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For Hospitals, Laboratories and Physician Practices

CLIA Catastrophe Imperils Specialty Labs
Reference Facility Loses Medicare Rights

Specialty Laboratories (Santa Monica, CA), one of the nation's major reference testing facilities, has been hit with the severest regulatory sanctions under CLIA for non-compliance, but has appealed the action. The core complaint against Specialty is that it has repeatedly failed to follow personnel licensing standards set by the California Department of Health Services.

The Centers for Medicare & Medicaid Services has revoked the lab's certificate under CLIA (Clinical Laboratory Improvement Amendments), effective Apr. 22, and suspended Medicare and Medicaid payments to the lab for services on and after Feb. 22.

Revocation of the CLIA certificate is stayed during the appeal, which was filed Apr. 17, says Greg Mann, a spokesman for the publicly traded lab company. If the revocation is upheld, Specialty will have to cease all human diagnostic clinical lab testing. By law, any lab performing such testing must have a valid CLIA certificate in order to test legally in the U.S.

During the appeal, Specialty plans to continue testing for Medicare beneficiaries and Medicaid recipients and, if successful in the appeal, says it is entitled to receive reimbursement retroactive to Feb. 22.

The government's forceful intervention is unusual and could represent beefed-up enforcement, says Gabriel Imperato, an attorney with Broad & Cassel (Ft. Lauderdale, FL).

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Enron Debacle Forces Compliance Programs To Re-Examine Accounting/Consulting Ties

The recent scandal involving energy giant Enron Corp. and the accounting firm Arthur Andersen has raised new questions about the objectivity of companies that provide both consulting and accounting services for businesses and the potential for conflict of interest.

While big accounting firms like Andersen, KPMG and Deloitte & Touche have long furnished a range of services to healthcare providers—such as helping design a compliance program and subsequently monitoring it as an Independent Review Organization under a corporate integrity agreement—some in the industry are now wondering whether it's time to take a closer look at those kinds of arrangements.

Do such arrangements present a legal or ethical conflict? We put that question to three prominent healthcare attorneys on the faculty of Washington G-2 Reports' 4th annual Compliance Forum, held Apr. 4-5 in Orlando, FL. While views varied, all three agreed that the Enron/Andersen debacle is changing the way healthcare providers look at their relationships with accounting/consulting firms.

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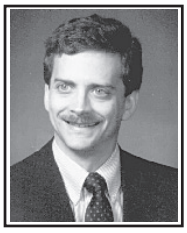
New Times

"I've never really seen a problem *per se* with having folks do both compliance and auditing," said **Carrie Valiant** with Epstein Becker & Green PC (Washington, DC). "I know that people over the years have developed close relationships with their auditors, and they want their auditors to continue to look at problems as they arise and help them. But these are new times, and there's [now] a question of the appearance of impropriety."

Board members of healthcare organizations have become especially sensitive to potential conflicts of interest, she noted. "I'm getting a lot of calls from people on boards who are now converts to compliance and voluntary disclosure because they feel that Enron has created a whole new standard. I have a feeling that most organizations will start to create separateness even if the accounting firms don't do it themselves because they feel they need it to sustain credibility in the activities they run."

What Hat Is That?

S. Craig Holden with Ober/Kaler in Baltimore, MD, said he has always advised clients not to use their audit firm for consulting, particularly when attorney-client privilege is involved, such as during an investigation, "because then you always have those delightful issues of what hat were they wearing when they found out [a particular] fact, and is it privileged and do they have to disclose it in the audit?"



During an audit, it's very common for auditors to express opinions about the adequacy of compliance procedures, which also potentially presents a problem, he added. "If those procedures are ones that their consulting arm created, guess what they're going to opine? You take away the independence of that outside check [when you use the same firm to both help design and audit a compliance program]. Now, having said that, I usually lose the battle because clients say, 'We're going to hire the auditor [to help with our compliance program]. We like our auditor, he's a nice fellow and he's in my office every day.' I think we may see that change now."

Burden Is On Provider

The responsibility for ensuring separation between consulting and auditing activities rests primarily with the healthcare provider, believes **Peter Kazon**, who is with Mintz Levin Cohn Ferris Glovsky & Popeo, PC, in Washington, DC.

"Basically, if you're going to do compliance, you have to feel comfortable with the people you're using, so if there are issues being created because of those relationships, it's really [the provider's] responsibility to ask, 'Do I have faith in the decisions and the reports and the conclusions that are being made?' If you don't, then it's your responsibility to have someone else come in to do the consulting piece."

Meanwhile, on Capitol Hill, the House has approved legislation (HR 3763) that would overhaul rules governing the accounting industry by creating a new auditor oversight board and barring accounting firms from providing certain consulting services to clients they audit. The bill delegates much of the responsibility for designing and implementing the new regulatory system to the Securities & Exchange Commission.

Consumer groups and some Democratic lawmakers have criticized the measure as not tough enough. Senate Banking Committee chairman Paul Sarbanes (D-MD) plans to propose more stringent restrictions on accounting firms.

Resources

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- S. Craig Holden: 410-347-7322
- Peter Kazon: 202-661-8739

OIG: "Providers May Keep Andersen As IRO"

Healthcare providers operating under corporate integrity agreements (CIAs) may continue to use the accounting firm of Arthur Andersen to audit and monitor compliance in their federal healthcare program operations, says the HHS Office of Inspector General.

