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We at Brownstone Publishers offer our heartfelt sympathy to our readers, sources, friends, and all others who are suffering because of the tragic events of Sept. 11, 2001. Our prayers are with you.

Seven Traps to Avoid When Establishing and Operating Screening Centers

Recently the benefits of screening CT scans for the full body and the heart have been creating a lot of buzz. Oprah even did a show featuring people whose lives were saved by screening CT scans. As the popularity of such scans increases, a screening center that offers them can provide a substantial income boost to its owners—typically radiologists, cardiologists, and other specialists. Because Medicare, Medicaid, and many private payors generally don't cover screening CT scans, the patient usually pays the fee. So these centers represent a lucrative opportunity for radiologists to tap into a market for self-pay medical services, where market forces rather than Medicare or managed care plans determine reimbursement. These centers also offer a way for radiologists to supplement declining third-party reimbursement.

But there are risks involved in setting up and running screening centers. Many radiology practices mistakenly assume that because Medicare, Medicaid, and most private payors aren't involved, the centers are virtually unregulated. This assumption is a big mistake, says Washington, DC, health care attorney William A. Sarraille. Screening centers are full of compliance traps for the unwary, he says.

We'll point out seven common traps: four that you should be aware of before you set up a screening center, and three that can arise during the operation of a screening center. And we'll give you some tips on how to avoid all of these potential traps, including a Model Policy (p. 3) that you can adapt and use.

What Screening Centers Do and How They Work

Screening centers offer expensive services like full-body CT scans and heart CT scans on a fee-for-service basis. These scans may be useful for preventative purposes, to establish a baseline, or to detect certain medical conditions in their very early stages. Medicare and most private payors don't pay for screening tests in the absence of specific signs and symptoms, so patients who want screening tests must pay for them themselves.

Here's how the screening center typically works:

- One or more physicians or medical practices will invest in a screening center—to secure the space and equipment and staff the center.
- The screening center generally advertises directly to patients, rather than to referring physicians.
- A patient schedules the screening scan on his own initiative—usually without a referral from a physician—and pays for the screening himself.
- The patient ordinarily doesn't have face-to-face contact with a physician at the center. Instead, the center's patient intake coordinator (ideally

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SEVEN TRAPS TO AVOID (continued from p. 1)

a nurse or someone with similar clinical expertise) will interview the patient and take a thorough clinical history. And the patient will get a report from the interpreting radiologist explaining, in layman's terms, the results of the scan.

4 TRAPS TO AVOID BEFORE YOU OPEN A SCREENING CENTER

Before opening a screening center, you should have an experienced health care attorney investigate the regulatory climate in your state, Sarraille warns. Many states have laws that affect the operation of these centers, so it's critical that you find out what laws apply to screening centers in your state before you set up one, Sarraille advises. The following four traps are set by common state laws that affect screening centers:

Trap #1: Violating Antikickback Laws

Even if federal antikickback laws won't apply to your screening center because it won't treat any Medicare or Medicaid patients, it's still critical that you check your state's antikickback laws. Many state laws bar a physician from paying anything, in cash or kind, to reward or induce referrals of medical services. These laws mirror the federal antikickback law but are much broader because they frequently cover *any* medical services, not just those reimbursed by a government-supported program. You may violate your state's antikickback law if your screening center offers investment interests to physicians in a position to refer patients for screening services as an inducement or reward for referrals. Similarly, awarding contracts for interpreting CT scans performed at the center to physicians who refer patients for screening CT scans can violate some of these states' laws. Also, say the screening CT scan finds evidence of disease and the patient is then referred to a physician who's an investor in the center or who refers patients to the center. This can be an antikickback violation if the referral is an effort to reward the physician for securing business for the center, rather than a straightforward effort to find a competent treating physician for the patient.

To avoid antikickback violations when setting up the screening center, Sarraille suggests that you:

- Avoid rewarding investors based on their referrals when deciding how to distribute any revenue from the center;
- Say in any contracts with physicians for CT scan interpretations or other services that the center will pay fair market value for these services;
- Identify local specialists so that you can give patients requiring follow-up services the names of several physicians in the appropriate specialty. Investors should know that center employees won't be encouraged to steer patients toward investors in the screening center.

