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For Hospitals, Laboratories and Physician Practices

Changes To HIPAA Privacy Rule Ease Use, Exchange Of Protected Health Information

Last March, the U.S. Department of Health & Human Services proposed a string of modifications to the medical privacy rule, promulgated in late 2000 in accord with HIPAA (the 1996 Health Insurance Portability & Accountability Act). HHS was responding to business and health industry groups which urged the Bush Administration to make the rule "more workable" and not jeopardize the quality of care.

Now, the Department has issued an amended final rule in the Aug. 14 *Federal Register* that incorporates most of the changes proposed earlier this year. HHS says the changes will reduce administrative burdens and make compliance easier for covered entities—healthcare providers, health plans and health clearinghouses.

Provider groups generally agree, saying the changes make the rule more fair and streamlined. "It strikes the right balance," says Richard Davidson, president of the American Hospital Association.

Some privacy advocates disagree. Sen. Edward Kennedy (D-MA) calls the changes a "serious setback," charging that "insurance companies and HMOs are given broad access to highly *Continued on p. 10*

Inside this issue

Medicare Prepares Contractors For Launch Of Uniform Lab Policies

The Centers for Medicare & Medicaid Services has sent instructions to local Medicare contractors on implementation of new national coverage determinations for 23 frequently ordered clinical diagnostic laboratory tests that account for an estimated 60% of Part B lab testing volume.

The national coverage determinations (NCDs) will replace varying local medical review policies (LMRPs) that carriers and fiscal intermediaries have established for these lab tests (*GCR, Jan. '02, p. 1*). The NCDs were crafted by a negotiated rulemaking committee convened at the direction of Congress; after a period of public comment, they were published in final form in the Nov. 23, 2001 *Federal Register*.

The new uniform lab test policies apply to clinical labs regardless of setting, whether in a physician office, a hospital or an independent facility. Their effective date is Nov. 25, 2002. But because requisite software changes won't be available to contractors by then, enforcement has been delayed until Jan. 1, 2003, CMS officials confirmed recently (*GCR, Aug. '02, p. 10*).

Each NCD lists the HCPCS/CPT code(s) covered, a narrative description of the testing, clinical indications for its use, limitations on its coverage and related ICD-9-CM diagnosis codes (for blood counts, only *non*-covered diagnosis codes are specified).

The diagnosis codes are grouped in three listings: *Continued on p. 4*

Use Of Standardized ABNs Mandatory As of Oct. 1
Final Instructions Revise "Timely Delivery" Requirement

Effective Oct. 1, healthcare providers and suppliers must begin using the new standardized formats for Part B Advance Beneficiary Notices (ABNs), according to the Centers for Medicare & Medicaid Services. For the past year, their use has been optional.

ABNs are given to Medicare beneficiaries when providers or suppliers know Medicare will not pay for the Part B item or service they are receiving, or when there is genuine doubt that Medicare will pay. The ABN alerts beneficiaries that they may be responsible for payment.

Two ABNs will be available: one for general use (CMS-R-131-G), the other specific to laboratory services (CMS-R-131-L). Labs may use either one. Both forms are online at *http://cms.hhs.gov/medicare/bni*.

"Timely Delivery" Standard

Final instructions to contractors on ABN implementation (Transmittal AB-02-114, issued July 31) offer some minor clarifications of an earlier draft, and most of the changes are beneficial to providers, says attorney Thomas Bartrum, with Baker, Donelson, Bearman & Caldwell (Nashville, TN).

The main substantive change that could be detrimental has to do with the "timely delivery" requirement. In the draft instructions released earlier this year, CMS said an ABN had to be delivered well enough in advance to allow the patient to make an informed decision. The final instructions state that, "as a general rule, ABN delivery should take place before a procedure is initiated and before physical preparation of the patient (*e.g.*, disrobing, placement in or attachment of diagnostic or treatment equipment) begins."

CMS explains that this does not result in a blanket prohibition on giving ABNs after the patient has entered an exam room or a draw station. The agency further acknowledges that situations may arise during an encounter when a physician or supplier sees a need for a previously unforeseen service that may require an ABN.

Even so, Bartrum believes the new language creates a higher standard for providers to meet.

"This adds more protection for the consumer, but I think it will make it a little more difficult for providers. I'm not sure the added difficulty is worth the benefit that [CMS] perceives. A carrier could take the position that whenever you've asked a patient to disrobe, the patient has been prepared for a possible procedure. I don't think it is CMS's intent that the ABN be presented before a patient is brought back to the exam room, but that's how this could be interpreted by carriers."

Resources

- Thomas Bartrum: 615-726-5720
- ABN final instructions, Transmittal AB-02-114, online at *www.hcfa.gov/pubforms/transmit/memos*

Clinical Laboratories Must Report Bioterror Agents
Facilities Face Sept. 10 Deadline For Notifying CDC

Clinical laboratories must report to the government by Sept. 10 whether they do or do not possess any "select agents" that could be used in a bioterrorist attack, says the Centers for Disease Control & Prevention.

The notification requirement was established by the Public Health Security & Bioterrorism Preparedness and Response Act of 2002, which was signed into law June 12.

Labs that attest in the negative will be exempt from additional registration and security requirements, according to an Aug. 6 *Federal Register* notice. To obtain the exemption, labs must complete a government form, which may be downloaded from the College of American Pathologists' Website, *www.cap.org/html/advocacy/fromgov/bioform.doc*.

