wish to eliminate the double-check system above and simply pull all the cards at the end of the month and check charts to verify if patients complied.
5. Follow-up attempts should include, at the very least, one phone call; if that is not successful, one letter.

All attempts should be documented in the chart. If the condition is serious (a potential cancer patient), send a certified letter with return receipt requested. This receipt is then filed in the chart with a copy of the letter for documentation purposes.

Documentation Which Supports Your Tracking System

It is important that the actions your office takes with regard to patient referrals and follow-up be documented in the patient charts. This documentation should include the following:

- discussions with patients regarding the need for a consult
- communication with a referring or consulting clinician, including written correspondence
- follow-up with patients regarding test results including the caller’s name, date, time, and the person contacted
- patient decisions not to have recommended tests or consultations, with documentation that the patient was advised of the potential consequences
- date and signature or initials of the reviewing clinician recorded on reports
- reminders to patients about recommended tests, consults, or follow-up
- missed and canceled appointments
- copies of any written correspondence regarding a referral or follow-up

Princeton's Risk Services has written a brief [article on tracking tests, consults and referrals](#). Another Risk Review article on the [risks of walk-in hours and urgi-care centers](#) focuses on tracking patients, as well as their tests and consults, in these special circumstances.

Patients Who Require Special Tracking

In some situations a practice may develop a process which would identify all patients of the practice who require routine testing or follow up, and a system to track those necessary tests from order to results. Patients who are on medications which require routine lab tests to monitor blood levels, such as anticoagulants, are an example of this type of system. In this situation the practice may:

- identify all practice patients who are on the monitored medication
- keep an [anticoagulation log](#) of all tests, their results, medication doses, and any comments

HUMAN RESOURCES

Practices related to the area of Human Resources (HR) are many and diverse, ranging from the administration of employee benefits, to employment practices such as “hiring and firing.” It is advised that your Human Resources policies and procedures be developed in conjunction with qualified legal counsel to ensure strict compliance with applicable state and federal laws including civil rights, the Americans with Disabilities Act, Family Leave, sexual harassment, and Workers’ Compensation. Members of your practice represent the practice and you, the physician. You can be held vicariously liable for their actions. That legal concept, along with the Americans with Disabilities Act (ADA) can be found in the [Legal section](#) of this toolkit.

As practices face a challenging healthcare market, one of the most important business decisions that can be made involves the choice of the team members who will care for your patients. Good employees, placed in the right jobs, contribute greatly to the success of the practice by improving patient satisfaction and reducing errors. Employees who perform unsatisfactorily, on the other hand, can undermine your success.

The following are some general recommendations for your HR practices, divided into specific categories. If your practice is very small, specifically, only one physician and one or no staff, you will need very few policies and much of this section can be scaled down to meet your requirements. There are still some important guidelines that even a practice with one staff member may find useful.

Hiring

- All practice positions should have job descriptions. A job description helps define the employee’s role within the practice. It is the basis for routine performance evaluations and discipline, if necessary. Further detail on job descriptions, and an example form, can be found in [Job Descriptions and Performance Evaluations for the Office Practice, March, 2008, Risk Review](#)
- Have criteria-based job descriptions that list routine responsibilities, including physical requirements (such as ability to assist patients on and off examination table, etc.) and those core competencies which are required for each position in the practice.
- The use of physician extenders such as nurse practitioners, physician assistants, and counseling psychologists, requires that there be specific policies to address:
 - scope of practice
 - allowable procedures and assessments
 - terms and extent of supervision
 - training required
- In the case of nurse practitioners and/or physician assistants it is also appropriate for the practice to have, on file, a written agreement between that physician extender and their collaborating physician. This agreement should address the above, plus:
 - coverage requirements (for both)
 - quality assurance (including outcomes review)
 - circumstances that will require immediate communication with the physician
 - documentation in the medical record (and review of same)
 - on-site visits for purpose of supervision (if the extender does not practice at the same site as the physician)

- The state of New Jersey has very specific regulations for nurse practitioners and physician assistants. It is vital that a practice using these extenders be familiar with these rules.
- Your interview process should focus on the candidate's behavioral capabilities as well as their educational and experiential qualifications. For instance, you might ask: "Tell me about a time when you were required to handle an angry customer." By allowing a few such open-ended questions in your interview, you may be able to make a better decision on the best candidate for the job you are trying to fill.
- Both the application and the interview process should avoid questions which could be interpreted as discriminatory. These would include things like age, religion, marital status, sexual preference, nationality, or ethnicity.
- During the interview, let the applicant know a little about your organization, communicating your practice's mission and values. This helps them decide whether your practice is where they want to work, leading to a better fit for both you and your new employee.

Credentialing and Employee Records

- Each practice should identify the person or persons who will be responsible for gathering and maintaining credentialing and recredentialing materials. Recredentialing may be done every two years; however, New Jersey State Board of Medical Examiners' Statutes and Regulations (www.state.nj.us/lps/ca/bme/bmelaws.pdf) has specific credentialing requirements for individuals with different types of certifications and medical training. Specifically, one employee may be required to be recredentialed every three years while another is every two. It is important for the practice to be aware of these regulations and to follow them.
- All certifications should be approved by the practice's governing body. In a large practice this may be the practice's Board; and in a small practice it may be the owning physician or physicians. Whatever form the governing body takes, this approval process should be formal. The member or members should sign off on their acceptance or rejection (with reasons) of the applicant's credentials.
- There should be a written agreement between the person being hired and the practice. This agreement can be in the form of a contract or an application. It should contain information such as:
 - personal data (biographical)
 - personal history, including: any criminal convictions or history of illegal drug use, loss of license, or loss/limitation of privileges
 - an attestation by the applicant that they are able to perform the job as explained in the job description
- There should be documented evidence that physicians and other licensed practitioners in your practice have the education, training, experience, licensure, competency and privileges, as appropriate, which are commensurate with their responsibilities in the practice. Relevant documents and information (obtained from primary sources) include:
 - diplomas of medical or other professional training
 - licensure verification
 - board certification verification
 - DEA number
 - continuing medical or other professional education certificates
 - work history
 - performance appraisals (references)

- malpractice history (open and closed claims)
- The practice should also obtain information from The Office of the Inspector General (OIG) List of Excluded Individuals/Entities at <http://www.oig.hhs.gov/exclusions/index.asp> for information on previous sanctions by Medicare and Medicaid.
- The practice should also do background criminal checks.
- If a physician or other licensed practitioner requires proctoring or supervision, this should be documented. The fact that the required proctoring or supervision is provided also must be documented.
- Keeping aware of current standards of practice within your specialty is essential. In a group practice, physician performance evaluations can be conducted through a regular peer review process that includes consideration of factors such as scheduling and attendance, patient satisfaction, malpractice claims, productivity, efficiency, discussion of difficult cases, and quality of medical record documentation.
- In the future, those practices whose physicians use Hospitalists and do not practice at a hospital or other facility may find it more challenging to credential their physicians. This may evolve as hospitals become less willing to credential physicians who do not maintain staff privileges. This is, of course, a concern primarily for those practices which have relied on hospital credentialing to credential their physicians in the practice. Those practices will have to find other ways to support the assertion that their physicians are capable of doing the tasks they wish to do.
- All licensed and/or certified members of the practice must show proof of license and/or certification and a copy of this proof must be maintained by the practice. This means that all nurses, aides, and technicians should be required to present their licenses or certifications each time one is renewed. The practice should keep a log of these anticipated renewals so that staff may be reminded to comply.
- File information on employee health, credentialing, and quality assurance should be kept separate from other standard information in personnel files.
- Maintain employee records for a period of five (5) years after termination of employment, but keep a permanent record of employee names, Social Security numbers, and dates of service.

Monitoring and Coaching Your Staff

- Schedule performance evaluations on a regular basis – including one at the end of a “probationary” period for new hires. Include:
 - information gained from physician and other manager supervision
 - feedback from patients, families, and others
 - positive feedback as well as constructive criticism
- Provide regular employee education/training and document that the training was given (and who attended). Training should include:
 - new policies
 - equipment and procedures
 - other subjects of importance to your office such as patient safety and patient satisfaction
- Administrative staff should be provided with training and supervision commensurate with their job responsibilities.
- Consider cross-training staff in multiple office functions that they are capable of handling to keep the work flow running smoothly (for example, many or all staff may be trained to answer the phones, or file reviewed reports in patient records)

- Hold regular employee staff meetings to address office issues. These issues might include:
 - review of office systems with the intent to improve your work processes
 - discussion of problems encountered, with a focus on finding solutions to those problems
- To ensure that monitoring and supervision of staff is handled appropriately:
 - ensure adequate supervision of clinical staff by physicians
 - require physician review or critique and countersigning of progress notes written by physician extenders or other supervised health professionals
 - know the physician-to-staff supervision ratio in your practice; work to maintain its adequacy
- For those infrequent occasions when discipline is required, the practice should practice tiered discipline and keep records of it. This would include:
 - discussions with each employee, done for the purpose of correcting their work or behavior in a positive manner
 - verbal warnings given to the employee
 - written warnings given to the employee
 - a formal letter of dismissal, given in conjunction with an exit discussion regarding the reasons for termination
- Termination should be handled with great care, and the termination discussion should be documented. More information may be found in the Princeton Insurance Risk Review Online article [Wrongful Termination](#).

Policy/Procedure Manual

It is important to develop written policies and procedures that address personnel practices such as professional conduct, confidentiality, dress code, continuing education, etc. The size of your policy/procedure manual in some ways may correspond to the size of your practice. Very small practices with one or two staff members will find they need only a few policies.

All staff and physicians should review the policy manual on hire and whenever a revision is made. The manual should always be available to them as a reference.

If your practice has only one staff member and you opt not to create a policy manual, you will still need to have the policy on confidentiality referenced in the [Legal section](#) of this toolkit and below.

For those practices which will develop more than that one policy, the following guidelines may be of assistance:

- Have each new employee sign and date an [employee confidentiality policy and agreement](#) upon hire. Place a copy in the employee's personnel file. Review annually with each employee and have them again sign and date the agreement. This policy is required by Federal law under HIPAA.
- Assure that the policy on professional conduct covers all members of the practice, from file clerks and front desk staff to physician owners. This policy should address how practice members conduct themselves with patients as well as with each other. How they carry out this part of their job should be part of their performance evaluations.
- Write policies in general terms whenever possible. Avoid using specific information such as the name of the lab you contract with if writing a policy about handling of lab

specimens. If you change labs, you will need to change the policy, and that is a detail easily forgotten or delayed.

- Write policies simply, clearly, making them easy to read and understand.
- Ensure that policies are dated and signed by the ranking member of the practice, or by a manager designated by that person.
- Review and update, as necessary, all policies on an annual basis. A cover sheet on the manual should record all dates of review and revision.
- The manual should have a table of contents.
- Archive old policies which have been revised and replaced, to use them as references if a suit is filed.

Physician Coverage

Your practice manual should contain provisions for physician coverage during an absence. The doctor needing coverage must do the following:

- notify the answering service and hospital(s) of the date(s) of his/her absence or unavailability
- inform all hospitalized patients of the coverage arrangements
- provide the covering doctor with information on patients with anticipated needs or problems, and document the communication(s)
- make his/her patients' medical records available to the covering doctor

The policies for physician coverage should also require that the covering doctor:

- practices in the same specialty as the physician being covered
- has privileges at the same hospital(s)
- has professional liability insurance with adequate coverage limits
- advises the covered doctor about any patient contacts or treatment rendered during the coverage period, and documents the discussion(s)

Special Circumstances

Locum Tenens

A practice which is expanding quickly or which has unexpectedly lost one of its physicians may wish to bring in a locum tenens for a period of months, or even a year while they determine how the practice will ultimately be structured or while they look for a full-time physician. The practice and the locum tenens physician may even mutually decide that he or she is the person to fill the permanent position. Bringing in a locum tenens requires the same careful planning as hiring a physician. The practice will want to:

- define the position and its responsibilities
- identify the steps in the process, the time they will take, and the method that will be used
 - recruitment (the position can be posted online; also there are a number of agencies with established service histories which can help you find a physician; some of these agencies will provide credentialing, salary, billing, and professional liability coverage)
 - credentialing and background checks
 - negotiations and contractual details (insurance coverage, etc.)
 - orientation
 - mentoring (the mentor can be a physician from the practice or a physician from an allied facility)

- the practice should have policies for working with locum tenens
 - peer review should be the same as for other practice physicians (scheduling and attendance, patient satisfaction, malpractice claims, productivity, efficiency, discussion of difficult cases, and quality of medical record documentation), though it should be done at more frequent intervals because of the locum tenens' short stay in the practice
 - peer review should also give consideration to office staff concerns
 - a termination process should be prepared before the locum tenens is brought into the practice and language from this process should be included in the contract to avoid potential wrongful termination claims

Manufacturer's Representatives

In some situations a manufacturer's representative may offer to help physicians and staff learn to use new equipment by demonstrating and helping them use it on patients. This would, of course, apply to practices that do on-site procedures. There should be careful policies and processes to follow if a practice allows a manufacturer's representative to be present during a procedure on a patient, whether or not the representative actually handles the equipment. These policies and processes would include:

- informing the patient of the representative's presence and the reason he or she is there
- allowing the patient to consent to or deny the representative's presence during their procedure (consent or denial is to be in writing)
- documenting the presence of the representative and what, if anything, that they did
- having a written policy on hand to guide both staff and representative on what the practice requires in this situation

Students in the Office as a Learning Experience

Students, from High School through Medical School may request to observe and gain experience in a physician practice. If a practice allows students to observe a policy and procedure should be developed to cover this situation. The policy should include:

- procurement and review of a contract with the school the student is from
- the contract and/or attendant documentation should provide information on:
 - liability coverage (including amount) provided by the student's school
 - responsibility for student health, immunization status, and worker compensation coverage (provided by the student's school)
 - criminal background check
 - information on the student's competency
 - signed confidentiality statement (signed by the student)
 - language regarding responsibility for any damage student may do to practice property (or loss)
 - requirement that student be oriented to practice
 - HIPAA business associates agreement (if the student is going to be exposed to patient information)
 - termination (of the contract) language should be written into the contract
- written consent is to be obtained from any patient before a student is involved in their care
- the practice should have a quality monitoring system for students who do any care in the practice
- files on the students should be maintained for seven years

MISCELLANEOUS LEGAL AND REGULATORY ISSUES

An office practice is a business, no matter its size. As a business it has legal obligations and can incur liabilities. The following sections give a brief overview of some of the legal doctrines and liabilities most often associated with medical practices. Also included are some practice operations which have legal implications. Not all practices will encounter some of these issues; however, it may be helpful to know that they can impact your practice.

Abuse, Neglect, and Domestic Violence

Children

The state of New Jersey (NJ) requires anyone who knows or suspects that a child is being abused to report that information to the Division of Youth and Family Services (DYFS), which is New Jersey's child protection and child welfare agency. DYFS is responsible for investigating allegations of child abuse and neglect and, if necessary, arranging for the child's protection. Child abuse may be physical or sexual. It also may take the form of neglect.

A special hotline is available for this purpose; it is 1-877-NJ ABUSE (652-2873). A report of this nature should not be delayed, and NJ regulations do allow for fines or imprisonment if someone fails to report known or suspected abuse.

Adults

NJ also provides an elder abuse hotline at 1-800-792-8820.

'Elder abuse' actually applies to anyone eighteen and older who, because of a physical or mental illness, disability or deficiency, lacks sufficient understanding or capacity to make, communicate, or carry out decisions concerning his or her well-being and is the subject of abuse, neglect or exploitation. (N.J.S.A. 52:27D-406 to 426.)

Elder abuse, like child abuse, may be physical or sexual. It may take the form of neglect, and it also includes financial abuse. Examples of financial abuse include inappropriately overcharging the individual and taking their money (if the abuser has access to their accounts) for personal use while not providing for the care of the incapacitated person.

Domestic Abuse

Domestic violence is found in all social strata. It is often missed as a clinical conclusion because the victim is not asked if they are being abused. Though the state of NJ does not mandate reporting of cases of domestic violence, understanding that your patient is being abused may help you give them care appropriate to their illness or injury, and encouragement to seek help. Your practice may wish to add screening for abuse in your intake forms; and if you clearly suspect that a patient is being abused by their partner, you can ask that partner to wait in the waiting room while you speak with and examine the patient. This is the same approach that you might take in the case of suspected elder abuse.

Advance Directives

An Advance Directive is a patient's document, detailing how they want their medical care to be handled if they were to become unable to direct it themselves. Discussing the development of an Advance Directive (sometimes called a Living Will) allows a competent adult patient to consider issues they may not have thought to discuss either with their physician or with their family.

The state of New Jersey has passed a law called the Advance Directives for Health Care Act. As a result of this Act the New Jersey Bioethics Commission published a brochure which explains Advance Directives, the process of making these decisions, and provides forms to use. This brochure is available online at http://www.state.nj.us/health/healthfacilities/documents/ltc/advance_directives.pdf.

Since incapacity can come as the result of unanticipated illness or accident as well as old age, discussions about Advance Directives can become part of a practice's normal conversation with new adult patients and at annual physicals. Patients who have these documents can update them at any time and may choose to revoke them, so it is also appropriate for the practice to update their file information regarding the patient's Advance Directive at annual physicals.

The Americans with Disabilities Act (ADA)

In 1990 the federal government enacted the ADA to ensure that all Americans with physical or mental impairments would have access to necessary services. This, of course, includes access to your office and includes surrounding grounds such as parking lots, curbs, and ramp approach to doorways as necessary. Doorways need to be wide enough to accommodate wheelchairs. At least one restroom needs to be equipped for wheelchair and other disability needs.

In New Jersey, the rights of the hearing impaired have taken center stage in a number of lawsuits alleging that healthcare facilities and physician practices failed to provide appropriately trained sign language interpreters for patients. The New Jersey Department of Health and Human Resources Division of the Deaf and Hard of Hearing provides a list of healthcare interpreters. Since this can be a significant expense for a small practice, some offices arrange to share an interpreter's services with other practices or with a local healthcare facility.

The ADA is not meant to be a burdensome law, but does require that all new construction (after January 26, 1993), and all major renovations to old construction, be in compliance with the law.

The law also affects hiring decisions for all practices which have at least 15 employees. Compliance with the ADA can include specifying on job descriptions those physical tasks and mental tasks that are required for the job. With this information, the right person, with or without disabilities, can be placed in that job.

Persons who require service animals are also allowed to have their service animals with them.

Failure to conform to the ADA can result in monetary penalties. More information on the ADA can be found in Princeton's [Reducing Risk documents](#).

Contract Management

A mechanism for effective contract management to reduce or eliminate potential liability is important to the financial security of a physician practice. Contracts to which a practice typically is a party include agreements, letters of intent, purchase orders, and service orders. Elements of a contract that are relevant in terms of managing associated risks include the following:

- intent
- duties and responsibilities of the parties
- termination date (no automatic renewal is preferable)
- termination conditions (e.g., disgrace, moral turpitude, inability to participate in Medicare/Medicaid)
- restrictive covenant (non-compete clause)
- insurance coverage
- compliance with applicable federal and state laws, regulations, etc.
- statement of confidentiality
- assignment of rights
- hold harmless/indemnification clauses (not broad or one-sided)
- corporate compliance (signed certification by all parties)
- notices (given in writing and sent by certified mail, return receipt requested, or by other guaranteed delivery service)
- governing law (preference is for your state's law, not the other party's)
- warranties/disclaimers (no broad disclaimer or "as is")

In order to reduce the risk of exposure to loss or liability in connection with contracts in your practice, it is recommended that you:

- obtain a legal review of all contracts by a qualified attorney before you sign
- develop a contract tracking system (e.g., Excel or Access) to track expiration dates, certificates of insurance, etc.

Corporate Compliance Program

A program for corporate compliance that includes internal controls and procedures that promote adherence to statutes and regulations is essential to protect your practice from claims of fraud and abuse. It is strongly recommended that your corporate compliance program be developed with guidance from qualified legal counsel.

Basic Compliance Program Elements

The Seven Basic Compliance Elements required by the Office of Inspector General are:

1. Establish compliance standards through the development of a code of conduct and written policies and procedures which address, at a minimum:
 - cultural code of conduct
 - ethics
 - sexual harassment
 - discrimination
 - patient values
 - marketing practices

- business practices
 - billing practices
 - hazardous materials and waste practices
2. Assign compliance monitoring efforts to a designated compliance officer or contact.
 3. Conduct comprehensive training and education on practice ethics and policies and procedures.
 4. Conduct internal monitoring and auditing focusing on high risk billing and coding issues through performance of periodic audits.
 5. Develop accessible lines of office communication such as:
 - discussions at staff meetings regarding fraudulent or erroneous conduct issues
 - implementing a non-punitive communication mechanism, such as a hotline for employees to confidentially report compliance issues needing investigation
 - community bulletin boards to update staff regarding compliance activities
 6. Enforce disciplinary standards by making clear or ensuring that employees are aware that compliance is treated seriously and that violations will be dealt with consistently and uniformly.
 7. Respond appropriately to detected violations through the investigation of allegations and the disclosure of incidents to the appropriate government entities.

Source: The Office of Inspector General's "Compliance Program Guidance for Individual and Small Group Physician Practices"

Handling Medical Board Complaints and Malpractice Claims

Every physician and physician practice should be prepared to deal with the unpleasant possibility of being sued or receiving a Medical Board complaint. To that end, it is important that procedures are in place for identifying and reporting claims to your risk manager or other designated individual in your office.

This section describes these situations, and identifies processes which your practice may need to put into place.

Malpractice Claims and Summons

A claim can be verbal or in writing and usually involves a patient or family member making a demand of your practice. Claims are to be taken seriously and reported to Princeton, as soon as they are received. In some situations steps may be taken to keep the claim from becoming a lawsuit. Princeton's Claims professionals will work with you to respond to claims appropriately.

Receipt of a summons is an actual notice that you have been sued. Like Board complaints, this is not a common occurrence for a physician or a practice, but recent statistics indicate that most physicians can expect to be sued at least once during their career.

The prudent practice will have written policies and procedures for claims management that require the following actions, by category:

- Designate one person in the practice to be responsible for accepting summons and complaint documents, and for following through on the steps below (it should also be noted that if this person is going to be away from work for an extended period of time another person will accept the responsibility)

- Report immediately all actual claims (served with legal summons and complaint), Board complaints, and potentially compensable events (i.e. incidents that you believe might result in an actual claim) to Princeton Insurance.
- Cooperate with the initial investigation made by Princeton Insurance and/or your assigned defense attorney.
- Gather and secure pertinent evidence such as the original medical record, x-ray films, appointment books, etc.
- **Never add, delete, or in any way alter these original records**
- Maintain confidentiality by not discussing the case with anyone other than your Princeton Insurance representative or your attorney.
- File any event reports and correspondence from Princeton Insurance or your attorney regarding a claim separate from patient charts.

Medical Board Complaints

Board complaints are becoming more common as patients become more aware that they can use the New Jersey Board of Medical Examiners as an avenue to get their complaints addressed. An overview of the Board and its processes can be found in a [Risk Review Online](#) article.

Every physician should be aware that a Board complaint should be reported to Princeton. Our Claims professionals and attorneys are available to help you respond to this process.

Health Insurance Portability and Accountability Act (HIPAA)

A physician has an ethical and legal duty to maintain the confidentiality of information in patients' medical records. The legal basis for confidentiality arises from the physician patient privilege which may only be waived by the patient.

Some state and federal laws also mandate that physicians preserve the confidentiality of medical information. For example, the HIPAA Privacy Rule requires you to have office policies and procedures that provide for administrative, physical, and technical safeguards to protect the privacy and security of patients' medical and other protected health information (PHI).

Special confidentiality protections also apply to specific information such as drug and alcohol treatment records, genetic testing, HIV/AIDS testing, and psychotherapy notes.

The following guidelines for protecting the confidentiality of PHI apply:

- all staff must be trained in maintaining patient confidentiality (including signing a confidentiality statement upon hiring and at time of annual performance appraisals)
- keep records of staff training on safeguarding patient privacy
- training topics for confidentiality of phi include:
 - patient sign-in procedures
 - procedures for reporting test results to patients (e.g., answering machines)
 - procedures for sending PHI via facsimile or e-mail
 - the "minimum necessary" standard
 - situations requiring mandatory reporting (e.g., child/elder abuse, communicable diseases, etc.)

- have a policy to ensure that medical records are released in accordance with state and federal regulations
- patients or their authorized representative must authorize the use or disclosure of their phi for purposes other than treatment, payment, or the healthcare operations of the practice, except when a disclosure is required by law
- a signed [HIPAA-compliant authorization form](#) is required for release of PHI
- track and document uses and disclosures of PHI
- practices are required to have and implement written policies and procedures that guard against unauthorized or inadvertent use or disclosure of PHI
- allocate office space for holding private conversations with patients
- patient charts and other documents with phi must be stored in a secure location
- physicians may disclose phi to a coroner for identifying a decedent, determining a cause of death, or other duties authorized by law

More information on [HIPAA](#) can be found in Princeton's Reducing Risk documents.

Informed Consent

Medical ethics and legal mandates require that a physician obtain a patient's informed consent before treating or operating on the patient. The underlying principle of informed consent is that patients have the right to determine what will be done with their bodies, i.e., the right of self-determination in medical treatment matters.

Informed consent is an important communication *process* between physicians and patients that can help support and enhance the physician-patient relationship. It is not merely signatures on a consent form. Properly done and documented, the informed consent process also may better align the patient's and physician's expectations of the treatment outcomes, increase patient confidence, and help prevent a malpractice claim in the event that a complication or unanticipated event occurs.

Failure to provide patients with sufficient information for an informed consent places a physician at risk for a legal claim for injury from a complication or unanticipated outcome of the procedure – even if it was not the result of negligence.

Physicians and their practices should be aware of the duties and documentation required for the informed consent process. They should also understand who can consent, and what information is necessary to fulfill the requirements of an informed consent. Furthermore, if a patient refuses recommended treatment after the process for informed consent is completed, the [informed refusal](#) must be documented. Your charting should note that material information about the proposed treatment or procedure – including the risks of not having the proposed treatment or procedure – was communicated to the patient, and that the patient expressed understanding of the potential consequences of refusal.

Because of this, and because it involves medical ethics and legal mandates, the informed consent process should be clearly understood and managed precisely in the office practice. Detailed information on [informed consent](#) may be found in the Princeton Reducing Risk documents.

Clinical Trials

Some office practices chose to become involved in clinical trials. It is important that the trial chosen be appropriate for the practice and its patients.

The practice's responsibility in these matters paraphrases medication safety rules:

- right study
- right patient
- right consent

Sponsors of clinical trials provide informed consent forms for patients who agree to become involved in the study. These forms can be long and complex. Princeton has developed a short [list of those elements](#) which may be found in these consent forms.

The practice will carefully monitor the study along with any others who are charged with its supervision. Practice staff should understand that it is essential that patient confidentiality be maintained during and after the study. It is easy to get caught up in the research and the complexity of the process, but physicians can minimize their risk by focusing on the patient and patient safety.

In the event of an adverse outcome, or outcomes, in the study, an investigation may determine:

- harm or injury suffered by the patient
- required treatment
- need for notification of appropriate agencies
- compensation, if appropriate, for injured patient

All phases of a clinical trial are carefully documented. The patient's medical record should also note that they are participating in a clinical trial, though the trial data is not recorded in the patient's medical record.

Managed Care

Managed care contracts require careful review of their terms with particular attention to the requirements that are placed on physicians in areas of payment, compliance with rules and regulations of the managed care organization (MCO), and any warranties or other representations about the standard of care provided. The following suggestions are offered for office policies and procedures for managed care relationships that you may be considering.

Patient care decisions are based on clinical judgment, not on the MCO. Should the MCO's policies, coverage, or authorization authority conflict with your judgment, you should clearly reiterate to the patient your desires and maintain your recommended course of treatment or diagnostics. Document your discussions to that effect, and if the patient refuses to proceed, document the decision through an informed refusal, or if necessary, a [letter](#). To the extent possible, and in the spirit of good patient relations, you should advocate for your patient with the MCO using [written](#) or telephonic communications.

Other policies and procedures for managed care should ensure that:

- managed care contracts receive careful legal review by experienced counsel
- managed care patients receive the same level and standard of care as patients seen on a fee-for-service basis
- physicians are aware of the appeal and grievance procedures of the MCO
- the managed care organization is contacted before a patient is discharged from your practice
- determination is made as to whether or not additional liability coverage is indicated by contractual obligation or out of your concerns regarding your patient care obligations under the terms of the managed care agreement

Mandatory Reporting to State Agencies

Physicians are required by law to report a variety of diseases and conditions. Keeping up with what is to be reported, to what agency, in what way, and under what conditions may seem a bit daunting. The state has provided written materials and online resources to aid in these responsibilities. Information on these state sources can be found in our Risk Review article on [mandatory reporting](#).

OSHA

The Occupational Safety and Health Act (OSHA) has regulations which apply to physician practices. These regulations will be addressed in greater detail in the Office Safety section of this toolkit. In brief, they address:

- bloodborne pathogens
- hazard communications (hazardous materials in the office)
- radiation safety
- safe exits
- electrical safety
- emergency plans (fire safety, emergency evacuation, etc.)
- eyewash stations (if there is a danger of chemical or biological materials splashing into staff eyes)

Subpoenas and Other Requests for Medical Records

Most practices will receive subpoenas. The majority of these subpoenas are requests for copies of medical records. Though they may seem routine, each should be handled with care. More information on [subpoenas](#) can be found in Princeton's Reducing Risk documents.

Other requests for copies of medical records may come in the form of attorney demands or requests from the patient or family themselves. Each request is to be in writing and in the form of [HIPAA compliant record release](#) form. Attorney requests may be in the form of a letter accompanied by a HIPAA compliant release form.

The practice should develop a process to review all record requests or subpoenas. To make this process more secure:

- these requests and subpoenas should only be handled by one person, with another person cross trained to back that person up

- the physician, or governing body, should be made aware of any requests which may indicate that a claim is being considered (for example, a request is received for a copy of a record on a patient who suffered a serious medication error several months ago)
- the physician, or governing body, should be made aware of the number of requests received each quarter, every six months, or every year (time span is dependent on the practice's choice of reporting rhythms)

More information on [release of records](#) can be found in Princeton's Risk Review article. There is also an article on [requests for psychiatric records](#).

Vicarious Liability (Apparent Authority)

A physician can be found liable for the actions of the physicians and other staff who work for and with him. There are two legal theories under which a physician can be held liable for medical negligence and malpractice; for his/her own negligence (i.e. "direct liability"), or for the negligent acts of others without any personal wrongdoing (i.e. "vicarious liability"). With the latter, liability is based upon the relationship between the physician and the person who actually committed the negligent act; with one of the most common situations being the employer-employee relationship, in which the employer is almost always liable for the negligent actions or omissions of his/her employee.

A physician may be responsible for the negligence of another healthcare provider under his or her supervision when it can be demonstrated that there was:

- negligent instruction (such as giving wrong directions)
- negligent qualifications or credentialing (i.e. assigning a duty to a healthcare professional who is unqualified to perform)
- failure to intervene (such as when the healthcare professional supervisor observes a negligent act that he/she could remedy but fails to do so)

With respect to non-employed individuals, there can be vicarious liability if the patient is reasonably under the impression that the negligent healthcare professional is an employee of the physician and in special contract relationships. Other situations may also result in vicarious liability as well, if it can be determined that a physician has the ability to exert control by any direct or indirect influence, as may possibly be the case of physicians who contract for the services of other providers – such as anesthesiologists, etc. This is known as control in fact (or de facto control). However, in these instances, cases are fact specific and the outcome can vary based on each professional's relative degree of fault. Generally, however, in non-employment situations, the physician will not be vicariously liable for the negligence of its nonemployee staff, but will be directly liable for his own negligence if he failed to credential or properly monitor the performance of his non-employee staff.

It is for this reason that physician owners, managers, and governing board members of practices need to know the people they work with and who work for them. This liability drives the need for many of the policies and procedures suggested in the Human Resources section of this toolkit. Even if you have a small practice and do not develop formal written policies, your practice should develop firm rules on:

- behavior with patients (how all practice members treat the patients and how they talk to them)
- the scope of each position's responsibility (clear job descriptions really do count)

- advice giving (unlicensed staff should not be put in this position, or be allowed to assume this role)
- triage (also should be restricted to licensed personnel, with the exception of receipt of the initial phone call and its hand off to a licensed care giver)
- prescription refill protocols
- telephone protocols (front line staff should not be allowed to 'protect' the physicians and nurses from calls, or to limit the calls getting to the physician at their own discretion)
- following state regulations as they regard credentials and work parameters for certifications, licensures, and also rules that govern practices

A hospital-based case of vicarious liability ([apparent authority](#)) is detailed in a Risk Alert on the same topic.

MEDICAL RECORDS

The medical record is the primary means of communication among healthcare providers about a patient's medical history and course of care and treatment. It is also a legal document that becomes important as evidence if there is a malpractice claim. Current, complete medical records which assist diagnosis and treatment, and which communicate pertinent information to other caregivers, provide excellent records for risk management purposes.

Documentation Guidelines

Avoid Insufficient Documentation

Most often, missing or inadequately recorded information is related to facts surrounding an adverse outcome. Cases such as these include omitting or under-documenting:

- clinical rationale for what treatment was rendered and what was not
- phone conversations that became pertinent to an adverse outcome
- discharge and follow-up advice
- informed consent discussions
- identification of caregivers
- dates and times care was rendered

To help make your medical records valuable in defending a claim, they should contain detailed and accurate entries that fully describe the patient's diagnosis, the treatment plan, care rendered, advice given, and all other matters that you believe are pertinent to the patient's medical course. Missing, incomplete, or illegible documentation can seriously impede patient care and the defense of a malpractice claim, **even when care was appropriate!**

Routine visit notes may include your diagnostic rationale, informed consent or shared decision-making discussions, and discharge or post-visit instructions. This and all medical record information should be up-to-date, clear and readable. The medical record is a resource for you, your staff, and others who care for the patient. Make sure that the information in the chart is the information you would want to have if you were assuming care of this patient, and that it explains both your discussions with the patient and your decision-making process when making diagnoses and treatment decisions.

If there are multiple caregivers responsible for this patient, the medical record should be clear regarding which practitioner has responsibility for which care. For example, a primary care physician's chart on a female patient should clearly indicate who her gynecologist is. The primary can receive copies of the patient's routine mammography and pap tests, which are filed on the chart. In this way his role as primary is fulfilled since he continues to monitor that she is receiving appropriate care whether he gives the care or it is the responsibility of another.

An example of documenting diagnostic rationale would be charting the reason for not following the written recommendation of a consultant. Without being lengthy, your note should indicate alternatives considered, your medical judgment and the clinical basis for your decision.

When dealing with conflicting data, such as disagreements over a clinical conclusion, read the other provider's notes, re-read your prior notes and review any other special study reports even if you have already read the films or seen the test data. Overlooked diagnostic reports, critical

notes, and consultations which point to a different available diagnostic or treatment path, and are not commented upon by the attending physician, may give rise to malpractice claims. Should it be necessary for you to document a different diagnosis or recommended treatment, factually state your opinion and your supporting rationale.

A note in the chart regarding informed consent or shared decision discussions is very important. A signed consent form does not take the place of this note. If your patient refuses a treatment or plan of care, this should be documented too, along with your note describing your conversation with the patient in which you explained the risks, benefits, and alternatives to the course the patient has chosen. More information on informed consent can be found in the [Legal/Regulatory section](#) of this toolkit. Information on shared decision-making can be found in the [Communication section](#).

Describe patient behavior, including non-compliant behavior. Be objective: “patient did not return for follow-up appointment,” rather than “patient is non-compliant.”

Discharge or post-visit instructions should include the time and action-specific directives such as: “If your temperature doesn’t return to normal by Wednesday, call me.” Follow-up plans should be included, particularly if a more serious or life threatening diagnosis is being ruled out.

Clinically pertinent telephone calls should be documented in the patient’s chart and include notations of prescriptions called in or instructions given regarding when to seek further medical care. It can be difficult to collect those stray bits of paper that phone notes have been scribbled on in restaurants or in the middle of the night. All that information needs to be transcribed into the chart. Physicians and practices have been known to give up on what seems to be a time-wasting paperwork task. Yet this documentation can be vital to good patient care.

Princeton has developed phone note pads which are small enough to fit in pocket or purse. Written notes tear off the pad and then peel completely away from their backing to stick firmly into a chart. Using a method of recordkeeping like this may make phone notes a little more likely to show up in the patient’s chart on a regular basis. More information on these note pads and how to obtain them can be found in 2 [Risk Review Online articles](#).

All records should have clearly documented medication records which include medication allergies or any prior adverse reactions to medications or contrast media. More information on medication safety can be found in [that section](#) of this toolkit.

[Understand Documentation Mechanics](#)

Mechanical errors such as inaccurate statements in factual information, errors in transcription or written orders, delayed or post-dated recordings, illegibility, incorrect methods used for corrections or adding an addendum may cast doubts about what was actually done for the patient, as well as when. Delays in documentation can be problematic for the defense of a claim when a note, written after an adverse event, seems to be defensive or self-serving. Also, notes which are incorrect, sloppy and haphazard can give the impression that you are an uncaring or incompetent provider. Therefore, when documenting in the medical record, consider the following:

- Use permanent ink, not soft felt pens or lead pencils.
- Write legibly; print if your handwriting is indecipherable. The use of [encounter forms](#), checklists, flow-sheets, and computer-assisted documentation for high volume activities,

can save time and may also reduce communication problems and errors caused by illegible handwriting.

- Date, time and sign all entries including your professional designation. Use precise time whenever possible. Precision contributes to an impression of thoroughness. Each entry should be in order, e.g. consecutive days.
- Use only abbreviations approved by your facility.
- Do not leave blank spaces between entries.
- Late entries and addendums should be identified as such. Document the date of the note being referenced.
- Do not erase, use whiteout or obliterate a notation. Incorrect entries should be corrected by drawing a single straight line through the mistake, then write “error” or “mistaken entry” above or next to it. Include your initials and the date of the correction.
- Do not alter existing documentation or withhold elements of a medical record once a malpractice claim emerges, since the plaintiff’s attorney or other third party usually already has a copy of the records. Changes are immediately obvious and even minor record alterations can greatly harm your credibility. Should you be named in a claim and the medical record is problematic, immediately point this out to your defense attorney.

Prevent Inappropriate Documentation

Only clinically pertinent information should be entered in the patient record. Consider the following:

- Incident reports are not part of the patient record; therefore, remarks about risk management issues, such as “incident report filed” should be avoided.
- Should an “adverse event” occur, only document the facts surrounding the actual event and the subsequent care rendered as a result of the event. Avoid self-serving or accusatory comments.
- Avoid subjective statements regarding prior treatment or poor outcomes presented as facts. When indicating the patient’s or family’s impression of their condition, use quotation marks, e.g. “cerebral palsy due to a birth injury.”
- Avoid oral or written criticisms of health care previously provided by other practitioners. Since all pertinent facts about prior care are rarely available, caution is advised in making judgments and comments until all complete information is considered. Should you disagree with a past or current caregiver, a factual summary of clinical events and honest answering of patient inquiries is advised.
- Derogatory remarks about patients do not belong in the record. Since patients have legal access to their records, such remarks will only increase anger.
- Arguments and conflict with other providers should never be included in the record. Finger pointing or self-serving remarks, especially after an adverse event, will only make the defense of a case much more complicated.

More general information regarding medical records and documentation can be found in a number of articles and documents that Princeton has published:

- information on [missing records](#)
- [general documentation](#) and [medical record](#) information
- [documentation tips](#) are found in Princeton’s Reducing Risk documents

Record Handling

Along with its system of documentation, a practice should have other systems to manage their records; that includes standard medical records, X-Ray films, practice logs, and other practice documentation. Some of these systems involve the structure of the chart itself, record storage, and systems for record retention. Record release will be discussed in a separate section below.

The practice should assign an administrator or custodian of records to implement and monitor these systems.

Chart Auditing

It is recommended that your practice develop and use a [system for periodic auditing](#) of medical record documentation to assure quality patient care. Chart auditing is discussed in a [Risk Review Online article](#). It is further recommended that you maintain a [signature log](#) in order to identify individuals who have made entries in the patients' charts should the need arise.

Chart Structure

Whether using paper records or electronic, the contents of a medical record should be organized in a manner that brings key information to the attention of staff and physicians easily. Electronic record software is generally designed to do this, but it is important to make sure that the practice likes the way the electronic charts are organized and flow before investing in that software. When designing the set-up of your paper records, the choice of type of folder and dividers becomes important. Focal documents like medication flow sheets should be located in a prominent area. Many practices choose to put them on the inside of the front cover of the file. Some file folders come with dividers, some dividers are purchased separately. Many dividers have clips on them to hold the documents in place.

As noted, there are many ways to set up a file, but a few key rules generally apply:

- all documents should be held firmly in place in the chart, there should be no loose papers
- in each section of the chart the most recent document (lab result, consult, etc.) is typically filed on top of all other documents in that section
- allergies (including notations of no known allergies) are posted in a prominent location
- all charts in the office should be set up in the same way

New Patients with Old Charts

Continuity of care is served by the medical record in another way. When a physician takes over the care of a patient from another physician, the medical record can be an excellent source of information. Time constraints often lead a physician to a cursory review, if any, of the chart which comes with the patient. This is especially true when a physician is taking over an entire practice from another physician. In these circumstances, it is important to use the chart as a resource along with the patient as historian. The patient alone may forget key information which could lead to medical error. More information on this subject may be found at a [Risk Review Online article](#).

Record Destruction

Medical record destruction needs to be handled carefully to protect patient confidentiality. All destroyed records need to be shredded or burned. If a vendor is used to accomplish this record destruction, then that vendor must abide by HIPAA confidentiality rules. Contracts with the vendor should be reviewed by the practice's attorney.

Though the record itself is destroyed, the practice should maintain a log of basic information on each patient which gives the following information:

- name
- date of birth
- social security number
- dates of first and last visit
- general problems and procedures performed in the office
- documentation of what was destroyed, how it was destroyed, and the date of destruction

Unplanned Record Destruction

Accidents or unexpected disasters can result in extensive water damage to important documents such as medical records and X-ray films. Storm damage, broken water pipes or an overflowing floor drain can result in unexpected destruction of stored medical records in a basement or storage room. Water damage can also be the often-unanticipated side effect of fire fighting efforts.

Damaged records require a quick response on the part of the practice. Insurance claims need to be filed. Other carriers need to be notified, and the records themselves have to be restored, destroyed, and/or reconstructed. You will need to keep a record of your efforts too.

Probably the most important thing a practice can do regarding this type of record damage is to take steps to prevent it. More details on the response to destroyed records and prevention of the same can be found in a [Risk Review article](#) on the subject.

Retention of Records

Storing records, especially paper charts, has given rise to another issue for physician practices. Many are running out of storage space and need to define policies for culling out the old records.

The New Jersey Board of Medical Examiners (BME) requires retention of medical records for seven years from the last professional contact or date of record entry, for adult patients. The Board does not specifically address different rules for pediatric charts, but Princeton recommends these charts be maintained the greater of seven years from the last entry or the date of the twenty-fourth birthday.

We also recommend that records of mentally incompetent patients and immunization records be kept indefinitely.

If a practice is involved with federal or state Health and Human Services programs, the concerned charts cannot be culled until approved by HHS or until it reaches the limit stated above, whichever is greater. If the practice is involved in a research program the program or the

FDA may set guidelines for culling of the charts; again, the charts cannot be culled before the recommendation given above.

Furthermore, a practice may need to keep a chart longer if that retention is requested by another physician of that patient, by someone acting legally on the patient's behalf and requesting in writing, or by the practice's legal counsel, risk manager, or insurance company. Finally, when working with managed care organizations it is important to be aware of any rules they may have regarding record retention.

[Storage of Old Records](#)

All practices should make arrangements for safe, dry storage of non-active charts and other documents of the practice. Areas of a building which are subject to leaks, overflowing drains, or general dampness can do serious damage to paper records and X-Rays. Fire safety also needs to be considered in the choice of storage locations. Prevention of damage from natural disaster and building leaks is addressed in the section on Unplanned Record Destruction.

When considering storage of electronic records, care should be taken to make sure that the records are securely backed up off site. An onsite back up can also be done, but it should not replace a very secure off site back up. This type of storage may be offered by your EHR vendor.

Release of Records

The New Jersey State Board of Medical Examiners' regulations obligate a physician to provide a copy of a patient's records, including reports and letters from other providers, to the patient or the patient's authorized representative within 30 days from the date that a request is received. This is required even if the physician suspects that he or she will be the target of a lawsuit by the patient.

No subpoena is required for you to produce medical records specified in a [HIPAA compliant authorization](#) that is signed by the patient or the patient's authorized representative. The regulations do permit you to charge a fee for the reproduction of the treatment record, not to exceed \$1 per page with a \$10 minimum charge and a \$100 maximum. Also, you may not refuse to provide the record because a patient has an outstanding balance with your office, if the record is needed by another health professional for the purpose of providing care.

A valid and signed authorization that satisfies the HIPAA Privacy Rule requirements for disclosure of medical information contains the following elements:

- a description of the information to be used or disclosed, e.g. "entire medical record" or "complete patient file"
- the person authorized to make disclosure, e.g., name of a specific physician or a category such as "any physician or medical facility that has provided services on my behalf"
- the person to whom the disclosure is to be made
- an expiration date or event such as "one year from date the authorization is signed" or "upon the minor reaching the age of majority"
- the purpose for which the information may be used or disclosed
- date
- the right of the patient to revoke the authorization

Use caution when the requested medical records include protected information such as HIV/AIDS, alcohol or drug abuse treatment records or psychotherapy notes. When a signed authorization is not specific regarding such information, check with the patient before providing it; if the patient agrees, be sure that the authorization specifies the information in question.

Retain the original letter and authorization requesting the medical records and document the date that you fulfilled the request and the information that was released.

An attorney's request for records may indeed indicate that you are the subject of a potential lawsuit. Knowing this, it is essential that you do not make any revisions or additions to the record for any reason. It is also advisable to secure the original record in a separate location to preserve its integrity and ensure that no part of it is misplaced.

The Board of Medical Examiners regulations **require** that a transcription of the record be provided at no charge if requested because of illegibility. Also, if a lawsuit follows, you will have the opportunity during the discovery phase to explain what is written in the treatment record. Do not rewrite the record, even if legibility is an issue.

A request for patient records may be a first step in the litigation process and, depending on the specifics of the situation, may be followed by formal notice of a lawsuit. Notify Princeton Insurance promptly whenever you suspect that you will become involved in a malpractice suit so that the company may begin representing your interests properly. A [Risk Review Online article](#) discusses general record release issues.

Questions have also been raised when records are requested on deceased patients. Releasing records to family, to the coroner, or to an estate executor all are unique situations. Releasing the records of deceased patients is discussed in a [Risk Review Online article](#).

Subpoenas for Medical Records

Physicians often receive subpoenas directing them to produce medical records and to testify regarding patient care they provided. A subpoena *ad testificandum* requires the subpoenaed person to give testimony. A subpoena *duces tecum* requires the subpoenaed individual to produce specified evidence such as medical records or x-rays at the same time he or she is to testify.

A Note of Caution: Despite the official language and appearance of a subpoena, do not assume that a subpoena is valid and must be honored without question. Some attorneys disregard the court rules and attempt to improperly use a subpoena *duces tecum* to obtain medical records without paying for them. A "discovery" or "records subpoena" improperly directs a physician to produce a copy of a patient's records and send them to the attorney's office in lieu of attendance at a deposition. This practice is not sanctioned by the courts. If you are served with such a subpoena, contact the attorney who served it and request that he or she either provide a signed authorization from the patient, along with payment of the fee permitted by the BME regulations, or that the records are produced at a deposition.

Releasing a patient's medical records in response to an improper subpoena that is not accompanied by a signed authorization from the patient may place a physician in legal and professional jeopardy for failure to protect the confidentiality of the patient's medical records.

A valid subpoena in a civil action in the Superior Court of New Jersey (state court) must meet the following requirements:

- be served in-person by an individual at least 18-years-old

- name (on its face sheet) the court and title of the action, including the names of the parties and the court docket number and type of action (civil, criminal, or administrative)
- be signed by either the clerk of the court or by an attorney for one of the parties in the action, or by a party to the action, and list the address and telephone number of the person who issued the subpoena
- be accompanied by payment of a witness fee and mileage
- direct properly when and where the witness is to appear:
 - trial – anywhere in New Jersey
 - deposition – the county in which the witness lives, works, or does business – at least ten days notice is required for a deposition
 - state agency – anywhere in New Jersey consistent with the agency's power

To protect both yourself and your patient, if you are served with a subpoena or court order regarding a patient, consider the following:

- designate an individual in your office who is responsible for handling attorney and other legal requests for patient records
- if you have any questions or concerns about a request for patient records, consult Princeton Insurance or an attorney familiar with healthcare law
- keep records of all authorized disclosures of patient-protected health information for a minimum of six years
- be aware of specific kinds of patient information that are subject to federal and state laws restricting or prohibiting disclosure such as HIV/AIDS, drug and alcohol treatment, and mental health records

Court Orders

A court order, unlike a subpoena, is issued by a judge who reviews the request and may conduct a hearing on the matter. A court order directing a healthcare practitioner to produce medical records must be followed. However, it is still advisable that you seek expert advice from an attorney familiar with healthcare law or from Princeton Insurance if you are served with a court order for patient records.

Release of Original X-Rays

X-rays are an integral part of a patient's medical record and often form the basis upon which accurate diagnoses and treatment are rendered.

Measures to secure and maintain x-rays should be given the same priority as the security and retention of medical records, not only from the standpoint of good patient care, but also for the adequate defense of a malpractice claim and possible allegations of records tampering.

Many physicians release original x-rays due to the financial and/or logistical difficulty of providing copies.

From a risk management standpoint, the safest practice is to provide copies of all x-rays and retain original films.

However, it is sometimes necessary and/or mandatory for original x-rays to be released. When that is the case, the following suggestions should be considered in establishing an effective tracking system:

- Both the film itself and the jacket in which it is stored should be labeled with the patient's name or some other identifier. The patient's name should be compared with the name on the film jacket prior to filing the x-rays.

- When original films are released, a [patient authorization form](#) releasing the films should be obtained. The form should describe the exact films being released and should include a time frame for return of the films.
- A record of original x-rays released should be maintained. It should include the patient's name, the date the films were released, the destination of the films, and the date the films are to be returned. A periodic review of this record should be performed to identify any x-rays that have not been returned in the specified time. Aggressive follow-up should be undertaken to retrieve all unreturned films.
- In the situation where the films are not returned and cannot be located, documentation should reflect efforts undertaken to retrieve the x-rays.

Electronic Health Records (EHR)

Electronic Health Records (EHR, often referred to as Electronic Medical Records or EMR), are slowly taking the place of paper records in healthcare facilities and physician practices. Electronic recordkeeping is meant to reduce problems inherent in paper record systems, to increase the speed at which medical information flows, and to more effectively link the many sources of medical information on each patient.

Electronic records and systems are not without their own problems and challenges. Princeton has a series of resources available on EHR. Princeton has written a guide to electronic records which is described in more detail in the following section.

Electronic Medical Records: Patient Safety & Risk Management Guide

The Princeton Insurance [Electronic Medical Records Patient Safety & Risk Management Guide](#) was created to provide information concerning the proper use of electronic medical records to improve the quality and safety of patient care while decreasing potential liability risk. Once successfully implemented, EMRs create efficiencies in time and productivity which can lead to more quality time with patients, time to see more patients and/or less hectic schedules. However, maximizing efficiencies could result in various shortcuts that may degrade the patient safety benefits. So used, EMRs could actually create and propagate both old and new errors, and the efficiencies could create a roadmap for a plaintiff's attorney to attempt to justify a legal action.

The guide cautions against those uses (including nonuse, modified, or improper use) of EMRs that may increase liability risk. It is not all-inclusive; rather it focuses on those areas most likely to involve liability or make litigation more difficult to defend. Included in the guide are sample screen shots/printouts from a variety of EMR vendors, numerous examples that demonstrate how EMRs can be used properly, and significant discussion of how these features may be improperly used to increase liability risk. Each section includes recommendations on how to avoid or mitigate potential liability risks associated with the use of EMRs, while using their key features to improve the quality, safety, and efficiency of healthcare delivery.

The guide is not intended to endorse any particular EMR system, nor to serve as a comprehensive "how to" implementation manual. Implementation and EMR features are discussed only to the extent that they affect patient safety and/or risk management. It does not discuss or compare the various pros and cons, including costs (both to implement and to maintain), of any particular EMR systems (or EMRs in general).

This guide should be used to supplement your current use of EMRs or for consideration of the extent to which you will implement certain EMR features. In this context, it should not be regarded as a standalone document for the implementation of EMRs.

MEDICATION SAFETY

Medication errors and adverse drug events are a major cause of injury to patients in all types of care settings – including physician offices. Many of these events are preventable with careful attention to the numerous components of medication safety including medication storage, prescribing, administering medications in the office, patient education, and record keeping.

Medication Storage and Control

Systems for medication storage and control that help prevent unauthorized access and guard against errors in dispensing (e.g. the use of expired drugs) are important components of patient safety in an office practice. To safeguard medications in your office you can:

- Store drugs, syringes, and needles in a secure room or location.
- Restrict access to controlled substances to authorized individuals, and take regular inventory.
- Require pharmaceutical sales representatives to log in sample drugs with their name, drug(s) delivered, lot numbers, quantity, and expiration date.
- Maintain logs for controlled substances and sample drugs that account for every dose distributed – note the date of dispensing, the patient’s name, medication name, amount dispensed, manufacturer, lot number, and the dispensing practitioner’s name (may document sample medications given out on the logs started by the pharmaceutical representatives to avoid duplication of efforts).
- Report the loss or theft of drugs to the police, the Drug Enforcement Agency (DEA), and applicable state authorities, as required.
- Check expiration dates of all medications, including vaccines and sample drugs, on a regular basis.
- Dispose of outdated medications in a manner that prevents unauthorized access and that conforms to local/state regulations regarding disposal of drugs.
- Secure prescription pads from unauthorized access.
- Report the loss or theft of prescription blanks and/or pads to the Office of Drug Control (NJPB Unit) within 72 hours of notice of loss or theft, and local pharmacies.

