

# Radiology Administrator's

## Compliance & Reimbursement Insider

NOVEMBER 2002

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## Screening Centers Come Under Scrutiny

A year ago, screening centers offering full-body CT scans to self-referred patients were the "next big thing." These screening centers seemed to be a great way for entrepreneurial radiologists to earn income without being bound by Medicare's restrictions and low fee schedule.

But lately some communities within the medical establishment have been critical of screening centers, and there's increasing regulatory pressure on these centers.

We'll tell you about these developments and what they might mean to radiologists and radiology practices that operate screening centers.

### Several Organizations Express Concerns About Screening Scans

There's still plenty of positive press from patients about screening centers. Several celebrities have come forward to say that they found serious conditions in very early, treatable stages because they had whole-body scans. But the medical and regulatory establishments have been expressing concerns:

**ACR.** The American College of Radiology (ACR) is one of the established specialty societies that have raised concerns about whether full-body CT scans and other self-referred screening services that screening centers typically offer are medically appropriate and useful.

For example, an ACR press release states: "To date there is no evidence that total body CT screening is cost effective or is effective in prolonging life. In addition, the ACR is concerned that this procedure will lead to the discovery of numerous findings that will not ultimately affect the patient's health but will result in increased patient anxiety, unnecessary follow-up examinations and treatments, and wasted expense."

Although organizations like ACR have no legal or regulatory authority over screening centers, their press releases can raise public awareness of a controversy and lead—directly or indirectly—to more regulatory activity, says Washington, D.C., health care attorney Allison Weber Shuren.

**Insider Says:** You can find the statement on body scans on the ACR Web site. Go to [www.acr.org](http://www.acr.org) and click on "screening."

**FDA.** The FDA has gotten into the act, too. In April the FDA posted a notice on its Web site that says, in part: "At this time the FDA knows of no data demonstrating that whole-body CT screening is effective in detecting any particular disease early enough for the disease to be managed, treated, or cured and advantageously spare a person at least some of the detriment associated with serious illness and premature death."

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## SCREENING CENTERS (continued from p. 1)

The FDA is concerned that people are paying for an uncertain benefit, that negative findings may lead to a false sense of security, and that positive findings may lead to unnecessary tests and procedures. Plus the FDA notice points out that a whole-body CT scan exposes the patient to a higher dose of radiation than the dose associated with conventional X-rays.

Finally, the FDA notice explains that any screening center advertisement that implies that the FDA has approved, cleared, licensed, or certified the facility is misleading because the FDA hasn't given its approval to the use of CT for screening purposes in the absence of specific signs and symptoms.

**Insider Says:** You can find the FDA's notice at [www.fda.gov/cdrh/ct/](http://www.fda.gov/cdrh/ct/).

## States Crack Down

Certain states, through their licensing boards or regulatory agencies, have begun applying pressure on screening centers, perhaps in part as a response to the publicity from the ACR and the FDA, Shuren notes. For example, the Pennsylvania Department of Environmental Protection (DEP), which regulates radiation-emitting facilities in the state, has issued the following warning: Any facility that exposes a person to radiation without a physician's referral may not operate unless it has a waiver from Pennsylvania's DEP. So far, no facilities have secured a waiver, and Shuren is skeptical that the DEP will issue one. More states may start acting against screening centers, possibly using their agencies that regulate radiation in the state to apply pressure.

## More Data May Ease the Pressure

Shuren points out that the statements by the ACR and the FDA only say there's no proof that whole-body screening scans offer a specific benefit to patients who have them. These statements don't say that the scans are harmful to patients—except to the extent that a patient has unnecessary procedures or services to investigate a screening finding that ultimately doesn't lead to a diagnosis of disease. And all the agencies and organizations that have come out against screening centers say that they're awaiting further study demonstrating that screening exams can be effective tools to maintain patient well-being. Studies are currently being conducted, and eventually there may be enough acceptable proof for the conservative medical establishment so that the current pressure on screening centers will let up.

