

Navigating in a complex healthcare environment.

Clinical risk management
reference manual for the
medical practice.



Table of contents

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1.00	Foreward	7
1.01	Purpose	8
1.02	Audience	8
1.03	Risk management philosophy	8
2.00	Professional liability in physician office practice	9
2.01	Rationale for practice-based risk management programs	10
2.02	Current liability trends	10
3.00	Communication	11
3.01	The basis of the physician-patient relationship	12
3.02	Definition of communication	12
3.03	Formats, types of communication	12
3.04	Courtesy, manners, and common sense	12
3.05	Patient rights and responsibilities	14
3.06	Patient privacy	14
3.07	Informed Consent: shared decision-making	15
3.08	Ethics of shared decision-making	15
3.09	Informed Consent: legal confirmation of shared decision-making	15
3.10	The physician may not delegate Informed Consent	15
3.11	Information that should be shared with patients	16
3.12	Non-physician staff and Informed Consent	16
3.13	Barriers to Informed Consent	16
3.14	Language challenges	16
3.15	Cultural values and personal preferences	17
3.16	Documentation of Informed Consent	17
3.17	Other statutory requirements	18
3.18	Informed Refusal	18
3.19	Informed Consent and minors	19
3.20	Resolving disputes with patients	19
3.21	Patient satisfaction	19
3.22	Learning from patient complaints	20
3.23	Reporting claims and incidents	20
3.24	Difficult physician-patient relationships	20
3.25	Frustration with the system	21
3.26	Defusing miscommunication	21
3.27	Terminating the physician-patient relationship	21
3.28	Other office communication issues	23
3.29	Conveying bad news	24
3.30	End-of-life care	25
3.31	Disclosing medical error	25
3.32	Confidentiality	27
3.33	Rationale for a confidentiality policy	27
3.34	General guidelines	27
3.35	Guidelines for sharing patient information via electronic media	28
3.36	Documentation	30
3.37	Documentation policies and procedures	30
3.38	Patient requests for omission of information	32
3.39	Electronic medical records (EMRs)	32

4.00	Patient care and clinical risk	33
4.01	Credentialing and clinical staff	34
4.02	Clinical guidelines	35
4.03	Common complaints	35
4.04	Repeat visits with unresolved complaints	35
4.05	Clinical intake	36
4.06	History and physical (H&P)	36
4.07	Management of referrals and consultations	36
4.08	The patient advocate	37
4.09	Laboratory and diagnostic services	37
4.10	Test results	37
4.11	Test tracking	37
4.12	Preventing medication errors	38
4.13	Medical emergencies	39
5.00	Practice overview	40
5.01	Scope of practice	41
5.02	Patient handbook	41
6.00	Staffing	43
6.01	Leadership	44
6.02	Organizational structure and supervision	44
6.03	Recruitment and hiring	44
6.04	Use of temporary staff	45
6.05	Floating staff assignments	45
6.06	Job descriptions	45
6.07	Medical assistants	45
6.08	Orientation, training and continuing education	45
6.09	Staff meetings	46
6.10	Employment practices liability	46
6.11	Professionalism	46
6.12	Performance reviews	47
6.13	Coverage issues	47
6.14	Students, interns, residents in the practice	47
7.00	Office operations and systems	48
7.01	Billing and collection policies	49
7.02	Cost of healthcare	49
7.03	Payment delays	50
7.04	Waived fees	50
7.05	Compliance with coding and billing requirements	50
7.06	Managed Care Organizations (MCOs)	51
7.07	Practice coverage	53
7.08	Notification	53
7.09	Transfer of duty	53
7.10	Locum tenens coverage	53
7.11	Medication management	53
7.12	Prescription pads	53

7.13	Medication storage	53
7.14	Controlled substances	54
7.15	Medication samples	54
7.16	Authentication	54
7.17	Advertising	54
7.18	Media relations	54
7.19	Contract administration	55
7.20	Closing a practice	55
7.21	Medical record maintenance	56
7.22	Safe disposal of medications	56
7.23	Insurance	56
7.24	Contracts	56
8.00	Appointment scheduling and patient registration	57
8.01	Telephone access	58
8.02	Telephone triage	58
8.03	Traffic flow	58
8.04	Patient registration and checkout	59
8.05	Waiting times	60
8.06	Missed and cancelled appointments	60
9.00	Medical records	61
9.01	Ownership	62
9.02	Confidentiality	62
9.03	Record release	62
9.04	Security	63
9.05	Structure and design	63
9.06	Patient identification	63
9.07	Length of record maintenance	63
9.08	Record format	64
9.09	Allergies	64
10.00	Facility management and safety	65
10.01	Location	66
10.02	Office appearance	66
10.03	Waiting room appearance	66
10.04	Examining room safety	67
10.05	Equipment safety	67
10.06	Emergency response	68
10.07	Fire and life safety	68
10.08	Disaster plan	68
10.09	Infection control	69
10.10	Hazardous waste management	69
10.11	Bioterrorism risks and exposures	70
10.12	Materials management	70
10.13	Management of salespersons and vendors	71
10.14	Preventing workplace violence	71

11.00	Legal and regulatory compliance	72
11.01	Corporate compliance plan	73
11.02	Implementing a corporate compliance plan	74
11.03	Other statutes and regulations	74
11.04	Voluntary accreditation	75
11.05	Office-based research	76
12.00	Risk identification strategies and claims issues	78
12.01	Incident reports	79
12.02	Design of an incident reporting system	79
12.03	Other sources of risk identification	80
12.04	Reporting a claim	81
12.05	Requests for patients' records	82
12.06	Response to a subpoena	82
12.07	Risk financing	83
13.00	Conclusion	84
14.00	Endnotes and bibliography	86

Foreward

1.00

Physicians' practices differ from one another. Because they do, doctors and their staffs can use this Manual to identify the risk management elements that are essential for their own, customized risk management programs. These elements should be prioritized and implemented according to a "doable" time schedule. The goal should be steady progress toward success, not overnight completion.

1.01 Purpose

Risk Management Reference Manual for the Medical Practice has been written to provide an overview of the elements that should be included in a practice-based risk management program. This document is not a "how to" manual. Rather, Medical Protective seeks to share with physicians and their staffs the important considerations that need to be addressed when designing and implementing a risk management program.

Risk Management Reference Manual for the Medical Practice also provides resources. It includes the basic structure of a risk management program, incorporating answers to frequently asked questions. The Manual lists additional resources for information on numerous topics. It shares the addresses of useful web sites.

1.02 Audience for Risk Management Manual for the Medical Practice

The intended audience for this Manual includes practice-based physicians, office managers, and clinical staff. Medical Protective hopes that the Manual will serve as a useful map, helping physicians and their teams follow the road signs along the highway of quality. Doctors should share the Manual with staff and employees, using it to develop policies, education and training, and team orientation. The Manual should not be viewed as a cookbook. Rather, it should be used to define the team's common priorities and goals. It should be available to everyone involved with the practice. When printed out and used properly, it will probably become dog-eared and covered with notes.

1.03 Risk management philosophy

For over a century, Medical Protective has been the expert on practice-based risk management issues. Over time, the company's approach to risk management has evolved away from the classic "medico-legal" approach to risk management. Instead of focusing on patients as potential plaintiffs, and instead of looking at every patient interaction as an incentive to practice defensive medicine, the soundest risk management program focuses instead on three fairly straightforward elements: a) communication strategies that focus on respectful and responsive working relationships throughout the healthcare continuum; b) commitment to quality care; and c) documentation of the care processes. The doctor who focuses on these three elements is already practicing sound risk management.

Professional Liability in Physician Office Practice

2.00

As patient care continues to move to the ambulatory setting, liability risk accompanies it. Over the last decade, the frequency (number) of claims has remained relatively flat while the severity (cost) of ambulatory and office-based claims has increased. Medical Protective data reveals that, from 1991 to 2002, the average indemnity payment increased 143 percent. The major factor contributing to this increase was the rising number of large indemnity payments: between 1991 and 1998 the yearly number of indemnity payments that exceeded \$1 million ranged from 1-9 while, from 1999 to 2002, the number of \$1 million-plus payments ranged from 12 to 21.¹

2.01 Rationale for practice-based risk management programs

Economic stresses, specifically within the insurance industry, have tightened the market. Long-term professional liability insurers have ceased to exist or have abandoned all or portions of the market. Insurance carriers are raising rates and tightening their underwriting guidelines. Physicians who were considered acceptable risks as recently as 2000, have noted substantial premium increases — or may have received cancellation notices.

Just as important as the elements of a risk management program, the rationales behind these elements are also essential to a workable program. It isn't enough to say "do this" or "do that." Physicians and their teams need to know the "why's" as well. What is society's perspective on patient injuries? How do the courts determine negligence, from a legal perspective? How do various regulatory and professional associations determine the issues that should become the foundations of effective risk management programs? These will be explained so that everyone associated with the practice acquires a better understanding of the variety of perspectives and expectations that surround healthcare. Although many of these issues occur outside the four walls of a medical practice, they have a profound effect on what will ultimately take place within the practice.

2.02 Current liability trends

According to Medical Protective closed-claim analysis, average indemnity payments increased from \$98,682 in 1991 to \$239,979 in 2002.² Similarly, the National Practitioner Data Bank (NPDB), repository for data on closed claims paid on behalf of healthcare providers, noted that the average indemnity payment for all medical specialties increased from \$154,491 in 1991 to \$268,571 in 2001. The NPDB Public Use File also noted that claims closed for over \$1 million grew from 1.30 percent (180 claims) in 1991 to 2.73 percent in 2001 (460 claims).³

Physicians will not be surprised to learn that high-risk specialties face greater risk when they provide care in a hospital setting. This can be attributed to the increased acuity of persons admitted to hospitals. As a result of the increase in outpatient services, it follows that primary care physicians, including family practice physicians and internists, are more likely to sustain liability for care they provide in-office. Diagnosis-related claims, including misdiagnosis, failure to diagnose and delay in diagnosis, were among the allegations most frequently cited by three of the major medical malpractice carriers, including Medical Protective and supported by NPDB reports. Leading the list of diagnosis-related claims were cancers, particularly breast cancer, and myocardial infarction. Common risk factors identified in these reports included flawed processes related to communication, documentation, and office systems. The introduction of more technology into office practice and complexity of procedures are other risk factors. Information related to these common risk factors should be available to all physicians so that they can take steps to address the risks in their everyday clinical activities.

Communication

3.00

The benefits of effective communication skills extend beyond patient (and physician) satisfaction with the healthcare interaction. Communication also influences the clinical aspects of care; studies have proven that communication improves doctors' ability to make sound medical decisions, thus leading to improved health outcomes, and a reduction in the number of malpractice claims.

3.01 The basis of the physician-patient relationship

Physician-patient rapport has often been referred to as “bedside manner.” Regardless of what it is called, it continues to be an important component of the difficult-to-define art of medicine. While most physicians do attempt to communicate effectively with their patients, many physicians report that their medical schools offered them little or no training in this area. A growing body of evidence indicates that communication skills can be learned and that they are essential to successful medical outcomes. As a result medical schools are increasingly attempting to standardize the way communication skills are taught and evaluated during medical training.⁴

3.02 Definition of communication

Communication can be defined in many ways. One definition states that communication is a process by which the message sent is the message received. If communication requires sufficient confirmation and feedback to ensure that both parties concur that the message was effectively transmitted, then rapport between physician and patient is key to positive working relationships.

3.03 Formats, types of communication

Communication in the medical practice may occur in a variety of formats: oral, written, or, increasingly, electronically — transmitted via telephone, fax, email or other technologies. Both verbal and nonverbal messages are important in building patients' trust and confidence. Effective communication skills benefit the physician in a number of ways:

- Improved ability to obtain a comprehensive patient history.
- Increased patient compliance resulting from patient education, answered patient questions and concerns, and decisions based on shared and realistic expectations.
- Improved ability to address the challenges inherent in making difficult decisions and sharing bad news.⁵

3.04 Courtesy, manners and common sense

Courtesy and good manners are the foundation of good communication. Sometimes they are ignored in the rushed atmosphere of a busy office practice. Practice policies, job descriptions, and training cannot be effective if they don't include the basics of interpersonal communication.

- **Respect: First impressions count. When doctor and staff are impolite to each other, patients notice. Respect begins with the healthcare team and then expands to include patients. Interactions with patients should begin with introductions, with explanation of titles, and with handshakes.**
- **Sincerity: Every human being has a different personal style: some physicians are gregarious, others are reserved; some staff members and employees are outgoing and friendly; others are more formal in their day-to-day interactions with patients. Poorly-contained joviality and effusiveness may be as off-putting as a surly demeanor. Concern and caring are evidenced by willingness to work with patients, to promptly address their needs/concerns, and to treat them as members of their own healthcare team.**

- **Shared goals and expectations:** Doctors and their patients build effective working relationships when each interaction addresses agreed-upon priorities. Doctor and patient should always prioritize what they hope to accomplish during their allotted time. By meeting priorities and by following through on the treatment course as described to the patient, the doctor reinforces the patient's perception that important matters are addressed and that their time together was well spent.
- Whenever possible, the doctor should sit down with the patient while taking a history or reviewing treatment options. Physical barriers, such as large desks or examination tables, create emotional as well as structural walls between the doctor and her patient.
- The ability to listen is “the most elegant diagnostic skill,” according to Sir William Osler. Patients need to tell their stories in their own way. Interruption is rude and may prevent an important piece of information from being shared. “Active listening” is the visible sign of an engaged listener. Head nodding, eye contact, body posture that shows interest — these are all skills that can be learned, but must be practiced in order to maximize their value.
- Open-ended questions consistently produce higher quality information:
 - Closed question: So, you get headaches?
 - Open-ended question: So, tell me about these headaches....
- The doctor must create an atmosphere that not only allows, but encourages questions. Often, patients need to hear the same information more than once in order to absorb it. Especially when people are in pain or afraid, reinforcement of the message is critical to memory and compliance. Patients' questions should be answered again, and again, even when the doctor believes that he has already answered the question. Advertisers use the “repeat” approach to send their messages because they know that humans need help retaining information in long-term memory.
- Eye contact is an important aid to face-to-face conversation. It is an important element but should be practiced. Even while taking notes, or consulting a computer screen, quick glances to reestablish eye contact will prevent an abrupt cessation of conversational flow.
- Body language rarely lies. Fidgeting, looking out the window, or hanging on the door knob are “brush offs.” They tell the patient that the doctor is disinterested and in a rush to move on. Likewise, it is important to maintain a neutral facial expression when patients are relating their complaints, particularly if they are conveying sensitive information such as a problem with substance abuse. If the patient senses that the doctor is judgmental or condemning, no further personal information will be forthcoming.
- Practice policies should specify respect for patient physical boundaries and physical proprieties. The patient should be asked whether or not he gives permission to be touched. He also has the right to know what the intended examination includes and how it will affect the course of his care.
- Doctors and staff should be sensitive about providing information and instructions in terms the patient can understand. Instructions should be time and symptom-specific. Patients should be asked to repeat instructions in their own words. Many practices require staff to review instructions with patients before the appointment ends.
- Before the patient encounter ends, doctors should encourage patients to ask questions about any other issues. It is not uncommon for patients to wait until the end of an appointment to bring up the issues that are actually most worrisome to them.

The risk management issues discussed above comprise but a few of the techniques that successful physicians use to create and enhance patient trust and rapport. They are critical elements in quality patient-physician relationships and in prevention of liability claims.

3.05 Patient rights

The relationship between physician and patients is based on ethical and moral precepts dating back to the Oath of Hippocrates, first used in the fourth century B.C. Basic concepts include doing good (beneficence), avoidance of harm (nonmaleficence), respect for privacy, confidentiality, and justice (fairness).⁶

The American Medical Association (AMA) notes that the patients share responsibility with physicians for their own healthcare. In addition to patient rights noted above, the AMA also states that physicians can contribute to a patient-physician alliance by being advocates for the following patient rights:

- **To receive information and discuss treatment options.**
- **To make decisions regarding healthcare.**
- **To obtain continuity of healthcare.**
- **To have available adequate healthcare.⁷**

All patients, to the extent possible, have a responsibility to:

- **Pursue healthy lifestyles.**
- **Participate in decisions about their healthcare.**
- **Cooperate fully in mutually agreed upon courses of treatment.**
- **Become knowledgeable about their health insurance.**
- **Take financial responsibility for their care.**

A number of medical specialty associations have developed patients' rights policies. These should be used to support effective doctor-patient relationships. Physicians should use models such as the AMA statement or their own professional association guidance to draft patient right statements. These should be posted in the office and included in the practice's patient handbook.

3.06 Patient privacy

In the healthcare environment, the right to privacy has several dimensions:⁸

- **Personal: One's body and the right to physical privacy.**
- **Data: Identifiable health and information, records, and data.**
- **Decision-based: Personal healthcare choices.**
- **Social: Family and other personal relationships.**

The design of office space and patient flow may facilitate or inhibit patient privacy. A review of practice interactions with patients might reveal verbal discussion of personal information being conducted through a staff window into the patient waiting area. Many practices do not use private areas for collection of insurance, billing, or other health-related information. Physical privacy is as important in the office setting as it is in a hospital. Patients should have access to appropriate gowns and drapes during patient examinations. Exam room doors should be kept closed, and chaperones should be present during clinical processes that might be viewed as invasive of the patient's personal privacy.