Trap #2: Violating Self-Referral Laws

Many states have self-referral laws—similar to the federal Stark law—that apply even to relationships with self-pay patients, Sarraille notes. Typically, these laws bar a physician from making a referral to an entity in which the physician (or an immediate family member of the physician) has a financial interest.

If your state has a self-referral law that will cover your screening center (some state self-referral laws exempt radiological services), Sarraille advises that you avoid seeking investors from the physician community who may be able to give referrals to or receive referrals from the center.

Trap #3: Violating Licensure Laws

Many state laws require screening centers to get special licenses or certificates of need (CONs), Sarraille says. Failure to get a license or CON, if one is required, may constitute the unauthorized practice of medicine or the operation of an unlicensed facility—violations that are crimes in many states, he says.

Your attorney will be able to shepherd your license and/or CON application through the approval process if your state requires one. But be aware that the process can be time-consuming and expensive, so find out what's required before you finalize plans to open a screening center. That way, you can make an informed decision about whether it's going to be cost-effective, Sarraille says. And you can get your attorney moving on this early in the process to avoid opening delays.

Trap #4: Violating Corporate Practice of Medicine Prohibitions

Sometimes the investors in a screening center will set up the center as an S corporation or other general business entity, instead of as a professional corporation. This is especially common when some of the investors aren't physicians. But in some states an arrangement like this will cause the investors to run afoul of corporate practice of medicine prohibitions, Sarraille explains. These prohibitions typically bar a nonprofessional entity—like an S corporation—from providing medical services. Some

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MODEL POLICY

Screen Out Patients Who Want Covered Services

Screening centers are designed to provide noncovered services to patients who will pay for the services themselves. It's ironic then that one of the biggest risks associated with screening centers is the possibility of getting into trouble with Medicare, says attorney William A. Sarraille. That's because if you're not careful, your screening center could inadvertently provide a covered service, which would lead to lots of problems. Not only would you get into trouble for violating Medicare limiting charge restrictions, but offering a Medicare-covered service, even by mistake, could trigger the federal Stark and antikickback laws.

The best way to prevent these problems is to invest time and effort into procedures to prevent a patient who needs a covered service from getting it at your screening center. A strictly enforced intake policy, although labor-intensive, will help ensure that you don't run afoul of Medicare rules or the rules of other payors. You can adapt the following policy for your screening center. Have your attorney review it to make sure it complies with all your state's laws.

INTAKE POLICY

1. PATIENT INTAKE MUST BE HANDLED ONLY BY AUTHORIZED PERSONNEL ACTING WITHIN THEIR APPROPRIATE SCOPE OF PRACTICE.

Nancy Nurse is responsible for handling all aspects of patient intake at ABC Screening Center. In her absence, Thomas Tech will assume patient intake responsibilities. Nancy Nurse and Thomas Tech will consult with the Medical Director as appropriate. No other employees of ABC Screening Center are authorized to handle patient intake.

2. PATIENTS SEEKING COVERED SERVICES MUST BE TURNED AWAY AND REFERRED TO APPROPRIATE SPECIALISTS OR PRIMARY CARE PHYSICIANS.

Patient intake personnel are responsible for interviewing the patient and ensuring that the service the patient seeks is not a covered service. Patient intake personnel, as a condition of their employment, are responsible for being familiar with the latest Local Medical Review Policies and other payors' coverage policies in effect in our locale. In the event that ABC Screening Center must refuse service to a patient because he or she requires or seeks a covered service, the patient intake personnel must refer the patient to his primary care physician and/or provide the patient with the names and phone numbers of appropriate local specialists.

3. ALL PATIENTS SEEKING TREATMENT AT ABC SCREENING CENTER MUST BE PRESCREENED AT THE TIME THEY CALL FOR AN APPOINTMENT.

Patients who call seeking appointments must speak with the patient intake personnel for a prescreening telephone interview before they will be offered an appointment. During the prescreening interview, intake personnel will evaluate whether patients are seeking covered services according to the Local Medical Review Policies of our Medicare carrier and the coverage polices of other payors. Only patients with histories and diagnoses that indicate noncovered services may be offered appointments.

4. PATIENTS MUST BE INFORMED DURING THEIR PRESCREENING THAT ABC SCREENING CENTER PROVIDES ONLY NONCOVERED SERVICES.

The patient intake personnel must clearly explain to the patient during the prescreening interview that if at any time the patient's history and/or signs, symptoms, or existing condition indicate that the patient seeks or requires a covered service from ABC Screening Center, ABC Screening Center will not provide the service.