Labs' response to the CDC notification request will reassure the government that most clinical laboratories do not maintain "select agents," says Jared Schwartz, MD, CAP secretary-treasurer and chair of the College's ad hoc committee on preparedness for national emergency.

CDC is in the process of mailing notification forms and guidance documentation to 190,000 laboratories and other facilities. The guidance document provides a step-by-step approach to complying with the notification requirement. It requires assignment of a "responsible facility official," which the guidance describes as a safety officer or a senior management official authorized to complete the form.

This official should not be someone "who actually possesses, uses or transfers such agents and toxins," according to the guidance. Penalties for making false statements on the notification form include a fine of up to $500,000, imprisonment for up to five years, or both, for each violation.

Resources

- CDC guidance, online at *www.cdc.gov/od/ohs/lrsat.htm*
- CAP: 800-393-9994, ext. 7118

Group Purchasing Organizations Agree To Operating Reforms
Novation, Premier Revise Physician-Preference Requirements

Two of the largest U.S. group purchasing organizations agreed this month to new operating principles and commitments designed to ensure that medical suppliers have equal access to member hospitals.

Novation, the nation's largest GPO, and Premier, the second largest, agreed to the reforms under pressure from the Senate Judiciary antitrust subcommittee. The agreements supplement an industry-wide code of conduct released July 30 by the Health Industry Group Purchasing Association. It was drafted at the request of subcommittee chair Sen. Herb Kohl (D-WI) and Sen. Mike DeWine (R-OH), who led a year-long investigation into how medical supplies are purchased.

> ***"Our new operating principles preserve the many benefits of group purchasing to hospitals while ensuring an open, fair marketplace for vendors"***
> ***—Mark McKenna***
> ***President, Novation***

Physician-Preference Items

Premier (San Diego, CA) has agreed to loosen its requirements for physician-preference items, which have been among the most problematic contracts for GPOs. All future contracts involving such items—implantables, pulse oximetry products and specialty urological products, for example—will offer choices through multiple sources, with no bundling of unrelated items and no commitment levels.

Premier will cap administrative fees at 3%, limit contract terms to three years (to the maximum extent possible) and not put its own private label on any hospital products.

The commitments, says company chairman and CEO Richard Norling, "are our good faith, prompt response to matters the [antitrust] subcommittee thought important."

For Novation (Irving, TX), its new operating principles focus almost entirely on physician-preference items. It will cap administrative fees for clinical-preference items at 3%, but reserves the right to award an exclusive contract to one manufacturer if there is no viable alternative.

Novation also agreed not to bundle clinical-preference items with commodities or with other unrelated clinical-preference items and not to require a certain commitment level in order to be a member of the GPO or to gain a base discount level.

"Our new operating principles preserve the many benefits of group purchasing to hospitals while ensuring an open, fair marketplace for vendors," says company president Mark McKenna.

While the agreements don't address every concern of subcommittee members, Kohl and DeWine in a joint statement praised both GPOs for recognizing the need for reform. Even so, additional work needs to be done, they said, indicating that the subcommittee will monitor compliance to ensure competition in the medical device marketplace.

Resources

- Senate Judiciary antitrust subcommittee: 202-224-5653
- Richard Norling: 704-733-5414
- Mark McKenna: 972-581-5116

OIG Approves Limited Discount Proposed by Dialysis Supplies Seller

A dialysis supplies seller could offer a uniform discount, based on aggregate annual purchases of equipment and supplies sold to a customer, without incurring administrative sanctions, the HHS Office of Inspector General concluded in an advisory opinion released Aug. 7.

But a second proposed discount, based on total annual purchases if a purchaser buys a minimum quantity of one or more certain items, could be more problematic, the OIG said.

While both of the above proposals are designed to encourage customers to purchase goods and could potentially violate the anti-kickback statute, the OIG determined that the first proposed discount had little risk of program abuse because the discount was applied uniformly, meaning it would impact all reimbursements similarly.

In addition, the OIG said, the requestor's willingness to comply with the discount safe harbor's standards for sellers reduced the risk of fraud and abuse.

The second proposed discount raised a greater risk of fraud and abuse because it resembles a bundled discount, according to the OIG. Such arrangements "are problematic because they may potentially shift costs among reimbursement systems, distort the true cost of items, lead to overutilization and make it difficult for federal healthcare programs to determine proper payment levels." In this case, the potential for administrative sanctions could not be ruled out.

The advisory opinion is available at *http://oig.hhs.gov/fraud/docs/advisoryopinions/2002/ao0210.pdf*.

Uniform Labs, *from page 1*

❖ "Covered by Medicare": Includes codes where there is a presumption of medical necessity. The claim, however, may be subject to review to determine whether the test was, in fact, reasonable and necessary. CMS has contracted with Computer Sciences Corporation to develop edit tables for this purpose. But contractors may institute local medical review edits to supplement or refine the ICD-9-CM codes in this listing, subject to certain restrictions, says CMS.

❖ "ICD-9-CM codes denied": Includes codes never covered by Medicare. If such a code is given as the reason for the test, a lab may bill the beneficiary for the test without billing Medicare first. Typically, this occurs when the service is not covered because it is performed for screening purposes and is not covered by an exception.