Medication Lists

Patients may see more than one physician or other practitioner; they are also likely to medicate themselves with over the counter (OTC) medications and supplements. Understanding all the drugs that your patient is taking may help you make decisions on their care. It is important, therefore, to:

- obtain a complete drug history – including prescription, OTC, vitamins, herbal products, and illicit drugs – at every patient’s initial visit and update it upon each visit or patient call
- consider doing periodic “brown-bag check-ups” by having patients bring in for review in your office all prescription, OTC, vitamins and herbal medications they take
- use a [medication flow sheet](#) for all prescriptions and file it in a prominent place in the patient charts in order to have ready access to the patient’s current and past drug history for treatment efficacy, to avoid medication interactions, and to track refills and renewals
- document all medication orders – including refills – in a prominent location (perhaps on or with the medication flow sheet) in the patient’s chart
- if a patient is referred or transferred to another practitioner outside of the practice, provide a complete list of the patient’s current medications

Allergy Documentation

- list patient drug allergy/sensitivity information in a prominent location in the patient's chart
- allergy information should include the name of the drug or other allergen such as latex, the date the allergy is identified, and the type of reaction or intolerance
- update the allergy list regularly and whenever you prescribe a new medication or make a change in medication
- if no known allergies, state so in the record – do not leave blank

Prescriptions

Prescriptions are a routine part of most practices. If the practice has a carefully developed set of processes to guide prescription writing and refills, and if the practice follows those processes faithfully, their liability should be minimized. Examples of these processes are:

- write or print prescriptions clearly and legibly to avoid errors
- use a current *Physician's Desk Reference*
- restrict handling of prescription refills and medication administration to staff that have been appropriately trained and credentialed
- do not routinely prescribe medications by telephone; if done on occasion do only when the prescriber is sufficiently familiar with the patient and his/her history
- document all medication orders in the patient's chart
- require that verbal orders be repeated or "read back" by the person taking the order, and again by the prescriber
- verbal orders to office staff for medication prescriptions or refills must be entered in the chart at the time of ordering, and signed later by the prescriber
- the patient's chart should be reviewed prior to refilling a prescription per phone request
- if the patient asks for a refill of a prescription and has not been seen in the office for that condition for a while, a limited amount may be prescribed until the patient can be reevaluated (this is particularly important for patients taking medications which require monitoring like anticoagulants, or which can be abused like opioids)
- medications such as anticoagulants which require routine lab tests for blood levels should be tracked as a group; that is, all patients taking that type of medication should be followed as a high-risk group within the practice, utilizing a special [flow sheet](#) which tracks their dosages, prescriptions, refills, and lab work; careful monitoring of their condition is necessary for good patient safety and reduced liability

Patient Drug Education

Take time to teach patients about new prescriptions and provide the following information:

- name (brand and generic) and purpose of the drug
- dosage and frequency
- route
- possible side effects and those that need to be reported to the doctor
- foods, beverages, or other medications/herbal remedies to avoid
- duration of the medication therapy
- refill status

Document any special instructions given. Also, if you prescribe an off-label use of a drug, document the applicable professional reference regarding this decision.

Medication Samples

In addition to recording the dispensing of medication samples in the patient's medical record, it's important to have a comprehensive system to track all medication samples received and dispensed, in case of a recall. This information should be maintained for at least six months to a year. Though there are various types of systems you can use, one type is a log located near the sample closet/area.

When using a log system, your practice can use [one log](#) to track receipt and dispensing of samples, or it can use a [dual log](#) system to do the same thing. In either case, to reduce staff workload, the pharmaceutical representative who drops off samples should be required to fill in the log for samples received. Staff and/or physicians would then fill in the part of the log which records which samples are dispensed.

Administering Vaccines, Medications, and Allergens in the Office

If your practice includes the administration of medications, allergens, or vaccines there are special concerns to be addressed. Injectable medications may have special side effects, or require specific injection techniques. Vaccines require very precise storage and are to be matched carefully by technique and route to the right age group (especially in children). With that in mind, your processes may include:

- proper vaccine storage, which includes using refrigerators without freezers to maintain temperatures with minimal fluctuations
- removal and non-use of any vaccine which has been exposed to freezing temperatures
- use of the seven "rights" of vaccine administration as advised by the Centers for Disease Control (CDC)
 - right patient
 - right vaccine
 - right time (patient is right age, vaccinated at the right interval)
 - right dose (based on age of patient, not weight)
 - right route (oral, intranasal, subcutaneous, or intramuscular)
 - right site (dependent on right route and age of patient)
 - right documentation
- proper handling of injectable medications
 - note if injection requires a special technique such as a "z" technique for injectable iron
 - make sure that staff are aware of this need and trained in the technique
 - advise patients of possible side effects of some injectables, such as tissue atrophy with some injected steroids
 - use of a double-check system for routine injections such as allergens, where the routine nature of the task can lead to error

OFFICE-BASED PROCEDURES AND DIAGNOSTICS

On-site Procedures

Office procedures are not a new concept. Physicians have been doing minor procedures like incisions and drainage of small cysts and abscesses outside of hospitals for centuries. But with the advent of new anesthetics and new methods for disinfection and sterilization, many more procedures of varying complexity have found their way into office practices and ambulatory surgical settings, becoming a source of additional revenue for many practices.

With that migration of surgery into an ambulatory setting comes new risks and regulation. Procedures performed in this setting should entail almost all, if not all, of the precautions taken in an inpatient surgical setting.

Unfortunately, there are no “universal regulations” which exist to provide a baseline of standards for office-based surgical procedures. Rather, pre-existing guidelines developed by accrediting organizations, medical specialty groups, state medical societies and some state/federal regulations, such as those promulgated by the NJ State Board of Medical Examiners (BME) are used when agencies audit practices and facilities. These standards and guidelines are some of the resources you have to assist your practice in establishing practice guidelines, until such time as industry efforts, currently underway, have evolved. Those future guidelines and the ones that you implement now are developed to protect both patients and practitioners.

Primary Areas of Risk

Patient Screening and Selection

- written guidelines to ensure that patient selection is appropriate for the office procedure should be established
- procedures should be of the duration and complexity that will permit patients to recover and be discharged home from the office
- patients should be assessed and screened to determine risks and appropriateness for the office setting (e.g. patients < ASA II); note that using the American Society of Anesthesiologists' (ASA) criterion, which measures a patient's physical status, provides a consistent approach to patient selection
- consider other risk indicators, when screening patients, such as a complicated medical history, obesity, cardiac or chronic respiratory conditions, sleep apnea, and seizure disorders, and whether anticipated blood loss of only 550 ml or less is expected
- pre-operative evaluation should include review of a patient's health and social history, a physical exam, appropriate diagnostic testing and/or specialist consultation
- there should be a requirement for pre-operative documentation of completion of all of the above

Anesthesia Plan of Care:

- ASA publications should be considered when developing the office-based surgical practice's anesthesia policies and procedures; see “Guidelines for Office-Based Anesthesia,” “Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists

(if administered by surgeon or surgeon supervises administration by non-anesthesiologists), “Guidelines for Preoperative Fasting,” and “Standards for Basic Anesthetic Monitoring”

- ensure that necessary monitoring equipment, medications and resuscitative capabilities are present and include the correct size for anticipated patient population (i.e., pediatrics, obese, etc.) are always available, working properly and fully stocked
- ensure that staff assisting and/or performing in any capacity in the administration of anesthesia are appropriately supervised, and follow established protocols

Staff Competencies and Credentialing:

- establish office practice provider credentialing guidelines that include
 - proof of adequate training/certification
 - documentation of delineation of privileges to perform equivalent or greater procedures at a local hospital or ambulatory care facility
 - periodic verification and documentation of practitioner credentials, including delineation of privileges, of all healthcare practitioners on file
- individuals administering anesthesia must be licensed, qualified and working within their scope of practice; non-physicians administering anesthesia are to be under the direct supervision of an anesthesiologist or the operating physician
- healthcare practitioners who either administer or supervise the administration of anesthesia must maintain current training in advanced resuscitation techniques (ACLS/PALS); all other clinical staff should maintain training in basic cardiopulmonary resuscitation
- staff members involved in surgical procedures need proven, ongoing competencies, not only for the procedure itself, but in managing any emergency that might ensue; written job descriptions outlining required competencies should exist for each staff member
- physicians and staff should have annual documented continuing education in their field

Informed consent:

- refer to the [Legal/Regulatory section](#) of this toolkit for an in-depth discussion of the informed consent process

Pre-op procedures

- pre-operative clearances (when warranted) should be obtained and documented
- pre-operative history and physical should be performed within 48 hours of planned procedure
- pre-operative anesthesia assessment (if anesthesia beyond local or conscious sedation will be used) by an anesthesiologist, or anesthesiologist working in conjunction with a supervising anesthesiologist, should be documented
- there should be uniform pre-op patient education provided for specific procedures
- pre-procedure review should be done of medications to ensure that medications and solutions both on and off the sterile field are labeled, drug concentrations are standardized, and emergency medications are placed in the surgical procedure area
- “time out” should be conducted with the operative team to verify correct patient, correct side & site, agreement on the procedure to be done, correct patient position, and availability of special equipment and materials
- site should be marked while the patient is fully alert

Intra-op procedures

- targets should be established (i.e. average length of time of procedures, should not exceed 6 hours in duration; and procedures should be limited to ≤ 2 hours and 20% of total body surface area if warming devices, forced air warmers, or iv warmers are not available)
- intra-operative physiologic monitoring should include:
 - continuous monitoring by individual not participating in the procedure
 - assessment of ventilation
 - oxygenation level
 - cardiovascular status
 - body temperature
 - neuromuscular function and status
 - patient positioning
- during regional or local anesthesia with no sedation, adequacy of ventilation is evaluated by continual observation of qualitative clinical signs
- during moderate or deep sedation, adequacy of ventilation is evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide (unless precluded or invalidated by the nature of the patient, procedure or equipment)

Post-op period

- a staff member trained in post-op recovery should remain with the patient at all times until patient is fully recovered
- the physician should be physically present during the intra-operative period and should remain available until the patient has been discharged home from the office
- at least one person with training in advanced resuscitative techniques (ACLS or PALS) should be immediately available until all patients are discharged
- there should be physician-defined discharge criteria, in writing, such as stable vital signs, responsiveness and orientation, voluntary movement, controlled pain and minimal nausea and vomiting

Post-discharge

- uniform post-op patient education should be provided for specific procedures
- written instructions and an emergency phone number should be provided to the patient and documented in the record, including pain management, post procedure diet, medications and activities, and a follow up appointment
- a complete list of medications should be provided to the patient on discharge
- patients should be informed of the surgeon's scheduled absence in the post-op period, and be given the name and phone number of the covering surgeon
- the surgeon should provide "hand-off communication" to the covering surgeon
- if sedation, regional block, or general anesthesia is used, patient must leave with a responsible adult who has been instructed with regard to the patient's care

Emergency Equipment/Supplies should include:

- patient monitoring equipment
- emergency medications (i.e. atropine, epinephrine, and appropriate rescue drugs)
- a defibrillator
- a latex allergy cart or tray

- an ambu-bag for positive pressure ventilation
- a safe and reliable source of oxygen
- at least two sources of suction
- pulse oximetry
- capnography,
- warming blankets,
- IV catheters
- IV fluid warmers

Process for Emergency Transport

- there should be a written emergency plan that includes written protocols for the timely and safe transfer of patients to a hospital within a reasonable proximity when extended care due to slow recovery, complications or emergency service is needed
- there should be written transfer agreements with hospitals in reasonable proximity to the practice in which all physicians performing surgery have admitting privileges
- all information relevant to the patient should be readily available to an authorized healthcare practitioner, in the event that a patient is transferred due to surgical complications

Written Policies and Procedures

- office-based surgical practices should have an identified medical director and written policies describing the organizational structure, including lines of authority, responsibilities, accountability and supervision of personnel
- clinical policies for surgical procedures should be in place
- procedure-specific checklists should exist to ensure completion of tasks associated with pre-op preparations for surgery
- written, easily accessible policies are in place to ensure that necessary personnel, equipment and procedures are available for emergencies – e.g. surgical and other fires, power outages, weather disasters, medical emergencies
- medical record documentation requirements, including those for the pre, intra and post op periods, as well as for emergencies and transfer of patients
- there should be a process in place to inform the primary care provider of the patient's status, post operatively

Performance Improvement/Quality Assurance activities:

- there should be a written process in place to track and trend patient outcomes; this process should include patient discussions and disclosure of procedure outcomes, including adverse outcomes
- a plan that promotes performance improvement is essential to use in monitoring the processes and safeguards of office-based practice, as compared against published data
- performance improvement data provides quality and risk indicators that are useful for credentialing, such as patient deaths, cardiopulmonary events, anaphylaxis and adverse drug reactions, infections, post-operative complications, patient satisfaction survey results and medication errors
- conduct post op follow up telephone calls, which are designed to gather specific data
- follow NJ BME rules and guidelines for office-based surgery
- consider accreditation through the Accreditation Association for Ambulatory Health Care (AAAHC), the Accreditation of Ambulatory Surgery Facilities (AAAASF), or the American

Osteopathic Association (AOA); this type of certification can help the practice stay in touch with the many requirements for patient safety, quality initiatives, performance improvement, and safety which are required by state and federal inspectors

Princeton has two articles which describe some of the risks of office-based procedures in a little more detail. One article discusses [medical clearance for surgery](#); and the other reviews [wrong site surgery](#).

Cosmetic Procedures

As in office-based surgical procedures, cosmetic procedures have become more common in office practices. The use of lasers, injections of Botox or fillers, skin peels, permanent make-up, and many other treatments are being done in office practices.

Cosmetic medicine is a rapidly evolving field, with new developments in chemicals, lasers, and treatments. Physicians who practice in this field not only need to keep up with those developments, but they also need to be aware of state regulations which set the boundaries within which they practice. As of July, 2011, the NJ BME regulations state that:

- the use of lasers is an invasive procedure and may only be performed by a licensed physician
- intermittent pulse light (IPL) is equivalent to laser and is subject to the same regulations
- laser hair removal may only be performed by physicians
- administering or injecting Botox is the practice of medicine and should be done by a physician, under the regulations of the board (this would include establishing a medical record, e.g. a history and physical, informed consent, and all confidentiality protections)
- microdermabrasion/glycolic acid peels may be done by other trained personnel under the direction of the physician

There are many other treatments and a number of aesthetician programs which train personnel in these treatments. Before deciding to add any new treatments to your practice or investing in equipment and supplies, it is recommended that you check with the board regarding their regulations regarding those treatments.

On-Site Diagnostics

If your office performs on-site clinical laboratory or radiology services, constant vigilance to ensure the safety and accuracy of the testing services offered is necessary. The owner and director of a clinical laboratory licensed by the state of New Jersey is jointly and separately responsible for compliance with the New Jersey Clinical Laboratory Improvement Act, NJSA 45:9-42.26 et seq, and its related regulations. Likewise, all radiological testing/services must be in compliance with the Nuclear Regulatory Commission (NRC) requirements.

Therefore, it is important that you know the laws that apply to your practice and make sure that your on-site diagnostics operate in compliance with all of the applicable rules and regulations. The following are some general recommendations for managing risks associated with the operation of on-site diagnostics:

- retain licensing documents with your practice's permanent documents
- train, supervise, and periodically test the proficiency of all diagnostic personnel

- maintain an inventory log of all diagnostic equipment and use it to monitor equipment maintenance, re-calibration and servicing
- check accuracy of all clinical procedures by tracking reports that are regularly reviewed by the directing physician
- instruct staff about legal requirements for specific conditions, such as HIV/AIDS testing and confidentiality
- maintain and revise written instructions/procedures, including maintenance and reporting results, on an annual basis

OFFICE SAFETY

An effective Safety Management Program can help prevent patient or staff accidents, as well as the loss of physical property. It is important to assess your practice's physical environment on an ongoing basis, as well as encourage your staff to bring any concerns forward via staff meetings, direct report, or a suggestion box to assist in determining any safety concerns that need to be addressed.

Medical Equipment

A patient injury from a medical device or piece of equipment may trigger a claim against both the physician practice and the equipment manufacturer. To reduce patient safety and liability risks associated with medical devices and equipment, your office should have an effective program for managing medical equipment.

Management of medical equipment in an office setting calls for the following:

- control and centralization of equipment selection and purchases
- a system for performance of periodic inspections, maintenance and repair of equipment – including emergency equipment – that is documented in either work orders or a written log
- documentation to support the practice's position that only qualified personnel who have been properly trained operate equipment
- a policy mandating the removal of defective equipment from patient care and the sequestration of equipment involved in any patient incident
- a system for reporting incidents of equipment malfunction
- a procedure to ensure that malfunctioning equipment involved in a patient incident is **not** released to the manufacturer, but is removed from service and held for testing by a third party, or until advised by Princeton Insurance
- retention of recall notices with notation of the item's serial number, to whom it was returned, and the date of the return
- posting of applicable telephone numbers in a prominent location for use by staff in an equipment emergency

Emergency Preparedness

Emergencies in the office practice setting are not uncommon. They may range from a medical emergency to environmental occurrences such as a fire or power outage. It is important that you have an emergency response plan appropriate to the practice and that all staff are trained in what to do in an emergency.

- develop *written* emergency policies and procedures for handling both medical and non-medical emergencies in your office
- conduct and document periodic emergency response training for all staff
- ensure that at least one staff member having current basic CPR certification is present during office hours
- maintain emergency equipment that is appropriate for your practice and is in good working order, such as crash cart resuscitation equipment, fire extinguishers and smoke detectors
- store emergency equipment in an accessible location known to all staff
- call 911 if transport to an emergency department is necessary – never drive a patient

- post an emergency evacuation plan throughout the office that specifies what each member of your staff is responsible for doing
- clearly identify all exits with exit signs (preferably lighted) and make sure that all exits are maintained free and clear of obstructions
- have a plan for back-up of your computer records in the event of a power interruption

Injection Safety

The Centers for Disease Control (CDC) and the State of New Jersey have focused on injection safety recently. This focus will persist because both patients and healthcare practitioners continue to be exposed to disease and infection by poorly handled needles, syringes, medication vials, and IV solution bags. Per the CDC's website on the subject of injection safety (<http://www.cdc.gov/injectionsafety/>), poor practices in these areas have resulted in:

- transmission of bloodborne viruses, including hepatitis C virus to patients
- notification of thousands of patients of possible exposure to bloodborne pathogens and recommendation that they be tested for HCV, HBV, and HIV
- referral of providers to licensing boards for disciplinary action
- malpractice suits filed by patients

The CDC recommends that staff:

- never administer medications from the same syringe to more than one patient, even if the needle is changed
- do not enter a vial with a used syringe or needle

The CDC further recommends that:

- medications packaged as single-use vials never be used for more than one patient
- medications packaged as multi-use vials be assigned to a single patient whenever possible
- bags or bottles of intravenous solution not be used as a common source of supply for more than one patient
- absolute adherence to proper infection control practices be maintained during the preparation and administration of injected medications

Infection Control Recommendations from the CDC

The CDC issues guidelines for infection control in a variety of situations. In July, 2011 they issued an updated Guide to Infection Prevention in Outpatient Settings. The guide can be found at: http://www.premierinc.com/safety/topics/guidelines/downloads/CDC_standards_ambulatory-care-July-2011.pdf.

An Infection Prevention Checklist for Outpatient Settings accompanies the guide. This checklist can be found at: <http://www.cdc.gov/HAI/pdfs/guidelines/ambulatory-care-checklist-07-2011.pdf>.

Infection control practices are no longer considered just a facility issue, especially when it comes to practices like hand washing. Patients are being educated about the same things on the websites they frequent. Your patients may ask you why you haven't washed your hands before you examine them.

Office Safety Manual

To assist you in developing an office safety manual, and monitoring your office's safety and security, Princeton has developed sample policies and procedures which you can use as templates for your own manual. These materials are listed below:

An Office Safety Manual

- [Policy & Procedure: Defibrillators/AEDs & Crash Carts](#)
- [Policy & Procedure: Electrical Safety](#)
- [Policy & Procedure: Electronic Equipment & Systems Protection](#)
- [Policy & Procedure: Emergency Response](#)
 - ◆ [911 Poster](#)
 - ◆ [RACE fire safety diagram](#)
- [Policy & Procedure: Fire Safety](#)
- [Policy & Procedure: Hazardous & Medical Waste](#)
- [Policy & Procedure: Infection Control](#)
- [Policy & Procedure: Investigating Events in the Office Practice](#)
 - ◆ [Event/Complaint Report](#)
 - ◆ [Instructions for Completing Event/Complaint Report](#)
- [Policy & Procedure: Medical Equipment Management](#)
 - ◆ [Medical Equipment Tracking Log](#)
- [Policy & Procedure: Security Management](#)
- [Environmental Safety Self Assessment](#)
- [Infection Control Self Assessment](#)

Helpful Links for Office Practices

- **OSHA Health Care Industry Quick Start Information and Links**
http://www.osha.gov/dcsp/compliance_assistance/quickstarts/health_care/index_hc.html
- **CDC Guidelines - Hand Hygiene in Healthcare Settings**
<http://www.cdc.gov/handhygiene/>
- **New Jersey Local Information Network Communications System Health Alert Network (NJLINCS HAN)** www.njlincs.net
- **Flu pandemic** www.NJflupandemic.gov
- **Respiratory Hygiene**
<http://www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm>
- **Cover Your Cough Flyer & Poster Download**
<http://www.cdc.gov/flu/protect/covercough.htm>
- **Association for Professionals in Infection Control** <http://www.apic.org/>
- **CDC Guide to Healthcare-associated Infections (HAI)** <http://www.cdc.gov/hai/>
- **CDC Topics on Tuberculosis** <http://www.cdc.gov/tb/>
- **Book or Article - Suggested Immunizations for Staff: Centers for Disease Control and Prevention. *MMWR Recomm Rep.* 2004; 43(RR-13):1–132.**
- **CDC Guide to Infection Prevention in Outpatient Settings.**
<http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-guidelines.html>.
- **CDC's Infection Prevention Checklist**
<http://www.cdc.gov/HAI/settings/outpatient/checklist/outpatient-care-checklist.html>
- **CDC's Safe Injection Practices to Prevent Transmission of Infections to Patients**
http://www.cdc.gov/injectionsafety/IP07_standardPrecaution.html .

* NOTE: Links above were valid at time of publication.

POLICY & PROCEDURE

DEFIBRILLATORS/AEDS AND CRASH CARTS

Policy Statement

Defibrillators/AEDs and Crash Carts are only effective during an emergency when all of the equipment is in proper working order. Crash carts are set up for the type of life threatening event expected to occur in this office (i.e., cardiac, anaphylaxis, etc.). Items found on the crash cart include [*defibrillator/AED unit, oxygen, drugs, etc., as appropriate*]. If your office treats pediatric patients then you should segregate adult life saving items from pediatric life saving items.

Procedure

1. Post the emergency response procedure next to the phones, including the telephone number to dial (i.e. 911, 9-911).
 - a. Check defibrillator/AED and/or crash cart daily (a crash cart checklist can make this much easier) to make sure it is ready for use, as follows:
 - b. The battery is charged and it is working properly; refer to the manufacturer's recommendations for any additional requirements.
 - c. The oxygen cylinder wrench is placed on the crash cart if not already attached to the cylinder. Open the cylinder to make sure it is full and that oxygen is coming from the flow indicator valve.
 - d. A detailed list of all the medications and their expiration dates is kept in the crash cart binder.
 - e. The drawers to the crash cart are locked at all times to ensure all of the medications, needles, syringes and other equipment remain intact.
2. A short backboard or similar device for CPR is available with other resuscitative equipment.

Once used:

3. EMTs may download any rescue data from the defibrillator/AED.
4. All supplies and equipment are checked and replaced immediately, as necessary, to ensure readiness for the next emergency.

POLICY & PROCEDURE

ELECTRICAL SAFETY

Policy Statement

Electricity is a powerful energy source that if not used properly or maintained can result in personal injury or death to staff or patients. It is the responsibility of all staff members to take proactive steps to minimize the potential for an electrical hazard, including a fire.

Procedure

1. Inspect all electrically powered equipment to ensure it contains an Underwriter's Laboratory (UL) label on the device or the power cord. If the device doesn't have a UL label, do not use it.
2. Inspect all electrical cords for fraying, cracks, or cuts and never place them under carpeting, rugs, or office furniture.
3. Inspect all electrical appliances and equipment on an annual basis for normal wear and tear that could lead to an electrical fire. Do not use faulty or damaged equipment.
4. Don't use electrical tape to protect cut or frayed cords. Remove the damaged cord from use.
5. Keep electrical cords out of the normal paths of traffic to prevent slips, trips, and falls.
6. Never staple or nail electrical cords to walls or floors.
7. Restrict the use of extension cords in the office. Extension cords should not be used as a permanent solution. If extra power is needed, contact a licensed electrician and have them install an additional circuit.
8. Never use a "cheater" plug or three-prong to two-prong adapter. This eliminates the grounding properties of the circuit.
9. Temporary extension cords may be used when decorating for the holidays, but make sure that the proper type of cord (indoor versus outdoor) is used for the job.
10. Replace existing extension cords with at least a 16 gauge Underwriters Laboratory (UL) approved cord.
11. Turn off any electrical device before you connect or disconnect it from an electrical outlet. Hold the electrical cord by the plug body and not by the cord itself. Using the cord will eventually damage the internal wiring.
12. Don't handle any electrical device with wet hands or when standing on a wet floor.
13. Install a Ground Fault Circuit Interrupter (GFCI) circuit for protection against an electrical shock in any location where electricity and water are within six feet of each other.
14. On a monthly basis and after an electrical storm, trip/test any GFCI circuits to ensure that they operate as designed.
15. Only use UL approved surge protectors in the office. Don't connect multiple surge protectors together. Mount surge protectors up off of the floor to prevent damage to it.

16. Do not use portable electrical space heaters. If a portable space heater must be used, ensure that:
 - it is UL-listed
 - it is purchased with an automatic shut-off, should the heater be knocked over or if it overheats
 - at least three feet of open space is maintained in front of the heater
 - an extension cord is not used to power the heater
 - if the unit does not work as designed, it is immediately unplugged, remembering to shut-off the heater before doing so
17. If an outlet is broken or loose, unplug any devices and contact a licensed electrician and have them make any necessary adjustments or repairs to the outlet.
18. Fit all outlets with cover plates.
19. Install plastic inserts in any open outlet slot in the office that could be exposed to children to protect against exposure and electric shock.
20. If any electrical device begins to emit an odor, smoke, sparks or makes strange noises (buzzing or sizzling), immediately shut the device off. Remove the power cord from the receptacle by using the plug body and not the cord. If the device still appears to be burning at this point, follow the emergency response procedure for fires.
21. When replacing light bulbs or tubes, use the wattage indicated on the fixture or lamp. Don't increase the wattage because you need more light. Halogen bulbs can produce high heat and should be placed away from combustible furnishings.
22. Maintain all primary entrance switches and panel distribution boards readily accessible and free from obstructions.
23. Maintain labels of the circuits in the electrical panel as to the area, room, or equipment that they control.
24. Cover any empty/missing circuit breakers with a plate.
25. Replace any blown fuses or reset any tripped circuit breakers in an electrical panel. Don't ever increase the capacity of the blown fuse.
26. Shut-off all electrical equipment before leaving the office after normal business hours.

POLICY & PROCEDURE

ELECTRONIC EQUIPMENT & SYSTEMS

PROTECTION

Policy Statement

It is important to protect computers and other electronic equipment from voltage fluctuations or total loss of power that could result in damaged equipment and/or loss of data.

Procedure

1. Plug electronic equipment, including the telephone system, computer monitor, modems, portable external drives, and speaker system, into individual surge protectors that offer the following features:
 - an indicator light
 - UL 1449 listed
 - protection against lightning strikes
 - some form of insurance coverage for devices plugged into the surge protector
 - A R-11 telephone jack if you are using a regular dial-up modem
 - a cable connection if you are using a cable modem
2. Do not plug the printer into the same surge protector as the computer. Printers typically use more electricity than other parts of the computer system, and when they are used, internal fluctuations may result which can then affect the computer's hard drive.
3. Another level of protection can be added to your office that is termed "a service entrance surge protection device" which is usually installed at the base of your electric meter or at your main electrical distribution panel. This device can reduce the power surge from a lightning strike or power fluctuation to a lower level before it reaches your office's internal electrical outlets. This device must be installed by a qualified electrician.
4. A direct lightning strike can overwhelm even the best surge protection devices so the best strategy is to unplug electrical equipment prior to a severe thunderstorm.
5. Consider using a UPS (uninterruptible power supply) to maintain a steady and continuous flow of electricity even when power is lost.
6. Conduct a data backup no less than every other day - daily being the best practice.
7. Maintain one copy of the back-up data at the office in a fire-proof safe and another copy off-site as well.

POLICY & PROCEDURE

EMERGENCY RESPONSE

Policy Statement

It is the responsibility of all staff to remain vigilant and prepare for an emergency before it happens. Every staff member must be trained and maintain knowledge of his or her own role within the emergency response plan. [911 posters](#) should be located at all phone locations to guide staff on what information to provide 911 dispatchers.

Procedure

Medical Emergency

1. Call 911 or ask someone to call on your behalf and report back that they have done so.
2. Provide as much medical information to 911 as possible; 911 may provide pre-arrival medical response guidelines to deal with the emergency.
3. Protect victim from further harm/injury by removing any immediate threat. Do not move the victim unnecessarily.
4. Provide first aid, if you have been trained to do so, until emergency first responders arrive.
5. Send someone outside to direct the emergency first responders.

Fire

1. If you do smell a burning odor, see visible smoke or fire, remember “**RACE**”; Rescue, Alarm, Close, and Extinguish.

R. Remove any individuals in the immediate area of the fire as soon as possible.

A. Pull the nearest fire alarm pull station and alert others in the office to the potential emergency.

- Respond to the emergency calmly and don't yell fire!
- Have someone call 911 to report the emergency. Refer to the 911 poster. Give the dispatcher:
 - the nature of the emergency, including information on people trapped or evacuating the building if that is the case
 - the address and nearest crossroad
 - phone number you are calling from
 - your name

C. Confine the fire by shutting the door to the room if that is possible. Close all doors and windows if possible to contain the fire. Turn off portable fans.

E. Extinguish the fire. If trained in the use of portable fire extinguishers and the fire is small, you may attempt to extinguish the fire. Remember “**PASS**”; Pull, Aim, Squeeze, and Sweep.

- Never allow the fire to get between you and the exit door.
2. Princeton has developed a set of [fire safety diagrams](#) that you can use to familiarize your staff with **RACE**, **PASS**, and other key information.

3. If a smoke alarm or pull station is activated in your office or building:
 - Begin to evacuate your office, including patients and staff. Have staff assist patients, if necessary.
 - Designate someone to quickly look throughout the office to ensure that all patients and staff have evacuated the area. Quickly check bathrooms, staff lounges and storerooms as you exit and shut doors.
 - Designate someone from your staff to call 911 to report the alarm if the fire department hasn't already been notified. Refer to the 911 poster.
 - Alert the other tenants in the building, if necessary, to the emergency so that they may exit the building.
 - Leave the area immediately; don't attempt to collect personal items.
 - Close all doors behind you as you move to the nearest exit or stairway. This will retard the spread of smoke and fire and lessen damage.
 - Do not use elevators.
 - If you can leave the room and you must pass through an area that is on fire to reach safety:
 - try a secondary means of egress
 - if that is not possible drop to your knees, on the floor, and crawl towards the nearest exit
 - before opening the door, feel the upper portion of the door; if the upper door or doorknob is hot, **do not open the door**
 - if the door or the doorknob is not hot, brace yourself against the door and open it slightly
 - if you can't exit the office make sure that you telephone 911 and report your situation to the fire department dispatcher
 - place wet towels around the door and open a window
 - place an article (clothing, drape) out of the window to alert the fire department of your location and yell to staff or bystanders to notify them as well
 - if your clothing or someone else's clothing catches fire drop to the ground; remember: Stop, drop to the ground, and roll; place your hands over your face to protect your face and your respiratory system; **don't ever run**
 - Keep the driveway or parking lot area clear of both patients and staff as the fire department arrives on scene.
 - Advise the fire department of the situation to the best of your knowledge, especially the location of medical gas cylinders or laboratory chemicals, if appropriate.
 - Don't re-enter the building or office until advised it is safe to do so by the fire official or chief.

Security Emergency

If there is a suspicious situation, interference with normal operations (i.e. demonstration), prevention of physical access to building or office, or a threat of physical harm or damage:

1. Dial 911 to notify the local police department as soon as possible and report the incident, including the following:

- nature of the incident
 - location of the incident
 - description of person(s) involved
 - description of property involved
2. Follow instructions.
 3. Assist local police upon arrival by supplying them with any additional information and asking others to cooperate.

Gas leak

1. Dial 911 to notify the local fire department. Give the dispatcher as much information that is known or available. Follow their instructions.
2. Do not switch on lights or any electrical equipment. Remember that electrical arcing can trigger an explosion.
3. Have patients, staff and visitors exit the office if you can and stand away from the building. Await the arrival of the fire department.

Hazardous Material Spill

If a hazardous material spill occurs that cannot be handled by an employee:

1. Dial 911. Be specific about the nature of the material involved if known and the exact location. Pull the Material Safety Data Sheet of the chemical if known and review the chemical information for appropriate actions.
2. Evacuate the affected area at once and seal it off to prevent contamination of other areas until the arrival of emergency personnel.
3. Avoid contact with anyone contaminated by the spill as much as possible. [Note: copious amounts of water from a garden hose may help.] Have those contaminated remain in the vicinity and identify themselves to the local emergency responders who will provide the necessary decontamination, first aid and clean up.
4. Do not re-enter the building or office until advised it is safe to do so by the police chief/designee.

Bomb Threat

When a bomb threat is received, the individual taking the call should:

1. Stay calm.
2. Make a note of the date and time the call was received.
3. Try to keep the caller talking as long as possible. The more he/she talks, the more you may learn.
4. Try to record everything the caller says, if possible. Write down the caller's exact words.
5. Ask the following questions, as well as others deemed appropriate by the individual receiving the call:
 - a. when is the bomb going to explode
 - b. exactly where is the bomb located
 - c. what does the bomb look like
 - d. what kind of bomb is it

- e. what will cause the bomb to explode
 - f. did you place the bomb; why
 - g. what is your address
 - h. what is your name
6. Listen closely to the voice of the caller and note the following:
- a. sex of the caller
 - b. age of the caller
 - c. race of the caller
 - d. accent (is the voice native to the area)
 - e. speech impediments or peculiar voice characteristics (i.e., drunk, lisp, etc.)
 - f. attitude of caller (i.e., calm, excited, etc.)
7. Note any strange or peculiar background noises (i.e. street noise, motor noise, music, television or radio programs, dishes rattling, baby crying, or other background noise that might offer a remote clue as to the origin of the call).
8. Once the caller hangs up:
- a. note the time
 - b. dial *57 to trace the call (there may be a charge) and make a note of what the recording indicates
 - c. dial *69 to obtain the phone number of the last call received and make a note of what the recording indicates
 - d. dial 911 and report the following information:
 - your name
 - location and telephone number from where you are calling
 - the situation
 - location of the device, if known
 - time it is set to detonate, if known
 - type of device, if known
 - exact time you received the call
 - the information you received after you dialed *57 and *69
 - any other information
9. Follow the instructions of the authorities.
10. If instructed, quickly inspect the area. Do not move or touch anything found that arouses suspicion. Note the description of the object and its exact location and promptly report it to the police.
11. If instructed, evacuate the building.
- a. leave all doors open
 - b. move far away from the building
 - c. do not move any vehicles
 - d. do not re-enter the building or office until advised it is safe to do so by the police chief/designee

Weather Emergencies

1. Remain calm.
2. Tune a battery operated radio to NOAA or a local radio station and follow the instructions.
3. Consider calling patients to reschedule appointments and closing the office.
4. Assist patients in exiting the building, if okay to do so. If you have access to a basement, consider using it for protection against a tornado.
5. Turn off utilities, if appropriate.
6. If you are trapped in the office/building, call 911 and wait for help. Avoid traveling in automobiles if the roads are extremely dangerous.
7. Keep your radio tuned to a local station for updates on the situation and vital information.

IN CASE OF

EMERGENCY



**DIAL
911**

**FIRE
POLICE
AMBULANCE**



POISON CONTROL: 1-800-222-1222

Provide the following information:

- Nature of the emergency, including if people are evacuating the building
- Address (*including floor, suite, etc.*):

- Nearest crossroad and/or landmark:

- Phone number you are calling from:

- Your name

Stay calm and don't hang up unless instructed to do so by the 911 operators.

If available, send someone outside to flag down the emergency first responders.

Advise the Fire Department, upon arrival, of the location of medical gas cylinders or laboratory chemicals, if applicable.

POLICY & PROCEDURE

FIRE SAFETY

Policy Statement

Fire prevention is the key to keeping the office and patients safe from fire. It is the responsibility of all staff members to control and minimize ignition sources/hazards and recognize the typical fire causes.

Procedure

Decorations

1. Use only non-combustible or fire-resistant decorations in the office. Decorations should carry a label indicating that they are non-combustible or fire-resistant.
2. Live pine trees or branches are not permitted inside the office. They can dry out and become very combustible because of the oils within their chemical make-up.
3. Artificial trees are not to be placed near exit passageways or doors.

Electrical Safety

1. Refer to *P&P: Electrical Safety*
2. Any lighting placed on an artificial tree is to be Underwriters Laboratory (UL) rated and inspected by staff prior to being placed on the tree. Old wires can become brittle and potentially dangerous when stored in attics or other places subjected to high heat.
3. Plug equipment directly into an outlet or surge protector as to not overload electrical circuits. Multiple cords can lead to overheating and result in a fire.
4. Immediately remove from use any cord that feels hot to the touch. (Any electrical device that smells hot, emits any odor or smoke should immediately be unplugged, removed from service and thrown out)

Keep lights, especially hi-intensity treatment lights, away from drapes, papers and other combustible items. Before any piece of electrical equipment is used, staff should inspect that device for frayed, cracked or broken wires. [Note: Never place extension cords underneath rugs, on the floor, around doors or other areas where individuals can walk over them]

Utility Systems

1. Maintain all electrical, heating and air conditioning systems in good operating condition. Regular preventive maintenance by a qualified person will minimize the potential for a fire to occur in these important utility systems.
2. Maintain proper operation of the clothes dryer.
 - a. clean the lint screen after every use
 - b. sweep up any accumulation of lint around the dryer (don't forget to check behind the dryer)
 - c. check the exhaust duct and outside vent for any blockage; disconnect the dry vent tubing and vacuum inside the tubing as a buildup can occur without visual evidence

3. Permanently label all main gas, water and electrical system shut-offs to assist in a quick shutdown in an emergency. Heat-producing devices like copy machines, coffeemakers, transformers and computer towers require air flow for ventilation. Don't store items around air or ventilation openings, periodically vacuum air or ventilation openings.

Smoking

1. Smoking is not permitted inside the office.
2. Signs are posted to alert both patients and visitors that this is a no-smoking facility.
3. A metal receptacle is provided to extinguish cigarettes outside the office in the designated smoking area.

Fire Alarm Systems and Extinguishers

1. Maintain fire extinguishers and fire alarm pull stations to be visible and accessible at all times. At no time should any piece of fire equipment be blocked or hidden from view.
2. Check portable fire extinguishers monthly and have them inspected on a yearly basis by a qualified fire protection contractor. Record inspection date on maintenance sticker.
3. Have the office fire alarm system and automatic sprinkler system (if applicable) tested and maintained by a qualified fire protection contractor according to the most stringent local and/or state fire prevention code (at least semi-annually).
4. If your office has a sprinkler system, do not store items closer than 18" below the sprinkler heads.
5. Test battery-powered smoke detectors on a monthly basis and replace the batteries on a semi-annual basis.
6. Have the local fire marshal or fire official walk through the office at least annually to review the fire equipment and fire prevention efforts. A copy of the most recent annual fire prevention inspection should be displayed or at least maintained in a file for regulatory compliance.
7. Post the emergency response procedure next to the phones, including the telephone number to dial (i.e. 911, 9-911).

Flammables / Combustibles

1. Never store flammable or combustible liquids in open containers or near heating sources (open flames, heating pipes or units) or near designated areas of egress.
2. Use approved safety cans for dispensing.
3. Do not store gasoline powered lawn mowers, leaf blowers or snow blowers inside the office. They should be stored in the garage or an outside shed.
4. Use approved non-flammable substitutes where possible.
5. Place propane gas grills away from the office and protect from vehicle damage. Always follow the manufacturer's fire safety guidelines. If you smell natural or propane gas notify the local fire department immediately and leave the office.
6. Don't place combustible items (i.e. towels, paper plates, bread wrappers) near the top of a gas stove.

7. Maintain at least 36" clearance surrounding the gas heater or hot water tank. Don't store oily rags in anything other than a safety container designed for the storage of oily rags.

Maintain Proper Egress

1. Keep hallways and corridors free of storage and other potential obstructions.
2. Don't place coat racks, potted plants or smaller pieces of furniture near exit passageways as these could easily be knocked over and partially block emergency egress.
3. Don't permit paper and other combustible waste to accumulate in storage areas.
4. Keep corridor doors to storage and trash rooms closed.
5. Maintain the fire escape at all times, including during periods of inclement weather. Make sure that the window opens easily.
6. Test emergency exit signs on a monthly basis for 30 seconds and on an annual basis for 90 minutes.
7. At the end of normal business hours:
 - a. remove trash and empty waste containers
 - b. walk through the office and look for items that might be out of place or could present a hazard if left unattended; at the end of the day designate someone to turn off all electrical devices that are not needed after normal business hours

Train Staff

1. Small fires can grow quickly in size and should not be underestimated.
2. Train staff on his/her role in the emergency response plan, including:
 - a. Location of fire alarm pull stations, portable fire extinguishers, and primary and secondary means of egress out of the building. Remember: The primary means of egress may be blocked by smoke in a fire and staff members will need to know alternative means of egress in that situation. Furthermore, if your office employs or treats wheelchair-bound individuals you will need a plan for their escape from the fire or have a place for them to wait for emergency assistance from emergency first responders.
 - b. Proper use of the fire alarm pull stations and portable fire extinguishers.
 - c. A simple emergency exit plan, which should be displayed inside the office. Remember: test doors before you open them. If the door is hot to the touch you will probably need to use an alternative means of egress. Also remember that heat and smoke rise in normal conditions and by crawling along the floor you may be able to exit the building on your own.
 - d. Designate a meeting point for staff outside of the office, remembering that responding fire apparatus may need to get very close to the building to operate effectively.
3. Conduct periodic emergency response drills on at least an annual basis to review the information with them.

POLICY & PROCEDURE

HAZARDOUS AND MEDICAL WASTE

Policy Statement

All hazardous and medical waste will be managed according to federal, state and local rules and regulations. There will be a designated person who is knowledgeable of federal, state and local rules and regulations governing the management of any hazardous and/or medical waste for which the facility may be responsible.

Definitions

Hazardous Waste:

1. Corrosive - a chemical capable of dissolving or wearing away of substances, including tissue, such as glutaraldehyde
2. Flammable - easily catches fire and tends to burn rapidly, such as formaldehyde vapors
3. Reactive - a reactive chemical is capable of participating in a rapid and sometimes violent reaction with other chemicals and substances, such as mixing phenol and formaldehyde
4. Toxic - can cause injury or death if swallowed, inhaled, or absorbed through the skin, such as anti-neoplastic drugs or mercury

Medical Waste:

1. Any waste used in a health care facility that, if not contained and managed properly, could result in the transfer of infection, such as:
 - microbiological wastes
 - blood and blood products
 - pathological wastes
 - used sharps
 - animal wastes
 - communicable disease, CDC class 4, isolation wastes
 - contaminated lab wastes
 - surgical and autopsy wastes that were in contact with infectious wastes
 - dialysis wastes
 - contaminated medical equipment
 - unused discarded sharps

Nuclear Waste:

1. Any substance that is radioactive

Procedure

Identify Waste

Determine by definition if the waste generated will be “Hazardous”, “Medical” or “Nuclear” Waste?

Labeling

1. Hazardous Waste - label as follows:

- “hazardous waste” in large print
- description of contents
- date collection in the container began
- name, address, business phone number, state permit or identification number (if applicable) for the generator of the waste
- name, address, business phone number, state permit or identification number (if applicable) of the transporters, treatment facilities, or other persons to whose control the medical waste is transferred
- date upon which the hazardous waste was packaged
- if possible attach MSDS label

2. Medical Waste - label as follows:

- “Biomedical Waste” or “Medical Waste” in large print
- international biohazard symbol if possible
- description of contents
- date collection in the container began
- name, address, business phone number, state permit or identification number (if applicable) for the generator of the waste
- name, address, business phone number, state permit or identification number (if applicable) of the transporters, treatment facilities, or other persons to whose control the medical waste is transferred
- date upon which the medical waste was packaged

3. Treated waste - label as follows:

- name, address, business phone number, for the generator of the waste
- date when the waste was treated
- treatment method utilized
- statement indicating that the waste has been treated and is no longer medical waste

4. Write labels using permanent ink and secure label in a manner that will prevent unintentional removal.

5. Use lettering no less than one inch in height and ensure the wording is readily visible if the container is in a lateral position.

Storage

1. Segregation and Containment

Segregate all waste materials at the time they are produced to prevent:

- cross contamination of non-hazardous or medical waste
- dangerous reactions with other wastes or materials
- maintain all hazardous and medical waste in an appropriate container per federal, state and/or local regulations
- frequently clean and/or disinfect carts used to transfer waste materials within the medical practice and do not use them for other duties
- store containers in the area where the waste is generated, if feasible

2. Hazardous Waste

- determine the maximum amount of waste that will be generated monthly
- contact the EPA and the RCRA to determine:
 - if a permit is needed to store any of the hazardous waste generated
 - the appropriate container type for any of the hazardous waste generated
 - the total allowable monthly volume that can be stored
 - the environmental conditions that may be required for storage including security
 - recommended inspection parameters and schedule
- keep all containers secure and closed unless being added to or emptied
- manage and store cytotoxic (anti-neoplastic agent) waste per OSHA guidelines

3. Medical Waste

- store medical waste near the area of generation or at the area of pick up if it will be transported off-site
- secure sharps containers from public access and consider full at $\frac{3}{4}$ of total volume
- maintain storage areas used for medical waste:
 - ensure they are durable, easily cleaned, and impermeable to liquids, protected from vermin and other vectors, and have proper environmental conditions and ventilation
 - do not use carpet or flooring with seams
 - secure and restrict access to designated personnel
 - post with biohazard symbols and warning signs both outside and inside

Disposal

1. Determine what the most effective method of disposal for this organization is based upon, but not limited to:

- federal, state and local regulations governing the type of waste generated
- resources available to the organization:
 - financial
 - facility size
 - personnel

- liability

2. On-site Disposal

- follow all federal, state and local regulations and guidelines
- maintain any required permits
- maintain records per OSHA and RCRA regulations and guidelines

3. Off-site Disposal

- determine an appropriate contractor based upon, but not limited to:
 - services offered
 - environmental offices referral
 - liability coverage
 - contingency strategies and capabilities
 - service record
 - interview
 - cost
 - contract
- maintain up to date regulations and confirm the contractor is following them
- maintain records per OSHA and RCRA regulations and guidelines

Contingency Planning

The contingency plan will provide reasonable means for back up storage and transportation should the primary system(s) fail.

1. have at least one extra container for each type of waste if feasible
2. have access to at least one alternative transportation system for both medical and hazardous waste
3. have a backup power source if power is needed to maintain waste storage

Spills

1. Small Spills

- train designated personnel with regards to management of small spills
- maintain an appropriate "Spill Kit" within the vicinity of waste generation for the type of waste being handled
- hazardous waste spill kit should contain at least:
 - several bags of kitty litter, saw dust or sand to absorb spilled liquids
 - brooms, dustpans and a square mouth shovel to sweep up the absorbent material
 - absorbent pillows or booms (available from spill kit suppliers) to contain larger liquid spills and prevent spills from entering drains
 - heavy duty plastic bags or plastic drums (with a lid) to contain hazardous material prior to disposal
 - appropriate personal protective clothing (such as chemical resistant gloves, safety glasses)

- a wheelie bin to contain all the above equipment and store hazardous material prior to disposal
- medical waste spill kit should contain at least:
 - a long sleeve gown, latex gloves, face mask with eye shield and shoe covers
 - disinfectant spray solution
 - towels for cleanup
 - Pick Up Powder with spatula
 - biohazard bags

2. Large spill

Refer to *P&P: Emergency Response*.

Nuclear Waste

Be familiar with and follow all Nuclear Regulatory Commission standards and regulations pertaining to any nuclear agents used on-site.

POLICY & PROCEDURE

INFECTION CONTROL

Policy Statement

Infection control plays an essential role in patient /family and employee safety. It is the responsibility of all physicians/dentists and staff members to take proactive steps to maintain the highest level possible for infection control. Because it cannot readily be determined at the time of an office visit that a patient has an infectious disease, the Center for Disease Control Bloodborne Pathogens and Standard Precautions will be followed.

Exposure Control Plan

The practice has an exposure control plan in compliance with OSHA regulations including:

1. A list of tasks identified as having potential for exposure to bloodborne pathogens
2. Methods to protect employees
3. Dates and procedures for providing Hepatitis B vaccinations
4. Procedures for post exposure evaluation and follow-up in case of exposure
5. Content and methods for training employees
6. Procedures for maintaining records

Education

1. Education related to infection control practices to ensure a safe environment for patients and personnel will be conducted upon hire and annually thereafter or when there are any changes to tasks or procedures.
2. Education places particular emphasis on proper use of personal protective equipment (PPE) for personnel at risk of accidental exposure to blood and/or body fluids. In addition, emphasis is placed on educating staff regarding transmission of TB, Hepatitis B & C, HIV and other communicable diseases.
3. Staff will be trained on implementing the practice's pre-pandemic and pandemic plan based on public health advisories, local & State Office of Emergency Management & the Department of Health & Human Services guidelines.
4. Education content will be based on OSHA and New Jersey Department of Health & Human Services regulations and CDC guidelines.

Personal Prevention, Wellness & Illness

1. Staff will be encouraged to know their immunization status and have their immunizations up-to-date. Immunization against HBV is recommended for all staff who may be exposed to blood, blood products, or sharps injuries. Flu vaccines will be encouraged.
2. If there is no documentation of a previous negative test within the past 12 months, a tuberculin skin test is recommended before the start of employment.
3. Staff with respiratory tract infections will consider using a mask when having direct patient contact.

4. Employees who provide direct patient contact should not wear artificial nails to prevent the transmission of bacteria that is harbored underneath fingernails.
5. Health care personnel with communicable diseases who pose a significant risk to patients and other personnel may require restrictive duty or absence from work. This is addressed through the practice's Human Resource policies.

Reporting Requirements

1. The New Jersey Department of Health & Human Services regulations, Disease and Injury Reporting Requirements: New Jersey physicians (applicable to physicians only) will be followed for reporting communicable diseases.
2. The practice's OSHA policy & procedure will be followed for recording and reporting exposures.

Standard Practices

Appointments & Triage

1. Strategies for appointments and triaging patients who are at higher risk for seriously transmittable infections will be utilized. Isolation of a patient will be utilized when warranted.
2. When a patient calls the office for an appointment, triage information will be obtained including; symptoms, signs (cough, fever, diarrhea, rash) and significant exposures, (recent travel or exposure to a person with a significant respiratory illness).
3. Every effort will be made to minimize contact in the waiting room with potentially infectious patients by placing the patient in an exam room as soon as possible.

Hand Hygiene

1. Hands will be washed with soap and water or alcohol-based hand rub:
 - following acts of personal hygiene (e.g., use of toilet, blowing nose)
 - before eating, drinking or serving food
 - before and after direct contact with individual patients
 - before preparing or handling sterile products or medications
 - between "clean" and "dirty" procedures on the same patient
 - after removing gloves
 - after contact with potentially soiled surfaces in the office environment or equipment in the treatment room
 - after contact with laboratory specimens
2. Gloves will be worn in any circumstance where there is potential for contact with blood, body fluids, secretions and excretions, mucous membranes, non-intact skin, and items or surfaces contaminated with body fluids, such as venipuncture and injections.
3. Disposable gloves (single use) will always be replaced as soon as practical when visibly contaminated or torn, punctured or when their ability to function as a barrier is compromised. Disposable gloves will not be washed or decontaminated for re-use.

4. Bar soap provides an environment for organisms to grow and will not be utilized. Disposable liquid soap containers with pumps will be used to minimize contamination. Empty containers must not be refilled without first washing, rinsing and drying thoroughly.
5. Hand lotion to prevent dry or cracked skin will be available. The use of petroleum-based lotion is prohibited due to the effect on glove integrity.

Personal Protective Equipment

1. Masks worn in combination with eye protection devices (such as goggles or glasses with solid side shield, or chin length face shields) are required when the instance of splashes, splatters, droplets of blood or other potentially infectious materials can reasonably be anticipated to contaminate an employee's eye, nose, or mouth.
2. When indicated, N95 respirators will be utilized according to recommended guidelines.
3. Since micro organisms can survive on uniforms for 56 days, uniforms must be laundered after each use.
4. Additional protective clothing (such as lab coats, gowns, aprons, and clinic jackets) shall be worn in instances when gross contamination can reasonably be expected. The additional protective clothing will be laundered prior to reuse.
5. If the situation warrants, scrub uniforms will be utilized. The wearing of scrubs outside the office environment is prohibited. Scrubs will be laundered in accordance with nationally recognized practice guidelines.

Respiratory Precautions

1. Signage will be in use in common areas, urging patients to utilize respiratory etiquette practices & if they have symptoms to alert staff on their arrival at the office.
2. Staff members are expected to utilize respiratory etiquette practices.
3. Respiratory etiquette includes:
 - covering the nose/mouth when coughing or sneezing; cough or sneeze into a tissue or elbow rather than the hand
 - using tissues to contain respiratory tract secretions and disposing of them in the nearest waste receptacle after use
 - performing hand hygiene with the use of alcohol-based hand rub, hand-washing with soap and water, or use of an antiseptic hand wash after having contact with respiratory tract secretions and contaminated objects or materials
4. Respiratory masks are available near the entrance for patient use. Patients will be encouraged to utilize the masks if tolerated (respirators such as N-95 or above are not necessary for this purpose).
5. Hand hygiene agents and tissues will be maintained throughout the waiting area.
6. Non-touch receptacles for used disposable paper products (e.g. tissues, masks & table paper) are available for use in exam rooms and waiting areas.
7. In addition to Standard Precautions, when interacting closely with a patient who is experiencing symptoms of a respiratory infection, particularly if a fever is present, staff will utilize Droplet Precautions (i.e., wearing a surgical or procedure mask for close contact).
8. TB precautions in accordance with CDC guidelines will be utilized.