In an Apr. 12 posting on its Website, the OIG said it is waiving the CIA requirement that would result in immediate cessation of Andersen's existing involvement as an independent review organization (IRO). But providers are prohibited from "entering into, renewing or extending engagements with Andersen."

The federal General Services Administration announced in March that it had suspended Andersen from taking on new federal business, one day after the firm was indicted for its alleged role in financial misconduct at Enron Corp.

Normally, suspension of a contractor by GSA invokes the "Ineligible Persons" clause of a provider's CIA, requiring the provider to stop involving the contractor in business operations related to federal healthcare programs. The OIG has decided, however, to waive that requirement "in the interest of causing minimal disruption to providers' ongoing business operations and reducing the financial burden to providers of having to engage another firm to duplicate work already performed by Andersen."

If a provider has other engagements with Andersen, the provider should confirm with the Centers for Medicare & Medicaid Services whether it has any additional obligations arising from Medicare provider agreements, the OIG advises.

The guidance on Andersen is posted among "Frequently Asked Questions" on the OIG Website at *http://oig.hhs.gov/fraud/cia/docs/ciafaq1.html*. Scroll down to item 7.

Where ABNs Are Concerned, Labs Bear Ultimate Liability
CMS Officials Clarify Issues In Completing The Form

Evolving guidance from the Centers for Medicare & Medicaid Services on the process for completing a valid Advance Beneficiary Notice (ABN) presents more challenges for laboratories, which ultimately will have to eat the cost of testing performed when an ABN is not completed properly.

The ABN alerts Medicare beneficiaries, prior to a Part B service being furnished, that they may be financially liable for the service in the event that Medicare denies payment. Two standard, single-page ABN formats have been approved by the government: one for general use, the other specific to laboratory testing. Currently, use of these standard forms is optional, but will become mandatory once CMS finalizes ABN instructions to Medicare contractors, expected later this year.

Attorney **Thomas Bartrum** with the firm of Baker Donelson Bearman & Caldwell (Nashville, TN) addressed the added challenges at the 4th annual Compliance Forum sponsored by Washington G-2 Reports in April in Orlando, FL. He presented responses from CMS officials to questions he posed regarding a lab's liability.

Questions & Answers

Q *If a lab receives a defective ABN from a physician, is the lab liable for covering the cost of the test(s) performed?*

A Yes. CMS takes the position that the lab is responsible for any errors in completing the ABN, even if there is no way to know there is a problem (as in rare cases when a physician signs the patient's name on the ABN). "If there's anything wrong with the ABN, the lab is going to bear the financial brunt of that error," Bartrum notes.

In fact, as CMS explains in "Frequently Asked Questions" on a laboratory's responsibilities regarding ABNs, the lab, not the physician, is financially at risk: "It is the lab's responsibility to execute the ABN. The physician may execute the ABN, but it is not a requirement." The agency does encourage physicians to complete ABNs in cases where a specimen is collected in the physician's office and sent to an outside lab.

Q *CMS has stated that an ABN may be obtained after a specimen is collected by a physician, but prior to the specimen being tested by a lab. The new national coverage policies for 23 frequently ordered diagnostic tests, due to take effect this November, define the "date of service" as the specimen collection date. Will this require that ABNs be executed prior to specimen collection?*

A According to Bartrum, CMS takes the position that the "date of service" definition under the national coverage policies will not change the ABN rules. "Even if the date of service for a lab test is the date of the draw, you could still go back and collect the ABN before the test is performed," he says. Bartrum has asked CMS to make this point clear to contractors, "otherwise, carriers will see the date of service as before the date of the ABN and will automatically reject those claims."

Q *Will CMS follow state law in determining when a beneficiary is competent to sign an ABN? For example, can someone who is considered a minor under state law (such as a 17-year-old beneficiary with end-stage renal disease) sign an ABN or would a parent or legal guardian have to sign it?*

A CMS has indicated that it will allow providers to use their discretion in determining whether a beneficiary is competent to sign an ABN and will allow contractors to make the final determination, Bartrum says.

"In the relatively rare case where a minor is a Medicare beneficiary, CMS would not look solely to state law to determine whether the beneficiary was competent to sign an ABN," he says. "Instead, so long as the beneficiary appears capable of understanding the ABN—that is, the person is not under great duress, senile or subject to communication barriers—the ABN should be effective."

Resources

- Thomas Bartrum: 615-726-5720
- Labs & ABNs, Frequently Asked Questions: *www.hcfa.gov/medlearn.refabn.htm*

Healthcare Fraud Recoveries Top $1.3 Billion In 2001

The Federal Government collected more than $1.3 billion during 2001 as a result of healthcare fraud, according to the Justice Department and the Department of Health & Human Services. Over 90% went back to the Medicare Trust Fund. An additional $42.8 million was recouped as the federal share of Medicaid restitution.

The government's efforts to detect and eliminate healthcare fraud have grown over the last five years, following passage of HIPAA (Health Insurance Portability & Accountability Act), which created a national Health Care Fraud & Abuse Control Program and gave prosecutors new criminal and civil enforcement tools and financial resources.

During the five years of the program, more than $2.9 billion has been returned to the Medicare Trust Fund while returns to the Federal Government have totaled more than $3 billion. In addition, more than 2,000 defendants were convicted on healthcare fraud-related offenses, and more than 15,000 entities or individuals were excluded from participating in Medicare and other federal healthcare programs.