## What Should You Do if You Offer Screening Services?

Many patients today prefer to take a proactive stand regarding their health, and they're willing to pay for it, Shuren notes.

So if a patient believes that she would feel better by getting a screening scan, there's no evidence that you'll harm the patient by providing it. And if you believe in screening scans and have an entrepreneurial bent, you can still legally operate screening centers in most states. But you should take a few precautions, Shuren says:

**Keep your equipment well maintained.** Don't give the agency that regulates radiation in your state an excuse to come knocking. So far, Pennsylv-

nia seems to be the only state where the DEP is barring screening centers from operating. But many states may start using radiation emission regulators to restrict the operation of screening centers—don't give them an excuse to visit you.

#### **Be careful in your advertising.**

Don't imply that any agency or organization has "approved" your screening services, and don't indicate that screening services have a specific medical benefit. If you do, you could run afoul of your state's medical practice regulations on advertising. And states often crack down on advertising as a way of punishing medical practitioners whom they can't get at another way, she explains.

**Conform strictly to your state's licensing requirements.** Since

screening centers seem to be questionable in some minds, be careful to toe the legal and regulatory lines. It might even be a good idea to invest in a little overkill—do more than the law in your state requires you to do. Again, you want to do all you can to keep your facility off your state regulators' radar screens.

**Be cautious about whom you screen.** If a patient may have a Medicare-covered diagnosis, don't do a screening scan on that patient, Shuren says. The only way to be sure you don't get into trouble with Medicare is to *never* perform a screening service on a Medicare patient with signs and symptoms that may indicate a covered diagnosis, Shuren warns.

**Consider having screen "ordered"** by treating physician or other appropriate provider. Shuren says you may be able to meet regulatory agency concerns in many states by having an appropriately licensed provider discuss risks and benefits with a patient, secure informed consent, and actually "order" the screening service. Check with your attorney to see whether that's likely to help in your state.

**Insider Says:** For detailed information about how to establish and operate a screening center properly, see "Seven Traps to Avoid When Establishing and Operating Screening Centers," *Insider*, Nov. 2001, p. 1. ■

#### **Insider Source**

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## Know the Rules for Balance Billing Medicare Patients

Medicare rules are confusing, and the rules about "balance billing"—that is, billing a Medicare patient for the balance of a charge that Medicare doesn't pay—are more confusing than most. To balance bill properly, you must know whether the physician is participating in the Medicare program or is accepting assignment. Plus you must know whether Medicare covers the service in the first place, says Atlanta-based reimbursement consultant Jackie Miller.

There are many variables to keep track of, so it's no wonder people get confused. We'll explain why there's so much confusion. And we'll give you a quick rundown on the rules.

### **What's the Confusion?**

Part of the problem is that the term balance billing is a misnomer, Miller notes. It implies that a physician may

bill a Medicare patient for the balance of the physician's "usual and customary" charge for a covered service. But under Medicare rules, you can never do that because physicians are limited in how much they can charge a Medicare patient for covered services.

### **Balance Billing Rules**

You must bill Medicare according to the physician's Medicare status. So you must know whether the physician is a participating physician—that is, one who has agreed to accept assignment on all Medicare claims for the year—or, if he's nonparticipating, whether he's accepting assignment for this particular claim. If the physician is not participating and not accepting assignment, there's yet another way to bill. Here's a quick rundown on the rules:

**If physician is participating physician.** The patient will assign his

rights to Medicare benefits to the physician, and the physician will directly bill Medicare for the physician's usual and customary charge for the service. Assuming the patient has met his deductible, Medicare will pay the physician 80 percent of the Medicare allowed amount for the service. The "allowed" amount is the amount that Medicare considers payment in full for a given service (the allowed amount is higher for participating physicians than it is for nonparticipating physicians).

If the patient hasn't met his deductible for the year, the participating physician must bill the patient the Medicare allowed amount for the service. (If you submit a bill to Medicare and the explanation of benefits says that the patient hasn't met his deductible, you can bill the patient). Plus the participating physician must always collect the

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**BALANCE BILLING** (continued from p. 3)

copayment from the patient—the copayment will be 20 percent of the Medicare allowed amount. But a participating physician may not bill a Medicare patient for any “balance” over the amount of the patient’s copayment and deductible, Miller cautions, because Medicare considers that a violation of the assignment agreement.