Medications, Solutions, & Immunizations

1. Multidose vials, if the product is available in single use form, will be avoided due to the ease of transmission of disease such as HBV and HCV.
2. If a single dose form is not available, refer to the product leaflet for recommended duration of use after entry of the multidose vial (some influenza vaccines are 10 days).
 - mark the product with the date it was first used to facilitate discarding at the appropriate time
3. Use strict aseptic technique when administering medications/vaccines. Never re-enter a vial with a used needle or syringe.
4. If a multi-use container is used, it is not to be kept in the immediate patient care area; it is to be stored according to the manufacturer's instructions. If its sterility has been compromised or is in any way in question, the container must be disposed of immediately.
5. Medication from a syringe may not be administered to multiple patients, even if the needle or cannula on the syringe is changed. The syringe is a single-use item, as are needles and cannulas.
6. Do not administer medication from a single-use vial or ampule to multiple patients, or combine the leftover contents of multiple containers for later use.
7. Medications and vaccines will be refrigerated only if directed by manufacturer and daily temperature control logs maintained.
8. Medication vials will be discarded, in accordance with State and local regulations, if contamination is suspected (if vaccine, contact the local department of health unit).
9. Open sterile irrigation solutions will be discarded at the end of each day. If possible, all efforts will be made to use small bottles and will be stored according to manufacturer's recommendations.
10. Fluids and administration sets (intravenous bags, their tubings, and connectors) are to be used for one patient only. This equipment is to be disposed of appropriately after use. If a needle or cannula has been connected to an intravenous set-up, it is considered used and must be discarded safely.
11. Expiration dates will be checked before each use.
12. When doing myelograms, lumbar puncture, and spinal or epidural anesthesia, surgical masks must be worn when placing the catheter and/or injecting material into the spinal canal or subdural space.

Handling Hazardous Material & Medical Waste

The practice's Hazardous & Medical Waste policy will be followed in regard to the handling and disposal of sharps and other medical waste. The following practices will also be followed to minimize the risk of exposure to substances.

1. Specimens of blood, saliva or tissue are placed in containers that prevent leakage during collection, handling, processing, storage, transport, or shipping.
2. The specimen containers are labeled or color-coded, closed prior to being transported, shipped or stored, and placed in second containers (if contaminated on the outside) that prevents leakage and is labeled or color-coded.

3. If the specimen could puncture the primary container, the primary container is placed in a secondary container that is puncture-resistant.
4. Contaminated needles will not be recapped, bent, cut or broken.
5. Discard sharps at point of use in a designated sharps container.
6. Each person using a sharp must dispose of it him/herself.
7. Any potentially contaminated broken glassware shall not be picked up directly with the hands. Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where sharps are placed.

Cleaning

There are four types of cleaning:

1. Sterilization destroys all forms of microbial life.
2. Disinfection reduces but does not totally eliminate microbes.
3. Cleaning is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products.
4. Antisepsis is the use of chemical agents to reduce the microbial flora of skin or mucous membranes.

Disinfection & Sterilization Techniques

All instruments that require sterilization will be processed in accordance with the CDC entitled Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.

1. At the end of the patient encounter, wipe all horizontal surfaces in the examining room that have been in contact with the patient, as well as equipment used to examine the patient (blood pressure cuff, stethoscope, etc.) according to the CDC Guidelines.
2. All equipment will be cleaned regularly according to the practice's schedule and stored to minimize contamination.
3. All reusable instruments that are used for mucus membrane or non-intact skin will receive a high level disinfection according to manufacturer's specifications and CDC Guidelines.
4. All reusable instruments that do not come in contact with blood, body fluids or non-intact skin will be processed according to the CDC Guidelines.

Cleaning Techniques

1. Paper sheeting will be utilized on exam tables and changed between patient encounters.
2. The office will be cleaned on a daily basis, including but not limited to exam room tables, furniture, knobs, countertops and computer key pads.
3. Efforts will be made to utilize furniture that does not incorporate cloth surfaces so it can be cleaned or disinfected efficiently and effectively.

Antisepsis Techniques

1. Alcohol will be used to prepare skin for immunizations and venipuncture.
2. Skin preparation agents will be allowed to dry to ensure that surface bacteria are killed.
3. Tincture of iodine or other CDC recommended agents will be used in skin preparation for invasive procedures, such as insertion of non-silicone catheters.
4. To prevent contamination, antiseptic agent bottles will be dated and will not be refilled.
5. Antiseptic agent bottles will be discarded if not used within three months.
6. When available, single-use pads of iodine and alcohol will be used to eliminate the need for bottles.

Please Note: The CDC recently (July 2011) published a Guide to Infection Prevention in Outpatient Settings. This guide should also become part of your practice policy; it can be found at <http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-guidelines.html>.

The CDC also published a guide to Safe Injection Practices to Prevent Transmission of Infections to Patients. As above, this guide should become part of your practice policy; it can be found at http://www.cdc.gov/injectionsafety/IP07_standardPrecaution.html.

To help you educate your staff in injection safety, the CDC offers an educational toolkit on the subject which provides videos and training tools. It also provides CME for providers through Medscape. This toolkit can be found at <http://www.oneandonlycampaign.org/content/healthcare-provider-toolkit-multimedia>.

POLICY & PROCEDURE

INVESTIGATING EVENTS

Policy Statement

As part of a risk management program, offices should utilize an event report to notify the responsible individual within the practice of all events with actual or potential injury to patients and visitors. The event report form also serves to document the event and provide a method to track and trend events over time so that improvements can be made.

The event reports are for internal use only and should NOT be provided to the patient, visitor, or family member involved. They are confidential documents and should be clearly marked as such. The event report form should NOT be photocopied once completed and should NOT be placed in the medical record or personnel files. Documentation in the medical record should NOT reference a report was completed. All information obtained in the investigation, as well as any additional documents, such as corrective actions, should NOT be stapled to the event report and should be maintained in a separate file, and never placed in the medical record.

Staff should be trained:

- When an event report should be completed and by whom
- To notify the responsible individual promptly of any injuries, loss of life, and/or criminal acts, and defer to appropriate people to contact law enforcement or regulatory agencies
- To treat any and all documents generated as part of the follow-up investigation as strictly confidential, to optimize opportunity for legal protection.

Definitions

An “Event” is considered to be any happening that is not consistent with the routine or usual operation of the practice, i.e., any deviation from policy and procedure. Injury does NOT have to occur. A “near miss” or the potential for injury and/or property damage is sufficient for an event report to be completed.

Procedure

When an event occurs, as soon as possible:

1. Ensure that any injured patient(s) or visitor(s) gets prompt medical attention. Safeguard other personnel in the area, if needed.
2. Notify the practice manager (or other designated individual) immediately.
3. Secure the area, and protect (under lock and key if possible) any physical evidence that could be important later (such as equipment used).
4. Document only the clinical facts surrounding the event in the medical record. DO NOT document that an event report was prepared.
5. Collect as much information as possible about the surrounding area before, during, and after the event:

- inspect the incident site immediately, but do not disturb the site unless it presents a hazard
 - identify and interview key affected staff, patients and witnesses
 - identify the physician/dentist to whom the event was reported (if applicable) and that individual's response (orders given, exam performed)
 - conduct interviews of staff, witnesses and others involved while details are still fresh to them
 - be a good listener
 - keep in mind that the focus is on prevention, so ask open-ended questions
 - get the facts, without placing blame or expressing opinions
 - pay attention to unsolicited comments
 - for important points, repeat back what you heard to clarify and confirm facts
 - if the event was not witnessed, try to speak with others (i.e. staff, person's relatives) who might have interacted earlier with the person involved
 - depending on the nature of the event, take photographs and measurements; sketch key aspects of the site; secure surveillance videotape, if available
 - collect physical evidence and samples for laboratory analysis, if applicable; physical evidence includes:
 - position of injured patients or visitors
 - for device/equipment related events, record pertinent serial numbers, manufacturer and model names, settings at time of event; safety or warning devices and/or personal protective equipment that was in use; refer to *P&P: Medical Equipment Management*
 - materials being used at the scene, including medications/injections/anesthesia/chemicals (records of doses, etc.)
 - condition of environment: lighting, temperature, smoke, dust, mist, fumes; housekeeping and sanitation conditions (i.e. spilled liquid on floor or other involved surfaces)
6. Complete an event report (state facts only, not opinions or assumptions).
- event report forms are most effective when completed by the person with the most knowledge about the event or the person who first becomes aware of or witnesses the event
7. Forward the completed report to the practice's responsible individual within 24 hours of the event.
8. The practice's responsible individual will:
- contact Princeton Insurance and consult with legal counsel, if appropriate (i.e. significant patient injury)
 - investigate the event (state facts only, not opinions or assumptions) as soon as possible
 - look back over the entire sequence of events that led to the event
 - collect background information after immediate investigation at the site (appropriate to event):
 - employee records: training information, licenses, certifications, and employment records

- equipment records: maintenance logs, service reports, work orders, operating manuals, and manufacturer instructions
- previous incident reports (involving same patient, employee, device or equipment)
- weather reports (as relevant to location and type of event)
- review existing documents, including: material safety data sheets (MSDS), job safety analyses, safety audit results, safety committee minutes, product/equipment specifications, equipment maintenance records, policies and procedures, floor plans/mechanical drawings and blueprints
- identify the contributing factors and root cause(s) of the reported event
- identify lessons learned that will help prevent similar events or near-misses from re-occurring
- present the results of the inquiry, de-identified to protect confidentiality, as quickly as possible to all staff to enhance the value of safety education for clinical and non-clinical staff

Event/Complaint Report

CONFIDENTIAL REPORT OF EVENT. THIS REPORT SHOULD NOT BE INCLUDED IN THE PATIENT RECORD.

SECTION 1. General Information

Name: _____ Date of Event: _____
Address: _____ Time of Event: _____ AM / PM

Phone #: _____
 Patient Male Record #: _____
 Visitor Female
Age: _____

Reason for Visit: _____
Location of Event (be specific): _____

SECTION 2. Type of Event/Complaint (check all that apply)

Bodily Injury (not resulting from a fall, procedure or equipment)

<input type="checkbox"/> Chemical	<input type="checkbox"/> Electrical	<input type="checkbox"/> Heating appliance
<input type="checkbox"/> Hot liquid	<input type="checkbox"/> Exposure to hazardous material	
<input type="checkbox"/> Other (specify)		

Equipment/Medical Device Related

<input type="checkbox"/> Disconnected/dislodged	<input type="checkbox"/> Electric power outage	<input type="checkbox"/> User related
<input type="checkbox"/> Mechanical issue	<input type="checkbox"/> Availability	
<input type="checkbox"/> Other (specify)		

Fall

<input type="checkbox"/> Dropped	<input type="checkbox"/> Found on floor	<input type="checkbox"/> Off scale/equipment
<input type="checkbox"/> Fainted	<input type="checkbox"/> Off chair/bed/exam table	<input type="checkbox"/> While ambulating
<input type="checkbox"/> Other (specify)		

Medication Related

<input type="checkbox"/> Adverse reaction	<input type="checkbox"/> Route	<input type="checkbox"/> Dosage
<input type="checkbox"/> Drug selection	<input type="checkbox"/> Medication missing	<input type="checkbox"/> Prescription pad missing
<input type="checkbox"/> Patient identification	<input type="checkbox"/> Other (specify)	

Patient Action Influencing Care

<input type="checkbox"/> Non-compliance	<input type="checkbox"/> Left AMA	<input type="checkbox"/> Left without being seen
<input type="checkbox"/> Refused treatment	<input type="checkbox"/> Other (specify)	

Patient Care Related

<input type="checkbox"/> Adverse reaction	<input type="checkbox"/> Consent related	<input type="checkbox"/> Patient monitoring
<input type="checkbox"/> Procedure related	<input type="checkbox"/> Specimen issue	<input type="checkbox"/> Tracking consultations/referrals
<input type="checkbox"/> Infection control (infections, exposure, sharps)	<input type="checkbox"/> Reporting/tracking of test results	<input type="checkbox"/> Medical emergency (i.e. 911 called)
	<input type="checkbox"/> Other (specify)	

Other

<input type="checkbox"/> Missing/damaged property	<input type="checkbox"/> Communication related	<input type="checkbox"/> Corporate compliance
<input type="checkbox"/> Patient complaint	<input type="checkbox"/> Non-medical emergency (i.e. fire, flood)	<input type="checkbox"/> Unauthorized disclosure of protected health information
<input type="checkbox"/> Security related	<input type="checkbox"/> Payment/billing related	
<input type="checkbox"/> Violence to self or others/use of weapon	<input type="checkbox"/> Other (specify)	

Event/Complaint Report

CONFIDENTIAL REPORT OF EVENT. THIS REPORT SHOULD NOT BE INCLUDED IN THE PATIENT RECORD.

SECTION 3. Additional Information

Brief factual description of the event, including key observations and patient's statement if not witnessed by staff (if medication related, indicate name of medication): _____

Injuries and parts of the body involved (i.e. bruised right knee): _____

Pre-existing issues (i.e. impaired mobility, cognitive factors, functional factors, environment, equipment, assistive devices): _____

Preventative measures in place prior to event (i.e. assistive devices, precautions, instructions): _____

Severity of the Injury	<input type="checkbox"/> Minor	<input type="checkbox"/> Significant	<input type="checkbox"/> Death	<input type="checkbox"/> Unknown	<input type="checkbox"/> N/A
Person Examined	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Declined		
Treatment Provided	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Declined		<input type="checkbox"/> Not indicated

Treatment Provided by _____
Type of Treatment Provided First Aid 911 Called Medical CPR/Defib
Be Specific: _____

Equipment/Medical Device Involved Yes No
Manufacturer: _____
Model #: _____ Lot/Batch #: _____
Secured/Removed from Service & Labeled "Not for Use" Yes No
Location: _____

Witness(es):
Name: _____
Address: _____
Phone #: _____

Name: _____
Address: _____
Phone #: _____

Authorities/Police Notified Yes No N/A
Authoritative Agency(ies): _____ Date/Time Notified: _____ AM / PM

Family Notified Yes No N/A
Name of Family Member Notified: _____ Date/Time Notified: _____ AM / PM

Name of Practice Manager/Physician/Dentist Director Notified: _____
Date/Time Notified: _____ AM / PM

Staff Person Completing Report:

Print Name & Title _____ Signature & Date _____

Practice Manager/Physician/Dentist Director Reviewing Report:

Print Name & Title _____ Signature & Date _____

POLICY & PROCEDURE

MEDICAL EQUIPMENT MANAGEMENT

Policy Statement

A physician/dentist has a duty to his/her patients to properly select, inspect, maintain and use medical equipment/devices (hereafter referred to as equipment), and supplies within his/her office practice. Thus, it is important to take all necessary safety precautions – whether the equipment is purchased, rented or leased – to increase patient safety and reduce the risk of a claim.

Procedure

1. Select new equipment based upon appropriateness for the office and desired use.
2. Inventory all equipment using the Medical Equipment Tracking Log.
3. Evaluate the equipment prior to use for inclusion in an equipment management program using risk-based criteria based upon your office practices, the history of the equipment and the equipment specifications, including:
 - equipment function
 - clinical application
 - preventive maintenance requirements
 - likelihood of equipment failure
 - and environmental/device use area
4. Assign the equipment a tier level (1, 2, or 3).
5. Test the equipment based upon the tier level assigned as indicated below:
 - Equipment in **Tier 1** should be tested on at least a semi-annual basis. An example of equipment within this tier is your life support and/or emergency equipment, such as items on crash carts and/or automated external defibrillators (AED).
 - Equipment in **Tier 2** should be tested on at least an annual basis. An example of equipment within this tier are monitors (i.e. blood pressure, ECG, heart rate, oxygen, stress exercise, etc.).
 - Equipment in **Tier 3** may only need to be visually inspected on an annual basis. Equipment within Tier 3 have little to no risk, such as a patient scale.
6. Train staff on how to properly use all equipment, as well as any back-up plans for when a piece of equipment needs to be serviced/repared. If a staff person has not been trained, the individual will not be allowed to use the equipment.
7. Maintain and use all equipment according to manufacturers' recommendations, and document all inspections, testing, preventative maintenance, and repairs on the Medical Equipment Tracking Log. Telephone numbers of the equipment vendors are posted [*insert location*].
8. Disinfect all re-usable equipment according to the guidelines for the Food and Drug Administration (FDA), and document accordingly.

9. Report any equipment malfunctions and/or incidents causing injury to a patient to practice administrator, or physician director. Refer to *P&P: Investigating Events in the Office Practice*.
10. Remove any equipment involved in a patient incident from service, secure it, and do not release it to anyone, until advised by Princeton Insurance.
11. Remove any defective equipment from the patient care area immediately, and identify it as such, so it is not used until it is repaired.

Medical Equipment Tracking Log

Name/Type of Equipment:		
Model #:	Serial #:	Tier Level:
<input type="checkbox"/> Own	<input type="checkbox"/> Lease	
Rationale for Choosing Equipment:		
Location of Equipment within Office:		
Warranty (length of time and what is included):		
Names of Staff/Users Trained on Equipment and Date Trained:		
Preventative Maintenance Requirements:		
Person/Vendor Responsible for Preventative Maintenance:		
Address:	Phone Number:	

Preventative Maintenance/Repairs

Date	PM / Repair	Description

POLICY & PROCEDURE

SECURITY MANAGEMENT

Policy Statement

The physician/dentist office should be assessed and maintained to protect your patients, employees and assets from theft and violence. Staff should be trained on what to do to help prevent security incidents and what to do in case one occurs.

Procedure

1. Conduct a security vulnerability assessment or some type of analysis. Evaluate your location based upon the crime rate in your surrounding community, the attractiveness to potential intruders and the possibility of violent behavior, and determine what processes, procedures, and materials you need to protect you and your employees, patients, and assets. Local police crime prevention officers may be contacted to provide additional security reviews or surveys to protect your staff, your patients and yourself.

Consider:

- Staff working at night and patients entering or leaving at night
 - Type of equipment or medication you have on premises
 - Possibility of:
 - violent/abusive patients (i.e. distraught family members, gang members, or patients with certain medical conditions and medication side effects)
 - workplace violence
 - your computer system and its vulnerability to hacking
 - theft
 - unauthorized entry
 - vandalism
2. Implement the following safety/security measures as deemed appropriate by the above analysis:
 - Require that no one is at the location alone and that certain doors are locked at a certain hour.
 - Lock doors to client waiting rooms from the inside and all outside doors from the outside (in accordance with fire codes) to prevent unauthorized entry.
 - Lock all doors and windows after all staff has left the office.
 - Provide proper and adequate lighting for the exterior of the building, including front and rear entrances and parking lots, especially if the office is open during evening hours. Lights should be difficult to reach and protected from damage. Label light standards so that outside lights can be readily identified and repaired when they are out.
 - Maintain your property, including fences, bushes, trees, etc., to eliminate places for people to hide. Secure any objects that may be used for breaking and entering. Ensure that housekeeping staff don't block doors open when taking out trash. Any confidential paperwork that needs to be discarded should be shredded.

- Secure expensive and/or sensitive equipment with metal cabling and locks. Place these items away from windows to prevent them from being visible from the street or parking lot.
 - Install alarm systems and/or panic buttons. Consider both entry and motion detectors. Have a direct link to the local police department or security monitoring company. Post a sign alerting people to the fact that you have an alarm system installed.
 - Install a low-cost camera system for high traffic areas and locations that contain sensitive or expensive equipment.
 - Establish a preventative maintenance program to ensure all security systems (i.e. alarms, cameras, etc.) are maintained, tested, and inspected per manufacturer's recommendations.
 - Make prompt repairs as needed (i.e. replace burned out lights and repair broken windows, doors, locks, etc.)
 - Secure prescription pads and medical records, especially during off hours.
 - Conduct criminal background checks and check references on all of your employees. Though it is important to trust your employees, it is also important to know who you are really working with.
 - Avoid isolation of a staff person in an exam room or other area of the office, in case they need assistance, while still ensuring patient privacy.
 - Maintain access to the emergency exits and seat patients so they do not block an employee's ability to exit the room. Two exits should be accessible whenever possible, especially in the reception area.
 - Engineer waiting rooms to be comfortable to avoid agitation during wait times (i.e. posting of information regarding services; appropriate room temperature; availability of current magazines, television, fresh water, restrooms, pay telephones; arrangement of furniture and other objects to prevent them from being used as weapons).
 - Limit the maximum wait time to see the physician/dentist to 15 minutes, and do not double-book.
 - Protect reception areas with safety glass and deep service counters.
 - Have all your patients, vendors, pharmacy representatives, etc. sign-in at the reception area. Verify identification.
 - Establish a procedure for tracking office keys provided to staff and their return once the staff person is no longer employed.
 - Install firewalls, antivirus, anti-spam, and anti-spyware on all computer systems.
 - Provide staff with individual usernames and passwords to access computers and specific software programs.
 - Back-up your computer system and files on a daily basis in case of a power failure.
 - Document any threats, assaults, or aggressive behavior in a patient's medical record to establish a pattern and to warn other staff.
3. Train staff on the above implemented safety/security measures. Non-compliance of the above measure is subject to corrective action.

4. Staff should report any security incidents to office manager or managing physician/dentist and document it on the Event Report. Refer to *P&P: Investigating Events*.
5. Continuously monitor any changes in the practice or in the surrounding community that may require changes to be made to the security program, policies and procedures.

ENVIRONMENTAL SAFETY SELF ASSESSMENT

EXTERNAL

Signage/Identification:

- There is signage displaying your business name and address. It is:
 - Visible from the street
 - Lit and visible after dark
- There is signage identifying the vehicle entrance and exit to the parking lot
 - If the same driveway is used to enter and exit, the directions of travel are clearly marked. (Concern is for multiple vehicles using the same area at the same time to exit or enter)
- Driveways go around a corner of the office building:
 - Drivers are alerted to watch for pedestrians or other vehicles
 - A safety mirror is installed for drivers and/or pedestrians
- Parking lot spaces are lined and clearly marked
- There are designated handicapped space(s) and they are easily accessible
- New patients are advised where they should park if there is no parking lot
- There is signage that directs patients to the main entrance. (Other doors and steps may be readily apparent to patients but are only used by staff) Make sure the handicapped entrance is adequately signed.
- Pedestrian crosswalks are marked
- Curb cutouts are properly identified to alert individuals of changes in height
- Signs, awnings and/or canopies are properly maintained. (Secured, not broken, or hanging down)
- There is signage to indicate the office is protected if a monitored central security station is used
- There is signage to prohibit skateboards, bicycles, and/or skating on the property

Driveways:

- Driveways are properly maintained. (No cracks or potholes visible)
- During winter weather driveways are cleared of snow and ice before the office opens and then throughout the day, as necessary

Sidewalks:

Determine if the sidewalks are the responsibility of the owner, tenant or municipality. If you are responsible, complete the assessment below:

- Sidewalks are properly maintained and level throughout its length. (No cracks, holes, broken sections or raised sections greater than ½")
- During winter weather sidewalks are cleared of snow and ice before the office opens and then throughout the day, as necessary
- There is a process for removing icicles if the building roof overhangs the sidewalk.
- The sidewalks are properly lit after dark
- Landscaping plants and materials are properly maintained. (Stones, mulch or mud are not being washed onto the sidewalk and trees and plants are cut back away from the sidewalk and driveway entrance for security. Tree roots are cut back so they don't push up sections of concrete sidewalk.)

Ramps/Stairs:

- Ramps/stairs are properly maintained (No cracks, broken stair treads, or holes)
- If ramps/stairs are constructed of wood:
 - They have non-slip paint or treads applied
 - Nails/bolts are secured and don't protrude into the walkway
- During winter weather ramps/stairs are cleared of snow and ice before the office opens and then throughout the day, as necessary
- Ramps/stairs are properly lit after dark
- Handrails are provided and secured
- Handrails do not have sharp, splintered, or rusted surfaces

ENVIRONMENTAL SAFETY

SELF ASSESSMENT

Fences:

- If fencing is used around the office it is in good condition. (No cracks, sagging or broken sections)

Trees/Hedges:

- Tree branches do not overhang sidewalks, parking lots, and stairs
- Trees are in good condition (no dead or broken branches lying on the grass, hanging down from overhead, or sticking out at eye level near walking surfaces)
- Tree branches are not in direct contact with incoming electric or telephone wires
- Tree branches are not resting on the roof
- Hedges are cutback for security purposes and should not obstruct the view of patients or staff exiting the premises

Parking Lots:

- Parking lot is properly maintained and relatively smooth and level (no cracks, no debris or potholes visible, snow, ice or rainwater will accumulate into any dips or depressions)
- Parking lot is paved
- During winter months parking lot is cleared of snow and ice before the office opens and then throughout the day, as necessary
 - Snow is not pushed into piles near walking surfaces; that snow could thaw and refreeze
- Storm water drains are located to catch run-off and are kept clear of leaves and debris
- Parking lot is properly lit after dark

Office Grounds:

- Office grounds are well maintained (Mowers, trimmers, and other power equipment are never left outside unattended)

Medical Specimen Boxes:

Medical specimen boxes are:

- Locked to prevent unauthorized access
- Kept out of normal pedestrian traffic patterns
- Marked to identify a biohazard concern

Disposal:

- Trash is being properly maintained in sealed bags in covered containers
- Needles are disposed of in designated sharps containers and those used containers are locked away until they are picked up for appropriate disposal
- Sharps containers are only filled $\frac{3}{4}$ full and then properly disposed of
- Infectious waste is properly identified, stored, and disposed of

INTERNAL:

Main Entrance:

- A disabled patient can get inside the door (lever doorknob set, limited force needed to open, wheelchair width 32")
- If a disabled patient can't get inside the door, there is a mechanism to alert staff for assistance. (Door bell or buzzer at wheelchair height, intercom system, CCTV camera, etc.)
- If the door is automatic opening it is periodically tested per the manufacturers recommendations
- A clear glass door is affixed with decals or other visible signage to alert individuals of the opening
- Lighting inside the main entrance is adequate for patient safety
- The inside floor is level with the outside landing
- The door threshold is level or beveled to permit easy access
- Doormats or walk-off rugs are used:
 - They are in good condition and lay flat and level against the floor
 - They are rotated during periods of wet inclement weather

ENVIRONMENTAL SAFETY

SELF ASSESSMENT

- "Wet floor" signs are readily available during periods of wet inclement weather
- There is an area that permits umbrellas to drain without draining onto the floor
- There is an area for wet or snow-covered clothing to dry without draining onto the floor
- There are emergency exit signs and emergency exit lighting units placed near the main entrance

Waiting Room:

- The path to the receptionist is easy to identify and accessible to a disabled patient
- Interior decorations are mounted high enough along the wall or walls that preclude children from injuring themselves
- Chairs and sofas are placed so that a clear exit path is maintained at all times
- Lighting inside the waiting room is adequate for patient safety
- There is signage to alert patients to report any allergies they might be aware of prior to treatment (i.e. latex)
- There is signage to ask patients if they have flu-like symptoms to advise the receptionist and to cover their coughs
- Furniture in the waiting room is clean, in good condition and well maintained. (Watch for sharp edges, fabric rips, wooden splinters or protruding nail heads)
- The floor is in good condition and without defects
- Electric cords for lamps are coiled to prevent a trip and fall injuries
- If toys are provided in the waiting room, they are routinely cleaned and disinfected and this is documented
- Toys are consistent with the age of the children that might use them (no detachable parts/ choking hazard)
- If a TV is provided, it is properly anchored to prevent injury to children and/or patients
- If the office utilizes hot water or steam heat there is protection surrounding the radiator to prevent burns
- Plastic child safety inserts are plugged into waiting room wall mounted receptacles
- A hands-free trash receptacle which is child resistant is available in the waiting area

Receptionist Area:

- There is wheelchair access for disabled patients
- Patient charts, telephone calls and personal conversations are kept private or inaudible
- A buzzer or other device alerts the receptionist when an individual enters the office
- Patient records and files are maintained behind a counter or reception area
- The counter top is protected against injury from splinters and cracked or broken pieces of surface area
- A list of emergency procedures and contact information is posted by the desk in case of an emergency

Treatment or Consultation Rooms:

- At least one room is designed to be wheelchair accessible including the door to the room
- Sharps containers are secured to the wall and not accessible to children
- Sharps containers are not more than $\frac{3}{4}$ full
- Trash cans have lids that are not easily removable
- There is a sink and hand cleanser in each treatment room that can be used to wash hands prior to and after each patient examination
- There is an examination glove box in each treatment room
- Each wet location (around a sink) has Ground Fault Circuit Interrupter (GFCI) receptacles or circuits protection
- There is a designated treatment room that can be used to isolate a patient if you suspect a communicable disease might be present
- Treatment items (i.e. paper gowns, masks, treatment table covers) are available for immediate use. (if cloth gowns are used, they are laundered and disinfected between each use)
- Patient treatment rooms are cleaned and disinfected according to CDC guidelines
- Patient treatment tables, scales and other patient items work properly and are in good repair

ENVIRONMENTAL SAFETY

SELF ASSESSMENT

Laboratory or Sterilizing Area:

- There is a hazard communication plan in place, including updated MSDS sheets and a spill procedure
- All employees are trained with regards to the hazard communication plan
- Chemicals are segregated according to the MSDS sheet to prevent potential incompatibility problems
- If corrosive chemicals are used, an eyewash station is installed per the American National Standards Institute (ANSI)
- There is one 2A10BC fire extinguisher in this room, and one for every forty feet distance per floor
- Gas valves and electrical circuits are properly labeled and accessible.
- Medical and chemical wastes are properly secured and stored prior to proper disposal

Mechanical Room or Space:

- Major pipe valves and electrical supply circuits are properly identified in case of an emergency requiring an immediate shutdown.
- Circuit panels are clearly labeled
- Circuit panels are easily accessible (nothing is stored in front of them)
- Components of the HVAC systems are given preventative maintenance on at least an annual basis by qualified individuals.
- The fire alarm and smoke detection systems are tested (if battery powered, the batteries are changed bi-annually) and inspected on an annual basis according to local fire safety requirements.
- If a sprinkler system is in place it is tested and inspected at least annually or more frequently according to the authority having jurisdiction.
- Medical gas cylinders are properly secured and a written procedure is in place to replace the cylinders.

Bathroom:

- At least one of the bathrooms is accessible by a disabled patient (i.e. the door is wide enough for wheelchair access and there is space for the wheelchair at the commode and under the sink)
- If the door is locked from the inside there are emergency access capabilities from the office/hallway side of the door.

Storage Closet, Alcove or Room:

- If the area is protected by an automatic sprinkler system, storage underneath the sprinkler heads is not less than 18 inches.
- Storage is kept up off the floor for proper cleaning.
- Aisle access is maintained for office staff.
- Heavy items are not permitted to be stored above shoulder height.

General Safety Considerations:

- Interior lighting is checked daily throughout the office to ensure that it is operating properly.
- All sink and floor drains are checked to ensure that they operate as designed and discharge water.
- Any water stained ceiling tiles are replaced once the source of the leaking water is repaired to prevent microbial growth.
- All areas of the office (i.e. floors, floor coverings, walls, doors, and furniture) are maintained in good condition and repair and are clean (opening seams on wall coverings are not only unsightly; they are also areas for dirt and contaminants to collect).
- All exit corridors and doors are kept free and clear for immediate use in an emergency (this may involve more than one means of egress depending upon occupant load and use)
- Latches on external doors with automatic closers should be checked to make sure they 'click' into place
- All portable fire extinguishers are maintained on an annual basis and inspected on a monthly basis.
- There is at least one portable fire extinguisher located on each floor of the building.
- Battery powered emergency exit signage is tested monthly for 90 seconds and operated annually for 90 minutes.
- Exit signs are readily visible and are spaced along the wall in such a manner that they can guide people out of the office during an emergency.

ENVIRONMENTAL SAFETY

SELF ASSESSMENT

- Electrical supply cords are free of fraying, cracks and exposed wires.
- Electrical receptacles are protected against access by children and proper coverplates are installed.
- All permanent electrical extension cords are removed from use and permanent power supplies are installed (this does not include items requiring electrical surge protection)
- Patient records and files are kept confidential (i.e. record content should not be verbally discussed in front of others, displayed visually or be accessible to the general public.)
- Prescription pads are kept secure and locked when not in use.
- All medications are properly stored and used per the manufacturer's guidelines.
- Controlled substances are secured, tracked and dispensed according to NJ regulations.
- If the office has an emergency crash cart it is inspected daily (AED or defibrillator is tested for proper operation, medications are checked for expiration dates, and other equipment such as airway maintenance items and tubing are checked for expiration dates. In the meantime they remain easily accessible.)
- All patient related diagnostic and testing equipment is inspected and maintained per the manufacturer's recommendations and that equipment is tested by a qualified contractor.
- Patient/Employee Safety is a standing agenda item at any office staff meeting.
- Staff is trained on handling office emergencies, including fire, medical, and weather related.

INFECTION CONTROL SELF ASSESSMENT

Bloodborne Pathogens (OSHA Regulations Standards - 29 CFR - 1910.1030)

- There is a written exposure control plan.
- The written exposure control plan is updated yearly.
- Employees follow universal precautions to prevent contact with blood or other potentially infectious materials.
- Hand washing facilities are readily accessible (cleanser and clean cloth, paper towels, or antiseptic towelettes may be substituted. When antiseptic hand cleansers or towelettes are used, wash hands with soap and running water as soon as possible).
- Hand washing signs are posted in appropriate areas.
- Employees wash their hands between patients, and immediately after removing gloves or other personal protective equipment.
- Personal protective equipment of appropriate sizes is readily accessible or issued to all employees.
- Employees follow universal precautions to prevent contact with blood or other potentially infectious materials.
- All equipment and working surfaces are cleaned and decontaminated immediately, or as soon as feasible, after contact with blood or other potentially infectious materials.
- Spills are cleaned up immediately and according to procedures.
- Containers used for sharps disposal are replaced routinely and not allowed to overfill.
- Containers of regulated waste are labeled with a biohazard warning label.
- Individuals who have contact with blood or other potentially infectious materials in the course of their work are provided training on bloodborne pathogens.
- Bloodborne pathogen training is provided annually.
- The individual(s) conducting the bloodborne pathogen training is knowledgeable in the subject matter.
- Records are maintained of training, indicating the dates of the training sessions, the contents of the training session, the names and qualifications of the person conducting the training, and the names of the persons attending the training sessions.
- Training records are maintained for at least 3 years.

Cleaning

- All restrooms are clean and sanitary.
- Trash from offices and other areas are removed and stored in a covered container or sealed plastic bags daily.
- For practices that treat children: toys are sanitized on a daily basis.
- There is a schedule for general cleaning.
- There is a designated treatment room that can be used to isolate a patient with a suspected communicable disease.
- Treatment items (i.e. paper gowns, masks, treatment table covers) are readily available and well stocked.
- Cleansing products are readily available for hand washing by employees and patients.
- Patient treatment rooms are cleaned and disinfected according to CDC guidelines.

Personnel & General Prevention

- The Exposure Control Plan is maintained and reviewed annually for effectiveness in reaching infection control goals.
- Employees have annual TB tests.
- Employee immunizations are up to date.
- A log is maintained tracking occurrences of employees and physicians/dentists for infections acquired on the job.
- An individual(s) is assigned the responsibility to assure the practice has up to date information regarding infection control practices, regulations, and public health information.
- There is a pre-pandemic and pandemic plan and checklist to appropriately respond to Department of Health and CDC advisories.
- Notification is given to public health authorities of communicable diseases as required by the State Department of Health.

CDC Infection Prevention Checklist

To augment the above check list on infection control, the practice can also follow the CDC's recently (July 2011) released Infection Prevention Checklist which can be found at <http://www.cdc.gov/HAI/pdfs/guidelines/ambulatory-care-checklist-07-2011.pdf>.

FORMS

Forms List

Sample Event/Complaint Report
Instructions for Completing an Event/Complaint Report
Sample Discharge Letter
Patient Satisfaction Survey
Staff Self Evaluation
In-Office Telephone Record
Telephone Call Log
Patient Agenda
Office Visit Follow-up Instructions
Communication Poster (English)
Communication Handout (English)
Communication Poster (Spanish)
Communication Handout (Spanish)
Request for Consultation
Consultation Log
Diagnostic Test Tracking Log
Follow-up Appointment Log
Anticoagulation Log
Employee Confidentiality Policy & Agreement
HIPAA Compliant Authorization
Informed Refusal
Informed Consent for Clinical Trials
Sample Informed Refusal Letter to Patient
Sample Letter to Insurance Carrier for Refusal to Authorize Payment
Patient Information Update
Documentation Checklist
Signature Log
Release of X-Rays
Medication Flowsheet
Sample Medication Log (1 page)
Sample Medication Log (2 page)
911 Poster
RACE Fire Diagram
Medical Equipment Tracking Log

Event/Complaint Report

CONFIDENTIAL REPORT OF EVENT. THIS REPORT SHOULD NOT BE INCLUDED IN THE PATIENT RECORD.

SECTION 1. General Information

Name: _____ Date of Event: _____
Address: _____ Time of Event: _____ AM / PM
_____ Phone #: _____
 Patient Male Record #: _____
 Visitor Female
Age: _____

Reason for Visit: _____
Location of Event (be specific): _____

SECTION 2. Type of Event/Complaint (check all that apply)

Bodily Injury (not resulting from a fall, procedure or equipment)

<input type="checkbox"/> Chemical	<input type="checkbox"/> Electrical	<input type="checkbox"/> Heating appliance
<input type="checkbox"/> Hot liquid	<input type="checkbox"/> Exposure to hazardous material	
<input type="checkbox"/> Other (specify)		

Equipment/Medical Device Related

<input type="checkbox"/> Disconnected/dislodged	<input type="checkbox"/> Electric power outage	<input type="checkbox"/> User related
<input type="checkbox"/> Mechanical issue	<input type="checkbox"/> Availability	
<input type="checkbox"/> Other (specify)		

Fall

<input type="checkbox"/> Dropped	<input type="checkbox"/> Found on floor	<input type="checkbox"/> Off scale/equipment
<input type="checkbox"/> Fainted	<input type="checkbox"/> Off chair/bed/exam table	<input type="checkbox"/> While ambulating
<input type="checkbox"/> Other (specify)		

Medication Related

<input type="checkbox"/> Adverse reaction	<input type="checkbox"/> Route	<input type="checkbox"/> Dosage
<input type="checkbox"/> Drug selection	<input type="checkbox"/> Medication missing	<input type="checkbox"/> Prescription pad missing
<input type="checkbox"/> Patient identification	<input type="checkbox"/> Other (specify)	

Patient Action Influencing Care

<input type="checkbox"/> Non-compliance	<input type="checkbox"/> Left AMA	<input type="checkbox"/> Left without being seen
<input type="checkbox"/> Refused treatment	<input type="checkbox"/> Other (specify)	

Patient Care Related

<input type="checkbox"/> Adverse reaction	<input type="checkbox"/> Consent related	<input type="checkbox"/> Patient monitoring
<input type="checkbox"/> Procedure related	<input type="checkbox"/> Specimen issue	<input type="checkbox"/> Tracking consultations/referrals
<input type="checkbox"/> Infection control (infections, exposure, sharps)	<input type="checkbox"/> Reporting/tracking of test results	<input type="checkbox"/> Medical emergency (i.e. 911 called)
	<input type="checkbox"/> Other (specify)	

Other

<input type="checkbox"/> Missing/damaged property	<input type="checkbox"/> Communication related	<input type="checkbox"/> Corporate compliance
<input type="checkbox"/> Patient complaint	<input type="checkbox"/> Non-medical emergency (i.e. fire, flood)	<input type="checkbox"/> Unauthorized disclosure of protected health information
<input type="checkbox"/> Security related	<input type="checkbox"/> Payment/billing related	
<input type="checkbox"/> Violence to self or others/use of weapon	<input type="checkbox"/> Other (specify)	

Event/Complaint Report

CONFIDENTIAL REPORT OF EVENT. THIS REPORT SHOULD NOT BE INCLUDED IN THE PATIENT RECORD.

SECTION 3. Additional Information

Brief factual description of the event, including key observations and patient's statement if not witnessed by staff (if medication related, indicate name of medication): _____

Injuries and parts of the body involved (i.e. bruised right knee): _____

Pre-existing issues (i.e. impaired mobility, cognitive factors, functional factors, environment, equipment, assistive devices): _____

Preventative measures in place prior to event (i.e. assistive devices, precautions, instructions): _____

Severity of the Injury	<input type="checkbox"/> Minor	<input type="checkbox"/> Significant	<input type="checkbox"/> Death	<input type="checkbox"/> Unknown	<input type="checkbox"/> N/A
Person Examined	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Declined		
Treatment Provided	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Declined		<input type="checkbox"/> Not indicated
Treatment Provided by _____					
Type of Treatment Provided		<input type="checkbox"/> First Aid	<input type="checkbox"/> 911 Called	<input type="checkbox"/> Medical	<input type="checkbox"/> CPR/Defib
Be Specific: _____					

Equipment/Medical Device Involved Yes No
Manufacturer: _____
Model #: _____ Lot/Batch #: _____
Secured/Removed from Service & Labeled "Not for Use" Yes No
Location: _____

Witness(es):
Name: _____
Address: _____
Phone #: _____

Name: _____
Address: _____
Phone #: _____

Authorities/Police Notified Yes No N/A
Authoritative Agency(ies): _____ Date/Time Notified: _____ AM / PM

Family Notified Yes No N/A
Name of Family Member Notified: _____ Date/Time Notified: _____ AM / PM

Name of Practice Manager/Physician/Dentist Director Notified: _____
Date/Time Notified: _____ AM / PM

Staff Person Completing Report:

Print Name & Title _____ Signature & Date _____

Practice Manager/Physician/Dentist Director Reviewing Report:

Print Name & Title _____ Signature & Date _____

Instructions for Completing an Event/Complaint Report

INTRODUCTION

These instructions are provided to assist in the reporting of events. These definitions are intended for the office practice to use as suggestions in order to maintain consistency in the reporting and tracking of events.

Purpose of the Event Report

The purpose of an event report is to notify the responsible individual within the physician/dentist office practice of all events with actual or potential injury to patients and visitors. The event report form also serves to document the event and provide a method to track and trend events over time so that improvements can be made.

What is an event?

An event is comprised of any happening that is not consistent with the routine or usual operation of the practice, i.e., any deviation from policy and procedure. Injury does NOT have to occur. A “near miss” or the potential for injury and/or property damage is sufficient for an event report to be completed.

When to do an event report?

An event report should be completed immediately following any unusual occurrence, once the persons involved have received the necessary treatment or attention if indicated. The report should also be completed for any deviation from the practice’s own policies and procedures. ONLY factual, objective information should be contained in the report. Documentation of blame or finger pointing is inappropriate.

Who should complete?

Completion of the report is the responsibility of the person with the most knowledge about the event or the person who witnessed the event. However, it is at the discretion of each practice to determine the most appropriate individual to complete the report, in accordance with the practice’s own policy and procedure.

After completing the form

Once completed, the form should be forwarded to the practice’s responsible individual within 24 hours of the event. These forms are for internal use only and should NOT be provided to the patient, visitor, or family member involved. The incident report form should NOT be photocopied once completed and should NOT be placed in the patient record. Documentation in the patient record should NOT reference a report was completed. Additional documents, such as corrective actions, should NOT be stapled to the event report. These instructions should NOT be stapled to the event forms.

GUIDELINES FOR COMPLETING THE FORM

It is recommended that the form be completed in the following order:

First: Complete Section 1.

Next: Complete Section 2.

Final: Complete Section 3.

Section 1 – General Information - Each section **must** be completed.

1. **Name, address, telephone number of patient/visitor involved in event**
2. **Date of event**
3. **Time of event** – indicate am or pm
4. **Type of person involved**
5. **Age, gender**
6. **Record #** - if applicable
7. **Reason for visit** –indicate why the individual was at the practice
8. **Location** - specify area that best describes the **PLACE** where the incident occurred

Section 2 – Type of Event - Check all that apply

1. **Bodily Injury** – Not resulting from a fall, procedure or equipment
 - a. **Chemical** (e.g. burn from prep solution, alcohol sponge, etc.)
 - b. **Hot Liquid** (e.g. burn related to a spill from coffee, soup, etc.)
 - c. **Electrical** (e.g. electrical shock that results in a burn)
 - d. **Heating Appliance** (e.g. heating pad, warming blanket, hoses, etc.)
 - e. **Exposure to Hazardous Material** (e.g. inhalation, ingestion, contact, exposure)
 - f. **Other** - any other bodily injury not defined above
2. **Equipment/Medical Device Related** - Complete questions describing equipment involved in Section 3 (device type, serial #, model #, and was device removed)
 - a. **Disconnected/dislodged** – (e.g. plug disconnected, catheter or tubing dislodged)
 - b. **Mechanical Issue** – (e.g. equipment malfunction)
 - c. **Electric Power Outage**
 - d. **Availability** – (e.g. equipment not available when needed)
 - e. **User Related** – (e.g. equipment used incorrectly or improperly, tampered with, improper equipment utilized for situation)
 - f. **Other** - any other equipment related event not defined above
3. **Fall**
 - a. **Dropped** (e.g. unexpected, sudden release of patient while being transferred from one place or position to another)
 - b. **Fainted** (e.g. witnessed/observed person experiencing a temporary loss of consciousness)
 - c. **While Ambulating** (e.g. witnessed/observed person falling while walking)
 - d. **Found on Floor** (e.g. witnessed/observed person in a lying or sitting position on the floor)
 - e. **Off Chair/Bed/Exam Table** (e.g. witnessed/observed person falling from chair/bed/table)
 - f. **Off Scale/Equipment** (e.g. witnessed/observed person falling from any equipment)
 - g. **Other** - any other equipment related event not defined above
4. **Medication Related** – **MUST** include the name of the drug and the dosage in the Brief Factual Description in Section 3).
 - a. **Adverse Reaction** (e.g. unfavorable response to any drug administered)
 - b. **Drug Selection** (e.g. incorrect drug ordered by prescriber or administered)
 - c. **Patient Identification** (e.g. administered to wrong patient)

- d. **Dosage** (e.g. incorrect dosage ordered by prescriber or administered)
 - e. **Route** (e.g. incorrect mode of administration)
 - f. **Prescription Pad Missing** (e.g. pad previously accounted for)
 - g. **Medication Missing** (e.g. drug not available when needed or drug previously accounted for)
 - h. **Other** - any other medication related event not defined above
5. **Patient Action Influencing Care**
- a. **Left AMA** (patient left against medical advice)
 - b. **Refused Treatment** (refusal of recommended treatment)
 - c. **Non-Compliance** (e.g. patient pattern of not showing for appointments or adhering to agreed upon plan of care)
 - d. **Left Without Being Seen** (e.g. left without being seen by a practitioner)
 - e. **Other** - any other patient action not defined above
6. **Patient Care Related**
- a. **Adverse Reaction** (other than medication related, any unfavorable response that caused or has potential to cause an injury, e.g. allergic reaction to latex)
 - b. **Procedure Related** (e.g. wrong site, incorrect procedure, incorrect preparation solution utilized, incorrect procedure technique)
 - c. **Medical Emergency** (e.g. respiratory/cardiac/diabetic/epileptic event)
 - d. **Tracking Consultations/Referrals** (e.g. failure to follow policy & procedure to ensure that recommended referrals are scheduled or done timely)
 - e. **Consent Related** (e.g. consent not completed correctly or in a timely manner, dated beyond allowable time frame in accordance with policy)
 - f. **Specimen Issue** (e.g. missing, destroyed, unusable)
 - g. **Reporting / Tracking of Test Results** (e.g. positive or borderline results not immediately communicated to practitioner, failure to follow policy & procedure to ensure that recommended tests are scheduled or done timely)
 - h. **Patient Monitoring** (e.g. monitoring not conducted in accordance with policy & procedure, incorrect monitoring)
 - i. **Infection Control** (e.g. infections, exposure to infectious diseases, sharps injury)
 - j. **Other** - any other patient care related event not defined above
7. **Other**
- a. **Missing/Damaged Property** (e.g. general power failure damages property)
 - b. **Patient Complaint** (e.g. patient experienced rude behavior by answering service staff member)
 - c. **Security Related** (e.g. office window found tampered with)
 - d. **Violence to Self or Others/Use of Weapon** (e.g. assault, suicide attempt)
 - e. **Communication Related** (e.g. failure to communicate plan of care with covering practitioner)
 - f. **Non-medical Emergency** (e.g. fire, flood)
 - g. **Payment/Billing Related** (HIPAA Business Associate agreement with any outside billing service not signed, bill sent to collection following patient event)
 - h. **Corporate Compliance** (e.g. cultural code of conduct breached, sexual misconduct, discrimination)
 - i. **Unauthorized Disclosure of Protected Health Information** (unauthorized viewing of patient record, discussion of health information in public environment)
 - j. **Other** - any other event not defined above

Section 3– Additional Information – Each section MUST be completed.

1. **Brief Factual Description of the Event, including Key Observations and Patient’s Statement if Not Witnessed by Staff** - Briefly state any supplemental, factual, objective information relating to this incident that is not determinable from use of the check boxes within the form. Quotes from the person involved should be written here. (e.g. Patient found on floor. Patient stated she “tripped on her shoelaces.”) If medication related name of medication and dosage **MUST** be indicated.
2. **Injuries and Parts of the Body Involved** (e.g. bruised right knee)
3. **Pre-existing Issues** (e.g. floor wet, floor dry, patient shoes untied, patient disoriented cognitively)
4. **Preventative Measures in Place Prior to Event** (e.g. inquired if patient allergic to latex, driveway salted by ABC contractor at 11:30 a.m.)
5. **Severity of Injury** - choose only one (the most serious at the time the event report is completed):
 - **Minor** - injury that does not require medical intervention, first aid only (i.e. contusion, abrasion, etc.)
 - **Significant** - injury that requires medical intervention or treatment (i.e. suturing, X-rays, medication, surgery, transfer to higher level of care, etc.)
 - **Death** - event contributed to or caused death
 - **Unknown** - unknown severity at time event report completed
 - **Not applicable** - event did not result in any harm
6. **Person Examined** (Yes, No, Declined)
7. **Treatment Provided** (Yes, No, Declined, Not Indicated)
8. **Treatment Provided by** - indicate whether first aid, emergency response personnel or, if medical treatment provided by staff or practitioner, indicate name. Specify treatment received such as CPR/Defib, dressing, medicated, sutured, X-rayed, or no further treatment.
9. **Equipment/Medical Device Involved** (indicate Yes or No, the manufacturer, model, Lot, & batch numbers, whether secured and removed from service, labeled “Not For Use”, and the location).
10. **Witnesses** - record the name and address of any witnesses to the event. If another staff member witnessed the event, record his or her name and document the practice’s address rather than home address.
11. **Authorities/Police Notified** – (e.g. prosecutor’s office, DYFS, Department of Health) – indicate Yes, No or Not Applicable. If notified indicate authoritative agency, date and time of notification.
12. **Family Notified** – (e.g. an elderly patient visiting the office alone, is treated by emergency response personnel for respiratory distress and is transported to the hospital) – include name, date, time notified.
13. **Name of Practice Manager/Physician/Dentist Director Notified** (include name, date, time).
14. **Staff Person Completing Report** (print name, title, sign and date).
15. **Practice Manager/Physician/Dentist Director Reviewing Report** (print name, title, sign and date). This individual is responsible for reviewing the information and assuring completeness of information.

SAMPLE DISCHARGE LETTER

(Date)

(Patient Name)

(Patient Address)

Dear **(Patient)**,

You will recall that we discussed our physician-patient relationship in my office on **(date of last visit or discussion)**. Also present were your **(wife, husband, etc.)** and my **(nurse, assistant, etc.)**.

As we discussed, I find it necessary to inform you that I will no longer be able to serve as your doctor as of **(date at least 30 days from date of letter)**. The primary difficulty has been **(indicate general reason, e.g., your failure to cooperate with the medical care plan, your behavior toward my staff, etc.)**.

I recommend that you promptly find another physician to provide for your medical needs **(state needs if continual medical attention is necessary, e.g., diabetes, hypertension)**. You may want to contact **(names and phone numbers of the state or local medical society, managed care referral service, etc.)** to obtain names of other physicians who are accepting new patients. Delays could jeopardize your health, so I urge you to act promptly.

I will remain available to provide medical services to you, on an emergency basis only, until **(same date as specified above in second paragraph)** while you have the opportunity to arrange for another physician to assume your care. A medical records release authorization form is enclosed for your convenience. Upon receipt of your signed authorization, I will forward a copy of your medical record. I will also be happy to discuss your medical condition(s) with the physician who assumes your care.

Very truly yours,

(Typed Physician Name)

cc: File

PATIENT SATISFACTION SURVEY

We would like to know how you feel about the services we provide so we can make sure we are meeting your needs. Your answers will help us improve our services. We will keep your answers confidential.

Thank you for helping us.

Please check how well you think we are doing in the following areas:	Great 5	Good 4	OK 3	Fair 2	Poor 1
Ease of getting care:					
How easy is it to get in to be seen?					
How convenient are the practice's hours?					
How convenient is the practice's location?					
How prompt does the practice return your phone calls?					
How easy is the practice's phone system to use?					
Waiting:					
The length of the wait in the waiting room is....					
The length of the wait in the exam room is....					
The length of the wait for tests to be done is....					
The length of the wait for test results is....					
Staff: Doctor, nurse practitioner [NP], or physician assistant [PA]					
How well does the Doctor/NP/PA listen to you?					
Does the Doctor/NP/PA takes enough time with you?					
How well does the Doctor/NP/PA explain what you want to know?					
Does the Doctor/NP/PA give you good advice and treatment?					
Overall, how satisfied are you with your Doctor?					
Is the nurse/medical assistant friendly and helpful?					
Does the nurse/medical assistant answer your questions?					
Are all other staff friendly and helpful?					
Do all other staff answer your questions?					
Payment:					
If you have to talk to someone about your bill, is there an area in the office where you can have privacy?					
If you have a question about your bill, do you receive a clear explanation?					
If you have questions about your healthcare coverage is there someone at the practice who can help you?					
Facility:					
Are the building and grounds neat and clean?					
Is it easy to figure out where to go to find the office?					
Do you feel comfortable and safe while you are waiting?					
Do you feel your privacy is maintained?					
Are you likely to refer friends and family to this practice?					
Do you consider this practice your regular source of care?	Yes _____	No _____			
What do you like least about our practice?					
What can we do to improve?					
Your age (circle one)	0-10	10-25	25-50	50-65	65+
Male _____ Female _____					
How long have you been a patient of this practice? _____					

Thank you, again, for your help!