5. PATIENT INTAKE PERSONNEL MUST INTERVIEW PATIENTS IN PERSON WHEN THEY ARRIVE FOR APPOINTMENTS.

The patient intake personnel must take another thorough and comprehensive clinical history when the patient arrives at ABC Screening Center for his appointment. If the history and discussion with the patient at this time indicate that the patient may be seeking or requires a covered service, the patient intake personnel will follow the procedure in paragraph 2 above.

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SEVEN TRAPS TO AVOID
(continued from p. 3)

states' laws define medical services so broadly that they include even the technical component services provided by screening centers.

States differ in the way they regulate the corporate practice of medicine. In some states a business corporation may not employ the interpreting physician. Or your state regulations may bar you from having nonphysician investors in your screening center (or you may have to get a CON if you do). These are other issues your attorney should investigate before you go forward with your plans for the center, Sarraille says.

3 TRAPS TO AVOID WHEN RUNNING A SCREENING CENTER

Once you're past the traps surrounding the establishment of your screening center, you must steer clear of the traps you can spring when you're running it, Sarraille cautions. They generally fall into one of three categories: violations of Medicare rules, malpractice concerns, and licensure issues.

Trap #5: Violating Medicare Rules

The biggest risk screening centers face, in Sarraille's opinion, is the danger that the center won't restrict its services to those that Medicare doesn't cover. If the center inadvertently provides a Medicare-covered service, it could land in hot water. Medicare investigators have begun to focus on situations in which providers offer covered services as noncovered services, charging rates above the Medicare fee schedule. So far, these investigations have focused on services other than full-body screenings—but that could change, he says.

When advising his clients, Sarraille recommends that screening centers have a strict weeding-out policy that will minimize the risk of inadvertently providing a Medicare-covered service. We've taken Sarraille's suggestions and created a Model Policy you can adapt and use in your screening center. Although the intake procedure in the policy is labor intensive, Sarraille points out that mistakenly providing a covered service to a Medicare patient can lead to the screening center's suddenly needing to comply with the federal Stark and antikickback laws. And you may be violating the Medicare limiting charge rules (the regulations that restrict how much a provider can charge for Medicare-covered services). Any of these violations can lead to trouble not only for the screening center but also for any owner or investor in the center who's a physician. So the time and expense involved in implementing an intake policy like our Model Policy is well worthwhile, Sarraille asserts.

Like our Model Policy, your intake policy should:

■ Designate a staff member to be responsible for patient intake [Policy, par. 1]. Ideally, this person will be a nurse or some similarly qualified clinical professional. This person must be intimately familiar with the Local Medical Review Policies in your locality, Sarraille says. That is, she must know which services the Medicare carrier and other payors cover for which diagnoses so that she can weed out those patients whose signs and symptoms indicate that they may need to receive covered services. And make sure to train a back-up person who will handle patient intake at those times when your designated person isn't available. The center's medical director should be available so that the designated person has a physician to consult when necessary.

■ Require the designated person to turn away any patient who seeks or requires covered services. The designated person can then either refer the patient to another provider for appropriate care or send the patient back to his primary care physician [Policy, par. 2]. Sarraille recommends that you give the designated person a list of specialists in the area, so she can give patients seeking covered services the names of several providers practicing the appropriate specialty.

Insider **Says:** Make sure you consider options that don't involve patients being directed only to physicians who are investors in the center, Sarraille suggests. That could be a violation of your state's antikickback ban, if it has one, to the extent that a restrictive referral list is meant to induce or reward referrals by the investors to the center.

■ Require the designated person to conduct a phone interview and take a thorough patient history over the phone—before the patient gets an appointment [Policy, par. 3]. That way, you can minimize the possibility that a patient will show up for an appointment and be turned away because the scan he wants may be a covered service, Sarraille explains. You should also use this procedure to assure that the patient is informed that insurance coverage isn't available for screening center services and that the patient will be responsible for payment.

■ Instruct the designated person to inform the patient that the center performs only services that aren't covered by Medicare or other payors [Policy, par. 4]. Telling the patient this up front may help the patient understand your position if you subsequently must turn the patient away, Sarraille remarks.