CLIA Catastrophe, *from page 1*

"I haven't heard of this happening before. Suspending Medicare payments can shut down a lab in short order. Doing that and revoking the license is pretty severe. CMS is really stepping out and taking the lead action on this, which is unique."

Unlicensed Personnel Allegations

CMS and the California Department of Health Services allege that Specialty Labs has allowed employees to perform and supervise clinical lab testing without the proper licensure required by the state.

Acting on a complaint, California officials inspected Specialty in June and October of 2001 and cited it for 20 deficiencies under state law and CLIA regulations. In February of this year, CMS issued a separate statement, citing 12 overlapping deficiencies based on the same inspections.

The lab submitted a corrective action plan to the state in December 2001 and a more detailed one to CMS in February 2002. The judgment of both authorities was that Specialty's response was not a "creditable allegation of compliance."

In April of this year, California notified Specialty that it would impose a directed plan of correction, random on-site monitoring and a fine. CMS went further in deciding to revoke the company's CLIA certification, suspend federal reimbursement, fine the lab $3,000 per day for each day of non-compliance and impose a directed plan of correction whereby CMS may notify the lab's customers of its non-compliance and the nature and effective date of any sanctions.

Since the most recent CMS action, Specialty has filed a supplement to the February corrective action plan that company officials believe will prove the lab is now in full compliance. According to Dan Angress, vice president of marketing, Specialty has stepped up efforts to find and hire licensed employees, discontinued lower volume tests, shifted licensed employees to higher volume areas, encouraged unlicensed employees to take the state licensing exam and shut down its cytogenetic testing division.

This is not the first time Specialty has been investigated by CMS. According to the company's annual report, CMS investigated Specialty in 1999, and the lab ultimately paid sanctions of $87,400 in 2000. Company officials declined to discuss the 1999 findings, saying they are not relevant to the current action.

Reimbursement Questions

Specialty Labs says that the sanctions apply only to testing for which it bills Medicare and Medicaid directly (estimated at less than 6% of its $175.2 million in revenue) and do not affect its billing of hospitals and other reference clients for Medicare/Medicaid work.

"Suspending Medicare payments can shut down a lab in short order. Doing that and revoking the license is pretty severe. CMS is really stepping out and taking the lead action on this, which is unique" —Gabriel Imperato

Attorneys at Hooper, Lundy & Bookman (Los Angeles, CA), which is representing the company, believe the sanctions should not affect the ability of Specialty's clients to bill Medicare or Medicaid for testing referred to and performed by the lab. Company officials have asked CMS to confirm this interpretation. At press time, they were awaiting a reply.

The HHS Office of Inspector General, which handles allegations of fraud and abuse and false claims, does not plan to pursue action against Specialty, says spokeswoman Judy Holtz. "We view this primarily as a Medicare certification issue."

What Went Wrong?

The compliance disaster at Specialty Labs raises two fundamental questions. Where was its compliance program all this time? And why did the alleged deficiencies escape its CLIA accrediting agent, the College of American Pathologists?

Specialty officials were reluctant to discuss issues concerning the company's compliance program, though Mann says they may be more willing to do so in the coming weeks as the lab works toward a resolution with CMS. And as we went to press, CAP officials were unavailable for comment.

Resources

- Greg Mann: 310-586-7261
- Dan Angress: 310-828-6543
- Gabriel Imperato: 954-764-7060
- Judy Holtz: 202-619-1343

Pneumonia Upcoding Settlement

The University Medical Center of Southern Nevada in Las Vegas will pay $1.16 million to settle allegations that it violated the False Claims Act by "upcoding" a pneumonia diagnosis code, the Justice Department said May 1.

The settlement includes a payment of $725,000 to be made within five days of the signing of the agreement and gives credit for $438,488 paid to the government in 1999 after the investigation began. The agreement contains substantial corporate integrity provisions that require the hospital to retain an independent review organization for regular billing/coding reviews, to provide coding and compliance training to employees and to retain a compliance officer and compliance committee.

The whistleblower lawsuit was originally filed in 1996 by Health Outcomes Technologies, a software company based in Doylestown, PA. It will get $162,888 of the settlement.

COMPLIANCE PERSPECTIVES

HIPAA Privacy Rule: How Proposed Changes Impact Compliance Programs

Erin Lewis Darling is a healthcare attorney with Mintz Levin Cohn Ferris Glovsky & Popeo, PC, in Washington, DC

The U.S. Department of Health & Human Services released on March 21 its much-anticipated Notice of Proposed Rulemaking (Proposed Rule) making significant and controversial modifications to the Privacy Regulation under HIPAA (Health Insurance Portability & Accountability Act). This article highlights the impact of these revisions on the compliance efforts of covered entities that engage in electronic data exchange transactions (healthcare providers, health plans and health clearinghouses).

The Disappearing Consent Requirement

Under the initial Privacy Regulation, published in December 2000, providers having a direct treatment relationship with an individual must obtain that person's written consent before using or disclosing his/her protected health information (PHI) for purposes of treatment, payment or healthcare operations (TPO). The Proposed Rule would eliminate this requirement, but give all providers the *option* of obtaining consent. If a provider opted to do so, it would have complete discretion in creating the consent form and process. It's important to remember, however, that state consent requirements would continue to apply.