GUIDELINES for Administering a Patient Satisfaction Survey

Based on an example from the Bureau of Primary Health Care

Giving the survey to patients

It is important that the survey be given to patients in a consistent manner so that survey results are as unbiased as possible. Below are three possible methods of distribution:

1. a stack of surveys can be prominently available at the office's check-out desk with envelopes for return mailing (with postage on them) or a box to drop completed surveys in
2. a staff member can hand the survey to each patient as they leave and ask them to complete the survey before they leave the office; patients who complete the survey hand it to the staff member, who immediately seals it in an envelope without looking at it
3. surveys can be mailed to all patients of the practice with self-addressed return envelopes; these envelopes should already have postage on them

No matter how your patients receive the survey, it is important to assure them that these surveys are being done to improve the quality of practice services, and that all replies are strictly confidential.

Estimating the cost of the survey

Practices may be hesitant to do a survey because of its cost in time and money. Before you do a survey, consider both the cost and the potential rewards.

The potential benefits Patient Satisfaction Surveys [link] are discussed in this Office Practice Toolkit. Their costs can be roughly estimated by:

- deciding which approach your practice will take to the survey
- calculating approximately how much paper supplies you will use (this could involve regular paper stock, letterhead, and envelopes)
- postage (if the survey is mailed)
- copying costs
- staff time (calculating the type of staff involved in the project, how many of each type, the number of hours of each type, and the number of hours times the salary cost per type)

Calculating a Sample Size

Definitions

Population

The population is the entire group of patients that you want to survey.

Sample

The sample is the part of your patient group that you actually survey.

Representative Sample

A representative sample is a portion of your patient population that has the same characteristics as the total patient population.

Types of samples

Subjective or Convenience Sample

- is possibly biased
- usually is not representative
- selection is made by ease of collection

Systematic Sample

- is random
- people selected have an equal chance of being selected because of the methodology (e.g., it could be a computer generated list, or it could be every fifth name on a list, etc.)
- can usually be supported if challenged that it is not random

Stratified Sample

- population is broken down into subgroups, then a random sample is taken from each subset
- can usually be supported if challenged that it is not random

Sample Size

It is important to get as large a sample of your patient population as possible to respond to your survey. If you have 800 patients and only 50 respond, their answers will not give you a clear picture of your patients' opinions about your office. This is why, whether mailing or handing out the survey, it is important to make the survey as easy for your patients as possible.

Data Collection and Analysis

Although this may seem like the most formidable part of surveying your patients, it should be straightforward with the use of computer software like Lotus 123 or Excel. Simply create a spreadsheet which mirrors your survey tool. Add a column for 'No response' to the right of 'Poor'. Each response cell can be programmed to calculate a percent of the responses received divided by whatever sample size you mailed or handed out (e.g., if you handed out 300 surveys then the cell would be programmed $x/300$).

When completed surveys come in, assign one or more clerical staff to enter the responses into the spreadsheet each day. As the responses build up, the percents in the cells will climb higher.

Those questions which are demographic in nature, or require patients to give their own response (such as "what do you like least about our practice"), can be tabulated separately.

When the majority of surveys are returned and entered into the program, the practice can print out a report which can be used for staff discussion and possible practice changes.

STAFF SELF-EVALUATION

Communication Assessment	Always	Frequently	Occasionally	Almost Never
I know the patient's name before I greet him/her.				
I use language the patient can understand.				
I support the M.D.'s comments to the patient.				
I am successful at calming anxious patients.				
Telephone Assessment				
I answer before the third ring.				
I answer with the name of the physician or practice.				
If necessary to put someone on hold I ask first and wait for positive acknowledgement.				
I quickly find out the reason for the call.				
I deliver messages promptly & accurately.				
I speak pleasantly.				
I avoid the use of slang & medical jargon.				
I call patients by name.				
Difficult patients are easy for me to handle.				
Regardless of the patient's age or position, I am comfortable in conversation.				
Rate Yourself				
3 points for each: Always				
2 points for each: Frequently				
1 point for each: Occasionally				
0 points for each: Almost Never				
Score				
37 – 45 Excellent				
28 – 36 Good				
Less than 27 – Needs Improvement				

NOTE: To be filled out by staff member in preparation for employment evaluations or to be used as a staff survey, evaluating patient satisfaction.

IN-OFFICE TELEPHONE RECORD

Date of Call: _____ Time: _____

Patient Name: _____ Age: _____

Name of Caller, if other than patient: _____

Call Received by: _____

Contact phone # (1): _____

Contact phone # (2): _____

Reason for call: _____

Current Medications: _____

Allergies: _____

Plan / Intervention: _____

Rx: _____

Pharmacy Name: _____ Phone: _____

Special Instructions: _____

Patient contacted by whom: _____

Date: _____ Time: _____ Initials: _____

Patient Visit Agenda

Thinking about your goals for today's visit can help you get the most out of your time spent with the physician. Please take a moment to write down what you would like to cover during your visit.

Today's Date: _____ Patient Name: _____

Main reason for today's visit: _____

Other concerns I would like to discuss:

Check all that apply:

I have prescriptions that need to be refilled:

Medication Name	Dose	When/How taken

I need a note for excuse from: _____ work _____ school

I need an insurance referral for: _____

I need forms filled out for: _____

Other (Explain): _____

Office Visit Summary & Instructions

Today's Date: _____ Patient Name: _____

Key Points of Visit:

New or Changed Medications:

Care Instructions:

Call Office Immediately For: _____

Tests to be Performed:

None: _____

Lab Work: _____

Radiology Tests: _____

Other: _____

Consultation Required:

Specialty: _____


Within: _____ days/weeks/months (circle one).

Follow-up after test or consultation is completed if you do not hear from us with results within: _____ days/weeks/months (circle one)

Handouts Given – List:

Schedule follow-up appointment in:

_____ days/weeks/months (circle one)



A message from your physician:

“Your health and satisfaction are important to me, and I want to provide the best possible care. I encourage you to become an active participant in your care and insist that your questions are fully answered. I invite you to...”

- **Speak up- be open and honest.**

Please tell me all your symptoms and concerns; I do not want you to feel embarrassed or shy about anything. It could be important to both of us.

State what you fear your problem might be. Unless I know what is bothering you, I may not be able to help you to the best of my ability.

If this is a follow-up visit, be sure to tell me if, and why, you are having difficulty following the treatment plan. We may need to design a new approach to your care together.

- **Ask questions and express concerns.**

Be informed. Your complete understanding is important to me. If I do not answer all your questions, ask me again.

- **Confirm your diagnosis and/or main problem.**

Make sure you understand and are comfortable with my interpretation of your symptoms and concerns.


- **Understand the recommended treatment and what you can expect from it.**

Know what you are being asked to do, and let me know if you do not think you will be able to do it. Know when you can expect to be better and when you need to see me again. It is very important that you understand any medication side effects and/or conflicts with other medications or illnesses.

Questions need answers.

“Ask all questions that you have. When we finish our appointment I want you to be able, at a minimum, to answer these questions. If you cannot, then I want you to ask me.”

- What do you think my main problem is?
- How long will I be sick and how soon should I see improvement?
- Under what conditions should I call you or come back?
- If tests are ordered, when will they be ready, and how will you notify me?
- If medicine is prescribed, what are the side effects I need to be aware of?



A message
from your
physician:

“Your health and satisfaction are important to me, and I want to provide the best possible care. I encourage you to become an active participant in your care and insist that your questions are fully answered. I invite you to...”

Speak up- be open and honest.

Please tell me all your symptoms and concerns; I do not want you to feel embarrassed or shy about anything. It could be important to both of us.

State what you fear your problem might be. Unless I know what is bothering you, I may not be able to help you to the best of my ability.

If this is a follow-up visit, be sure to tell me if, and why, you are having difficulty following the treatment plan. We may need to design a new approach to your care together.

Ask questions and express concerns.

Be informed. Your complete understanding is important to me. If I do not answer all your questions, ask me again.

Confirm your diagnosis and/or main problem.

Make sure you understand and are comfortable with my interpretation of your symptoms and concerns.

Understand the recommended treatment and what you can expect from it.

Know what you are being asked to do, and let me know if you do not think you will be able to do it. Know when you can expect to be better and when you need to see me again. It is very important that you understand any medication side effects and/or conflicts with other medications or illnesses.

(see reverse side)

Questions need answers.

“Ask all questions that you have. When we finish our appointment I want you to be able, at a minimum, to answer these questions. If you cannot, then I want you to ask me.”

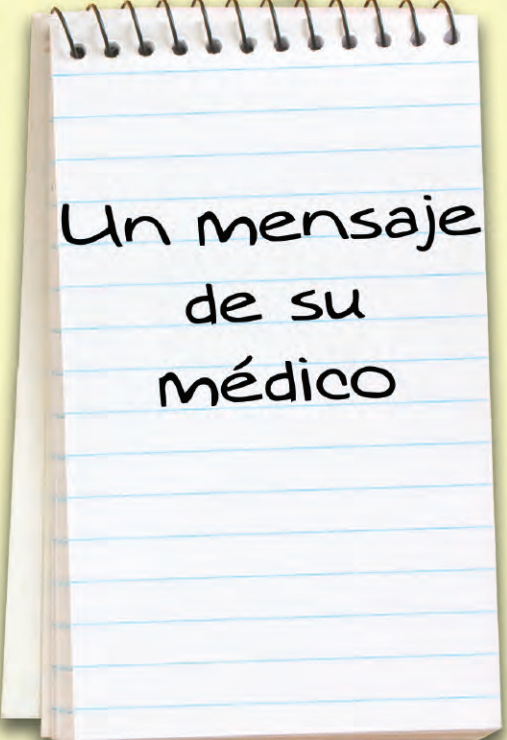
What do you think my main problem is?

How long will I be sick and how soon should I see improvement?

Under what conditions should I call you or come back?

If tests are ordered, when will they be ready, and how will you notify me?

If medicine is prescribed, what are the side effects I need to be aware of?



Un mensaje de su médico

“Su salud y satisfacción son importantes para mí, y quiero proporcionarle los mejores cuidados posibles. Le animo a que participe activamente en sus cuidados e insista en que le contesten sus preguntas plenamente. Le invito a...”

- **Decir lo que piensa – ser abierto(a) y franco(a).**

Por favor, cuénteme todos sus síntomas e inquietudes; no quiero que se sienta avergonzado(a) o tímido(a) acerca de nada. Podría ser importante tanto para usted como para mí.

Diga cuál teme que sea su problema. A menos que yo sepa lo que le preocupa, quizás no pueda ayudarle al máximo de mi capacidad.

Si ésta es una visita de seguimiento, no dude en decirme si tiene dificultades para seguir el plan de tratamiento y por qué. Es posible que necesitemos diseñar juntos una nueva estrategia para sus cuidados.

- **Hacer preguntas y expresar sus inquietudes.**

Infórmese. Es importante para mí que usted entienda todo plenamente. Si no contesto todas sus preguntas, vuelva a preguntarme.

- **Confirmar su diagnóstico o su problema principal.**

Esté seguro(a) de que entiende y está conforme con mi interpretación de sus síntomas e inquietudes.

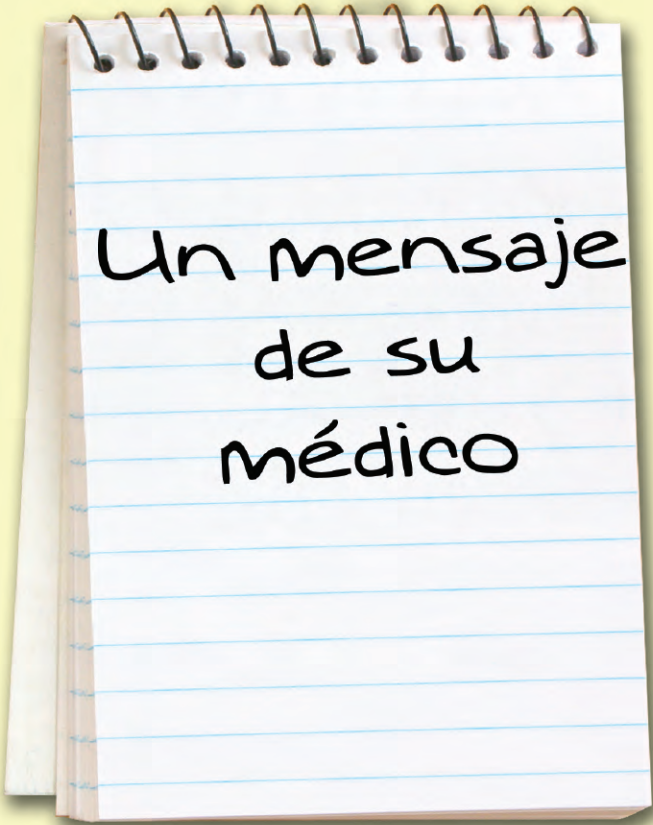
- **Entender el tratamiento recomendado y lo que puede esperar de éste.**

Sepa lo que le piden que haga usted y hágame saber si no cree que podrá hacerlo. Sepa cuándo puede esperar una mejoría y cuándo es necesario verme otra vez. Es muy importante que entienda cualquier efecto secundario de los medicamentos o conflictos entre éstos y otros medicamentos o enfermedades.

Las preguntas necesitan respuestas.

“Haga todas las preguntas que tenga. Cuando terminemos con nuestra cita quiero que pueda, como mínimo, contestar estas preguntas. Si no puede, quiero que me pregunte”.

- ¿Cuál cree usted que es mi problema principal?
- ¿Cuánto tiempo estaré enfermo(a) y cuán pronto debo ver una mejoría?
- ¿En qué circunstancias debo llamarlo(a) o regresar?
- Si me ha ordenado pruebas, ¿cuándo estarán listas y cómo me notificará usted?
- Si me ha recetado medicinas, ¿cuáles son los efectos secundarios que necesito vigilar?



Un mensaje de su médico

“Su salud y satisfacción son importantes para mí, y quiero proporcionarle los mejores cuidados posibles. Le animo a que participe activamente en sus cuidados e insista en que le contesten sus preguntas plenamente. Le invito a...”

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(lea al dorso)

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Si me ha recetado medicinas, ¿cuáles son los efectos secundarios que necesito vigilar?

REQUEST FOR CONSULTATION

Patient name: _____ Age: _____ DOB: _____

To: Dr. _____ From: Dr. _____

Ph. #: _____ Fax #: _____ Ph. #: _____ Fax #: _____

Referring Diagnosis: _____

Reason for Consultation:

- Consult for opinion only
- Consult and recommend treatment
- Consult and treat specific problem _____
- Consult and assume total care of patient

Patient history: _____

Significant family history: _____

Current meds: _____

Tests performed: _____

Urgency of Consult:

- Urgent, consultation needed immediately
- Please see patient within _____ hours
- Not urgent, may see within _____ days

Other requests:

- Please call with results
- Please send written consult report

Method of Request:

- In person
- Phone to doctor
- Message with office / service
- Fax

I have noted the referral and the reason for the referral in my plan of care.

Signature: _____ Date: _____ Time: _____

EMPLOYEE CONFIDENTIALITY POLICY AND AGREEMENT

The relationship between the physician and patient is highly confidential. Information about a patient, his or her illness, and/or their personal life must be kept strictly confidential. As an employee of our office, you may acquire information on a patient during the course of a work day. **ALL** such information, whether that information is medical, financial, or personal in nature, must be kept highly confidential. Under no circumstances should any information regarding our patients be discussed.

ANY EMPLOYEE FOUND IN VIOLATION OF THE ABOVE POLICY WILL BE SUBJECT TO IMMEDIATE TERMINATION AND/OR OTHER ALTERNATIVE ACTION.

I hereby acknowledge that I understand and will adhere to the above referenced office confidentiality policy. Patient information shall not be disclosed to anyone, under any circumstances, without the fully executed authorization of the patient. **ANY** unauthorized disclosure of patient information is grounds for disciplinary action, including immediate dismissal.

SIGNATURE: _____

PRINTED NAME: _____

DATE: _____

SUPERVISOR: _____

HIPAA COMPLIANT AUTHORIZATION

Patient name: _____ Date of Birth: _____

Previous name: _____

I. Authorization

You may use or disclose the following health care information (check all that apply):

- All health care information in my medical record
- Health care information in my medical record relating to the following treatment or condition:

Health care information in my medical record for the dates(s): _____

Other (e.g., x rays, bills), specify date(s): _____

You may use or disclose the following health care information regarding testing, diagnosis, and treatment, should it be found in my records, only if checked below:

- HIV (AIDS virus) Sexually transmitted diseases
- Psychiatric disorders/mental health Drug and/or alcohol use

You may disclose this health care information to:

Name (or title) and organization or category of persons (i.e. all treating physicians, etc.): _____

Address (optional): _____ City: _____ State: ____ Zip: _____

Reason(s) for this authorization (check all that apply):

- At my request Other (specify) _____

This authorization ends:

- On (date): _____
- When the following event occurs: _____
- In 90 days from the date signed (if disclosure is to a financial institution or an employer of the patient for purposes other than payment)

II. My Rights

I understand I do not have to sign this authorization in order to get health care benefits (treatment, payment or enrollment). However, I do have to sign an authorization form:

- To take part in a research study or
- To receive health care when the purpose is to create health care information for a third party.

I may revoke this authorization in writing. If I did, it would not affect any actions already taken by the physician based upon this authorization. I may not be able to revoke this authorization if its purpose was to obtain insurance. Two ways to revoke this authorization are:

- Fill out a revocation form.
- Write a letter to the physician.

Once health care information is disclosed, the person or organization that receives it may re-disclose it. Privacy laws may no longer protect it.

Patient or legally authorized individual signature

Date

Time

Printed name if signed on behalf of the patient

Relationship (parent, legal guardian, personal representative)

INFORMED REFUSAL

Consent is a process. It is the communication between a patient and a physician in which each party asks questions and exchanges information, resulting in both the patient and the physician agreeing to specific medical, surgical, pharmaceutical, or diagnostic interventions.

It is the obligation of the physician to provide you, the patient, with the information and advice needed to make your healthcare choices. Ultimately, however, the decision for your healthcare rests with you. This form will serve to acknowledge your refusal of the interventions and treatments prescribed by your physician.

I, _____ acknowledge that:

1. Dr. _____ has recommended _____

2. The recommendation has been made to me for the purpose of _____

3. I have decided to refuse the recommendation. _____ (initials)

4. My decision has been made after considering both the prescribed treatment as well as any other alternative forms of treatment or diagnostic study for my condition. I fully understand that each of the alternative forms of treatment/diagnostic study has its own potential benefits, risks, and complications. _____ (initials)

5. I completely understand that there are possible risks, complications, and side effects involved in refusing medical treatment. I also understand that it is impossible to list every risk, complication, and/or side effect involved in my refusal, however I have been educated to some of them. They could include, but not be limited to, the following:

Although these risks, complications and side effects may be rare, they do sometimes occur and cannot be predicted or prevented by the health care provider. I acknowledge that no guarantee has been made to me about the results of refusing the prescribed treatment/diagnostic study. _____ (initials)

6. I am aware that the potential risks and complications can result in additional medical or surgical treatment, prolonged hospitalization or even permanent disability, severe injuries or death. _____ (initials)

7. I certify that I have read (or had read to me) the entire contents of this form. I acknowledge that the possible risks and consequences created by my refusal to permit the recommended treatment have been fully explained to me. I understand the possible benefits for allowing the recommended treatment and the possible risks and consequences to myself because of my refusal for same.

Patient Signature

Witness

Date

INFORMED CONSENT FOR CLINICAL TRIALS

INFORMED CONSENT FOR CLINICAL RESEARCH SHOULD BE OBTAINED FROM ALL SUBJECTS AND SHOULD CONTAIN THE FOLLOWING ELEMENTS:

1. That the trial involves research.
2. The purpose of the trial.
3. The trial treatment(s) and the probability for random assignment to each treatment.
4. The trial procedures to be followed, including all invasive procedures.
5. The subject's responsibilities.
6. Those aspects of the trial which are experimental.
7. The foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus or nursing infant.
8. The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.
9. That the monitor(s), the auditor(s), the IRB/Ethics Committee, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.
10. Those records, identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, it will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.
11. That the findings of the study will be recorded in a publicly available databank maintained by the National Institutes of Health/National Library of Medicine, available at <http://www.ClinicalTrials.gov>.ⁱ
12. That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.
13. The person(s) to contact for further information regarding the trial and the rights of the trial subjects and whom to contact in the event of a trial-related injury.
14. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.
15. The expected duration of the subject's participation in the trial.
16. The approximate number of subjects involved in the trial.

17. The alternative procedure(s) or course(s) of treatment that may be available to the subject and their important potential benefits and risks.
18. The compensation and/or treatment available to the subject in the event of a trial-related injury.
19. The anticipated prorated payment, if any, to the subject for participating in the trial.
20. The anticipated expenses, if any, to the subject for participating in the trial.
21. That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

Source: *The Trial Investigator's GCP (Good Clinical Practice) Handbook: a practical guide to ICH requirements.*

Note about ICH: Because of differences in GCP procedures in Europe, the USA and the 3rd largest pharmaceutical market, Japan, regulatory authorities and representatives of the pharmaceutical companies of these regions, together with observers from Scandinavia, Australia, Canada and the WHO – collectively known as ICH – held a series of meetings to develop a set of universally-accepted GCPs. In May, 1996, the ICH GCPs were finalized and these have now become the standard by which all clinical trials have to be performed in order to achieve universal recognition.

ⁱ *FDA Requires Statement on Clinical Trial Informed Consent Documents*, ECRI, Healthcare Risk Control, HRC Alerts, January 11, 2011.

SAMPLE INFORMED REFUSAL LETTER TO PATIENT

(Date)

(Patient Name)

(Patient Address)

(Patient Address)

Dear **(Patient Name)**:

Please be advised that I have deep concern regarding your decision to forego the **(treatment/test)**, based on your insurance carrier's refusal to authorize payment for the test. On **(date)**, when I prescribed **(treatment/test)**, I had explained the medical benefits, risks and alternative treatment options for same, and my firm belief that it was a medical necessity. During our conversation on **(date)**, I again explained, and elaborated on, the potential consequences of your refusal.

For your health and well-being, I recommend that you seriously reconsider your decision to forego the **(treatment/test)** in light of the potential consequences of not having it performed. I also recommend that you appeal the denial of benefits from your insurance carrier. My staff and I will gladly assist you with the appeal. Please call the office and speak with **(Name of staff member)** if you would like our assistance.

Should you wish to discuss this further, please do not hesitate to contact me.

Very truly yours,

(Typed Name)

SAMPLE LETTER TO INSURANCE CARRIER FOR REFUSAL TO
AUTHORIZE PAYMENT

(Date)

(Medical Director)
(Name of Insurance Company)
(Address)

RE: *(Patient Name)*

Dear *(Medical Director)*:

On *(date)* I prescribed *(treatment/test)* for the aforementioned patient. On *(date)* your company refused to authorize payment for that *(treatment/test)*. I find that I must take issue with your determination. In my professional medical opinion, I firmly believe that *(Patient Name)* would benefit from the prescribed *(treatment/test)* for the following reasons:

List patient's illness/condition, describe why such a treatment/test is necessary, describe problems that could ensue because of failure to perform test

For these reasons, I urge you to reconsider your refusal to authorize payment for the *(treatment/test)* I have prescribed for my patient. By copy of this letter to my patient I emphasize my suggestion that s/he obtain the *(treatment/test)*, despite your refusal to authorize payment.

Very truly yours,

(Typed Physician Name)

cc: *(Patient Name)*

PATIENT INFORMATION UPDATE

Name: _____ Today's date: _____

SINCE YOUR LAST VISIT:

1. Has your name changed? YES NO
(If yes, what was the old name?) _____
What name do you use for health insurance if different than above? _____

2. Do you have a different address? YES NO
(If yes, please indicate new address)

3. Has your marital status changed? YES NO
(If yes, please indicate your new status) _____

4. Has your telephone number changed? YES NO
(If yes, please indicate your new telephone number) _____

5. Has your place of employment changed? YES NO
(If yes, please indicate your new employer name and address)

New employer telephone number: _____

6. Has your health coverage changed? YES NO
(If yes, please indicate name and policy number)

7. Please note any changes in your health:
Illness: _____
Accident: _____
Allergies: _____
Medications being taken (including over the counter/herbals): _____

Hospitalizations: _____

8. May we leave medical information/diagnostic study results on your voice mail?
Home: _____ Work: _____ Cell: _____ NO MESSAGES
Signature: _____

DOCUMENTATION CHECKLIST

- Black or Blue Ink Used
- Legible
- Patient ID on Each Page/Monitor Strip
- All Pages Permanently Attached
- Chronological Order
- Dictated Within 24 Hours
- Factual/Objective
- Medical History Present and Updated
- Signed/Dated Notes
- All Alterations/Changes are signed and dated
- No Inappropriate Information or Language
- No "Post-Its"
- Billing Information Separate from Clinical Notes
- Allergies Prominently Noted/Dated/Updated
- Immunizations Noted

- Lab Work:
 - Log of Specimens Sent To Lab
 - Receipt of Results Initialed/Dated

- "Tickler" File Re:
 - Outstanding Lab Work
 - Returned Reports
 - Outstanding Consults/Referrals

- Problem List

- Current Medications Noted:
 - Samples Given
 - Lot # Noted
 - Handwritten Rx's
 - Telephone Refills

- Treatment Plan
- Patient Education
- Discharge Instructions or Follow-Up Plan for Each Encounter
- Treatment Non-Compliance and Missed/Cancelled Appointments Noted
- Follow-Up on Missed/Cancelled Appointments Noted

- Telephone:
 - Messages from Patient Noted
 - Contact by Physician or Other Appropriate Staff

- Informed Consent Documentation (includes information communicated) with Signatures of Practitioner, Patient and Witness on any consent form used

RELEASE OF X-RAYS

PATIENT'S NAME: _____

Films Released To: _____ Date: _____

As requested, we are lending you film(s) as a courtesy for the benefit of this patient.

Since these films are legally a part of our permanent medical records, do not send them to any other physician or hospital without our release and the patient's authorization.

Please return the films within 30 days of this date, or as soon as they have served their purpose.

Your cooperation in this matter will be appreciated, providing us opportunities to extend this courtesy to you in the future.

Recipient of Films: _____ Date: _____
(Signature)

Copy and file in permanent jacket, medical chart, and loan jacket

MEDICATION FLOW SHEET

Last name: _____ First Name: _____ MI: _____

Pt #: _____ DOB: _____

Male Female

Pharmacy Name: _____

Pharmacy Phone #: _____

Allergies: _____ _____ _____ _____ _____
--

Date	Start/Stop Dates	Medication	Dose/Route/Frequency	Pt. Med Education/Source*	Prescriber	Refills* (date, amount, initials)			
						1 st	2 nd	3 rd	4 th

* Patient education 'Source' may be written, verbal, video, or web-based; Refills should follow strict office policy, requiring patient be seen at regular intervals (frequency to depend on drug indications and medical condition)

IN CASE OF

EMERGENCY



**DIAL
911**

**FIRE
POLICE
AMBULANCE**



POISON CONTROL: 1-800-222-1222

Provide the following information:

- Nature of the emergency, including if people are evacuating the building
- Address (*including floor, suite, etc.*):

- Nearest crossroad and/or landmark:

- Phone number you are calling from:

- Your name

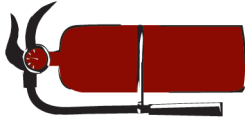
Stay calm and don't hang up unless instructed to do so by the 911 operators.

If available, send someone outside to flag down the emergency first responders.

Advise the Fire Department, upon arrival, of the location of medical gas cylinders or laboratory chemicals, if applicable.

Before Fire Occurs

- ▶ Report all fire and safety hazards to your supervisor.



- ▶ Read through the Emergency Procedures Manual and be familiar with the hospital's fire plan.
- ▶ Know the location of the fire alarm pull station.
- ▶ Know which type of extinguisher to use and how to use it.

When Fire Occurs

Rescue people in immediate danger.

Alarm (pull fire alarm), call the operator (ext. _____), confirm location.

Close all doors.

Exercise good judgment when deciding to extinguish the fire.

Using the Extinguisher

Pull the pin.

Aim the extinguisher at the base of the fire.

Squeeze the handle while holding the extinguisher upright.

Sweep back and forth to extinguish the fire.

Place the extinguisher on its side or give it to maintenance after it's used.

Remember: Don't let the fire get between you and your exit.

Types of Fires and Extinguishers

A **Ordinary**
paper, cloth, mattress
Use Water (A) or Dry
Chemical (ABC)

B **Flammable liquids**
alcohol, grease, etc.
Use CO² (BC) or Dry
Chemical (ABC)

C **Electrical**
*Motors, biomedical
equipment*
Use CO² (BC) or Dry
Chemical (ABC)

**REDUCING RISK
DOCUMENTS
AND
RISK REVIEW ONLINE
ARTICLES**

Reducing Risk Documents and Risk Review Online Articles

Event Reporting

Guide to Investigating Events in the Physician Practice

Discharging a Patient from Your Medical Practice

Ceasing to or Leaving a Practice

When Patients Don't Return for Follow-up Care

Treatment of Minors

Informed Consent

Incorporating Shared and Informed Decision Techniques into Your Patient Interactions

Patients and Tape Recorders

Surreptitious Recordings by Patients

Consultations: Who Follows the Patient?

Tracking and follow-up of tests, consults, and referrals to achieve patient safety and service excellence

Urgi-Care Centers and Walk-In Hours Present Special Risks

Job Descriptions and Performance Evaluations for the Office Practice

Preventing Wrongful Termination Lawsuits

The Americans with Disabilities Act

The Scope, Purpose, and Methods of the New Jersey Board of Medical Examiners - A Practical Guide for Practicing Physicians

HIPAA Privacy Rule

NJ Physicians Mandatory Disease & Injury Reporting

Subpoenas for Medical Records in New Jersey State Court Civil Actions

Releasing Records: Reduce the Confusion

Psych Records Requests

Risk Alert – “Apparent Authority”

Management & Documentation of After-hours Calls

Documenting Phone Calls - physician office practice toolkit resources to assist you

What is the legal exposure when a patient's chart is missing, incomplete or destroyed?

Another Article on Documentation?

Medical Records: Best Friend or Worst Enemy?

Protect Your Practice with Your Pen: Documentation Tips

Analyzing charts to limit liability

Assuming the Care of a New Patient

Unexpected Medical Record Damage

Dealing With Deceased Patients' Medical Records

Medical Clearance for Surgery: “Red flags” prompt further action

Wrong Site Surgery

Reducing Risk

A Publication on Healthcare Risk Management from Princeton Insurance

Event Reporting

Introduction

A system for reporting events (often called incidents) is an important component of patient safety in a medical or dental office practice. An event reporting system helps to assure that occurrences, injuries, near misses, etc. are promptly identified, investigated, and analyzed to determine if improvements or changes are required. The purpose of event reporting is to improve patient care; prevent adverse events from being repeated; and protect patients, visitors, and staff from harm.

The involvement and support of all physicians and management staff are essential for an effective event reporting system. The office culture must be non-punitive and convey the message to all staff that event reporting is valued. The system should be easy to use, and improvements resulting from the event reporting must be evident. All staff must be educated on what and how to report and its importance.

Events to Report

In healthcare, a reportable event or incident is defined broadly as any situation that is not consistent with either the routine operation of a facility/office, or the routine care of a particular patient. *Injury does not have to occur.* The potential for injury and/or property damage is sufficient for an occurrence to be considered an event. Incidents may involve patients, medical staff, employees, and visitors.

Reportable events in the office setting include:

- Bodily injury or near injury to any individual
- Emotional trauma (e.g., angry or violent outburst)
- Any use of emergency measures such as CPR
- Medication or treatment errors or allergic reactions
- Medical device-related events
- Any observed breaches of health/safety/privacy standards, office policy or procedure
- Statements or actions by any person that suggest a possible legal claim against the practice

Event Report Content

The event report should contain only factual and objective information; there should be no conclusions, opinions, accusations, or admissions. Event reporting is not meant to place blame on any individual, nor is it an admission of negligence.

In most instances, the employee or staff member who is involved in or observes an event should complete the event report. The report should be completed timely, preferably at the time the event is witnessed or discovered.

An event report form should contain the following information:

- Date and time of the report
- Date and time of the event
- Name, address and telephone number of the person affected (e.g., patient, employee, visitor)
- Name, address and telephone number of person(s) witnessing the event
- Location of the event
- Factual description of the event, including key observations

- Condition of the affected person immediately after the event, including any complaints of injury and observed injuries
- The identity of the staff member to whom the event was reported and, if applicable, the response, such as examining the patient or giving an order
- The manufacturer, model and lot or batch number of any medical device involved
- Identity and signature of the individual preparing the report

All professional and office staff must be instructed in the proper methods for reporting events. They should also be directed not to write any personal notes about an event, since such writings could be discovered in a lawsuit and may contain damaging comments. Proper reporting of factual information only in event forms reduces the likelihood that a plaintiff's attorney would find any benefit in their use or discovery.

Medical Record Documentation

Document in the medical record the pertinent factual information regarding any unanticipated event that results in an injury to a patient. Include a description of what occurred and any medical or other attention that was provided immediately following the event. *The fact that an event report was prepared should never be documented in the medical record.*

Application of Event Report Data

Data from event reports should be collected and analyzed to identify the factors or processes that are contributing to the reported events, and to identify areas for change or improvement. Analysis should be followed by development and implementation of efforts to eliminate or reduce the factors identified as contributing to the incident. Soliciting ideas from all staff for improvement can also contribute to team building and a sense of shared responsibility for accomplishing the selected goals. Provide regular feedback to all staff on the results of the practice's efforts to improve patient care and reduce risks.

Confidentiality of the Event Report

Event reports are *confidential* documents and should be clearly marked as such. They are not part of the patient's medical record and must be kept separate from the medical record. They also should be protected from access by unauthorized personnel, and the number of persons having access to them should be as limited as possible. Do not make copies of event reports.

Event reports also should not be placed in personnel files or be used as the basis for a disciplinary action, as this would discourage reporting and be inconsistent with a non-punitive culture of care. However, employees should be advised that failure to report an event could lead to disciplinary action and termination. If in doubt about whether an event is reportable, the prudent course for all personnel is to report it.

In New Jersey there are no state laws that absolutely protect an event report in a physician's or dentist's office from discovery during the course of a malpractice lawsuit. However, no healthcare practitioner should ever be deterred from completing and acting upon an event report. The benefits of promoting patient safety and reducing the risk of other lawsuits outweigh the potential risk of a properly prepared event report being discovered in a lawsuit.

For more information about reducing risk at your practice, please view our risk management newsletter at www.RiskReviewOnline.com. To access additional Reducing Risk documents, visit our website at www.PrincetonInsurance.com and click on "Risk Management – Publications."

This material is not to be construed as establishing professional practice standards or providing legal advice. Compliance with any of the recommendations contained herein in no way guarantees the fulfillment of your obligations as may be required by any local, state or federal laws, regulations or other requirements. Readers are advised to consult a qualified attorney or other professional regarding the information and issues discussed herein, and for advice pertaining to a specific situation.

Reducing Risk

A Publication on Healthcare Risk Management from Princeton Insurance

Guide to Investigating Events in the Physician Practice

*Note: This **Reducing Risk Resource** article is directed to the physicians and management staff who have responsibility for risk management at office-based physician practices, ambulatory care centers, and radiology centers. For the sake of brevity, whenever the term “physician practice” is used throughout this article, it is intended to apply as well to ambulatory care and radiology centers. In the article, it is assumed that the physician practice has established procedures for reporting an incident or adverse event, and “near-misses” (collectively, “events”). Decisions about content and format of event reporting forms, types of events required to be reported, and by whom, as well as policies for analysis and dissemination of information obtained, are beyond the scope of this article and therefore not addressed.*

Introduction

This article presents practical guidelines for investigating unexpected events that happen during, or as a result of, care provided in the physician office practice setting. It also discusses some of the reasons for undertaking internal investigation of these events.

Surveys have shown that approximately 80 percent of ambulatory care in the U.S. is provided in office-based physician practices.¹ The number of annual patient visits to physicians has also been increasing. As the delivery of medical care and services has grown, so too has the need to introduce risk management and patient safety principles into the physician practice setting.

Event Reporting

Event reports have historically been, and continue to be, a basic risk management tool that can help to identify unexpected events, injuries, and potential claims. Such reports help give early notice of not only negative outcomes but also “near-misses” that may happen in the complex course of a patient’s healthcare experience. See [downloadable PDFs of sample Event Report Form](#) and [Instructions for use in your office](#):

Healthcare practitioners use a variety of terms to describe events that are or should be reported. The list includes, but is not limited to, the following: events, incidents, variances, occurrences, adverse events, errors, near-misses, and potentially compensable events (“PCEs”). In this article, we will use the term “event” to refer to instances/situations which typically warrant being reported for risk management purposes. However, many other definitions have been put forth, such as this broad description: “any circumstance that is unexpected within the normal operations of the institution or the anticipated disease/treatment process of a patient.” Another approach states it as simply “injuries related to medical management.”² A “near-miss” refers to an unplanned event that did not, but could have, resulted in personal injury or property damage. And finally, the Joint Commission uses yet another term - “sentinel event” - which it defines as “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.”³

¹ Cherry DK, Wood well DA. National Ambulatory Medical Care Survey: 2000 Summary [online] 2002 June 5. Available from Internet: <http://www.cdc.gov/nchs/data/ad/ad328.pdf>. [Also from ECRI-HRC-Out-Patient Settings 2, July 2003]

² Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. *N Engl J Med* 1991; 324(6):370-6.

³ The Joint Commission: Sentinel event policy and procedures [Online] 2006 October. A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called “sentinel” because they signal the need for immediate investigation and response. The terms “sentinel event” and “medical error” are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events.

An effective event reporting education program should give staff an understanding of the situations when a report should be completed and by whom. Event report forms are most effective when completed by the person who first becomes aware of or witnesses the event. The clinical facts surrounding an event should always be documented in the medical record. However, the actual reports should never be placed in or alluded to in the medical record.

Some physician practices may have experience with event reporting in general, or as a means of communicating adverse events to their insurance carriers. Many, however, have not routinely done so. Moreover, staff assigned the responsibility of trying to manage risks and patient safety in a physician practice, in contrast to a hospital environment, will encounter challenges arising from differences in office cultures, types of risk exposures and level of safety knowledge and interest among personnel. A survey commissioned by the Accreditation Association of Ambulatory Health Care's Institute for Quality Improvement revealed that only one-third of the respondents indicated that they report and collect information on adverse medical events, and most of these were not physician practices, but ambulatory surgery centers.⁴

We also note that many states, including New Jersey, have enacted laws that mandate reporting of specific types of medically related adverse events that occur in licensed health care facilities in the state to the governing authority for healthcare oversight. In general, state reporting requirements will apply to large surgical centers or ambulatory care facilities that are licensed by the state, but not to physician practices.

Conducting an Investigation

As part of implementing a risk management and patient safety program, each physician practice will need to implement its own policies and procedures for event reporting, investigation and analysis of data collected from events, and follow-up improvement and monitoring mechanisms. We offer the following suggestions to assist the practice manager or other designated individual responsible for investigating events.

- Policy should state and staff should be trained to notify the practice manager (or other designated individual) promptly of any injuries, loss of life, and/or criminal acts, and defer to appropriate people to contact law enforcement or regulatory agencies.
- Ensure that any injured patient(s) or visitor(s) get prompt medical attention. Safeguard other personnel in the area, if needed.
- Secure the area, and protect (under lock if possible) any physical evidence that could be important later.
- Collect as much information as possible about the area before, during, and after the event:
 - Inspect the incident site immediately, but do not disturb the site unless it presents a hazard.
 - Identify and interview key affected healthcare workers, patients, and witnesses. Identify the physician to whom the event was reported (if applicable) and that physician's response (orders given).
 - If the event was not witnessed, try to speak with others, such as your office staff, co-workers, or relatives, who might have interacted earlier with the person involved.
 - Take photographs and measurements; sketch key aspects of the site; secure surveillance videotape, if available.
 - Collect physical evidence and samples for laboratory analysis, if applicable. Physical evidence includes:
 - ◆ Position of injured patients or visitors.
 - ◆ For device/equipment related events, record pertinent serial numbers, manufacturer and model names, settings at time of event; safety or warning devices and/or personal protective equipment that was in use.
 - ◆ Materials being used at the scene, including medications/injections/anesthesia/chemicals (records of doses, etc.).
 - ◆ Condition of environment: lighting, temperature, smoke, dust, mist, fumes; housekeeping and sanitation conditions (e.g. spilled liquid on floor or other involved surfaces).

Additional Points to Remember

The person conducting the investigation (after an event has been reported) and preparing a follow-up report should try to look back over the entire sequence of events that led to the event (with or without injury), going as far back in time as the investigator feels is

⁴ American Health Consultants Ambulatory Care studies show room for concern and comfort. Healthcare Benchmarks 2001 Oct. 8(10): 109-11. [See FN 13 in ECRI-HRC Analysis; vol. 3, Out-Patient Settings 2 - "Overview: managing Risks in Physician Practices"; July 2003.]

relevant, rather than focusing only on the injury. This allows an organization to identify and implement a wider variety of potential actions to continually improve patient care.

Staff should treat any and all documents generated as part of the follow-up investigation as strictly confidential, to optimize opportunity for legal protection. All information obtained in the investigation should be maintained in a separate file, and never placed in the patient's medical record.

As with event reporting, persons with responsibility for preparing investigation follow-up reports should state facts only, not personal opinions, assumptions, or conclusions.

The practice manager or other designated individual should consider seeking advice and guidance from legal counsel about the design of follow-up reports and how to standardize follow-up procedures.

Collect background information after immediate investigation at the site (appropriate to event):

- Employee records: training information, licenses, certifications, and employment records
- Equipment records: maintenance logs, service reports, work orders, operating manuals, and manufacturer instructions
- Previous incident reports (involving same patient, device or equipment)
- Weather reports (as relevant to location of event)
- Review existing documents, including: material safety data sheets (MSDS), job safety analyses, safety audit results, safety committee minutes, product/equipment specifications, equipment maintenance records, policies and procedures, floor plans/mechanical drawings and blueprints.

Interviewing Tips

- Conduct interviews of staff, witnesses and others involved while details are still fresh to them.
- Be a good listener.
- Keep in mind that the focus is on prevention, so ask open-ended questions.
- Get the facts, without placing blame or expressing opinions.
- Pay attention to unsolicited comments.
- For important points, repeat back what you heard to clarify and confirm facts.

Timing

- Each investigation should be conducted as soon after the event as possible. A delay of only a few hours may permit important evidence to be destroyed or removed, intentionally or unintentionally.
- The designated investigator or committee should present the results of the inquiry as quickly as possible to all staff; this enhances the value of safety education for clinical and non-clinical staff.

After Investigation: Analyze and Learn

The ultimate objectives - and value - of investigating events are to:

- Identify the contributing factors and root cause(s) of the reported events;
- Learn lessons that will help prevent similar events or near-misses from re-occurring;
- Support efforts to eliminate and control those factors.

After a thorough investigation (as outlined above) has been completed, and the necessary reports have been written and submitted (per internal procedures and externally mandated requirements), the practice manager or other designated individual(s) should consider the following actions:

- Analyze the data collected in the investigation to determine possible causes.
- Use aggregate event data (types, numbers of events, locations, etc) to identify and uncover trends in organizational risks. Provide findings from aggregate data analysis to appropriate clinical and non-clinical management of the practice.
- Use findings to develop risk prevention and safety strategies. Develop a system to measure the effectiveness of corrective actions implemented and revise as needed.
- Give staff feedback on findings of data analysis and results of their risk-reduction efforts.

Follow-up Reports and Legal Protection

NJ law does not protect adverse event or follow-up reports from discovery during legal proceedings, with limited exceptions.⁵ Nevertheless, fear of discovery of documents should not prevent the practice manager investigating events and recommending corrective action to improve patient care and overall safety. Moreover, not correcting a known hazardous condition can place staff and patients at risk. It can also make a subsequent claim against the practice more difficult to defend.

In the absence of statutory protection, practice managers or other designated individuals should consider the following actions:

- Consult with legal counsel on follow-up report design.
- Implement standardized investigation and documentation procedures.
- Educate all clinicians and staff on the importance of recording only objective, factual information.
- Discourage staff from making personal notes, or writing private recollections, opinions, or accusations that might later be used against the organization or provider in a lawsuit.
- Inform their legal counsel of staff members who have direct knowledge of an event.

Potential Benefits

In return for the time, effort, and costs expended in conducting a thorough event investigation, the physician practice may find there are benefits to be gained.

- **Predict and Protect:** Collecting information about the type and number of events in the practice will enhance the ability to predict future occurrences, and then enable the practice to take preventative actions that will better protect patients and visitors from similar risk. It can also help protect the practice from future claims and lawsuits, thus avoiding financial loss.
- **Correct and Improve:** The information allows the practice to make system improvements. It also demonstrates management's commitment to safety.
- **Defend:** Timely reporting allows the practice manager or other designated individual to do a thorough investigation. This in turn will allow a quick response to the event and provide valuable information that will support a defense in case of a future lawsuit.
- **Educate:** Knowledge of types, numbers, and severity of events will enable management to develop more effective, targeted educational programs. The staff's heightened awareness of events can also help to reduce or avoid recurrence.

In summary, effective event investigations can have a significant impact on both risk reduction and patient safety for the physician practice.

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⁵ Reports made in compliance with the NJ Patient Safety Act (N.J.S.A. 26:2H-12.23-12.25), enacted in April 2004, effective Oct. 2004, are protected from discovery. This law requires a health care facility to report to the Dept. of Health and Senior Services (DHSS) every "serious preventable adverse event" that occurs in the facility. The Act is applicable only to licensed health care facilities in NJ, including general, long term care and mental health hospitals, and their licensed ambulatory care and satellite facilities. Thus, most physician practices would not have to comply with, nor be protected by, this law.

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Discharging a Patient from Your Medical Practice

Introduction

Occasionally, you may encounter patients who you no longer wish to treat. Reasons for ending the physician-patient relationship may include chronic non-compliance, rudeness to office staff, or non-payment of bills. While these patient behaviors can affect the interactive care-giving process, they may also identify patients with a propensity to file a claim against you. To help reduce the risk of a future claim, a physician may terminate or discharge a patient from the practice.

There are, however, certain exceptions that apply to terminating a patient. You may not terminate your professional relationship for any discriminatory purpose or in violation of any laws or rules prohibiting discrimination such as the Americans with Disabilities Act. You also are not permitted to terminate a patient where you know, or reasonably should know, that no other healthcare provider is currently able to provide the patient the type of care or services that you are providing to the patient.

If the patient is a member of a managed care network, you should consider discussing your intentions to discharge the patient with the health plan administrators, as special conditions may apply. They also can provide a list of other member physicians in the region who are accepting new patients.

You also are required by the New Jersey Board of Medical Examiner regulations to provide a patient whom you have discharged with a copy of his or her medical records without charge.

Reduce the Risk of Abandonment

Abandonment occurs when a physician suddenly terminates a patient relationship without giving the patient sufficient time to locate another practitioner. A patient, however, may withdraw from a physician's care at any time without notifying the physician.

To reduce the risk of allegations of abandonment, it is recommended that, if possible, you discuss with the patient in person the difficulties in the physician-patient relationship and your intention to discharge the patient from the practice. Be sure to document the discussion fully in the patient's medical record, also noting the presence of any witnesses such as a patient's family member or a member of your office staff. **Caution:** Documentation in medical records should never include subjective or disparaging statements or judgments about a patient.

Write a Formal Discharge Letter

You are required by law to notify the patient in writing of the termination. The letter must state that you will no longer provide care to the patient as of a date certain. The date certain must be at least 30 days from the date of the letter. You must also state in the letter that you will be available to provide emergency care or services, including provision of necessary prescriptions, during the 30-day notice period.

The discharge letter should also include:

- A description of any urgent medical problems the patient may have, including, if appropriate, a time frame within which the patient should be seen by another physician, and the potential implications or consequences if treatment is not received.

- An offer to forward copies of the patient's medical records to the subsequent treating physician (You may also include a HIPPA compliant authorization for the patient's convenience.)
- The name and phone number of a local physician referral service or the local/state medical society to assist the patient in locating a physician who is accepting new patients.

The discharge letter should be marked "personal/confidential" and mailed by certified mail, return receipt requested, to the patient's last known address. File a copy of the letter and the receipt in the patient's medical record. If the letter is returned unclaimed, mail it again. If it is returned a second time, file it in the patient's medical record as proof of your attempts to contact the patient. It is also suggested that you mail a copy of the letter by regular, first-class mail, in case the certified letter is not claimed.

A sample discharge letter is included here for reference on page 4.

Inform Your Staff

Communicate with your staff when you have formally discharged a patient from your practice. Office staff should not schedule an appointment for a discharged patient after the termination date specified in the letter, as doing so may reestablish a physician-patient relationship.

If you are covering for another physician and must see a former patient that you discharged, be sure to inform the patient that you are seeing him/her as the covering physician for the new physician and are not resuming your former physician-patient relationship. Document this communication in your progress note in the patient's medical record.

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Sample Discharge Letter

Dear (Patient),

You will recall that we discussed our physician-patient relationship in my office on (date of last visit or discussion). Also present were your (wife, husband, etc.) and my (nurse, assistant, etc.)

As we discussed, I find it necessary to inform you that I will no longer be able to serve as your doctor as of (date at least 30 days from date of letter). The primary difficulty has been (indicate general reason, e.g., your failure to cooperate with the medical care plan, your behavior toward my staff, etc.).

I recommend that you promptly find another physician to provide for your medical needs (state needs if continual medical attention is necessary, e.g., diabetes, hypertension). You may want to contact (names and phone numbers of the state or local medical society, managed care referral service, etc.) to obtain names of other physicians who are accepting new patients. Any delay could jeopardize your health, so I urge you to act promptly.

I will remain available to provide medical services to you, on an emergency basis only, until (same date as specified above in second paragraph) while you have the opportunity to arrange for another physician to assume your care. A medical records release authorization form is enclosed for your convenience. Upon receipt of your signed authorization, I will forward a copy of your medical record. I will also be happy to discuss your case with the physician who assumes your care.

Very truly yours,

(Your name)

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Ceasing to or Leaving a Practice

Introduction

There are important risk management issues to consider when leaving a practice, whether for retirement, relocation, illness or other reasons. The decision to cease practicing or to leave a practice requires careful planning to provide continuity of patient care; avoid allegations of abandonment; provide patient and healthcare provider access to medical records; and maintain the integrity, security, and confidentiality of the medical records.

In order to assure compliance with all applicable contracts and federal and state laws, it is recommended that planning be performed in consultation with legal counsel experienced in healthcare law. It is also advisable to work with your insurance agent or broker to assure adequate continuity of professional liability insurance coverage after you leave your practice.

The following are several risk management guidelines to consider as you plan for ceasing or leaving a practice.

Know the Applicable Board of Medical Examiners Regulations

A physician who ceases to practice or anticipates that he or she will remain out of practice for more than three months is required by the New Jersey State Board of Medical Examiners regulations to:

- Establish a procedure for patients to obtain a copy of their treatment records or to have their records transferred to another healthcare professional who is assuming the practice responsibilities.
- Publish a notice of the cessation of the practice in a newspaper of general circulation in the practice's geographic location. The notice must include the process for obtaining a copy of the medical record. The notice must be published at least once each month for the first three months after the cessation.
- Make reasonable efforts to directly notify any patient treated during the six months immediately preceding the cessation.

Inform Your Patients

It is important to prevent potential allegations of abandonment by properly notifying patients of your intention to leave a practice. An organized plan for notifying patients of the decision to cease practicing, along with appropriate documentation of the actions taken to assure continuing care, will assist in defending any allegations of abandonment.

At least three months prior to your departure, mail a notification letter by certified mail, return receipt requested, and first class mail, to your patients. Patients who are acutely or chronically ill and in need of continual medical management should, if possible, be informed in person during an office visit, followed with the official notification letter. It may be prudent to recommend that the patient be seen as soon as possible by his or her new physician in order for you to communicate with the new provider and coordinate continuing care.

Documentation of your efforts to assure continuity of care is an integral component of practice closure. This includes discussions with the patient and other providers, as well as maintaining a copy of the notification letter and the return receipt in the medical record.

You may also want to consider additional means of informing your patients such as posting a sign in the office waiting room and giving a written notice to patients seen in the office.

Notification Letter Content

- Identify the reason for ceasing to practice (e.g. retiring, relocating).
- Include the official end or closing date.
- Emphasize the importance of continued care for appropriate management of known conditions and preventive care.
- If another provider is to assume the practice, include an introduction of the physician and how he or she may be contacted. The patient also should be notified that his or her medical record will remain with that physician.
- Provide a referral for continuity of patient care. If the practice is to be closed, the notification letter should provide resources for the patient to obtain a new physician such as the names of two to three appropriate physicians who are within the same area of practice and known to you, the name and contact information for the state medical society, or the patient's managed care physician referral service.
- Make clear that the choice of a physician to continue care is ultimately the patient's.
- Explain what patients need to do to obtain a copy of their medical records. You may also offer to have a copy sent to the physician selected to continue their care. Include an authorization for release of medical records with the notification letter.

Manage Medical Records

Planning for the cessation of your practice must also address mechanisms for patients to obtain a copy of their medical records and for record retrieval and record retention as required by law. The physical medical record is the property of the physician. However, the patient is the owner of the information contained within the medical record.

The patient has the right to obtain a copy of his or her medical record without charge when a physician ceases to practice, or when a physician moves to another practice and the patient chooses to follow the physician to the new practice. A signed and dated authorization form is required to release a copy of the record to another provider. The authorization should be placed in the patient's medical record.

Federal laws govern the protection of records of patients who have received services pertaining to HIV/AIDS, mental illness, alcohol and drug abuse education, training, treatment, rehabilitation, or research. Specific authorization is required before this information is released.

It is recommended that the departing physician and the physician who assumes the practice have a written agreement drafted by legal counsel experienced in health law and contracts that addresses pertinent issues, including medical records. The agreement likely would cover matters such as who is responsible for maintaining the original medical records; the process for retrieval of records; maintaining the security, integrity and confidentiality of the records; and records destruction.