■ Require the designated person to take the patient's history again when he appears for the appointment. The designated person must double-check any patient complaints to make sure the service he receives isn't a covered service [Policy, par. 5]. If the patient's history, signs, symptoms, or existing condition indicates that the service he

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is scheduled to receive may be a covered service, the designated person must direct him elsewhere. The designated person can either refer the patient to an appropriate specialist or tell him to return to his primary care physician. In order to avoid a patient's claim of abandonment or failure to make a referral, the designated person should document these communications carefully and give a copy to the patient, Sarraille emphasizes.

Trap #6: Increasing Malpractice Risk

Many radiologists who set up screening centers don't realize that providing screening services may create a risk of malpractice lawsuits. These radiologists mistakenly believe that they must have a face-to-face encounter with a patient, or at least perform some sort of medically necessary service, in order to establish a physician/patient relationship that could form the basis of a malpractice lawsuit. That's not true, Sarraille asserts, and you must be aware of this when operating your screening center.

Some patients will expect that the screening center has assumed some responsibility for the patient's care. This is especially true if the screening test identifies a condition that requires treatment. Later, after the patient has sought treatment for the condition, he may sue both the treating physician and the screening center that first identified the condition if there's a problem in treatment. Even if the patient loses the lawsuit, defending yourself will be an expense and a hassle.

Here are a few tips on how to lessen your exposure if your center is sued for malpractice:

Keep the center separate. Try to keep the center geographically and legally separate from your radiology practice, Sarraille advises. That way, it's less likely that the patient will name your practice in a malpractice lawsuit. It also makes it harder for the patient to convince a judge or jury that he was being reasonable when he alleges that he relied on the center for treatment information, as opposed to just screening information.

Get the center its own malpractice insurance. Make sure each screening center has its own separate malpractice coverage. That way, if there are lawsuits at the center, they'll be less likely to affect the premiums your practice pays for its medical malpractice insurance.

Implement a result communication policy. Establish a policy for communicating the results of a screening scan to the patient—especially for patients whose screening scans show some evidence of a condition that requires treatment. A good result communication policy, Sarraille says, will direct the staff to do the following:

- Make sure the report of the scan results is clear to the patient. Because a screening center usually reports directly to the patient, not to a referring physician, the report shouldn't use the same language as the radiologist's report you would send to a referring physician. Instead, the radiologist's interpretation of the scan should be in clear, layman's language, to the extent possible, Sarraille explains.
- Send the patient's primary care physician a copy of the radiologist's interpretation of the scan results. This should be a standard radiologist's report because it's going to another physician. If the patient sues you, this can help you prove that you did all you could to ensure the patient received appropriate care, Sarraille notes. If the results of the scan indicate a potential problem, it's a good idea for a staff member to call the primary care physician's office, rather than just mail the radiologist's report to the physician's office, he advises. And document the call in the record, too.
- Give the patient a list of appropriate specialists in the area who can treat any problem or potential condition the scan detects if he doesn't have a primary care physician. Again, choose referral options based on the physician's competence and the patient's convenience, not whether the physicians can or will refer patients to the screening center, Sarraille says.

Trap #7: Violating State Licensing Board Restrictions

Because state licensing boards tend to be conservative, new concepts like screening centers invite their scrutiny, Sarraille remarks. For example, many states' professional conduct laws or regulations restrict the way providers market medical services. Screening centers typically use direct marketing approaches to potential patients, Sarraille notes. Although direct marketing is permitted in most states, the content of marketing materials is subject to various restrictions, like the ban on testimonials in some states. And you should make sure any claim you make in your advertising is reasonable, documented, and independently verifiable.

In states with particularly active or conservative medical licensing boards, failing to follow both the spirit and the letter of the advertising restrictions can cause big trouble, Sarraille cautions. To make sure your advertising passes muster in your state, run any advertising copy by your attorney before you use it, Sarraille emphasizes. The attorney will know the restrictions in your state and should have some sense of how your state's medical board views provider advertising. ■

Insider Source

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IN THE NEWS

CMS Releases New OPPS Fee Schedule

On Aug. 14, 2001, CMS published the new fee schedule for the hospital outpatient prospective payment system (OPPS). The new fee schedule contains a few changes that may be significant for radiology practices that perform services in a hospital outpatient setting, says radiology billing and coding consultant Melody Mulaik. We'll explain the significant changes and show you how they may affect your practice.