**If physician isn’t participating but accepts assignment.** Some physicians choose not to participate in Medicare but may accept assignment on a case-by-case basis. When a nonparticipating physician accepts assignment, the Medicare allowed amount is 95 percent of the allowed amount that participating physicians get, Miller explains. Like participating physicians, the nonparticipating physician who accepts assignment may not bill a Medicare patient for any amount other than the patient’s copayment and deductible for Medicare covered services. So a nonparticipating physician will get less money for the same service than the participating physician because the Medicare allowed amount is less for

nonparticipating physicians. The nonparticipating physician can’t bill the patient to make up the 5 percent difference, Miller emphasizes.

**If physician doesn’t participate in Medicare or accept assignment.**

In this case, the physician may bill the patient directly but for no more than the Medicare limiting charge. The limiting charge is more than the allowed amount that participating and nonparticipating physicians may charge. Miller explains that the current Medicare limiting charge is 115 percent of the allowed amount for assigned claims submitted by nonparticipating providers or 109.25 percent of the allowed amount for participating providers.

**Insider Says:** Even a nonparticipating physician who isn’t accepting assignment for a particular claim must submit the claim to Medicare on the patient’s behalf, Miller cautions. And the physician may not charge the patient for any administrative expenses associated with submitting the claim.

**If patient receives services that Medicare doesn’t cover.** Of course,

the above discussion applies only to Medicare covered services. If Medicare normally covers a particular service but may not in this case—because of frequency limitations, for example—the physician must get the patient to sign an advance beneficiary notice (ABN), regardless of whether the physician participates in Medicare. The physician then will be able to charge the patient directly for his usual and customary charge for the service. That’s because when the patient has signed an ABN and Medicare has denied the service as not reasonable and necessary, the physician isn’t restricted to charging the allowable or the limiting charge. If the service is simply never covered by Medicare—say a screening exam that Medicare doesn’t cover—then there’s no allowable charge or limiting charge, and the physician can bill the patient directly for his usual and customary charge for the service, says Miller. ■

**Insider Source**

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**D O S & D O N ’ T S****✓ Consider Outsourcing Compliance Training**

Regular compliance training of medical practice staff is an integral part of any effective compliance plan. Some practices keep this compliance training responsibility in-house—that is, a physician, office or billing manager, compliance officer, or administrator is responsible for developing training materials and conducting staff training. But it may be smarter for you to outsource this compliance training responsibility, advises Atlanta health care consultant Jackie Miller.

Keeping training in-house may be penny-wise and pound-foolish, Miller warns. She cites three reasons why it may be smart and cost-effective to outsource compliance training:

**1) Up-to-date and accurate information.** Because compliance is a complex topic, physicians and staff with “regular” jobs often can’t stay on top of every change and nuance of applicable law and regulation, Miller notes. But a compliance consultant will have up-to-the-minute information from the best, most reliable sources, she says.

**2) Efficient use of staff time.** If a staff member is asked to take on compliance training responsibilities, some of her other duties may get short shrift, Miller remarks. Plus someone who isn’t used to conducting training sessions may not do it as efficiently or effectively as a compliance training professional would. A compliance training professional is generally better at presenting the information your staff needs to know in the most concise and prac-

tical way—and that means your staff gets trained faster and better.

**3) Compliance credibility.** Information presented by an outside consultant may carry more weight than the same information conveyed by someone in-house—say, a practice administrator, compliance officer, or other staff member, Miller remarks. So if some members of your staff aren't buying into an aspect of your compliance program or its implementation, hiring a consultant to come in and deliver the message may just do the trick. In that case, the money spent on the consultant will have been well worth the price, Miller says.