Medical records of adult patients should be retained for a minimum of seven (7) years from the latest date of contact with the practice. If the patient is a minor, retain the records for the longer of seven (7) years from the latest date of contact with the practice, or until the patient reaches the age of twenty-three (23). The Medicare and Medicaid programs also require that you retain records in their original or legally reproduced form for at least five (5) years to comply with their Conditions of Participation. Managed care companies that you contract with may also have other requirements for record retention.

In order to comply with requirements for record retention after you cease practice, consider utilizing the services of a commercial storage firm. A HIPAA business associate agreement incorporating specific provisions to protect the security, integrity and confidentiality of the records would be required. The agreement should also include prohibitions against selling, sharing, discussing, transferring, or otherwise disclosing confidential information with any other individuals or businesses, and provisions requiring protection of the records from loss, theft, unauthorized destruction or other unauthorized access.

At some point in time, a physician may determine that there is no requirement or value in retaining certain medical records. In order to defend against possible allegations of spoliation of evidence in the event of a legal claim, have a written protocol and practice that address the destruction of medical records. You should be able to demonstrate that a particular record was destroyed in accordance with routine practice and applicable regulations, as opposed to a wrongful intent.

Destruction of medical records must ensure confidentiality of the patients' protected health information. The records should be burned or shredded so as to be rendered unreadable. It is also recommended that you maintain a log of the patients whose

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medical records have been destroyed. Information to be kept includes the patient's name and date of birth, and the date that the records were destroyed.

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When Patients Don't Return for Follow-up Care

Introduction

Communication breakdowns are a major contributing factor in patient safety and malpractice claims. A patient who misses appointments and suffers an injury as a result may have cause for a lawsuit if he or she has evidence that the physician did not provide clear information or make reasonable efforts to make sure the patient understood and complied with advice, including follow-up appointments. While follow-up can be time-consuming, it is well worth the effort to prevent medical errors, unanticipated outcomes and potential liability.

Handling Missed Appointments

To help prevent missed appointments, practices have developed a telephone confirmation call to remind patients of their appointments and, when indicated, of the importance of the visit – especially for patients in active treatment. To cut down on the volume of missed appointments, some studies suggest that the confirmation call should be placed at least two days ahead of the scheduled appointment.

Standard of care, laws and ethics require that a physician-patient relationship be based on educated, informed/shared decision making. During office visits, patients should be educated on their disease process, care plan expectation, any perceived issues the patient has regarding non-adherence to plan of care, and consequences of not continuing with follow-up testing or treatment. Alternative plans, if appropriate, may be explored, agreed upon, and documented in the medical record. The discussion may be supplemented by educational material to be reviewed with the patient at the time of visits. The medical record documentation should reflect what information was shared with the patient, questions asked by the patient and responses given, and that the patient understood the proposed plan, benefits and the consequences of non-compliance.

Physician practices may consider utilizing a patient agreement or contract which is discussed with and signed by the patient. During subsequent visits an informed refusal form should be signed if the patient will not comply with the plan. A generic practice policy statement including patient responsibilities regarding compliance, follow-up and missed appointments may also be implemented. A signed copy of the policy statement, such as is done with HIPAA privacy statements, may be maintained in the patient's record.

If a patient misses a scheduled appointment, every effort should be made to find out why as soon as possible. When there is an urgent clinical reason, the physician should initiate a phone call to encourage patient follow-up. In those instances where the physician initiates communication, an explanation recommending the patient's treatment course, its benefits, and risks of not adhering to the proposed treatment should be clearly communicated and documented. Office practices should keep clear, consistent records of missed appointments and follow up.

In non-urgent situations, the physician should instruct staff, and there should be a notation in the medical record, to call the patient to find out the reason for the missed appointment and to reschedule, being sure to give the time frame. (e.g. "call patient to reschedule, must be seen within one week"). Staff should document their attempts at contacting the patient, what was said to the patient and the patient's response.

While there is no standard number of attempts that should be made, many practices attempt contact three times. A missed appointment letter should also be sent. If patients repeatedly (e.g. three missed appointments) do not return to the office, a letter urging patients to follow-up should be sent. The "non-adherence" letter gives such patients one last chance to schedule an appointment before assuming that the patient has terminated the relationship. If patients still do not return to the office a formal

discharge from the practice may be in order. Evidence of patient receipt via certified mail of the correspondence should be retained in the patient's record.

The missed appointment, non-adherence and discharge letters should state the patient's disease and consequences of not continuing medical/surgical care. If the patient has a condition that requires specific care, the letter should state the care and the consequences of not receiving the care. If the patient has a condition that needs regular follow-up, state the frequency and urgency of the follow-up, and state the consequences of not obtaining the follow-up at the recommended time. All letters should be in clear, reader-friendly language at a fourth grade reading level in order to be understandable and in compliance with limited-English proficiency guidelines.

A tracking process, either through a paper log book or electronic medical record system, provides a comprehensive, consistent process for monitoring of patients. This can be incorporated into the existing tracking method for routine screenings, consultations and diagnostic tests. A tracking log enables the practice to document that either follow-up was completed, informed refusal has been signed or that "reasonable" attempts to contact the patient have been exercised.

The practice may also track missed/cancelled appointments for specific diagnosis or conditions which the physician determines crucial for patient follow-up. Such circumstances in a surgical office practice may include routine post-operative surgery follow-up. In other practice settings these would include routine screenings for breast, prostate, and cervical cancer screenings, pediatric immunizations, or diabetes and hypertension monitoring.

Summary

Inadequate physician-patient communication is a primary contributory factor in patient safety and professional liability. Follow-up is a crucial and challenging aspect of the care continuum.

Informed/shared decision making, communication and documentation are essential elements of a comprehensive, consistent process. The informed/shared decision-making process between physician and patients is important to ensure the patient understands their disease, plan of care and responsibilities. Communication with the patient before and during scheduled appointments, as well as after missed appointments is key to preventing medical errors, unanticipated outcomes and potential liability.

The Princeton Insurance Physician Office Practice Tool Kit, which is available to Princeton Insurance insureds, contains several guidelines and sample forms, including *Office Visit Follow-up Instructions*, *Follow-up Systems & Appointment Log*, *Informed Refusal* and *Discharging a Patient from Your Practice* guidelines & letter.

The following sample letters are included for reference:

- Sample Missed Appointment Letter
- Sample Letter to Non-Compliant Patient

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SAMPLE LETTER TO NONCOMPLIANT PATIENT

(Date)

(Patient Name)

(Patient Address)

Dear *(Patient Name)*,

You have *(canceled or did not show)* for your follow-up appointment on *(indicate date)* without rescheduling. We have tried multiple times to reschedule your missed appointment. To date, you have not responded to our efforts. Since we have not heard from you, we can only conclude that you have terminated your care with our practice.

Continued care is essential to your health, and failure to adhere to the agreed upon plan of care may have significant consequences. *(If the patient has a condition that requires specific care, state the care as well as the consequences of not following up in clear layman's terms. If the patient has a condition that needs periodic follow-up, state the frequency and urgency of the follow-up, and state the consequences of not getting the follow-up at the recommended time interval in clear, patient-friendly language.)*

I find it necessary to inform you that if we do not hear from you by *(date at least 30 days from date of letter)* I will no longer be able to serve as your physician. I recommend that you promptly find another physician to provide for your medical needs *(state needs if continual medical attention is necessary, e.g., HgbA1C for diabetes management)*. You may want to contact *(names and phone numbers of the state or local medical society, managed care referral service, etc.)* to obtain names of other physicians who are accepting new patients. Delays could jeopardize your health, so I urge you to act promptly.

I will remain available to provide medical services to you, on an emergency basis only, until *(same date as specified in paragraph 3 above)* while you have the opportunity to arrange for another physician to assume your care. A medical records release authorization form is enclosed for your convenience. Upon receipt of your signed authorization, I will forward a copy of your medical record. I will also be happy to discuss your medical condition(s) with the physician who assumes your care.

Very truly yours,

(Typed Physician Name)

cc: File

SAMPLE MISSED APPOINTMENT LETTER

(Date)

(Patient Name)

(Patient Address)

Dear *(Patient Name)*,

You have *(cancelled or did not show)* for your follow-up appointment on *(indicate date)* without rescheduling. We were unable to reach you by telephone.

Continued care is essential to your health, and failure to adhere to the agreed upon plan of care may have significant consequences. It is important to your health that you schedule an appointment within the next *(indicate number of days/weeks/months)*. You will recall we discussed your need for a follow-up appointment in my office on *(indicate date of last visit or discussion)*. *(If the patient has a condition that requires specific care, state the care as well as the consequences of not following up in clear layman's terms. If the patient has a condition that needs periodic follow-up, state the frequency and urgency of the follow-up, and state the consequences of not getting the follow-up at the recommended time interval in clear, patient-friendly language.)*

Delays could jeopardize your health, so I urge you to act promptly and contact our office as soon as possible to reschedule.

Very truly yours,

(Typed Physician Name)

cc: File

Ask the Expert

In each publication of Risk Review, an outside guest or a member of our team of expert risk management and loss prevention consultants will answer a question from a reader. If you are concerned about a risk management or safety issue at your practice or facility, let us know and we may answer it in a future issue.

Treatment of Minors

By Karen J. M. Savage, Esq. & Carolyn R. Sleeper, Esq.
Attorneys specializing in medical malpractice



The treatment of unaccompanied minors presenting to a physician for treatment, whether in the context of an Emergency Department, health care facility or office, has far reaching implications. The concept of informed consent or informed choice is much broader than the paper signed by a patient. The doctrine encompasses medical treatment and the physician must disclose to a patient probable risks, benefits and all medically reasonable course of treatment.

The provision of emergency care for minors without the consent of a parent or guardian, under EMTALA, the Emergency Medical Treatment and Active Labor Act, requires a medical screening for anyone who presents to an Emergency Department, including unaccompanied minors, to determine whether an emergency medical condition exists. (*Pediatrics* Vol. 111 No. 3 March 2003, pp 703-706). EMTALA, as a federal law, preempts conflicting or state laws, thus, provision of emergency treatment for minors without a consenting parent or guardian is essentially rendered moot. If an emergency condition exists, EMTALA requires stabilization and if necessary, transfer to an appropriate facility. If an emergency medical condition is not identified, then the EMTALA regulations no longer apply and consent of the minor's parent or guardian should be sought. (*Id.*)

Of course, the determination of what constitutes an "emergency medical condition" can be cause for debate. This is a challenge that is currently under review by the New Jersey Supreme Court in a case involving the insertion of a chest tube in an emergency department for pneumothorax. *Legouri v. Elmann, et al*, 188 NJ 485 (2006). The minor patient was



unconscious and the physician proceeded without obtaining consent of family members. The plaintiff's attorney argued that although prompt treatment was necessary, it was not so emergent as to preclude communication with the family. As one family member was a physician, it was also argued that they would have selected a physician with more experience to insert the chest tube. The New Jersey Supreme Court will be rendering a decision as to whether every medical issue obviates the need for informed consent. *Id.*

But what about the murky realm of a minor who presents for treatment and may not necessarily require emergent care, however does require treatment. After all, a minor is considered to be incompetent in the realm of informed consent and legal decisions. In situations involving adolescents and teenagers, there is often a conflict between the principles underlying the informed consent doctrine and the principles underlying the patient's right to confidentiality. Although common law and statutory law has supported physicians in providing emergency care for minors in the emergency department, there are areas worthy of further discussion.

A minor female has come seeking an abortion. Do I have a duty to inform her parents or guardian?

Vice President of Healthcare Risk Services
Tom Snyder x852

Manager, Healthcare Risk Services
Phyllis DeCola x897

Manager, Risk Services
Francis Roth x868

Phone: 609.452.9404
www.RiskReviewOnline.com



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No. A minor female's fundamental rights are not extinguished by virtue of not having attained the age of majority. New Jersey addressed this issue in the New Jersey Supreme Court case of Planned Parenthood of Central New Jersey, et al v. Farmer, 165 N.J. 609 (2000), following the Parental Notification for Abortion Act (N.J.S.A 9:17A-1.1 et. seq.) The Act required a physician to wait at least 48 hours after written notice about a pending abortion to the unemancipated minor's parents. The Court held the Act unconstitutional and found that it burdened the fundamental right of a woman to control her body and destiny. Additionally, the State did not provide adequate justification distinguishing between minors seeking abortions and those seeking pregnancy related care, thus, the Act violated the minor's right to equal protection set forth in the New Jersey Constitution.

A minor female has come seeking pregnancy related care. Do I have a duty to inform her parents or guardian?

No. The minor female maintains the same rights related to confidentiality as any person who has achieved the age of majority. N.J.A.C. 13:35-6.5 provides that the minor is deemed his/her own authorized representative when the condition being treated relates to pregnancy, sexually transmitted disease or substance abuse.

Can a minor consent to the prevention of pregnancy?

Yes. Although there is no specific New Jersey statute that specifically authorizes a minor to consent to contraceptive care, a minor maintains the same rights as an adult. Under Title X of the of Public Service Act, those providers who receive Title X funds must provide contraceptive care without requiring consent or notification of the minor's parent or guardian. Title X is a federally based program solely dedicated to family planning and reproductive health. Services are delivered through hospitals, clinics, health care centers, and state and local health departments. Congress enacted Title X for the purpose of providing comprehensive family planning services to all, including minors. 42 U.S.C.A 300, note 4.

A minor, seeking treatment, appears to have been sexually assaulted. Do I have a duty to notify her parents or guardian?

Yes and No. New Jersey statute, specifically N.J.S.A. 9:17A-4, provides that in the case of a minor who appears to have been sexually assaulted, and who is at least thirteen (13) years of age may consent for treatment, however it also states that parents or guardian of the minor must be notified immediately *unless the attending physician believes it is in the best interests of the patient not to do so*. Failure to locate the parent or guardian however, does not preclude rendering necessary emergency treatment.

Do I have a duty to report the incident of sexual assault to the police?

No. A victim of sexual assault should be provided with a rape counselor who will ensure that all communications between the victim and the rape counselor are confidential. N.J.S.A 2A:84A-22.15 provides for such confidential communications. Pursuant to N.J.S.A. 52:4b-22, hospitals must afford the victim an opportunity to contact a rape care advocate prior to investigative, medical and forensic procedures occurring. Additionally,

the victim may have the advocate present during the evaluation. The advocate will ensure that the victim is fully cognizant of her options to report the sexual assault to the authorities.

Do I have a duty to report the incident to the Division for Youth and Family Services (DYFS)?

Maybe. If you have reasonable cause to believe the minor was sexually assaulted by a caretaker, co-inhabitant, or someone in a supervisory role, then you must contact the Division for Youth and Family Services.

A minor presents for treatment for a venereal disease. Do I have an obligation to inform the minor's parents or guardian?

No. By New Jersey statute, minors, who are at least thirteen (13) years of age and believe that s/he may be afflicted with a venereal disease, may consent to treatment. Specifically, N.J.S.A 9:17A-4 asserts that any consent rendered by the minor is considered binding and would not be subject to disaffirmance by reason of minority.

A minor presents under the influence of drugs and/or alcohol. Do I have a duty to inform his/her parents or guardian?

No. Consent for treatment for drug use, drug abuse, alcohol use or alcohol abuse by a minor is as binding as if a person who had reached the age of majority and requires the consent of no other person, including parents or guardians. Treatment consented to, by the minor, is confidential information between the physician, treatment facility or provider and the minor. N.J.S.A 9:17a-4

What if a minor who has overdosed is brought to the Emergency Department, requires stabilization and treatment? Do the same rights apply?

Yes. You do not require the consent of a parent or guardian, as long as the medical or surgical treatment provided is for the minor's drug use, drug abuse, alcohol use or alcohol abuse. Specifically, N.J.S.A. 9:17A-4 provides that when a minor believes that s/he is suffering from the use of drugs and/or alcohol or is dependent on drugs and/or alcohol, s/he may consent to confidential treatment, as long as the treatment provider is a licensed physician, licensed or certified alcohol treatment specialist or licensed treatment facility, just as if s/he had attained the age of majority.

A minor has mental health issues and requires treatment. Is there a duty to inform his/her parents or guardian?

Yes. Typically, minors in New Jersey have the right to consent, on their own, to treatment involving contraception, pregnancy, abortion, sexually transmitted diseases and substance abuse. Mental health issues falls outside those defined parameters and requires parental notification.

The minor is insured through a parent's or guardian's private health coverage. Can I still ensure confidential treatment?

No. Minors must be aware that if they are covered under their parents' health insurance and s/he intends to utilize it for payment for services rendered, a statement of benefits may be sent, as a matter of course, by

the insurance company to the policy holder. Additionally, some insurers may not authorize payment for treatment rendered to an unaccompanied minor.

The minor child is obtaining treatment for pregnancy, contraception or abortion care using Medicaid. Is confidentiality ensured through this insurance?

Yes. Federal laws protect the minor receiving family planning treatment and care for services obtained under Medicaid. Those health facilities that receive federal funding under Title X of the Public Health Services Act must provide confidential family planning services to minors.

I have reason to believe that the minor is being physically or sexually abused. What are my obligations to report?

You must immediately report. Under N.J.S.A. 9:6-8.10, an “abused child” is defined as any minor under the age of eighteen (18) whose parent, guardian or someone in control subjects the minor to harmful acts or omissions of care. This may include, but is not limited to, the failure to provide the basic necessities of adequate food, clothing, shelter, excessive corporal punishment, excessive physical restraint or willful abandonment. New Jersey statute requires any person who has reasonable cause to believe that a child is being abused to immediately contact the Division for Youth and Family Services.

A child who is accompanied by a parent or guardian requests confidential treatment. What are my obligations to inform the parent?

This is a murkier situation to maneuver. Although you may follow the guidelines above, the physician should be assessing the minors age, maturity and level of understanding. Ambiguities in the rights of minors to obtain confidential medical treatment may be resolved by getting a parent or guardian to assent to an agreement of confidentiality. *ACLU: Guide to Minors’ Right to Confidential Reproductive Healthcare*, January 2006, citing 42 U.S.C. 300(A)L 42 C.F.R. 59.5(a)(1); 42 U.S.C. 1396D(a)(4)(C). In those instances, a federal privacy regulation specifically protects a minor’s right to confidentiality when a parent or guardian signs a waiver of assent. (Id.)

Treating minors can be a confusing endeavor, particularly when rendering care for services where they may have the authority to consent to treatment. At times, state law may be preempted by federal law, or be trumped by the minor’s Constitutional rights. At this juncture, minors have the right to render consent for treatment in a number of situations including those services involving contraceptive counseling and services; abortion; pregnancy related medical care; testing and treatment for sexually transmitted diseases; and treatment for sexual assault. However, it is important to assess the minor’s judgment, maturity and implications of the treatment sought and the ultimate goal of providing timely and appropriate care. ❖

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Reducing Risk

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Informed Consent

Introduction

Informed consent is an important communication process between a physician and patient that helps to create trust and foster joint decision making. The informed consent process can support and enhance the physician-patient relationship. Properly done and documented, the informed consent process also may better align the patient's and physician's expectations of the treatment outcomes, increase patient confidence, and help to prevent a malpractice claim.

Medical ethics and legal mandates require that a physician must obtain a patient's informed consent before treating or operating on the patient. The purpose of this requirement is to protect the patient's right to self-determination in medical treatment matters.

Informed consent is not merely a signature on a consent form. The physician must personally advise the patient, in a manner the patient understands, of all material medical information and risks of treatment. Providing this information enables the patient to make an intelligent and informed decision about whether to undergo a proposed treatment or procedure.

Failure to provide patients with sufficient information for informed consent places a physician at risk for a legal claim for injury from a complication or unanticipated outcome of the procedure—even if it was not the result of negligence.

The Physician's Duty

A physician has a non-delegable duty to obtain the patient's informed consent before he or she may treat or operate on a patient. The physician must communicate—in a manner understandable to the patient—the treatment options and their benefits and risks.

A doctor has a duty to communicate to the patient the treatment alternatives that he or she recommends, as well as all medically reasonable alternatives, including non-treatment, which the doctor does not recommend. The physician also must discuss the probable benefits, risks, and outcomes of each alternative. A physician may not impose his or her treatment preferences on a patient, or disregard a patient's expressed choice.

An informed consent requires that the patient be informed of material medical information and the risks of the proposed treatment. Material medical information is that which a "reasonably prudent patient" in the patient's situation, as known or that should be known by the physician—taking into account factors such as the patient's age, sex, occupation, diagnosis, and medical history—would be likely to attach significance to in making a treatment choice.

The patient does not have to be told of every conceivable risk. Material risks include any risk where the possible harm is great, even if the probability of occurrence is small. Material risks also include those risks where the potential harm is minimal but the possibility of occurrence is high.

In the situation where the proposed procedure or treatment is purely elective, such as cosmetic surgery, the prudent physician will provide a more exhaustive disclosure concerning the risks and other significant relevant information such as possible unpleasant side effects, what to expect during the recovery period, and associated lifestyle changes.

Information Essential for an Informed Consent

Taking into account what the physician knows or should know is the patient's need for information, the information generally required to be discussed with a patient in order to obtain an informed consent includes:

- A description of the patient's condition, including diagnosis or suspected diagnosis

- The nature and purpose of the proposed treatment or procedure and the anticipated benefits
- The material risks, complications, or side effects of the proposed treatment or surgery, including death or serious injury, if applicable
- Medically reasonable available options or alternatives, including non-treatment, and the probable benefits and risks of each alternative
- The material risks of not having the proposed treatment or procedure

Use non-technical language to communicate the above essential information to your patients. Involve the patient's family members to the extent possible. Encourage questions. It is also recommended that you ask the patient confirmatory questions or to restate in his or her words the information that you provided in order to assess their understanding and to identify any areas requiring clarification or more information. Never guarantee a result or tell a patient that a proposed procedure is routine or simple.

Exceptions

Exceptions to the obligation to obtain an informed consent include the following:

- **Emergency**—the patient presents with a life-threatening injury or illness requiring immediate attention and is unable to communicate and there is no time to obtain consent from another appropriate person. Only care that is medically necessary to remedy the emergency situation is permitted.
- **Waiver by Patient**—the patient may expressly waive the right to be informed of the risks and alternatives to treatment. A patient's waiver of informed consent is treatment-specific; informed consent must be obtained for other proposed treatments or procedures.
- **Therapeutic Privilege**—disclosure of all known risks of treatment believed to cause the patient the risk of significant harm (typically psychological). The patient should be evaluated by a provider not otherwise involved in his/her care before invoking this exception. Permission from the patient to discuss the information with his or her family should be sought.

The facts surrounding the application of any of these exceptions must be carefully evaluated and documented by the physician in the patient's medical record.

Legal and Mental Capacity to Consent

Informed consent is based upon the premise that a patient has the legal right to make his or her own decisions on medical treatment. The law presumes that an adult is competent to make a treatment choice, i.e., has the mental capacity to consent to or refuse treatment. However, minors generally do not have the legal right to consent. An adult may in some circumstances also lack the mental capability to consent. In such instances the law provides:

Minors

- A. A minor under the age of 18 generally may not give consent.
- B. Exceptions:
 1. Emancipated or married minors may consent.
 2. A minor who is pregnant may consent to treatment related to the pregnancy.
 3. A minor who is a parent may consent to treatment for his or her child.
 4. Minors may consent to treatment for drug or alcohol use/dependency, sexual assault, and venereal disease.

Adults

- A. Unless otherwise determined, an adult individual is deemed competent to consent.
 1. Circumstances such as being under the influence of alcohol or drugs, medications, etc. may constitute grounds to determine that a patient is temporarily incompetent to consent.
 2. An individual with a condition that may eventually render him or her incompetent to consent, such as dementia, may still be competent to consent at a given point in time. Evaluation of the patient's ability to understand, ask questions, etc. is required.
- B. A legal guardian or court-appointed representative may consent to treatment for an incompetent adult.

Documentation of Informed Consent

The informed consent process must be fully documented in the patient's medical record. Record the date(s) and time(s) and pertinent content of your informed consent discussions with the patient. Also document any other activities that were part of the process to inform the patient, such as providing the patient with informational pamphlets or audio-visual materials. Your documentation must be detailed enough to reflect that the patient was provided with the information required to give an informed consent, demonstrated understanding of the information, and gave or refused consent to treatment.

Use of a "boiler plate" consent form routinely used by physicians and healthcare facilities does not relieve a physician of the obligation to discuss the material risks, benefits, and alternatives with the patient. The patient's signature on a "boiler plate" consent form stating that the patient is giving informed consent, unaccompanied by supporting documentation of the consent process, may not protect a provider against a claim alleging failure to obtain a proper informed consent.

Any consent form that you use should be written in lay language at a fifth grade reading level, and medical terms used in it should be explained. The form must be dated, timed, and signed by the physician and the patient or the patient's authorized representative. Any adult member of your office staff may witness the patient's signature on the consent form.

If you use a procedure-specific consent form to assist you with informing your patients, file the original signed and dated form in the patient's medical record. Give the patient a copy to have for review and discussion at home with family members. Note in the patient's record that the patient was given a copy of the signed form.

If an interpreter was used for the informed consent discussion(s), document in the patient's medical record the interpreted language, the name and relationship, if any, of the interpreter, and the date and time of the discussions. Also keep a copy of any translated documents that were used in the process.

Documentation of Informed Refusal

In the same way that there must be documentation of informed consent, there must be documentation of a patient's informed refusal of care or treatment. A signed, preprinted refusal form is only written documentation that the patient refused care or treatment, not that the refusal was made with knowledge of the potential consequences of refusing care.

Carefully document in the patient's medical record the information about the proposed treatment or procedure that was communicated to the patient for an informed consent, including the material risks of not having the proposed treatment or procedure, and that the patient expressed his/her understanding of the probable consequences of refusal.

Your office practices manual should contain policies and procedures explaining the informed consent and informed refusal processes utilized in your office.

The Nurse or Allied Healthcare Professional's Role

A nurse, dental or medical assistant, or other allied healthcare professional may witness the informed consent process between a patient and physician, and may witness the patient's signature on a consent form. They may not be delegated the responsibility of obtaining an informed consent on behalf of a physician.

However, in much the same way that the physician must discuss with the patient medical information concerning the treatment or procedure, a nurse also has an independent duty to inform the patient of nursing care and services rendered.

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Incorporating Shared and Informed Decision Techniques into Your Patient Interactions

By Sharon Koob, RN, BSBA, CPHRM, ARM
Princeton Insurance Healthcare Risk Consultant

In routine office medicine most physicians do not encounter a frequent need for the informed consent process unless their practice is heavily focused on procedures, such as the practice of a surgeon or a gastroenterologist. Yet almost all physicians and their patients frequently engage in dialogues which require the patient to make decisions regarding their care. These decisions may involve acquiescence to a relatively straightforward treatment regimen (think tetanus shot for a puncture wound) or they may entail a complex decision set surrounding a medication which offers potential serious side effects as well as its benefits (think Procrit, for example).

To address appropriate decision-making on the part of the patient, communication studies have searched for an effective approach which will reach the patient, while not requiring too much time or other resources on the part of the clinician. Shared decisions and informed decision-making are two techniques which have been found to be most effective. Finding a way to use these techniques to their best effect can improve the quality of your relationship with your patients and the quality of the care you give while simultaneously reducing your liability. Finding a way to use them without greatly stretching time and ability is the challenge which has turned some physicians away from a concerted approach to these processes. This article will review these processes in an attempt to help you effectively move your practice in this direction without instituting radical changes.

Much of the publicized research on shared or informed decision-making focuses on very serious decisions such as determining what type of cancer treatment to choose.



Your practice, however, may seem more mundane. It is appropriate to review the difference between shared decisions and informed decisions so that they can be put in the context of the interactions you have with your patients.

Shared decision-making is defined by the U. S. Preventive Services Task Force (USPSTF) as a process involving the clinician and the patient "in which the patient:

- Understands the risk or seriousness of the disease or condition to be prevented
- Understands the preventive service, including the risks, benefits, alternatives, and uncertainties
- Has weighted his or her values regarding the potential benefits and harms associated with the service
- Has engaged in decision making at a level at which he or she desires and feels comfortable

This process has the goal of an informed and joint decision."

The task force also describes informed decision-making as the "individual's overall process of gathering relevant health information from both his or her clinician and from other clinical and non clinical sources, with or without independent clarification of values."¹

As you review these descriptions you may see that you already have informed decision and shared decision conversations with patients during at least some of their visits; these conversations may not be conducted in detail every time they transpire but they do happen. You undoubtedly run into some barriers too. Certainly, there are some patients who show less inclination to be informed; and you encounter different levels of patient

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Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404
www.RiskReviewOnline.com

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comprehension of the material you share with them. It is likely that you encounter time constraints which require you to shorten these conversations more than you may wish; and you may find it difficult to explain some of the intricacies of available choices to your patients in a manner which they would understand. Yet clear communication with your patients is of value to them and to you.

This type of interaction with your patients is beneficial in at least four areas. It is an ethical practice in that it treats the patient as an autonomous decision maker; it is educational in that it improves the patient's knowledge of their condition, their options, and helps create a more realistic situation in which they can make their decisions with, hopefully, less mental and emotional conflict; it is utilitarian in that it recognizes that the best choice in any situation has to involve the patient's personal preferences; and it can improve the interpersonal relationship between practitioner and patient, promoting patient trust and possibly enhancing their confidence.²

Informed or shared decisions cannot be abandoned in favor of the informed consent process as it is practiced by many clinicians. Informed consent is a legal doctrine which requires that clinicians disclose required medical information and patients consent to or decline of the treatment; this consent or refusal is formalized with the patient's (or patient representative's) signature. The key factor in the informed consent process is the information dialogue, not the signature. Many clinicians have viewed the informed consent process as a quick conversation followed by a signature obtained on an appropriately worded form. This cursory approach to the informed consent process assures routine filings of informed consent claims in court.

Shared and informed decisions are intended to bring the patient into the process at whatever level they are comfortable (and able); changing these decisions to an informed consent only adds a level of paperwork to the process. Informed consent should remain necessary for procedures and other specific treatments, as determined by your practice and/or the facilities you are allied with. Appropriate informed consent must include shared decision-making dialogues, to the best of the patient or patient representative's ability. That is what makes them truly "informed".

Then how can you best incorporate these decision processes into your clinician/patient dialogue? It may first be appropriate to categorize the types of decisions that you ask your patients to make.

- Basic decisions such as recommending a laboratory test may only require a brief description of the test, the decision to be made (whether to have it, where to have it, etc.) and a request for the patient's preference.
- Intermediate decisions such as recommending a new medication would require a little more dialogue about the medication (what it is for, how it acts, its side effects, etc.) and its alternatives (other medications, available alternative therapies, and the possible outcome of not taking the medication at all); once again, you would elicit the patient's feedback in the form of questions or a decision.
- Complex decisions such as procedures, of course, require the most detailed interactive discussion and often become part of the informed consent process; that is, the discussion may end with a signed consent or refusal form.³

Understanding these three levels of decisions can help each clinician evaluate the nature of patient decisions made routinely in their office and the frequency with which each level of decision is made. An approach can be tailored to address the practice's needs to upgrade and/or change current practices. For example, practices which are very busy and have a great deal of basic level decision-making requirements may consider involving supporting clinical staff in patient education and discussions.⁴

Clinicians who are required to do more intermediate and complex decision discussions with their patients may find that decision aids are helpful in some situations. These aids can be pamphlets, videotapes, web-based tools, and other unbiased material which can augment the information that the clinician has provided. In 1999 O'Conner, et al. published their research which showed that these tools could be effective in helping patients make decisions on their treatment when they were faced with a multitude of choices in a very difficult situation.⁵

Clinicians may also find themselves faced with patients who have more than one intermediate or complex decision to make. In these situations it is appropriate for the physician and patient to agree upon the highest priority discussion topic and focus their initial conversation on that. Further topics can be spread over other visits, as agreed upon by both physician and patient.⁶

Clinicians who are involved in frequent intermediate and complex discussions with patients also may benefit from a systematic approach to these dialogues. The USPSTF suggests one possible approach "as:

◆ ASSESS

the patient's health needs (acute issues/eligibility for preventive services)
the patient's desired role in decision making

◆ ADVISE

- Inform the patient about recommended preventive service
- If time permits, inform the patient about other services with:
 - ◆ High visibility
 - ◆ Special individual importance
- If needed, provide balanced, evidence-based information about the service:
 - ◆ Benefits
 - ◆ Harms
 - ◆ Alternatives
 - ◆ Scientific uncertainties
- If appropriate make a recommendation

◆ AGREE

- Elicit patient's values and determine preferences
- Negotiate a course of action

◆ ASSIST

- Deliver or prescribe service

✦ ARRANGE

- Follow-up or plan to revisit in the future⁷

This list breaks the dialogue down into its basic elements and incorporates most discussion points. The clinician will, of course, modify it as necessary to meet the needs of the situation; it specifies areas where the most frequent of changes are made. As in almost all situations, having a systematic approach to these conversations can help a clinician focus their approach and make sure that no elements are left out of the dialogue.

As in all other efforts to improve care and reduce liability, improving communication in this manner should include documentation of these conversations, especially those of intermediate and complex nature. It is also imperative that patient concerns be documented so that the record reflects key elements addressed in these interactions.

As each clinician reviews their practice for areas of risk and quality improvement, shared and informed decision-making processes should be enhanced or added to the daily routine of care. Ultimately these practices will improve communication and, therefore, your relationship with your patients; because you have improved these communications you have an opportunity to give better quality care; and ultimately you can reduce your liability because you have improved the quality of your care, improved your relationships with your patients, and improved the documentation of your interactions with them.

Changing communication patterns is not always easy. This article has given some basic steps and the reasons to implement them. If you, the clinician, find that you would like to know more about enhancing actual dialogues you may have with your patients, Princeton Insurance Company offers a Communication course to interested physicians and other practitioners. The course is available for varying lengths of time and of fers CMEs or CEUs. Please contact Barbara Butler at 609-452-9404, x 5213. ❖

Resources

¹ Sheridan, Stacey L., MD, MPH, Russell T. Harris, MD, MPH, Steven H. Woolf, MD, MPH, for the Shared Decision-Making Workgroup of the U.S. Preventive Services Task Force, *Shared Decision Making About Screening and Chemoprevention: A Suggested Approach from the U.S. Preventive Services Task Force*, American Journal of Preventive Medicine, 2004

² Sheridan, Stacey L., MD, MPH, Russell T. Harris, MD, MPH, Steven H. Woolf, MD, MPH, for the Shared Decision-Making Workgroup of the U.S. Preventive Services Task Force, *Shared Decision Making About Screening and Chemoprevention: A Suggested Approach from the U.S. Preventive Services Task Force*, American Journal of Preventive Medicine, 2004

³ Braddock, C. H., Edwards, K.A., Hasenberg, N.M., Laidley, T.L, & Levinson, W. (1999). *Informed Decision Making in Outpatient Practice*, Journal of the American Medical Association. 282:2313-2320.

⁴ Sheridan, Stacey L., MD, MPH, Russell T. Harris, MD, MPH, Steven H. Woolf, MD, MPH, for the Shared Decision-Making Workgroup of the U.S. Preventive Services Task Force, *Shared Decision Making About Screening and Chemoprevention: A Suggested Approach from the U.S. Preventive Services Task Force*, American Journal of Preventive Medicine, 2004

⁵ O'Connor, A.M., Fiset, V., deGrasse, C., Graham, I.D., Evenas, W., Stacey, D., Laupacis, A., & Tugwell, P. (1999). Decision Aids for Patients,

Considering Options Affecting Cancer Outcomes: Evidence of Efficacy and Policy Implications. *Journal of the National Cancer Institute. Monographs*, (25) (25) 67-80.

⁶ Sheridan, Stacey L., MD, MPH, Russell T. Harris, MD, MPH, Steven H. Woolf, MD, MPH, for the Shared Decision-Making Workgroup of the U.S. Preventive Services Task Force, *Shared Decision Making About Screening and Chemoprevention: A Suggested Approach from the U.S. Preventive Services Task Force*, American Journal of Preventive Medicine, 2004

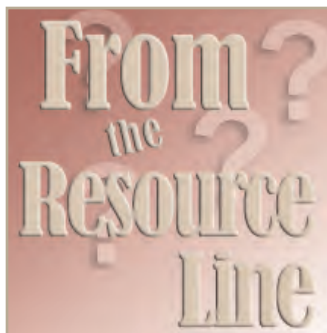
⁷ *ibid* ❖

Your Direct Link to Better Risk Management Practices

From The Resource Line

In each publication of Risk Review, an outside guest or a member of our team of expert risk management and loss prevention consultants will answer a question from our Risk Resource Line. If you are concerned about a risk management or safety issue at your practice or facility, let us know and we may answer it in a future issue. Our number is 1.866.Rx4.RISK.

By Donna Knight, CPHRM, CPHQ
Princeton Insurance Healthcare Risk
Consultant



Question: My patient asked if she could tape record her office visit. How do I handle this situation?

Answer: How you respond in this type of situation is dependent upon patient needs, your existing relationship, your comfort level with being recorded, and any other relevant circumstances. Once you have examined the factors in a given scenario, the next step is to plan your approach. Each scenario and circumstance requires careful consideration and perhaps a different approach.

Patient Needs

It is important to take into consideration the patient's level of independence, healthcare literacy, culture, English proficiency, as well as any disabilities the patient may have. Audio recording may be the optimal mode of communication for some patients by helping to improve patient adherence to treatment plans and self-management and serving as a future reference to

instructions or education, thereby improving a patient's health outcomes. Providers may also benefit since recording provides a memorialization of what was actually said, thereby preventing miscommunication.

Consider the example of an elderly patient who lives alone, with whom you have a long standing and trusting relationship and asks if she may audiotape her visit so that she can better remember your care instructions and adequately relay her clinical condition to her son and daughter. Presuming that you are comfortable with being audio recorded, this type of situation is an opportunity for you to engage your patient and her family in a partnership of care that may improve self-management of her health condition and foster greater patient satisfaction with very little extra time spent on your part.

Patients and tape recorders:

What you should know



However, despite this potential benefit of recordings, there are also risks, the degree of which is impacted by some of the following factors.

Existing Relationship and Other Relevant Circumstances

Is the existing relationship between you and your patient one of mutual respect, as in the example above, or

one of distrust, as might exist following an unanticipated outcome – either with or without medical error? Certain circumstances, such as the disclosure of medical errors - whether yours or that of another practitioner - require careful, thoughtful deliberation. These sensitive situations require honesty and diplomacy on your part; however, recordings should not be permitted without the express consent of an attorney acting on your behalf.*

Your Comfort Level

It is important to examine your own comfort level with being tape-recorded. Not everyone is comfortable with public speaking or with being tape-recorded. Do you experience dry mouth, quivering voice, sweating, or increased heart rate? Do you forget what you had planned to say? If you are uncomfortable, it is not recommended that you agree

Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404
www.RiskReviewOnline.com

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to recording since your discomfort may have a negative impact on what is actually said and how the recording sounds to the listener.

Your Approach

After examining all of the factors, you may want to consider the following approaches:

1. If the factors are not ideal and you have the opportunity (e.g. no emergent patient need, an inflammatory scenario, a mistrusting relationship, or an unanticipated outcome), contact the Princeton Insurance Risk Resource Line at 1-866-Rx-4-Risk (866-794-7475) prior to agreeing to any recording. It is a good idea to have a plan of action in place in the event you are suddenly confronted with this type of situation and do not have time to contact Princeton Insurance. If you are not comfortable with the request, by all means, share your thoughts with the patient, such as:

✓ “I appreciate my relationship with my patients and I want to be comfortable with our interactions with a degree of candor,” or

✓ “In general, I am not comfortable speaking into a recorder of any type in any situation. I do not want my anxiety to hinder effective communication with you.”

2. If all of the factors are ideal (e.g. based on patient need, your relationship, “benign” circumstances, and you are comfortable), consider methods to coordinate and facilitate the situation so that you have control of what is recorded, and when.

For example, in the aforementioned example, you might consider first focusing on the history and physical, a discussion of the findings and agreed upon plan, and then a summary of the visit. An advantage to this approach is that you have control over what is recorded as opposed to a free flow dialogue which may be damaging to your defense should a claim ever arise in the future.

3. Offer to provide a written summary of relevant points as opposed to a tape recording.

4. Implement a standard format for instructional and educational material.

5. Utilize a standard patient summary form that provides an overview of the interaction, including a review of discussion, diagnosis, implications, required follow-up, self-management, instructions and/or education, and medications. An electronic medical record system may be helpful here, or if paper-based, an example of one such form is the “Office Visit Follow-up Instructions” form found in our Physician

Office Practice Toolkit.

6. If you decide to allow the recording, it is advisable that you retain an original copy the tape. Be prepared for these scenarios by having your own tape recorder available. Properly label the tape with the patient’s name, ID, and date of recording, and store tapes in a fire-safe container. To avoid the temptation of recording over used tapes, be sure to have an adequate supply of blank tapes on-hand.

Advance Planning

Anticipation and preparation are important to your ability in maintaining control should this situation arise in your practice. Identify, in advance, the ideal and not so ideal factors and plan what your approach might be. Remember to consider when preparing for such situations the particular patient needs, your existing relationship, other relevant circumstances, and your own comfort level. For example, think about the type of patients you have seen in your practice that made you uncomfortable and the most effective method of managing interactions with these patients in the future.

Different scenarios and circumstances require careful consideration and different approaches. It is important to remember that some scenarios and circumstances, such as unanticipated outcomes with or without error, may require collaboration with Princeton Insurance representatives and/or legal counsel. In any setting other than your own office, such as the hospital, patient or family requests such as this should be first discussed with the facility’s risk manager. It is recommended that you become familiar with the policies and procedures of the facility so you are prepared for future situations.

Recognizing the importance of quality provider-patient communications (deficits in communication patterns with patients are allegations appearing with regularity in malpractice claims); Princeton now provides training in provider-patient communication. For more information about the courses, contact the Risk Resource Line at 1-866-Rx-4-Risk (866-794-7475), or see article on Communication Courses in this issue.

* For guidance with disclosing unanticipated events, call the Princeton Insurance Risk Resource Line at 866-RX 4 Risk (866-794-7475) to speak with a Risk Services Consultant. ❖

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Surreptitious Recordings by Patients

This issue's response by:

Russ Pride, MA, CPHRM

Princeton Insurance Healthcare Risk Consultant

An insured physician called our Resource Line to ask: How does the law protect me from any one of my patients secretly taping my encounters with them without my prior knowledge and expressed authorization and using the information against me? How might I prevent this from occurring?

Privacy and confidentiality laws (HIPAA) were enacted with the aim to protect patients and their health information from being used, abused, showcased or made a spectacle of in the name of research, teaching, meta-analyses, and other endeavors.¹ As a result, healthcare providers are educated extensively as to how, under what circumstances, and with what means patient information will be used, and ultimately how and when the information will be destroyed – all with the ultimate goal to protect the dignity and privacy of the patient.

It is not irrational or absurd to assume, then, that there must be similar protections in place to safeguard the healthcare provider from certain acts perpetrated upon them by unscrupulous patients, such as the clandestine recording of office visits or treatment plan discussions and recommendations (without first asking if or apprising the healthcare provider

that a recording of the clinician-patient encounter will be made). Why? You have no control as to how the taped product will be used. The recording may be edited, taking your comments and genuine concern for the patient and manipulating these into seemingly questionable, suggestible and negligent sound bytes that may construct the foundation of a claim against you.

Since there are no such protections for healthcare providers, how can you shield yourself from these situations? The proliferation of cell phones with their huge capabilities and diminutive size make it far too easy to record any kind of event, including consultations with healthcare professionals. Ponder this: how many people recorded the destruction of the Twin Towers in New York or the watery landing of a jet on the Hudson River? Might yours be the patient encounter that finds its airing on YouTube or another website?

Depending upon the nature of your services and the set-up of your practice/office, consider the following:

Use your printed materials that describe your practice and your services to patients to address the issue of audio and/or video taping by patients, patient support members, etc.

If you have a practice website, make your position regarding taping of office visits, telephone discussions, etc. very clear and obvious on the web page so there is no dispute about your stance with regard to this practice before it occurs.

Informed consent discussions and informed consent forms should articulate your practice's position with regard to audio and video taping of sessions. Describe under what circumstances taping may be permitted and outline the steps to be followed in order to make the session being taped as useful to the patient as is possible.

As is practical, require patients to leave their personal belongings, such as handbags, loose fitting outer garments, and any other materials in which recording equipment may be retained with a family member, or place in a secure patient-belongings storage area.

Ask the patient to produce his/her cell phone and turn it off for the duration of the office visit. Don't continue the visit until you are assured this has been done.

Create a consent form for this purpose that must be completed by the patient and signed by you before any such taping is permitted. The consent should specify the reason for the taping request and what will be done with



Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404

www.RiskReviewOnline.com

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it. Consider making your own tape of this session so you have an original copy. It's not beyond the realm of reason to suspect that any recording, once it leaves your office, can be tampered with, altered, etc, and turn any innocent discussion, recommendation, etc. into something malicious and "proof" of negligence or professional incompetence.

Not all patients should be viewed as harboring unscrupulous intentions where recording of office visits is concerned. There may be perfectly acceptable conditions under which a patient may want to record the visit for good reason. How often have you encountered a patient who wants to record the discussion about a diagnosis or proposed treatment, fearing that s/he may forget important details once the visit has concluded? Consider encouraging the patient to invite a spouse, partner or family member to be present for the office visit. Alternatively, dictating your progress notes in the patient's presence to capture the essence of the visit, discussion of diagnosis, treatment and patient questions or providing a visit summary for the patient to have in order to remember details, recommendations, and the like are viable alternatives to recording the visit.

The lesson here is a familiar and sensible one: the best defense is a good offense. Discourage recordings if the intent appears to be something other than recording information to share with the patient's family. Or, at the very least, attempt to control the circumstances under which the recording will be permitted. Document in the patient's medical record the request and the rationale for the taping and your understanding as to how the tape will be used by the patient. Consider the use of an Authorization or Consent Form both you and the patient will sign before any recording begins. Remind returning patients periodically as well as new patients about your "no recording" policy. And make your own recording of the encounter using your own equipment if the patient insists on taping the encounter .

If a patient is determined to make a recording without your knowledge or consent, chances are s/he will find a way . But, you can minimize the chances for a recording to be made without your prior knowledge and consent by considering some of these steps. ❖

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Footnote:

¹ These laws are designed to protect the patient in a relationship that historically has imbued the physician with a kind of paternalistic power due to his/her medical knowledge, training and experience. The patient, on the other hand, is ignorant, by and large, of medical issues and is forced to place his or her trust into the hands of a professional. Laws help to moderate this "imbalance" by placing responsibility on providers to treat patient information with the highest degree of respect and confidentiality as is achievable. ❖

Questions and/or
suggestions are welcome.
Call the Healthcare Risk
Services Department at
1-866-RX4-RISK

The lesson here is a familiar and sensible one:
the best defense is a good offense.

Risk Management

Consultations: Who Follows the Patient?

by Sharon Koob, RN, BSBA, CPHRM, ARM
Princeton Insurance Healthcare Risk Consultant

The American Association of Family Physicians (AAFP) has specifically defined the difference between the terms "consultation," "referral," and "transfer of care" because these terms have been used interchangeably.ⁱ The words *consultation* and *referral* seem to be transposed more frequently. Confusion over the use and meaning of common terms can lead to misunderstanding. We are all aware of the recent push taken by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and all other leading quality of care organizations to remove, restrict, or minimize the use of confusing abbreviations. Confusing terms can lead to medical error as easily as confusing abbreviations.

First, it is important to identify the differences in meaning among these three terms. The AAFP defines *consultation* as:

a request from one physician to another for an advisory opinion. The consultant performs the requested service and makes written recommendations regarding diagnosis and treatment to the requesting physician. The requesting physician utilizes the consultant's opinion combined with his own professional judgment and other considerations (e.g. patient preferences, other consultations, family concerns, comorbidities) to provide treatment for the patient.

This description is consistent with the meaning of consultation as defined in the Current Procedural Terminology (CPT) manual.

The AAFP defines *referral* as:

a request from one physician to another to assume responsibility for management of one or more of a patient's specified problems. This may be for a specified period of time, until the problem(s)



resolution, or on an ongoing basis. This represents a temporary or partial transfer of care to another physician for a particular condition. It is the responsibility of the physician accepting the referral to maintain appropriate and timely communication with the referring physician and to seek approval from the referring physician for treating or referring the patient for any other condition that is not part of the original referral.

Finally, the AAFP defines *transfer of care* as:

a transfer of care occurs when one physician turns over responsibility for the comprehensive care of a patient to another physician. The transfer may be initiated by either the patient or by the patient's physician, and it may be either permanent or for a limited period of time until the patient's condition improves or resolves. When initiated by the patient's physician, the transferring physician should explicitly inform the patient of the transfer, and assist the patient with timely transfer of care consistent with local practice.ⁱⁱ

If these definitions are used consistently, there should be no confusion whether a physician will follow a patient or not when a consult is ordered. A consult will require a written report, a phone discussion in urgent situations, and no more. Yet some physicians do find themselves in practice situations

Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404

www.RiskReviewOnline.com

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which seem to limit their control over the situation. Managed care plans with continually changing lists of providers which the patients choose from lead to frustration in the primary care office; and the permission slip which gets the patient into another other doctor's office is called a "referral" form. A patient's primary physician may not even know the physician the patient will be going to see for the ordered consult.

Obtaining a consult in the ambulatory care setting can be more challenging than the inpatient venue because of situations like this. The caregiver's goal, however, is to give the patient safe and good quality care no matter what coverage obstacles may exist.

There are steps that can be taken to bridge the gap between the primary caregiver who is asking for a consult and the physician receiving that request. These actions can be handled in two levels of intensity, depending on the urgency of the consult.

For a routine test, such as a colonoscopy, the physician asking for the test should send:

- A written order for the test
- The reason for the test
- The results of any tests which may be germane to the consultant
- Any patient or patient's family history which might be germane to the test
- Current medications (including over-the-counter, herbs, vitamins, and other supplements) that the patient is on
- A request for a written report of the test

The request for the test and the information sent are to be documented in the patient's medical record.

It is clear that it is easier to do this routinely if your office maintains a form which can be used as a check-off sheet, a place to write the information noted above, and a place to attach information such as lab or imaging study reports.

For urgent consults, the same type of sheet and the same items apply, but two more things are added. The form will also have a place for your working diagnosis or impression; and it will have a place for you to indicate the urgency of your request. To make things simple, you can have one form which has all the things for both routine and urgent consults on it.

There is one last and very important thing that you can do to make sure that this urgent consult is given the attention it requires – you must call the consulting physician directly even if you do not know them. Connecting with this doctor will help make an impression about the case and it will also help the two of you exchange ideas and concerns about the patients. The consulting physician should be encouraged to call you as soon as the exam is complete so that you can collaborate on the best plan of treatment for your patient.

All of this, of course, is to be recorded in the chart and followed up in your office. A dropped consult request, whether it is a routine test or an urgent exam, may mean that a patient will suffer a serious illness, treatment which could have been avoided, and/or death. Moreover, you may face a lawsuit.ⁱⁱⁱ

To improve the consultation process and ensure patient safety, we recommend:

- The use of a standard consultation request form, such as that found in

Princeton's Physician Office Practice Toolkit

- Consistent use of correct terms to promote a clearer understanding of the process
- A system to continually monitor your consult requests to be sure they are being done, that you are receiving results in a timely manner and that you are following up with your patients in a timely manner on both positive and negative findings. ❖



ⁱ Consultations, Referrals, and Transfers of Care – Differences, www.aafp.org/online/en/home/policy/policies/c/consultreftransf.html

ⁱⁱ *ibid*

ⁱⁱⁱ Worsley, Barbara, "Patient Handoff: Not Just for Hospitals", The SCPIE Companies, page 2. ❖

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Risk Management

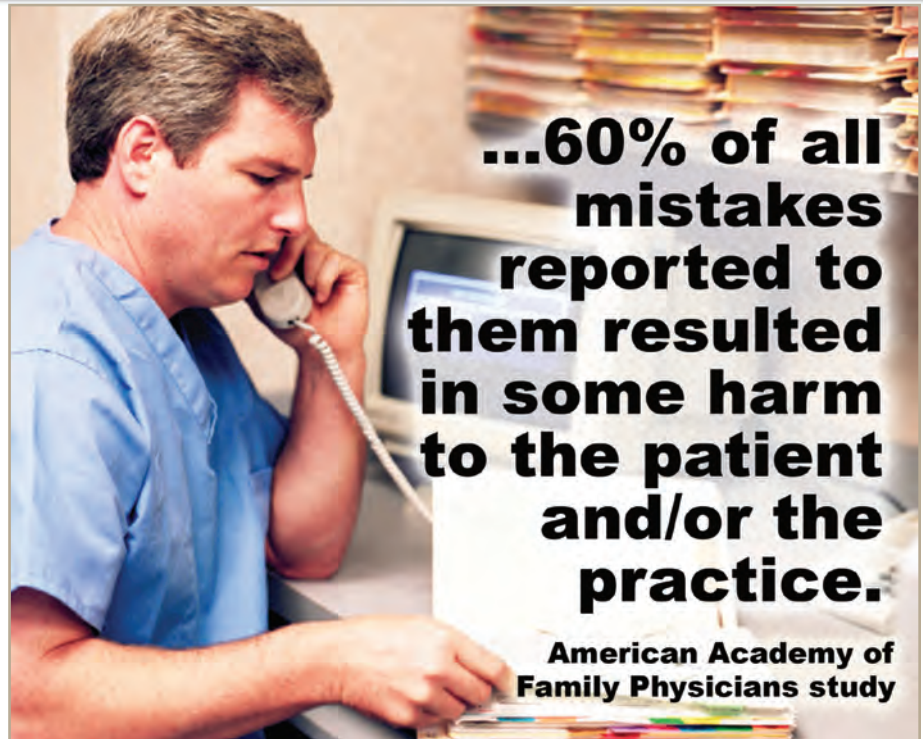
Tracking and follow-up of tests, consults, and referrals to achieve patient safety and service excellence

by Sharon Koob, RN, BSBA, CPHRM, ARM
Princeton Insurance Healthcare Risk Consultant

Data from the National Ambulatory Medical Care Survey indicates that the average family physician sees approximately 100 office patients a week; the study also finds that this same physician orders diagnostic tests on approximately 39% of those patients. Tracking those tests during the pre-result and post-result stages, as well as tracking consults and referrals ordered, represents organizational challenges for your office.