The consent requirement has triggered substantial debate within the healthcare community, among privacy advocates and on Capitol Hill, as evidenced by the history of this provision throughout the rulemaking process. As first proposed, the rule would have let providers use or disclose PHI for TPO without consent; the final Privacy Regulation requires only those providers with a direct treatment relationship to obtain consent, while the latest proposed revision would make it optional for all providers.

For certain, many providers welcome being relieved of an additional paperwork and logistical burden, especially those with multiple locations who would have to log and track consents in order to ensure compliance. However, the Proposed Rule includes a new requirement that providers having a direct treatment relationship with the individual make a good-faith effort to obtain written acknowledgement from the individual of receipt of the provider's *Notice of Privacy Practices*. Providers with an indirect treatment relationship (often clinical laboratories) would not have to obtain an acknowledgement. Thus, the Proposed Rule creates a mechanism to ensure that there is still an opportunity for individuals to discuss with providers how their PHI will be used and disclosed in the course of the relationship.

The written acknowledgement would be required at the first service delivery—the same time that the *Notice* must be provided. The form would be left to the provider's discretion. If a provider were unsuccessful in obtaining an acknowledgement, so long as it documented its good-faith efforts to obtain the acknowledgement and the reason it was unable to, the provider would be in compliance.

Some have argued that the existing consent requirement does not afford meaningful privacy protection anyway, because it generally refers individuals to the provider's *Notice* for information on how their PHI would be used and disclosed, their rights, and the provider's obligations under the Privacy Regulation. Thus, under both the Privacy Regulation

Major Proposed Revisions

- Consent optional, Notice acknowledgment required
- More leeway to share protected health information (PHI) among covered entities
- Minimum necessary and tracking requirements not applicable to disclosures made per an authorization
- Marketing provisions simplified
- No business associate contracts required until service agreement is modified or renewed
- Permits certain incidental use/disclosure as long as basic safeguards are in effect
- Use of PHI for research made easier

Source: Mintz Levin

and the Proposed Rule, most of the important information is contained in the *Notice*, not the consent. Since the proposed revision merely substitutes the acknowledgement for the consent requirement, in some sense the change may not be terribly significant.

Where the consent requirement in the Privacy Regulation created difficulties because providers had to obtain consent before they used an individual's PHI for any purpose (*e.g.*, to prepare prescriptions, make appointments, etc.), the acknowledgement resolves many of these problems because it is required one step later in the process—at first service delivery. This is an important change that seems more reasonable and workable for most healthcare providers.

Disclosing Among Covered Entities

A more significant, but less publicized part of the Proposed Rule would give covered entities more freedom to share PHI with other covered entities as well as non-covered providers. Currently, once covered entities obtain consent, they may disclose PHI for treatment purposes, and use and disclose PHI for their own payment and healthcare operational purposes.

However, in order to disclose PHI for payment or operations involving another entity, covered entities must obtain the individual's authorization. For example, where a laboratory needed additional patient information from the treating physician in order to bill the patient's insurer, the patient would have to sign an authorization before the physician could disclose that information to the lab.

The Proposed Rule remedies this situation by permitting covered entities to disclose PHI for the payment activities of other covered entities and non-covered providers. In addition, it would let covered entities disclose PHI to other covered entities for certain healthcare operations of those entities, so long as each entity has, or has had, a relationship with the individual. Where the relationship between the individual and the covered entity has ended, the covered entity could disclose only PHI related to the past relationship. In particular, covered entities would be allowed to disclose PHI to another covered entity for:

- quality assessment/improvement activities (*e.g.*, laboratories are required under CLIA to perform certain quality control reviews, which often require additional clinical information from the physician);
- population-based activities relating to improving health or reducing healthcare costs;
- case management;
- conduct of training programs;
- accreditation, certification, licensing or credentialing; and
- fraud & abuse detection and compliance programs.

Streamlining Authorization Standards

While a consent is a general document giving the provider permission to use or disclose PHI for TPO purposes, an authorization is a more detailed, customized document that gives the provider permission to use specified PHI for specified purposes beyond TPO.

In response to providers' concerns that the authorization provisions were too complex and confusing, the Proposed Rule would consolidate authorization requirements—all authorizations would have to contain the same core elements, including a description of the information to be used or disclosed, the persons authorized to use or disclose the PHI and the persons authorized to receive it, a description of each purpose for the use or disclosure; and certain statements about the individual's rights. These changes are intended to ease the administrative burden by letting covered entities create a standardized authorization form.

The Proposed Rule also contemplates a change to another controversial aspect. Under the Privacy Regulation, all authorizations must disclose whether a covered entity will receive remuneration as a result of obtaining an authorization; the Proposed Rule stipulates that only authorizations for marketing activities would have to include such information, if applicable.

Further, the Proposed Rule clarifies that disclosures made pursuant to a valid authorization do not have to be included in accountings provided to the individual. This will significantly reduce a covered entity's obligation to account for disclosures, essentially only requiring them to track and account for disclosures made for "national priority purposes" (*e.g.*, disclosures required by law, for health oversight, to law enforcement, in judicial or administrative proceedings). For providers such as clinical laboratories that often do not have the capability to track and link information in the ways required by the Privacy Regulation, this is an important clarification.

Expanding The Marketing Provisions

The Proposed Rule significantly modifies the Privacy Regulation's requirements related to marketing, in many cases relaxing or simplifying them. The marketing provisions in the Privacy Regulation triggered a public outcry from both industry and consumer groups because of the way "marketing" was defined and the types of communications excluded from the definition.

