Business law critical to your practice

Preventive law, like preventive medicine, can make all the difference

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It is no surprise that the law is playing an ever more important role in the practice of medicine. Concerns about legal issues are a source of stress for ObGyns, including increasing worries about the economics of professional liability, the anxiety of defending a legal claim, and ambiguity about what is required for compliance.[1] In this article my goal is to demystify some of the most important legal principles affecting your practice and provide suggestions for avoiding legal problems.

Medical malpractice: A form of negligence

Most ObGyns instinctively think first of medical malpractice when "legal problems" are mentioned—not an unreasonable response because obstetrics has a high incidence of malpractice claims. In one study, 77% of the American College of Obstetricians and Gynecologists (ACOG) Fellows reported that they have been sued.[2]

At its core, malpractice is a form of negligence, or, medical practice that falls below the quality of care that a reasonably careful practitioner would provide under the circumstances. When practice falls below that "standard of care," and it causes injury, there may be malpractice liability. Insurance usually covers the cost of defending malpractice lawsuits and paying liability (although liability is the result of a minority of malpractice suits). There are, however, collateral consequences, including the time, stress, and disruption associated with defending the suit. In addition, malpractice may trigger review by the institutions with which the physician is associated, or in extreme cases, by licensing authorities. Large malpractice settlements or verdicts must be reported to the National Practitioner Database (sometimes colloquially referred to the "problem physician" database) or a similar state database.

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Regulation and reimbursement ("compliance") policies

The practice of medicine is closely regulated by federal and state bodies. Many regulations apply through reimbursement policies related to Medicare and Medicaid. While malpractice liability may, at worst, result in a financial award (with the cost of defense and any award paid by insurance), regulatory problems may result in a number of unpleasant consequences, most of which are *not* covered by insurance. In addition to loss of reimbursement, civil penalties (even criminal penalties in extreme cases), loss of hospital privileges, licensure discipline, and loss of Medicare-Medicaid eligibility may result from regulatory noncompliance.[3]

There are multivolume sets discussing these legal requirements, so here we will look only at a tiny tip of the regulatory iceberg by mentioning some common regulatory areas.

Fraud and abuse laws refer to a bundle of federal (and some state) statutes and

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The Business of Medicine: A new series

This article is the third installment of the new series, "The Business of Medicine," edited by Joseph Sanfilippo, MD, MBA. In September, David Kim, MD, MBA, MPH, offered marketing strategies using social media. Last month, Dr. Sanfilippo presented ways to ensure patient satisfaction and service excellence in your practice. Watch next time for "Accounting 101." Other featured topics will include investing in your practice, billing and coding, gaining the competitive advantage, understanding "best practices," and striving for cost-effective care.

Protecting patient confidentiality is an ethical, legal, and licensure obligation

regulations that are intended to ensure that public-funded programs such as Medicare and Medicaid are not cheated or overpaying for services. It is a violation to provide low-quality services to government-funded programs. Proper payment and coding and ensuring that services were actually performed by the professional listed (not someone else) are examples of traps for the unwary. Submitting inaccurate records may result in action to recover incorrect payments and in civil penalties. In extreme cases where there is intentional misrepresentation, there have been criminal charges and loss of future Medicare-Medicaid eligibility.

Anti-kickback, self-referral, and Stark limitations are intended to avoid unnecessary or overpriced services. When someone is receiving a benefit for ordering or recommending a product or service, it is reasonable to expect that an incentive might affect the decision to order it, likely resulting in unnecessary or suboptimal services. It is illegal to receive a kickback for using, ordering, or recommending a product or service (a pharmaceutical company could not pay a physician $10 for each prescription written for its product). It is also illegal for physicians to refer patients to other entities in which they have a financial interest (a physician could not refer a patient to a lab in which the physician has partial ownership). The Stark laws and state prohibitions on self-referral have complex series of "safe harbor" exceptions in an ocean of prohibitions.[4]

HIPAA and confidentiality regulations are intended to protect patient privacy. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) has extensive regulations concerning both privacy and security. The medical community is well-versed in HIPAA regulations and sensitive (perhaps hypersensitive) to its requirements. Most states have patient privacy regulations that apply in addition to HIPAA and are commonly less well known.

Protecting patient confidentiality is an ethical, legal, and licensure obligation. Protecting patient confidentiality is, therefore, general duty and not tied to a specific federal program.[5]

Insurance Fraud is the private side of fraud and abuse. Submitting private insurance claims that are false or a misrepresentation of service is generally a violation of the contract between the provider and the insurance company. It may also be a crime—it is, after all, a form of theft. Serious fraud may result in the loss of the license to practice.

The False Claims Act and Whistleblower laws make it a civil offense (and, in extreme cases, a criminal offense), to present to the government a false claim for payment of services. It may be false in the sense that the service was not provided or in the sense that service was of inadequate quality. These statutes (both federal and state) also allow for a private whistleblower to receive some of the proceeds if he or she helps the government recoup wrongful payments. Disgruntled former employees are a common source of whistleblowing.[6]

Abuse-reporting statutes are part of every state's law but vary considerably. They require certain professions, including physicians, to report known or suspected abuse of children, dependent adults, and often, other groups. The failure to make required reports can result in civil liability or even (rarely) criminal charges.

How organizational and commercial law affects ObGyns

Physicians are generally members of organizations that are engaged in the business of health care (even nonprofit organizations have business interests). There are 2 major legal building blocks of these

business relationships: contracts and agency.[7]

Contracts are agreements between 2 or more persons or entities that carry with them legally enforceable obligations. The 3 common elements are an offer by one party, acceptance by another, and consideration (exchanging one thing of value for another). Contracts are binding in the sense that, if there is a breach of the promise by one party, the other party may seek monetary damages for the loss of the benefit of the bargain (and in limited circumstances, require that the contract be performed).