And what if you don't track tests, consults, or referrals? A study of office tracking errors conducted by the American Academy of Family Physicians found that 60% of all mistakes reported to them resulted in some harm to the patient and/or the practice. These include delay in care; lost time for the patient; emotional, physical, and financial distress for the patient; and emotional, financial or time distress for physician or practice.

Has your office ever experienced the following? A test result is filed in the chart before the ordering physician has a chance to review it; the chart is then filed away. This is at best a nuisance, but it can also result in serious harm. Consider this closed Princeton case: a patient underwent routine testing for a medical condition. The results of the latest annual test were filed away before the physician saw them; he dictated his letter to the primary physician based on the results of the previous year's test, which



apparently were easily visible in the chart (it seems that the current test was not). The current test showed a cancerous growth, and the physician did not find that result until the following year when he again went through the chart. Ultimately, the patient went through multiple procedures and cancer treatment but expired less than a year later. This case was also devastating financially.

Of course you want to avoid a liability suit which could result from a filing error, but there are other concerns in situations like these. It can be difficult to live with the knowledge that a patient suffered harm because a tracking and follow-up process was not assiduously followed. Your practice also may endure "bad press" by word of mouth, and it can take approximately ten years to regain your good name. This is a list of reasons for having a tracking system – there is no counterpoint list arguing for absence of a process.

Developing a system

The following will review the basics of tracking systems and methods to help you evaluate your current system. How well does it work? What would you like to improve about it? Do you, or will you, be using technology (an Electronic Medical Record System or a computer program designed to assist your tracking process). Remember: applying technology to your current process will not improve a process if it is already flawed; it will simply help you make mistakes faster. Fix the process before you computerize it.

Once you have clarified your process, what you would like to improve, and

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Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404

www.RiskReviewOnline.com

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what tools you plan to use, you can go on to identify what you need to track and follow-up. Remember that errors occur in both pre- and post-result phases of the testing process.

Implementing the system

In the pre-result phase, your practice's responsibility is primarily follow-up and double-checking. If you have ordered a test, consult, or referral, was the patient given the correct instructions on how to proceed to get this test, consult, or referral? Were they given the correct phone number to call, or were they told to call their provider to get an appropriate referral and find out from that provider where to get the service (as is often the case with some health plans)?

Then, was this order put in a tickler file to be rechecked in an appropriate time period? A follow-up check should indicate whether the test was done or whether it is scheduled. If no activity has occurred, the patient should be contacted so that they may be encouraged to get the test, consult, or referral as quickly as possible. This is also a good time to find out if they are having problems with scheduling, or if they misunderstood your instructions; treat situations like this as opportunities to find and correct loopholes in your tracking process.

Good communication with the patient at the time of their visit can help their adherence with your orders. Enlist them in the process; if they understand why you have ordered these things, they are more likely to follow-up with them.

When the test results come back, the second phase of your system begins. In this stage of the process, your practice will focus on the review, documentation, and follow-up of these results. This is the post-result phase.

Now your tickler file can be readdressed to note that the order was accomplished, the patient's chart can be pulled and the test results affixed to the outside of it for the physician to review. Once the test result has been reviewed, it should be initialed and dated by the reviewer; but there is more to do before it can take its place in the chart and the chart can be filed away.

In the third stage, the practice notifies the patient of the results of the test and follows up on the next steps of the care plan. To effectively address this phase, the practice must develop a system for notification of the patient of all test results – normal and abnormal. This system of notification may be by phone or by mail. If it is by phone then it must include a note in the patient's chart that they were notified, what they were notified of, when, and by whom. If it is by letter, a copy of the letter is to be filed in the patient's chart.

If the physician has ordered specific follow-up to the test, this needs to be communicated to the patient. Once again, the information to be tracked will go in the office's tickler file and the process will begin all over again.

Now the chart can be filed.

Making it work

Some offices find a stamp in the chart is an effective documentation of the second and third phases of their tracking systems. The stamp is a simple set of lines for staff and physician initials in categories such as: received by ____; reviewed by ____; patient notified by ____; filed by _____. Each line has a corresponding line for time and date.

Chart documentation should always include the physician's recommendations for treatment at the time of the patient's visit and any recommendations which may be made after test or consult results are received. This information is used to help document the doctor's rationale for treatment.

Consult and referral reports should be handled in the same way as tests, except that physicians may need to call the consulting or referring physician before and/or after the patient is seen. Those calls are also documented in the patient's record.

Summary

This is a basic tracking system, and each of fice can amend it to fit their

needs. However, key elements need to remain. For instance, it is very important that patients are notified of the results of all tests and consults. This is done so that no results and no patients "fall through the cracks" – it offers a side benefit of increased patient satisfaction with your practice.

If your office uses Electronic Medical Records, that system must have an embedded process which encompasses these basic elements. A process like this will automatically generate "reminders" which go on a task list – this list opens every day with the tasks which must be done that day and the name of the person responsible

for them. The tasks are not removed from the daily list until the person responsible completes the task.

This electronic process, like your manual tickler file, helps you and your staff remain faithful in follow-up to each step in the tracking process. As already noted, by increasing the accuracy of your practice's tracking and follow-up system, you will enhance patient safety while you reduce your practice's liability.

The Princeton Healthcare Risk Services staff is available to answer questions about tracking and follow-up systems - we also work with of fices to institute and/or improve processes. Call us at 1-866-Rx4-RISK. ❖

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Risk Management

July 2008

Urgi-Care Centers and Walk-In Hours Present Special Risks

by Sharon Koob, RN, BSBA, CPHRM, ARM
Princeton Insurance Healthcare Risk Consultant

Urgi-care centers and multi-physician practices have attempted to meet the need of today's patient by allowing a drop-in approach for unexpected medical needs. This has been very successful and very helpful for patients who did not want to wait for hours in an emergency room for non-emergent care. It also is of benefit to patients who have not yet established a relationship with a primary physician, or who have developed an urgent but not emergent need outside of office hours. This system can work very well if the patient has a primary physician (PCP) who is apprised of this urgent care; with that knowledge, the PCP can work with the patients to manage their own care. If there is no coordination of care, problems can develop.

Patients who come and go whenever they feel the need of treatment may consider an urgent care or walk-in practice as their "treating physician." They may not have any other doctor, or they may see specialists in the same casual manner. If the facility is unaware that they are the de facto primary caregiver for this patient, there can be a lack of continuity of care just as if the patient were going to the emergency room on a sporadic basis. This represents a liability risk for the facility.

A patient who is seen in this fashion may not see the same doctor at each visit, especially if the practice or clinic is large. In keeping with the "urgent" nature of each visit, practitioners and staff may document less and may fail to follow up on the tests they have suggested. Bluntly stated, the episodes of care may lack connection, causing redundancies and missed opportunities; and even when there is an attempt to give appropriate treatment, it may not be documented.

Following are several urgent care cases/scenarios:

Case 1 An elderly man with Type II diabetes was seen in an urgent care facility for early signs of neuropathy in one of his great toes. His foot was carefully examined and a thorough history was taken of his diabetes; documentation was good. No other systems were assessed, however. Specifically, his neurological orientation was not carefully evaluated. Since he was not accompanied by any family members, there was no one else to get his history from or to give instructions to. The patient took his discharge instruction sheet and left. He never followed up on the discharge instructions; he forgot them due to his early stage dementia. By the time his children, who lived out of town, caught on to his "foot problems" the neuropathy was seriously advanced, he had problems with infections, and he had to have part of his toe amputated.

Case 2 A woman frequented an urgent care facility over a period of years, presenting about once every year or two. She was seen by various physicians of the center for a number of complaints. Frequently she was asked to return for further testing regarding one problem or another, but she invariably did not come back as scheduled. When she did return, it would be for another issue, and she usually managed to evade any ordered tests beyond routine blood work, which could be done without advance preparation. She saw other physicians, usually specialists, in between her visits to the urgent care center and had several surgeries throughout the years. Ultimately, on a visit to another treating facility, she was found to have an advanced cancer which may have been diagnosed by one or more of the many tests or exams she evaded.

RECOMMENDATIONS:

For Patient Check-in and Evaluation

- Triage of walk-ins should be done by a physician, NP, or PA; 1[i] this triage must be done within the first minutes of the patient's arrival just as if the facility was an emergency department.
- Pull and review their old chart. For ease of review, an up-to-date case summary sheet at the beginning of the record can be a help.
- Do not assume you remember the patient from prior visits; ask necessary questions again.
- Do the appropriate, not minimal, physical exam and document it.
- Use critical thinking in your decision-making process, and document that decision process; treat each patient as the missed diagnosis case you are determined to avoid.
- Utilize strict protocols for rule-out MIs, fractures, 1[iii] and meningitis; the care of patients who fall into these and similar categories should be carefully documented.

Documentation

- Patient history and physical exam, to include mental status evaluation, must be clearly and completely documented.
- Documentation of critical thinking in the diagnostic process must include rule-outs.
- Vital signs, pulse oximetry, and neuro checks as appropriate must be done and recorded for specific types of care.
- Written discharge instructions should be reviewed with the patient, and family as appropriate, by the physician, NP, or PA; 1[iii] care should be taken to use interpreters if necessary and document their use.

Policies and Procedures

- Have a tracking system in place to ensure that the patient follows through on their care plan.
- Shift change hand-off procedures should be well developed and formal; they should apply to all levels of caregiver. 1[iv]
- Policy/procedure should carefully limit telephone advice and discourage telephone orders. 1[v]

General Issues

- Signage, facility documents given to the public, and the organization's website (if one is utilized) should clearly state the type of practice it is; documents and website should include disclaimer language which explains that the care given is urgent in nature and is not to be considered on-going health management. For those urgent care facilities that provide worker's compensation treatment, the wording will have to be altered appropriately.
- If the facility is strictly urgent care, all admission and discharge paperwork should have disclaimers, which state that the facility only provides care on an urgent basis and that all patients should seek health management from a qualified PCP.
- If the patient is a walk-in without a regular physician, the patient should be given materials on finding a PCP or choose to be followed by a physician of the practice that has just treated them; it should be clearly documented in their chart that they were seen and will be continuing care with the practice or that they were seen as urgent care only and have been given materials instructing them about finding a PCP.

1[i] Garfinkel-Weiss, Gail. "Reduce Liability Risk When Treating...Elderly Patients." Modern Medicine. <http://www.modernmedicine.com/>. Page 1.

1[ii] Ibid. Page 2.

1[iii] Ibid. Page 2.

1[iv] AAUCM Medical Malpractice Insurance, American Academy of Urgent Care Medicine, <http://www.aaucm.org/malpractice.asp>, page 1.

1[v] Ibid.

Job Descriptions and Performance Evaluations for the Office Practice

By Amy Slufik,
Physician Risk Representative, Princeton Insurance

Patient dissatisfaction is a major contributor to malpractice claims, especially in the event that the patient experiences an adverse outcome. A cordial, caring and efficient staff, however, has a tremendous impact on patient satisfaction by setting the overall tone of the office culture. From the greeting at the window to the payment process after a visit, office practice employees contribute substantially to a patient's first and lasting impression of the practice and of the physicians, dentists or chiropractors who employ them. Good staff performance, whether through direct patient care or in the provision of administrative tasks, is essential to the safety of patients, efficiency in your business operations and overall patient satisfaction.

Yet, office practices often utilize a subjective method of evaluating new and existing staff performance. Well-crafted and detailed job descriptions and performance evaluations, on the other hand, are effective management tools that are important in supporting many employment actions such as hiring, compensation, promotion, discipline and termination. They provide the practice with an objective method of evaluating employees according to performance outcomes, and not on the subjective opinion of their abilities alone. Direct performance can be observed and measured, whereas the traits and attributes of employees (which may or may not contribute to performance) must be guessed at, or inferred. Whether a small office practice with few employees or a larger office practice with many employees, it is important to develop and utilize a consistent approach.

Job descriptions:

- Provide a basis to evaluate your employee's performance
- Clearly communicate to your employees what is expected of them, including the skills which are required for the position

Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404
www.RiskReviewOnline.com

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- Provide a training outline
- Ensure an effective, consistent hiring process
- Assist in comparing the duties of the various positions within your office to establish relative pay rates

What should be included in a job description?

- Name of the office practice/employer
- Effective date
- Position title
- Name of employee
- Name of individual to whom employee reports
- Job summary (i.e. general overview of the position)
- General responsibilities for all employees (i.e. confidentiality, courtesy, etc.)
- Core competencies (i.e. specific duties/tasks for that position) listed in order of importance and/or frequency
- Working conditions (i.e. hours, health or safety hazards, physical requirements, etc.)
- Job requirements (i.e. education, special training, experience, abilities, certifications/licensing, clinical skills, technical skills, occupational skills, etc.)

If a job description is being created from an already existing position and it is unclear exactly what that individual does, simply ask the employee to explain what they do each day and select the key areas to establish a list of the specific duties/tasks. Next, have your employees assist in determining

continued on page 2

what measurable actions will help to gauge whether tasks are being performed satisfactorily, so that they may be incorporated into their performance evaluations.

Performance evaluations are based upon a direct comparison of the employee's job description to the employee's actual job performance during a specific time period to provide ongoing feedback and define concrete goals. They provide supportive written documentation for:

- Acknowledging an employee for exceptional performance
- Disciplinary action
- Identifying employees who need to improve
- Evaluating an employee's progress after training

Creating a performance evaluation from an existing job description is easy.

1. List the areas you want to evaluate from the identified general responsibilities and core competencies.
2. Develop criteria/standards for each general responsibility and core competency, indicating how you expect each to be done satisfactorily, but be careful not to establish an unrealistically high standard to meet. For example, one of the core competencies for a medical assistant may be to schedule appointments and tests. The criteria/standards defining that core competency may be to pre-certify patients for insurance coverage, set up referral contacts, and review all requisitions for completeness.
3. Apply a rating scale to each general responsibility and core competency you are evaluating. The rating scale could be simple:

- (1) Did not meet standards
- (2) Met standards
- (3) Exceeded standards

They can also be a little more complex:

- (1) Failed to develop as anticipated
- (2) Performance is below the standards set for the position, training is needed
- (3) Performance is satisfactory
- (4) Performance is consistently higher than the standards set for the position
- (5) Requirements and standards set for the position are always exceeded

In summary, performance evaluations should include the following:

- Name of the office practice/employer
- Position title
- Name of employee
- Period of time you are evaluating (i.e. 1/1/07 – 12/31/07)
- The general responsibilities and core competencies to be evaluated and the criteria/standards defining them

- A rating scale
- Specific acknowledgements/accomplishments
- Specific areas for improvement (be specific, i.e. training, certification, behavior change)

This is also a great opportunity to have an in-depth discussion with each employee in order to uncover areas in which the employee is having difficulty and to indicate ways to assist that individual, discuss their specific accomplishments and/or other job responsibilities they may be interested in, as well as develop goals for that employee for the upcoming year.

Remember that performance evaluations should be conducted at the end of an employee's probationary period, usually three months, and then at least annually thereafter. In addition, review the Employee Confidentiality Policy and Agreement with your employees and have them again sign and date it, as well as verify that their certifications and licensing requirements are up to date.

All employees should receive a copy of their job description upon hire. It is also a good idea to review the developed job descriptions on a periodic basis to ensure that they are being updated to include any technological changes (i.e. new equipment, including the skills required), as well as any changes to the office practice in general. Any changes made to the job description should be done with the agreement of the employee, and the employee should be given an updated copy for their records. All employment-related policies, procedures and forms should be reviewed by the practice's legal counsel with knowledge of employment practices liability. ❖

References:

Appraisal Methods: Results Method, Management by Objectives (MBO) (n.d.). Archer North. Retrieved December 21, 2007 from <http://www.performance-appraisal.com/results.htm>

Criteria-Based Job Descriptions (February 2005). SESCO Report, Volume LVI, Issue 2. Retrieved December 21, 2007

Human Resources Management (n.d.). OMA Practice Advisory Services. Retrieved December 20, 2007 from <https://www.oma.org/practiceadvisory/Staff/hr.htm>

Job Descriptions: An Employers' Handbook (2007). Human Resources and Social Development Canada. Retrieved December 19, 2007 from http://www23.hrdc-drhc.gc.ca/2001/e/generic/NOC_HB_070316_en.pdf

Performance Evaluation Overview (n.d.). PTDA. Retrieved December 21, 2007 from http://www.ptda.org/AM/PrinterTemplate.cfm?Section=Job_Descriptions_Evaluations&Template=/CM/HTMLDisplay.cfm&ContentID=2281&FuseFlag=1

Staff Job Composite: Medical Assistant (2007). Saint Louis University. Retrieved December 19, 2007 ❖

This material is not to be construed as establishing professional practice standards or providing legal advice. Compliance with any of the recommendations contained herein in no way guarantees the fulfillment of your obligations as may be required by any local, state or federal laws, regulations or other requirements. Readers are advised to consult a qualified attorney or other professional regarding the information and issues discussed herein, and for advice pertaining to a specific situation.

Job Description Form

On the next page of this article, we have included a sample Job Description Form for use in your office.

This form can also be downloaded on the RiskReviewOnline.com site as well.

(Look for the link within the [Job Descriptions and Performance Evaluations for the Office Practice](#) article in RiskReview, March 2008).

JOB DESCRIPTION

Effective Date: _____

Position/Title: _____ Name of Employee: _____

Name & Title To Whom Employee Reports: _____

Job Summary: _____

General Responsibilities: _____

Core Competencies: _____

Working Conditions: _____

Job Requirements: _____



Your Direct Link to Better Risk Management Practices

General Liability

In this section of Risk Review, our risk management experts highlight important information, tips and recommendations as they relate to safety and security issues that could arise at your practice or facility.

Preventing Wrongful Termination Lawsuits

By: Amy Slufik

Physician Risk Representative, Princeton Insurance

Note: In an effort to provide you with the latest information regarding risk management and loss prevention, Risk Review will sometimes feature articles that discuss situations that are not covered by Princeton Insurance. This article offers details about how to prevent wrongful termination lawsuits – please be advised that Princeton Insurance DOES NOT offer this type of coverage. If you are interested in learning more about wrongful termination coverage, or would like to review the details of your policy, always contact your independent agent.

Employees are becoming more and more knowledgeable about their rights, resulting in an increase of wrongful termination claims, as well as an increase in the amount of damages and legal costs to defend them. There are several laws that employers need to be aware of when terminating an employee, including the Conscientious Employee Protection Act (CEPA) which protects employees from retaliation, the Age Discrimination in Employment Act, Americans with Disabilities Act, the Equal Pay Act, and the Civil Rights Act. These laws are constantly changing, and it is important that employers are knowledgeable and keep up with them.

Most employees are hired for an indefinite period of time and are considered employees “at will,” though an employee can be hired via express contract for a specific period of time or the “at will” provision may be overridden by an implied contract (i.e. employer assuring continued employment, salary increases, bonuses, commendations, etc.). Though the State of New Jersey recognizes the concept of employment “at will,” which means that an employer can terminate an employee at any time, for any reason or no reason, and without giving the employee prior notice, this will not prevent a lawsuit based upon violation of the above

Vice President of Healthcare Risk Services
Tom Snyder x852

Manager, Healthcare Risk Services
Phyllis DeCola x897

Manager, Risk Services
Francis Roth x868

Phone: 609.452.9404

www.RiskReviewOnline.com

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employment laws.

Handbooks and policies

Employers should have a written employee handbook and employee policies and procedures which include the types of conduct that are subject to disciplinary action, including termination.

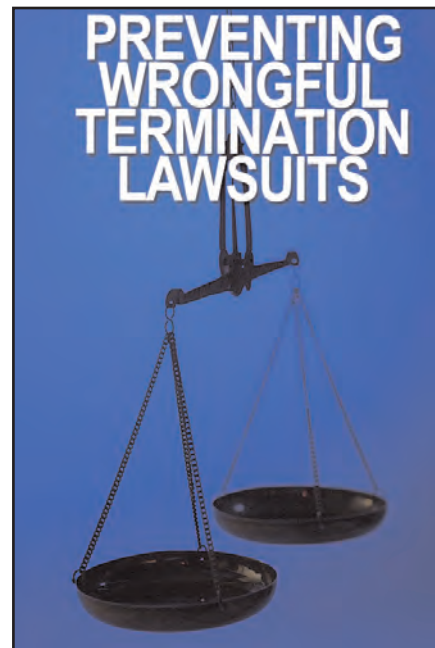
Employers should also make sure their employees are aware of the handbook and employee policies and procedures, whether they are posted in a conspicuous place and/or given to the employee and a written acknowledgement of receipt is obtained. The state recognizes that employee

handbooks, etc. can be considered contracts, unless there is a prominently displayed disclaimer, so it is important to have your employee handbooks and other employee policies and procedures reviewed by an employment law attorney, not only initially, but after any changes or amendments.

Performance expectations should be outlined in a written job description and provided to the employee. Also, these expectations, specific examples of not meeting the expectations, ways to improve, and the consequences of continuing to not meet the expectations should be reviewed at least annually with the employee during a written performance evaluation and filed in the employee’s personnel file after the employee signs it acknowledging the meeting. Any additional follow-up meetings should be documented in the same fashion. Disciplinary action, including termination, should be based upon the employee’s performance and/or conduct, not on their age, race, color, national origin, religion, gender, prior complaints, etc. Employers have to be especially careful when an employee falls within a class protected by acts mentioned above.

Be mindful – don’t retaliate

It is also important to treat an employee who complains about discrimination or harassment with care. Retaliation is often subjective and can include actions that the employer takes with the best of intentions. Remember to focus on the wrongdoer, not the complaining employee when trying to resolve a situation. The employer needs to fix the problem, not remove the complaining employee from the situation. Even if the original complaint turns out to be unsubstantiated, as long as an employee can prove that there were negative effects as a result, the



continued on page 2

employee can win a retaliation claim. Steps to take to prevent retaliation is to establish a policy against it, communicate with the complaining employee, keep the complaints received confidential, and document everything, consider sending the complaining employee a letter confirming your discussion. Remember, you can take actions against a complaining employee for other reasons, but be prepared to show that you have valid reasons unrelated to the complaint, including documentation of prior warnings.

Stick to the rules

When disciplining an employee it is very important to follow your company's written policies and procedures. Make sure managers work with Human Resources and are trained properly on these policies. Follow a progressive disciplinary action approach, whenever appropriate, which includes the use of verbal and written warnings, probation, suspension, transfer and/or demotion. Make sure the disciplinary action is in proportion to the seriousness of the action/violation; be consistent with the type and severity of the corrective action imposed on other employees under similar circumstances, no matter who the employee is. This progressive approach will prove that the company's policy was applied fairly and allow for the employee to be aware of their action/violation and an opportunity to correct their behavior. Ample time should be given to the employee to improve his/her performance as determined by your company's policy, but be fair and consistent. In general, several warnings should be given to the employee before termination is considered, unless it's related to extreme misconduct.

Every step of the process should be thoroughly documented in common sense language that can be easily followed, with specific corrective actions and, if possible, quantifiable performance measures. Verbal and written warnings, with specifics about the particular issue, details of the conversation, and the potential consequences, should be documented and signed by the employee acknowledging the discussion and placed in the employee's personnel file. It is important that no evidence is destroyed, because, if this is discovered, the courts will more than likely assume it would have supported the plaintiff. Key personnel documents should be kept for at least a few years.

Take time to investigate all sides

Employers should carefully investigate the situation surrounding the disciplinary action/termination and make sure they have a specific, legitimate, non-discriminatory reason for terminating the employee. Obtain all sides of the story and be fair to everyone involved, obtain sufficient evidence to back-up your decision, and make sure you are not swayed by one individual's version, especially if the person has their own agenda. Never terminate an employee on the spot. If the action/violation is extremely serious, consider suspending the employee (with or without pay) pending the outcome of the investigation to allow you sufficient time to confirm the circumstances surrounding the action in order to discipline appropriately. Make sure you keep the names of the individuals you spoke with confidential, especially from the person being terminated. Consider contacting your employment law attorney for guidance.

Take the proper steps before termination

Before terminating an employee, make sure your decision was well thought out and that you have reviewed and taken into consideration all prior disciplinary actions for the same type of action/violation, as well as the possible impact of the employment laws. Have at least one high-level

management representative trained in employment-related matters review the situation, making sure there is solid evidence and the reason would be considered fair and reasonable by an unbiased third party hearing both sides of the story (i.e. jury) prior to approving the termination. Discuss your termination decision with only those that need to know (i.e. supervisor, legal counsel). If you have already had several discussions with the employee via verbal and written warnings, termination should not be a surprise.

Once you have decided to terminate the employee, schedule a meeting; don't wait any longer than you have to. Make sure you are prepared. Include Human Resource representatives, the employee's supervisor, and one other person who can serve as a credible witness, if needed. Have the final paycheck available at the meeting, if possible. Allow the employee to briefly discuss the decision with you and/or vent, but don't make promises you can't keep and don't argue. Tell the employee the truth and be sure not to candy coat it to spare their feelings because it may have repercussions. Treat the employee with respect and dignity; do not embarrass the employee and do not badmouth them after they leave. If the employee needs to be escorted out immediately, monitor their exit, but don't get security involved unless absolutely necessary.

In summary

To prevent wrongful termination lawsuits, consider the following:

- Do not make promises you can't keep;
- Establish policies and procedures and make sure all employees are familiar with them;
- Be fair and consistent;
- Tell the truth;
- Use a progressive discipline approach, where possible, except in cases of extreme misconduct;
- Consider other disciplinary actions, other than termination;
- Treat employees with dignity and respect;
- Do not discuss the termination of an employee with others, unless they need to know; and
- Consider evaluating your termination process on a regular basis, comparing the policy and the actions taken, looking for strengths and weaknesses and revising as necessary.

References:

- Business 21 Publishing (2005). Supervisor Slip-Ups that Lead to Termination Lawsuits. Special Report from the "B21 Coach" Series. Retrieved July 27, 2006, from <http://www.b21pubs.com/semktg/b21coachterminationsformFree1a.htm?src=overture&OVRAW=Wrongful%20Termination%20cases&OVKEY=wrongful%20termination%20cases&OVMTCS=standard>
- Employment Practices Liability Insurance: Common Risks and Controls. (2002). Loss Control Technical Information Paper Series (TIPS). Retrieved July 27, 2006 from The Hartford Loss Control Department Website: <http://www.thehartford.com/corporate/losscontrol/TIPS/520-602.pdf#search='Preventing%20Wrongful%20Termination'>
- How can I Fire Someone Safely? (n.d.). Retrieved July 27, 2006, from <http://www.allbusiness.com/employment/termination/1074>
- Lee, T. (2001). Firing Employees without Getting Burned. The New Jersey

Small Business Journal. Retrieved July 27, 2006, from http://www.leadtrac.com/terminating_employees_without_getting_burned.htm

Porter, J. M. (2002, August 19). "How to Avoid Wrongful Termination Lawsuits". Orange County Business Journal. Retrieved July 27, 2006, from <http://www.sycr.com/pdfs/OCBJ-porter-081902.pdf#search='Prevent%20wrongful%20termination%20cases'>

Preventing Retaliation Claims by Employees. (n.d.). Retrieved July 27, 2006, from <http://www.nolo.com/article.cfm/ObjectID/23E1AF4F-8B15-478C-8238E129CD7DE451/catID/DE34C24C-9CBE-42EF-917012F2F6758F92/111/259/283/ART/>

Situations Where You Have to be Extra Careful when Firing Employees. (n.d.). Retrieved July 27, 2006, from <http://www.allbusiness.com/employment/termination/1469>

Ten Tips to Prevent Termination Headaches. (n.d.). Retrieved July 27, 2006, from http://www.ppspublishers.com/articles/gl/bulletin_ten_tips.htm

Top 10 Employee Firing Mistakes. (n.d.). Retrieved July 27, 2006, from <http://www.allbusiness.com/employment/termination/4010>

Wrongful Termination. (n.d.). Retrieved July 27, 2006, from <http://www.fairmeasures.com/issues/termination/> ❖

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Reducing Risk

A Publication on Healthcare Risk Management from Princeton Insurance

The Americans with Disabilities Act

Introduction

The Americans with Disabilities Act (“ADA”) guarantees people with disabilities equal opportunity in public accommodations, employment, transportation, government services, and telecommunications.

The ADA requires all private medical and dental offices to ensure that the goods, services, and facilities they provide are accessible to all individuals with disabilities. The ADA impacts various areas of office practice management including physical access; patient care issues such as communicating with deaf or blind patients; and employment issues such as hiring practices and job descriptions.

Title III ADA Obligations

Title III of the ADA requires that places of “public accommodation” which includes medical and dental offices, be made free of barriers to effective communication and physical access. Title III obligations apply to all private healthcare providers, regardless of the size of their office or the number of employees. Individuals protected from discrimination under Title III include patients, visitors, and office staff.

Although the size and financial resources of a business may affect the type or extent of the accommodations required to meet the obligations imposed by the ADA, small size alone does not relieve a small business from the responsibility of meeting its Title III obligations.

Failure to comply with the ADA places a medical or dental practice at risk for litigation, imposition of court orders, and money damages, including fines. Intent to discriminate against an individual with a disability is not required; failure to provide an accommodation is enough to establish a violation.

The ADA and New Jersey Law

The ADA and the New Jersey Law Against Discrimination, N.J.S.A. 10:5-1 *et seq.* (“LAD”) are related. The LAD prohibits discrimination against any individual who has or previously had a physical or mental handicap. Courts in New Jersey look to federal law on the ADA and an earlier federal law, The Rehabilitation Act of 1973, Section 504, for guidance in cases involving discrimination claims by individuals with handicaps or disabilities.

Protected Individuals

The ADA protects “individuals with disabilities.” An individual is considered to have a disability if he or she:

- has a physical or mental impairment that substantially limits a major life activity such as self-care, walking, seeing, hearing, speaking, breathing, learning, and working
- has a record of having such an impairment—e.g. a person who recovered from cancer
- is regarded as having such an impairment—e.g. a person with a severe facial deformity

Specifically named disabilities in Title III include:

- vision, speech or hearing impairments
- physiological conditions or disorders such as cancer, heart disease, diabetes, cerebral palsy, multiple sclerosis
- cosmetic disfigurements and anatomical losses
- alcoholism

- Mental or psychological disorders
- Contagious and non-contagious diseases, whether or not symptomatic (TB and HIV/AIDS are specifically named)
- Drug addiction (current illegal users of drugs are specifically excluded)

Modifications in Policies, Practices, and Procedures

The ADA requires that “reasonable modifications” be made to policies, practices, and procedures that are necessary to accommodate individuals with disabilities. Modifications are not required where either a fundamental alteration in the nature of the goods or services provided, or an “undue burden” would result. For example, a physician is not required to accept patients outside of his or her specialty, as that would fundamentally alter the nature of the medical practice.

An “undue burden” is something that involves a “significant difficulty or expense.” Factors to consider include the nature and cost of the accommodation, the overall financial resources of the practice, the number of employees, and the difficulty of locating or providing the aid or service. The issue of whether or not a modification would be an undue burden is determined on an individual basis.

Effective Communication Using Auxiliary Aids and Services

Healthcare providers have a duty to provide effective communication, using auxiliary aids and services, to patients, customers, and other individuals with disabilities who are seeking or using their services. This duty extends to individuals who may not be patients, such as the deaf parent of a hearing child.

The communication with individuals with disabilities must be as effective as communication with others. The healthcare provider should consult with the individual with the disability and consider the individual's self-assessed needs as to which auxiliary aid or service will achieve effective communication.

A healthcare provider may not charge a patient for the cost of providing an auxiliary aid or service, either directly or through the patient's insurance. The costs of providing auxiliary aids and services are to be treated as part of the annual overhead costs of operating a business. However, tax credits for a portion of the eligible costs of providing auxiliary aids and services, and other costs of ADA compliance, are available.

Blind or Vision Impaired Patients

For the patient who is blind or has impaired vision, auxiliary aids and services include:

- qualified readers
- Braille or large print literature
- audio recordings
- computer disks

Deaf or Hard of Hearing Patients

For a patient who is deaf or hard of hearing, auxiliary aids, and services include:

- qualified sign language or other interpreter, versed in medical or dental terms and concepts, and not related to the patient
- written forms or information sheets
- exchange of written notes
- teletypewriter (TTY, also known as a TDD)
- telephones that have amplifiers or are compatible with hearing aids

Situations Where an Interpreter for the Deaf May Be Required

Some patient encounters, due to their complexity, critical nature, or length, may require a qualified sign language or other interpreter for effective communication. Examples are:

- discussing a patient's symptoms and medical history
- explaining medical conditions, tests, treatment options, medications, surgery
- providing a diagnosis, prognosis and treatment recommendation
- communicating information to obtain an informed consent
- communicating with a patient during treatment and testing procedures
- providing mental health services

- providing information about blood or organ donations
- discussing billing or insurance matters
- presenting education programs such as diabetes management or nutrition

Barrier Removal in Existing Facilities

The ADA requires barrier removal in existing facilities only where it is “readily achievable” to accomplish. “Readily achievable” means the barrier removal can be easily accomplished without much difficulty or expense. Examples of “readily achievable” barrier removal include rearranging furniture, building a ramp over a few stairs used to enter the facility, installing grab bars where only routine reinforcement of the wall is required, lowering telephones, and posting permanent large print signage.

In leased places of public accommodation such as professional offices, the ADA places the legal obligation for barrier removal and the provision of auxiliary aids and services on both the landlord and tenant. The terms of a lease may specify who is to make the changes and provide the aids and services, but both the landlord and tenant remain legally responsible for ADA compliance.

All alterations to an existing facility that could affect the usability of the facility must be made ADA compliant to the maximum extent possible. However, the requirements for additional accessibility are only required to the extent that they are technically feasible and the cost does not represent a disproportionate percentage of the total cost of the renovations.

An important exception is the ADA requirement that if renovations are to be performed to a multistory building containing the offices of healthcare providers, an elevator must be added to the building. Finally, the building must be more accessible at the completion of the alterations or renovations than it was before they were started.

For more information about reducing risk at your practice, please view our risk management newsletter at www.RiskReviewOnline.com. To access additional Reducing Risk documents, visit our website at www.PrincetonInsurance.com and click on “risk management – publications”.

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Your Direct Link to Better Risk Management Practices

THE SCOPE, PURPOSE, AND METHODS OF THE NEW JERSEY BOARD OF MEDICAL EXAMINERS A PRACTICAL GUIDE FOR PRACTICING PHYSICIANS

By Michael J. Keating, Esq., medical malpractice defense attorney

Upon completion of medical school and post-graduate training, a physician is qualified to evaluate and treat patients in a variety of clinical settings, including private practice and as a member of a hospital medical staff. Formal medical education and training alone, however, do not entitle a physician to begin treating patients. A physician must first apply for and obtain a license to practice medicine in the state in which he or she intends to practice. In the State of New Jersey, this process is conducted by the New Jersey Board of Medical Examiners (hereinafter "Medical Board") which grants medical licenses.

In addition to this important credentialing function, the Medical Board is responsible for overseeing nearly every aspect of the practice of medicine, including practice standards, ethics issues, issues relating to potential impairment and incapacity of licensees, and reviewing and processing disciplinary actions against physicians found to be in violation of Medical Board regulations. The Medical Board also performs the important function of issuing advisory opinions and letters to update or clarify the scope and meaning of existing regulations or evolving practice areas.

In short, the Medical Board decides who will receive a license, makes the rules, enforces the rules, sits in judgment of those accused of breaking the rules, and imposes punishment for violations. Notwithstanding this, most physicians in this state know little or nothing about this government agency, although they are required under law to be familiar with all applicable Medical Board rules, regulations, and standards.

During the course of their career, many physicians can expect to have an encounter with the Medical Board, and the range of possible issues extends from the minor and trivial to a serious disciplinary action that could result in the suspension or even revocation of a physician's right to

practice medicine. This article will provide physicians with a practical guide to the Medical Board, including its structure, function and methods of enforcement. The article will summarize the type of cases that typically come before the Board for review, and outline the legal process that is followed. Finally, the article will provide the practical advice for management of any potential encounter with the Medical Board.



Statutory framework and purpose

The Medical Board was created by the New Jersey State Legislature, by statutory framework, in an effort to maintain high professional medical and healthcare standards by establishing an administrative body to review and control access to the profession and to investigate licensees accused or suspected of substandard treatment, unethical or professionally inappropriate conduct. The Medical Board is organized under the State Division of Consumer Affairs. It has an administrative staff, an Executive Director, and is made up of physicians from different specialties and lay people, who are appointed by the Governor, and who each serve for a fixed term. In addition, the "legal legwork" of the Medical Board, that is, the investigation of patient complaints and the institution of disciplinary proceedings, is conducted by members of the State Attorney General's Office, including private investigators, forensic experts, and designated attorneys assigned to process and handle licensing board matters.

The initial function of the Medical Board is to review and process all applications for licensure, by either recent training program graduates or physicians licensed in other states. This is largely accomplished through credentialing review by administrative staff prior to the issuance of a license. This is a responsibility that the Medical Board members take very

Vice President of Healthcare Risk Services
Tom Snyder x852

Manager, Healthcare Risk Services
Phyllis DeCola x897

Manager, Risk Services
Francis Roth x868

Phone: 609.452.9404

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seriously, and any applicant can expect rigorous scrutiny and review prior to the issuance of a license. The process can take months to complete.

In an era when prior disciplinary matters and malpractice settlements are routinely reported to the National Practitioners Data Bank, an applicant can expect to be asked detailed questions about any prior professional problems or issues. An application can be denied based on a determination by the Medical Board that the applicant, though otherwise qualified, has a problematic past. The applicant may be required to appear before a committee of the Medical Board to explain and provide documentation regarding prior malpractice cases, resignations from a medical staff, or complaints filed by patients or colleagues with other state licensing boards. Prior to undergoing such a process, the concerned practitioner with such issues in his or her past should consult with an attorney who has experience in handling Medical Board matters and who is known to the personnel in the Medical Board of office.

Disciplinary review standards and procedures

A significant amount of the Medical Board's resources are committed to investigating and, in certain instances, prosecuting complaints against physicians for alleged professional misconduct, substandard treatment, or ethical violations. Complaints are referred to the Medical Board by a wide variety of sources, and these sources are kept confidential by statute and not revealed to a physician under investigation. While disgruntled patients account for a large percentage of the complaints filed, physicians would be surprised to learn that complaints come from many other sources, as well, including other physicians, nurses, former employees, and hospital administrators. The Medical Board regulations require that any physician or healthcare provider with knowledge of alleged improper conduct has an affirmative obligation to report such a matter to the Medical Board.

The Medical Board also investigates physicians even in the absence of a complaint, and relies on its own investigative techniques, such as pharmacy surveys, medical chart review, and, in rare cases, the placement of undercover investigative agents in a physician's office. These agents often pose as "new" patients in an effort to investigate physicians who are suspected of engaging in ongoing and serious inappropriate conduct such as prescription abuse, insurance fraud, or sexual misconduct.

The subject matter of complaints is varied, but typically include patients or family members upset with untoward outcomes, chronic pain patients treated with narcotics or other controlled medications, allegations of patient abandonment or improper/inadequate referral, insurance and third-party reimbursement improprieties, physician substance abuse, and alleged sexual misconduct.

Methods

The typical complaint is referred to the Medical Board by the filing of a written complaint form. To facilitate patient complaints, allegations can now be made by an "on-line" filing system. Once a complaint has been received, the Medical Board is obligated to conduct an investigation of the physician. The investigation is generally limited to the allegations in the complaint, but not always so. The Board has the discretion and authority to conduct a broad-ranging inquiry into any aspect of the physician's practice or professional life during the course of subsequent proceedings. New Jersey courts have held that a physician responding to such an investigative inquiry has virtually no "due process" rights and, therefore, is

usually unable to learn, in advance, information about the scope of the inquiry. Many cases that start as a simple patient complaint over what appears to be a minor matter often develop into a more serious and extensive inquiry, involving issues completely unrelated to the initial complaint.

During this initial phase of the process, physicians often feel intimidated as they find themselves in an entirely new professional arena, with less due process rights and procedures than a defendant has in a criminal investigation. Even though the role of counsel during this initial phase is limited by statute and case law, a physician in such a circumstance should always rely upon the informal guidance and strategy recommendations of an attorney with Medical Board experience. A physician should never have any contact or provide any information to the Medical Board in an investigation without the guidance of an attorney.

The Medical Board generally requests a written response by the physician to the allegations in the complaint. The majority of complaints are resolved during this phase. If the matter involves serious allegations or the resolution of factual disputes (such as alleged sexual misconduct cases), the Medical Board generally "invites" the physician to appear before an investigative committee for questioning. The committee, referred to as the Preliminary Evaluation Committee ("PEC"), is made up of designated physicians and laypersons of the Medical Board.

Legal representation is critical for such an appearance. A Deputy Attorney General, who provides preliminary instructions regarding the proceedings, generally initiates the PEC appearance. Routine questions are then asked about the physician's training, background, and practice activities. The physician must verify that he or she is current in all CME requirements (which arise from a Medical Board regulation). Following the preliminary matters, any member of the Committee may ask the physician any question on virtually any subject. The format ranges from friendly, collegial exchange to brutal, ongoing cross-examination. The atmosphere cannot be predicted in advance, although it depends to some degree on the personality of the PEC members and the seriousness of the alleged misconduct.

Generally speaking, PEC members are prominent physicians from around the state from various specialties and, in this author's experience, they generally treat a physician with respect and dignity. There are, however, notable exceptions, and as information is given to the PEC by sworn testimony, which is stenographically recorded, mistakes or inappropriate comments made during difficult cross-examination can make the matter difficult to defend and resolve on a favorable basis.

Following the PEC appearance, the Committee members prepare minutes reflecting findings and recommendations for disposition. Medical Board members have broad discretion in this area. If the PEC finds probable gross negligence or unethical conduct, an effort is often made to resolve the case by offering the doctor a settlement, which is usually structured to address the problem. If the concern is quality of care, retraining or remedial CME may be recommended. In more serious matters, the proposed settlement may include language reprimanding the physician for improper conduct, imposing substantial fines or civil penalties, requiring that a physician practice under direct supervision of another physician, or in some cases, suspension or revocation of the physician's license to practice medicine.

If the case cannot be resolved by way of settlement, the Medical Board has the option of referring the matter to the Enforcement Bureau of the Attorney General's Office. For serious misconduct, the Medical Board will recommend the filing of a complaint with the Office of Administrative Law ("OAL"). If this occurs, the complaint is generally assigned for disposition to an Administrative Law Judge for pretrial discovery and trial. Depending on what occurs during the trial, the Judge can recommend a wide variety of remedial measures or sanctions, which include substantial financial penalties and license suspension or revocation.

Most physicians are, not surprisingly, unfamiliar with the procedural mechanics of a Medical Board complaint. Once a complaint is filed, the physician has due process rights such as pretrial discovery, the right to cross-examine adverse witnesses, and the right to serve expert reports in support of his or her position. Unfortunately, the statutes and applicable case law make it very difficult for a physician to prevail in a disciplinary matter once it has been referred to the OAL for disposition. The Medical Board is not bound by the judge's findings and recommendations; they are only advisory. A physician can go through a protracted and expensive trial and prevail, only to discover that the Medical Board has made separate findings, apart from the judge, and imposed sanctions notwithstanding a favorable judicial recommendation.

Recent case law has demonstrated that appellate courts are willing to give the Medical Board wide discretion and latitude in this area. The courts assume that the Medical Board members are acting in good faith and, as experts, know what they are doing in defining and enforcing applicable practice standards and ethical requirements. The judges, who do not consider themselves to be experts in medical matters, are very reluctant to overturn a Board disposition in the absence of a clear showing that fundamental due process procedures and rules were not followed, and that the proceeding was, therefore, fundamentally unfair. The appellate courts will not overturn a Medical Board decision, including one imposing sanctions, merely because it is different, even contrary, to the findings and recommendations of the Administrative Law Judge.

There are additional procedural disadvantages for the physician. If the Administrative Law Judge or Medical Board finds gross negligence, statutory provisions permit the Medical Board to compel the physician to pay the Medical Board's legal fees and expenses incurred in the trial. Such fees and expenses are often substantial in contested matters, often in excess of \$50,000. The prospect of such an assessment can create great anxiety and concern to a physician who is already faced with the prospect of losing his or her medical license and, in essence, livelihood. This procedural reality makes the Deputy Attorney General and the Medical Board members reluctant to compromise during any settlement negotiations. With statutory discretion and limited appellate review, the affected physician has very limited options and often must accept any terms that are offered.

What to do if you receive an inquiry

Practitioners should be aware of the potential risks and exposure associated with a Medical Board inquiry. As in medicine, the best results come from early diagnosis, appropriate management, and cooperation with the Medical Board. If a case moves from the PEC into the formal complaint stage, it has the tendency to become a "run-away train." The longer the proceedings go, the more difficult the case can be to resolve. The best strategy is to cooperate with the Medical Board members early in

the investigation and influence, to the best degree that you can, their perception of your case.

It is important to be represented early on by an experienced attorney who regularly handles Medical Board matters and is well known to the PEC members and the Deputy Attorneys General who handle licensing board matters. It is critically important to have the right advice and the right strategy, as early information and documentation is provided. Even in a serious matter, significant "damage control" can be achieved through informal negotiations. A solution can be found to almost any type of case. As the Board members serve on an appointed basis, meet infrequently, and have limited enforcement resources, there are generally options for resolving a case short of formal proceedings. The Board members are eager to settle most cases in order to avoid protracted litigation, which ties up personnel and resources.

The good news

These are difficult times for physicians and hospitals. Medical malpractice cases, managed care, increased costs, complex regulations regarding medical records, privacy, and a host of other issues are all coalescing to make the current practice of medicine a difficult and anxiety-producing experience. Most practitioners would be alarmed to learn that there is another component to this picture, that is, their license is issued by what is, in effect, a government agency and the license can be taken away or suspended because of a mistake. A physician facing a Medical Board matter can literally be facing the end of his or her career.

There is a good side to this story, however. Obviously, in a profession as important, complex, and technical as medicine, there has to be some oversight regarding who gets in, what the rules are, and who is punished. Such oversight is inevitable. The medical profession is fortunate, in a sense, that this function is performed by physicians.

In this author's experience, the members of the Medical Board (and the related agency, the Medical Practitioner Review Board, which screens disciplinary cases for the Medical Board by reviewing malpractice settlements) are, generally speaking, responsible and experienced practitioners from different specialties who understand the current practice environment and the stress and pressure currently facing the medical community. In 25 years of representing physicians before the Medical Board, I have rarely seen an unfair result. The Board must be sensitive to the public's perception that the medical profession does an inadequate job in policing its own.

The average practitioner need not fear a Medical Board inquiry. With the appropriate advice and counsel, most cases can be managed informally and without protracted or involved legal proceedings. Any physician receiving a Medical Board inquiry should first contact his or her professional liability insurance carrier to determine the scope of coverage and representation. The doctor should retain an experienced lawyer, who will make every reasonable effort to resolve the matter with as little time and associated stress as possible. The overall prognosis is usually good. ❖

Reducing Risk

A Publication on Healthcare Risk Management from Princeton Insurance

HIPAA Privacy Rule

Background

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) was enacted by Congress in part to address the need for national standards to protect the privacy of medical records and other personal health information.

HIPAA authorized the Department of Health and Human Services (“HHS”) to establish regulations to protect the security and privacy of protected health information (“PHI”). PHI includes information in medical records and other individually identifiable health information that either identifies an individual—or “there is reasonable basis to believe” can be used to identify the individual—that is maintained, received or transmitted in any form or medium, including written, electronic and oral, by a HIPAA covered entity.

A HIPAA covered entity is a physician practice or any other healthcare provider that electronically transmits healthcare information including claims, referrals and health plan eligibility or enrollment, or has another entity do so on its behalf. Health plans and healthcare clearinghouses are also HIPAA covered entities.

There are, in limited circumstances, some physicians or groups which are exempted from HIPAA privacy requirements. A provider or group may be exempt if they have less than ten full time employees and all their claims transactions made to all payors are completed on paper. OR the physician or group could be of any size, all claims transactions to all payors are made solely on paper, and the practice does not participate in Medicare. When wondering if your practice qualifies for this exemption, it is important to remember that faxed transmissions are electronic.

The regulations for privacy and confidentiality of PHI are known as the Privacy Rule. The Privacy Rule went into effect on April 14, 2003. All covered entity healthcare providers, including medical and dental practitioners, are required to comply with the Privacy Rule.

It is important to note that the privacy regulations state what must be done, not how to accomplish it. A “reasonableness” standard pervades, giving covered entities flexibility to design policies and procedures suitable for their size and needs to meet the standards. Also, HIPAA will be an ongoing factor in healthcare practice that will continue to evolve.

A physician or dental practice must assess its privacy practices on an ongoing basis and revise them as needed to remain in compliance with HIPAA. The following provides a brief overview of the regulations and some general office practice guidelines.

HIPAA Privacy Principles

The privacy principles outline the basic components and intent of HIPAA:

- **Consumer Control** — provides consumers with new rights to understand and control how their PHI is used
- **Boundaries on Use and Disclosure of PHI** — limits the use and disclosure of PHI to the minimum amount necessary to meet the purpose and requires authorization for use or disclosure of PHI that is requested for non-health purposes
 - **Use** — the sharing, employment, application, utilization, examination or analysis of PHI within the covered entity’s practice
 - **Disclosure** — the release, transfer, provision of access to, or the divulging of PHI to someone outside the practice
- **Ensure Security of PHI** — requires covered entities to adopt written privacy policies and procedures

- **Establish Accountability** — provides for civil and/or criminal penalties for covered entities that violate a patient's privacy rights
- **Balance Public Responsibility with Privacy Protections** — allows disclosures of PHI without patient authorization for certain public needs such as reporting of diseases or abuse

Consumer Rights

This federal legislation grants consumers the legal right to:

- Be informed about the provider's privacy practices
- Inspect and copy their medical records
- Request amendments and corrections to their medical records
- Restrict disclosures of their PHI
- Obtain an accounting of all non-routine uses and disclosures of PHI
- Complain to the office practice and HHS about any Privacy Rule violations

What You Need to Know and Do to Comply with HIPAA

HIPAA and Other Laws and Regulations

The Privacy Rule is intended to enhance the privacy protections that many existing laws and regulations already provide. A law or regulation that is "more stringent" than HIPAA, i.e., offers stronger privacy protections than HIPAA, continues to apply. State reporting laws, health plan reporting and information, specific exemptions determined by the secretary of HHS, and state health privacy provisions which are more stringent preempt HIPAA. Additionally, laws that regulate controlled substances, or pertain to required reporting and to licensure or certification of individuals or facilities, still apply.

Minimum Necessary Standard

The "minimum necessary" provision requires covered entities to make reasonable efforts to limit the use and disclosure of, and requests for, PHI to the *minimum necessary* to meet the intended purpose of the request. Covered entities are permitted to make their own determination of what PHI is reasonably necessary for a particular purpose. The minimum necessary standard does not apply to disclosures to other healthcare providers for treatment purposes or to disclosures made pursuant to a valid authorization as discussed below.

The Privacy Rule permits incidental disclosures of PHI that result from a permitted use or disclosure as long as the provider takes appropriate and "reasonable safeguards" to protect against inadvertent disclosure, e.g., discussing a patient's care in a separate area of office, speaking in "hushed tones." However, *erroneous or careless disclosures are not excused*. Using office sign-in sheets that do not display medical information and calling out names in a waiting area are permitted.

To comply with the "minimum necessary" standard, a physician's office must:

- Make "reasonable efforts" to limit the use and disclosure of PHI to the "minimum necessary to accomplish the intended purpose" of a request for PHI
- Have policies and procedures for its business practices that reasonably minimize the amount of PHI used, disclosed, and requested, and limit access to PHI.

Notice of Privacy Practices

Physician offices must give their patients a written notice of privacy practices that informs patients about their privacy rights and the office's privacy practices. The notice must be given to all patients before or at their initial encounter and anytime thereafter upon request.

Providers are required to make a good faith effort to obtain the patient's written acknowledgment of receipt of their notice of privacy practices. The form of the acknowledgment used is discretionary and may be as simple as having the patient date and sign or initial the cover page of the notice.

Written acknowledgment of the patient's receipt of the notice of privacy practices is *not* a prerequisite for treating a patient. However, if a signed acknowledgment is not obtained, the attempt and the reason it was not obtained must be documented in the medical record.

Uses and disclosures of PHI for the treatment, payment, and healthcare operations ("TPO") of your practice must conform to your notice of privacy practices and are permitted even if a patient refuses to give an acknowledgment. Uses and disclosures of PHI for non-TPO purposes require a signed authorization form as discussed below.

Many websites for healthcare providers have sample notices of privacy practices, including the Medical Society of New Jersey at www.msnj.org, which makes HIPAA materials available to its members. Attorney review of your practice's Notice of Privacy Practices for HIPAA compliance is always advisable.

Authorizations

A signed authorization must be obtained before PHI is used or disclosed for any purpose other than TPO, such as releasing information for a life insurance application or for use in marketing. A provider may not refuse to treat a patient who does not give authorization. A copy of all signed authorizations must be maintained in order to document the practice's uses and disclosure of PHI. Patients are permitted to request an accounting of non-routine uses and disclosures of their PHI that they have not authorized for the six years prior to the date that they make a request for an accounting.

The privacy regulations require specific elements in an authorization form:

- A description of the PHI to be used or disclosed by the covered entity
- The person who is authorized to use or disclose the PHI
- The person to whom the PHI is to be disclosed
- The purpose for the requested use or disclosure
- The date or a specified event on which the authorization will expire
- Statement that the individual has the right to revoke the authorization in writing and a description of how the authorization may be revoked
- Statement that the PHI disclosed in accordance with the authorization may possibly be redisclosed by the recipient and no longer protected by the privacy rule regulations
- Statement that the patient may not be required to sign an authorization in order to receive treatment or coverage.
- The date and signature of the patient or the patient's authorized representative with a description of the representative's authority to act on behalf of the patient.

Psychotherapy Notes Exception

Psychotherapy *notes* must be separated from the rest of a patient's medical record. Release of psychotherapy notes for *any* purpose, including treatment, payment, or healthcare operations (TPO), requires a separate authorization. Patients do not have the right to read and copy or request amendments to psychotherapy notes in their medical records unless the record is involved in litigation by the patient.

PHI of Minors

State law, including statutes, regulations and case law, governs disclosures of a minor's PHI to parents. For legal advice regarding a specific law, consult a qualified attorney.