❖ "ICD-9-CM codes that do not support medical necessity": Includes diagnoses that generally are not covered for the test, but for which there are limited exceptions. Additional documentation could support medical necessity in certain circumstances, notes CMS, adding that the ordering physician or the lab should obtain an Advance Beneficiary Notice when billing for tests whose diagnoses are on this listing. CMS says it is working to develop a mechanism to recognize that additional information has been sent to supplement the claim. Contractors with a mechanism already in place may continue to use it. Otherwise, labs should submit claims in hard copy, with the additional documentation attached. Contractors are to re-open any claims brought to their attention where documentation was sent to support a lab's electronic claim but was not associated with the claim when it was processed.

Lab Tests Payable Under New Uniform National Policies

	HCPCS Code
Culture, bacterial, urine	87086, 87088, 87184, 87186
HIV prognosis, including monitoring	87536, 87539
HIV testing, diagnosis	86689, 86701, 86702, 86703, 87390, 87391, 87534, 87535, 87537, 87538
Blood counts	85007, 85008, 85013, 85014, 85018, 85021, 85022, 85023, 85024, 85025, 85027, 85031, 85048, 85590, 85595
Partial thromboplastin time	85730
Prothrombin time	85610
Serum iron studies	82728, 83540, 83550, 84466
Collagen crosslinks, any method	82523
Blood glucose testing	82947, 82948, 82962
Glycated hemoglobin/glycated protein	82985, 83036
Thyroid testing	84436, 84439, 84443, 84479
Lipids	80061, 82465, 83715, 83716, 83718, 83721, 84478
Digoxin therapeutic drug assay	80162
Alpha-fetoprotein	82105
Carcinoembryonic antigen (CEA)	82378
Human chorionic gonadotropin (hCG)	84702
Tumor antigen by immunoassay, CA 125	86304
Tumor antigen by immunoassay, CA 15-3 (27.29)	86300
Tumor antigen by immunoassay, CA 19-9	86301
Prostate specific antigen (PSA)	84153
Gamma glutamyl transferase (GGT)	82977
Hepatitis panel/acute hepatitis panel	80074
Fecal occult blood	82270

Source: CMS Transmittal AB-02-110, online at *www.hcfa.gov/pubforms/transmit/AB02110.pdf*

Local Policies May Not Conflict

Contractors may not develop or maintain LMRPs that conflict with the new lab test NCDs, according to CMS, but they may use LMRPs to supplement the NCDs (such as a policy on appropriate frequency in cases where the NCD is silent).

Moreover, LMRPs may be developed to supplement the NCD code lists where the narrative of the NCD indicates that only certain subgroups of a broad code would be covered. For example, the NCD for prothrombin time indicates that a PT test may be used to assess patients taking warfarin. The related ICD-9-CM code is V58.61, but it may not be used as a principal diagnosis.

"It would be acceptable," CMS advises contractors, "to develop an LMRP that explains that you require the reporting of V58.61 in addition to one of the cardiac diagnoses in the covered list for this policy if you believe the narrative policy does not support use of that code alone."

COMPLIANCE PERSPECTIVES

The Enron Era: Lessons For Healthcare Compliance Programs

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Enron and the succession of business misconduct cases involving Worldcom, Adelphia, Rite Aid and others have made business misconduct an everyday topic of discussion. But there is a dangerous risk that those in the healthcare field may dismiss these cases as not applying to them. After all, most providers are not large publicly traded corporations and do not deal in the exotic virtual trading world of Enron. Those in the healthcare field may believe they already know what their risks are and who to watch out for.

The important lessons of Enron and its progeny are not, however, about the single issue of earnings management. They strike much deeper and broader, and raise issues for all organizations that intend to give life to a commitment to obey the law and do the right thing.

The following are some of the lessons that emerge from these recent corporate debacles and questions that you should ask to assess your risk. This review is organized around the U.S. Sentencing Guidelines (USSG) template to address the practical implications for compliance programs. (The HHS Office of Inspector General used the USSG template in developing its compliance guidance to healthcare sectors.)

USSG Item 1: Standards & Procedures

❖ Is your code of conduct binding—*i.e.,* is it the law of your company or just high-sounding words?

❖ Do your professional advisors—lawyers and accountants—have to follow your code in advising what conduct is acceptable for your company? Or can they give advice on how to scrape by with the minimum, even though your code talks about following "the highest ethical standards"?

❖ Has your risk assessment matched the real risks in your business? Are you listening to the warning signals, such as those from the government and the plaintiffs' bar? Or are you living in the past?

❖ Does your program have strong procedures designed to check the misuse of power anywhere in the company? For example, if you waived a conflict of interest, would you have real "Chinese walls" separating those with the conflict from any role in company decision-making?

Enron had a code of conduct, but apparently the ethical standards were not applied in judging potential business transactions. Sherron Watkins, an Enron vice president who tried to warn the CEO about the risks, alleged the Enron culture was "arrogant" and "intimidating." The troublesome partnerships, which saw the company's chief financial officer on both sides of transactions, were supposed to be monitored carefully, but allegedly were not. There do not appear to be any signs of an organized approach to compliance related to earnings management and accounting fraud.

USSG Item 2: Compliance Infrastructure

❖ Does your compliance officer have the "clout" to be able to resist a high-powered CFO or company president intent on meeting objectives regardless of the consequences? (See *Tests of Strength in Compliance Programs*, 12 ETHIKOS* 7, Sept./Oct. 1998).

❖ Does your board of directors or trustees include an audit committee composed exclusively of outside directors? Does the compliance program report to that independent committee?

❖ Is your audit committee prepared for the compliance task? Are the members truly independent, without other ties to management?

