G-2 Compliance Report

WASHINGTON G-2 REPORTS

Vol. IV, No. 4, April 2002

For Hospitals, Laboratories and Physician Practices

Govt. Would Drop HIPAA Prior Consent Standard

Other Changes Proposed To Simplify Privacy Rule

Significant revisions to the federal rule on medical privacy would make it easier for healthcare providers to treat patients without obtaining their written consent beforehand, but providers would still have to ensure that patients are informed of their right to protect their personal health information from unauthorized use or disclosure.

A series of proposed changes to the rule, which implements provisions of the Health Insurance Portability & Accountability Act (HIPAA), were announced Mar. 21 by the U.S. Department of Health & Human Services. The changes are published in the Mar. 27 *Federal Register*, and the public will have 30 days to submit comments.

Consent Constraints Loosened

Under the current final rule, healthcare organizations must obtain a patient's written consent to use or disclose his/her protected health information for treatment, payment and healthcare operations—commonly referred to as TPO.

The new proposal would remove the consent requirements for TPO, though providers would still have the option of obtaining consent. In addition, consent would no longer be necessary in most instances when one provider makes a patient's information available to another provider for the other provider's TPO purposes. A patient's authorization, which is a more detailed and specific form of permission, would still be needed to use or disclose most information for non-TPO purposes.

In place of the prior consent standard, HHS would require a healthcare provider that has a direct treatment relationship with patients to make a "good faith" effort to obtain their written acknowledgement

Continued on p. 4

Inside this issue

Tighter Grip Sought On "Home Brew" Tests

A proposal by the Food & Drug Administration to require premarket approval of analyte-specific reagents (ASRs) used in certain HIV genotype assays developed in-house by laboratories could potentially stifle growth of the "home brew" test market, say experts.

Since 1998, clinical labs that are CLIA-certified for high-complexity testing, along with medical device manufacturers, have been operating under FDA regulations that classify most ASRs as class I devices, exempt from premarket approval.

Draft guidance released by FDA last August, however, would reclassify ASRs used in genotyping systems to detect HIV mutations as class III devices requiring premarket approval before they may be distributed or sold. Previously, these systems, when used for treatment purposes (but not diagnosis), were thought to be class I.

Continued on p. 2

"Home Brew", *from page 1*

"This is clearly intended to discourage or prevent manufacturers of these ASRs from distributing them to clinical labs for incorporation in in-house developed assays," says David Sundwall, MD, president of the American Clinical Laboratory Association (Washington, DC).

The guidance, if adopted by FDA, could prove chilling not only for in-house HIV genotype tests, but also for other such "home brew" tests, believes Ronald Weiss, MD, professor of pathology and director of laboratories for ARUP Labs (Salt Lake City, UT). "This is a rapidly developing area. There are a lot of independent labs and academic medical center labs that are at the cutting edge of not only HIV testing but also other kinds of genetic testing. This could have a very negative impact in those areas."

ARUP is one of many labs nationwide that develop in-house assays, including those for genetic testing. These tests typically are used to identify individuals at high risk for a variety of heritable conditions, including metabolic and neurological disorders as well as certain cancers.

According to industry estimates, the market for molecular testing at clinical labs—most of it done with "home brews"—is expected to grow about 18% per year from $1.6 billion in 2001 to $4.2 billion in 2007.

Stricter Enforcement Urged

FDA has been batting around for more than a decade different ideas on how to regulate "home brews." In 1998, it opted to begin minimal oversight (*see sidebar*).

In 1999, the Clinical Laboratory Improvement Advisory Committee, which advises the U.S. Department of Health & Human Services on CLIA scientific and technical issues, recommended that the CLIA rules be augmented by a new specialty for genetic testing with specific requirements addressing such sensitive areas as quality control, confidentiality and informed consent.

In July 2000, the HHS Secretary's Advisory Committee on Genetic Testing (SACGT) recommended that all new genetic tests be reviewed by FDA before being used for clinical care or public health purposes. It also recommended that labs which develop a "home brew" test for their own use and without government money be subject to FDA oversight.

"Wrong Approach"

The August draft guidance on premarket notification for in vitro HIV drug resistance genotype assays is an attempt by FDA to begin responding to SACGT's recommendations, Sundwall believes. But both he and Weiss think that ranking ASRs used in these tests as class III medical devices is not medically justified, will stifle innovation and negatively affect the quality of treatment.

"There are only one or two FDA-approved HIV genotyping tests," notes Weiss. "If in-house genotype tests have to go through FDA premarket approval, any subsequent enhancements would have to go back through the approval process. Even if we get a more expedited process, we're still talking several months," which will not allow labs to keep up with the rapidly mutating HIV virus and will slow benefits to physicians and patients.

In comments to FDA, the American Clinical Laboratory Association notes that the scientific foundation of HIV drug resistance genotyping is constantly changing as new mutations of the virus are discovered, new drug resistance patterns are identified and existing technology becomes outdated. Clinical labs are at the forefront of these discoveries, ACLA says.

Ronald Weiss

David Sundwall

"There is no medical justification for this proposed change in how these tests are treated," says ACLA. "[We're] not aware of any medical concern about problems with the results of HIV drug resistance genotyping tests developed in-house using ASRs."

Any concerns about in-house lab testing are more appropriately addressed through the CLIA regulatory process, adds Sundwall, who is in discussions with officials in FDA's Center for Biologics Evaluation & Research over possible changes to the draft guidance.