Unless a capable adult patient has given permission, no other individual(s) should be present in the examination room. Vendors should not be allowed in the examination room. All employees of a practice should receive formal training about the importance of maintaining patient privacy. See Section 11 of this Manual for additional information about Legal and regulatory compliance and the privacy provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

3.07 Informed Consent: shared decision-making

Informed Consent results from a shared decision-making process that includes a patient's and physician's collaborative effort to arrive at the most appropriate plan of care for that patient. A signed form alone does not constitute an adequate Informed Consent. A signature is beneficial only if it documents that physician and patient shared in the decision. The collaboration takes into account the patient's condition, values and preferences. Shared decision-making is an ongoing process that begins when the physician first undertakes the patient's care and continues throughout the patient-physician relationship. A properly-structured Informed Consent dialogue creates mutually agreed-upon and realistic expectations regarding healthcare outcomes. It creates a trust-based relationship that will weather unexpected events. The Informed Consent discussion and strengthening of the patient-physician relationship is more critical in loss prevention than the use of technologies such as videotapes or computerized consents.

Physicians can do much to reduce Informed Consent claims by engaging in shared decision-making with their patients, building patient trust, creating realistic expectations, and documenting the Informed Consent process.

3.08 Ethics of shared decision-making

Informed Consent is based on the ethical principle of self-determination, i.e. that competent adults have the right to make decisions about their own health, including the right to refuse treatment. The elements of Informed Consent include:

- **Disclosure of information.**
- **Patient competence.**
- **Voluntariness of choice.**
- **Physician responsibility.**

3.09 Informed Consent: legal confirmation of shared decision-making

Informed Consent is also a legal concept based on the duty of the physician to disclose to each patient information he or she will need in order to make an informed decision about their care. The amount of disclosure legally required varies somewhat by state. In some states, the standard is based on the patient, requiring that disclosure should focus on information that a reasonable individual would want to know in order to make a sound decision. In other states, the standard specifies that the information disclosed may be based on information that a reasonable physician would normally disclose to a patient.⁹ Each physician should know which standard is applied in the state where he or she practices.

3.10 The physician may not delegate Informed Consent

Physicians have a non-delegable duty to perform the shared decision-making process, i.e. the information disclosure. Physician consultants should obtain consent for the procedures they perform and should not assume that the referring physician has completed this process. Except for general administrative consents, the Informed Consent process should never be assigned to office or nursing staff.

3.11 Information that should be shared with patients

Prudent risk management suggests that the following information should be discussed in every jurisdiction:

- The patient's injury or condition.
- The proposed intervention or treatment.
- The specific risks and benefits of that treatment.
- Risks to the patient if treatment is not undertaken.
- Alternatives available.
- Expected outcomes of the proposed plan and its alternatives.
- Estimated costs of the treatment and its alternatives.
- The patient's questions and understanding of the proposed plan.
- The patient's voluntary decision about the plan.

Physicians should discuss those risks material to the patient's informed decision-making. Remote risks generally need not be disclosed, although many doctors do advise patients of the risk of death or serious morbidity. This approach is especially wise when patients' co-morbid conditions or life situations make such information more urgent. For example, a surgeon will want to discuss and document in greater detail the risks of a knee procedure if the patient is a professional football player.

3.12 Non-physician staff and Informed Consent

Non-physician staff may assist with completion of forms once the physician has carried out the information disclosure. Appropriately trained and credentialed staff may also assist with specified educational portions of the Informed Consent process. If the patient has questions or is wavering about the decision, then the patient should be referred back to the physician. If non-physician staff or practitioners are credentialed within the scope of their training, experience and license to perform certain invasive procedures in a medical practice, state regulations may specify (additional) accountability for the Informed Consent.

3.13 Barriers to Informed Consent

Special circumstances may complicate the communication process and require additional interactions, processes, and participants to become involved. These circumstances may include: disabilities, cultural barriers, or language barriers. All practices should develop policies that will help them address these barriers.

3.14 Language challenges

From time to time physicians and patients report contradictory recollections of an Informed Consent discussion. The doctor may aver that he or she did share Medical Protective Clinical Risk Management Reference Manual for the Medical Practice¹⁴ important information with the patient. But the patient may recall only that the doctor used medical jargon and acronyms. The clinician must adjust his or her vocabulary and conversational style to accommodate the patient. When the doctor is unwilling or unable to perform this important communication step, the communication process instantly breaks down.

- **AT&T Language Line Services can be reached at 800-528-5888 for information and fees.**
- **Local ethnic clubs and associations provide translators in many communities.**
- **Hospitals and public health services may offer resources for local translators.**
- **Other translation services can be located on the Internet by searching on the words “translation services.”**

For non-English speaking patients, use of a translation service may be indicated. While family members can sometimes provide translation, the disadvantages are that patient privacy and confidentiality are not protected and patients are less likely to speak freely if a family member will gain access to intimate details of their health history. Allowing minor children to translate for family members may be inappropriate, particularly if sensitive information is to be discussed. Also, when family members or volunteers translate, the physician may not always have a clear understanding of the exact phrasing and vocabulary used in the translation.

Patients who have auditory, speech or visual disabilities may require other accommodations such as use of TDD (telephone devices for the deaf). Occasionally hearing impaired individuals may demand access to a sign translator, a service that the physician may be told he must provide. Instead, doctor and patient should rather be deciding what method will most support the effectiveness of the doctor-patient relationship. In many instances, written communication or the use of a keyboard ensures the clinician of the opportunity to know exactly which terms and explanations have been used. While slower than a translator, written communication ensures the opportunity to clarify and protects patient confidentiality.

3.15 Cultural values and personal preferences

Patients make decisions within the context of their culture and experience. Increasingly, patients want to use herbal therapies and complementary healthcare practitioners in their care. In a multicultural society, some patients may want to consult a lay healer specific to their culture. Physicians should be open to discussing these alternatives so that they know about other therapies the patient is using, can incorporate therapies they feel are useful into the overall treatment plan, or can warn the patient about practices they believe are potentially harmful. Physicians who care for minority, immigrant and ethnically diverse communities may want to research the long list of web sites available on “cultural diversity,” many of which offer free resources and educational materials.

3.16 Documentation of Informed Consent

While not a guarantee against malpractice claims, documentation of the Informed Consent discussion can provide critical support in the defense of a claim. Documentation in the patient’s record can be completed in several ways:

- **A procedure-specific form that contains full documentation of the information provided to the patient.**
- **A generic form with a checklist format.**
- **A generic form that lists the elements of consent discussed with spaces available to include the specific procedure and diagnosis.**
- **Generic, all-inclusive note in the patient’s record. The factors discussed should be included as well as any relevant patient comments, and the date and time of the consent.**
- **State-mandated forms, if required, for specific procedures.**
- **Manufacturer-provided forms, such as those available with implantable contraceptives.**

Regardless of the method used, discussion of any patient-specific risks, e.g. obesity, diabetes, prior surgery, should be documented. Medical practices should implement one set of policies that will be used by the entire medical staff to document patient education and Informed Consent. Such policies should address state or federally-required forms, or specific educational materials/forms that the doctors have selected for their value to patient understanding. A witness' signature is not required, unless otherwise mandated by the state. A witness' signature merely verifies that the named patient signed the form. A written policy outlining the staff's role in supporting education and forms completion is also useful.

When the patient selects a healthcare treatment on a voluntary basis, this means that the patient made the decision without coercion from family or medical personnel. Coercion and competency sometimes become issues in claims. A common allegation of this type is that an Informed Consent discussion did not take place. It is not uncommon for a patient to assert that, after being medicated for a procedure, a form was thrust upon him and he was required to sign the document, or be denied care. Every medical practice should ensure that its Informed Consent procedures and its documentation policies prevent even inadvertent high-pressure tactics from being implemented in order to obtain a speedy patient consent.

3.17 Other statutory requirements

Some states address Informed Consent by compelling use of templates and/or forms that should be completed for specific procedures or patient populations, such as: sterilization; certain types of contraception; Medicaid patient status; or HIV testing. Other statutes address end-of-life issues such as the right-to-die. And, a growing list of federal requirements impact Informed Consent — including HIPAA, Medicare and possibly EMTALA (Emergency Treatment and Active Labor Act otherwise known as the “anti-dumping” act), depending on the physician's office practice location and affiliations. Each physician should know the Informed Consent requirements in effect for his or her state and ensure that office policies and procedures ensure compliance. Local medical or specialty societies or a physician's personal attorney should be able to provide this information.

3.18 Informed refusal

Competent adults have the right to refuse treatment, or to withdraw or change consent at any time. When this occurs, the physician will want to document his or her assessment of:

- **The patient's mental status with considerations of possible substance abuse, physical condition (diabetes, Alzheimer's, stroke, etc.), or mental illness. Clinical assessments necessary to establish or confirm these elements should be documented.**
- **The patient's reason(s) for refusing care. Documentation should emphasize attempts to clarify a possible misunderstanding of the recommended treatment plan. The possible consequences for refusing care should be reinforced.**
- **The family's ability to be involved, supportive and to act as witnesses of the patient's refusal. Documentation should include family's responses.¹⁰**

Another difficult situation occurs when parents, usually for religious reasons, refuse essential treatment for minor children. In life-threatening situations, the physician should contact the ethics committee of the hospital where he or she has admitting privileges and where the minor child/children would be likely to receive treatment.

3.19 Informed Consent and minors

Treatment of minors in non-emergency situations without the consent of their parents is addressed in most states by statute. Because these statutes vary, it is difficult to be specific. Such statutes generally include definitions of “mature or emancipated” minors, or have provisions allowing minors to consent for treatment of sexually transmitted diseases, sexual assault, pregnancy and substance abuse. Physicians, particularly those who treat adolescents, need to know their state statutes and develop office policies regarding treatment of unaccompanied minors.

3.20 Resolving disputes with patients

Patient dissatisfaction can lead to poor public relations and revenue loss as unhappy patients complain to family and friends. A medical practice may lose part of its patient base without knowing the cause. A study in *The Journal of Family Practice* found that dissatisfaction with interpersonal communication, inability to access information, and distrust of primary care physicians were the major reasons cited for switching doctors.¹¹

Complaints may also be early indicators of a potential lawsuit, particularly if the complaint is not resolved. Hickson and others reported in a recent *JAMA* article their findings that unsolicited complaints captured and recorded by a medical group were positively associated with physicians’ risk management experience. Patients were more likely to complain about surgeons and to sue surgeons in a 1992-1998 study of 645 physicians. Lawsuits were related to complaints, even when data were adjusted for the physician’s volume of clinical activity. A small group of physicians (eight percent) accounted for 48 percent of all claims.¹²

These and similar studies indicate that physicians need an objective way to assess how patients perceive their practice. A mechanism to manage complaints is strongly recommended. Also, practice policies should ensure that physicians as well as staff are held accountable for collegial and professional behavior with their peers as well as with patients.

3.21 Patient satisfaction

Measurements should be periodically implemented to assess patient satisfaction. These methods can be relatively simple, such as a brief survey that the patient can complete at the checkout desk or perhaps a post card mailing using pre-stamped foldover cards. The survey should encourage feedback on all providers and services offered by the practice. Surveys should be brief and questions should be worded in a neutral manner, avoiding bias. The questions should ask for specific rather than vague responses. Rather than asking “Was your wait time acceptable?” a question might obtain more useful responses if it asked how long the patient waited to see a clinician, e.g. “15 minutes or less, 16-30 minutes or more than 30 minutes.” Staff should be encouraged to document both the positive and negative feedback they hear from patients. This information may provide numerous opportunities to improve the efficiency and effectiveness of an office practice.

Medical societies and specialty associations are resources for a variety of patient satisfaction surveys, many of which are designed to garner input from specific patient demographic groups.

Doctors who participate in managed care plans will be asked, from time to time, to participate in one of the plan's membership surveys. These data may be used in practitioner performance evaluations.

3.22 Learning from patient complaints

Patient complaints may be caused by administrative issues such as waiting times or billing mix-ups, behavioral issues such as a rude interchange with a receptionist or clinician, and clinical issues such as the patient's perception that the physician overlooked a symptom or did not answer questions. An office complaint management program should include doctor and staff accountabilities as well as information and data collection protocols and implementation commitments. Elements to consider include:

- **A method to facilitate patient feedback, such as a suggestion box or hotline.**
- **Staff who are designated because of their training and experience to respond to patient complaints sensitively and non-defensively. Patients should know which staff members have this designation and how they can be contacted. In addition, all staff benefit from training in customer relations.**
- **A time frame for response to complaints. Any patient who voices a concern or complaint should receive a telephone call or letter within one-to-two working days indicating that the doctor is aware of the matter and appreciates having it brought to the practice's attention. The timing for actual follow-up should also be specified by policy.**
- **Defined actions that staff can implement without their supervisor's approval, e.g. sending flowers or a small gift certificate to apologize for a billing mix-up or a scheduling error.**
- **Fee waivers or cancellations should be implemented as part of the practice's customer satisfaction policy, not to acknowledge negligence or dishonesty. Fee waivers or cancellations should require physician approval, just as any account sent to collections should also require physician signoff.**
- **A system should be incorporated to track and analyze complaint-related data over time. In this way, patterns can be identified and problems addressed before they become insurmountable.**
- **Staff need feedback.¹³ Proactive staff who have been trained in customer satisfaction and dispute resolution techniques may comprise a medical practice's greatest risk management asset.**

3.23 Reporting claims and incidents

As part of their insurance agreement with any professional liability carrier, physicians are obligated to report a threat of suit or claims in a timely manner. This requirement ensures that the maximum amount of preventive action can be implemented as early as possible and it provides emotional support for the insured doctor. See Section 12 of this Manual for additional information about Reporting Claims.

3.24 Difficult physician-patient relationships

A physician may have a patient whom he or she finds particularly difficult: the non-compliant patient; the chronic complainer; the "doctor shopper;" the disruptive patient, etc. A patient labeled difficult by one physician may not be seen as quite so difficult by another.¹⁴ Physicians have the right to choose those patients they wish to treat and, as long as discrimination laws are not broken and the patient is not abandoned, a physician may choose to terminate the physician-patient relationship with a difficult patient. However, many patients are burdened by educational, emotional, and physical limitations which are the logical cause of their "difficultness."

3.25 Frustrations with the system

Navigating the healthcare system in America today is a difficult, frustrating and time-consuming task for insiders such as physicians and nurses. No wonder patients sometimes feel angry and confused. When the system works at its best, healthcare professionals take the time to consider and respond to patient's need: to have some control over their lives; to preserve self-esteem; to be treated respectfully as an individual; to know what is going on; to be treated honestly, etc. Developing communication strategies will defuse difficult situations before they develop.¹⁵ And, it would be less than honest to place the blame for all miscommunication on the "difficulty" of patients. Physicians and staff should also recognize their own "hot buttons," and try to be objective when these triggers occur.

3.26 Defusing miscommunication

Analysis of why a patient is being difficult may lead to a solution to the problem without terminating the relationship. While effective physician-patient communication may help to identify many of these reasons, a well-trained staff is the doctor's greatest ally in discovering and resolving many of these issues. But staff must first be educated and enabled — and then the doctors must respond and support interventions.

The patient-focused practice will want to use every means available to identify and address non-compliance. Some topics that might lead to clinician and staff processes follow:

- **The patient should be included in the discussion. He or she should be asked what has gone wrong and for suggestions that might provide a solution to the non-compliance.**
- **Verbal instructions should always be supplemented with written materials.**
- **Patients should be asked to repeat the treatment or medication plan in his/her own words to ensure that the instructions are understood.**
- **New patients should be given a copy of the patient handbook. It should explain office policy about scheduling appointments, no-shows, bill payment, etc.**
- **Compassion for patients and boundaries for unacceptable behavior are not mutually exclusive.**

Disruptive patients present another set of challenges. When addressing a potentially violent situation, physicians should first assess whether or not the disruptive behavior may be due to substance abuse, an acute physical condition, or mental illness. The patient should be instructed that the behavior is unacceptable and must stop before care can continue. Staff, patient, and visitor safety should be the primary consideration if the patient is potentially violent to self or others. Every practice should have an established "security" protocol, with code phrases that initiate a call for law enforcement support. Violence may occur in nearly every work environment. Practice policies should indicate preparation and training are in place to deal with these situations.

3.27 Terminating the physician-patient relationship

Physicians may decide to terminate physician-patient relationships for a variety of reasons. Perhaps numerous attempts at communication have proven unsuccessful. Perhaps the patient has repeatedly refused to obtain needed screening or treatment. Perhaps the patient is persistently rude or belligerent to staff and/or to the doctor. Perhaps the patient and physician are simply too different, in any of a multitude of ways, to be able to work as a team.

Generally physicians have the right to treat those patients whom they wish to treat. However, physicians should use care in discharging from their care patients who are members of a protected class. Federal and state laws prohibit discrimination based on race, religion, color, etc, and other laws, such as American with Disabilities Act (ADA) may also apply. When confronted with an issue that might be affected by these laws, physicians should seek legal advice.

When the physician-patient relationship becomes untenable, the doctor should review the patient's record before deciding to discharge the patient. While it is true that healthcare professionals may terminate the physician-patient relationship, it would also be wise for the doctor to have documentation that supports the decision. Is the record factual and objective? Does the record include negative and subjective comments about the patient? Have patient instructions and education been documented? If the patient has made a string of complaints or accusations against the practice, or if the patient has made inappropriate remarks to physician or staff, it would be beneficial if these issues have been noted in the record, using quotation marks to preserve the patient's actual statements, where relevant. Does the documentation note that the doctor and staff have attempted to resolve the problems/address the issues? Has the doctor consistently documented treatment recommendations and warnings to the patient about possible negative effects of non-compliance? Non-compliance should have been documented at the time it occurred, not when the patient sustained an injury. If the record provides no support for the decision to terminate the relationship, then the doctor may be wise to continue treating patient, at least until such time as the documentation supports the decision.