Changes in APCs May Affect Revenue

Some radiology practices will see changes in revenues due to the new fee schedule. That's because under OPPS, outpatient procedures are lumped together with other procedures that have similar relative value units (RVUs, which reflect the complexity or expense of doing a procedure) into groups called APCs. Every procedure in an APC group gets the same reimbursement. Some interventional radiology and radiation oncology procedures were moved from one APC group to another. This means the reimbursement for doing these procedures will change, Mulaik explains.

Most Changes Occurred in Interventional Codes

CMS significantly adjusted the way it classifies some interventional radiology procedures, Mulaik says. Several CPT procedure codes* that were in APC group 0279 were shifted to the new APC group 0287: 75831—Venography, renal, unilateral, selective, RS&I; 75840—Venography, adrenal, unilateral, selective, RS&I; 75842—Venography, adrenal, bilateral, selective, RS&I; 75860—Venography, sinus or jugular, catheter, RS&I; 75870—Venography, superior sagittal sinus, RS&I; 75872—Venography, epidural, RS&I; and 75880—Venography, orbital, RS&I.

These shifts will result in a revenue decrease for those procedures, Mulaik says. But it may be counterbalanced by increases for other procedure codes that were shifted from APC group 0279 to APC group 0280: 75960—Transcatheter introduction of intravascular stent(s) (noncoronary vessel), percutaneous and/or open, RS&I, each vessel; 75961—Transcatheter retrieval, percutaneous, of intravascular foreign body (for example, fracture venous or arterial catheter), RS&I; 75964—Transluminal balloon angioplasty, each additional peripheral artery, RS&I (list separately, in addition to code for primary procedure); 75968—Transluminal balloon angioplasty, each additional visceral artery, RS&I (list separately, in addition to code for primary procedure); 75970—Transcatheter biopsy, RS&I; and 75978—Transluminal balloon angioplasty, venous (for example, subclavian stenosis), RS&I.

Those procedures will generate higher revenue under the new fee schedule, Mulaik reports. So, she says, practices that perform transcatheter procedures "will possibly come out about even" as a result of the changes.

Revenue Increases Likely for Radiation Oncology

Radiation oncologists may be the winners under the new fee schedule, Mulaik notes. Two radiology oncology procedure codes were shifted from APC group 0311 to APC group 0304: 77336—Continuing medical physics consultation, including assessment of treatment parameters, quality assurance of dose delivery, and review of patient treatment documentation in support of the radiation oncologist, reported per week of therapy; and 77399—Unlisted procedure, medical radiation physics, dosimetry and treatment devices, and special services. One code (77370—Special medical radiation physics consultation) was shifted from APC group 0311 to APC group 0305. This will result in a revenue increase for all three codes, Mulaik says. ■

Insider Source

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What You Should Know About the New Guidance on HIPAA Privacy Regs

On July 6, 2001, the Department of Health and Human Services (HHS) issued guidance on the final HIPAA privacy regulations. This guidance is the first in a series of guidance materials that HHS expects to issue to explain and clarify key provisions of the final HIPAA privacy regulations. It urges health care organizations and providers to "begin the process of implementing" the privacy regulations so that they can meet the April 14, 2003 (or April 14, 2004 for small health plans) date for compliance with the regulations. It's written in an easy-to-read style and provides technical assistance to health care organizations to help with their HIPAA compliance efforts.

We'll tell you which topics the guidance covers and, with the help of health information experts, explain its importance for you. We'll also tell you what the guidance says about when and where you can expect more changes in the privacy regulations and what future guidance may cover.

You can find the new guidance at http://www.hhs.gov/ocr/hipaa/finalmaster.html.

Nine Areas Are Covered

The guidance covers only nine areas of the final privacy regulations. It starts with a general overview of the privacy regulations. Next, it uses a question and answer format to explain in general what the privacy regulations do, why they're needed, what they require, and who must comply with them and when.