### **X Don't Count on OIG's Assurances that It Won't Prosecute Mistakes**

Don't assume that your good intentions will keep you out of trouble if you make a billing or coding error. Some physician practices mistakenly believe that as long as they didn't intend to do anything dishonest, they won't have problems with their carrier or with the OIG because of an error they made. And there's support for that belief in the OIG's *draft compliance program guidance for small physician practices*, which the OIG released in June 2000. It included a section explaining the difference between fraudulent and "erroneous" claims made to the

Medicare program. The guidance says: "Under the law, physicians are not subject to criminal or civil penalties for innocent errors, or even negligence....The OIG is very mindful of the difference between innocent errors ('erroneous claims') on the one hand, and reckless or intentional conduct, on the other."

Don't take too much comfort from the OIG's assurances, warns Philadelphia health care attorney Joan Roediger. Failure to discover an error, correct it, and return any overpayment may lead to prosecution, even if you didn't make the error intentionally. "The fact is, a pattern of innocent errors may allow the OIG to infer an intent to defraud, or at least a reckless disregard for the rules," Roediger explains. "Innocent" errors can lead the OIG to your door, and once the OIG has arrived, you must defend yourself and prove that any pattern of erroneous claims was merely an innocent mistake, she says. Even if you never face criminal charges or pay a penalty, responding to an OIG investigator is time-consuming, anxiety-causing, and expensive. ■

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## **Give Your Malpractice Insurer an Annual Checkup**

If your practice employs physicians, chances are that your practice pays for their malpractice insurance. But many practices don't think about their malpractice insurance until the premium bills come due. Then they pay the bills and don't think about their insurance again until the next year. But another "malpractice crisis" makes evaluating physicians' malpractice coverage more important than ever: Premiums are rising sharply even for the best physicians, and as some malpractice insurers are leaving the business, practices and their physicians may be left scrambling to find new coverage from a shrinking pool of insurers.

Experts differ on how to solve the problem once and for all. Although

you can't do much about rising premiums, you can take certain steps to ensure that your radiologists' malpractice insurance coverage protects them and is appropriate for your practice. We'll tell you how, and we'll give you a Model Contract Clause (see p. 6) you can add to your contracts with your employees, that can help your practice avoid being saddled with huge premium increases.

### **Review Your Malpractice Insurance Every Year**

New Jersey health care attorney Michael Schaff suggests that practices take a close look at their physicians' malpractice insurer and their coverage at least annually. Here's what you should do:

**Check insurer's financial health.** Schaff says you should research the financial health of a malpractice insurer just as you would a company whose stock you were interested in buying. Physicians have a tough time when a malpractice insurer suddenly closes its doors or decides not to renew the policy of its covered physicians. To avoid being left in the lurch, make sure your insurer is financially sound. Schaff has the following suggestions:

- If the insurer is a publicly traded company, read its SEC filings;
- Check the Web site of your state's insurance department for important information about the insurer, like the amount of its reserves

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**ANNUAL CHECKUP** (continued from p. 5)

and any complaints about the way it handles claims; and

- Call the general counsel's office or economic affairs office of your state medical society and ask if it has heard anything about your insurer. Your medical society often knows a lot about how local malpractice insurers are performing.

**Assess whether you have appropriate coverage.** Read all of your radiologists' insurance policies carefully to find out what they cover. They should cover all the procedures the radiologist performs, services she provides, and clinical decisions she makes. Also, check to make sure you're not paying for coverage of services she doesn't provide. If she has coverage she doesn't need—like coverage for high-risk procedures she doesn't perform—ask the insurer to eliminate that coverage and adjust the premiums accordingly.

**Insider Says:** If your radiologists perform high-risk procedures only occasionally, they may want to consider eliminating those high-risk procedures. Sometimes doing so can save enough in malpractice insurance premiums to make it worthwhile, Schaff says.

**Identify potential for savings.**

Many malpractice insurers offer reduced premiums for physicians with a clean malpractice history over a certain number of years. And many insurers offer discounts if your physicians take advantage of events such as risk management seminars. During your annual review you should be looking for these discounts to see if they're worthwhile in your case.