❖ Is the audit committee empowered? Does it have access to independent resources, such as separate outside counsel? Do members have the necessary background, training and tools to monitor compliance?

❖ If you have outside auditors, do they report to the audit committee and do they have sufficient independence?

*Bimonthly publication that examines ethical and compliance issues in business. Published by Singer Publications, *http://singerpubs.com/ethikos*.

❖ Is the compliance officer required to report on a direct and unfiltered basis to the audit committee, including meetings in executive session? Must that officer report promptly any allegation regarding a senior officer and do so before such matters are acted on (including any decision not to act)?

❖ Is the compliance officer formally elected by the board, as an executive officer, with his/her removal requiring board approval? Especially for non-publicly traded companies, has an employment contract for the compliance officer been considered? (See Murphy, *Enhancing the Compliance Officer's Authority: Preparing An Employment Contract*, 11 ETHIKOS 5, May/June 1998).

❖ Do any cuts in the budget of the compliance program or transfers of key personnel require approval of the audit committee?

❖ Is there a compliance presence, such as a compliance liaison, in every business unit (such as the finance department) with significant compliance risk?

Enron's audit committee apparently was not attuned to compliance program needs and apparently depended on information from the very managers, lawyers and accountants involved in the partnership process. The partnerships were run by very high-powered executives and managers in Enron, who tried to get at least one person who resisted them fired. The audit committee apparently was not made aware when managers or lawyers raised questions about the senior managers' involvement in the partnerships.

USSG Item 3: Delegating Responsibility, Assessing Leaders

❖ Were the people responsible for the Enron conflicts of interest the types of people who would be promoted in your company? Would a manager who suggested an arrangement to enrich himself in dealings with the company be permitted to have management responsibilities?

❖ Does the company's assessment and promotion system screen out those with a possible propensity to break the company's ethical standards?

❖ What signals are the company's rewards systems sending? Are earnings results all that matter for compensation, recognition and promotions? Are cost savings more important than patient and employee safety?

Enron appears to have been focused on growing earnings and increasing the share price, and providing extravagant rewards to those who achieved this objective with little attention to the means used.

USSG Item 4: Communicating Effectively

❖ Is compliance and ethics training more than boring lectures and weak, text-based programs that do not connect emotionally with employees? Is it powerful enough to have an impact in a high-intensity culture?

❖ Are you verifying that employees have actually taken the training? Does the training reach deep into the company?

❖ Do all employees understand the system for raising questions and reporting concerns and why they should use it? Do they know that retaliation is prohibited?

❖ Do all employees understand that conflicts of interest are prohibited, why conflicts are wrong and what the dangers are?

❖ Has the program addressed the training and background needs of the board and audit committee? Are they trained in the high-risk areas?

❖ If your company is publicly traded, do the board members know what *Caremark* requires of them and what makes a compliance program effective? Do they understand the personal risks if they fail to act on allegations of misconduct?

❖ Is the audit committee supplied with the tools and resources it needs to manage an effective compliance program?

❖ Do you reach all at-risk employees on the types of subjects that led to trouble for Enron, Arthur Andersen, Adelphia and the other high-profile violators:

(1) Conflicts of interest: Too often overlooked are the serious legal and reputation risks, especially in matters involving executives.

(2) Cover-up, responding to problems, investigations, destroying evidence: Be aware that legal restrictions on document destruction start even before the subpoena arrives.

(3) For publicly traded companies, earnings management and securities fraud: This can involve surprisingly large numbers of people.

(4) Also for publicly traded companies, insider trading ("pump and dump"), such as selling when allegations of serious misconduct emerge.

(5) Code of conduct/whistleblower systems: Does everyone get the message? Do they know that retaliation is a "firing offense," even at the highest levels of the company?

From Sherron Watkins' description of the Enron culture, it does not appear that a compliance and ethics message reached employees and especially not the senior managers. The board and the compliance program do not appear to have addressed the types of risks that ultimately destroyed the company: conflicts of interest, earnings management and securities law issues, failure to escalate compliance concerns and how to react to government investigations.

USSG Item 5: Steps To Prevent Violations

❖ Does your internal audit organization help keep outside auditors on their toes? Have you avoided combining internal and external audit functions?

❖ Are your outside auditors sufficiently independent, or do consulting and other contracts compromise that independence? Should you rotate the outside auditors? Should the audit committee have access to outside experts to help in assessing such questions?

❖ Have you assigned the law department an official monitoring role to assure that shareholders' interests (or for non-profit trusts, those to whom the trust owes its duties), and not those of management, are protected, and to assure that the company's activities conform to its code of conduct, not just legal minimums?
❖ Where there is high risk (for example, the Enron partnerships with senior executives on both sides of the negotiating table), do you have systems to assure especially tight monitoring? Is the audit committee kept close to the facts?
❖ Are you using surveys and focus groups to surface troublesome trends and signals about the culture?
❖ Do you use annual questionnaires requiring managers to report on all conflicts?
❖ Is there a strong alternative reporting system, such as a well-publicized helpline, to protect employee anonymity and make it easy for employees to raise questions?
❖ Do you avoid giving employees impractical advice on reporting misconduct, like telling them to call the CEO to report misconduct?
❖ Are detailed reports on the helpline and investigations carefully monitored by the audit committee on an unfiltered basis?