Then there's a section for each of the nine areas. Each one begins with a summary of what the privacy regulations require for that area, followed by questions and answers for that area. The answers explain and clarify what is and isn't permitted by the final privacy regulations. The guidance includes many examples. The nine areas are:

1) Consent. According to the guidance, the final privacy regulations require a health care provider to get patient consent before using or disclosing protected health information (PHI) for treatment, payment, or health care operations. The guidance helps clarify the following issues related to consent:

- It explains the difference between consent and authorization. For example, while consent grants general permission to use or disclose PHI, an authorization's permission is limited to the purposes and the parties specified in the authorization.
- It clarifies that a health care provider must get consent from a patient only once—rather than annually—and that consent may cover multiple patient visits and different medical conditions. This clarification should ease the administrative burden of HIPAA compliance for smaller providers, such as small groups of physicians or sole practitioners, suggests health information consultant Mary Brandt. But to be safe, many larger providers, such as hospitals and ambulatory surgery centers, may still opt to have their patients sign a new consent at each admission, since it may be easier than locating the old consent, she adds.
- It clarifies that the privacy regulations currently allow family or friends to pick up a patient's prescription if the pharmacist reasonably believes it's in the patient's best interest to do so.
- It confirms that health plans and health care clearinghouses *may*, but aren't required to, get patient consent to use or disclose PHI for treatment, payment, or health care operations.

2) Minimum necessary. According to the guidance, the final privacy regulations require a health care organization to limit its use and disclosure of PHI to the minimum necessary to accomplish the intended purpose. The guidance emphasizes that organizations must take only reasonable steps to comply with the minimum necessary standard. That is, each organization has the flexibility to adopt steps that are appropriate for its own size, structure, and business practices, notes Brandt. Compliance with the minimum necessary standard will require each organization to identify and classify who within the organization needs access to PHI and then establish policies and procedures for the use and disclosure of PHI, she explains.

The guidance says that the minimum necessary standard doesn't apply when PHI is:

- Disclosed to a health care provider for treatment purposes;
- Disclosed directly to a patient at the patient's request;
- Used or disclosed following a valid patient authorization;
- Used or disclosed to comply with the HIPAA transactions standards;
- Disclosed to HHS for HIPAA enforcement purposes; and
- Used or disclosed when required by other laws.

3) Oral Communications. The guidance confirms that, in addition to paper and electronic forms of PHI, the final privacy regulations also cover oral communications of PHI. The guidance explains that if oral communications weren't covered, PHI could be disclosed to anyone at any time in spoken form.

But the guidance also stresses that health care providers must be

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HIPAA PRIVACY REGS
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free to discuss PHI with each other in treatment settings, when appropriate. And it lists several common situations in which such discussions are allowed (for example, at nursing stations; over the phone with a patient, family member, or another provider; in joint treatment areas; and during training rounds).

Plus the guidance says that calling out patient names in waiting rooms is permitted, and that HHS will propose amendments to the privacy regulations to confirm that these and similar practices will be permitted. Even so, many providers have taken a conservative approach to HIPAA compliance and have already changed their waiting room practices to limit unnecessary disclosures of PHI, notes Brandt. For example, some physician offices and clinics are now using half-page forms for patients to sign in upon arrival. The completed form is given to the office staff, instead of having all patients listed on a sign-in sheet. And some hospitals now page patients and family members by number rather than name.

4) Business associate contracts. The guidance explains that, according to the final privacy regulations, health care organizations must have a written contract with each "business associate"—that's any entity that performs a function on its behalf involving the use or disclosure of PHI. The guidance clarifies a health care organization's responsibility for a business associate's violation of the privacy regulations. It explains that health care organizations aren't automatically legally responsible for their business associates' privacy violations, says health information attorney Edward Shay. And it says that organizations aren't required to actively monitor the conduct and practices of each of their business associates.

But an organization should include provisions in its business associate contracts requiring the business associate to notify it of any privacy violations. And the organization must take reasonable steps to stop or fix any privacy violation or breach by its business associates once the organization learns of it, he explains. Only if the health care organization fails to take such steps would it be out of compliance with the regulations. This clarification is a big relief to health care organizations, which contract with dozens of business associates, he adds.

***Insider* Says:** Business associates don't have to comply with all of the privacy regulations requirements that apply to health care providers, plans, and clearinghouses, the guidance notes. Instead, business associates are subject to a much narrower set of requirements, and only because of the provisions that are supposed to be in their contracts with health care organizations. For instance, they're not required to appoint a privacy official or to establish detailed policies and procedures regarding PHI.