In particular, many were concerned that the provisions did not

adequately protect consumers from unwanted PHI disclosures to commercial entities, the re-disclosure of the information by these entities and unwanted solicitations. Others argued that the provisions should be based on an opt-in system, or that consumers should at least be able to opt out before any marketing occurred.

In direct response to these concerns, the Proposed Rule attempts to replace many of the nuances in the Privacy Regulation with more concrete rules. It would require covered entities to obtain the individual's authorization before making any marketing communications. It continues to carve out from the definition of "marketing" those communications describing who is participating in a healthcare network, whether a particular service is covered and to what extent, and those related to treatment of the individual.

The Proposed Rule also clarifies that communications on case management or care coordination for the individual who is the subject of the PHI are not considered marketing. These communications are carved out regardless of whether made orally or in writing and regardless of whether the entity receives payment from a third party for making them.

This is a significant change from the Privacy Regulation, which only permits such communications to be made without authorization where made orally or where made in writing and the covered entity does not receive remuneration. Though HHS considers this revision necessary to facilitate important treatment communications, privacy advocates and some lawmakers continue to object to these broad carve-outs.

The Proposed Rule explicitly requires authorization for use or disclosure of PHI for marketing purposes, as defined by regulation. Covered entities would still be barred from selling lists of patients or enrollees to third parties and from disclosing PHI to third parties for independent marketing activities without the individual's express authorization.

The Proposed Rule retains two exceptions to the authorization requirement: face-to-face communications between a covered entity and the individual, and communications in the form of promotional gifts of nominal value. If the entity making the communication expects to receive direct or indirect remuneration from a third party, this must be stated in the authorization.

Although the marketing provisions are among the most controversial in the Proposed Rule, many of the proposed revisions simply reorganize the existing marketing requirements. The most significant change is the fact that written communications which fall within the carve-outs described above and for which entities are paid by a third party would be excluded from the definition of "marketing" and thus not require the individual's authorization.

In the minds of many legislators and privacy advocates, this seriously expands the ability of entities to use PHI for marketing purposes without an individual's permission.

Business Associates: Transition Period

Under the Privacy Regulation, a covered entity may disclose PHI to a business associate that performs specified functions on its behalf, so long as the entity obtains reasonable assurances (*i.e.*, a written agreement) that the PHI will be safeguarded appropriately.

The Proposed Rule grants covered entities with existing business associate agreements up to an extra year to become compliant. Thus, covered entities with such agreements, even if the agreements don't comply with the business associate contract requirements of the Privacy Regulation, would have until, at the latest, Apr. 14, 2004 to amend their agreements. However, if an agreement comes up for renewal or is modified between the effective date of the Proposed Rule and Apr. 14, 2004, provisions must be added at that time to comply with the business associate requirements. The extension does not relieve a covered entity of the responsibility to make PHI available to HHS or to comply with patients' rights provisions, even if such information is held by a business associate.

To help covered entities comply, the Proposed Rule offers model language for a business associate contract. Its use is not mandatory, nor is it intended to constitute a complete agreement. Even so, the model language will likely prove useful as an addendum to existing business associate agreements or to otherwise help simplify the contracting process.

"Minimum Necessary" Communications

In response to concerns that the "minimum necessary" provisions might restrict certain common and essential healthcare communications and practices, the Proposed Rule would exempt any uses or disclosures for which the covered entity has received a valid authorization. This will allow researchers, for instance, much more latitude to tap individuals' PHI in the course of research projects. The Proposed Rule also would make the "minimum necessary" standards for requests for PHI more consistent with the standards for PHI disclosures.

The important revision proposed is to add permission for certain incidental uses and disclosures that occur as a result of an otherwise permitted use or disclosure. There

had been concern that the "minimum necessary" standards might stifle or unnecessarily burden many current practices, such as discussions among treatment providers. Though HHS stated in its July 2001 guidance that the Privacy Regulation is not intended to impede customary and necessary healthcare communications or practices, nor require that all risk of incidental use or disclosure be eliminated, there was still a perception that covered entities would have to prevent any incidental use or disclosure, such as when individuals in a waiting room sign their name on a log sheet and see the names of other patients.

To dispel these misconceptions, the Proposed Rule describes an incidental use or disclosure as one that cannot reasonably be prevented, is limited in nature, and occurs as a by-product of an otherwise permitted use or disclosure under the Privacy Regulation.

Covered entities should continue developing and implementing HIPAA compliance plans, to the extent possible, as the final regulatory requirements are hammered out

For instance, this might occur when healthcare staff are orally coordinating patient services at a hospital nursing station and a visitor passing by overhears part of the conversation.

This new provision is limited, however, in that it would only permit incidental uses or disclosures to the extent that the covered entity has applied reasonable safeguards as required by the Privacy Regulation and implemented the "minimum necessary" standard as required. In addition, this provision would not excuse erroneous uses or disclosures or those that result from mistake or neglect (*e.g.*, mistakenly sending PHI via electronic mail to the wrong recipient).

Relaxing Research Requirements

The Privacy Regulation requires that no PHI be used or disclosed for research purposes unless the individual's authorization has been obtained, except in limited circumstances. The Proposed Rule would significantly ease this restriction by clarifying and streamlining the approval criteria for waiving a research participant's authorization; relaxing standards for certain elements of research authorizations; allowing research authorizations to be combined with other legal permissions related to the research study; and expanding the transition provisions related to research.