**Comparison shop.** Even if you're happy with your malpractice insurer and confident that it's financially stable, comparing the premiums the malpractice insurers in your area are

offering is still a good idea, Schaff recommends. If another insurer offers substantially lower premiums for the same coverage, you may want to investigate that insurer more thoroughly before deciding if you want to switch.

**Add clause to employee contracts.** A period of steeply rising premiums can be particularly difficult if you're paying the premiums for several physicians. That's especially true if one or more of them has a history or a practice pattern that causes his premium rates to be higher than most.

To protect practices from situations like this, Schaff usually includes a clause in the employee

contract like our Model Contract Clause. It says that the practice will pay the employee physician's malpractice insurance premiums that are within 20 percent of the average for other physicians of the same specialty (or subspecialty) in the practice. And if the employee physician's premium exceeds that 20 percent threshold, then either he may pay the excess or the practice may terminate him. ■

**Insider Source**

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**MODEL CONTRACT CLAUSE****Use Clause to Limit Malpractice Premium Hikes**

If your practice pays for its employee physicians' malpractice insurance, you can protect it from steeply rising premiums by adding the following Model Contract Clause to your employment contracts.

Drafted with the help of New Jersey health care attorney Michael Schaff, our Model Contract Clause says that the practice will pay the employee physician's malpractice

insurance premiums that are within 20 percent of the average for other physicians of the same specialty (or subspecialty) in the practice. And if the employee physician's premium exceeds that 20 percent threshold, then either he may pay the excess or the practice may terminate him. Show this clause to your attorney before adapting it for use in your employment contracts.

**MALPRACTICE INSURANCE**

- a. **Malpractice insurance for physician.** Practice will provide Physician with medical malpractice insurance coverage (claims made OR occurrence) in the amounts of \$1 million per occurrence/\$3 million aggregate annually, provided, however, that the premium for Physician's coverage does not exceed the average premium for all other physicians practicing Physician's specialty in the Practice plus 20 percent (Excess Practice Average).
- b. **Physician may opt to pay excess.** In the event that Physician's premium exceeds the Excess Practice Average, Physician has the option, which must be exercised within 10 days of receipt of the insurance premium invoice, of paying that portion of the premium that exceeds the Excess Practice Average.
- c. **Practice's right to terminate employment.** If Physician does not exercise his option to pay the amount of the premium that exceeds the Excess Practice Average, or should Physician not pay such amount to the practice within 10 days of his exercising the option, Practice may, at its option, terminate Physician's employment for cause.

## How to Create a Business Associate Contract

The HIPAA privacy regulations require that you have a contract with each of your business associates. That contract must include certain assurances from the business associate about how it will safeguard the protected health information (PHI) that you share with it. Creating a business associate contract is a big task. Where should you start, and what must you include?

With the help of health care attorney Jackie Selby, we'll explain what language you must include in each of your business associate contracts. If you already have a written contract with a business associate, there's no need to terminate it. Instead, you can create a business associate contract amendment that includes the required language and attach it to the original contract. And we'll give you Model Contract Language, drafted by Selby, that you can adapt and use to create your business associate contracts or amendments to existing contracts. Be sure to show the language to your attorney before using it.

### When Must Business Associate Contracts Be in Place?

The original date for compliance with the business associate requirements was April 14, 2003. But in August 2002, the HIPAA privacy regulations were changed. The changes allow a health care organization to operate under its existing contracts with its business associates for up to one year beyond the April 14, 2003, compliance date. This extra time is available to an organization for any contract (or other written arrangement) with a business associate that's in effect before Oct. 15, 2002, provided that the contract or arrangement isn't renewed or modified from Oct. 15, 2002, until April 14, 2003.

The bottom line—you won't need to amend your contracts with your business associates to comply with the HIPAA privacy regulations' business associate requirements until the earlier of: 1) the date the contract is renewed or modified after April 14, 2003; or 2) April 14, 2004.