5) Parents and minors. The guidance addresses a parent's right to access her minor child's health information. Generally, under the privacy regulations, a parent, as the child's personal representative, is entitled to see a child's health information. But there are several exceptions to the general rule, explains Brandt. For instance, an organization may not be required to disclose a child's PHI to the parent when:

- The parent agrees to a confidential relationship between the child and the health care provider of the child (for example, when a parent takes a teenage daughter to a gynecologist for an examination or to a psychologist for counseling);
- The provider believes that the child has been abused or neglected by the parent; or
- Disclosing the information to the parent could endanger the child.

The guidance also points out that, no matter what HIPAA says, state law (including court orders) controls the disclosure or nondisclosure of a minor's health information to a parent. For instance, HIPAA won't consider a parent to be a minor's personal representative entitled to disclosure if a state law allows the minor to consent to mental health treatment without parental consent or if a court appoints a guardian (other than the parent) for the minor.

6) Health-related communications and marketing. The guidance explains the conditions under which PHI may be used or disclosed for marketing purposes. Generally, patient authorization is required when using or disclosing PHI for marketing purposes, but there are three exceptions, explains Brandt. The exceptions are for marketing communications that are:

- Face-to-face;
- For a product of nominal value (such as a toothbrush); or
- For a health-related product or service, as long as the communication identifies the organization making it; states if the organization is being compensated; and informs individuals of how to opt out of further marketing communications (and the organization makes reasonable efforts to honor those requests). In addition, if the communication targets specific individuals, the organization must have determined that the product or service might benefit those individuals, and the communication must identify the conditions or characteristics being targeted and explain how the product or service relates to that individual's health.

The guidance also gives examples of activities that aren't considered marketing. Among them are:

- Describing the participating plans or providers in its network;

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■ Identifying a pharmacy that accepts a particular drug coverage;

■ Describing the services offered by a provider;

■ Recommending a specific brand name or over-the-counter drug;

■ Making referrals; and

■ Sending appointment reminders.

7) Medical research. According to the guidance, the privacy regulations allow the use or disclosure of PHI for medical research purposes without patient authorization only under certain circumstances, explains Shay. The guidance explains these circumstances. For example:

■ A health care organization may always use PHI without patient authorization after it's been de-identified—that is, when all of the patient's identifying information has been removed, he says.

■ PHI may also be used without a patient's authorization if the organization gets a waiver of such authorization by an institutional review board or privacy board, whichever is applicable, he adds.

***Insider* Says:** Don't forget that, under certain circumstances, PHI may continue to be used or disclosed for an ongoing research project as long as the patient gave legal permission (such as a consent or authorization) prior to the compliance date, Shay points out. In future issues, the *Insider* will give you more information on how to comply with the final HIPAA privacy regulations' detailed requirements for medical research.

8) Government access to PHI. The guidance explains when PHI may be used by or disclosed to various government entities. The guidance points out that government-operated health plans and providers—such as Medicare and Medicaid—are subject to the same HIPAA requirements as all other health care organizations. The guidance also notes that the final privacy regulations grant the Office of Civil Rights (OCR) access to PHI but only for investigative or enforcement purposes. And the guidance emphasizes that the information OCR will seek for such purposes will be carefully limited and protected. It also states that, although the privacy regulations allow certain disclosures to be made for law enforcement purposes, any state law that's stricter than HIPAA in this respect—that is, that has tighter limits on such uses and disclosures of PHI—will control.

9) Payment. The guidance explains the conditions under which PHI may be used or disclosed for payment purposes. Some of the examples of payment activities given in the guidance are billing and collection, determining health plan eligibility, and disclosures to consumer reporting agencies. The guidance explains that only limited disclosure of PHI may be made to consumer credit reporting and debt collection agencies, and notes that there appears to be no conflict between the privacy regulations and the Fair Credit Reporting or Fair Debt Reporting Acts. The guidance also points out that a collection agency hired by a health care organization would be considered the organization's business associate.

What Will Future Guidance Cover?

The guidance says that it's the first of a series of guidance materials and to expect similar materials in the future. What areas of the privacy regulations are likely to be covered in future? Many areas in the privacy regulations were the subject of dozens of public comments but weren't covered in this first guidance, Shay points out. For example, the guidance doesn't mention: the standard for when HIPAA preempts state law; an individual's right to request an amendment to his or her own PHI; the precise role of a privacy official; the transition provisions; or enforcement of the regulations. It's likely that at least these areas of the privacy regulations will be addressed in future guidance materials, he suggests.

