MISCELLANEOUS LEGAL AND REGULATORY ISSUES

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

Abuse, Neglect, and Domestic Violence

Children

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

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

Adults

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

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

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

Domestic Abuse

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

Advance Directives

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

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

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

The Americans with Disabilities Act (ADA)

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

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

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

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

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

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

Contract Management

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

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

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

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

Corporate Compliance Program

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

Basic Compliance Program Elements

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

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

- business practices
- billing practices
- hazardous materials and waste practices

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

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

Handling Medical Board Complaints and Malpractice Claims

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

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

Malpractice Claims and Summons

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

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

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

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

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

Medical Board Complaints

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

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

Health Insurance Portability and Accountability Act (HIPAA)

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

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

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

The following guidelines for protecting the confidentiality of PHI apply:

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

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

More information on HIPAA can be found in Princeton's Reducing Risk documents.

Informed Consent

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

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

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

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

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

Clinical Trials

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

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

- right study
- right patient
- right consent

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

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

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

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

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

Managed Care

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

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

Other policies and procedures for managed care should ensure that:

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

Mandatory Reporting to State Agencies

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

OSHA

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

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

Subpoenas and Other Requests for Medical Records

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

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

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

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

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

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

Vicarious Liability (Apparent Authority)

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

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

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

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

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

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

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

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