### How Business Associate Language Will Protect You

You get important protections by having all the required language in your contracts with your business associates by the compliance date. Not having the required language in a contract is, by itself, a HIPAA violation, explains Selby. So if one of your business associates wrongfully discloses a patient's PHI to an unauthorized person and you can't show that you have a contract with the required language in it, you'll be in violation of HIPAA's privacy regulations. And you'll be in even more trouble because the Department of Health and Human Services (HHS) will go after *you*, not your business associate, for the wrongful disclosure, Selby says.

But if you have all the required business associate language in place and you took reasonable steps to respond to a business associate's HIPAA privacy violation, you're probably off the hook for the violation.

Having all the required business associate language in the contract also could protect you if you're sued for the privacy and security violations of your business associates. For example, if a patient sues you because your business associate violated her privacy, the contract language could help your defense by showing that you complied with HIPAA.

Although HIPAA compliance isn't required until at least 2003, there are several reasons to include the business associate language in your contracts now, rather than wait, advises Selby. Putting this language in place sooner rather than later shows that you're proactive on HIPAA compliance. It may also protect you from an inappropriate use or disclosure of PHI that occurs between now and the compliance date. And starting now helps you make sure you'll meet the HIPAA compliance dates, she adds.

### 11 Requirements for Business Associate Contracts

Here's a rundown on 11 requirements that the HIPAA privacy regulations set for business associate contracts, and Model Contract Language you can use to meet each requirement. Note that the Model Contract Language refers to the business associate as "Business Associate" and to the provider as "XYZ Provider." You'll have to adapt this language for each contract. You'll also have to define PHI elsewhere in the contract or amendment.

**1) Set permitted uses and disclosures of PHI.** Your business associate contract must address the permitted uses and disclosures of PHI that the business associate may make, says Selby. You should tailor the permitted uses and disclosures to the particular service or function that the business associate will provide to you, she adds. For instance, a dictation company uses and discloses PHI differently from a document shredding company. So your contract language should state the purposes for which uses and disclosures of PHI may be made and describe the types of persons to

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**BUSINESS ASSOCIATE CONTRACT**

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whom the business associate may make further disclosures.

You can set these parameters broadly or narrowly, depending on the business associate. But it's important to be specific about what they are so that the business associate can be held responsible for a violation, warns Selby.

**Model Contract Language**

Business Associate shall be permitted to use and disclose PHI provided by XYZ Provider as follows:

- (i) To the following persons: *[insert specific persons, parties, e.g., employees, agents, and contractors]*; and
- (ii) For the following stated purposes: *[insert general description of purposes, e.g., as required for Business Associate to provide the dictation services described in Section X of this Contract]*.

**2) Limit uses and disclosures to those in contract.** The regulations require your business associate contract to bar the business associate from using or disclosing PHI except as permitted or required by the contract. Also, the contract must bar the business associate from using or disclosing PHI except as required by law, says Selby.

**Model Contract Language**

Business Associate shall not use or disclose PHI provided by XYZ Provider except as provided in this Contract or as required by law.

**3) Require adoption of safeguards.** The regulations require that you adopt appropriate safeguards to protect the privacy of your PHI. You must require the business associate to do the same. For example, if your business associate is a dictation company, you may insist that it use some form of encryption whenever sending PHI electronically, explains Selby.

Although the regulations don't mandate it, you may want to require

the business associate to give you a written description of the safeguards that it has in place to protect PHI and attach this description to the contract, Selby suggests. Plus you may want the option to approve these safeguards and any changes made to them during the contract, she adds.

**Model Contract Language**

Business Associate shall implement and maintain appropriate safeguards to prevent the use or disclosure of PHI, other than as provided in this Contract. *[Optional: A description of such safeguards shall be attached to this Contract as an exhibit hereto and shall be considered a part hereof. XYZ Provider's approval of such safeguards and any of Business Associate's measures to update or add safeguards during the Contract shall be required.]*

**4) Require reporting of violations.** The regulations say that you must require your business associate to promptly report to you any uses or disclosures of PHI that violate the business associate contract. Having this requirement in your business associate contracts is important because the regulations also require you to take immediate steps to mitigate—that is, lessen—any harm that's caused by such violations, Selby points out.