Patient Requests for PHI

Patients have the right to inspect and obtain a copy of their PHI for as long as the provider maintains the information. A physician may only deny a patient access to the information if he/she believes that it would endanger the patient's life or safety. A patient who is denied access must be given the opportunity to have the reason for the denial reviewed by a healthcare professional who was not involved in the initial decision to deny access.

The requested information must be provided to the patient within thirty (30) days if it is stored on site, or within sixty (60) days if stored off site. The regulations also mandate that PHI must be maintained for a minimum of six (6) years. Note that the "more

stringent” New Jersey law requires that you keep patient records for a minimum of seven (7) years from the date of the last entry in the record.

Patient Requests to Amend PHI

Patients may request that their PHI be amended. A request to amend may be denied for any of the following reasons: 1) the PHI was not created by the covered entity; 2) the PHI is not part of the record available for inspection; or 3) the record is already accurate and complete. A denial of a request to amend PHI must be provided to the patient in writing, and contain specific information set forth in the privacy regulations. The provider has sixty (60) days from the date of receipt of a request to respond; a one-time only thirty (30) day extension is permitted. If an extension is needed, the provider must notify the patient in writing, stating the reason for the delay, and the date that the response to the request will be provided.

Marketing

- Definition of marketing is “to make a communication about a product or service to encourage recipients of the communication to purchase or use the product or service”
- Exceptions to the definition of “marketing” are communications about: 1) the patient’s treatment; 2) descriptions of networks and covered services provided by a covered entity; and 3) case management or recommendations for treatment alternatives and care options.
- Any communication that meets the definition of marketing and does not qualify as an exception requires an authorization prior to the use of PHI for any marketing-related purpose.
- Healthcare communications such as disease management, wellness programs, prescription refill reminders, and appointment notices are permitted.
- Authorization is required before a covered entity may send a patient any marketing materials, sell a patient mailing list, or disclose a patient’s PHI to another person for marketing purposes.

Medical Research

The Privacy Rule permits covered entities to use and disclose PHI for research purposes where specific conditions are met. The Privacy Rule defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

A covered entity may use or disclose for research purposes PHI that has been de-identified or its use or disclosure authorized by the individual. The general requirements for authorizations apply, along with several specific authorization provisions for research. A research authorization may also be combined with a consent form to participate in the research or with any other legal permission related to the research.

The Privacy Rule also allows covered entities to use and disclose PHI for research in certain circumstances, without the patient’s authorization:

- Documented Institutional Review Board (“IRB”) or Privacy Board approval based upon meeting specific criteria and requiring documentation of specific information pertaining to the waiver
- Preparatory to Research with use or disclosure only for preparation of a research protocol or similar preparatory purposes
- Research on PHI of Decedents permits use of Limited Data Sets with a requisite Data Use Agreement.

Accounting of research disclosures of PHI is not required for disclosures made with a patient’s authorization or for disclosures of the limited data set to researchers with a data use agreement. A simplified accounting of disclosures with patient authorization is permitted where at least 50 records are involved; in such cases, the accounting consists of a list of all protocols for which the PHI may have been disclosed, along with the researcher’s name and contact information.

Other requirements also apply to clinical research. Consultation with your IRB or a qualified health law attorney is recommended.

Complying with the Privacy Rule

The following outlines the necessary components that your practice must have in place in order to comply with the HIPAA Privacy Rule regulations:

1. Designate a Privacy Officer to perform the following responsibilities:
 - Oversee the HIPAA compliance program (may delegate tasks)
 - Perform a “gap” assessment to compare where your privacy practices, policies and procedures are, or need to be, in order to be HIPAA compliant
 - Develop and implement HIPAA policies and procedures and review and revise as needed
 - Document your practice’s efforts to be HIPAA compliant
 - Handle patient privacy rights complaints, employee sanctions for HIPAA privacy violations and communications with DHHS
 - Note: Sample privacy officer job descriptions are available at http://library.ahima.org/xpedio/groups/public/documents/ahima/bok2_001073.hcsp?dDocName=bok2_001073 and other websites.
2. Develop a Notice of Privacy Practices that is:
 - Written in plain, easily understandable language
 - Given to each patient before or at their initial encounter and anytime thereafter upon request
 - Posted in a prominent location in your office, and on your practice’s website
 - Compliant with the Privacy Rule regulations that specify content in areas of uses and disclosures; patient’s rights; complaints; and duties of the provider
 - Note: Sample notices are available on the internet as discussed above.
3. Develop an Authorization Form
 - Note: Sample authorization forms are available on the internet as discussed above.
4. Develop Policies/Procedures for PHI to address the following:
 - “Minimum necessary” uses and disclosures of PHI—identify staff who need routine access to PHI and the type of information they need, e.g., nurse would have access to complete medical record as opposed to a receptionist who may only need access to the information on the face sheet
 - Handling requests regarding PHI
 - Mechanisms to track and document uses and disclosures of PHI
 - Safeguards to protect PHI
 - Handling patient complaints re: practice’s HIPAA compliance
 - Dealing with privacy policy/procedure infractions by staff
5. Train Staff about the Privacy Rule
 - Training required for all staff, based on their job functions, i.e. role-based
 - Employee training was required by April 14, 2003. If not done already, provide training *as soon as possible*. New employees must be trained within a reasonable time after they start work
 - Training must be documented—dates, attendees and topics
 - Varied training formats permitted such as lunch hour discussions, self-teaching videos and printed material
 - Additional training required for all employees upon changes to HIPAA regulations or to a practice’s privacy policy/procedures
6. Identify Your Business Associates and Review Existing Contracts
 - Business Associates (“BA”) are defined as persons who provide certain functions, activities or services involving the use or disclosure of PHI *on behalf of a covered entity*, e.g., physician’s answering service, collection agency, accountant.
 - Covered entities are required to have written contracts with their BAs that contain specific safeguards to prevent misuse of PHI and require the BA to assist them with complying with their HIPAA patient rights obligations.
 - Covered entities are not liable for the privacy violations of a BA.
 - Contracts with BAs must contain specific elements. Model contract language was published with the March 27, 2002 proposed changes and is available from HHS.

Additional Information

The Privacy Rule addresses many other areas including hybrid entities, limited data sets of PHI, and de-identification of PHI. Physicians are advised to consult an experienced health law attorney for information and advice regarding the regulations that have been discussed in general terms above. Other sources of information include professional associations and the Centers for Medicare and Medicaid Services.

Much HIPAA information is also available on the internet. A list of some HIPAA resource web sites follows.

Selected HIPAA Resources

Centers for Medicare and Medicaid Services (CMS)

https://www.cms.gov/HIPAAgenInfo/01_Overview.asp#TopOfPage

CMS HIPAA page.

Office of Civil Rights (OCR)

<http://www.hhs.gov/ocr/hipaa>

OCR HIPAA page. Includes December 4, 2002 guidance on the Privacy Rule with explanations of its provisions and FAQ's; September 24, 2003 FAQs on authorizations; and 1/14/05 FAQ's on disclosing PHI in litigation.

American Medical Association (AMA)

<http://www.ama-assn.org/go/hipaa>

AMA web page for HIPAA information and related links.

US Department of Health and Human Services (HHS)

<http://aspe.hhs.gov/admsimp>

HHS HIPAA page

HIPAA Pro

<http://www.hipaapro.com/hipaa>

Site for rules, regulations, news, Q& A's, articles and free e-mail newsletter, *HIPAA Weekly Advisor*

The International Association of Privacy Professionals

<http://www.privacyassociation.org>

Site for information on personal data privacy with sample HIPAA privacy officer job description.

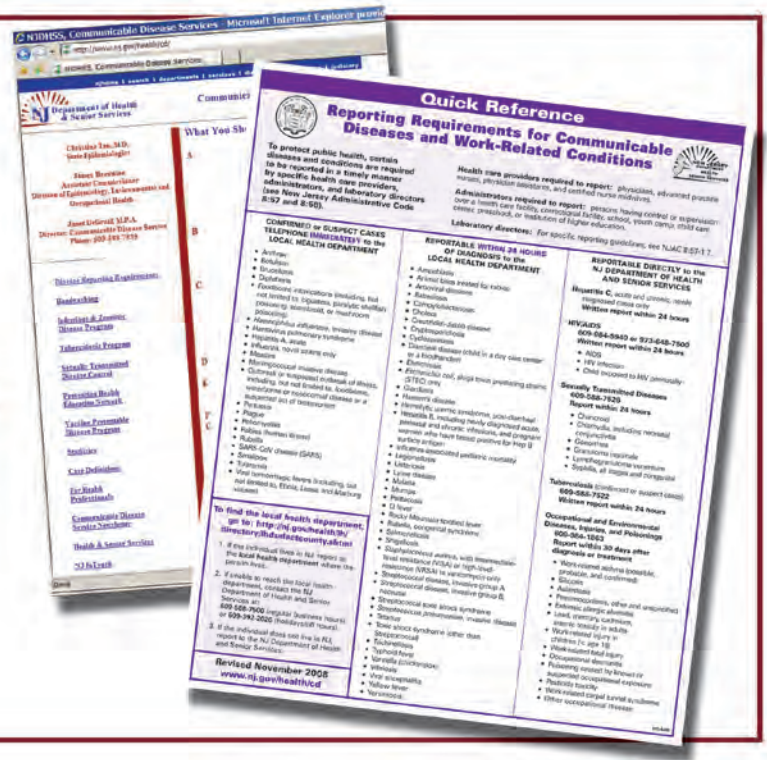
For more information about reducing risk at your practice, please view our risk management newsletter at www.RiskReviewOnline.com.

To access additional Reducing Risk documents, visit our website at www.PrincetonInsurance.com and click on "Risk Management – Publications."

This material is not to be construed as establishing professional practice standards or providing legal advice. Compliance with any of the recommendations contained herein in no way guarantees the fulfillment of your obligations as may be required by any local, state or federal laws, regulations or other requirements. Readers are advised to consult a qualified attorney or other professional regarding the information and issues discussed herein, and for advice pertaining to a specific situation.

Your Direct Link to Better Risk Management Practices

New Jersey Physicians Mandatory Disease & Injury Reporting - An Overview



By Lilly Cowan, JD, ARM, CPCU, Princeton Insurance Healthcare Risk Consultant

Physicians licensed in New Jersey are required to report, in a timely manner, a multitude of diseases and conditions, in accordance with state law. The regulations promulgated to implement the laws are intended to protect the public health, record vital statistical data and provide a link to services for residents of New Jersey.

New Jersey law mandates reporting for a wide array of issues, including but not limited to communicable diseases, work-related conditions, birth defects, elder and child abuse and drivers who have seizure disorders. It is the responsibility of the physician to notify the appropriate state agency (or local health department where the patient

resides for communicable diseases); each agency has particular reporting procedures (written, verbal), time-frames and forms to be completed.

The Department of Health and Senior Services (NJDHSS), Public Health Services Branch, Communicable Disease Service, has developed several useful documents about reporting communicable diseases. One is a brochure that explains the healthcare provider's role in reporting diseases and also provides links to related websites, available online at www.nj.gov/health/cd/documents/why_report.pdf. There is also a full-sheet "Quick Reference" that lists reportable diseases, reporting time periods, phone numbers and agencies to which to report, available at www.nj.gov/health/cd/documents/reportable_diseases.pdf. This document also comes in a magnet form and a convenient wallet-sized brochure, both of which can be obtained from your local health department. You can find your local health department at www.nj.gov/health/lh/directory/lhdselectcounty.shtml.

The Board of Medical Examiners rules reinforce the NJDHSS regulations with respect to reporting communicable diseases, cases of AIDS and infection with HIV. Failure to report these conditions constitutes professional misconduct and subjects the licensee to

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Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404

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disciplinary action by the Board (New Jersey Administrative Code 13:35-6.24).

Physicians should also be aware that NJDHSS recently proposed new rules and amendments to the reporting requirements for communicable diseases and work-related conditions. Once the rule-making process is completed, the adoption will be published in the NJ Register, and the new rules and amendments will be published in the N.J.A.C. at title 8, chapters 57 and 58. We would encourage you to read the regulations for a complete review of the requirements. Both publications can be accessed here: www.lexisnexis.com/njoal (see the December 2008 letter to physicians from NJ Acting Deputy Commissioner/Acting State Epidemiologist: www.cityofenglewood.org/health_state_letter1208.pdf).

Another resource that might be helpful is a list of toll-free numbers, organized by topic, for issues administered by the NJDHSS (www.nj.gov/health/tollfree.shtml).

The following chart presents links for your convenience in accessing more information about the various conditions for which reporting by physicians is required in New Jersey.

This material is not to be construed as establishing professional practice standards or providing legal advice. Information contained herein about reporting requirements is intended as an overview only and in no way guarantees the fulfillment of your obligations as may be required by any local, state or federal laws, regulations or other requirements. Readers are advised to consult a qualified attorney or other professional regarding the information and issues discussed herein, and for advice pertaining to a specific situation.

Condition	NJ Dept. or Agency	Online Link (for reporting forms, etc.)
Communicable Diseases <i>Includes: Animal bites, Hepatitis, HIV/AIDS, STD, TB</i>	NJDHSS, Communicable Disease Service	www.nj.gov/health/cd Local health departments in NJ www.nj.gov/health/lh/directory/lhdselectcounty.shtml
Work-related Conditions	NJDHSS - Occupational Health Surveillance Program	www.nj.gov/health/eoh/survweb
Abuse of Institutionalized Elderly	NJDHSS- Dept of Public Advocate, Div of Elder Advocacy	www.state.nj.us/publicadvocate/seniors/elder/mandatoryreportingdescrypt.htm
Birth Defects	NJHSS-Special Child, Adult and Early Intervention Services	www.nj.gov/health/fhs/sch/schr.shtml
Cancer	Cancer Epidemiology Services and Registry	www.nj.gov/health/ces/cancer_reporting_phy.shtml
Medical Conditions and Driving (Seizure disorders, etc.)	NJ Motor Vehicle Commission (MVC), Medical Review Unit	www.njmvc.gov
Child Abuse and Neglect	NJ Dept of Human Services-Div of Youth and Family Services	www.state.nj.us/dcf/abuse/how

Reducing Risk

A Publication on Healthcare Risk Management from Princeton Insurance

Subpoenas for Medical Records in New Jersey State Court Civil Actions

General Information

Physicians and other healthcare providers often receive subpoenas directing them to produce medical records and to testify regarding patient care they provided. It is important that practitioners know the purpose of a subpoena and their duties and rights in responding to one, as well as their legal obligations to protect the confidentiality of patients' medical records.

A healthcare practitioner may release medical records anytime upon receipt of a HIPAA-compliant, signed authorization from a patient or the patient's authorized representative. Records specified in the patient authorization must be produced, including reports and letters from other providers.

New Jersey State Board of Medical Examiners regulations require that a copy of the requested records be supplied within 30 days of receipt of the request and permit a charge of \$1.00 per page, with a maximum charge of \$100 and a minimum charge of \$10.00.

A subpoena is a command for a person to appear at a specified time and place to give testimony. Despite its appearance and legal language, it is not reviewed or issued by a judge, unless otherwise indicated. Subpoenas may be served in civil (non-criminal), criminal, and administrative agency proceedings.

Subpoenas are either for discovery (deposition) or trial purposes. A subpoena *ad testificandum* requires that the subpoenaed person give testimony. A subpoena *duces tecum* requires that the individual testify and produce specified documents or other evidence at that time.

Medical records may be *subpoenaed* for production only at the time testimony is to be given for a deposition or for a trial. A subpoena for drug or alcohol abuse-related treatment records generally is invalid on its own unless accompanied by a court order directing the production of the records.

Unlike a subpoena, a court *order* is issued by a judge who reviews the request and may conduct a hearing on the matter. A court order directing a healthcare practitioner to produce medical records must be followed.

The majority of subpoenas served on healthcare practitioners in New Jersey are issued in state and federal court civil actions. A subpoena issued by the Federal District Court for the District of New Jersey in a civil action has legal force in the entire state. A subpoena served by a federal court in a criminal action has legal force anywhere in the US. Federal courts outside the state of New Jersey have jurisdiction in civil actions over individuals who reside, work or do business within 100 miles of the court proceeding. Subpoenas from state courts and administrative agencies outside New Jersey are without effect in New Jersey.

Lessons from the Crescenzo v. Crane Case

Despite the official appearance and legal language of a subpoena, a prudent healthcare practitioner will not assume that a subpoena is valid and must be honored without question. Releasing a patient's medical records in response to a subpoena that is not accompanied by a signed authorization from the patient may place a practitioner in legal and professional jeopardy.

The risks of doing so are dramatically presented in the case of *Crescenzo v. Crane*, 350 N.J. Super. 531 (App. Div. 2002), *cert. den.* 174 N.J. 364 (2002) in which the appellate court ruled that physicians can be legally liable for disclosing medical records in response to an improper subpoena without the patient's consent or knowledge.

In *Crescenzo*, the attorney for a husband in a divorce action served the wife's family practice physician with a subpoena *duces tecum* for the wife's medical records which contained notes regarding treatment for depression. The subpoena did not satisfy the legal requirements for a valid subpoena, and it was not accompanied by a signed authorization from the wife permitting the release of her medical records.

No notice of a scheduled deposition was included with the subpoena. A cover letter sent by the attorney with the subpoena stated that if the doctor forwarded the medical records, there would be no need for his testimony. The attorney did not obtain an authorization from the wife for the release of her medical records, nor did he send a copy of the subpoena cover letter to either his opposing counsel or the wife.

The physician forwarded the records to the husband's attorney who later introduced them at a custody hearing as evidence on the issue of the wife's fitness as a parent.

The wife sued her physician for claims arising from the disclosure of her medical records including medical malpractice; breach of confidentiality; and violation of the physician-patient privilege. She later moved to amend her complaint to add a claim against her husband's attorney. The trial court dismissed the plaintiff's action. The Appellate Division court reversed the decision of the trial court and permitted the plaintiff to pursue her claims against both her physician and the attorney.

The appellate court specifically rejected the physician's argument that failure to comply with the subpoena would have placed him in legal jeopardy and he could have been held in contempt of court.

The appellate court noted several options available to a physician to resolve a conflict between preserving the confidentiality of a patient's medical records and complying with a subpoena for the records:

- Obtain a signed authorization from the patient
- Contact the patient or the attorney who served the subpoena
- Seek legal advice from personal counsel before responding to the subpoena

Pursuing any of the above options would have revealed the legal deficiencies with the subpoena and averted the legal claims against the physician for the disclosure of his patient's medical records.

A Valid Subpoena

A valid subpoena in a civil action in the Superior Court of New Jersey (state court) must meet the following requirements:

- Be served in person by an individual at least 18-years-old
- Name on its face the court and the title of the action, including names of the parties and the court docket number and type of action (civil, criminal or administrative)
- Be signed by either the clerk of the court or by an attorney for one of the parties, or by a party in the name of the court clerk, and list the address and telephone number of the attorney or party who issued the subpoena
- Direct properly when and where the witness is to appear:
 - Trial—anywhere within New Jersey
 - Deposition—the county in which the witness lives, works or does business in person and “only at a reasonably convenient time”
 - State Agency—anywhere within New Jersey consistent with the agency's powers
- Be accompanied by payment of a witness fee and mileage

A Valid Subpoena Duces Tecum

In addition to the general requirements for a valid subpoena, the New Jersey Rules of Court specify the requirements for a valid discovery subpoena in a civil action in the New Jersey state courts. *Rule 4:14-7(c)* which pertains to a subpoena *duces tecum* requires:

- The subpoena must compel attendance at a deposition simultaneously with the production of the subpoenaed evidence at a designated time and place
- The subpoena must state that the subpoenaed evidence shall not be produced or released until the date specified for the deposition
- The subpoena must state that if the subpoenaed witness is notified that a motion to quash the subpoena has been filed, the subpoenaed evidence shall not be produced or released until ordered by the court, or all parties to the action consent to the release
- The subpoena must be served simultaneously at least 10 days prior to the date of the scheduled deposition on the witness and all parties to the action who shall have the right to inspect and copy the subpoenaed evidence
- If evidence is produced by a subpoenaed witness who does not attend the deposition, the party who receives the evidence must notify all the other parties of the nature and contents of the evidence, and make it available for inspection and copying.

A witness subpoenaed to give deposition testimony may also be entitled to additional fees including reimbursement for out-of-pocket expenses and lost earnings.

A Note of Caution: Some attorneys disregard the court rules and attempt to improperly use a subpoena *duces tecum* to obtain medical records without paying for them. A “discovery” or “records subpoena” improperly directs a physician to produce a copy of a patient’s records and send them to the attorney’s office in lieu of attendance at a deposition. *This practice is not sanctioned by the courts.* If served with such a subpoena, contact the attorney who served the subpoena. Request that the attorney either provide a signed authorization from the patient and payment of the fee allowed by the Board of Medical Examiners regulations, or that the records be produced at a deposition or trial.

The HIPAA Privacy Rule and Subpoenas for Medical Records

Disclosure of protected health information (PHI) consistent with the scope of a signed authorization by the patient or the patient’s authorized representative is permitted by the HIPAA Privacy Rule. The Privacy Rule also permits a healthcare provider to disclose PHI in response to a court order. Information disclosed in response to an authorization or a court order must be limited to that expressly specified in the authorization or the order.

If served with a subpoena for PHI that is not accompanied by a court order or signed authorization, the Privacy Rule requires that a practitioner receive “satisfactory assurances” from the party seeking the PHI that reasonable efforts have been made to either ensure that the patient whose records are being requested has been given notice of the request, or to secure a qualified protective order as defined by HIPAA. These assurances are required to be in writing with accompanying documentation.

HIPAA defines “satisfactory assurances” as follows:

- The party requesting the PHI has made a good faith attempt to provide written notice to the individual whose PHI is being sought
- The notice includes sufficient information about the litigation or proceeding to which the requested PHI pertains to permit the person to raise an objection with the court or administrative tribunal
- The time for the person to raise objections in court or with the administrative tribunal has passed and no objections were filed, or all objections filed by the individual have been resolved and the disclosures being sought comport with the resolution.

A “qualified protective order” is defined by HIPAA as an order of a court or administrative tribunal, or a stipulation by the parties in the litigation, that prohibits the parties from using or disclosing the PHI for any purpose other than the legal proceeding for which the information was requested, and mandates the return or destruction of the PHI at the end of the litigation or proceeding.

The Privacy Rule also permits a practitioner to disclose PHI in response to a subpoena without receiving satisfactory assurances if he or she makes “reasonable efforts” to provide notice to the individual. However, as demonstrated by the ruling in the *Crescenzo* case discussed above, the New Jersey state courts are moving in the direction of requiring that a signed patient authorization to release medical records accompany a valid subpoena for the records.

It is strongly recommended that healthcare practitioners adopt a policy requiring a HIPAA compliant, signed authorization from the patient as a condition for releasing medical records requested by a subpoena. In the absence of an authorization, contact the patient or the attorney who issued the subpoena to discuss the situation and request a signed authorization.

A Few Words about Trial Subpoenas

Trial subpoenas are not covered by the requirements that apply to discovery subpoenas. The Court Rules permit *ex parte* service of a trial subpoena, meaning that notice to the other parties to the lawsuit is not required. A fact witness subpoenaed to testify at trial is paid an appearance fee and mileage, but is not entitled to reimbursement for lost wages. A healthcare practitioner who is served with a trial subpoena should contact the attorney who issued the subpoena to attempt to work out a mutually agreed upon appearance time.

If subpoenaed only to produce medical records at trial, you may be able to substitute in your place the records custodian for your office. Sometimes the parties to a lawsuit may consent to receipt of a certified copy of the original records without a court appearance by either the practitioner or the records custodian. Contact the attorney who served the subpoena to discuss these options. If the attorney who served the subpoena makes unreasonable demands on you, contact the court or personal counsel.

Conclusion

Healthcare practitioners served with a subpoena commanding them to produce medical records of their patients should *not* assume that the subpoena is valid and must be obeyed without any further thought or action on their part.

Where a proper signed authorization from a patient whose records are subpoenaed accompanies the subpoena, the healthcare provider may produce the requested medical records, consistent with the scope of the authorization, without fear of violating the law, medical ethics, or professional licensing standards.

Absent a proper signed authorization from the patient, the prudent practitioner will contact the patient or the attorney who served the subpoena to discuss the situation and request an authorization. If no authorization is provided, or if the subpoena does not appear valid, the subpoenaed practitioner should contact his or her personal attorney or Princeton Insurance Company for advice and guidance before producing a patient’s confidential medical records.

For more information about reducing risk at your practice, please view our risk management newsletter at www.RiskReviewOnline.com. To access additional Reducing Risk documents, visit our website at www.PrincetonInsurance.com and click on “Risk Management – Publications.”

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RELEASING RECORDS: Reduce the Confusion

Sharon L. Koob, RN, BSBA, CPHRM, ARM
Princeton Insurance Healthcare Risk Consultant

It's another busy day in your practice and your incoming mail includes requests for medical record copies for three of your patients. The first request is a hand-written note from a patient; the second is a demand from a copy service, asking on behalf of a worker compensation carrier who is handling a patient's injury coverage; and the third is a three-page document from an attorney who indicates that their office represents another of your patients. None of these documents look alike; how do you know which ones to comply with, and exactly what information can you release?

First, let's address the question of whether to release records.

The New Jersey Board of Medical Examiners' regulations (13:35-6.5(c))¹ and the federal government's HIPAA statute give patients the right to a copy of their own medical information, except in cases where the physician feels that subjective information contained in the record could cause the patient emotional or physical harm. Situations in which medical information could cause a patient to do harm to themselves, or suffer serious emotional trauma, are unusual; so in most cases your patient has a right to a copy of their records.

You may offer to write a summary of the record for the requesting party. This is not done frequently because physicians rarely have the time to write this summary; and requestors usually want the actual record copy. However, it can be helpful in situations where the record covers many years of care, and copying would represent an excessive use of time and material resources.

If the patient authorizes it, a copy of their record may also be given to their representative. This representative could be a family member, an attorney, or another person designated by the patient.

How is a patient's medical information appropriately released?

HIPAA refers to the patient's medical information as Personal Health



Information, or PHI; and requires that each practice have specific policies and procedures on appropriate release of this PHI. All staff in the practice must, by HIPAA regulation, be trained in this release policy so that a patient's confidentiality is not breached unintentionally or without authorization. There are situations when PHI may be released without obtaining the patient's specific authorization: record information can be released for treatment purposes, as in sending copies to a physician you have asked to consult; information can be released to providers so that you may be paid for your services; and information may be used for the healthcare operation of your practice. Information used for the healthcare operation of your practice could be data extracted from records for quality management and similar studies. Some disclosure is also required by law. For instance, PHI may be released to a coroner for the purpose of identifying a decedent or determining the cause of death; a practitioner is required to report certain communicable diseases, gunshot wounds, or abuse (child and elder); and records are also released for peer review.

Other release of PHI must be officially authorized by the patient or their surviving representative²; and HIPAA is clear in its description of valid authorizations. According to HIPAA regulations an authorization must:

- Be in writing
- Be in specific terms
- Be in plain language
- Include language which gives the authorizing party the right to revoke the authorization in writing at any time
- Identify:
 - ◆ who wishes the information disclosed
 - ◆ to whom the information is to be disclosed
 - ◆ the expiration date of the authorization³

Authorization does not automatically free an office to release certain private information. Forms should have areas wherein the patient or representative can specify whether to release information on HIV, psychiatric issues,

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Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404

www.RiskReviewOnline.com

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drug/alcohol issues, or sexually transmitted diseases. If these areas are not specifically referenced in the release form, the office should contact the patient to obtain explicit permission or denial for the release of any of this sensitive information.

Occasionally, a patient or their representative family member may request record copies verbally. This request may come in a phone call or in person. To prepare for this situation, each office should have a HIPAA-compliant authorization form available for the requesting party to complete.

As required by HIPAA statute and noted earlier, all office staff should be trained to understand the patient's right to their records; training should also include staff awareness of the authorization form's availability. A staff member's comfort in this situation will help reassure patients of their right to their records, and assure them that the office will assist them willingly. If the record is requested by a member of the patient's family, however, the office has both a right and a responsibility to ascertain whether this family member is the patient's designated representative. If the patient is in charge of their own affairs, then the patient must sign the authorization.

Your office also has a right, by New Jersey statute, to charge a reasonable amount for record copying. According to statutory language, the charge can be "no greater than \$1.00 per page or \$100.00, whichever is less."⁴ If the

record is less than 10 pages, you may charge up to \$10.00 to cover your costs; and if you are writing a summary, you may not charge any more than the record itself would have cost (according to these rules).

If the requestor is asking for copies of items that cannot be duplicated in a regular copy machine (such as x-rays), you may pass on what you were charged for obtaining the copies. You may add an administrative fee of \$10.00 or 10 percent of the cost of reproducing the items (whichever is less). This charge for special items may not be more than the fee for the rest of the copying.⁵

Princeton Insurance provided an example Authorization Form in the Physician Practice Toolkit. This form has recently been updated and can be found in the Confidentiality of Patient Information section of the toolkit, located on the secure Princeton website.

Whether using the Princeton example form, a document the office has developed for itself, or just trying to interpret a lengthy attorney release, office staff should be aware of what information is necessary in a HIPAA-compliant authorization. An authorization is comprised of three groups of information: data (names, dates, times), authorization specifics, and patient rights information. Following is a checklist utilizing these group headings. You can use this checklist to quickly review any type of written request:

Data

- Patient Name
- Previous Name of Patient
- Date of Birth
- Patient Signature
- Legal Representative's Signature
- Relationship of Legal Representative to Patient
- Printed Name of Signatory
- Signature Date and Time

Authorization Specifics

- Release Authorized for:
 - All records
 - Healthcare information related to the following treatment or condition: _____
 - Healthcare information from [date] to [date]
 - Other information (x-rays, billing, etc.) specified here: _____
 - Date range for other information requested: [date] to [date]
- Specific Release Granted For:
 - HIV (AIDS virus) information
 - Psychiatric disorders/mental health issues
 - Sexually transmitted diseases
 - Drug/alcohol use and/or treatment

- Release Records To (Information must be specific)

- Reason for Authorization

- Patient's request
- Other (be specific)

- Authorization Ends

- On (specific date)
- At the occurrence of a specific event/s (specify)
- In 90 days from date of signature

Description of Patient Rights

- Do Not Have to Sign to Get Treatment or Benefits

- Do Have to Sign if:

- Taking part in a research study
- Receiving care for the purpose of creating health information for a third party

- Have the Right to Revoke This Authorization

- Would need to fill out a revocation form, or
- Would need to write a letter to the practice, requesting revocation

- Revocation May Not Be Possible if Authorization Was for the Purpose of Obtaining Insurance

- Healthcare Information Released by Authorization is No Longer Protected by Privacy Laws

Maintaining a good relationship with your patients and their families is important to your practice. Record requests can be uncomfortable for both the patient and the staff. Understanding your patients' and your rights and responsibilities will help preserve the goodwill that you and your staff have worked so hard to achieve. ❖

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Resources:

¹ New Jersey Office of the Attorney General, Division of Consumer Affairs, State Board of Medical Examiners, Statutes and Regulations, <http://www.state.nj.us/lps/ca/bme/bmelaws.pdf>, April 2006, page 182.

² "What Do I Need to Know About Releasing Copies of Medical Records of Deceased Patients in My Practice?" *Risk Review: a Publication of Princeton Insurance*, Archives, Ask the Expert, January 2007, <http://www.riskreviewonline.com/RiskReviewOnline/Archives/Jan2007/AskTheExpert/>.

³ U.S. Department of Health & Human Services, HHS.gov, Health Information Privacy, Summary of the HIPAA Privacy Rule, Authorized Uses and Disclosures, <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html>.

⁴ New Jersey Office of the Attorney General, Division of Consumer Affairs, State Board of Medical Examiners, Statutes and Regulations, <http://www.state.nj.us/lps/ca/bme/bmelaws.pdf>, April 2006, page 182-183.

⁵ Ibid. ❖

Psych Records Requests

By Russ Pride, MA, CPHRM

Princeton Insurance Healthcare Risk Consultant

Psychiatrists sometimes ask what they are obligated to provide when receiving a request for records. Often these records contain sensitive (and potentially harmful) information about the patient or others (such as spouse, parent, sibling, offspring) if disclosed as part of the fulfillment of the records request.

A request for records can present a quandary for the psychiatrist, psychologist or psychotherapist

Note: "Medical records" hereafter will be used to encompass mental health and behavioral health information, in addition to medical data, such as results (for labs, xrays, mental assessments and personality tests), prescriptions, consults, and referrals. Likewise, from this point forward, "patient" will be construed to include the patient (for medical treatment) or the client (for psychotherapeutic treatment).

The following are issues to consider when a request is received.

Step 1: The rationale for the request

While requests can be made for a variety of reasons, usually they are made to satisfy one of three principle needs:

- The patient is moving away from the area in which you practice and wants to take the records with him/her in order to make available to the new provider a summary of care rendered while working with you.
- Another party – acting on the patient's behalf – requires information contained in the patient's record, such as:
 - the Social Security Administration (to determine eligibility for disability benefits)
 - Worker's Compensation (to assess or verify the emotional and mental impact of injuries sustained on the job)



- insurance carriers, managed care entities or a TPA (third party administrator) for reimbursement
- other healthcare providers or healthcare systems (such as hospital, clinic or rehabilitation facility) to provide ancillary or specialized care to your patient
- An attorney representing the patient, the patient's guardian or some other special interest

Step 2: Making the proper request for release of information

In any of the above-mentioned instances, the request should:

- be in writing
- include a HIPAA-compliant authorization signed by the patient or the patient's legal guardian
 - "Legal guardian" may be a parent – in those cases where the patient is a minor – or a court-appointed guardian for those individuals deemed incompetent (for minor children 14 years and older, signatures of both the minor patient and the parent/guardian are recommended).
 - The authorization should be time-specific (e.g., from 01-01-2004 through 12-31-2006).

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Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404

www.RiskReviewOnline.com

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- Unless otherwise noted, the authorization should be regarded as “in effect” for one year from the date of execution, but not longer .
- And finally, there should be a caveat to the effect that the authorization is revocable immediately upon receipt of a written request by the patient or the patient’s guardian to do so.

Be vigilant regarding the details. Information with respect to a patient’s drug and alcohol treatment, HIV/AIDS diagnosis and treatment, or mental health diagnosis and treatment requires an authorization that is specific in the identification and authorization to release information for each of these areas. The sample HIPAA-compliant authorization to release form that is available for downloading from the Physician Office Practice Toolkit, found on our secure website at [princetoninsurance.com](http://www.princetoninsurance.com),* provides a box that needs to be checked for each of the areas referenced above. Make certain the information you release is the information requested, and be sure to maintain the request in the patient’s record.

If you have other questions with regard to HIPAA, refer to Princeton’s *Reducing Risk* publication, “HIPAA Privacy Rule,” found on our website at [princetoninsurance.com](http://www.princetoninsurance.com)* (click on the “Healthcare Risk Services Information” button) or copy and paste this address directly into your internet browser: http://www.pinsco.com/downloads/reducing_risk/HIPAA.Privacy.Rule.Alert.May05.pdf

Step 3: What information to provide to satisfy the request

For the lion’s share of records request, the information that will satisfy the request includes:

- Dates of treatment (beginning date, dates of service and last date of contact, if applicable)
- A summary of the treatment, including
 - the treatment plan goals

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- patient adherence to that plan
 - an indication as to how successful the treatment plan was in meeting treatment goals
 - an explanation for how the treatment plan was revised during the treatment period and for what purpose(s)
- Likewise, if prescribing medications, a list of meds should be included, along with any labs required to monitor toxicity levels, efficacy dosages, and so on

Information that is deemed to be potentially injurious to that individual’s overall health and welfare may be withheld from certain requests for records (usually those made directly from the patient).

An inquiry frequently accompanying our insureds’ questions about the release of information relates to “costs.” For both psychiatrists and psychologists, the regulations pertaining directly to record requests and costs are found at the following websites:

For licensed psychiatrists, the prevailing regulations concerning requests for records are found in the New Jersey State Board of Medical Examiners Regulations, §13:35-6.5 (c). http://www.njconsumeraffairs.gov/laws/BME_Regs.pdf

For licensed psychologists and psychotherapists, the corresponding regulations are found in the New Jersey Board of Psychological Examiners §13:42-8. <http://www.njconsumeraffairs.gov/laws/psychologyregs.pdf> .

Step 4: Getting the information to the requestor

If you are not doing so already, consider implementing and maintaining a sign-out sheet specifically for the purpose of tracking the following information related to a request for records:

- the date on which the records were picked-up
- the printed name and the signature of the patient or the patient’s designee picking up the records

If the patient is unable to pick up the records in person, arrangements should be made *in advance*, permitting the patient’s designee to obtain the records in the patient’s absence.

The patient representative or designee should present written proof that s/he is acting at the behest of the patient (a note signed by the patient). This document should include the following:

- identify by name the patient’s designee
- require photo ID as proof of the individual’s identity, if not your patient
- make a photocopy of this ID and maintain in the medical record attached to the patient’s request for records

If not being picked up in person by the patient or the patient’s designee (such as in the case of an attorney request or court order), the information in the record may be delivered via certified mail with a return receipt requested (which is to be maintained in the patient’s medical record).

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Exercise caution when faxing sensitive, behavioral health-related information presents another potential risk exposure (such as a breach of confidentiality, violation of privacy or violation of HIPAA regulations). Special care must be exercised if an urgent situation mandates the use of facsimile technology in order to transmit patient information.

- Prepare a cover page which explicitly states the confidential nature of the fax and details the steps to be followed in the event the fax ends up in the hands of a recipient other than the one intended by you.
- Prior to transmission, call the receiver to verify the receiving fax machine is operative and to alert the party that you are ready to transmit.
- Once the transmission is complete, save a printed copy of the transmission receipt and also call the intended recipient to verify receipt of the information you faxed. Make a note of this call on the transmission receipt page and keep with the patient's record.

And finally, do not attach patient information to an email or send patient information in an email. The chances are too great that patient confidentiality and privacy may be compromised or violated if your computer or your recipient's computer does not have the appropriate firewalls in place to guard against and thwart malicious attempts by hackers to gain access to the information in your possession.

To summarize

Most record requests can be handled routinely as prescribed by state and federal regulation. A request should be submitted in writing by the patient or the patient's representative and include a fully executed, HIPAA-compliant Request for Records form bearing the patient's signature.

In most instances, a summary of treatment is acceptable in lieu of a photocopied complete record.

In those instances where a request is out-of-the-ordinary (such as a court demand or a request from a government agency), and you have questions about how to respond, contact the Princeton Insurance Healthcare Risk Services Department at 1-866-Rx4-RISK. We'll be happy to assist you. ❖

**You must be a registered user at PrincetonInsurance.com to access the insured secure site, where the Physician Office Practice Toolkit and other valuable resources can be located. If you need help registering, call our Help Desk at 1-800-334-0588. ❖*

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Reducing Risk

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Risk Alert – “Apparent Authority”

ESTATE OF CORDERO v. CHRIST HOSPITAL

Appellate Division, A-1289-07T1, approved for publication October 29, 2008.

Issue: Was the hospital vicariously liable for Dr. Z's negligence, because she was its apparent agent, under a theory of “apparent authority”? To avoid liability, what actions can a hospital take to make a patient aware that a particular physician is not an agent of the hospital?

Facts

On Sept. 14, 2003, R. Cordero, a 51 year old insulin-dependent diabetic, sought care at the Christ Hospital ED for vomiting. She was diagnosed with renal failure, admitted, and underwent surgery on Sept. 22, to implant a catheter that would facilitate ongoing dialysis. Dr. Z was the anesthesiologist on-call that day, and was assigned to provide anesthesia services during Cordero's procedure.

Dr. Z was a member of defendant Hudson Anesthesia Group, whose members provided anesthesia services at Christ Hospital under a contract. Dr. Z introduced herself to Cordero just before surgery, but had no interaction with Cordero's family. During the surgery, after the catheter was implanted without incident, the patient's blood pressure and heart rate dropped; Dr. Z was unable to stabilize the patient, necessitating calling a “Code.” The Code Team resuscitated Cordero, but she suffered brain damage and never regained consciousness. She died 3½ years later.

Analysis

Plaintiffs (estate and husband of patient R. Cordero), appealed from the trial court's order granting summary judgment in favor of the hospital. Plaintiffs asserted that the evidence was adequate to permit a jury to find that the Hospital was liable for Dr. Z's negligence under a theory of “apparent authority,” which applies when a “hospital, by its actions, has held out a particular physician as its agent and/or employee and ... a patient has accepted treatment from that physician in the reasonable belief that it is being rendered in behalf of the hospital.” (See Basil v. Wolf, 193 N.J. 38, 67 (2007), approving Arthur v. St. Peters Hosp., 169 N.J. Super. 575, 581 (Law. Div.1979)).

The Appellate court in Cordero, reversing the trial court's dismissal of plaintiffs' claim, held that “when a hospital provides a doctor for a patient, and when the totality of the circumstances created by the hospital's action and inaction would lead a patient to reasonably believe that the doctor's care is rendered on behalf of the hospital, then the hospital has held out that doctor as its agent.” Furthermore, “when a patient accepts a doctor's care under such circumstances, the patient's acceptance in the reasonable belief that the doctor is rendering treatment on behalf of the hospital may be presumed, unless rebutted.”

The court identified several circumstances to consider in evaluating whether the hospital's conduct would lead a similarly situated patient to believe that a particular doctor was or was not acting with authority in behalf of the hospital.

- Whether the hospital supplied the doctor;
- Nature of medical care and whether the specialty, like anesthesia, radiology or emergency care, is typically provided in, and an integral part of medical treatment received in a hospital;
- Any notice of the doctor's independence from the hospital or disclaimers of responsibility;
- Patient's opportunity to reject the care or select a different doctor;

- Patient's contact with the doctor prior to the incident at issue;
- Patient's special knowledge about the doctor's contractual arrangement with the hospital;

The court assessed the adequacy of the hospital's indications of authority, under the standards it had set forth. Based on all the evidence, the court concluded that the hospital had created a "misimpression" of agency and then did nothing to correct it. (e.g., The hospital did not issue a disclaimer of responsibility for Dr. Z's actions, did not require Dr. Z to issue a disclaimer of agency, offered no evidence that the patient had had an opportunity to reject Dr. Z and choose another doctor, no evidence that the patient had special knowledge about the hospital's relationship with Dr. Z.) Consequently, plaintiffs were entitled to a rebuttable presumption that Cordero accepted Dr. Z's care in a reasonable belief that Dr. Z's care was provided in behalf of the Hospital.

Risk Reduction Strategies:

In light of the Court's ruling in Cordero, we would encourage hospitals to consider implementing the following actions:

- Insert a disclaimer of responsibility (for care/services to be provided by certain physicians or groups), in ED consent forms, hospital admission agreements, etc. However, such disclaimers need to be conspicuous and written in language that the patient can understand, or they will probably not be effective.
- Signage may be useful, when located in patient and public areas in the facility. For example, they may be placed in waiting areas, the ED, Radiology and other areas. Signs need to state that certain physicians are not employees, but rather provide their services as independent contractors. (Appropriate to status of physicians in each facility).
- Signage can be reinforced by having the physicians wear identification badges, indicating the practice/group with which they are associated.
- We would also recommend giving a copy of the notice, as stated in the signs, to all patients (or family members/guardians as appropriate) and, if possible, have the patient sign that he/she has received it.
- Hospitals should take care that their web sites accurately reflect the status of and relationship with the physicians providing care within the organization.

For more information about reducing risk at your practice, please view our risk management newsletter at www.RiskReviewOnline.com. To access additional Reducing Risk documents, visit our website at www.PrincetonInsurance.com and click on "Risk Management – Publications."

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Management & documentation of after-hours calls

*Tools to assist
with documenting
after-hours calls*

The Risk: The failure to properly handle and document after-hours telephone calls can adversely affect patient care and lead to potential liability exposure for the physician. Further, should a telephone conversation become an issue in a lawsuit, and it is not documented, the jury is less likely to believe the recollection of the physician, who receives a large number of calls on a daily basis.

Recommendations:

1. Establish a system to respond to after-hours telephone calls. This system should include a consistent process to help ensure that all after-hours calls are responded to in a reasonable time frame and are documented in the patient's medical record.

2. Medical record documentation of after-hours calls should include the following:

- Patient's name
- Name of the caller, if different than the patient, and the individual's relationship to the patient
- Date and time of the call
- Reason or nature of the call, including a description of the patient's symptoms or complaint
- Medical advice or information that was provided, including any medications that are prescribed.

3. If the patient's condition warrants the prescription of medications, it is important to inquire about and document any medication allergies, as well as any other medications the patient may be taking.

4. When providing after-hours coverage for another physician's practice, a process should be in place to ensure that documented telephone conversations are promptly forwarded to that practice.

5. If you use an answering service, it should be periodically evaluated for courtesy, efficiency, accuracy, and proper recordkeeping.

Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404

www.RiskReviewOnline.com

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6. The use of answering machines for after-hours calls is not recommended for the following reasons:

- There are no safeguards in the event of an answering machine malfunction.
- Patients do not always understand that no one will call back, even if this is stated in the message, due to limited English capacity, anxiety, or other impediments.
- If, as a last resort, an answering machine must be used, the message should be brief and simple: "The office is now closed. Please go to the emergency department if you believe this is an emergency." ❖

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- Risk Tool for Your Practice -

PATIENT TELEPHONE CALL RECORD

Courtesy of:
Princeton Insurance
PARTNERSHIP. PREVENTION. PROTECTION.

Patient Telephone Call Record

Date:	Time:	am/pm	Patient Name:
Current Meds:			Age:
Caller:			Allergies:
Reason for call:			Pharmacy:
			Pharmacy Phone:
Recommendations:			
Patient's Physician: (If different)			
Your signature:			

Place in patient's records

Princeton Insurance has developed phone message pads that physicians can carry with them, use to write brief notes and affix to patient records upon returning to the office using the adhesive backing.

To obtain your own supply of patient telephone call record pads, please call the Risk Resource Line at 1-866-RX-4RISK. ❖

The failure to properly handle and document after-hours telephone calls can adversely affect patient care and lead to potential liability exposure for the physician.

Documenting Phone Calls - physician office practice toolkit resources to assist you

By Amy Slufik

Physician Risk Representative, Princeton Insurance

and Jeffrey Broomhead

Physician Risk Representative, Princeton Insurance

One key area of record-keeping that is often overlooked is the documentation of patient phone calls, whether during or after of fice hours. When dealing with patient phone calls in the of fice, it is important to have the patient's chart available to review prior relevant clinical information and document current communication. When calls are received out of the of fice, especially at an inconvenient moment, such as during the movies, dinner at a restaurant, or in the middle of the night, it is also important to have a process in place to capture timely documentation of the communication. Adequate phone call documentation reflects clinical decision-making, supports actions taken, and provides for safe continuum of care.

The following claim analyses highlight the lack of documentation of patient phone calls, which played a significant role in the defense of the claim. In each of these cases, the claimant prevailed and significant indemnity payments were made on behalf of the defendant physicians.

Case 1

Claimant was a 77-year-old female who alleged negligent post-operative management of cataract surgery, resulting in permanent loss of vision in her left eye.

Case Summary

(Day 1, Monday) The patient had surgery by Dr. 1 to extract the cataract of her left eye.

(Day 5, Saturday) Patient experienced white spots in vision of left eye and called Dr. 1's office after hours. Dr. 2 was on call and responded to the patient. Dr. 2 testified that the patient only complained of cloudy and hazy vision (no complaint of white spots). Dr. 2 advised the patient that this was not an emergency and it could wait until her next scheduled appointment in two days. Dr. 2 did not examine the patient or contact Dr. 1 regarding the patient's complaint. Dr. 2 did not document any notes of the phone conversation with the patient.

(Day 7, Monday) Patient was seen at Dr. 1's office for next scheduled appointment and on physical exam was found to have reduced visual acuity. Patient informed Dr. 1 she had white spots in vision since Day 5. Dr. 1 diagnosed the patient with Endophthalmitis and immediately referred her to a retina/vitreous specialist, who saw her on the same day and agreed with Dr 1's diagnosis. The specialist performed a Pars Plana Vitrectomy to administer antibiotics.

(Day 19) Dr. 1 was continuing to follow the patient. Her left eye visual acuity was 20/400.

Outcome

(Three years later) Patient was seen by Dr. 3 and was found to have Ischemic optic atrophy of the left eye, resulting in significant and permanently reduced visual acuity of the left eye.

Risk Issues

There was a question of what exactly the symptoms were that the patient identified to Dr. 2. Documentation of the phone call and the specifics of the call, including the complaint and advice given, could have clarified this in the medical record and prevented a claim from being filed, by supporting Dr. 2's testimony.

Dr. 2 did not notify Dr. 1 of the patient's phone call. Covering or on-call physicians should advise the covered physician about any patient contacts

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Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404

www.RiskReviewOnline.com

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or treatments rendered during the coverage period at the time of the handoff, and document the discussion.

Conclusion

Comprehensive and concise documentation serves first to promote a continuum of care; in addition it demonstrates the process of critical thinking upon which doctors base their actions. It is also important to communicate with the patient's physician when covering for another physician to ensure everyone involved in the patient's care is kept informed.

Case 2

Claimant was a 28-year-old female alleging negligent performance of answering service and office staff, resulting in delayed treatment.

Case Summary

(Day 1) 28-year-old female patient presented to Emergency Department with fractured ankle. Dr. 1 attempted a closed reduction of the fracture and was unsuccessful. Patient was admitted for surgery on the following day .

(Day 2) Patient had ORIF, with plates and screws, and a cast applied by Dr. 2. The patient was discharged to home the next day with instructions to follow up with Dr. 1 in one week.

(Day 6) Patient called Dr. 1's office and spoke to answering service. She requested to speak with Dr. 1 secondary to a "pop" she felt, complaints of pain and that the cast was loose. She also needed a prescription for pain medication at a pharmacy close to her home. According to the claimant's testimony, the answering service was rude and inappropriate with her and stated that the on-call doctor would call her . The on-call doctor never called the patient. The answering service records did not reflect patient's need to speak with the on-call doctor, just that the patient wanted to pick up drug samples at the doctor's office.

(Day 11) Patient called Dr. 1's office four times requesting to speak with the doctor with complaint of pain and need for pain medication, as well as a new foul-smelling odor emanating from the cast. The office made an appointment for the patient to see the doctor in four days and told the patient that the doctor would not fill any prescriptions after hours and that the doctor would not be contacted. The office had no record of the phone call.

(Day 12) Patient called Dr. 1 again with complaint of severe pain and foul odor. The doctor's office had no record of this call. The patient had phone bills proving all phone calls made to the doctor's office.

(Day 15) The patient went to Dr. 1's office for scheduled appointment where it was found that she had a significant infection of the ORIF site.

The patient informed Dr. 1 of the phone calls she made to the answering service and office. The patient was immediately admitted for surgical debridement and skin flap.

Outcome

The patient was discharged to home two weeks later with a PICC line and visiting nurse services. The wound healed with significant scarring, permanent numbness and weakness.

Risk Issues

There was inadequate policy and protocol for both the answering service and the office staff with regard to triaging patient phone calls to determine which ones require immediate attention; there was also no policy or protocol requiring documentation of calls.

There was incomplete and inconsistent documentation of phone conversations between the patient and the answering service, as well as the office staff.

Conclusion

A clear policy and protocol for both the answering service and the office staff should be developed for conducting telephone assessments and triage, and to document and communicate patient questions and concerns. Both staff and the answering service compliance should be routinely monitored.

Summary

Documentation is a critical part of patient care as it serves to memorialize the doctor's thought process, the patient's state of health, and is the foundation for defense of a medical malpractice claim. In some cases, concise documentation will prevent a claim from being filed. Lack of and incomplete records can aid the plaintiff's attorney in demonstrating negligent care, even when standards of care are met.

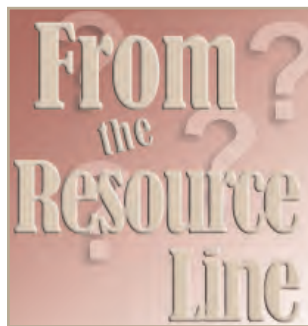
The Princeton Insurance Physician Office Practice Toolkit was developed for and provided to office-based physicians. It includes a convenient off-hours patient telephone call record pad, which is designed to improve documentation of out-of-office patient phone calls. The toolkit also contains a sample telephone call log for in-office use.

To request additional patient telephone call record pads, please call our Risk Resource Line at 1-866-Rx4-Risk. ❖

From the Resource Line

In each publication of Risk Review, an outside guest or a member of our team of expert risk management and loss prevention consultants will answer a question from our Risk Resource Line. If you are concerned about a risk management or safety issue at your practice or facility, let us know and we may answer it in a future issue. Our number is 1.866.Rx4.RISK.

By Lilly Cowan, JD, ARM, CPCU
Princeton Insurance Healthcare Risk
Consultant



Question: What is the legal exposure when a patient's chart is missing, incomplete or destroyed?

Answer: Missing patient records plague your private practice, you waste time looking everywhere for a chart that isn't in your file room or you attempt to review a patient's history and lab report, but the documents are not in the chart. While these seem to be common scenarios in many medical practices, the consequences may be more serious than you realize.

The medical record serves many purposes, with the primary one being to plan for patient care and provide continuity in information about the patient's medical treatment. As a permanent record, it informs other healthcare providers about the patient's health history, including illnesses and impairments.

The record is used to perform quality and peer review evaluations by internal and external entities such as state licensing and regulatory agencies. For hospitals, the medical record is an important element of the accreditation process (e.g., Joint Commission). In fact, the safety of patients, promptness of reimbursement and the outcome of litigation all depend on the adequacy, completeness, timeliness, legibility and accuracy of medical records.

New Jersey law requires physicians ("licensees") to prepare a contemporaneous, permanent professional treatment record for each patient. All treatment records, bills and claim forms must accurately reflect the treatment or services rendered. Treatment records must be maintained for seven years from the date of the most recent entry.

Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404
www.RiskReviewOnline.com

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The regulations outline the categories of data that should be documented in the record (NJAC, Board of Medical Examiners' General Rules of Practice; § 13:35-6.5, b).

This section of the rules also includes criteria for maintaining computerized records and requirements for access to or release of information, confidentiality and transfer of records (the latter when licensee is planning to cease practice for more than three months).

Changes can be made

In general, appropriate and timely changes to a medical record are not a significant problem in litigation; however, unexplained alterations or late entries will attract attention.

New Jersey law expressly allows corrections and additions to be made to existing records, as long as each change is clearly identified as such, dated and initialed by the licensee (NJAC § 13:35-6.5,b, 2).