Enron outsourced its internal audit function to Arthur Andersen, which also engaged in a lucrative consulting practice with the company. The legal department and outside counsel appear to have ignored the company's own ethical standards regarding dealings with the partnerships. There also does not appear to have been an anonymous 800 reporting line; instead, employees were told to call the CEO or write a letter. There also does not appear to have been a reporting system that would escalate serious issues to the audit committee.

USSG Item 6: Discipline

❖ Is discipline for anyone threatening retaliation severe, especially if it's a high-level manager? If a manager demanded an employee be fired for trying to do the right thing or challenging misconduct, would that type of threat bring swift disciplinary action against the manager?
❖ Would your company discipline a senior manager, who was responsible for results in an area rife with misconduct, for failing to detect the misconduct even though the manager claimed not to know what had been going on?

No disciplinary steps appear to have been taken at Enron against anyone for threatening another employee for resisting misconduct. This was true both for retaliation attempts against the lawyer who took a tough negotiation stand in dealing with the partnerships and against Sherron Watkins.

USSG Item 7: Responding Effectively

❖ Do you have standards for conducting investigations that would prohibit someone from conducting an investigation when he/she has already been involved in the matter being investigated?
❖ Would those standards and procedures prohibit telling investigators not to do things that are necessary in the investigators' professional judgment to conduct an investigation? The HCCA Code of Ethics for Health Care Compliance Professionals, Rule 3.1 and Commentary, expressly prohibits just such limits on the scope of an investigation.
❖ Do you have systems in place to assure that records are retained from the moment you learn of an investigation? Would your system freeze all records disposal, including electronic records? Would you seize records promptly so they cannot be destroyed?

The general counsel of Enron retained the same firm to investigate the partnerships that had been involved in advising on them. He allegedly instructed this firm not to "second guess" the very accounting that was at issue and not to examine all the transactions. Upon word of the Securities & Exchange Commission investigations, employees in Andersen and Enron allegedly shredded documents. At Andersen, an e-mail reminder of the firm's existing records retention and disposal policy, sent by a company lawyer, was used as an explanation for the records disposal activities in the Houston office.

Third-Parties

❖ Do you require outside professional firms you retain, *e.g.*, accounting and law firms, to have compliance programs?
❖ Have you trained your professional service providers on your code of conduct, so they apply the code's standards when reviewing any issues at your company?

It does not appear that Andersen had a USSG type of compliance program, which would have encouraged employees to escalate ethical concerns and prohibited destruction of potential evidence. It also appears that neither outside counsel nor Andersen applied Enron's ethical standards in considering the permissibility of the partnerships and other transactions.

Documentation

❖ If you are undertaking these types of diligent compliance steps, can you prove it? For example, can you document your employees' compliance training?
❖ Do you have the code of conduct from your outside accounting and law firms? Is it at least as thorough and rigorous as your company's?
❖ Have you audited your compliance files to be sure they are complete?

At this point, there is not much that any Enron or Andersen compliance files could do for them, since it appears they did not have the necessary program steps in place. But if your company does take steps to have an effective and empowered program, you need to be able to prove what you have done.

Conclusion

Could the types of ethical and legal lapses that we have seen spread across the front page of the *Wall Street Journal* hit the healthcare field? These high-profile cases are not about arcane aspects of corporate accounting; rather, they are about the nature of human beings, greed and the uses and abuses of power. Think back over the healthcare industry's own history: Who would have thought, 15 years ago, that the healthcare field itself would be swept by waves of prosecutions for fraud?

One bright spot for providers, however, is that compliance practitioners in healthcare may, in fact, have an advantage over practitioners in other fields.

Much of what happened at Enron and Andersen might have been avoided if those companies had had compliance practitioners bound by strong professional standards oriented toward the needs and realities of effective compliance programs. In healthcare there are such standards: The Code of Ethics for Health Care Compliance Professionals, adopted in 1999 by the Health Care Compliance Association. Reading these standards today, it is as if they had been written *after* the Enron and Andersen cases.

The HCCA's ethics standards would not allow a compliance professional to accept the artificial limits on investigations imposed at Enron. They would not allow a professional to aid in a retaliation scheme, and they would have required the compliance professionals to report what was happening to the board. Rather than standing by, or even assisting in questionable conduct, a compliance professional subject to these standards would have been duty-bound to resist actively any illegal or unethical conduct.

It is certainly not possible to prevent all forms of corporate misconduct, but that does not excuse the recent display of corruption at the highest levels of corporate leadership. We in business owe something more to the public and our investors—all organizations should adopt rigorous compliance and ethics programs, drawing from the lessons of these recent cases. We must fully empower the compliance professionals who run these programs, and see to it that they are governed by a strong set of ethical principles to guide them through those tests of ethical character that will determine whether our companies do the expedient thing or the right thing.

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The Enron Era: 10 Warnings For Healthcare Compliance

Enron and its progeny are not just about big-company securities fraud. The lessons apply to any organization, including those in healthcare:

1. Remember that power tends to corrupt, and absolute power tends to corrupt absolutely. The offenders in the recent round of corporate scandals were the CEOs and CFOs—people with real power. Avoid giving anyone unchecked power. That's why your compliance officer needs to have real power and unlimited access to the decision-makers, and your board needs to be independent and empowered.

2. Risk management means keeping alert. The warnings are probably there now about the next big compliance risk that could affect your organization—if you just look and listen. Before the Enron debacle, the SEC had loudly announced its focus on earnings management—but no one listened.

3. Your code of conduct can't be a coffee-table decoration. It must be the "law of your organization," binding on all your employees, lawyers, accountants and executives. Any lawyer or accountant who gives advice that ignores the code should be shown the door.