Timing of the termination may be critical in the defense of any allegation of abandonment. Terminating the relationship at a critical juncture in patient care is not recommended. Also, if the doctor is the sole practitioner of a certain specialty in an area, it may take longer to terminate the relationship. Termination of a patient relationship can be problematic if the reason is non-payment of bills. It is important to verify if a contract obligates the continued provision of care. If the patient is not undergoing active treatment, the doctor may advise the patient, either by phone or via a letter that a payment plan must be established and adhered to — or the patient will be discharged from the practice. The patient should be given adequate time to respond; however, if no response is forthcoming, a termination letter should be sent. *If the non-paying patient is in the midst of active treatment, such as a course of chemotherapy, it would be wise if the doctor seeks legal advice before sending any notice of termination.*

A formal process to terminate the relationship should be followed to avoid allegations of patient abandonment. This entails:

- **A certified mail, return-receipt-requested copy of the letter should be sent to the patient. Because some patients may refuse to accept delivery of a certified letter, the doctor may choose to mail a regular mail copy of the letter at the same time that the certified letter is sent. Or, the doctor may elect to send the certified letter first and wait to see if the patient accepts it; if not, the regular mail copy should then be sent. In either event, copies should be retained in the patient's file.**
- **Generally, the doctor is under no obligation to provide a reason for withdrawing from the patient's care. Some physicians may wish to do so, but the statement should be brief. It should not be argumentative or punitive in tone.**

- The letter should commit the doctor to helping the patient through the transition period by offering to provide emergency care only for the time being, usually 30 days. This provides the patient sufficient time to obtain the services of another physician. As mentioned above, some specialists or physicians who practice in remote areas may need to provide a longer transition period.
- The termination date should be clearly stated.
- Whenever possible, the doctor should provide the patient with resources for accessing another treater. Depending on the community, local hospitals, medical societies, or public health services may provide the names of doctors who are accepting new patients. Generally, it is not a good idea to refer the patient directly to another physician.
- The patient should be offered record transfer to another physician on receipt of an appropriate written patient authorization.¹⁶ This form should be included in the termination letter.
- A copy of the discharge letter should be maintained in the patient's now inactive file. The return receipt, when obtained, should also be maintained in the file.
- Staff should be notified to place the patient's name on a No Schedule List so that the patient is not inadvertently readmitted to the practice.

Managed care organizations (MCOs) may require compliance with additional steps before a physician can unilaterally discharge a patient from his/her care. Warning letters may be required or an extended waiting period may ensure that the patient has adequate time to select another physician from the MCO panel. Likewise, some state health programs may have special grievance procedures that must be followed. In general, it would be advisable for each practice to research local requirements before finalizing discharge policies.

3.28 Other office communication issues

Effective communication among all staff is another important patient safety mechanism. While patient-to-physician communication issues are noted most frequently in claims, physician-to-physician, physician-to-nurse, and other staff communication breakdowns can also present liability exposures. Periodic staff meetings may be a good way to encourage positive discussion of issues that impact office efficiency and patient satisfaction. Tension between and among staff members creates an unpleasant office atmosphere that can readily be discerned by patients. Staff should be empowered to share patient-related information and to help each other when the office is especially busy. Everyone on the staff should be expected to politely and calmly point out to any other staff, including physicians, that an error appears to be in-the-making, e.g. physician is about to inject hip joint of wrong patient. A few awkward moments are likely to produce a much more desirable outcome than a medical error with the potential for serious patient injury. With the patient's authorization, relevant patient data should be shared with other treaters who may also be caring for the same patient.

3.29 Conveying bad news

Conveying bad news is clearly a difficult task, full of pitfalls for physicians who struggle to do a good job with little prior guidance beyond the on-the-job training of medical apprenticeship. This situation may change significantly for future physicians if, as proposed, more formal communication skills courses are added to medical school curricula. In the meanwhile, guidance is available. Some suggestions from experts include:

- **Doctors should plan communication processes just as they plan clinical processes. In the event of an unexpected outcome, it would be well to have prepared the message, in an appropriate format, before the patient encounter. Doctors should plan what they are going to say before meeting with a patient. Subtle word choices can make a difference between a message that is perceived as a harsh death sentence versus an equally grave message that conveys the physician's empathy and preserves some hope. It is possible to be both compassionate and forthright at the same time. Human emotions are acceptable ways of expressing feelings. Physicians and staff should be prepared to deal with emotions — their own as well as their patients'.**
- **The revelation of bad news should be considered from the patient's point of view, not the from the clinician's.**
- **Patients need to be kept informed as a work-up or treatment proceeds. For example, when a patient is advised to undergo a prostate biopsy, he should be told that cancer is one of the diagnoses under consideration. This approach may cause some anxiety. But it will also prepare the patient should the report bring bad news.¹⁷ Due to the amount of healthcare information available nowadays, many patients will realize the implications of certain tests anyhow. By sharing information as care progresses, the compassionate physician also builds the patient's trust and confidence.**
- **Common courtesy as well as legal and ethical constraints require that sensitive conversations should take place in a secluded area that protects the patient's confidentiality and privacy. This venue should provide a place where people can sit and talk. The doctor should also sit.**
- **People report being stunned and unable to process anything else that was said when they first learned of a potentially-terminal diagnosis. The diagnosis of a chronic disease, which requires life-long medical management and may result in disability or other impairment, is also difficult news for patients to hear. The patient will need time to absorb the news before the physician launches into treatment options. The physician's use of silence, following the initial diagnostic revelation, can be an effective communication tool and very supportive. It is often beneficial to schedule another visit; at that time treatment options can be reviewed. Alternatively, some patients want to know right away what can be done to fight the disease. Knowledge of the patient will guide the best approach.**
- **Patients should be encouraged to be partners in their care. Patients with chronic diseases who are active participants in their treatment plan seem to have better outcomes. If the patient is interested in trying complementary therapies along with more traditional treatments, his/her physician should be seen as an ally in making optimal decisions rather than as a skeptic who denies the benefits of any care other than the care the physician provides.**
- **In the face of bad news, physicians offer hope. Some patients survive deadly diseases and other live much longer than originally predicted. New treatments for life-threatening diseases emerge all the time.¹⁸ Even when there is no hope of a cure, the physician may be the patient's greatest ally in achieving other goals, e.g. staying at home and controlling pain.**

3.30 End-of-life care

After conveying the bad news of a life-threatening disease, the physician may continue to care for the patient for some weeks or years. In addition to the points made in the prior section, some other strategies may help to maintain good rapport with the patient and family even at the end of life:

- **Doctors must communicate often with the patient and family members throughout the clinical course. A realistic appraisal of the situation helps the patient and family to come to grips with dying — making a will, saying goodbye, addressing spiritual needs.**
- **Continue to support the patient, perhaps by seeing the patient in the office, if feasible, even if other specialists are treating the patient. Physicians report that patients often gain emotional support from their appointments beyond actual medical intervention. And many patients feel abandoned when a beloved primary care physician or specialist “disappears” once the patient has been transferred to the care of other doctors.**
- **Pain control is adequate. Despite the current emphasis on adequate pain management and availability of professional guidelines, patients continue to complain, and sometimes to sue, about inadequate pain control.**
- **Other caregivers, such as social services, hospice care, and visiting nurses, should be involved early on. In addition to the emotional and technical assistance that they provide to patients and their families, these healthcare professionals may help physicians obtain the compliance and support they need in order to maximize the patient’s care. Because there is some current research to show that physicians are often tardy in referring patients for hospice care, these specialists may also help providers do a better job of obtaining necessary end-of-life services in a timely manner.**
- **The family must focus on the patient’s wishes.¹⁹ This approach may be helpful when one family member wants the physician to “do everything possible.” It is the physician who may help the family understand that further medical intervention is futile, may prolong the patient’s suffering, and may contradict the patient’s requests.**
- **The patient’s advance directives should be available, and updated. In the face of ominous signs, the doctor should offer the patient the opportunity to alter his/her directives. The patient does have the right to have a change of heart.**
- **Many families report how touched they were by the simple act of a telephone call or a sympathy card, especially if the doctor was not able to be present when the patient died.**
- **All contact with patient and family should be documented, including discussions about treatment options.**
- **Delinquent bills should be reviewed before being sent to a collection agency. Only the treating physician knows if the care was absolutely beyond reproach. Malpractice claims have arisen when a grieving family received a collection notice soon after the patient’s death.²⁰**

3.31 Disclosing medical error

Medicine has long recognized the physician’s ethical responsibility to disclose accidents, injuries and bad results stemming from medical treatment. Nonetheless, embarrassment, fear of malpractice allegations, not knowing what to say and a professional culture that has not encouraged discussion of mistakes has made it difficult for physicians to feel comfortable disclosing errors to patients. Studies show that patients do want to be informed of errors. And, practically speaking, patients may find out about errors on their own and become furious about a perceived cover-up.²¹

The National Patient Safety Foundation, professional associations such as the American Society for Healthcare Risk Management (ASHRM), and patient safety experts now endorse a position of disclosure of medical error. For physicians with hospital privileges, the Joint Commission on Accreditation of Healthcare Organization's new Patient Safety Standards became effective July 1, 2001. The JCAHO disclosure standard (RI.1.2.2) reads, "Patients, and when appropriate their families, are informed about the outcomes of care, including unanticipated outcomes." Most hospital medical staffs are developing or refining their disclosure policies and procedures in the wake of the new standard. Hospital policies may provide guidance for physicians in the office practice setting.

While many physicians and other healthcare providers are concerned that disclosure of medical errors will inevitably lead to malpractice litigation, some insurers and healthcare organizations have gone on record as supporting early and honest disclosure.²² The Veterans Affairs Medical Center in Lexington, Kentucky has operated under a disclosure policy since 1987. The policy includes honest disclosure of mistakes, appropriate follow-up care and early settlement offers, when indicated, based on reasonable calculations of actual loss. A study of this facility's claims experience from 1990 to 1996 indicated that the policy has had a moderating effect on malpractice liability payments. The study authors note that the disclosure policy seems to reduce the anger and desire for revenge that often motivates litigation and drives punitive judgments.²³

Medical practices should develop a policy on disclosure of medical error and should consider some of the following issues raised by Wu et al:²⁴

- **What is an error?**
- **Who decides that an error should be disclosed? The treating physician alone or the group? What if the treating physician disagrees with the group?**
- **What should a physician do if he or she discovers another physician's error?**
- **What if the error was made by the physician's nurse or medical assistant?**
- **Is there an ideal time to tell the patient?**
- **Who should disclose the error to the patient?**
- **What should the physician do if the patient is incompetent?**
- **Are there other patient circumstances where disclosure of error may not be in the best interests of the patient?**²⁵
- **Would a bioethics consultation be advisable?**
- **Should other resources be involved such as the clergy or social services?**
- **What to say?**
- **What to document?**
- **How to manage ongoing communication with the patient and family?**
- **How are extra expenses, such as hospital, laboratory and physician fees, going to be handled?**
- **How can physicians obtain training in disclosing errors?**
- **What support systems are in place for the physician who has to disclose an error?**
- **How to coordinate other issues that may arise, such as media contacts, federal or state agency inquiry or litigation?**
- **When should the practice risk manager or quality director get involved? And, who will fill this role if the practice does not have either of these officers?**
- **When should Medical Protective be notified? Will other possible exposures require the retention of personal counsel?**
- **Who decides if the error meets state mandated reporting?**

For *general information* about disclosure issues, physicians can contact their professional associations/medical societies, healthcare attorney, or a Medical Protective risk management consultant. For assistance with a *specific disclosure issue*, physicians should contact their Medical Protective claims representative.

3.32 Confidentiality

Protecting patient confidentiality is an ethical as well as legal duty. Protecting confidentiality means that a physician or other practice staff will not disclose patient-identifiable medical information provided by the patient or learned in the course of treatment without the patient's authorization. An increasing patchwork of state and federal laws address patient confidentiality and release of information. State laws may be even more specific in certain conditions, such as treatment of mental illness or definition of an emancipated minor. There are exceptions to confidentiality protections such as the physician's duty to protect the patient from harming himself or the duty to warn a named individual from harm by the patient. State-required infectious disease or incident reporting and required reporting of gunshot and knife wounds are other exceptions to confidentiality protections. The local medical society may be of assistance in identification of state-specific requirements.

3.33 Rationale for a confidentiality policy

Every practice should have a written confidentiality policy that all staff should be required to read and sign annually as a condition of employment. All staff should be trained regarding the confidentiality policy. The need for patient confidentiality should be reinforced periodically. Discussing patients in building elevators or lunchrooms, where the public can overhear, is one of the common ways confidentiality is violated. Physicians and office practice administrators in small communities should be especially vigilant about confidentiality protections; a patient's private information can be quickly broadcast all over town if there is a confidentiality violation.

3.34 General guidelines

Some of the areas that a confidentiality policy should address include:

- **Definition of confidentiality.**
- **Synopsis of applicable state and federal requirements including health conditions with special requirements.**
- **Issues that comprise a breach of confidentiality and steps that must be implemented to address staff discipline or dismissal.**
- **Required patient record releases or authorizations.**
- **Subpoena and court order requests for records.**
- **Who can consent to the release; criteria that define emancipated minor status.**
- **Required contents of the written release.**
- **Exceptions: Required reporting to state, local department of health or police, duty to warn. Policy should specify the individual who has authority to make the decision about an exception.**
- **Access by researchers if applicable.**
- **Required agreements from vendors.**

- Confidentiality requirements for electronic transfer of patient's health information via email, network system, fax, message machine, telephone, and other telecommunication.²⁶
- Current status of implied consent. While sharing patient information with other consulting physicians or the hospital to which the patient was admitted used to be assumed as appropriate due to implied patient consent, that assumption under HIPAA may no longer be valid. These requirements will evolve over time and it would be wise for practices to establish regular update sessions to ensure compliance. In the meantime, whenever there is doubt about the correct policy to follow, it would be wise to obtain a signed patient consent for release of information to a specific provider or entity.

3.35 Guidelines for sharing of patient information via other electronic media

Each practice should establish general guidelines regarding electronically-shared patient information.

- **Facsimile machines:** Medical practices should develop written policies that determine which health-related information should not be faxed. Convenience alone is an insufficient reason for faxing material. The personal nature of some health information should automatically preclude it from delivery by fax, from both a common sense and a HIPAA-compliance perspective. Fax policies should address:
 - All faxed material should be protected by a cover sheet. The cover sheet should include language stipulating that the included material is intended for the addressee only. It should also request that persons who receive a fax that was not intended for them should contact the sending party.
 - When contacted by a party who has received an errant fax, the call should be referred to a specified individual, generally the office manager, who should thank the caller and document the agreement to address the situation: a) that they mail the errant fax back to the office or b) that they destroy the document. In either event confidentiality has been violated and the patient should be notified.
 - Health-related information should never be faxed to general mailrooms. A fax should be sent only after it has been determined that the addressee is available to receive the document.
 - Fax privacy statements should be reviewed by legal counsel as should all documents that relate to the practice's HIPAA compliance; additional language or confidentiality disclaimers may be recommended by the practice's attorney.
 - Thermal paper decomposes rapidly and is inappropriate for use with any kind of health information. Faxes should be filed in the appropriate place in the patient's file.
- **Computerized information:** Practice policies should restrict access to those who have a legitimate need to access information. Policies should spell out the employee-related security accountabilities for such issues as: passwords, levels of access, firewall software, virus protection, screen-savers, and automatic logoffs. Unauthorized browsing should be prevented. Employees who are terminated from employment should not have access to the system; they should be escorted from the office immediately. Whenever an employee leaves, regardless of the circumstances, all security codes should be changed. As security enhancements become available, systems should be updated. Every practice should document its HIPAA compliance plan as it relates to the secure transfer of electronic patient information.

- **Message machine or voice mail:** New patients should be asked if it is acceptable for a representative of the practice to leave a message on message machines or voice mail, either at home or at work. If the patient agrees, this should be documented in the contact information portion of the patient's record. Some messaging systems permit access by coworkers or other family members. The patient may not want these people to know that he or she has seen a physician or undergone a test. Even if the patient does permit voice messages, any message left should be neutral, totally devoid of any clinical detail. The caller should mention his or her name, leave a telephone number, office hours, and request a call back.
- **Cellular and cordless phones:** Physicians should be reminded that conversations conducted on cordless phones may not be secure. Discussions that involve confidential information (and the vast majority of clinical topics are confidential!) should be deferred until a secure phone line is available.
- **Patient-physician email:** Currently this technology is being used by a small percentage of physicians but will likely increase in coming years. Practices that do use patient-physician email, must develop written guidelines to firmly establish ground rules for email use. A signed agreement should stipulate that the patient has read, understood, and will abide by the email communication policy.

The policy should make clear to patients that the practice will do all it can to maintain the confidentiality of patient information, but that it cannot guarantee the privacy or security of email. The patient should receive a copy of this agreement and another copy should be maintained in the patient's file. The agreement should spell out communication guidelines, appropriate format for messages, turnaround times for response, security and confidentiality provisions and compliance with the guidelines.

Fine-tuning of practice email policies will inevitably pinpoint other issues to be resolved. A few examples follow:

- **Physicians should not forward patient email to other physicians, generally consultants, without the patient's written permission.**
- **If a general health-related message is disseminated to an entire patient panel, e.g. flu shot clinic date and time, the format should prevent a recipient from accessing the names or email addresses of other patients.**
- **Email should not be used when time-sensitive, urgent or emergency healthcare issues are involved.**

Many confidentiality guidelines established via state and federal regulations predate the widespread use of telecommunication. Consequently, some gray areas may cause concern when doctors attempt to implement confidentiality policies that comply with telecommunication technologies. Before a medical practice implements its confidentiality plan, the entire system should be reviewed by an experienced healthcare attorney. It should also be periodically updated to ensure compliance with fluid changes in state and federal regulations and to take advantage of changes in technology, e.g. improved security systems.

