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Legal considerations
Along with the host of possible benefits, using technology presents a number of complicated legal issues. Many of these issues are familiar but pose new complications (e.g., HIPAA compliance, antikickback statutes, and Stark anti-referral rules) as practices bring HIT into the office environment. Others are more specific to technology and/or to the business relationship of the practice and the vendor. This information is not intended as a substitute for the services of a knowledgeable attorney in the negotiation of specific contracts.

Anti-kickback and Stark Rules
Among the primary legal barriers are the anti-kickback statutes and the Stark anti-referral rules. Anti-kickback laws come into play when a practice or physician gives something of value for referrals. Stark issues arise when a physician refers to an entity with which he or she has a financial relationship. Despite the serious limitations these regulations impose, regulators have taken action to help protect certain types of arrangements that involve third-party financial support for providing to practices e-prescribing or EMR hardware, software, and training services.

E-prescribing
E-prescribing presents many advantages to physicians and patients, ranging from efficiency and convenience to fewer clinical errors. The U.S. Office of Inspector General recently proposed a new safe harbor to foster e-prescribing. A parallel exception also has been developed under Stark. Because safe harbors for e-prescribing are subject to regulations, physicians should always find out if government regulators have issued additional guidance before entering into these types of arrangements.

Restrictions Regarding E-Prescribing Relationships
Any physician considering entering into an e-prescribing relationship with support from a third party should be aware of the following restrictions:
• The only services a third party may provide the physician are hardware, software, and training needed solely to send and receive electronic prescription drug information.
• Only the following entities may provide items and services: (1) a hospital to physicians who are members of its medical staff; (2) a group practice to physicians who are members of the group; and (3) a
prescription drug plan sponsor or Medicare Advantage plan that offers drug coverage.

Electronic Medical Records
There is a similar exception to Stark for EMRs that protects non-abusive arrangements under which third parties provide medical practices the software and training they need to receive, transmit, and maintain EMRs.
The restrictions applied to this exception are exactly the same as the restrictions on the provision of EMR technology with a single addition. When a third party provides EMR technology, it must contain e-prescribing capabilities that comply with the electronic prescription drug standards under Medicare Part D at the time the items and services are furnished. As with e-prescribing, be sure to find out if government regulators have issued additional guidance before pursuing this type of arrangement.

Technology Liability Exposure
New information technology may carry different types of risk that require different types of liability insurance coverage and/or an expansion of the risks covered under your current policies. If your EMR system does not properly back up files and a patient's record is lost, does your general liability insurance cover any resulting claim? What if the integrity of an e-prescription is compromised upon transmittal and dosages are changed? Technology is not simply an instrument to be used to increase practice efficiency; it comes with the added responsibility of ensuring that the technology works properly. As the prevalence of technology increases, physicians are subject to a higher standard of care. Physicians should take this additional responsibility into account when negotiating contracts and when purchasing the practice's insurance coverage. Consider these factors:
• The items or services donated must be used to access or be part of an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items are furnished.
• There can be no restriction on the use of other systems.

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• It is not proper to take into account the volume or value of referrals or other business generated between the parties.
• The parties must sign a written agreement that: (1) specifies the items or services being provided and their values; (2) covers all of the e-prescribing services to be furnished by the entity; and (3) contains a certification by the physician that the items and services are not technically or functionally equivalent to items and services that he or she already possesses.
• Your practice will need to expand its general liability coverage to include any harm to patients that might result from equipment malfunctions, data transmission errors, incomplete or inaccurate data resulting in inaccurate medical diagnoses, misappropriation of confidential health care information, and other technology-related mishaps. Your medical liability policy will not cover these events.
• If you are a physician using the Internet or a telemedicine connection to provide medical services, you should determine whether your medical liability policy covers services provided electronically. Most medical liability insurance covers only "face-to-face" encounters within the state in which the physician practices and is licensed. Consequently, physicians who provide services to patients outside the state over the Internet or who engage in telemedicine can be exposed to claims if state law requires that the physician be licensed in the state where the
test results are delivered. Always be sure to obtain written assurances from vendors that they are responsible for claims that may arise as a result of a defect or malfunction of their products. On the other hand, HIT significantly lowers risk; therefore, most liability carriers are willing to offer premium discounts to users.

HIPAA

The Health Insurance Portability and Accountability Act (HIPAA) requires medical practices to protect the confidentiality and integrity of patient information. HIPAA policies and procedures are extensive and complicated, and the majority of physician offices need to comply with the regulations as they apply to HIT. For this reason, practices should obtain written assurances from their technology vendors that they comply with HIPAA and will remain in compliance through the term of any agreement.

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Questions to Ask Your Vendor About HIPAA

1. Does your product give physicians the ability to document compliance with HIPAA?
2. Does your product notify the physician of authorizations that have been revoked or expired?

In addition, be sure to obtain a nondisclosure agreement from any vendor who has direct exposure to your practice's patient data. Note that with the adoption of any new technology, the practice may need to reissue its Notice of Privacy Practices (NPP) and obtain updated authorizations. The NPP should disclose whether the physician e-prescribes or communicates with patients via e-mail.

Telemedicine

Telemedicine consists of a health care service initiated by a physician to obtain an assessment from another health professional — generally another physician — that requires the use of advanced telecommunications
(i.e., that cannot be provided via the telephone or fax). The initiating physician may be asking for assistance in diagnosing a patient, a consultation on a patient's treatment plan, guidance in performing some particular treatment, or an interpretation of imaging studies. The defining characteristic of telemedicine is that the consulting physician
is seeing either the patient, or complex data about the patient, electronically. Historically, telemedicine served and still serves as a health care alternative in remote areas where some medical specialties are in short supply. But in recent years, it has become more common because it enables specialists to review a patient's record and/or provide care when the patient seeks care in a location remote from his or her medical record. For example, a radiologist in South Texas can easily review imaging studies and other data for a patient from Iowa vacationing in Texas. When incorporating telemedicine into a practice, check with your state's requirements to ensure compliance. For example, a practice should create and follow written protocols that document a good faith effort to prevent fraud and abuse by addressing the following issues:
• Authentication and authorization of users;
• Authentication of the origin of information;

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• Prevention of unauthorized access to information;

• System security, including the integrity of information collected, the
• program, and the system;
• Information storage, maintenance, and transmission;
• System and information usage; and
• Synchronization and verification of patient data.

The Internet
Check your state's regulations, but the law generally holds online treatment and consult recommendations, including e-prescriptions, to the same standards as traditional face-to-face settings. While the Internet enables physicians to deliver health care in a more efficient and cost-effective manner, physicians who use the Internet for patient care should first establish a face-to-face, patient-physician relationship. Evaluating a patient by phone, via the Internet, or over e-mail is not an acceptable standard of care.

The patient-physician relationship should include at a minimum the following elements:
• Establishing that a person requesting treatment is in fact who the person claims to be;
• Using acceptable medical practices such as patient history, mental status, physical examination, and appropriate diagnostic and laboratory testing to establish and diagnose underlying conditions, and identify appropriate treatment and/or any contraindications to treatment;
• Discussing with the patient the diagnosis and evidence for diagnosis in addition to the risks and benefits of various treatment options;
• Ensuring physician availability and/or coverage for appropriate followup care; and
• Making certain the communications are documented in the patient's record.

Web Sites
Traditionally, Web sites have been used as a means of marketing. However, more and more physicians are creating Web sites as a means of providing treatment and directly communicating with patients. The use of Web sites triggers both federal and state regulations including many of the legal issues raised in the preceding discussion of the internet.