Although not required by HIPAA, you may want to require your business associate to impose sanctions on its employees, subcontractors, and agents for such violations, suggests

Selby. You may also want the right to require the business associate to take additional steps or adopt additional safeguards to prevent such violations from recurring, she says.

**Model Contract Language**

Business Associate shall report to XYZ Provider within *[insert #, e.g., 2]* days of discovery, any use or disclosure of PHI made in violation of this Contract or any law. *[Optional: Business Associate shall implement and maintain sanctions for any employee, subcontractor, or agent who violates the requirements in this Contract or the HIPAA privacy regulations. Business Associate shall, as requested by XYZ Provider, take steps to mitigate any harmful effect of any such violation of this Contract.]*

**5) Require same restrictions for business associate's agents and subcontractors.** Your business associate may use agents and subcontractors for all or part of the services it provides to you, warns Selby. Make sure you're protected from the acts of these other parties by requiring the business associate to impose the same restrictions on them that you impose on it, she advises. It's also a good idea (but not required by HIPAA) to give yourself the right to review and approve the business associate's agreements with those agents and subcontractors, she adds.

**Model Contract Language**

Business Associate shall ensure that any agents and subcontractors

**► HHS Offers Sample Contract Language**

The August 2002 changes to the HIPAA privacy regulations include an appendix to the preamble with sample contract provisions provided by HHS. These provisions can be incorporated into your business associate contracts. In the preamble to the changes, HHS explains that these sample provisions are to be used as a guide to help organizations meet some of the business associate requirements. But HHS cautions that you don't have to use the sample provisions to comply with the business associate requirements, nor do the provisions alone create a binding contract. That is, you'll also need to add other provisions to each of your contracts to accurately reflect the relationship you have with the particular business associate and any applicable state law requirements.

tors to whom it provides PHI received from XYZ Provider (or created or received by Business Associate on behalf of XYZ Provider) agree in writing to the same restrictions, terms, and conditions relating to PHI that apply to Business Associate in this Contract. [Optional: XYZ Provider shall have the option to review and approve all such written agreements between Business Associate and its agents and subcontractors prior to their effectiveness.]

#### **6) Provide patients with access to PHI held by business associate.**

The regulations require that you provide your patients with a right of access to inspect and copy their own PHI. Since some of their PHI may be held by your business associates, you'll need to ensure that every business associate will provide access, Selby explains.

You may want the business associate to send the PHI to you, rather than directly to your patients. That way, you can be sure that patients get their PHI. After all, you're ultimately responsible if patients don't get requested PHI. And because the privacy regulations require that you respond to individual requests for access to PHI within 30 days of getting the request, you'll want to require your business associate to respond more quickly—say, in 10 days—so you'll have enough time to forward the PHI to patients. To avoid confusion, you may also want to set a specific format in which the PHI should be sent—such as computer disk, Selby adds.

#### **Model Contract Language**

Business Associate shall make an individual's PHI available to XYZ Provider within [insert #, e.g., 10] days of an individual's request for such information as notified by XYZ Provider. [Optional: PHI shall be provided as follows: [insert format, e.g., computer disk.]

**7) Require business associate to make amendments to PHI.** Patients also have the right to request that their

PHI be amended or corrected. If you grant a patient's request, the regulations require you to amend the patient's PHI, inform the patient of the change, and notify others that may need to know of the change, including your business associates who have access to the patient's PHI, explains Selby. So you'll need to include language in your business associate contracts requiring the business associate to make such amendments or corrections, she suggests. You should also give a time frame in which the business associate must comply with this requirement, she adds.

#### **Model Contract Language**

Business Associate shall make PHI available for amendment and correction and shall incorporate any amendments or corrections to PHI within [insert #, e.g., 10] days of notification by XYZ Provider.