Of most interest to researchers, the Proposed Rule seeks comment on an alternative approach to de-identifying PHI. The Privacy Regulation permits a covered entity to de-identify PHI so that it may be used and disclosed freely, without being subject to the Privacy Regulation's protections. It provides two methods for de-identifying PHI: obtaining a certification from a statistician or removing all of a list of 18 identifiers.

The proposed revision would permit uses and disclosures of a limited data set which does not include facially identifiable information but in which certain identifiers would remain. Disclosure of this data set would be allowed only for research, public health, and healthcare operations. The limited data set would include admission, discharge, and service dates; date of death; age; and five-digit zip code. In addition, a covered entity would have to condition disclosure of the data set on the recipients agreeing to certain limits. This proposal is an attempt, in part, to respond to researchers' concerns that if information is de-identified in compliance with the Privacy Regulation, it will be useless for research because all the significant variables will have been removed.

Not The Last Word

The public got only 30 days to comment on the Proposed Rule. Although complex proposals of this type generally afford longer comment periods, HHS must expedite the Proposed Rule because, by statute, any changes to the Privacy Regulation must be final six months before the compliance deadline of Apr. 14, 2003.

The healthcare industry seems to welcome most of the proposed changes; however, privacy advocates and some lawmakers have already expressed serious concerns about their scope, in some cases labeling the proposal a "gutting" of privacy protections. Hearings are underway in Congress, and it is certain we haven't heard the last word on the subject.

Nonetheless, covered entities have less than a year to comply with most provisions of the Privacy Regulation, and there is no indication that this date will change, despite repeated industry attempts to secure more time.

Thus, covered entities should continue developing and implementing HIPAA compliance plans, to the extent possible, as the final regulatory requirements are hammered out. Even with major details still unresolved, those covered entities that start preparing for implementation sooner rather than later won't be left scrambling on Apr. 14, 2003.

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HIPAA Electronic Data Exchange Standards

Form Available To Request Compliance Deadline Extension

Healthcare providers that need more time to come into compliance with a final rule governing HIPAA electronic transactions and code sets (TCS) can now request it, using a model form developed by the U.S. Department of Health & Human Services.

The form, released in late March, lets entities covered under HIPAA (Health Insurance Portability & Accountability Act) get an additional year—until Oct. 16, 2003—to comply with TCS requirements (*GCR, Apr. '02, p. 3*). The compliance deadline in the final rule is Oct. 16, 2002 (except for small health plans, which already got an additional year to comply).

The model form and related instructions are online at *www.cms.gov/hipaa/hipaa2/default*. At press time, HHS plans to have an electronic filing system in place so that providers can complete the form and submit it online. For now, providers can print the form, complete it and submit it through the mail.

Just filing the form is sufficient to receive the extension, notes HHS. Providers that submit online will receive a confirmation number to serve as acknowledgement of the extension.

To secure the extra year (until Oct. 16, 2003) to achieve compliance, covered entities—including providers, health plans and health clearinghouses—must submit their extension request by Oct. 15, 2002.

Go Ahead & File

Should covered entities request an extension? In most cases, yes, says Reece Hirsch, an attorney with Davis Wright Tremaine LLP (San Francisco, CA). HHS and various "Designated Standards Maintenance Organizations," or DSMOs, are still refining the implementation guides for the TCS standards, and revisions are expected in the coming months, he notes.

"If you go compliant today, there's a possibility you'll have to do some tweaking, which could entail some costs," he says. "There's no harm in asking for the extra year."

What's more, the standards may change and chances are good that many business associates and trading partners will not meet the TCS standards by this October, which could effect the entity's compliance.

Even though HHS has indicated in its Frequently Asked Questions that covered entities may certify they are compliant even if their business associates are not, Hirsch thinks providers should not do so since FAQs sometimes contain misstatements and do not have the force of law.

Resource

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OSHA Opts For Voluntary Ergonomics Guidelines

The Occupational Safety & Health Administration plans to issue industry-specific, voluntary guidelines to reduce workers' exposure to musculoskeletal disorders (MSDs) on the job.

The agency had released a controversial ergonomics rule in the waning days of the Clinton Administration, but early in 2001, Congress killed it. The mandatory requirements were backed by organized labor, but opposed by business and health industry groups on grounds they were too costly and intrusive.

OSHA administrator John Henshaw said his agency would begin work immediately on industry- and task-specific guidelines to reduce MSD hazards. The agency expects to begin releasing guidelines for selected industries this year and is encouraging other businesses and industries to immediately develop additional guidelines on their own.

OSHA opted for guidelines rather than a new rule because of the difficulty in developing simple compliance criteria that could apply to a broad range of industries.

Four-Pronged Approach

According to Henshaw, OSHA will take a four-pronged approach:

1. Target industries and tasks where results will be the quickest and most effective.
2. Develop an enforcement plan with a legal strategy designed for successful prosecution. Special OSHA ergonomics teams will work with Labor Department attorneys and hand-picked experts to bring actions under OSHA's general duty clause where necessary.
3. Provide outreach and assistance, with a particular focus on small businesses.
4. Increase research on ergonomics through establishment of a national advisory committee to OSHA.