4. Make sure anyone working in your compliance program subscribes to and follows the HCCA Code of Ethics for Health Care Compliance Professionals. The missteps in the recent scandals that gave the professionals such a bad name would have been clearly prohibited under the HCCA code. (See Heller, Murphy & Meaney, *Guide To Professional Development In Compliance*, Aspen Pub., 2001).

5. There is no substitute for ethics—a commitment, starting with the CEO and going down the line, to do the right thing, not just the minimum they think the law requires. The executives at Enron aimed for the bottom—and missed.

6. Third-party professionals—the accountants and lawyers—have had a dismal record. Make sure your outside professionals share your commitments and have their own strong ethics and compliance programs (they are as much "organizations" for compliance purposes as your organization is).

7. Training needs to be powerful enough to have an impact in today's high-intensity environment, and it needs to reach those who can get you in trouble. Do you reach all the executives, is training mandatory and do you test all employees to ensure they received the message?

8. Whistleblowers—usually those inside who care about your organization—may be your last chance to avoid disaster. Make it safe and easy for employees to alert you to potential misconduct, make sure your investigation is professional, diligent and unbiased, and make sure any bad news reaches the top.

9. Conflicts of interest can be lethal, especially higher up in the organization, yet this risk is often underestimated. (See Kaplan, Murphy and Swenson, *Are Conflicts Of Interest Your Program's Achilles Heel?* 15 ETHIKOS 1, Sept./Oct. 2001).

10. Check and challenge. Step back from day-to-day activities and ask if things make sense. Don't be so focused exclusively on the "beans" that are easy to count, like billing accuracy; audit and look for the difficult and dangerous things, like senior executive misconduct.

FTC Picks Up The Pace Of Healthcare Probes

Concerned about rising medical costs, the Federal Trade Commission in recent months has stepped up its review of hospital mergers and physician practice behavior.

Since Timothy Muris became the FTC chairman in June 2001, the Commission has increased spending on healthcare antitrust operations by 50%. Currently, it is investigating at least six hospital mergers in five different geographic areas, David Marx Jr. tells *GCR*. Marx is an antitrust attorney in the Chicago office of McDermott, Will & Emery. The FTC has not publicly disclosed the transactions under review.

"Healthcare is an area of particular interest to chairman Muris," says Marx. "There has been considerable consolidation in the industry by hospitals, healthcare systems and physician providers, and we're seeing healthcare costs increasing at a more rapid rate now than they appeared to increase over the past several years on average. There's a question about why that's occurring."

Effects Of Hospital Mergers

While the FTC has focused in the past on the potential impact of hospital mergers before they occur, it now is scrutinizing mergers that have already occurred, Marx notes. Specifically, Muris wants to know whether the mergers have resulted in higher prices because of less competition.

If the Commission concludes that mergers have led to higher prices without benefiting patients, it could try to dissolve these mergers through administrative and legal procedures, Marx adds. The government has been unsuccessful in its last seven attempts to prevent mergers before they occur, but it may have more success in demonstrating that actual mergers have had an anti-competitive effect, he believes.

"To the extent that hospitals or healthcare systems may have perceived that federal antitrust agencies were going out of the business of challenging potentially anti-competitive hospital mergers, the merger retrospective is at least fair warning that FTC has not abandoned the field."

Physician Practice Conduct

Earlier this year, FTC settled with three doctors' groups accused of collaborating to fix prices—one in Napa Valley, CA, and two in Denver, CO—and continues to actively investigate similar cases.

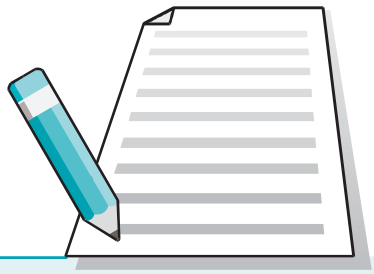
Then in August alone, FTC announced settlements in two more cases involving physicians. In one case, eight Denver-area physician practice groups specializing in obstetrics and gynecology agreed to refrain from entering into agreements to fix fees and refusing to deal with payers except on collectively agreed-to terms. In the other case, System Health Providers and its parent, Genesis Physicians Group Inc. (both based in Dallas, TX), agreed to settle FTC charges that they restrained trade unreasonably and hindered competition in physician services. (Details of the agreements are online at *www.ftc.gov/opa/2002/08/index.htm.*)

"We've seen a recent flurry of cases," says Marx. "I'm aware of a number of investigations of physician provider networks that have not yet resulted in enforcement action, but clearly the FTC is aggressively pursing investigations where it thinks that anti-competitive conduct by physician providers may have occurred. Competing providers who are attempting to negotiate collectively with payers would be wise to obtain advice from knowledgeable antitrust counsel before engaging in discussions."

Resource

❖ David Marx Jr.: 312-372-2000

For the Record



It's the policy in our laboratory (also good laboratory practice) to always include an aerobic culture whenever an anaerobic culture is ordered. Most often the aerobic culture is ordered by the physician, but sometimes it isn't necessarily reflected in the chart. It does not matter if the individual is an inpatient, outpatient or non-patient. Due to the billing set-up in our lab information system, a charge will be encountered for the aerobic culture. Is this allowed?