For additional information, physicians are urged to contact their Medical Protective Risk Management Consultant at 800-981-3213.

3.36 Documentation

Documentation in the medical record fulfills many purposes. It records and forwards the course of patient care. It facilitates communication among caregivers. It forms the basis for coding and billing. It provides data pertinent to quality improvement. And, it may provide information that is critical to the defense of a legal action. Every practice needs to adopt a uniform system for patient records. Consistency should be built into the system. That includes: the format for documentation, the forms that are used, and the requirements for entries, completion, and review. Continuity of care is one of the most important reasons for a uniform system. The covering physician or other referral physicians within a group practice should be able to quickly and consistently locate critical information. Managed care contracts may also mandate the use of a uniform system. More recently, office practices have proven vulnerable to allegations of fraud and abuse because office records did not support coding and billing submitted to federal and state-funded health programs.

Numerous office practice documentation systems are in use. The American Medical Association (AMA) has been working for several years with the Centers for Medicare and Medicaid Services (CMS) and the Current Procedural Terminology (CPT) Committee to develop and refine the Evaluation and Management (E&M) Documentation Guidelines and updated CPT codes as a basis for Medicare reimbursement. These guidelines use a checklist system to address: history, physical examination, and medical decision-making to document levels of service. The controversial process is complex and not easily applied to patients with co-morbidities.

3.37 Documentation policies and procedures

In order to ensure consistency of documentation, regardless of who enters the information, practices should develop systems that clarify the who, when, where, why, and how of documentation. Issues that should be addressed through policies and training include:

- **Use of black ink and standardized dictation methods.**
- **Consistency in use of patient identifiers in every aspect of the record. Date, time and signatures on all entries.**
- **Entries should always be written in both chronological and continuous order; they should never be backdated.**
- **Written policy should specify the required times for completing documentation and for late entry policies.**
- **Follow-up procedures for ongoing patient problems.**
- **Medication lists: prescriptions, samples, over-the-counter, and herbal and nutritional supplements.**
- **Alternative or complementary therapies, including related patient education.**
- **Allergies.**
- **Current immunizations.**
- **Documentation of recommended screening tests and dates completed.**
- **Entry of patient clinical complaint, history, physical findings and treatment.**
- **Treatment plans, including the rationale(s) for treatment, especially at critical junctures of care, such as decision to admit or not admit a patient who may be suicidal.**
- **Rationale(s) for decisions not to implement particular practice guidelines.**
- **“Watchful waiting” protocols should define call-back and monitoring requirements as well as triggers for further investigation, referral, or aggressive treatment.**

- Patient self-care instructions, referrals, follow-up visits and care, including preservation of copies of pre-printed instruction sheets.
- Use of patient education materials: selection, development, dissemination, documentation, update timing and methods, retirement and archival systems.
- Consistency in addressing and documenting patient non-compliance and persistent patient risk behaviors, e.g. smoking, refusal to obtain a mammogram, etc.
- Education and systems designed to address patients' advance directives, living wills and powers-of-attorney. Also, updates on patients' wishes related to these issues.²⁷
- Systems designed to address patient dissatisfaction or abusive behavior.
- Procedures that ensure consultant reports have been read and initialed.
- Record maintenance requirements that will prevent lost or missing pages or allow inappropriate entries, e.g. yellow "stickies" in the record.
- One set of standards for placing corrections/additions in patient records. These standards should include methods for inclusion of addenda, especially in light of an unexpected outcome.
- An approved set of abbreviations is used throughout the practice. Periodic updates occur.
- Oversight of usage of diagnostic terms. For example, clinicians should be trained to refer to objective data, rather than to assumptions: "patient reacted to medication" might be better documented as, "...patient called to report upset stomach approximately one hour after taking tetracycline."
- Systems designed to ensure that telephone triage, telephone advice, telephone referral, and any clinical situation that might be addressed via telephone are implemented in the same manner by all staff, that responses (scripts, answers to frequently asked questions, etc.) are approved by physicians, and that staff are trained and monitored for implementation.
- Documentation systems for missed/canceled appointments, reschedule follow-up, and unsuccessful attempts to contact patients.
- Documentation methods that appropriately define how clinicians may disagree with each other in a patient's record. Training should emphasize the obligation to collegially address patients' needs, rather than to disparage or compete with other members of the healthcare team.

Issues that are often directly related to liability and will require risk management planning include:

- Risks associated with alteration of a patient record. Training and accountability should be included in plans to address this major factor in loss of liability suits.
- Policy development that precludes negative or judgmental remarks about patients, their families, or any member of the healthcare community.

- Proper use of check lists and forms.
- Proper notation methods that prevent misunderstandings about the level of care or the timing of care.
- A list of “No No’s” that educates staff about the risks associated with:
 - Stamping systems that say: Dictated But Not Read.
 - Use of correction fluid to obliterate information already entered into a patient record.
 - The mistaken assumption that physicians need not oversee transcribed documents to ensure accuracy.
 - Waging war in the patient record.
 - Inclusion of Incident Reports or lawsuit-related correspondence in the record.
 - Second guessing of the legal system, including the use of legal terms, such as “negligence,” “duty” or “liability,” in a patient record.
 - Speculation on or criticism of the actions of other healthcare workers or professionals.

3.38 Patient requests for omission of information

Patients sometimes ask their physicians to omit certain pieces of information from the record. The reasons may be due to concerns over insurance coverage or something in the patient’s history. In compliance with the practice’s established guidelines on confidentiality and the importance of comprehensive documentation of patient information, the physician will be better prepared to explain to the patient: a) the importance of accurate and complete notes for the ongoing care of the patient and b) the steps the practice takes to maintain record confidentiality. If the patient is concerned about a condition that has protected status, such as HIV/AIDs, additional discussion about the regulatory requirements and assurance of confidentiality may be necessary.

3.39 Electronic medical records

Some group practices have converted to electronic medical records (EMR). Electronic medical records should abide by all the required documentation standards that would be implemented in a paper-based system. Additionally, they should be password protected. Usually only the EMR program administrator should be able to make a change to an electronic medical record to prevent tampering. When an error is noted, both the original documentation plus the correction and the reason for the correction should be maintained in the EMR.

State requirements may vary. Practitioners should stay abreast of these differences, particularly if the doctor accepts patients from more than one state. The signature must be secure and the system should prevent use by anyone other than the owner of that signature. Electronic record systems should be able to generate a printed document. This is essential because medical practices regularly receive authorized requests for printed copies of records.

As EMR technology continues to evolve more practices will transition to electronic systems. It is essential that any purchasing or contract decisions include risk management assessments of new hardware, software, or services.

Refer to **Section 9, Medical Records**, in the Manual for additional record administration information.

Patient care and
clinical risk

4.00

While lawsuits most often result from unexpected outcomes, administrative and business-related issues frequently serve as the “final straw” that turns a patient into a plaintiff. This section identifies administrative and operation risks that occur in clinical practice and suggests a variety of approaches that can be used to address them in a risk management program.

4.01 Credentialing of clinical staff

Public policy suggests, and courts have reaffirmed, that physicians, the medical group corporate entity, the practice/group medical director, and its’ directors and officers have legal obligations to ensure the accuracy and completeness of the credentialing process for clinical staff. Advance practice nurses, other non-physician clinicians, and alternative medicine practitioners should also be included in the credentialing process.

To ensure patient safety and to avoid liability, each practice should implement a formal credentialing process similar to that used by hospitals. Managed care plans may require use of their credentialing process for physicians who participate in the plan. While it is true that a credentialing mechanism requires time and oversight, in the long run it proves much more cost effective than the alternative. When the credentialing procedure is not implemented, the practice is likely to incur even greater investments of time and money should negative information come to light once the practice has signed an agreement with an unsatisfactory clinician.

Formal credentialing processes should include:

- **Verification of professional standing. Photocopies of such documents are generally not acceptable as copies may be easily altered or forged:**
 - **Education: diplomas.**
 - **Completion of residency program(s).**
 - **Licenses: Include alternative and complementary licenses, if applicable.**
 - **Board certification.**
 - **Prior affiliations.**
- **Compliance with state requirements, e.g. scope of practice definitions.**
- **Compliance with corporate policy specifications that credentials should be periodically updated. For example, the NCQA requires credentialing every three years.**
 - **Maintenance in each individual’s human resources file of documentation that all training, in-service, and Continuing Education (especially that necessary for maintenance of a license or certificate) is preserved.**
 - **Malpractice history.**
 - **Proof of insurance coverage.**
 - **Criminal background check.**
 - **Pre-employment drug testing, as permitted/required by state law.**
 - **Verification that the applicant has not been excluded as a Medicare/Medicaid provider.**
 - **Notations that additional information has been pursued when gaps appear in the employment history, insurance coverage, or education.**
 - **Vague reference letters or the inability to produce original licenses, diplomas, etc. should be cause for immediate further investigation.**

4.02 Clinical guidelines

Process variation is one of the system factors that contribute to medical error. When every physician in the practice uses a different protocol, e.g. for lower back pain or work-up of breast lumps, there is increased opportunity for confusion on the part of covering clinicians or for certain parts of care to fall between the cracks. Use of clinical guidelines or care paths for frequently seen problems can increase patient safety and practice efficiency. Clinical guidelines are especially important for two areas that figure prominently in diagnostic-related claims:

Formalized prevention and screening policies: Based on the scope of service, physicians should identify all those preventive and screening services that should be offered to patients. This range of services will vary by specialty. Practitioners should reach consensus and select one set of screening recommendations or practice guidelines.

- **Documentation of physician and staff ownership and actions related to prevention and screening: Patients cannot assume greater responsibility for their health unless they are educated about the benefits of prevention and screening services. Tickler systems or computerized patient and physician reminders will provide notice that periodic screening tests are due.**
- **Documentation should include: notices to patients of screening deadlines; patient reminders; follow-up contacts on missed appointments; patient non-compliance; test tracking; and follow-up on abnormal results.²⁸**

4.03 Common complaints

Guidelines should be used for work-up and evaluation of presenting complaints or problems common to high risk diagnoses, such as breast lump, chest pain, abdominal pain with change in bowel habits, or unresolved cough of unclear etiology. Professional groups have developed algorithms, for work-up of these commonly-seen problems, which might serve as a basis for practice guidelines. A higher index of suspicion is advisable for complaints associated with high-risk diagnoses. Young people can develop cancer.

- **Another common cause of complaints is the conflict between a managed care plan's required practice guidelines and the practice's professional guidelines. Doctors should review managed care plans' referral and consultation requirements to determine their comfort level with compliance.**
- **When screening guidelines conflict, the physicians should decide, as a group, which approach the practice will use. Screening guidelines should be determined by the practice, not individually by practitioner.**

4.04 Repeat visits with unresolved complaints

Both staff and physician should recognize the red flag raised by the patient who returns to the office with the same or similar complaints of unclear etiology. The patient may have an undiagnosed problem; treating symptoms alone may be inadequate.

- **Recommended approaches might include: Review of the patient's record, including the History & Physical discussion and physical examination (H&P). The physician should document his/her rationale for deciding whether or not a test/exam should be repeated. Consultation should be sought as needed. The H&P should reflect the treatment plan and integration with test results.**

4.05 Clinical intake

Tracking vital signs and weight over time may help identify diagnoses, plus the record of this activity demonstrates that the physician appropriately monitored the patient. Staff should be trained to record vital signs and weight of each patient on every visit, and other clinical information as pertinent to the chief complaint. The information should be signed and dated by the staff member who recorded the information. The physician should recheck any vital sign value that is questionable.

4.06 History and physical

A thorough history and physical (H&P) examination with follow-up of any areas of concern are key elements in good medical practice. Written and/or verbal H&P updates should always ask about and document patients' responses to questions about tobacco, drug, and alcohol abuse. Use of complementary and alternative therapies and/or nutritional supplements and herbs should also be noted.

4.07 Management of referrals and consultation

Consultation is a prudent step when the patient's problem is beyond the scope of the physician's practice or when a challenging diagnostic question arises. Each practice should initiate a policy that defines its interactions with consultants. A policy for managing consultation and referral should include:

- **Communication with the patient regarding the need/reason for the referral.**
- **Use of a consultation request form that identifies the reason for the consult and any relevant medical information that will help the specialist focus on target issues.**
- **Authorization release form should be used when diagnostic results will be forwarded to another entity or physician.**
- **Scheduling of follow-up appointments and referrals/consultations.**
- **Managed care-specific referral requirements.**
- **Identification of coordinating physician when multiple providers are managing various diagnoses/conditions.**
- **Implementation of a referral tracking mechanism that should include:**
 - **Patient name and identifier (patient record number, birth date).**
 - **Name of physician to whom patient was referred.**
 - **Date of referral.**
 - **Purpose of referral.**
 - **Date of appointment (if made for patient. Staff should encourage high-risk patients to schedule new appointments while still in the office).**
 - **Date report or consultation note received.²⁹**
 - **Practices that self-refer should ensure that they are compliant with Stark II federal regulations.³⁰**

The consultant physician should acknowledge his/her responsibility to ensure that the informed decision-making process culminates in a documented Informed Consent. This practice also helps to establish rapport with the patient. The consultant should telephone the referring physician if urgent action is indicated. A written report should always be sent to the referring physician. Consultants' written reports should not be filed in the patient's record until the referring physician has read and initialed the report.

4.08 The patient advocate

The referring physician and consulting physician should formally agree on who will communicate diagnostic or treatment information to the patient and who will manage specific aspects of the patient's care. If the referring physician decides not to proceed with the consultant's advice, the rationale for choosing another treatment plan should be thoroughly explained to the patient and carefully documented.

Some managed care plans require that the primary care physician approve every specialist referral; others permit the patient to see selected specialists without a referral. Managed care plans generally track specialist and referral utilization. If a patient requests consultation and the primary physician does not feel that is medically indicated, the physician should explain the medical reasons that specialist assessment is not needed currently and document the discussion. These situations can become difficult, and present liability risks, if the patient believes that monetary considerations are driving the medical decision. Good communication and documentation of the clinical rationale for decisions are essential.

4.09 Laboratory and diagnostic services

An equal or equivalent standard of care should be provided for patients across all care settings. Thus, if a physician offers laboratory or diagnostic services within the practice, appropriate standards of care must be met. Practices that provide laboratory services must meet the minimum standards of practice required by The Clinical Laboratory Improvement Amendments (CLIA) of 1988.³¹

If other types of diagnostic tests are offered in the office, such as X-ray, ultrasound, EKG or endoscopy, standards and requirements of the relevant professional associations and regulatory bodies should be met. Staff who work in the X-ray area should wear dosimeters, frequently check the readings, and abide by safety level requirements. Refer also to Section 10 in the Manual for additional information about Equipment Safety.

4.10 Test results

Misfiled or overlooked test results have been implicated in significant patient injury. Test results should not be filed in the patient record until the ordering clinician reviews the results, initials the report, the patient is notified, and a decision on care has been documented. The practice must develop a mechanism that will ensure the immediate reporting and follow-up of panic results to the ordering clinician.

4.11 Test tracking

Every practice needs a system to track laboratory and diagnostic tests throughout the entire process to ensure that:

- **Ordered tests are scheduled.**
- **Scheduled tests are completed.**
- **Test results are received by the practice.**
- **The ordering clinician reviews and initials all test results.**
- **A test reporting form and patient notification process are both in place.**
- **The physician follows-up on test results.**
- **Test results are filed in the correct patient record.**
- **Decision(s) on care are documented.**

4.12 Preventing medication errors

The Institutes of Medicine's 1991 and 2001 reports on the Quality of healthcare in America identified current medication practices as a source of significant preventable error and death.³² In the past few years, The Institutes for Safe Medication Practices (ISMP), The American Society of healthcare Pharmacists (ASHP), The National Patient Safety Foundation (NPSF) and many other professional associations have led the way in identification of unsafe patterns of practice and methods to improve medication systems. Although much of this work has focused on the acute care setting, the findings and recommendations regarding patterns of error in prescriptions are applicable to the office practice setting.

Some causes of error and patient-safety practices related to prescription writing include:

- **Illegible handwriting:** Physicians should write or print clearly and write only one medication per prescription. Priority should be given to pharmacy calls seeking to clarify prescriptions. Such calls frequently prevent serious medication errors. Computerized order entry is recommended as the systems approach to this problem.
- **Distractions:** Disruptions and distractions lead to errors in prescriptions and medication administration. Doctors are more likely to make an error when trying to write a prescription and juggle three other priorities at once. Pages, phone calls and cramped, noisy work areas all create distractions.
- **Monitoring:** Order and review processes should be in place when laboratory tests are required to monitor the effects of certain medications, e.g. periodic liver and renal function tests.
- **Supervision of non-physicians:** State practice acts should clarify which practitioners may prescribe and administer medication. The supervision requirements, if any, for each state should address the prescription of medications by advanced practice nurses. Medication responsibilities should not be delegated to unlicensed personnel.
- **Patient education:** Patients should be given clear directions on how and when to take medication. They should also be provided information on name, dose, frequency, route, indications, desired actions and possible side effects of each of the medications prescribed.
- **Refills:** The patient's record should be reviewed before refills are approved. The number of refills should be limited and patients should be reevaluated before additional refills are ordered. Doctors should be conscious of state requirements and possible manipulative behaviors patients may use when trying to obtain refills for controlled substances. Knowledge of state requirements is essential.
- **Look-alike and sound alike names:** Doctors and staff must be alert to sound-alike, look-alike drugs prescribed by the doctors or samples given to patients.
- **Poorly designed labels:** Manufacturers' labels are marketing tools, not clinical instructions. Doctors and staff need to carefully read labels in order to confirm the correct drug, dosage, and concentration.
- **Dosage errors:** Dosage errors are frequently caused by:
 - Failure to use or inconsistent use of the metric system.
 - Inappropriate use of abbreviations or symbols.
 - Failure to use leading/trailing zeros.
- **Calculation errors:** A policy that requires double-checking of all dosage calculations should be established, and adhered to. Caution should be implemented when an office maintains different dilutions of the same medication.