Criminal sanctions for destruction

Criminal penalties are authorized if a medical record is intentionally destroyed to commit a fraudulent act. It is against the law in New Jersey (fourth degree crime) to destroy, alter or falsify medical records with the intent to deceive or mislead anyone. This includes but is not limited to a diagnosis, test, medication, treatment or psychological test concerning a patient (NJSA § 2C:21-4.1; NJ Code of Criminal Justice). This offense was added as part of the Professional Medical Conduct Reform Act of 1989.

The state must prove four material elements: (1) that the record relates to the care of a medical, surgical or podiatric patient; (2) that the defendant destroyed, falsified or altered the record; (3) that the defendant did this purposefully; (4) that the defendant had a purpose to deceive or mislead a person as to the information.

Attempts to change the record will harm the defense, especially if the patient obtained a copy of it before it was altered. If the plaintiff can show that the record was changed without justification, the credibility of the whole record may be destroyed.

"Missing" Record

Ultimately, the medical record serves as the basis for your defense in a malpractice suit. When a record (or part thereof) is missing, it will be difficult, if not impossible, to prove that the physician provided a certain type of treatment or otherwise acted appropriately. Court decisions have shown that if you can't produce the documentation, and can't reasonably explain why the record can't be found, then your version of events will be suspect. Thus, even if you provided appropriate medical care, if you can't produce the documentation, then it didn't happen.

Operative or procedure reports or discharge summaries dictated too long after an event may handicap other physicians who care for the patient or who are on-call for another physician. Serious diagnostic and treatment errors have resulted in injury and litigation because these reports were not available. And, as with altered records, reports dictated too long after a complication is identified lack credibility, whether or not the complication resulted from negligence.

Spoliation of Evidence

The law implies a duty to preserve evidence in your possession that is likely to be

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used in litigation. Spoliation of evidence is a legal term for the "intentional destruction, mutilation, alteration or concealment of evidence" (Black's Law Dictionary, 1409 [7th ed. 1999]). The party responsible for the loss of evidence can suffer severe consequences. The trial judge has wide discretion in evaluating the impact of the missing evidence in each case, and determining an appropriate penalty.

In a well-known New Jersey malpractice case in which the patient/plaintiff lost (due to materiality of the missing evidence), the judge ruled that the plaintiff could bring a second claim against the physician/defendant for fraudulent concealment. Further, the judge held that the plaintiff was entitled to damages amounting to what could have been recovered in the underlying case, had the evidence been available for the trial, plus punitive damages for defendant's intentional wrongdoing (*Rosenblit v. Zimmerman*, 166 N.J. 391; 2001).

Other penalties that courts may impose include monetary sanctions, directed verdict against the party responsible for the spoliation and various jury instructions (e.g., jury can infer that the spoliation was fraudulently destroyed because it would have been damaging to your position.)

Recently, the term "spoliation" has been broadened to include inadvertent or negligent loss of evidence. Negligent spoliation can occur several ways. For example, medical records or imaging films might be inadvertently filed under an incorrect patient name. In this situation, the consequences for the responsible party are less severe.

Destruction due to catastrophe

Paper records can be destroyed (or severely damaged) as a result of a catastrophic event such as fire or flood; electronic records can be destroyed or their security and integrity can be compromised as a result of a computer malfunction or major power failure.

Certainly, the loss of patients' medical records would disrupt your practice operations and create significant problems for some patients. However, beyond the business (recovery operations, billing issues) and follow-up issues related to trying to take care of patients without their medical records, it is unlikely that you would be held liable for the loss of these files, under the spoliation theory. In order to bring a valid claim, a patient would have to prove that the physician or someone on the practice staff negligently caused the event that led to the records' destruction (e.g., employee smoked in the records area and accidentally started a fire).

Handling & maintaining records

As a physician in an office practice, you have a responsibility to maintain and preserve medical records. Consider the following strategies for developing policies, procedures and systems for handling your medical records.

Retention of records: Follow state and federal requirements for retention of records (In New Jersey, seven years minimum). Keep at least as long as the statute of limitations for malpractice claims. Follow the same standard for records of minor patients, but begin counting after patient has reached legal age of majority.

Records destruction: Establish a policy with guidelines for destroying records "in the ordinary course of business." Routine destruction is done when the retention period has expired or the record has been transferred to a different medium (microfilm, computer file). The method needs to be thorough (e.g., shredding, incineration) in order to avoid any breach of confidentiality. Exception: Do not destroy documents if you have reason to believe they will be required for present or future litigation.

Records release: Do not release original records, specimens or radiology film unless required by law. When records are requested for legal proceedings, make every effort to submit a copy. Have a policy addressing removal of medical records; prohibit all physicians, employees, contractors or agents from removing records from the premises.

Tracking/sign-out procedure: Develop policies and procedures to prevent loss of records; confirm in writing the return of original films, records, slides, or specimens. Establish secure record storage areas, and limit access only to authorized users. Develop and implement procedures to identify charts that are misfiled, incomplete, improperly altered, removed or viewed by unauthorized individuals or lost. Depending on status of an identified event (patient who complains about care, incident, notice of suit), it may be prudent to sequester the original record, and make it available only under direct supervision. It might also be prudent to make copies and store those copies at a location other than the office, so that they will be available if the original records are accidentally lost or destroyed, and update versions as needed. This will also avoid the possibility of records that are important to the defense of a malpractice claim being inappropriately altered.

Timeliness of transcription: Require physicians to enter notes the day of the patient visit. Monitor the time it takes to transcribe and file information in the patient charts once dictated. Ensure that dictated notes are authenticated (i.e. reviewed and signed) by the responsible provider. Uncorrected errors in transcription can lead to errors in patient care and erode a provider's credibility in a malpractice case.

Correction policies: Ensure that physicians and office staff understand that they should never attempt to change or falsify data in a patient chart, especially not after an adverse event or notice of lawsuit. Instruct physicians on proper error correction and amendment protocols. See resource: American Health Information Management Association provides guidelines for error correction and amendments, including computerized records.*

Transfer to other medium: When medical records are being transferred to another medium (e.g. stored on a disc, scanned into a computer), develop a system to verify that the transfer was done without alteration and that the documents are readily retrievable. Verification should be recorded in a log.

Disaster preparedness and recovery: Practice should protect records in a way that minimizes risk of damage from fire and water-related disasters, and power failures. Facilities must have back-up systems in place to access records during an emergency and methods to recover medical records damaged by disaster (e.g., restoration companies for fire/water/storm damage). Be mindful of privacy and confidentiality of patient information.

Sale or transfer: To comply with New Jersey law, send out adequate advance notice to all patients regarding the sale or transfer of a practice; provide advice on how they may continue care and obtain copies of their records or have them transferred to another provider.

Conclusion

As a physician, you have a duty to your patients to maintain adequate and accurate patient medical records, whether the care is provided in the office or within a hospital or a nursing home.

The recommendations offered here can help you reduce your potential liability for loss or destruction of medical documentation and other evidence. ❖

Another Article on Documentation?

By Donna Knight, CPHRM, CPHQ
Healthcare Risk Consultant

The topic of medical record documentation is about as exciting as watching paint dry. However, time after time we find that missing, incomplete, or illegible documentation seriously impedes safe patient care and the defense of malpractice claims, even when care was appropriate. The medical record is a legal document and, as such, demonstrates adherence to state and federal regulations, evidence-based practice guidelines as promulgated by professional organizations, and it provides the information necessary to support billing and reimbursement. It is also the provider's greatest defense in the event of a claim by providing a contemporaneously written record of the "what, when, why and hows" of the care provided.

The documentation elements that often lead to unanticipated outcomes, medical errors, and claims include:

- Missing documentation that leads to failure to diagnose, such as after hours telephone calls, a record of direct provider-to-provider communication, adherence to or reasons for not following evidence-based practice guidelines (e.g. rationale for choosing one particular course of action over another), and follow-up of ordered tests and consultations
- Unsafe medication documentation practices, such as utilization of trailing zeros and not utilizing leading zeros, or the use of abbreviations that lead to medical errors
- Illegibility

Documentation do's and don'ts

- Use permanent ink, not soft felt pens or lead pencils.

Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404
www.RiskReviewOnline.com

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- Write legibly; print if your handwriting is indecipherable. The use of encounter forms, checklists, flow-sheets, and computer-assisted documentation for high-volume activities can save time and may also reduce communication problems and errors caused by illegible handwriting.
- Date, time and sign all entries, including your professional designation. Use precise time whenever possible. Precision contributes to an impression of thoroughness.
- Each entry should be in chronological order. Late entries and addendums should be identified as such. Document the date and time of all added note entries.
- Use only abbreviations approved by the facilities in which you have privileges and consider adopting these abbreviations at your practice site (for the complete Joint Commission list of "Do Not Use" documentation go to <http://www.jointcommission.org/PatientSafety/DoNotUseList/>).
- When utilizing progress note style forms, do not leave blank lines between entries.
- Do not erase, use "whiteout" or obliterate a notation. Incorrect entries should be corrected by drawing a single straight line through the mistake, then write "mistaken entry" above or next to it. Include your initials and the date of the correction. ❖

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Medical Records: Best Friend or Worst Enemy?

By John O'Farrell
Vice President, Claims

Physicians are legally obligated to maintain adequate and accurate patient medical records, whether they practice in a hospital or ambulatory setting. A permanent legal document, the medical record often serves as a critically important means of communication among healthcare providers concerning a patient's medical history and course of treatment. The medical record also provides information that supports the need for a particular diagnostic test or type of treatment in the event of a reimbursement or utilization dispute.

From a risk management perspective, the medical record is a crucial factor in preventing and minimizing potentially adverse medical consequences. It is also a key element in defending malpractice claims and lawsuits since it documents the patient's history with which the physician began, the physician's critical thinking in evaluating the current situation, the basis for the diagnosis and treatment the physician offered and prescribed, the sequence in which care was provided, the patient's response to treatment, and any reluctance or failure by the patient to heed the physician's advice. In contrast, a poorly maintained or improperly modified or altered record will be used to attack and undermine not only the physician's diagnostic acumen and the appropriateness of the care that was provided, but also the physician's credibility regarding what was discussed with the patient, including the patient's reluctance or refusal to heed the physician's advice. As such, the medical record has sometimes been referred to as the "witness whose memory is never lost."

Common Pitfalls in Malpractice Litigation

Unclear, incomplete, or inaccurate record entries

It is critical to document contemporaneously the care of fered, provided, or rejected as completely as possible, including the date, time and signature of the healthcare provider who is making the entry. Without dates and times, it

becomes very difficult to establish timelines of care, either for reference by other healthcare providers or for use in malpractice litigation.

Beyond that, the absence of timely and accurate documentation provides the obviously dissatisfied plaintiff with the means to challenge the quality of care the physician provided during their relationship, including disputing the history that was given, potential diagnoses that were discussed, tests that were either ordered or suggested, referrals that were recommended or declined, etc. Leaving the documentation door open enables the unhappy plaintiff with a selective memory to retrospectively create issues and scenarios that never existed but which a creative lawyer and his willing expert can use to suggest that the physician did not, in fact, provide the care required under the circumstances.

In short, untimely, poorly maintained, incomplete, illegible or improperly altered medical records can be, and often are, used to suggest not only that the physician provided inadequate medical care, but also that he/she subsequently attempted to "doctor" the treatment record to conceal that fact. Conversely, a timely, contemporaneously created and well-documented record can serve as the physician's first line of defense in such claims.

Spoilation

The term "spoliation" generally refers to the destruction or concealment of evidence. In the context of a malpractice case, the concept can be a potent weapon used not only to compromise the defense of the medical case, but also to inflame the jury's passions against the defendant physician.

The law requires physicians to ensure that medical treatment records accurately reflect the treatment or services provided. The law further specifies that corrections or changes to entries in such records may be made only where the change is clearly identified as such and then simultaneously dated and initialed by the person making the change.



Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404

www.RiskReviewOnline.com

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It is illegal for a person to alter medical records with the intent to deceive or mislead anyone. The liability resulting from such an act may be civil, or in some cases, criminal. In a civil malpractice action, for example, the court may instruct the jury that if they conclude that the alteration was intentionally done to deceive or mislead anyone, they may infer that the physician altered the record because he/she believed the original would have been unfavorable to him/her in the trial of the case. Evidence of such alteration may also serve as the basis for the plaintiff asserting a separate and independent claim for fraudulent concealment against the physician seeking to recover both compensatory and punitive damages.

Spoliation may take the form of destroying the original record, of rewriting the original record, or creating a new and different record. It may also consist of erasing, obliterating or adding information to the original record after the original note was made. Although there may be times when a non-contemporaneous entry in a medical record is appropriate, the physician making such an entry should be certain to follow the rules whenever making such an addition or change.

The Impact Extends Beyond Patient Care and Litigation Concerns

The failure to maintain adequate and accurate records may not only jeopardize the welfare of the patient, but also constitutes unlawful and unprofessional conduct. In addition, it may affect the availability of insurance for a malpractice claim in which improper record keeping is involved.

- Insurance companies may deny coverage if the insured fraudulently destroys, rewrites, creates, alters or modifies a medical record.
- In New Jersey, the purposeful destruction, alteration or falsification of records relating to the care of medical, surgical or podiatric patients in order to deceive or mislead is a crime of the fourth degree (N.J.A.C.2C:21-4.1).
- The NJ Board of Medical Examiners considers unlawful alteration to be an act of professional misconduct, and can therefore levy sanctions and fines against offending license holders.

Spoliation Detection

Experts such as forensic chemists, ink-dating, fingerprint and DNA specialists employ a number of techniques to detect record alterations. For example, the ink-dating technique can detect an alteration made with a different pen, as well as determine the age of the document or a particular ink. The ink specialist may also utilize an infrared image converter or special lasers to confirm that ink of the same color was used at different times.

Obviously, such expert testimony confirming that an alteration has occurred will be used to undermine the credibility of the healthcare provider involved in the spoliation. It may also serve to inflame the jury's view of what justice requires to "set things right," thereby increasing the amount of compensatory damages that the jury may award to the aggrieved patient, as well as fueling a separate and additional punitive damages award.

Correcting a Record

Obviously, the most troubling record change cases are those in which records have been intentionally altered to cover up diagnostic, treatment or charting deficiencies or errors. However, even legitimate, well-intended modifications to records can give rise to suspicion of improper intent if not correctly done.

So what should one do if he/she discovers a mistake or omission? How should one correct an error in charting? To begin with, charting errors should be corrected as soon as they are detected. Equally important, the correction should be open, transparent and clear, leaving no room for any suggestion that it was made surreptitiously or for any reason other than ensuring that the patient's record is accurate and complete.

If the error consists of incorrect information, the best way to make the correction is simply to draw a single line through the incorrect information without obliterating it, making sure that what has been stricken out can still be read. Then enter the correct information either above, below or next to the lined-out entry. Lastly, the person making the correction should write his/her initials and the date the change is being made next to the corrected entry.

If the error consists of a failure to include information that should have been included in the record but was inadvertently omitted, the best approach is to simply write a note captioned "Addendum" or "Late Entry," noting that the information being supplied was inadvertently omitted when it had first been obtained, e.g., when a particular complaint had been received, when a specific finding had been made, when a particular test, treatment or referral had been discussed and recommended, when the patient had agreed with or rejected proposed testing, referral or treatment, etc. Again, all such notes should be initialed and dated on the date they are entered.

Adding or correcting a note to ensure that the patient's record is accurate and complete is important to maintaining the integrity of the medical record and to advancing proper patient care. It may also be of benefit in later defending the physician accused of not having provided the patient with proper medical care.

Obviously, the best practice is always to complete the records correctly the first time. But where that doesn't occur, it is imperative that any addition or correction be made in a clear, open manner so that the belated entry does not become the basis for a colorable claim of spoliation or cover-up.

In summary, altering an original medical record for any reason other than safeguarding the patient or documenting the care actually provided is not only wrong, it is also fraught with risk. There are many ways for external reviewers to detect record alteration, and even the most "clever" attempts will likely be discovered. Furthermore, electronic medical records make alterations even easier to spot with time-stamping, metadata, and the potential existence of multiple versions.

Perception can be, and often is, interpreted as reality. As a famous Greek philosopher once observed, "We judge the present by looking at the past." The medical record we analyze today should provide an accurate picture of what occurred during the physician-patient relationship. Diligence and honesty in documentation will go a long way toward enabling the innocent physician to successfully defend a future malpractice claim challenging the quality of the care he/she provided. ❖

This material is not to be construed as establishing professional practice standards or providing legal advice. Compliance with any of the recommendations contained herein in no way guarantees the fulfillment of your obligations as may be required by any local, state or federal laws, regulations or other requirements. Readers are advised to consult a qualified attorney or other professional regarding the information and issues discussed herein, and for advice pertaining to a specific situation. ❖

Reducing Risk

A Publication on Healthcare Risk Management from Princeton Insurance

Protect Your Practice with Your Pen: Documentation Tips

Introduction

The medical record is the primary tool for documenting the care provided to a patient, and for communicating among other healthcare providers about that care. Proper documentation in the medical record—which is a legal document—is an essential component of quality patient care and effective risk management.

Documentation that is absent, incomplete, improper, or illegible can negatively affect the quality and continuity of patient care, as well as the defense of a malpractice claim, even when the care given was appropriate. If a patient's care is called into question, the medical record is looked to as a primary source of information and, depending upon the quality of the documentation, becomes either an asset or a liability for defending a malpractice claim. It is a fact that the quality and content of the documentation contained in medical records often is a major factor in whether a malpractice suit is won or lost.

Essential Documented Content in a Medical Record

The goal for medical record documentation is to have complete, timely, factual, and accurate information that assists in diagnosis and treatment, and clearly communicates pertinent information to other caregivers. Documentation that is complete and legible will provide the best record that the patient care you provided was within the standard of care. To gauge the adequacy of your documentation, consider what you would want to know if you were assuming management of the care of a patient unknown to you.

The New Jersey Board of Medical Examiners regulations require that treatment records, bills and claim forms “accurately reflect the treatment or services rendered” including the patient complaint, history, exam findings, progress notes, orders for tests or consults and results, diagnosis or medical impression, treatment ordered such as medications and recommended follow-up, communication of test results, and documentation of the existence of any advance directive for healthcare with inquiry regarding same documented on an intake history form, and in other appropriate circumstances such as a serious illness. (N.J.A.C. 13:35-6.5)

All other information relevant to a patient's course of treatment and care also must be documented, including the following:

- Informed consent discussions
Document the material risks, benefits, and alternatives that were discussed, the fact that patient questions were invited and answered, and that the patient consented to or refused treatment.
- Rationale for excluding a differential diagnosis or deviating from evidence-based standards of care
- Rationale for care provided or not provided when there is a discrepancy with the observations or recommendations of another practitioner:
When dealing with conflicting matters between providers, such as a disagreement on a diagnosis or plan of care, review your notes and the other provider's notes and all other pertinent reports. Overlooked diagnostic reports, critical notes, and reports of consultations pointing to a different diagnosis or treatments that are not commented upon by the attending physician in the medical record may give rise to a malpractice claim for delayed or missed diagnosis.

- Follow-up instructions
Note or keep a copy of follow-up instructions given to a patient in the medical record. Identify any family or friends of the patient who were present when the instructions were given. Give specific instructions, e.g. "Check your temperature tomorrow morning and call me if it is 101 degrees or higher." This is opposed to a vague instruction such as, "Call me if you run a high fever."
- Patient education, including discussions, demonstrations and use of teaching aids such as models, pamphlets, videos, or internet resources
- Follow-up of referrals for a test or consult, particularly if a serious or life-threatening disease or condition is being ruled out
- Clinically pertinent telephone calls with notations regarding the caller, symptoms or complaints offered, prescriptions and instructions given, and any referrals
- Medication allergies and any adverse reactions to medications or contrast media
- Description of pertinent patient behavior such as missed appointments or failure to follow treatment recommendations
Use language that is objective, not judgmental, or disparaging, e.g. "Patient did not return for recheck of BP," rather than, "Patient is non-compliant."
- Reports of tests and consultations dated and initialed upon review
- E-mail communications with patients, stored in either paper or electronic form

Inappropriate Content in a Medical Record

Documentation concerning matters other than the patient's health history, diagnosis, treatment, and response to care is inappropriate in a medical record. The following are examples of content that does not belong in a medical record:

- Event reports
An event report is a separate document that is not part of a medical record. The reports and comments related to risk management issues, such as "incident report filed" or "malpractice carrier contacted" should never be noted in a medical record.
- Self-serving or accusatory comments regarding an adverse event or unanticipated outcome
Document only the facts surrounding the occurrence and any subsequent care rendered as a result. Avoid documenting conclusions about events that were not witnessed, e.g., "Patient fell off exam table"; instead, document facts, e.g. "Patient found on floor next to exam table."
- Subjective patient/family member statements regarding prior treatment or poor outcomes presented as fact
Use quotes to record a patient's or family member's subjective impression of their condition, e.g., "Mother states child has cerebral palsy due to a birth injury."
- Criticism of care provided or perceived mistakes made by other practitioners
Since all pertinent facts about prior care are rarely available, caution is advised in making judgments. If you disagree with a past or current caregiver, document a factual summary of pertinent clinical events and the rationale for your plan of care. Questions about prior care should generally be referred back to that provider.
- Derogatory comments about a patient or a patient's family member
- Arguments and conflict with other providers
Finger pointing or argumentative remarks, especially after an adverse event, will only make the defense of a case much more complicated for all caregivers involved.

Documentation Mechanics

Errors in medical record documentation such as inaccuracies, omissions, illegibility, or incorrect methods to make a correction may cast doubts about the quality of the care that was provided, as well as the credibility of the provider. Incorrect or messy notes can convey the impression that a practitioner is careless or incompetent. Delays in making entries can be problematic for the defense of a claim when a note written after an adverse event appears to be defensive or self-serving.

Adherence to the following guidelines will help ensure that your documentation is proper and effective and convey the impression of a careful, competent practitioner:

Reducing Risk

- Use permanent black or blue ink, not felt pens or pencils.
- Write legibly. Print if your handwriting is not legible.
- The use of encounter forms, checklists, flow sheets, and computer-assisted documentation for high-volume activities can save time and may also reduce miscommunications and errors caused by illegible handwriting.
- Date, time and sign all entries with your name and professional designation. All entries should be in chronological order.
- Use only approved standard abbreviations.
- Do not skip lines or leave blank spaces between entries.
- Late entries should be identified as such. Record the date and time the late entry is recorded and note the entry being referenced.
- Never use liquid correction fluid or erase a notation. Incorrect entries should be corrected by drawing a single straight line through the mistake; write “error” above the line with your initials; and then write the correct word or statement.
- **Do not alter** or update existing medical record documentation or destroy or withhold elements of a medical record after an untoward event occurs or a legal claim is filed. Alteration of a medical record is a criminal offense. Even a minor alteration, once discovered, can greatly damage or destroy a practitioner’s credibility.

For more information about reducing risk at your practice, please view our risk management newsletter at www.RiskReviewOnline.com. To access additional Reducing Risk documents, visit our website at www.PrincetonInsurance.com and click on “Risk Management – Publications.”

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Analyzing charts to limit liability

by Sharon Koob, Princeton Insurance Healthcare Risk Consultant

Between late 2004 and early 2006, the Professional Liability staff members of Princeton Insurance have worked with client nursing managers and risk managers in a new approach to an old problem, documentation. This article will share the results of this work. The effort put into this project has set up a system that physicians can use to improve documentation in their office practices too.

Documentation as an Ongoing Issue

Medical record documentation (often referred to as "charting") has three authoritative functions. Documentation is done as a professional responsibility, to satisfy regulatory standards, and to communicate medical information.

Healthcare professionals are responsible for keeping records of the care that is given to their patients. Clear documentation of the patient's condition, medical/nursing decisions that are made, the interventions that are implemented as a result of those decisions, and the results of those interventions should all be found in the medical record.

Both state and federal governments have issued regulations which specify what type of documentation must be done in certain circumstances. Federal laws such as EMTALA, and CMS regulations for long-term care facilities, focus on specific areas of care. State regulations such as those promulgated through the Department of Health (DOH) are often written to cover all areas of acute care facilities.

Documentation in the record itself serves the immediate purpose of intra-staff and physician communication. In this role it becomes paramount that medical record documentation, or "charting", be taken very seriously by all who participate in the function. Yet poor documentation chronically continues to play a part in malpractice claims. Demanding schedules, distractions in the workplace, and a lack of comprehension of the serious nature of medical record documentation can lead writers to make mistakes they may have to live with in court.

Auditing Charts to Improve Documentation

In mid-2004 the Professional Liability (PL) group of Healthcare Risk Services updated its chart audit tool as part of the second phase of its service plan. The PL consultants began a series of meetings with nursing leaders of each insured facility. The nursing managers were taught how to audit a chart for liability issues. At these presentations each nursing manager brought a chart from his or her own area. The program included instruction about the audit tool and general principles of charting liability. After this initial introduction the nursing managers reviewed the chart they had with them, using the Princeton PL tool.

All of the nurse managers were very comfortable reviewing charts, but were more accustomed to searching for quality or utilization indicators. Looking at a chart in this distinctly different way gave rise to many discussions. In some cases the managers discovered changes that they wished to make in forms or in processes that their facility used. In some cases, the managers found examples of very good documentation that they could build on with their staff. In many situations, however, they found repeated instances of poor documentation which could lead to medical errors and increased facility or individual liability if a claim were made.

The Audit Tool

The audit tool itself was set up to look at a variety of common charting problems which appear with varying frequency in liability claims. The audit tool provides forty-five different special areas of a routine chart to review. It also has four specialty areas, Behavioral Health, Emergency Department, Obstetrics, and Oncology to review since these areas often

have very specialized documentation of their own. Specialty nurse managers who audited their own area charts focused more on their specialty portion of the audit and only reviewed a portion of the forty-five specific questions for a typical medical-surgical chart.

While this proved to be a very rigorous project for the nurse managers, and took more of their time than the PL group would ordinarily schedule, it had a long-lasting impact on the documentation processes at a number of facilities. It was an opportunity for the nurse managers to sit down as a group and focus on the state of their medical records. The discussions the meetings engendered lead to improvements in both the records themselves and the charting processes that both nurses and physicians struggle with.

The Results of the Survey

Thirty-two facilities completed audits and submitted results for review. Although recommendations were written in all forty-five areas and three of the specialty areas, only sixteen issues occurred so frequently that they receive special attention here.

The leading two issues were illegibility and reassessment.

- Illegible charting leads directly to medical errors and makes a malpractice claim more difficult to defend. For purposes of this audit, the issue of illegibility included the use of incorrect ink color and inappropriate abbreviations as well as unreadable handwriting. Medication error cases have developed because of difficult to read physician orders. Plaintiff attorneys have the right to, and often do, ask a provider or staff member to transcribe large sections of a medical record because it is indecipherable. For a physician, this is time spent away from the practice or the OR suite; it is money lost. Sections of a medical record, blown up to posterboard size and put in front of a jury, serve to highlight illegible sections of that chart; jurors may see this handwriting as evidence of carelessness or a practitioner who was too busy to pay proper attention to detail.
- Reassessments should occur at specific points during the patient's care. This is a JCAHO requirement and it represents good medical care. A patient who has been given a pain medication should be reassessed for pain relief and for fall potential. A patient who has just had anesthesia or who has had a change in certain medications should be reassessed for fall potential. Problems can occur, however, when required reassessments are not documented in the patient's record. This audit emphasized the fact that reassessment documentation is a weakness among caregivers. Plaintiff attorneys can make use of an undocumented reassessment if an untoward event occurs.

The next five issues to occur with great frequency were: lack of patient ID on every page; improper corrections; informed consent problems; discharge planning issues; and troubles with telephone orders.

- When patient identification data is not placed on both sides of each record sheet, a different patient's information can be recorded on the chart. Also, if the chart is pulled apart in preparation for copying, for microfilming, or just for storage, those unmarked sheets can be lost. The lost portion of record may be crucial to a malpractice case, or future care.
- Corrections become a problem when they are not done as the facility's policy/procedure requires. An unclear correction in a medical record can easily be misread by another caregiver and, if the case becomes a malpractice claim, the plaintiff attorney may try to make it appear to be an alteration in the record.
- Consent is a process, not just a form. With that in mind, the auditors looked at documentation regarding consent discussions in the progress notes, on the consent forms themselves, and on any other indicators of consent in the patient's medical record. What they found was a number of issues that concerned them. Most frequently, they found consent discussion documentation missing from the progress notes or on the consent form itself, if that was facility policy. They also noted inappropriately completed consent forms. Any situation involving a question of consent can lead both to medical error and to malpractice claims. Patients may feel they understand what they

were agreeing to and/or physicians may feel that patients comprehended the situation they were in, yet misunderstandings happen frequently. Clear documentation is one way to help minimize the threat of malpractice claims in consent situations.

- Unclear or incomplete discharge planning records may lead to medical error and can be a plaintiff's adjunct to the "he said/she said" battle in many malpractice claims. With little or no discharge planning recorded in the record, and only a poorly documented copy of the discharge instruction sheet given to the patient when leaving the facility, the care givers and facility are open for liability if a claim is brought. All the court will have to decide upon is your word versus the plaintiff's recollection.
- Telephone orders have caused a number of problems. They showed up on the chart audit frequently because physicians did not sign the order or did not date and/or time their signatures. Physician signatures, with date and time on all telephone orders, are now mandated by CMS. This signature must be done within forty-eight hours and must be done by the treating physician or a physician who is authorized to sign for him/her. This will change the preferred practice of some physicians, but the change moves medical practice toward better patient care, better documentation of that care, and a minimization of that physician's liability.

The remainder of the frequently noted chart review problems, and the issues surrounding them picked up on review, are listed below:

- Failing to sign, date, and/or time each chart entry
- Inadequate or absent documentation of Advance Directives
- Pain assessments
- Patient education
- Treatment goals
- Timing (which refers to documenting the time that something happened: i.e...When was the family at the bedside?)
- Care decisions and treatment plans
- Contemporaneous charting (includes notes that are not dated and timed and notes that are not comprehensive in nature By comprehensive, the tool described a note as being fully descriptive rather than simply saying "informed consent discussion done." This part of the review was focused only on physician areas of the record.)

Altered Records

Though they did not occur with a frequency that would qualify as the top issues for purposes of this article, it is important to note that the auditors found two altered charts during this review process. An altered chart should never exist. Alterations in the record, even when innocently made, appear to be done to cover up a mistake. No amount of explanation can clear up that perception and an altered record makes a claim very difficult to win.

Conclusion

This documentation audit is a new approach to teaching documentation liability. By showing nurse managers how to audit a chart for liability issues the PL group extended its reach to virtually all nursing staff in the participating client facilities. The nurse managers who attended the sessions were encouraged to periodically audit a chart or two with the audit tool to keep in practice and to monitor documentation in their areas. They were also encouraged to teach their staff the same audit techniques and to have individual members of their staff review one or two charts on a periodic basis. In this way, more nurses could become sensitized to the types of documentation which contribute to errors and inflame malpractice suits.

The PL staff members also were and still are involved in follow-up with managers and staff by assisting with in-services, utilizing the new Documentation ICG, and by responding to questions that have developed from individualized audits that managers and staff have done on their own. Some of the facilities took portions of the Princeton audit tool and



incorporated it into their own routine audits. Some of the facilities sent in further chart audits over a series of quarters to track their progress.

Finding a way to document comprehensively and clearly is a challenge for every medical provider and staff member in an increasingly complex healthcare system, yet it continues to be a fundamental requirement of good medical practice. This project was designed to train more people in the ability to search out and promote good documentation practices. It was also designed to keep that training going so that it would not be a "one time only" experience. The audit tool can also be used by physician practices to do routine chart reviews, just as the facilities have done, so that practice documentation can conform to the best standards for the dual purposes of better patient care and protecting practitioners and caregivers from liability.

Assuming the Care of a New Patient

By Donna Knight, Princeton Insurance Healthcare Risk Consultant

Assuming care of a new patient from departing or retiring physicians within a group practice or within the community presents unique responsibilities to physicians. Physicians who do not review prior medical records, but instead rely on the patient's account of their clinical history run the risk of missing pertinent clinical information that may lead to poor patient outcomes and potential liability.

Some patients may be poor clinical historians and/or may not completely understand significant information or instructions shared with them by prior physicians. To promote safe, quality continuity of care and avoid allegations of failure to diagnose or failure to follow-up, the new physician assuming care of the patient should obtain the medical record from the prior physician and review it before the patient's first visit.

Requesting and reviewing a summary from the prior physician may not provide safe, quality patient care or insulate from liability. Consider those circumstances in which the prior physician notes a patient complaint but did not follow through. The information may not be included in the physician's summary. Only through review of the prior medical record and current assessment of the patient would the new physician be aware of significant information that must be addressed with the patient in the future.

Once the physician reviews the medical record an entry in the medical record noting pertinent history and current healthcare plans and needs should be made. An example of such documentation includes: "4/17/07. Assuming care from Dr. Smith who retired. Chart reviewed; continue medical management of diabetes; appointment scheduled in one month; order labs, consider nephrology consult if kidney function continued to decline."

Reviewing the prior medical record before the patient's first visit will save valuable time during the actual visit. This process may avoid the need to skim through the record during the visit thereby averting the risk of missing important clinical information. ❖



Vice President of Healthcare Risk Services
Tom Snyder x852

Manager, Healthcare Risk Services
Phyllis DeCola x897

Phone: 609.452.9404
www.RiskReviewOnline.com

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Unexpected Medical Record Damage

protecting your records when the water rushes in

Accidents or unexpected disasters can result in extensive water damage to important documents such as medical records and X-ray films. In recent years, New Jersey has seen its share of flooding, including the most recent damage from Hurricane Irene and subsequent heavy rain. Broken water pipes or an overflowing floor drain can cause unexpected damage to stored medical records in a basement or storage room. Water damage can also be the often-unanticipated side effect of fire fighting efforts.

When a practice faces a loss such as water damaged records and X-ray films, there are steps that should be taken:

- Report the loss to your insurance carriers (general liability and property)
- Check the records themselves
 - Are there some which are only partially destroyed and may be restored?
 - Are there records which are totally destroyed?

Reporting to your carrier

To facilitate any claim you make, you may wish to take pictures of the damage. A series of pictures over the period of clean-up may also be beneficial, especially when dealing with a loss suffered due to fire-related water damage.

Keep a copy of the letter you send to your property carrier, and copies of the pictures, too. If you are named in a malpractice suit and asked to produce the records, this evidence will help respond to any allegations that records were negligently or willfully destroyed (spoliation).

Partially destroyed records

Moisture in any form and paper don't mix; paper when exposed to water begins to deteriorate. The same process occurs with an X-ray film jacket but in a slower process. Moisture infiltrates the paper's cell structure, followed by swelling and discoloration. An environment is then created that will permit the growth of mold and bacteria on the surface of the paper or X-ray film jacket. This can occur in a domino-like effect, spreading from folder to folder.

Water-damaged medical records, film, and file jackets can be restored. The complete restoration of water-soaked documents can be an expensive process, yet it may be wise to attempt to salvage them. This process has to begin as quickly as possible, and a restoration company needs to be contacted. Since this company will be working with your patients' records, you will need to have a HIPAA Business Associate agreement with them.

The restoration company will place the materials into commercial freezers. Freezing, followed by vacuum freeze drying, has been shown to be one of the most effective methods of removing water from paper records and films. This is done to stop the process of deterioration or destruction. Once frozen, the materials are moved to a freeze-drying chamber. Air within the freeze drying chamber is removed through a vacuum process and the temperature lowered. The moisture within the materials is converted to a vapor state and then taken out of the chamber. The temperature within the freeze drying chamber is gradually increased over time, and any residue moisture is removed. Freeze-drying methods have been used in the recovery of books, manuscripts, leather, maps, historical and collectible items and textiles in the form of flags, needlework, silks and tapestries.

If water damage has resulted from fire-fighting measures, cooperation with the fire marshal and health and safety officials is vital for a realistic appraisal of the feasibility of a safe salvage effort. Fire officers will decide when a building is safe to enter. In these instances, salvage operations are planned so that the environment of water-damaged areas can be stabilized and controlled both before and during the removal of the medical records and films. In warm weather, mold growth may be expected to appear within 48 hours. Mold can also be expected to appear in poorly ventilated areas within the same time frame. It is therefore imperative to

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reduce high humidity and temperature and vent the areas as soon as feasible. Water-soaked material must be kept as cool as possible with good air circulation. To leave such materials more than 48 hours in temperatures 70 degrees Fahrenheit or higher and a relative humidity above 60% without good circulation will certainly result in heavy mold growth and lead to a higher recovery/restoration cost.

Completely destroyed records

When records are completely destroyed, the challenge to the practice will be twofold. The destroyed records will need appropriate disposal, and new records will have to be constructed from information the practice can assemble.

Destroying damaged records completely must be done to protect patient confidentiality and comply with HIPAA regulations. Dry the records and then shred them if possible. No intact record or X-ray may be discarded. As noted above, be aware of the likelihood that mold will develop. Lower humidity and ventilate the area where records are stored. When ready to destroy the records, the practice should keep a log of all records that are destroyed, as is done with planned record destruction. This log should include the following information:

- name
- date of birth
- social security number
- dates of first and last visit
- general problems and procedures performed in the office
- documentation of what was destroyed, how it was destroyed, and the date of destruction

Reconstructing records can be done by pulling together information from other systems and files available to the practice. Patients should be notified of the flood event and the damage done to records. A history form can be sent to each patient along with this notification letter with a request that the patient complete this form to the best of their ability. A copy of this letter should be filed in the patient's reconstructed medical record.

Once each chart is rebuilt, there should be clear documentation explaining that it was reconstructed. This documentation should include at least the following:

- date chart was reconstructed
- reason for reconstruction
- sources of information for reconstruction
- efforts made to obtain other information (if applicable)
- a statement that, due to reconstruction, the information contained in the chart as of the reconstruction date is considered inexact

Medicare and the patients' other insurance carriers may also expect to be notified that patient records have been lost. These organizations expect the practice to provide medical record documentation to support patient claims. When the medical record is destroyed they may want the practice to sign a form which attests to the unexpected loss of the record.

Prevention

It may feel like it's too late to talk about preventing this sort of damage, but each hurricane or nor'easter produces calls from practices that had never flooded before and thought they were safe. Some had taken what they thought were appropriate precautions, only to find later they were not enough.

It is appropriate to evaluate your storage space at least twice a year, though a quarterly examination would be even better. More frequent inspections are appropriate when weather is unusually harsh, no matter the season. Weather extremes expose the vulnerabilities of buildings much more quickly.

Routine prevention steps should include stacking records and X-rays off the floor. Use shelving units, if possible, and position them as high off of the floor as possible. Keep in mind; however, that storing records too high can pose a potential injury concern for staff. A sturdy step stool may be needed to safely access these records. And, if you know the storm of the century is coming, take time to pull those lower boxes up out of the basement.

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Finally, develop a system of routine record destruction so that you only keep the records you are supposed to keep. This will reduce the clutter in your storage area and reduce the number of records exposed to the risk of storm damage. You will find more information on routine record retention and destruction systems in the Princeton Insurance Office Practice Toolkit.

In summary, each facility or physician/dental office should perform a risk and hazard vulnerability assessment and include document restoration as part of emergency preparedness and disaster planning.

Ask your local emergency management office if your office is located in a known floodplain. Determine the elevation of your office in relation to local rivers, creeks, bays and the ocean. If your practice could be subject to flooding, medical records should be located at the highest level possible inside the office. Plastic tarps can be placed in rolls over the stored records and then unrolled when a storm approaches to protect against rain and roof damage. Take any paper out of the lower drawers of your desks and file cabinets and place them in plastic bags or plastic containers that can be placed on top of the units.

Physicians who maintain paper records should also consider storing copies of their administrative records (financial, insurance, patient scheduling, patient lists) off-site in a secured area outside the floodplain area.

For more helpful resources, visit: <http://www.archives.gov/preservation/disaster-response/salvage-procedures.html>.

Your Direct Link to Better Risk Management Practices

Ask the Expert

In each publication of Risk Review, an outside guest or a member of our team of expert risk management and loss prevention consultants will answer a question from a reader. If you are concerned about a risk management or safety issue at your practice or facility, let us know and we may answer it in a future issue.

Dealing With Deceased Patients' Medical Records

By: Denise L. Sanders, Esq.

Question: What do I need to know about releasing copies of medical records of deceased patients in my practice?

Answer: Unless involved in performing autopsies, most physicians generally do not consider the liability that exists from the way patients are treated *after* they die. However, at a time when many different areas of law can apply to the same issue, it is important to understand how to deal with a patient's medical records, once he passes away.

The main body of law that governs patient records is the Health Insurance Portability and Accountability Act's (HIPAA) Privacy Rule, which requires a covered entity (which includes a physician and/or medical practice) to protect the medical records, or "Protected Health Information" ("PHI"), of a patient. This obligation continues even post-mortem, and is quite similar to the obligation that exists when a patient is still alive. The primary, and obvious, distinction is that authority over records can no longer belong to a deceased patient. Upon death, this authority gets transferred to the patient's "personal representative." Under 45 CFR § 164.502(g)(4), a covered entity must treat a person as a personal representative, "If under applicable law an executor, administrator or other person has authority to act on behalf of a deceased individual or of the individual's estate."

A personal representative is generally appointed in a will, where an individual selects the person to carry out her wishes at death. This person is then granted either a letter testamentary or a letter of administration. If a personal representative has been appointed, it is important to note that



authorization to release records then lies only with that person, who may be someone other than a former spouse or another family member. In fact, even if a decedent had provided a surviving

party with a separate form granting authorization to obtain or grant disclosure of medical records, there is risk in relying on that as continuing authority. Even though the actual person whose records are at issue granted authority to another person to obtain or release the deceased's records, technically that person loses authority to the appointed representative immediately upon death. To avoid this conflict, a separate authorization should be included from the deceased's representative for any further disclosure of the patient's PHI. Any use or disclosure that has already been made in reliance on the now deceased patient's authorization is valid, however.

If an individual dies without appointing a personal representative in a will, then state intestate laws govern. In New Jersey, this authority would automatically first pass either to a surviving spouse or a surviving domestic partner, who receives the same treatment for these purposes under New Jersey law. To officially become appointed through intestate law, a party must first consent to the responsibility (See N.J.S.A. 10:3B-2.)

Exceptions

Since privacy laws were created to protect patients from having their personal histories made public in ways against their wills, exceptions were created to avoid preventing professionals from carrying out their jobs in good faith. For example, healthcare providers can exchange the PHI of a deceased patient among one another if the purpose is to treat another patient, mainly in the case of a relative with a potentially similar genetic makeup. Also, in the event that covered entities want to notify family members or representatives of a death, or need to identify deceased persons to establish the cause of death, authorization is likewise not required. Some additional exceptions for professionals permit funeral directors, organ procurement organizations, and law enforcement personnel to obtain information consistent with carrying out their jobs.

Beyond these carefully carved out exceptions, PHI can also be



Vice President of
Healthcare Risk Services
Tom Snyder x852

Manager, Healthcare Risk Services
Phyllis DeCola x897

Manager, Risk Services
Francis Roth x868

www.RiskReviewOnline.com

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transferred under the umbrella of research, but only if the researcher provides a covered entity with assurance that the information will strictly be used for, and is necessary for, research on the PHI of decedents, and provides supporting documentation to confirm the death of the individual.

Perhaps the most unnerving requests for medical records are those associated with any pending or future litigation. PHI requested for purposes of litigation are subject to an entirely different set of very specific rules, the precise details of which are beyond the scope of this article, but physicians should always first ensure that the PHI requested for legal proceedings can legally be disclosed. If a physician is a party to the litigation (e.g., a defendant in a medical malpractice suit or plaintiff in a suit for reimbursement), PHI can be used or disclosed as part of the physician's "health care operations" (See 45 CFR 164.501), including for the purpose of justifying a particular course of treatment. However, physicians can only offer this information for that narrowly defined purpose.

When a physician is not a party to the litigation, and consent cannot be obtained to release PHI, physicians are again charged with the burden of making reasonable efforts to ensure that the PHI is being used only for the narrow purpose that it was intended for. The specific intentions can be found by reading the original requesting document, which may appear in various forms including a subpoena or court order. Moreover, when responding to a subpoena, covered entities must confirm that efforts have been made to inform the patient that a request has been made for disclosure of her medical records and the patient given a sufficient time to respond or object. In the event that the party for whom the records apply is deceased, efforts to locate and notify the representative should then be undertaken instead.

Even after patients die, physicians and covered entities can still face liability for them.

This article is intended to make healthcare professionals aware of these risks and to serve as a general guideline for dealing with requests for the PHI of a deceased patient. This article does not offer any legal advice and should not be relied on for such. Prior to sending any records or taking any action that could be governed under HIPAA, it is suggested that physicians consult their personal attorney.

Ms. Sanders is an attorney specializing in healthcare law. ❖

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Medical Clearance for Surgery: “Red flags” prompt further action

Insufficient preoperative history and physical, medical clearance and lack of communication with other providers regarding pre-existing conditions can result in postoperative complications.

When medical clearance is warranted, a note from the consulting provider scribbled on a prescription pad indicating “cleared pending labs” is a *red flag* for you and your office staff. The optimal process to acquire clearance would be to provide the patient and/or the consulting physician with a standard form indicating the exact medical/clinical information needed for you to make an accurate assessment of the patient as a surgical candidate. A *red flag*, such as the situation described above, should be an automatic trigger for

staff to be proactive in their follow-up – in this case to ascertain the results of labs or other tests recommended prior to surgery.

If a preoperative consult is ordered, direct communication with the consulting physician assures that the consultant’s impression of the patient’s condition and appropriateness for surgery is conveyed. This discussion should be documented in the medical record. Consultation reports that are not received should also be an indication for staff to actively follow-up to assure receipt prior to surgery.

It is also prudent to review past medical history with the patient prior to procedures. This process ensures that you have all of the appropriate information needed to assess the patient’s risk for surgery and to institute any pre-procedure measures that might be necessary to improve postoperative outcomes. ❖

Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404

www.RiskReviewOnline.com

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Wrong Site Surgery

Mary Jane Shevlin, BSN, MA, CPHRM, CPHQ
Princeton Insurance Healthcare Risk Consultant

Despite years of patient-safety efforts, an increasing number of healthcare facilities have reported mistakenly removing the wrong limbs or organs, slicing into the wrong side of bodies and performing surgery on the wrong patients. The Joint Commission, in its September 7, 2007 publication of the Sentinel Event Statistics, indicates that wrong site surgery remains the highest reported event. Last year, healthcare facilities reported 94 operations to the commission that involved the wrong body part or the wrong patient. While some states, including New Jersey, require hospitals to report such slip-ups, many hospitals across the nation are not obligated to account for them publicly. Since the introduction of the Joint Commission's Sentinel Event Policy, the Joint Commission has reviewed numerous cases related to surgery and have identified several factors that may contribute to the increased risk of wrong site surgery. These risk factors include:

- more than one surgeon involved in the case, either because more than one surgery is contemplated or the care of the patient required more than one surgeon
- unusual time pressures, related to an unusual start time because of emergent situations or pressure to speed up the pre-operative procedure
- incorrect site preparation by the staff and incorrect interpretation of X-rays
- unusual patient characteristics such as physical deformity or morbid obesity that might alter the usual process for equipment set-up or positioning of the patient

The root causes identified most often are related to the following major themes:

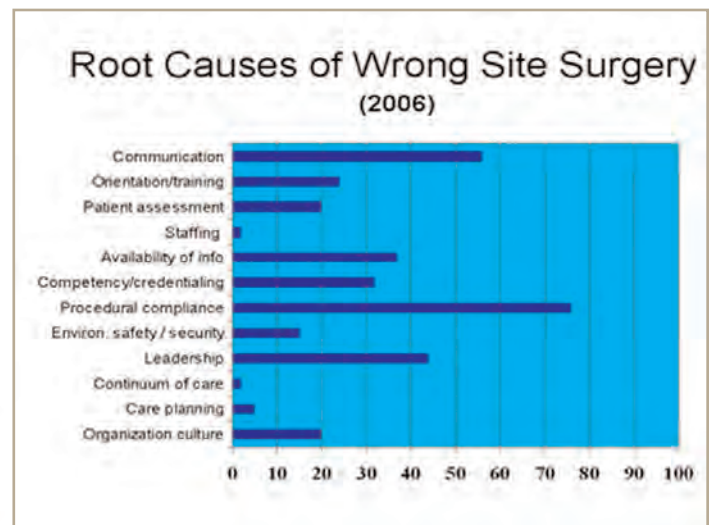
- incomplete or inaccurate communication among members of the surgical team
- inadequate pre-operative assessment of the patient and the procedure



or lack of procedure to verify the correct surgical site

- the failure to engage the patient or family member in the procedure of identifying the correct surgery

The following graph published by the Joint Commission shows further breakdown.



Furthermore, the Joint Commission's evaluation of 126 root cause analyses (RCAs) revealed the following specialties were the most commonly involved in the reported wrong site surgeries:

- Orthopedic/podiatric (41%)
- General Surgery (20%)

Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404
www.RiskReviewOnline.com

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- Neurosurgery (14%)
- Urology (11%)
- Maxillofacial, cardiovascular, otorhinolaryngology, and ophthalmology (14%)

In New Jersey, the New Jersey Healthcare Quality Assessment and Patient Safety Initiative Summary Report does not break down the specialties involved in wrong site surgery; however, the report published in December 2007 indicates the following incidence of surgery-related events in the last two years:

Year	Wrong Body Part	Wrong Patient	Wrong Procedure
2005	10%	3%	3%
2006	20%	2%	4%

The study by Kwaan, Studert, et. al. of 2.8 million operations over a 20-year period, published in *Archives of Surgery*, suggests that the rate of “wrong site” surgery anywhere other than the spine is one in every 1 12,994 operations. According to the authors, the study excluded the spine because surgical sites on the spine are verified with x-rays. The study, which was funded by the Federal Agency for Health Care Research and Quality, concludes that the rate is “exceedingly rare” but “unacceptable.”

The incidence of wrong site surgery has captured national attention, and current patient safety experts say more vigilance is needed. It is clear that the Joint Commission considers this of grave concern – it has convened two summits, one in May 2003 and a second one in February 2007.

After the first summit, the Universal Protocol for preventing wrong site surgery, wrong procedure and wrong person surgery was adapted. It gained wide support from numerous professional organizations such as the American College of Surgeons, the Agency for Healthcare Research and Quality, the American Academy of Orthopedic Surgeons and others who support the initiatives in patient safety. This protocol emphasizes three minimum requirements, namely: pre-operative site verification, marking and time-out.

Preoperative or Pre-procedure Verification

The preoperative or pre-procedural verification process starts at the time the surgery or invasive procedure is scheduled. The Operating Room (OR) schedule must include the exact site, digit, level laterality (including “left” or “right” and “bilateral”) without using any abbreviations except in designating spinal levels such as C-Cervical, L-lumbar, S-sacral and T-thoracic - e.g. L-4-5.

Best practice models suggest that the staff responsible for accepting requests to schedule procedures must verify the information provided by the surgeon/physician either by read-back, fax or email as agreed upon by both institution and physician.

At the time of surgery, verification of the correct person, procedure site and side is carried out with the participation of the patient who is awake and aware, if possible. Any inconsistencies or discrepancies/uncertainties about proper site or procedure should be resolved by the surgeon with confirmation agreement by the patient and at least one of the inspecting caregivers. Protocols should explicitly address the manner in which inconsistencies are resolved.

The same procedure of verification is applicable in all clinical settings where invasive procedures are performed, including but not limited to endoscopy,

cardiac catheterization and radiology interventional suites, emergency departments, and intensive care units.

Marking the Operative/Procedure Site

The intended site is marked so that the mark is visible after the patient is prepped and draped. The physician either marks the spot for surgery with his/her initials or the word “YES” - never with an “X”. The mark must be made using an FDA-approved marker that is sufficiently permanent to remain visible after completion of the skin prep.

The Joint Commission also encourages patients to insist on such a mark. To support this requirement, the Joint Commission published a speak-up brochure for the patients, with tips on how they can help to prevent wrong site surgery.

If a smaller mark is necessary as in the pediatric ophthalmology cases, a dot near the eye may constitute the site marking. Some hospitals have adopted a special purpose wristband as an option.

Time Out

As doctors are required to mark the site, nurses are supposed to call a “time out,” A “time out” provides the opportunity to call everyone’s attention to a final safety check in an effort to ensure that the right procedure is performed on the right patient.

The New York State Surgical Invasive Protocol published in 2006 suggests that “time out” must be conducted in the location where the procedure will be done, after the patient is prepped and draped. This applies to all invasive procedures performed in all settings and must involve the entire operative/procedure team.

“Time out” using active communication techniques should include the following:

1. Identification of the patient using two identifiers
2. Identification of the correct site and laterality if applicable
3. Procedure to be performed and proper positioning of the patient
4. Availability of special equipment or implants
5. Radiological review, when applicable to the case and confirmation that the images displayed belong to the patient in the correct orientation

Other Protocols:

A vast array of intervention tools exist, and common strategies are evident in these protocols. What is evident in most of these protocols is the use of a standardized checklist to document information related to the site verification and the “time out” process. Monitoring compliance is another common element.

In conclusion, the incidence of wrong-site surgery must be viewed not as the failure of one individual but the failing of a complex system. Dr. Charles Chodroff, senior vice president of WellSpan Health, advises disciplinary action will not prevent systems errors but that “studying the psychology of errors will more effectively identify factors that can improve performance and detect systems breakdowns before they occur; and therefore improve safety.”

Below is a list of organizations that have developed resources in doing the “right things to correct wrong site surgery.” ♦

Resources

1. Joint Commission: www.jcaho.org - Sentinel Event Alert
2. Institute of Healthcare Improvement – through Collaboratives, www.ihl.org
3. American Academy of Orthopedic Surgeons
4. Association of periOperative Registered Nurses: www.aorn.org (for the AORN toolkit)
5. New York State Department of Health: <http://www.health.state.ny.us/nysdoh/commish/2001/preop.htm>
6. Agency for Healthcare Research and Quality: <http://www.ahrq.gov/consumer/20tips.htm>
7. The Institute for Clinical Systems Improvement
8. Veterans Administration, Department of Veterans Affairs: “Seven Absolutes to Avoid Surgical Site Errors”
9. National Patient Safety Agency (UK)
10. NASS - National Association of Spinal Surgery, SmaX Campaign (Sign, Mark and X-ray) ❖

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