Reaction Mixed

Reaction to the voluntary guidelines announcement was split largely along labor vs. business lines. AFL-CIO president John Sweeney called the plan "a meaningless measure that yet again delays action and provides workers no protection against ergonomics hazards—the nation's biggest safety problem." The U.S. Chamber of Commerce issued a statement of qualified support.

Sheila Dunn, DA, head of Quality America, a consulting company based in Asheville, NC, calls the plan "toothless" and believes it will have a limited effect on labs.

Resources

❖ OSHA information on new plan: *www.osha.gov/ergonomics/index.html/*
❖ Sheila Dunn: 828-645-3661

Uncovering Problems In Your Billing Process

Tried & True Techniques For Laboratory Auditing

How much money does your laboratory lose each year because of billing problems?

If you don't know or you aren't sure, chances are you're losing more than you think, warns **Christine Anusbigian**, a manager with Deloitte & Touche's healthcare regulatory services division (Detroit, MI).

Speaking at the 4th annual Compliance Forum held by Washington G-2 Reports in Orlando, FL, on Apr. 4-5, Anusbigian advised periodic billing reviews to verify CPT and ICD-9 coding appropriateness and accuracy. Such reviews lead to more accurate billing and, in most cases, add to the organization's bottomline, she explained.

"You may think you have resolved some billing issues through development of policies and procedures, but a review of data or requisition forms alone probably will not reveal problems," she noted. "The issues are most likely identified and confirmed through a documentation-to-claim review."

How You Benefit

What are the chief benefits of a billing review? It enables a lab to determine which services a physician has ordered, whether documentation in the medical record supports the services provided and whether the services are captured and described accurately on the claim for payment, Anusbigian said.

Who should conduct the review and how often? It should be done at least once a year by someone with extensive knowledge of payment mechanisms, coding rules, Medicare guidance and other payer requirements.

Ideally, she said, the reviewer should be someone who is independent of line management (to allow for objectivity) and someone who is comfortable drawing on the expertise of others in the organization (such as lab technical specialists and staff in health information management and the patient accounts department).

First Steps

To begin, select a sample of medical records (at least 30) that includes both prospective and retrospective claims as well as claims with different dates of service. While you may start with Medicare claims, you eventually may want to include claims to other payers as well, Anusbigian said.

Before beginning the actual audit, gather the necessary documentation, such as claim forms (UB-92 or HCFA-1500), the physician order/requisition, the test results and the remittance notice which shows how the test was paid. Also have on hand selected reference materials: for example, CPT, HCPCS and ICD-9 code books; Medicare carrier or intermediary manuals/bulletins; local medical review policies for your area; fee schedules; APC calculator; compliance guidance from the government and your own organization's program, etc.

To track the claims, develop a record review form using a program such as Excel and a list of error codes, Anusbigian advised (*see below; also p. 11*). To protect patients' privacy, don't use their names on the form; instead, establish a master list that assigns an ID number to each patient in the sample and use that number on the form.

Record Review Form *(sample)*

Sample ID _____ Patient ID _____ QA Reviewer _____

Reviewer _____

Order DX _____ Physician Name on Order _____

Claim DX _____ Collection Date on Order _____

Corrected DX _____ Order Date on Order _____

Do patient name and ID match on order, results, UB & RA? _____ Y or N

ABN Y or N Appropriate Y or N

									Documentation Present				
Date of Service	CPT Billed	Client Payment	LMRP for test Y or N	Test Covered	Revised CPT	Correct Payment	Error Code 1	Error Code 2	Order	Results	UB	RA	Comments

Error Codes

(sample; for use with Record Review Form)

00 - No error (variance)
01 - Unbundled
02 - Duplicate billing
03 – No order
04 – No test results
05 – Inappropriate standing order
06 – Add-on test
07 – Procedure code change
08 – LMRP not met – service paid
09 – LMRP not met – service denied
10 – Incorrect modifier
11 – Incomplete panel results
12 – Incorrect diagnosis code
13 – Blanket ABN
14 – Lost charge
15 – Orders present, test not done
16 – Wrong date of service
17 – Stat change
18 – Handling charge
19 – Missing HCPCS
20 – Incorrect revenue code
21 – Invalid CPT code
22 – No physician name on order
23 – Diagnostic test billed as screening
24 – Screening test billed as diagnostic

Culling The Claims

Once you have assembled the claims, medical records and reference materials, begin going through each claim, assessing whether it has the necessary documentation and was completed accurately (*see above for common errors*).

The billing review won't catch all types of errors, Anusbigian cautioned. For example, a typical review won't reveal problems with the appropriate billing of professional and technical components of pathology services or with potential violations of anti-kickback or physician self-referral laws.

Start by completing the basic information on the review form, such as the sample ID, the patient ID and documentation for each claim. Then for each claim, list the date of service, the code(s) billed and whether the patient paid anything.

Next, pull the actual test order and verify that the diagnosis was coded correctly. If not, list the correct code and the correct payment. You should also determine whether any local medical review policy affects coverage/payment for the service. List error codes for problems identified—this will later enable you to categorize and summarize results. It also is a good idea to check whether you have appropriate documentation for the test order, the test results and the claim that was filed for payment.

Acting On Results

Once the audit is done, calculate the error rate by incorrect codes and by dollar amount. This information can be used to develop an action plan to reduce future errors, Anusbigian noted.