4.13 Medical emergencies

Every practice needs an emergency management plan that addresses initial response and emergency patient transfer to an acute setting. The amount and type of emergency equipment needed within an office practice depends on the patient population served, the types of procedures performed, and the technical ability of the staff to use the equipment. If the practice has emergency equipment, it must be appropriately maintained and stocked. Pediatric size equipment should also be available if the practice serves a sizable pediatric population. Staff must be trained in the use of the equipment with training and refreshers documented in employee files.

Emergency numbers should be readily available to all staff. In those few parts of the country that do not have access to 911 service, fire, police and emergency medical service (EMS) phone numbers must be posted next to every telephone. Wherever available, speed dial emergency numbers should be programmed into every phone. Staff should be trained in Basic Life Support (BLS).

Refer to **Section 10** of this Manual for additional information about **Facility Management**.

Practice overview

5.00

Physicians should explicitly define the scope and nature of the medical services their practices will offer. Definition of scope of office practice should serve as a basis for recruitment, selection and training of staff, office design and equipment purchase and maintenance, office systems, marketing, and patient education. Clarification of the scope of services also helps create awareness about the full scope of risks to be addressed.

5.01 Scope of practice

In defining scope of services, each practice must first decide whether it will offer:

- Primary care.
- Specialty care.
- Prevention and screening services.
- Alternative and complementary medicine services.
- Formal wellness education services.
- Emergency or urgent care.
- Laboratory and diagnostic testing, including X-ray, ultrasound or electrocardiogram (EKG) and endoscopy.
- Ambulatory surgery.
- Definitions of population(s) served.

5.02 Patient handbook

A patient handbook will clarify patient expectations and increase staff efficiency, as they do not have to repeat basic information for each patient. A simple printed patient handbook could be offered to each new patient, with an additional supply placed in waiting areas. If the practice has a web site, the handbook should also be posted there.

Elements of the patient handbook should include:

- **The practice Mission Statement, its philosophy of patient care.** It should avoid making excessive promises, rather it should promise a “best effort” approach to care.
- **Biographies of clinicians:** names, specialization and brief synopsis of key credentials should be included.
- **Scope of services offered by practice:** See Section 11 of this Manual for further information about Contract Administration.
- **Affiliations:** Should include a list of hospitals where clinicians have privileges.
- **Office hours and locations:** Access to evening or week-end hours should be noted.
- **Office telephone and fax numbers:** These should specify which phone numbers/extensions should be used to schedule appointments, discuss billing/insurance issues, access clinical advice, refill prescriptions, request a specialist consultation, etc.
- **Appointments and cancellations:** Notices should emphasize the practice’s policy about the need to keep appointments or to provide a minimum of 24-hour notice. Charges for “no shows” should be noted.
- **After-hours coverage:** Patients should be told whether there is after-hours coverage and how it can be accessed.

- **Answering service:** After-hours phone numbers and instructions for accessing should be included.
- **Emergencies:** Instructions should include: 911 or other emergency access codes or transport to nearest hospital emergency department, including address and general directions.
- **Telephone advice:** Generally, it is best to implement a policy that allows the staff person who interacts with the patient or the doctor to determine that the patient must first be examined by a physician before advice can be provided.
- **Prescriptions:** Procedures for new prescriptions and refills should be explained. Refills should be encouraged during office hours only.
- **Workplace absences, medical leave and temporary disability forms:** The process should be outlined, including instructions for completing forms.
- **Insurance and health plans:** Billing and collection policies should be spelled out. Information should be included about which plans the practice participates in and its role in the payment/reimbursement process. Patient payment responsibilities should be specified. See *Section 7* of the Manual for additional information about *Payment and Billing* policies.

The patient handbook should be reviewed and updated on a periodic basis. It is essential that the information included in the handbook be current; expired or obsolete information undermines the patient's perception of quality and, in some circumstances, might cause harm.

Staffing

6.00

In office practice, the physician employs a variety of clinical and non-clinical staff. The physician is liable for the negligent acts of these individuals. Sound medical ethics and integrity should serve as the cornerstone of every practice. This section identifies risk issues that occur when a practice minimizes the importance of professionalism and sound business practices.

6.01 Leadership

Expectations for professionalism and courtesy should be established by the physicians who should also model this behavior. Sound staff hiring, training, continuing education and reevaluation practices are ways that the physician protects the legal, ethical and clinical standards of the practice. Use of a human resources handbook will help establish the correct environment and ensure that all members of the practice team are on the same page.

6.02 Organizational structure and supervision

The organization should be structured so that every employee understands the chain of command. When establishing a human resources function it is important that employees not only know who supervises and/or evaluates their work but who serves as a resource for questions or guidance. Aside from written job descriptions which specify reporting roles, an organizational chart may also prove useful to illustrate functional areas and supervisory relationships.

6.03 Recruitment and hiring

Formal recruiting, interviewing, credentialing, and hiring processes should be in place and should be applied consistently to all applicants. The process should include the following:

- **Verification of education, licensing and certifications. Applicants should be required to produce originals rather than photocopies of these documents.**
- **Prior employment experience, including references from previous employers or supervisors.**
- **Assurance that hiring or promotion decision do not violate Americans with Disabilities Act (ADA) requirements.**
- **Background check, including felony activity. Pre-employment drug testing if consistent with state law and, if relevant, policies related to random drug testing are specified.**
- **Verification of U.S. citizenship. Check that individuals who are not citizens of the United States are in compliance with federal immigration laws.**
- **Insurance coverage: Some licensed staff may carry their own liability coverage. When this is the case, a copy of the insurance policy should be maintained in the individual's human resources file.**
- **Review of prior on-the-job training for medical assistants. Additionally, the physician should have separate confirmation of the medical assistant's capabilities. Some states have specific statutes regarding what medical assistants may and may not do. Civil and criminal penalties may be incurred if unlicensed personnel are permitted or required to perform tasks that are beyond the scope of their licensure.**

6.04 Use of temporary staff

If a practice uses part-time, per diem, or temporary staff, the same selection and hiring processes that are used for full-time staff should also apply to these individuals. Issues to be addressed when establishing the procedures for using non-employee staff include:

- **Employment policies of the hiring agency.**
- **Insurance coverage provided to temporary staff by the hiring agency.**
- **Credentialing processes used by the hiring agency.**
- **Orientation, training, and oversight of temporary staff.**
- **Evaluation and feedback processes.**

6.05 Floating staff assignments

If full-time employees are required to float from clinical area to area in a multi-disciplinary practice, these individuals must be cross-trained in the areas and skills they are expected to cover.

6.06 Job descriptions

Written job descriptions should define the skills and licensure or certification required for the position. They should specify procedures that may be performed by licensed staff members and those that may be performed by physicians only.

6.07 Medical assistants

Medical assistants engage in a wide variety of administrative, clerical and clinical tasks. Because they are involved with so many critical aspects of practice function, medical assistants must have strong interpersonal and time management skills.

6.08 Orientation, training and continuing education

In order to support professional growth, each practice should implement an orientation and on-the-job training program that is provided to each new employee. Examples of topics that should be addressed include:

- **Chain of command.**
- **Confidentiality: Required review and signature of office confidentiality policy.**
- **Communication with staff and patients: Verbal and nonverbal, telephone and face-to-face training should address both customer satisfaction as well as safety issues.**
- **Mechanisms for responding to complaints.**
- **Proper responses to (or referral of) clinical questions.**
- **Universal precautions and basic infection control, e.g. proper hand washing.**
- **Hazardous waste disposal.**
- **Equipment safety and maintenance.**
- **Emergency response preparedness.**
- **Disaster plan knowledge.**
- **Incident reporting mechanisms.**
- **Skills evaluation and training.**
- **Compliance with other regulatory mandates.**

6.09 Staff meetings

Staff meetings are most effective when they are scheduled on the same day and time, at least once each month. Their success also depends on the attendance and participation of the physicians and senior administrative team. Staff meetings will help address numerous performance improvement needs. Among them, doctors and staff can work together to identify target issues and to address policy development and training needs. The practice manager should maintain a log or file of orientation, training, in-service, or formal education provided for or offered to staff.

6.10 Employment practices liability

Each practice should develop policies that address employment liability. All staff should be required to review and to comply with these policies. Examples of some of the policies that should be formally addressed are:

- Sexual harassment.
- Americans with Disabilities Act (ADA).
- Occupational Safety and Health Administration (OSHA) requirements.
- Workplace diversity.
- Proper hiring, progressive discipline and firing.
- Whistle-blowing and retaliation.
- Workplace violence.
- Other state employment requirements.

6.11 Professionalism

A professional work environment is essential to the success of any healthcare endeavor. Workplace policies should mandate courtesy and cooperation of all physicians, clinical staff, and support personnel. Each practice should establish an official dress code that, minimally, requires a neat, clean appearance at all times. Nametags should identify individuals by name and by title or official certification.

6.12 Performance reviews

All employees should expect to receive and to participate in scheduled periodic performance evaluations. These should be conducted by the office practice administrator or supervising physician. Evaluations should include objective assessments of compliance with the individual's job description, compliance with office policies and procedures, ability to work well and to interact effectively with staff and patients, as well as opportunities for education and advancement.³³

6.13 Coverage issues

The practice should define the office parameters for working hours, after hours coverage including on call scheduling, shift coverage if used, and vacation requests. Written definition and consistent application of the policies will set expectations for staff and decrease staff complaints of favoritism.

6.14 Students, interns, residents in the practice

Some practices provide in-office practice experience for vocational or clinical students. When students, interns, or residents work in the practice, a contract should define the exact dimensions of their training experience, parameters of activities they may/may not participate in, documentation of competencies, and the structure that will ensure student supervision, and performance evaluation and feedback. Such contracts should be reviewed by the practice's attorney.

Formalized orientation sessions should be mandated for the students as well as for their supervisors. Students should be required to wear name tags that include their status as students, and the name of their supervising organization. Issues such as patient notification of the presence of students (and the rights of patients to opt out of student participation/observation) should also be formally addressed.

Office operations and systems

7.00

Every medical practice is a business. As cost-containment becomes ever-more-important and as patients seek to become more involved and more in control of their healthcare, the efficiency and responsiveness of a physician's staff may effect patient satisfaction to the same degree as the physician's communication style and communication skill. This section examines the operational aspects of medical care including: patient privacy; confidentiality of health information; billing policies, insurance coverage; and access to clinical care.

7.01 Billing and collection policies

Each office should establish a set of policies regarding fees, billing and participation in state, federal and commercial insurance and managed care plans. It would also be wise to develop a policy that addresses issues such as true financial need, delinquent bills and use of collection agencies.

7.02 Cost of healthcare

It is important to prevent confusion over which types of treatment(s) may be covered by insurance and which are unlikely to be covered.³⁴ Frank discussions with patients about the costs or fees associated with treatment options may help prevent "sticker shock." A patient is less likely to complain about the amount of a bill if that matter has been covered before the treatment is initiated.

Expenses for drugs and medications is another area of concern. Medication costs are soaring at the same time that The Centers for Medicare and Medicaid Services (CMS) and employers are attempting to cut back on payments. The out-of-pocket expenses of alternative therapies should also be discussed with patients as part of the shared decision-making process. Many prescription medications are not compatible with herbal treatments and some self-therapy drugs pose risks for patients undergoing invasive procedures, e.g. St. John's Wort is a blood thinner.

Experts report that most Americans are self-treating to some extent. Cost constraints and/or availability of certain drugs have led some patients to purchase medications in other countries. Non-compliance in the appropriate use of prescription medication is rampant. For financial reasons, patients may deviate from prescription regimens, "stockpile" medications, or simply refuse to fill prescriptions. Any of these choices may expose the patient to risk of injury. Education is part of the solution. Issues that a medical practice might cover to help patients be more knowledgeable and more compliant include:

- **Non-compliance should be documented since medication-related injuries are currently the most common cause of patient injury in the U.S.**
- **Patients should be aware of by-mail purchasing opportunities provided by many employers.**
- **They should be encouraged to "shop around" for the best deals on prescription drugs from reliable pharmacies. Drug prices vary from chain to chain and the savvy shopper may find some bargains.**
- **Patients need to be strongly advised about the risks associated with non-compliance with their physician's prescription and/or dosage instructions.**
- **Patients should be educated about attempts by pharmaceutical houses to transfer prescriptions to newer (and often more expensive) formulations — usually when a generic or over-the-counter formulation is about to hit the market.**

7.03 Payment delays

A collection agency should not become involved unless the physician who treated the patient has signed off on this step. Only the physician is likely to recall whether there had been a complication or unexpected outcome. Does the bill include fees for management of the complication or unexpected outcome? If the patient has had legitimate complaints during the course of care, or if the patient is deceased, the physician might prefer to write off or to discount the bill. In any event, since the risks are the physicians, so too, the decision should be the physician's.

In circumstances where assessment of the care provided does not appear to warrant a discount, the physician should contact the patient to learn why the patient is not paying the bill. The motive for this contact should be to see if there are clinical or financial difficulties that the physician may be able to work with the patient to resolve. Following this discussion, the physician will have a better foundation for his/her decision to: a) urge the patient to return for additional treatment; b) work out a relaxed payment plan; or c) turn the account over to collections.

The office manager should be aware of the reputation and the collection strategies employed by the group's collection agency. The practice may avoid liability by using agencies whose techniques are not so aggressive that they may constitute harassment.

7.04 Waived fees

Each physician should consult with his/her attorney or directly with a Medical Protective claims specialist before waiving fees for management of unexpected outcomes or iatrogenic injury. The attorney and insurer may recommend a number of risk management strategies, including prompt waiver of fees or steps to ensure that the patient receives additional care. Early risk management intervention may avert or minimize the results of a professional liability claim.

In some states it is advisable to use a release-from-negligence form, but these must be carefully worded in order to avoid an inadvertent admission of negligence. In other states, such forms are discredited by the courts and, in and of themselves, may be presumed to acknowledge guilt. In the event that a consultant is called in to handle a complication, Medical Protective's claims specialists and/or the physician's attorney will also be able to provide advice on billing arrangements.³⁵

7.05 Compliance with coding and billing requirements

Coding and billing for office practice, particularly for Medicare and Medicaid patients, is very complex and subject to liability for fraud and abuse as well as for noncompliance with the new Health Insurance Portability and Accountability Act (HIPAA):

- **Anti-fraud and abuse regulations:**

Employees who handle billing and coding must be carefully trained. Billing errors must be prevented wherever possible. In the event that errors do occur, current regulations assume that practices have in place appropriate mechanisms for promptly identifying and resolving such errors. Failure to comply with fraud and abuse preventative standards place the practice's corporate entity, its officers, clinicians, and employees at significant legal and financial risk.

If billing and coding are outsourced, the practice must confirm in writing that the billing company also complies with state and federal regulations.

- The Centers for Medicare and Medicaid Services (CMS) offers policy statements, interpretations thereof, and answers to Frequently Asked Questions (FAQs) at its web site www.cms.gov.
- Medical Protective insureds can access business associate agreement templates by visiting the company's web site www.medpro.com.

- ***Health Insurance Portability and Accountability Act of 1996 (HIPAA)***
In tandem with federal regulations designed to prevent rampant error or intentional misconduct in billing processes, the government has also implemented a series of standards related to the collection, transmission, and security of healthcare information. Under the auspices of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), every medical practice should now be in compliance with these expansive regulations.

The Electronic healthcare Transactions and Code Sets Standards took effect in October 2002 and, except for those practices that have filed for extensions, all medical practices should now have in place mechanisms to ensure the consistent coding and transmission of health information.

The Individually Identifiable Health Information standards became effective in April 2002 and enforcement began in April 2003.

- It is beyond the scope of this Manual to provide in-depth information about either of these complex sets of rules. Suffice it to say that every physician, practice administrator, and employee should have a firm understanding of their individual and corporate obligations to comply. Failure to comply with HIPAA places the practice's corporate entity, its officers, clinicians, and employees at significant legal and financial risk. Further information about this and other regulatory and compliance issues may be obtained by contacting a Medical Protective Risk Management Consultant at 800-981-3213.

7.06 Managed care organizations

Physicians are aware of the liability exposures that may be caused by managed care agreements. It has been alleged that managed care places constraints on the physician-patient relationship, focuses on limiting rather than providing access to needed care, and pressures physicians to violate generally accepted standards of care.³⁶ The managed care arrangement is most effective when the primary care physician is allowed to determine the acceptable course of care, focusing on appropriate standards as well as on efficiency and cost savings.

- **Contracts**

All provisions of a managed care contract should be thoroughly reviewed before it is signed.

Special attention should be given to:

- The terms and definitions.
- Selection/deselection criteria.
- Quality guidelines.
- Contract renewal/termination process.
- Documented HIPAA compliance.
- Credentialing process for panel members, including specialists.
- Adequate access to specialists.
- MCO proof of liability insurance.
- Elimination of “hold harmless” agreements may obligate the provider to assume liability for the negligence of others.³⁷

- ***Working within the MCO system***

Many physicians juggle the requirements of multiple managed care plans. In order to ensure compliance with each MCO contract and to reduce provider and staff frustration, practices should develop:

- Contact lists for: required gatekeepers/specialists; case managers; the MCO Medical director, and other key people.
- Access lists including: electronic contact systems; telephone numbers; fax numbers; and mailing addresses.
- Process steps including: required forms; formulary; referral network utilization requirements; benefit options; the appeals process.
- A system to ensure appropriate procedures are implemented and documented when a physician’s clinical decision differs from MCO requirements. These steps should include: clearly-defined treatment plan; case manager consultation; check list to ensure completion of each step of the MCO’s guidelines; outcome data and professional literature supportive of the physician’s case.
- Formalized staff training and processes to maximize the efficiency of:
 - Access to key MCO contacts to facilitate authorizations, pre-certifications, and appeals.
 - Checklists to ensure that required processes are completed for each patient.³⁸

- ***Denial of benefits***

Following the appeals process, the MCO may still deny benefits. When this occurs, the physician should initiate a shared decision-making discussion with the patient. This discussion should address the clinical risks associated with failure to follow through on the physician’s recommendations. Such discussions should also include the financial implications of proceeding with non-covered care. The physician’s clinical judgment should continue to guide the process.