We put this question from a lab technician to coding/billing consultant Joan Logue of Health System Concepts (Longwood, FL). According to Logue, performing an aerobic culture in addition to the physician-ordered anaerobic culture is considered standard medical practice. Anaerobic infections are usually polymicrobic, and the need for the additional aerobic culture is well documented in the authoritative medical literature, such as Bailey & Scott's *Diagnostic Microbiology*.

However, to routinely bill for the aerobic culture, a lab should make every effort to ensure that physicians are aware of its policy to perform and bill for both cultures, Logue advises. The policy should be approved by the executive medical staff committee and should be included in the lab's test catalog. The lab requisition also should indicate that an order for an anaerobic culture includes the aerobic culture.

Have a compliance question you'd like answered? E-mail it to Kimberly Scott, managing editor, at ***kimscott@yahoo.com***.

HIPAA Privacy Rule, *from page 1*

sensitive personal medical information."

The privacy rule takes effect Apr. 14, 2003 (for small health plans, Apr. 14, 2004).

Consent Now Optional

One major change affects the consent and notice requirements. Covered entities will not have to get an individual's written consent before using or disclosing his/her personal health information for routine healthcare delivery purposes—determining the course of treatment, paying claims or other healthcare operations. While getting advance consent is optional, consent requirements already in place may continue.

But covered entities must get written acknowledgment from the patients that they received notice of their privacy rights and the entity's privacy practices. Direct treatment providers must make only a "good faith" effort to get such an acknowledgment.

In satisfying this requirement, providers may use a "layered" notice, HHS suggests. Beneath a short summary of privacy rights and privacy protections, there may be a longer notice spelling out all the mandatory elements. Providers have flexibility too in documenting the written acknowledgment; for example, the patient may sign or simply initial the cover sheet of the notice or logbook.

The patient's advance permission is required, however, for each type of non-routine use or disclosure of his/her personal health information.

Incidental use or disclosure has been a troubling issue for providers. Many worried they might be barred from conferring with patients, parents or other providers in waiting rooms, nurses' stations or other areas where discussions might be overheard. HHS now expressly permits certain incidental uses/disclosures that occur as a byproduct of an otherwise permitted use or disclosure.

The privacy rule isn't violated, HHS says, as long as the covered entity has met the requirements for reasonable safeguards on personal health information and release of only the minimum necessary.

Providers also will not need prior consent before disclosing patients' information for fraud and abuse investigations, nor are they prohibited from sharing such information with other covered entities when a fraud probe is being conducted. And disclosures are not barred when the information is sought by government oversight agencies such as the HHS Office of Inspector General.

Facilitating Data Exchange

The amended final rule clarifies that covered entities may disclose protected health information for treatment, payment and operational activities of another covered entity or healthcare provider.

"What's significant," notes attorney Peter Adler in the Washington, DC office of Foley & Lardner, "is that not only may covered entities use protected health information for their own purposes, such as treatment, but they may also disclose it to another covered entity for its payment activities and healthcare operations, such as quality assurance and improvement. It allows more of an exchange between covered entities."

Pathologist Exemption

Pathologists are designated as "indirect treatment providers"; thus, they don't have to document in writing patients' receipt of the privacy notice. The College of American Pathologists, which pressed HHS for the exemption, said it was pleased.

Privacy Rule: Key Changes At A Glance

- Eliminates prior written consent for use/disclosure of personal protected health information (PHI) for routine healthcare delivery
- Requires direct treatment providers to make a "good faith" effort to inform patients of their privacy rights
- Requires prior written authorization for certain "marketing" communications and other non-routine uses/disclosures
- Gives covered entities an extra year to bring business associate contracts into compliance with privacy rule requirements
- Defers to state, other applicable laws on parental access to their child's medical records
- Simplifies authorization of PHI disclosure for research purposes

"Minimum Necessary" Standard

This standard requires that covered entities and their business associates not use/disclose protected health information beyond what is reasonably necessary for the purposes of the use/disclosure. Exempt are uses/disclosures for which the patient's advance written authorization has been received.

Marketing Strictures

Covered entities must obtain a patient's prior written authorization to use his/her personal health information for marketing purposes, except for a face-to-face encounter or a communication that involves a promotional gift of nominal value.

Without that advance authorization, a covered entity is prohibited from selling lists of patients or enrollees to third parties or from disclosing protected health information to a third party for that party's marketing activities.

The rule clarifies that marketing does not include doctors talking with patients about treatment options or the covered entity's communications about its own health-related products and services. For example, a health plan may inform

patients about additional plan coverage and value-added items like discounts for eyeglasses or prescription drugs.

Business Associates

Covered entities (except small health plans) have up to one year beyond the Apr. 14, 2003 compliance date to alter existing written contracts to conform to business associate requirements of the privacy rule. The amended final rule offers sample business associate contract language.

Despite strong protests from CAP and other organizations, the "business associate" definition does encompass any organization that accredits covered entities. CAP had argued that as a recognized CLIA accrediting body, it should be considered a "health oversight agency," rather than a business associate of the labs it accredits.

HHS did note, however, that the business associate provisions could be satisfied through template contract forms that could be applied to each accredited entity, according to a CAP spokesperson.

Covered entities also may disclose sets of limited data under "data use agreements" with non-covered entities for accreditation and other healthcare operations. To qualify as a limited data set, certain direct identifiers must be removed. The set may include date of admission or discharge, birth or death, and five-digit zip code, for example.

Patients' Access To Records

Patients retain the right to copy and review their medical records and to request changes to correct any errors.