Agency is essentially the mechanism that allows a person to legally work for or on behalf of another. A "principal" authorizes an agent to take actions for, and bind, the principal. All employment, partnership, and "agent" relationships create an agency. The principal is generally responsible for the actions of the agent—at least within the scope of the agent's authority. For example, the principal is responsible for the torts (civil liability resulting from the breach of a socially imposed duty, but generally not arising from a contract) of an agent doing the principal's business. The agent has the obligation to act in good faith for the benefit of the principal and to abide by the instructions of the principal.

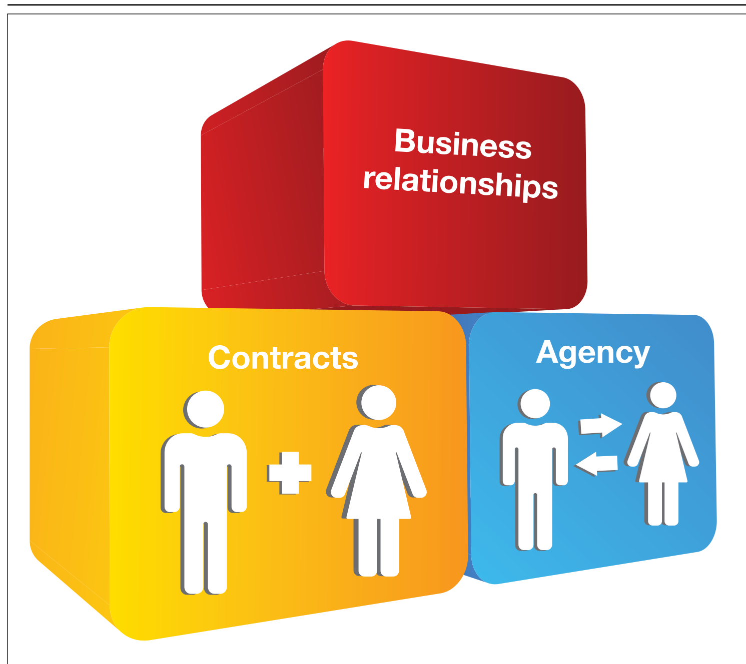
Corporate structures

There are a variety of corporate organizational structures; the basic types are corporations, partnerships, and unincorporated associations. These generally are available to nonprofit and for-profit organizations. As a general matter, corporations limit the owners' personal liability; partnerships have tax advantages. A number of laws now allow the creation of entities that have both liability and tax advantages (subchapter S corporations, limited liability companies, and limited liability partnerships).

Other areas of business law

Employment law, which now affects almost every aspect of hiring, dismissal, payment, and fringe benefits, is not a single law but a series of state and federal statutes, regulations, and court decisions.[8]

Contracts and Agency: Building blocks of business relationships



Competition is regulated through a number of **antitrust laws** as well as **fair business practices.** These affect the ability of health care entities to merge, fix prices, and split markets.[9]

There are literally hundreds of other laws that affect the way health care entities can operate. Conducting a careful compliance review is of considerable importance.[10]

Dos and don'ts of preventive law

The business of medicine is subject to many laws and keeping track of all of these is generally beyond the expertise of the ObGyn. Here are a few practical suggestions for thriving in this legal milieu.

Understanding the law

DO establish an ongoing relationship with an attorney you can trust who is knowledgeable in health law. Consult with this attorney not only on an as-needed basis but also for an "annual checkup" of legal issues affecting your practice.

The principal is responsible for the actions of the agent doing the principal's business

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DON'T guess what the law is. Laws vary from state to state and change frequently. Taking curbstone advice or suggestions from a podcast is a good way to develop problems.

Error reduction

DO take risk management seriously. Implement plans to improve patient safety and reduce errors.[11]

DON'T ignore angry or hostile patients. Their hostility may be directed at you—an undesirable state. The same goes for disgruntled (or former) employees, who may become whistleblowers.

Insurance

DO review your insurance coverage annually, preferably with an expert or your attorney. Insurance policies and your insurance needs change frequently.

DON'T assume you have all the insurance you need or that insurance will cover all legal claims arising from your practice. Intentional torts, some antitrust claims, licensure discipline, and civil fines, for example, may not be covered.

Take risk management seriously by engaging in regular insurance and compliance review

Informed consent and ethics

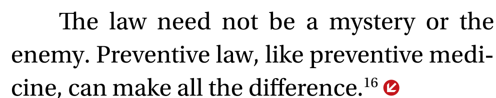
DO use the informed consent process as a means of improving communication between you and your patients to address their concerns and discuss expectations. Autonomy is a basic ethical value of medicine and informed consent helps to achieve that goal.

DON'T ignore ethics. Ethical obligations are not just essential to maintaining a license, hospital privileges, and professional standing.[12] They also help guide you toward good practice that avoids liability.

Compliance, disputes, and arbitration

DO engage in continuing compliance review. That includes understanding the contracts and professional arrangements in which you practice and all of the requirements of third-party payers (especially government entities). There are a wide range of other compliance obligations that require ongoing attention.

DON'T sign arbitration agreements without understanding exactly what you are agreeing to. There are advantages to arbitration,[13] but there are disadvantages, too.[14] The courts generally enforce arbitration agreements, even ones that are unfair or one-sided.[15]



The law need not be a mystery or the enemy. Preventive law, like preventive medicine, can make all the difference.[16]

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