The patient who refuses to accept recommended care does so at his or her risk and practice policy should specify that the physician will not approve such decisions. Careful documentation of the physician’s advocacy efforts should appear in the patient’s record. Documentation of Informed Consent and/or Informed Refusal should also appear. Regardless of the frustrations that may arise during the appeals process, physicians should avoid making emotional comments about MCOs in any conversation or written communication with either the patient or the MCO representative(s).

7.07 Practice coverage

Physicians should make practice coverage arrangements for those times when they will not be able to see patients. It is strongly recommended that such arrangements should ensure coverage by a physician with comparable capabilities and scope of practice. The covering physician should have privileges at the same hospital as the attending physician. The covering physician must also have adequate levels of insurance coverage for professional liability. Physicians in solo practice may have to trade off with a colleague from a neighboring practice or community. If at all possible patients should be warned if they may have to travel some distance to receive care.

7.08 Notification

Coverage schedules and contacts should be available to answering services, hospitals and emergency departments where the attending physician has admitting privileges. Hospitalized patients should be informed if another physician will be caring for them after hours or on specific days. Patients should not be surprised to learn that their in-hospital care will be provided by a hospitalist, rather than by their personal physician. Office telephone message systems should contain current coverage information and what to do in an emergency.

7.09 Transfer of duty

The covering physician should always be provided with information on hospitalized patients, any anticipated problems, pregnant patients near term and how to access patient records, as needed. The care process should include a mechanism that will ensure medical care and advice are documented in the patient's record.

7.10 Locum tenens coverage

When coverage is provided by a locum tenens physician, the same selection and credentialing procedures should be implemented that would have been implemented if that physician were to be hired as an employee of the practice.

7.11 Medication management

Medication issues are a frequent cause of professional liability for physicians. Each practice should review its medication policies and procedures to maximize security, protect patient safety and confidentiality, and to ensure compliance with federal and state regulations.

7.12 Prescription pads

Every practice should have in place a mechanism to prevent unauthorized persons from accessing prescription pads. Physicians should never presign or postdate blank prescription forms. Other prescription-related policies should include: the reporting of lost or stolen prescription blanks/pads to Drug Enforcement Administration (DEA) and local law enforcement.

7.13 Medication storage

Medications, syringes and needles must be stored in dry, secure locations. The practice must ascertain that all elements of its medication plan comply with OSHA and other relevant standards for employee safety.

7.14 Controlled substances

The best risk avoidance technique precludes the availability of controlled substances within a medical office, unless there are compelling reasons to the contrary. When practice policy necessitates the presence of such drugs, process should be in place to ensure consistency in the ordering, storing, counting, and dispensing of controlled substances. Policy should prevent the control of the various aspects of the system by only one individual — and that includes physicians. Regular inventory checks should note improper handling or maintenance; missing controlled substances should be immediately reported to the Drug Enforcement Administration (DEA) and local law enforcement.

7.15 Medication samples

Most medical offices provide free samples as a service to patients. This custom is not without risk, however. Inventories of these drugs should be documented and regularly updated; expired drugs should be disposed of in an appropriate manner. Provision of samples, including doses, should be documented in patients' records, along with dosing instructions and patient education. It is a federal requirement that a physician must request medication samples in writing from a pharmaceutical rep and that the pharmaceutical rep may not provide samples without the physician's written request. Compliance with this regulation is being more closely scrutinized and medical practices are strongly advised to ensure that such a policy is in place — and followed. The Institute for Safe Medical Practice notes that the provision of samples to patients is a cause of medication errors.³⁸ For additional information about sample-associated risks the ISMP Web site may be accessed at: www.ismp.org

7.16 Authentication

Medical assistants or other office personnel should never be allowed to use the physician's signature stamp to authorize prescription refills. Stamps should be protected with at least as much oversight as prescription pads. Section 9 of this Manual focuses on the Medical Record and includes additional information about the proper use of signature stamps or electronic signatures for the prescription order/refill process.

7.17 Advertising

The American Medical Association's Statement on Ethics notes that physician advertising should not:

- **Mislead because of omission(s) of material information.**
- **Contain false or misleading statements.**
- **Intentionally deceive.**
- **Include testimonials.**
- **Imply or guarantee certain results.**³⁹

7.18 Media relations

Office policy should specify that all requests from the media for comments or interviews should be referred to a specified individual, such as the office practice administrator or the physician who has been designated as the media contact person.

Designated media contacts should also know the circumstances in which legal advice should be sought before media requests are met. In general, training for media contacts should ensure that they have a plan for an initial best response and that they consistently avoid speculation about an outcome or about the care provided by any provider or healthcare entity.

7.19 Contract administration

A physician in office practice may be involved in numerous contractual agreements. These might include: MCOs; vendors of office supplies and equipment; service agreements; outsourced billing and dictation; building leases; insurance; partnerships; employee contracts; employee benefits providers; construction projects; agreements to serve as a training site for students; arrangements to serve as medical director for a long-term care facility; temporary staff/locum tenens agencies; answering services; collections agencies, etc. In a group of two or more physicians, if each physician is making contractual arrangements on his own, the state of the practice's contractual commitments can quickly become disorganized. Contractual provisions and commitments may be inadvertently overlooked presenting a liability risk. Or, contracts may be automatically renewed without adequate review by the practice of the quality and cost of services received.

To prevent contract liability and organize contract administration:

- **The practice should empower one individual with responsibility for oversight of the contract administration process, generally the office practice administrator.**
- **Written policy should specify which individual(s) have authority to sign contracts on behalf of the practice or group.**
- **A formal process should ensure timely review of all contracts at least 30 days before renewal. Review should include analysis of the quality of service provided by the contracted entity and should provide sufficient time to notify the vendor if the contract will not be renewed.**
- **All sections of the contract should be reviewed, including attachments and amendments, before the contract is signed.**
- **All contracted parties should document their compliance with applicable state and federal regulations, e.g. HIPAA.**
- **Where jurisdictions allow, employed physicians should be parties to a formal employment agreement.**
- **All contracts should be maintained in one secure location. A separate index of all contracts, and their current disposition, should also be maintained.**
- **Every new or renewed contract should be reviewed for hold harmless or indemnification clauses. Practices must ensure that they are not promising to indemnify another party.**
- **Providers of professional services must produce documentation of adequate levels of professional and general liability insurance.**
- **All contracts should be reviewed by a lawyer who is qualified to provide this type of assessment.⁴⁰**

7.20 Closing a practice

Patient well being should be a primary concern when a practice must be closed. Patients should be given ample written notice, e.g. 90 days, of the scheduled closing. Dissemination of the information should use a variety of methods. Notification should include:

- **In-person announcements during office appointment.**
- **Form letters.**
- **Ads in local newspapers.**
- **Office answering machine messages.**

Verbal and written notices should explain to patients that they may obtain copies of their records but the process requires a signed authorization. When letters are used, these forms should be enclosed. When possible, patients should be provided with resources that may help them access another physician, e.g. the phone number of the local medical society or a community health services referral hot line.

If the office is closed suddenly due to the physician's illness or death, the office practice administrator or practice executor should notify the physician's patients as soon as possible by telephone and mail. The office's answering machine message should be changed to provide notice to patients. Among the issues that should be included in the telephone message should be a caution that patients should go to the local Emergency Department if they need to access immediate care. The local Emergency Department should be notified of the circumstances and of the possible increased patient load.

7.21 Medical record maintenance

All of the requirements for maintenance of medical records remain in place when a practice is closed. If the physician is deceased, the executor of the estate is responsible to ensure proper maintenance of the records. Refer to Section 9 of this Manual for additional information about Security of Records and Record Maintenance.

7.22 Safe disposal of medications

Each practice should implement a system for the safe destruction or disposal of medications, solutions, and other medical office supplies.

7.23 Insurance

Physicians should never cancel their professional or general liability insurance until they have discussed their plans with their Medical Protective marketing representative. Certain types of insurance require the purchase of "tail" coverage to protect the doctor's interests should claims arise after the practice has been sold or closed or the doctor is deceased. Likewise, premises insurance should not be cancelled until such time as the physician is no longer the legal tenant or owner of the office building or property.

7.24 Contracts

Vendors, MCOs, and other organizations with whom the practice has business arrangements, must be given sufficient notice in accordance with the terms of a contract. Whether or not the physician is present, the practice administrator, a senior partner, or the executor of the physician's estate should document all such notices, including the date and time of notification.

Additional information about closing a medical practice can be accessed at the web site of the American Medical Association at www.ama.org.

Appointment scheduling and patient registration

8.00

The opportunity for good customer relations begins when a prospective patient calls for an appointment and visits the office for the first time. Promptly-answered phone calls, knowledgeable staff who are friendly and patient, quick access to appointments and reasonable office waits are non-clinical factors that influence patients' impression of the practice even before they meet the physician. Physicians obtain significant risk management benefits when front office staff are friendly, able to cope with multiple demands and repetitious questions, and enjoy working with the public. Customer service training is a valuable investment in patient satisfaction. Patients should always know the name and professional designation of staff members with whom they interact.

8.01 Telephone access

In many industries performance standards support quality improvement. One example might be a policy specifying that phone calls should always be answered before the fourth ring.

Staff who answer the telephone require training. Physician-approved scripts for most common questions or patient requests will ensure consistency in responses and reduce the likelihood of error in the information transmitted. Scripted topics might address:

- **Appropriate greeting, identification of the practice, offer of assistance, and requests for permission to place a caller on hold.**
- **Beyond referral to the appropriate resource, scripts should also define steps to be implemented when patients request response from a clinician; appointments; prescriptions/refills; urgent questions and/or referrals to the ED.**
- **Office staff should not refer to themselves as nurses unless they are licensed personnel.**
- **Common courtesies should be built into framework for every telephone interaction.**
- **Telephone systems that offer automated menus should provide callers with the option to opt out of the menu and immediately access a staff member.**

8.02 Telephone triage

Receptionists sometimes become so protective of the physicians' time that they create barriers to access which could be detrimental to patient safety in acute or urgent situations. Practice policy should preclude non-clinical staff from making triage decisions about patients who may need acute care or same-day appointments.⁴¹ In general, healthcare providers should not diagnose conditions over the phone. A physician-approved list of key complaints and symptoms should specify which calls will be immediately referred to a physician. Triage protocols including annual in-service training, should identify information that staff may/may not provide to patients. The triage system should allow medical information to be given only to established patients.

A system should be in place that will prioritize clinician return phone calls. All call messages should be reviewed by a clinician by day's end.⁴²

8.03 Traffic flow

Acceptable appointment scheduling systems focus on providing the patient access to care in accordance with: the urgency of the need; effective use of the physician's time; implementation of practice resources; and patient-acceptable waiting times.

Suggestions for improving the efficiency of the scheduling process include:

- **Appointments should be categorized by group designations based on the amount of time needed for each group.** For example, a family practice might break its appointments into the following groups: new patient; return visit; consultation; immunization; lab work only; summer camp or school physicals, etc.
- **Use of resources:** availability of exam rooms, medical assistants, and equipment is a scheduling consideration. Time for room setup, cleaning, and patient preparation should also be factored into the schedule. Coordination of non-physician staff can maximize use of the physician's time.
- **A pre-determined number of appointments should be reserved each day for patients with urgent problems.**
- **Tracking patterns for scheduling and noting logjams will produce data that can help improve the process.**
- **At the time an appointment is booked, the patient should be reminded to bring appropriate documents, e.g. referrals, etc., as well as insurance information.** New patients should be given an appointment that is scheduled fifteen minutes earlier than the time scheduled to see the physician. This buffer allows for collection of insurance information and completion of personal health information, and any other necessary transactions.
- **When a new patient makes an appointment, the office should mail a confirmation, a copy of the patient handbook, and a map or directions.**
- **Patients should receive reminder phone calls or mailed notices.** These courtesies help reduce no-shows. Patients must be asked for permission before messages may be left on answering machines.⁴³
- **A brief "morning huddle" that includes all staff will fine-tune the day's schedule, anticipate urgent matters, and address issues left over from the previous day.**
- **Room setups should be standardized and should be based on the uses assigned to various rooms, staff time needed to complete room readiness, and the cleaning/stocking/safety processes that must be completed before a patient can be given access to a room.**
- **A systematic approach should ensure that patients are given adequate verbal and written instructions, including multiple opportunities to ask questions and clarify their understanding of information imparted.** An organized approach to this important educational responsibility will reduce non-compliance and the need for staff to address multiple misunderstandings and miscommunications.⁴⁴
- **Contingency plans and cross-training will reduce the number of problems that might occur when a staff member quits or is out sick.**⁴⁵
- **Patient satisfaction with access and scheduling systems should be periodically measured.** The results will provide indicators for elements that need improvement.

8.04 Patient registration and checkout

A standardized check-in process will ensure consistency and prevent the potential for error. If patients have been scheduled correctly, they should report with appropriate forms, emergency contacts, and insurance verification. This will streamline the registration process. Staff must be zealous about protecting patient privacy. Persons in the waiting room should not be able to overhear discussions about health issues or insurance matters.

Many practices have stopped using front desk sign-in lists and instead have transitioned to individual sign-in sheets (often attached to small clip boards) which the patient will use to provide: time of appointment; time of arrival; scheduled physician; purpose of appointment; medication and/or diagnostic updates; and insurance and/or contact information updates. Specific questions or concerns can also be noted on this form and front office staff can use it to help direct patient flow, update information, and check on waiting times.

If co-pays are collected prior to the visit, patients should be called, individually, to a private area or cubicle to complete this transaction.

Before the patient leaves following the appointment, staff should use a checkout list to ensure that all elements of the visit have been completed. Some of these include:

- **Patient has all necessary prescriptions and/or orders for tests or consults.**
- **If a referral is in order, staff should attempt to schedule this appointment while the patient is still in the office. Failing this, patient should be reminded of the importance of following through with the consult.**
- **Billing matters should be addressed, including insurance status, payment as required, resolution of any discussions about insurance or payment schedules, etc. All billing transactions should be conducted in a private area.**

8.05 Waiting times

Patient satisfaction is improved when patients are seen within approximately 15 minutes of scheduled appointment times.⁴⁶ Front office staff should monitor waiting times during the day and keep clinicians and other staff informed. Likewise patient care staff should let front office staff know if backlogs develop. Patients in the waiting area should be kept informed if waiting times start to exceed 20 minutes behind scheduled appointments. Staff should apologize for delays and keep waiting patients informed. If the wait time exceeds 45 minutes, patients should be offered the option to reschedule.

8.06 Missed and cancelled appointments

Office staff should document and follow up on patients who miss or cancel an appointment. In order to support the patient's need for continuing care, staff should attempt to promptly reschedule the appointment. Efforts to contact the patient should be documented in the patient record. The follow-up policy should take into account the severity of the patient's condition. If the missed visit was for follow-up on a positive test result or for continuing care of an active problem, a greater number of efforts will be made to contact the patient — and documented. Following numerous attempts to contact the patient, a final attempt should include a letter sent via certified mail, return-receipt-requested. A copy of this letter should be retained in the patient's file.

Missed appointments should not be deleted from either a paper or computerized appointment schedule. Instead, a notation should be entered indicating that the appointment was missed.

Medical records

9.00

Medical records or health information administration is based on a specialized body of knowledge and relevant state and federal laws. Advice from a registered health information administrator (RHIA) consultant may be useful to a practice, particularly when setting up a medical record system and periodically to update policies and procedures that will help the practice stay current with changing requirements. The following suggestions address selected aspects of medical records administration that present risk management concerns.

9.01 Ownership

The physician “owns” the physical medical record and has responsibility for its custody, security and confidentiality. The patient “owns” the information in the medical record and has a right to the information upon proper authorization.

9.02 Confidentiality

Confidentiality of the medical record should be protected at all times. Only those individuals or entities who have been authorized by the patient should be able to access the patient’s health-related information. For additional information about Patient Confidentiality, refer to Section 11 of this Manual, which addresses HIPAA and other types of Regulatory Compliance.

9.03 Record release

Copies of the medical record may be released only upon receipt of a signed patient authorization or a court order. The authorization should specify those portions of the record requested and to whom the copies should be sent. The original record should remain in the custody of the physician. Certain conditions, such as mental illness, substance abuse, or HIV status, may be covered by federal as well as state-specific protections and will require separate authorization procedures. The practice manager should provide regular updates about state regulations that address such issues as release of record information to or regarding emancipated minors and disputes regarding parental custody.

The physician should review the patient record and authorization prior to any release of record copies to the patient’s attorney or pursuant to a court order. *Where there is concern that a request for records indicates a potential professional liability claim, the Medical Protective claim specialist should be notified.*

Not all requests for records are related to threats of lawsuits. In many cases an attorney’s request for record may involve other matters, such as a worker’s compensation claim. Medical Protective should be contacted whenever a physician is uncertain how to respond to a request for records.