HHS appears to have left intact a provision in the original rule exempting laboratories from having to provide test results to patients. Under CLIA (the 1988 Clinical Laboratory Improvement Amendments), labs are required to provide test results only to "authorized persons" as defined by state law. In most cases, this is the ordering physician, not the patient, but HHS has noted previously that patients typically can get the results from their provider.

As CAP observes: "Patients' right of access to their protected health information under HIPAA does not apply where CLIA would prohibit the lab from providing this type of information directly to the patient."

Research

A single set of authorization requirements now applies to all uses/disclosures requiring an authorization, including those for any research purpose. An authorization for use/disclosure may be combined with any other research-related authorization, including informed consent to participate in a research study. A research authorization may have an expiration date of "none," "end of the study" or similar statement to allow use of protected health information in a research database or repository.

Employment Records

Protected health information does not include employment records held by a covered entity in its role as an employer.

Resources

- Peter Adler: 202-945-6146
- College of American Pathologists: 800-392-9994
- *Federal Register*, Aug. 14, '02, online at *www.access.gpo.gov/su_docs*. The amended privacy rule is also posted at *www.hhs.gov/ocr/hipaa*

GAO Wary Of Single Code Set Under HIPAA

The merit of replacing dual procedural code sets—those for reporting inpatient hospital procedures, physician services and other medical services—with a single code set may not be advisable for practical reasons, concludes the General Accounting Office in a new report on HIPAA.

The Health Insurance Portability & Accountability Act, signed into law in 1996, required the Department of Health & Human Services to adopt standard code sets for describing health-related services in connection with financial and administrative transactions, such as filing claims for payment. In August 2000, HHS selected ICD-9-CM, Vol. 3, for reporting inpatient hospital procedures and CPT codes for reporting physician and other medical services, including outpatient hospital procedures.

Despite the attempt at simplification, many in the healthcare industry have raised concern about the limitations of these code sets, resulting in inefficiencies in recordkeeping and data reporting, says GAO. HHS recognized that these code sets would need to be revised in the future, particularly the ICD-9 codes, and specifically cited the International Classification of Diseases, 10th Revision, Procedural Coding System (referred to by GAO as 10-PCS).

While 10-PCS is generally considered an improvement, its implementation poses challenges, GAO believes. "Because 10-PCS is a distinct departure from the design and logic of ICD-9-CM, Vol. 3, the existing healthcare administrative system would need to be changed significantly to accommodate [it], imposing additional financial costs and administrative burdens on members of the healthcare industry that are currently undertaking changes to comply with the adopted standard code sets under HIPAA."

GAO concludes that use of dual code sets for reporting medical procedures is acceptable under HIPAA and advises more study on implementation of a single code set.

Resource

- GAO Report, "HIPAA Standards: Dual Code Sets Are Acceptable for Reporting Medical Procedures," *www.gao.gov/cgi-bin/getrpt?GAO-02-796*

The Back Page

News-At-A-Glance

Pneumonia Upcoding: A Boston hospital group has agreed to pay $3 million to resolve allegations that it submitted fraudulent claims to Medicare in bacterial pneumonia billings, U.S. attorney Michael Sullivan announced Aug. 22. Southcoast Hospital Group Inc. (formerly Charlton Hospital and St. Luke's Hospital) allegedly submitted claims from Oct. 1, 1992 through Sept. 30, 1995 with the principal diagnosis code of 482.89 for complex pneumonia, due to "other specified bacteria." But claims under that code were not supported by the corresponding medical records, Sullivan said. The settlement is the most recent in the government's pneumonia upcoding investigation.

State Privacy Standards: State legislatures may well propose privacy requirements that go beyond the federal standards set under HIPAA (the 1996 Health Insurance Portability & Accountability Act, predicts attorney Bruce Merlin Fried with Shaw Pittman (Washington, DC). Speaking at an Aug. 23 HIPAA colloquium at Harvard University, Fried said lingering dissatisfaction with the federal decision to drop the written consent requirement will prompt states to enact stronger laws of their own. When states have privacy standards more stringent than the federal, state law takes precedence. "I suspect we will see a real uptick in state legislation in this area, starting next January," Fried opined.

JCAHO Safety Goals: The Joint Commission on Accreditation of Healthcare Organizations recently announced six National Patient Safety Goals designed to give healthcare organizations focused, practical recommendations to reduce specific healthcare errors. The six goals, which go into effect Jan. 1, 2003, focus on confusion in identifying patients, miscommunication among caregivers, wrong-site surgery, infusion pump errors, medical mix-ups and malfunctioning clinical alarm systems. For more information, go to *www.jcaho.org.*

Hospital Compliance: Revisions to the current compliance guidance for hospitals should be modest and take into account existing compliance efforts by hospitals, says American Hospital Association executive vice president Rick Pollack. In a letter to the HHS Office of Inspector General, Pollack urged the OIG not to implement minimum training requirements for employees. The OIG has indicated it will revise the hospital guidance, first unveiled on Feb. 23, 1998, though no specific date has been announced.

Gifts To Beneficiaries: The HHS Office of Inspector General has released "bright-line" guidance on acceptable practices regarding gifts and other inducements to Medicare beneficiaries. Along with restating prohibited practices, the OIG says it is considering soliciting public comment on possible regulatory exceptions for complimentary local transportation and free goods/services in government-sponsored clinical trials. The Special Advisory Bulletin is online at *www.oig.hhs.gov/fraud/docs/alertsandbulletins.*

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