***Insider* Says:** Many health care organizations have been concerned about whether they can rely on HHS guidance in their compliance efforts. Although government agencies often issue guidance on various issues, laws and regulations have greater legal force than guidance, Shay cautions. So it's okay to rely on the guidance, but if it conflicts with the regulations, the regulations will prevail, he says. At this point, though, no major conflicts between the guidance and the regulations have been identified.

What Changes Are Expected to the Final Regulations?

The guidance says that HHS will propose formal changes to some areas of the privacy regulations. The regulations already include a provision that allows them to be changed any time during the first year they're in effect (after April 14, 2001) and annually thereafter, explains Shay. So you can expect to see HHS' first set of proposed changes by April 2002, which would still allow time for compliance by April 2003, he points out.

The guidance states that HHS will propose changes to the privacy regulations so that they:

■ Allow pharmacists to fill phoned-in prescriptions before getting patient consent;

■ Broaden the scope of allowable communications to ensure that providers can provide quick and effective health care;

■ Allow providers to make a referral appointment for a first-time patient before getting that patient's consent; and

■ Change the scope of the minimum necessary standard.

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The guidance also states that HHS may reevaluate the final privacy regulations to ensure that parents have appropriate access to the health information of their minor child.

***Insider* Says:** Any proposed changes will be published in the *Federal Register* and will be open to public comment. ■

Insider Sources

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Limit Financial Penalty for Failure to Follow Plan Policies

The Situation

Physicians sometimes fail to follow a plan's policies and procedures. At times these failures may be considered habitual and deliberate. But other failures to follow to the plan's policies and procedures may be one-time or unintentional mistakes. For example, a radiologist may inadvertently fail to get the plan's required preauthorization before treating a plan member or neglect to submit a copy of her current year's medical license.

The Form Contract

A large national HMO's form contract includes a clause called "Compliance and Participation in Programs." Most contracts have similar clauses. The clause begins by saying that the participating physician must comply with and participate in the plan's protocols and programs, including its utilization and other programs and those "otherwise established or directed by the Medical Director." The clause then says:

> If Participating Physician fails to adhere to the above referenced requirements as they relate to the provision of, or arrangement for, Covered Services, then Participating Physician shall be financially responsible for the cost of the Covered Services that were provided. Participating Physician shall bill no other party including, but not limited to, Plan, the Self-Insurer of the Coverage Plan, and/or Covered Persons, for such services.

The Problem

This clause is unfair to physicians. If you're subject to a clause like this, it requires you to pay for a covered service, even one that was medically necessary, if at any time you failed to follow any of the plan's policies or procedures for that covered service. While it may make sense to penalize a physician for repeated, deliberate violations that cost the plan a lot of money, it's very harsh to impose a penalty on you if you make an error once or if your violation is relatively minor or easily corrected.

This clause also makes it possible for you to violate the plan's policies and procedures without knowing it and to be penalized for that violation. The clause requires the physician to comply with all protocols and programs, including those "as otherwise established or directed by the Medical Director." But the contract doesn't require the plan to notify the physician of new protocols or programs.

The Concession

The *Insider* has learned from internal instructions to plan negotiating representatives that plans will limit their ability to require you to pay for these covered services—if you bring it up during negotiations. For instance, the national HMO whose clause we quoted above gives its negotiating representatives authority to have the penalty apply only if the provider "knowingly and repeatedly" fails to follow the plan's policies and procedures. It's willing to insert the words "knowingly and repeatedly" before the word "fails" in the first sentence of the language we've quoted above.

The HMO also allows its negotiating representatives to change the clause so that the provider would have to absorb the cost of his own services but not have to pay for the services of other providers, such as specialists he may have referred a member to without preauthorization.

If the plan representative you're negotiating with won't agree to that limitation, ask that your potential financial penalty be capped at a set dollar amount. The HMO also gives its negotiating representatives authority to agree to this compromise.

How Concession Helps

The concession makes the penalty fairer. The plan can impose the penalty only if you violated its policies and procedures repeatedly and on purpose. And the amount of the penalty is more limited, as well. It may be reasonable for a plan to impose a penalty on a physician who flagrantly disregards its policies and costs the plan substantial revenue. But you don't want to pay a penalty for an honest one-time mistake or an act that you didn't even know was a violation. It's a harsh punishment the plan shouldn't be able to impose so easily. ■

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