The physician should not refuse to release copies of the record because the patient has not paid his bill. A reasonable charge for making copies of the medical record is appropriate. Refer also to the section on **Subpoenas** in **Section 12, Risk Identification Strategies and Claims Issues**, in this Manual.

9.04 Security

Records must be stored in a secured, lockable location. In accordance with HIPAA requirements, only authorized staff may have access to records. Records should never be stored in a garage, basement, or car trunk. Should it become necessary, a professional record storage company should be used for off-site storage. The practice should formulate a policy that precludes record removal from the office, except in response to a subpoena duces tecum or to a court order. Physicians should not take records home or to the hospital to complete them. Records left in back seats of cars have been stolen. And records taken to the hospital may be lost or read by unauthorized individuals.

9.05 Structure and design

Regardless of the number of physicians in a practice, only one uniform record format should be used. Proprietary companies sell a variety of office practice record systems. Many professional associations also offer record keeping software, templates, and forms. Filing of patient records should be accomplished through the use of a single, comprehensive filing system.

Each patient record should be assigned its own, unique account number. Several persons' records should not be co-mingled in a "family" file.

9.06 Patient identification

Each page of the patient record should document the patient's name and his/her unique patient account number. Name similarities can present a risk if information is misfiled or attributed to the wrong patient. A system that cross-matches similarities may prevent such errors. The patient's birth date, account number, or other identifier may be added as necessary to reduce the likelihood of errors in treatment, diagnosis, or filing of information.⁴⁷

9.07 Length of record maintenance

Medical Protective data collected from 1998-2002 indicates that: 79 percent of claims are opened within three years of the date of service; 93 percent of claims are opened within five years of the date of service; and 95 percent of claims are opened within 10 years of the date of service. While most states require maintenance of medical records for seven years, physicians are advised to use this guideline as a minimum rather than as a standard. And, certain records should be maintained for as long as possible, including: pediatric records; records of patients who complained about the outcome of their care; cases in which the physician was displeased with the outcome; and cases involving implantable devices.

Since the statute may not begin to toll in certain types of claims until the patient realizes that he or she has a basis for a claim and since the statute is often considerably longer for minors, many practices automatically keep the records for a minimum of 23 years. If a practice determines that it must purge some records, it would be wise to seek legal advice before proceeding.

Old records may also be very useful in cases involving recalls or advisories by medication or implants manufacturers. Long-term unexpected outcomes may require years and perhaps generations of follow up. The DES babies provide a tragic example. In this case, women were identified as being at high risk for cervical cancers because, years earlier they had taken this drug during pregnancy. Not only were they at risk but evidence suggests that the children born of those pregnancies also have significant cancer risks.

Practices should also establish a policy that precludes the immediate destruction of records just because a patient has passed away. Such records should be maintained, at a minimum, for the length of the statute of limitations, but legal advice is likely to recommend even longer retention. When records are to be destroyed, they should be shredded, preferably by a company that provides such services. They should never be thrown away. Computers that are being taken out of service should have their hard drives professionally stripped before the computer is sold or destroyed.

9.08 Record format

A problem/complaint list and current medication list should be maintained at the front of every patient's medical record. These should be updated every time the patient visits the practice.

9.09 Allergies

Allergies should be prominently displayed at the front of the patient record. Some practices use a brightly-colored sticker to denote allergy status.

Facility management
and safety

10.00

The possibility of injury extends beyond clinical intervention. Patients have the right to an assurance of safety when they are in the healthcare environment. This right assumes that, as a place of public accommodation, a medical practice will have in place those same security and safety measures that other businesses also implement. This section examines these liability exposures.

10.01 Location

The office location should be readily identifiable, with adequate lighting in parking, entrance and hallway areas. Periodic checks should be made to ensure that the office is correctly listed in the building directory. Interior signage should help new patients access the office's entrances and exits. Access such as ramps and elevators should be available for persons who need assistance. Parking spaces should be reserved at a convenient entrance for disabled persons. The parking lot or garage should be free of hazards such as broken pavement and oil slicks. In winter, the parking area, sidewalks and building entrance should have good snow removal with treatment of icy spots.

10.02 Office appearance

Restrooms must be clean. At least one restroom should provide facilities for the disabled. Local regulations may specify additional required accommodations.

Slips and falls are one of the most frequent causes of general liability in office practice. Floors should be free of clutter and other hazards. Hard-surfaced floors should be assessed for slipperiness, especially when wet. Some areas may require mats or special grit-containing waxes that reduce the risks of slips/falls. Cleaning staff should use signs to identify wet surfaces. Worn carpeting should be promptly replaced.

10.03 Waiting room appearance

The waiting area should be clean and comfortable with adequate seating and reading material of general interest. Many physicians take advantage of a "teachable moment" by providing health and wellness educational material in their waiting areas.

With either the open counter or glass window design, a separate alcove or cubicle is needed to protect patient privacy when financial and other personal business is discussed.

Some offices and clinics provide televisions in their waiting areas. While many patients enjoy watching television, others dislike program choices or the noise level. One option is to use a television to show health education videos. If a television will be placed in the waiting room, it should be located in a separate area so that patients who don't want to watch it can avoid it.⁴⁸ Office staff should control both channel selection and volume.

Many offices offer a selection of toys and books for their pediatric patients. Since children's activities are not always appropriately monitored, selection of toys should be limited to items that cannot be swallowed and that are durable enough that they cannot be broken, even with rough use. Broken toys should be immediately removed from the play area. Staff education should help the receptionist and other employees feel comfortable in reminding inattentive parents of their responsibility for supervising their children's activities. The practice that provides toys for children to play with must also determine who will wash/disinfect the toys on a regular basis. Because books are not washable, they may not be appropriate for use in office waiting rooms.

10.04 Examining room safety

Examining rooms must be kept scrupulously clean. Patients require a private space for changing and therefore also need a safe place to hang clothing and belongings. Sharps, syringes, needles, medications and blank prescription pads should not be accessible in examining rooms.

Examining areas must be child proof. Personal protective equipment, such as gloves, should be stocked in each room for clinical and non-clinical staff safety. Staff should be educated about assisting patients onto and down from examining tables. When patients must leave an examining room for tests or other procedures, the practice should offer a means of protecting patients' belongings. As an alternative, patients should be advised to keep their purses or wallets with them. A posted notice should specify that the practice cannot assume responsibility for personal belongings.

10.05 Equipment safety

An up-to-date inventory of all medical equipment and devices, including manufacturers' names and serial numbers should be maintained in a secure location. Each piece of equipment should have a separate file. The file should preserve manufacturers' instructions, warranties, and service agreements for that piece of equipment. The inventory and accompanying materials will be invaluable in case of loss, equipment malfunction, or adverse events involving equipment.

Equipment should be used only for its intended use. The manufacturer's instructions should define the appropriate use for each piece of equipment. For more complex equipment, the purchase agreement should require staff training. All staff who use equipment should be trained and the training should be documented in each individual's human resources file.

Modification of a piece of equipment will generally void the manufacturer's warranty placing any liability risks associated with that piece of equipment on the practice, on the individual who modified the equipment, and on the user.

A written maintenance plan should include the scheduled dates for inspection and maintenance of all equipment. If a service company carries out the practice's maintenance, the practice administrator, or a designated individual, must ensure that the schedule is adhered to and that copies of the maintenance reports are maintained in appropriate files. If a piece of equipment is essential for safe patient care, e.g. emergency oxygen, the contract with the vendor should stipulate its ability to provide replacement equipment should the practice's equipment need to be removed from service. A designated individual must also note and act upon any recall or warning notices.

As part of emergency preparedness, staff should be trained to respond to equipment malfunctions, e.g. sparks, wiring starts to smoke, etc. Obviously, such an occurrence would require that a test or procedure should be halted and patient and staff safety protected.

If a piece of equipment is involved in an unexpected event, it should be pulled from service. The equipment should be tagged out of service, and should be sequestered so that it cannot be used. As quickly as possible, the equipment should be examined by an independent test firm or lab. The equipment should not be returned to the manufacturer until test results have been reported by the independent agency. IV bags and tubing should be handled in the same manner.⁴⁹

10.06 Emergency response

No practice can adequately address emergencies without planning and training. Without adequate preventive and educational tools in place, the best-equipped office may be unable to achieve satisfactory results. Practice policies should clearly define accountabilities and mandated training and updates that should ensure preparedness for a variety of emergency situations.

10.07 Fire and life safety

The first step in any fire safety plan is the safe evacuation of patients and employees from the building. Diagrams posted in all patient and employee areas of the office should note all possible exits. All exits must be adequately marked and lighted. Exit doors should never be blocked or locked so that they cannot be opened from the inside. The fire department should be alerted after patient and staff evacuation has begun. In areas where the 911 code is not available, fire emergency telephone numbers, including area codes, must be prominently displayed by each telephone. If possible, every office telephone should be programmed to include speed dial emergency numbers.

For prevention, fire alarms, sprinklers and detectors should be in working order and periodically inspected and maintained. Fire extinguishers should be strategically located throughout the office. As likely first responders, staff should be trained in their use. Staff should close interior doors to contain the fire. Staff can attempt to extinguish the fire but only if they can do so safely. Staff should conduct patients to a predetermined evacuation spot away from the office. All patients and staff must be accounted for.

A no smoking policy should remain in effect throughout the office. Periodic fire drills will identify opportunities for additional training and safety measures. Office policy should require the full cooperation of any persons in the office with fire drills that may be conducted by building management. Many fire departments offer on site fire prevention and safety training. Additionally, some provide safety assessments of fabrics and materials to aid practices in selecting the safest elements for their practice décor.

10.08 Disaster plan

A written disaster plan provides the same opportunities to protect life and limb that fire safety plans provide. Depending on the practice's location, a disaster plan may need to encompass preparedness for earthquakes, hurricanes, or tornadoes.

In addition to weather-related disasters, administrative disasters include the possibility of: computer system failures; physical plant disasters such as loss of electricity; community disaster or mass casualty; and miscellaneous disasters such as a bomb threat or abduction of a child from the office. Each practice should determine the likelihood of a particular disaster occurring and take reasonable steps to prepare for that contingency. Steps might include:

- **A breakdown of the activities that might be required of each staff member.**
- **Decisions about office closure.**
- **Notifications to employees, patients, vendors, other healthcare providers, the public.**
- **Relevant local resources, such as local and state emergency response providers.**
- **The contents, location, and accessibility of an off-site temporary office.**

- Access to patient and financial records and/or a related recovery plan.
- An action list noting the steps necessary to implement the plan.
- Staff training and periodic disaster drills.⁵⁰
- The purchase of appropriate levels of insurance.

10.09 Infection control

With a public already concerned about HIV, AIDS and hepatitis, as well as new threats such as West Nile virus and SARS, physicians must also include the possibility of bioterrorism in their office-based infection control programs. The plan should address basic day-to-day infection control practices, hazardous material handling and disposal, diagnosis and treatment of potential bio-terrorism related diseases, and a list of contact information for relevant resources. It is critical that physicians update their knowledge about the diagnosis and treatment of current and evolving infectious diseases. The infection control plan should address safety protections for employees as well as for patients.

10.10 Hazardous waste management

Although the risk from biohazardous waste generally is low, contaminated sharps (needles, scalpels or lancets) have been associated with infectious disease transmission. Physicians should develop biohazard waste plans that comply with their state, county and municipal regulations. Definitions vary from state to state as to the elements that would designate a medical practice as a small producer of biohazardous waste.

Each state has an Environmental Protection Agency (EPA) office that will provide doctors the germane definitions and required management policies for that area. State medical associations should also be able to provide this information. Once physicians are aware of their states' definitions of hazardous waste, it will then be possible to assess the amount of waste generated by the practice and to determine whether or not the practice is therefore subject to state tracking requirements.

Local and state contact information to determine biohazard status can be obtained at www.epa.gov.

Most states define biohazardous waste as waste capable of transmitting infectious diseases, and therefore include materials sufficiently contaminated with blood or body fluids to transmit disease. The office practice plan should include a plan to segregate materials so that disposal costs can be contained. This should include segregation for:

- Sharps sealed in a container.
- Biohazardous waste contaminated with blood or body fluids or from patients with infectious diseases, placed in a small container, with liner, lid and labeling as biohazardous waste. The lid should be kept closed. An additional biohazardous waste container may be required for chemotherapy-related materials.
- Trash or other non-contaminated material, such as paper wrappers, should be stored in a third type of container, e.g. a wastepaper can.

10.11 Bioterrorism risks and exposures

Most physicians already have a heightened awareness of the possibility of bioterrorism-related outbreaks of anthrax, plague, botulism and small pox in their community. However, few physicians have ever seen these diseases. Preparedness would be greatly enhanced if physicians seek ways to recognize and treat these diseases. Given the media coverage and public concern about these deadly infectious diseases, failure to diagnose may have consequences far beyond the possibility of liability. Physicians need to build close ties with local public health authorities so that reporting, responding, and care processes can be coordinated. The Centers for Disease Control (CDC) recommend that physicians have an updated telephone list of the following:

- Infection control professionals.
- Epidemiologists.
- Infectious disease specialists.
- Local government leaders.
- State and local health departments.
- Federal Bureau of Investigation (FBI) field office.
- CDC Emergency Response Office.
- Clinical microbiology lab.⁵¹

Many medical specialty associations and state medical societies have developed materials to help physicians prepare for a potential bioterrorism attack. There are many Internet resources including the following:

- The Association for Professionals in Infection Control and Epidemiology offers practical tools and educational materials: www.apic.org
- The American Medical Association posts consensus statements on clinical guidelines and decontamination guidelines: www.ama-assn.org
- The American Academy of Family Practitioners shares links to educational resources www.aafp.org
- The Johns Hopkins Center for Civilian Biodefense Studies includes information on preparedness and response: www.hopkins-biodefense.org

New materials continue to emerge from federal and state agencies on emergency planning and response. The CDC and local authorities will provide the most current guidelines.

10.12 Materials management

The office practice administrator should supervise appropriate purchasing, storage, inventory control, disposal processes (for both medicines as well as materials). Competitive bids should be a standard part of the purchasing process. Price alone may not always be the primary issue and decision-makers also should consider the ability of vendor(s) to provide service and emergency replacement of essential materials. More offices are using “just-in-time” purchasing and eliminating the onsite storage of large inventories.

Considerations for purchase and storage should include:

- **Safe practices for the storage of any flammable/toxic materials.**
- **Medications and infusions fluids should not be stored in the same areas where cleaning materials or other chemicals not intended for patient use are stored.**
- **Storage areas must be locked to prevent diversion or inappropriate access by unauthorized individuals.**
- **A mechanism should be in place that will track hazardous materials from the time they are brought into the office until their final use/disposal.**

10.13 Management of salespersons and vendors

All salespersons and vendors should be required to sign in at the front desk. Office policy should also require that they wear identification badges while in the office and sign out again when they leave. Salespersons and vendors should not be allowed in the examining or procedure areas with a patient, e.g. to demonstrate use of equipment. Patients who have been waiting for their appointment for more than 15 minutes may become annoyed when they see salespersons gaining access, while they, the patients, must continue to wait. Even if the sales visit was scheduled, there may be a perception that the salesperson received preferential treatment.

10.14 Preventing workplace violence

Workplace violence is the leading cause of workplace-associated death for women.⁵² As more care moves to ambulatory and office practice settings, the risk of violence in the workplace must be anticipated and appropriate responses planned. Office practices may be at risk from an employee's violent ex-lover or spouse, an angry ex-employee or a violent patient.

Physicians' offices, particularly small practices, may not have advanced security technology, such as silent alarms, closed circuit monitoring, or metal detectors, but should have some of the basics such as good lighting in parking areas and hallways, working door and window locks, and restricted access to employee areas. Staff also can be trained to recognize and handle threatening, aggressive and violent behavior through de-escalation techniques. Employees should report any incidents or threats of violence to the practice manager and/or physicians. This includes any incident of yelling, pushing, verbal abuse, racial or sexual slurs. An employee who has been the victim of work-related violence should be offered medical care and counseling.

OSHA offers several self-assessment and prevention tools such as:

- [Workplace Violence Checklist](#)
- [Violence Incident Report Forms](#)
- [Guidelines for Preventing Workplace Violence for healthcare](#)
- [Social Service Workers at: www.osha.gov](#)

Legal and regulatory
compliance

11.00

11.00 Legal and regulatory compliance

Corporate compliance refers to physicians' required cooperation with several federal mandates designed to prevent inadvertent or intentional mishandling of some of the business-related aspects of healthcare. These regulations should not be taken lightly since failure to comply entails significant civil and, in some cases, criminal penalties.

Several areas of office practice should be covered by compliance plans and may be interwoven to ensure an overall approach, to prevent duplication of structures, and to prevent oversights.

Specifically, federal compliance rules address two key areas:

- **healthcare fraud and abuse is defined as the willful misrepresentation of facts resulting in receipt of an authorized benefit under a (federal) healthcare plan. Abuse consists of knowingly ordering, providing services or billing for the delivery of unnecessary services or of billing that does not reflect actual costs or that charges for services that were not provided. Major statutes addressing fraud and abuse include:**
- **Anti-kickback Statute of the 1977 Medicare and Medicaid Anti-Fraud and Abuse Amendment to the Social Security Act.**
- **The Criminal False Claims Act.**
- **The Civil False Claims Act.**
- **The Civil Monetary Penalties Act .**
 - **Stark I and Stark II: Prohibits physicians from referring patients to entities in which they have a financial interest.**
 - **Health Insurance Portability and Accountability Act of 1996 (HIPAA).**
 - **Various state anti-fraud provisions.**

Clearly a wide range of anti-fraud provisions are being enforced by the Federal Bureau of Investigation (FBI), Office of Inspector General (OIG) and state Medicaid fraud units, departments of health, and attorneys general, among others.⁵³

- ***HIPAA Privacy and Security Provisions:*** HIPAA, being a relatively recent act, merits some in-depth description. HIPAA mandates two sets of standards, both designed under the auspices of the Center for Medicare and Medicaid Services (CMS), formerly HCFA or the healthcare Financing Administration.
- ***Electronic healthcare Transactions and Code Set Standards*** comprised the first component of the HIPAA standards and are designed to ensure consistency in the way that healthcare information is transmitted between entities. The Administrative Simplification provisions (HIPAA, Title II) require the Department of Health and Human Services (HHS) to establish national standards for electronic healthcare transactions and national identifiers for providers, health plans and employers. These standards theoretically will improve the efficiency and effectiveness of the nation's healthcare system by encouraging electronic data exchange. Many professional associations have protested that the regulations are too complex and burdensome to implement within the required time frame.