**8) Require PHI to be available for an accounting.** Patients also have the right to request and get an accounting—that is, a detailed list—of all disclosures of their PHI that your organization made in the six years before the date of the request. Although the accounting needn't include any disclosures that were made to carry out treatment, payment, and health care operations, it must list other disclosures made, including those made to or by your business associates, Selby points out. And the accounting must include details of the disclosures, including the date made, the name of the person or organization receiving the PHI, the recipient's address, if known, a short description of the PHI disclosed, and the reason for the disclosure.

You'll need to require your business associate to keep track of this information and give it to you when you request it. And since you need to comply with an accounting request within 60 days, you'll want to require

your business associate to respond to your request quickly—say within 10 days, Selby advises.

#### **Model Contract Language**

Business Associate shall maintain an ongoing log of the details relating to any disclosures of PHI it makes (including, but not limited to, the date made, the name of the person or organization receiving the PHI, the recipient's address, if known, a description of the PHI disclosed, and the reason for the disclosure). Business Associate shall, within [insert #, e.g., 10] days of XYZ Provider's request, make such log available to XYZ Provider, as needed for XYZ Provider to provide a proper accounting of disclosures to its patients.

**9) Require business associate to make its practices, books, and records available to HHS.** The regulations require that you cooperate with HHS and provide access to information needed for HHS to determine your organization's compliance with the HIPAA requirements. To meet this requirement, you want your business associate to agree to make information it has relating to your patients' PHI available to HHS, explains Selby. You may also want to require your business associate to give you a copy of any information that it provides to HHS in relation to your organization, she suggests.

#### **Model Contract Language**

Business Associate shall make its internal practices, books, and records relating to the use and disclosure of PHI received from XYZ Provider (or created or received by Business Associate on behalf of XYZ Provider) available to the Secretary of the Department of Health and Human Services (HHS) or its designee for purposes of determining XYZ Provider's compliance with HIPAA and with the Privacy Regulations issued pursuant thereto. [Optional: Business Associate shall provide XYZ Provider with copies of any information it has made available to HHS under this section of this Contract.]

(continued on p. 10)

**BUSINESS ASSOCIATE CONTRACT**

(continued from p. 9)

**10) Include option to terminate contract for violations.** Make sure you have the right to terminate the contract if your business associate violates one of its "material," or significant, terms, Selby says. You don't want to be stuck with a business associate you can't trust. For example, if you discover that your business associate adopted appropriate safeguards to protect your PHI but then failed to follow some of those safeguards during the term of the contract, you'll want out of the contract, she points out.

**Model Contract Language**

XYZ Provider may immediately terminate this Contract if XYZ Provider determines that Business Associate has violated a material term of this Contract.

**11) Require return or destruction of PHI when contract ends.** If your contract with the business associate ends for any reason, you'll need to ensure that all PHI still in

the business associate's possession is either returned to you or destroyed, advises Selby. This requirement is essential, particularly if you're terminating the contract because of a contract violation by the business associate, she says. You may also want to require the business associate to certify in writing that all such PHI has been returned or destroyed.

But the regulations acknowledge that, for some reason, the business associate may not be able to return or destroy all PHI. So you must require it to continue to safeguard this PHI after the contract ends and limit the PHI's use for as long as the business associate retains it.

**Model Contract Language**

Within [insert #, e.g., 2] days of expiration or earlier termination of this Contract, Business Associate shall return or destroy all PHI received from XYZ Provider (or created or received by Business Associate on behalf of XYZ Provider)

that Business Associate still maintains in any form and retain no copies of such PHI. [Optional: Business Associate shall provide a written certification that all such PHI has been returned or destroyed.] If such return or destruction is infeasible, Business Associate shall use such PHI only for purposes that make such return or destruction infeasible and the provisions of this Contract shall survive with respect to such PHI. ■

**Insider Source**

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**SHOW YOUR LAWYER**

For more information about the cases and/or laws referred to in this issue, show your lawyer the legal citations listed below.

- Draft compliance program guidance for small physician practices: Draft OIG Compliance Program Guidance for Individual and Small Physician Practices, Fed. Reg. 6/12/2000.