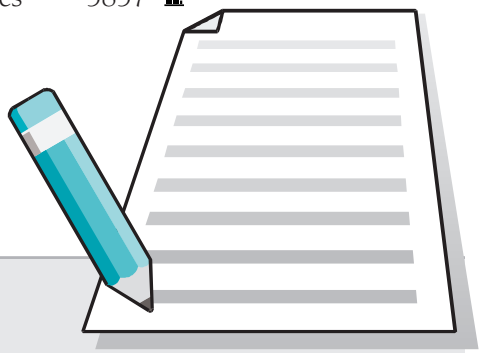
This plan, which should be crafted in conjunction with your organization's compliance office, will involve identifying the root causes of the errors found and listing steps needed to correct each type of error. For example, one lab might identify problems with obtaining valid Advance Beneficiary Notices and system edits, while another might identify problems with the actual input of codes.

"Once you've done this, you'll also have to identify and quantify any overpayments and take steps to repay them," she said, adding that once you've performed this type of billing review a couple of times, you should see your lab's error rates drop significantly.

Resource

❖ Christine Anusbigian: 313-396-5857

For the Record



Billing For Lab Tests To SNF Residents

It's not just providers that get confused by Medicare rules on billing for clinical diagnostic laboratory tests to residents of a skilled nursing facility (SNF). The Centers for Medicare & Medicaid Services does too.

The agency recently corrected a program memorandum issued last November (PM A-01-135), which erroneously indicated that testing of SNF residents could be billed only by the entity that actually provided the testing.

In fact, lab services for SNF residents in a Part A covered stay are subject to consolidated billing. This means that only the SNF may bill Medicare for the services and receive payment. When a lab furnishes the services under arrangements with the SNF, the lab must bill the SNF and be paid by the SNF. (Consolidated billing on the Part B side was approved, then rescinded by Congress, so labs may continue to bill Part B directly or may, under arrangements, bill the SNF.)

According to the correction memo (AB-02-043), "SNFs *must* make arrangements under Part A and *may* make arrangements under Part B under which the SNF bills the intermediary and receives payment from the program. Under this process, the SNF pays the lab for services whatever amount the SNF and the lab agree on, and the beneficiary may not be charged by the lab."

The arrangement may include Part A only or may include Part A and Part B. For Part B services, such an arrangement is voluntary on the part of both the lab and the SNF.

"In the absence of such an arrangement under Part B, the lab may bill Medicare for lab services furnished to residents for whom Part A cannot be paid, and for SNF outpatients, and the SNF may not bill Medicare for these services," the memo continues. "Hospital labs and labs in other SNFs would bill the intermediary. Independent labs would bill the carrier."

For the full text of the correction memo, go online to *www.hcfa.gov/pubforms/transmit/memos*.

Have a compliance question you'd like answered? E-mail it to Kimberly Scott, managing editor, at *kimscott@yahoo.com*. We'll select one to address in this column.

The Back Page

News-At-A-Glance

Provider Update: The Centers for Medicare & Medicaid Services has issued the first edition of a new quarterly publication listing the latest changes in Medicare and Medicaid regulations, as well as transmittals to contractors, over the previous three months and those scheduled for the next three months. Billed as "the one source for national Medicare provider information," it will be published in the future on the first business day of the first month of each quarter (January, April, July, October). The update is available online at *cms.hhs.gov/providerupdate*.

Managing Appeals: New guidance to Medicare contractors on managing potential backlogs in the appeals workload advises prioritizing appeals according to a list established by the Centers for Medicare & Medicaid Services. In a recent program memo, CMS says contractors should continue using a first-in, first-out method for processing appeals and should make it a top priority to finalize decisions by administrative law judges and the HHS Departmental Appeals Board. The memo (Transmittal AB-02-034) is posted online at *www.hcfa.gov/pubforms/transmit/memos*.

False Claims Act: The U.S. Department of Justice is doing a good job in making sure that U.S. attorneys follow guidance designed to ensure fair and responsible use of the federal False Claims Act (FCA), concludes the main congressional watchdog agency.

The General Accounting Office examined Justice's monitoring of its FCA guidelines, which instruct attorneys at Justice and in U.S. attorney's offices nationwide to determine, in advance of alleging FCA violations, that the facts and the law sufficiently establish that a false claim has been submitted. Past use of the Act, particularly in hospital lab unbundling cases, had infuriated hospitals and other provider groups, which lobbied Congress to get Justice to set some ground rules.

GAO's study included a look at whether the attorneys follow the FCA guidelines in such national probes as lab unbundling, pneumonia upcoding and transfer of patients by hospitals under Medicare's inpatient prospective payment system.

The report (GAO-02-546) is available online at *www.gao.gov/cgi-bin/getrpt?/GAO-02-546*.

Headway On HIPAA: Most healthcare organizations are well along in efforts to comply with privacy standards under HIPAA (Health Insurance Portability & Accountability Act), according to a readiness survey by the Health Care Compliance Association, which released the results on Apr. 22.

Of the 253 organizations responding, most reported having held one or two hours of training on HIPAA privacy standards for the majority of their stakeholders, including physicians, staff, executives and board members. In addition, 96% reported that they had established a HIPAA task force, 83% have designated a privacy officer, 67% have designated a security officer and 61% have developed an organizational structure to delineate responsibilities for HIPAA privacy and security requirements. More on the study is available at *www.hcca-info.org/*

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