All medical practices should have been in compliance with the Administrative Simplification requirements by October 16, 2002 — unless they filed for an Exception For Compliance which was available through the Centers for Medicare & Medicaid Services (CMS). The deadline for filing for the exception expired on October 15, 2002.

- *Standards for Privacy of Individually Identifiable Health Information* comprise the second component of HIPAA. They became effective in April 2002 and enforcement commenced in April 2003. The HIPAA Security Standards specify the administrative responsibilities, business-related safeguards, and technology privacy systems that physicians must have in place if they are to comply with the privacy-related aspects of HIPAA.⁵⁴

11.01 Corporate compliance plan

The OIG has spelled out the basic elements that should be included in a corporate compliance program designed to meet anti-fraud and abuse and HIPAA regulations. Each office practice should implement the following:

- A code of conduct or Mission Statement and written policies and procedures.
- A designated compliance officer or leader.
- Comprehensive training and education on practice ethics and policies and procedures.
- An internal auditing and monitoring program.
- A system that will ensure accessible lines of communication.
- Policies and procedures that define and ensure disciplinary action — and that prevent retaliation against those who report non-compliance.
- A method to detect and investigate alleged violations and to disclose to appropriate government entities as indicated.⁵⁵

11.02 Implementing a corporate compliance program

Once a compliance officer has been named, the practice should consider forming a work group to assist with program development. Some next steps might be:

- A gap analysis: What written policies are currently in place? What additions or updates are still needed?
- What resources are available? The working group should specify which computer systems, human experts, and financial investments are needed and how they will be provided.
- Has the practice obtained written agreements that ensure that vendors and business associates also comply with regulations?
- Have collaborative opportunities been identified through other local practices or hospitals?
- Do local medical societies or health information organizations offer training?
- Has the practice set written goals, timelines and assigned responsibilities for their completion?⁵⁶

Physicians should understand the limitations on coverage for corporate compliance issues. For example, a physician cannot purchase insurance against the assessment of fines, per se, since they result from allegedly illegal actions. In some instances Medical Protective does provide limited administrative and legal services and physicians and their compliance officers should be aware of these options.

11.03 Other statutes and regulations

In addition to the fraud and abuse and HIPAA regulations, a wide range of other federal, state and local regulations also apply to office practices. Most medical practices will find HIPAA compliance time-consuming and expensive. But no practice should have to reinvent the wheel. County and state medical societies and local hospitals should be willing to network with physicians since the compliance of all participants in the healthcare continuum also reduces levels of risk for all.

Whenever possible, compliance should be woven into the practice's Mission Statement, ensuring that physicians and staff understand and fully cooperate with the intended effects of various statutes and regulations. It is to the practice's advantage if one corporate compliance plan addresses all the regulations for which the practice has implemented specific policies and procedures. While it may prove impossible to implement all of these diverse elements at once, the practice should identify the elements of the compliance plan and prioritize implementation of one or two aspects, using leadership and staff accountabilities and formalized time tables to ensure completion. Staging can continue until they have addressed all issues.

Physicians' practices should also stay current with other regulations that may apply:

- **Emergency Medical Treatment and Active Labor Act (EMTALA):** EMTALA is the anti-dumping regulation which originally impacted only emergency departments. Expanded interpretations have extended the scope of EMTALA to other entities on the hospital campus.
- **Safe Medical Devices Act (SMDA) of 1990:** This Act, under the auspices of the FDA, addresses reporting of serious injuries and deaths related to medical devices, and tracking of implanted devices. See the Equipment safety section of the manual.
- **Fair Credit Reporting Act:** Contains rules for performing background checks on prospective employees and investigation of sexual harassment
- **American with Disabilities Act (ADA):** This Act makes it unlawful to discriminate in employment against an individual with a disability. It also requires that places of public accommodation, which include physician's offices, be accessible to disabled persons. Interpretation of this Act in specific cases is very complex, so legal advice should be sought when issues arise.
- **Occupational Safety and Health Administration (OSHA)** is a federal agency, under the Department of Labor, which regulates workplace safety and health. OSHA promulgates numerous regulations and guidelines. The Environmental Protection Agency (EPA) regulates water and air quality and pollution-related issues. Clinical Laboratories Improvement Act (CLIA): Establishes accreditation and quality standards for physician office laboratories.
- **Drug Enforcement Administration (DEA)** addresses controlled substance prescription and accountability.

State and local regulations may address a number of other areas relevant to office practice:

- **Required reporting of child, elder, and (in some states) domestic abuse.**
- **Reportable communicable diseases.**
- **Advance directives or living wills.**
- **Prescription and dispensing (Medical and Pharmacy Practice Acts) regulations.**
- **Advanced Nurse Practice Acts.**
- **Informed Consent.**
- **Reportable injuries, e.g. gunshot wounds.**
- **Retention of medical records.**
- **Serious incident reporting or other office risk management requirements.**
- **Worker's compensation and other employment-related laws.**

11.04 Voluntary accreditation

Several voluntary surveying and accreditation bodies offer, for a fee, accreditation programs that apply to the physician office, especially when that office is part of an integrated delivery system or a provider in a managed care or preferred provider organization. While these programs are voluntary, accreditation may confer “deemed” status for participation in federally-funded health programs such as Medicare and provide an enhanced public image. Accreditation is generally based on an onsite survey to measure compliance with the accreditation standards and, for some programs, collection and submission of health status and patient satisfaction data. Accreditation standards may overlap with regulatory and patient safety guidelines.

Accrediting bodies tend to update their standards and survey processes frequently so practice managers should check with the individual agency for the most current information. Consumer interest in healthcare quality suggests that accreditation programs will continue to flourish — along with healthcare regulatory and licensing bodies.

11.05 Office-based research

If physicians conduct any research or investigational procedures or treatments in the office setting, they must have the requisite training and experience. They must also abide by standards established to protect the rights of human subjects and, in association with the ethical requirements established for human research, they must also obtain an appropriate and valid Informed Consent from each participating patient. The Informed Consent form should be specific to the research study. Investigational or research protocols and their attendant Informed Consent forms are typically very detailed. The consent forms' complex language may prove intimidating to patients. It is critical that the physician go over the consent with each patient in language the patient can understand. Some important points to clarify with study patients, if applicable:

- **Do patients understand that the treatment or procedure is part of a research study, e.g. experimental in nature?**
- **Do patients understand that the treatment may have no benefit to them and may also carry risks?**
- **Do patients understand that they may be randomly assigned to a cohort that receives no treatment, or receives a placebo?**
- **Do patients understand what services they may receive free, such as periodic lab tests, and what they will be expected to pay for?**

Investigational protocols should be undertaken cautiously in the office setting. The records of patients who participate in any study should be maintained forever, regardless of the outcome. If a claim or adverse reaction results, the physician will need to be able to verify adequate training, patient consent and that patient safety was not compromised. Seeking input from a hospital Institutional Review Board (IRB) may prove helpful and may even be required in certain joint studies.

When participating in a research project sponsored by another corporate entity, e.g. a pharmaceutical company, physicians are strongly advised to seek legal review and advice before signing any contract. Not only is it important that there be no agreement to indemnify third parties, but the ownership, IRB oversight, and research protocols should be clearly defined to protect human subjects and to prevent litigation.⁵⁷

Risk identification
strategies and
claims issues

12.00

Risk management is a process used to prevent losses to an organization. Losses are generally financial, such as those associated with a claim, but may also include loss of reputation, market share, and emotional stress. Every office practice needs the basic elements of a risk management program which should include: risk identification and analysis; loss prevention; claims management; and risk financing. A larger practice might have a written risk management plan and an individual assigned to coordinate the risk management functions. Many critical loss prevention activities, such as good communication and documentation, as well as a myriad of patient safety functions, have been detailed in previous sections.

12.01 Incident reports

Hospitals have used incident reporting as a risk management approach for years but these systems are less frequently implemented in the office setting. Nonetheless, every office practice needs a policy and procedures designed to identify and manage incidents or unexpected outcome. Through data gathered and analyzed physicians can put into place systems to improve patient safety and to prevent patient dissatisfaction. Poor management of unexpected outcomes frequently results in professional liability claims, especially when the patient believes that his/her injury was preventable and that subsequent attention to the matter or care provided were inadequate. Incident or unexpected outcome reporting can identify office system weaknesses that, if not improved, could lead to serious injury and damages.

Managed care organizations may mandate the use of their reporting systems for participating providers. Accrediting bodies and some states require an incident reporting system for office practice. Incidents include any happening that is not consistent with the routine care of a patient or an event that is not consistent with the routine operations of an office practice.⁵⁸

Incidents may be caused by a variety of factors and do not necessarily reflect human or medical error. Systematic analysis of each event is needed to identify all of the factors that may have contributed to the event.

12.02 Design of an incident reporting system

It is essential that any practice wishing to implement quality/performance improvement systems, including the use of incident reports, should obtain legal advice before doing so. Some states stipulate that quality/performance improvement documents are protected from demands for production of medical documents when legal action is filed. As part of quality or performance improvement programs, incident reports, when correctly used and maintained, fall within this category. A number of other states, however, do not have such protections in place.

When a qualified attorney determines that it is safe for a medical practice to implement quality initiatives, including incident reports, the following issues should be addressed as the incident reporting system is designed:

- **Everyone participates, including clinical and non-clinical staff.**
- **Written policy should include a working definition of the term “reportable incident” and should also provide a list of examples of events that must be reported, including possible unexpected outcomes. The downside of using lists of reportable events is that no list can ever be complete.**

- However, staff orientation may be aided by listing some examples of reportable office practice events such as:
 - Missing personal property.
 - Patient or visitor falls.
 - Medication errors.
 - Patient death.
 - Patient complaints.
 - Patient/family violence.
 - Infusion therapy events, such as extravasation.
 - Unexpected reactions to immunizations.
 - Alleged violations of privacy.
 - Alleged violations of confidentiality.
 - Need for medical intervention following an invasive procedure, e.g. hematoma requiring evacuation.
 - Unplanned hospital admission subsequent to an invasive procedure.
 - Unexpected outcome of office-based anesthesia.
 - Provision of necessary clinical care for the patient, family or employee should be the first response to an incident. A clinician should be summoned to care for the patient if the primary physician is not available.
 - Written policy should determine who will discuss the incident with the patient, if the patient is not already aware of the event.
 - Written policy should ensure staff training and implementation of office protocols to provide emotional support along with any needed clinical care.

- When indicated, consultant care should be promptly provided. In emergencies, the practice's patient transfer process should be implemented. For less serious incidents, the patient should be detained in the office until a physician declares that he or she is stable enough to leave and/or until the patient has obtained a safe means of transportation home.
- Any evidence relevant to an incident should be retained. Examples might include IV bags, tubing, or other types of medical equipment. Defective equipment must be immediately removed from service; it should be tagged or labeled. It should not be sent back to the manufacturer unless Medical Protective has approved the return.
- If an incident involved a slip or fall, the area should be photographed to show the condition of the floor or pavement. Many lawsuits occur because the physician attempted to avoid the patient following an unexpected outcome. As a result, the patient may feel abandoned by the physician or may decide that the physician is attempting to cover up a mistake.
- The practice manager or the individual who fills the role as the practice's risk manager should orient staff to policies and procedures related to unexpected outcomes. This includes review of the practice's policy on confidentiality.
- Incident reports should be maintained in accordance with standards established for preservation of quality/performance improvement information. Due to the nature of the information it should be stored in a locked file drawer or password-protected computer file. Written pages should each be labeled as confidential information in accordance with state statute and legal advice. These documents should not be photocopied or disseminated. The patient's record should never include a notation that an incident report was initiated.

- Incident report data should be reviewed at least monthly with the goal of identifying patterns or trends that might suggest needed office process improvements. Staff should receive feedback and encouragement in order to maximize participation.
- Physicians should err on the side of caution. When in doubt, an unexpected outcome should be promptly reported to a Medical Protective claims representative.

12.03 Other sources of risk identification

If the physician or staff miss the opportunity to identify an incident, notice of its occurrence may be brought to the practice's attention via other avenues. The patient's attorney may request a copy of the patient's records. The patient may have filed a written complaint with a state or professional association. An accrediting body may follow up on a survey report. A local health department or other governmental agency may require submission of patient-related information. These incidents should be treated in the same way as an incident that was identified at the time of occurrence. Prompt follow-up may help to prevent escalation into litigation.

12.04 Reporting a claim

The Medical Protective insurance policy provides coverage for the physician's care and treatment of patients, as long as the physician is providing health-care related services, and as long as the physician promptly reports certain events to his/her Medical Protective claims specialist or insurance agent. Specific occurrences that should always be reported include any error in diagnosis or treatment that could have contributed to:

- **Unexpected patient death.**
- **Diminished life expectancy.**
- **Loss of an extremity.**
- **Permanent or partial impairment of a bodily function.**
- **Loss or impairment of one of the five senses.**
- **Serious patient adverse outcome.**
- **Severe disfigurement.**

Patient/family threat of lawsuit concerning dissatisfaction with services or dissatisfaction with the fee for services, including:

- **Patient demand for compensation or monetary damages.**
- **Verbal or written threats of legal action as a result of treatment or failure to render treatment.**
- **Rumor, hearsay, or any indication of a problem with services rendered.**
- **Anticipated complication.**
- **Unanticipated complication.**
- **Communication error such as a medication error, breach of confidentiality, question of follow-up with treating physician.**
- **Request for records by an attorney, patient, or former patient (which should be released only upon completion of a proper authorization).**
- **Other risk issues:**
 - **Attorney calls to discuss a patient's care.**
 - **Formal letter/paper served upon insured in which he or she is named as a defendant or witness (petition/lawsuit).**

- Request for arbitration due to a contractual agreement with a patient or court order.
- Request for deposition or interview regarding incidents in which an insured was involved as a treating physician or consultant.
- Notice that a specific drug or device has been named as a target of a mass tort action.
- Service or receipt of a subpoena.

Whenever a claim or suit seems imminent insureds should:

- Contact their Medical Protective claims representative immediately.
- Secure medical record(s).
- Neither physician nor staff should make any additional entries, corrections, or deletions to the record.
- Neither should the doctor or staff write a narrative or explanation of the circumstances of the incident. Rather, these steps should be taken only under the direct supervision of an assigned defense attorney.
- No comments/statement or written reply/no further conversations should be held with the patient/family or their attorney. Rather, they should be referred to the Medical Protective field claims manager.
- Neither doctor nor staff should talk about the possible legal action/complaint with anyone other than a Medical Protective representative or a defense attorney assigned to represent the physician.

12.05 Requests for patients' records

An attorney's request for records may not necessarily presage a malpractice claim. Rather, the request may occur in reference to a workmen's compensation case or another issue. The physician should not respond to the requesting attorney personally. If the attorney's letter encloses a patient's written authorization for release of medical records, copies should be provided only of those portions of the record specified in the authorization. **Records should never be altered.** The practice may charge a reasonable fee for photocopying; in fact, many practices establish policies related to requests for copies of patients' records. Charges for records copies should be reasonable. State regulations may determine what is "reasonable." Copies of records should be mailed via certified mail, return-receipt-requested. Any questions or concerns about demands for any records, by any party, should be promptly referred to the doctor's Medical Protective claims specialist.

12.06 Response to a subpoena

All subpoenas, demands for records, and court orders are time-sensitive. They require immediate action if the Medical Protective defense team is to be able to maximize its efforts on the doctor's behalf. All such legal demands and documents should be immediately reported to a Medical Protective claims specialist.

Staff should receive training about appropriate responses and behaviors when these documents are received in the practice. Training should also include appropriate responses to telephone calls from attorneys or other alleged representatives of patients' interests.

12.07 Risk financing

The complexity of medical practice today creates many types of risks: clinical, employment-related, environmental, financial, etc. These risks are compounded in group practice situations because of the greater number of physicians and staff and larger scope of practice. The various topics discussed in this Manual attest to the potential risks in office practice.

Each practice should identify its risks and define approaches for dealing with each type of risk. The types of risk most often addressed by the purchase of insurance are:

- **Professional liability for physicians and other licensed personnel.**
- **General liability.**
- **Directors and officers liability:**
 - **For corporations.**
 - **For medical group practices.**
 - **For other business entities, if necessary.**
- **Property, plant and equipment.**
- **Worker's compensation.**
- **Employment-related liability.**
- **Umbrella coverage.**

An insurance professional will help the practice determine what levels of coverage are adequate as the practice grows and as insurance trends affect the marketplace.

The major focus of any risk management program includes:

- **Patient safety and satisfaction.**
- **Adequate risk financing, including appropriate levels of insurance.**

Conclusion

13.00

Physicians and their staffs should not have to reinvent the wheel when establishing or updating their practices' risk management programs. Whenever a question occurs or the good intention seems to become bogged down with implementation challenges, assistance is available through the Medical Protective web site at www.medpro.com or via a phone call to the Clinical Risk Management Department at 800-981-3213.

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