"We're not saying there is no need for regulation of genetic testing, but we are saying this is not the right way to go about it," he notes.

Resources

- David Sundwall: 202-637-9466
- Ronald Weiss: 800-242-2787, x5188
- *FDA Draft Guidance on Pre-market Notifications for In Vitro HIV Drug Resistance Genotype Assays*, available online at *www. fda.gov/cber/gdlns/pmhivdrg.htm*

In The Past, FDA Toed Cautious Line On "Home Brew"

In the 1990s, FDA decided against "home brew" premarket approval on grounds this might adversely affect delivery of these testing services to patients who need them. Instead, it introduced minimal regulatory oversight.

A November 1998 final rule specified general controls for the tests' active ingredients, also known as analyte-specific reagents (ASRs). The controls covered registration and listing, quality systems and post-market reporting. ASR use was restricted to facilities CLIA-certified for high-complexity testing.

The 1998 rule also required that labs which develop their own test from an ASR must include, as part of the test results, a disclaimer that the test has not been approved by FDA.

Most ASRs are class I devices, exempt from premarket notification. Certain tests, like those used in blood banking, are class II, subject to special controls. Tests to diagnose contagious diseases, such as HIV or tuberculosis, or other tests to assure the safety of blood and blood products, are class III, subject to premarket approval.

HHS To Issue Guidance On Compliance Deadline Extensions

Under a congressional reprieve signed into law last Dec. 27, entities covered under the electronic data exchange provisions of HIPAA (Health Insurance Portability & Accountability Act) got an additional year—to Oct. 16, 2003—to comply with final standards governing electronic transactions and code sets. The original deadline was Oct. 16 of this year.

To take advantage of the extra time granted, healthcare providers, health plans and healthcare clearinghouses must file a request for an extension by this coming Oct. 15. The request must include a plan showing how the entity will achieve compliance by the 2003 deadline.

Those failing to meet the original deadline or to apply for an extension risk possible exclusion from Medicare. According to a list of frequently asked questions (FAQs) compiled by the Centers for Medicare & Medicaid Services, the agency will propose regulations explaining how this new exclusion authority will be used.

Wait For Official Word

At press time, the U.S. Department of Health & Human Services is telling affected entities to wait. It is not yet accepting extension requests. HHS says it will issue instructions on how to submit a compliance extension plan, and CMS plans to issue a model application for extension requests (supposedly by Mar. 31). Once the Department begins accepting requests, it will encourage affected entities to file them electronically.

To obtain an extension, the entity must submit a compliance budget, schedule, work plan and implementation strategy. HHS also wants providers and payers to indicate whether they will be using a contractor or vendor, to assess compliance problems and to report their timeframe for testing.

The government does not have to approve the compliance extension plans, HHS notes in a series of FAQs: "Submission of an extension plan is sufficient to secure the one-year extension."

A sample of the plans will be given to the National Committee on Vital & Health Statistics to review for common compliance problems, then recommend solutions. The plans also will be available to the public under the Freedom of Information Act, HHS says. Any confidential or proprietary information will be redacted prior to release to the committee or the public.

HIPAA Electronic Data Exchange Standards: *What's Required?*

Transactions Affected

The standards specified in the Aug. 17, 2000 final rule apply to certain types of business transactions, including the following administrative and financial functions:

- Health claims and equivalent encounter information.
- Enrollment and disenrollment in a health plan.
- Eligibility for a health plan.
- Payment and remittance advice.
- Health plan premium payments.
- Health claim status.
- Referral certification and authorization.
- Coordination of benefits.

Transaction Standards, Code Sets

Covered entities must use the electronic transaction standards developed by the American National Standards Institute (ANSI ASC X12N standards, version 4010) as well as specific code sets for medical data:

- ICD-9-CM codes for diagnosis and treatment.
- HCPCS (HCFA Common Procedure Coding System) and CPT-4 (Current Procedural Terminology, 4th Edition) codes for physician, lab, diagnostic and other health-related services.

Local codes (HCPCS Level III) will be eliminated after Dec. 31, 2003. Users needing codes will have to apply directly to the appropriate organizations for national codes.

Data Storage, Retrieval

While the standards apply only to electronic transactions, any covered entity that performs the business functions listed above—whether electronically, on paper or by phone—must be able to support the electronic standards for that transaction. It may do so either directly or through a clearinghouse.

Because the standards apply only to electronic data interchange (EDI)—when data are transmitted electronically between providers and health plans as part of a standard transaction—data may be stored in any format as long as it can be translated into the standard transaction when required.

Medicare Requirement

Separately, Congress late last year enacted a requirement that all Medicare claims for services and supplies under Parts A and B be submitted electronically by Oct. 16, 2003, with some exceptions for small providers.

Resources

- *Federal Register*, Aug. 17, '00. Online at *www.access.gpo.gov/su_docs*
- HHS: FAQs, *http://aspe.hhs.gov/admnsimp*
- Implementation guides for electronic data standards: available at no cost from the Washington Publishing Company at *www.wpc-edi.com/hipaa/HIPAA_40.asp*

HIPAA, *from page 1*

that they have received the provider's Notice of Privacy Practices. Failure to obtain the acknowledgement, however, would not prohibit doctors and other providers from treating patients.

This change, says HHS Secretary Tommy Thompson, would ensure that patients can consider a provider's privacy policies before making healthcare decisions, while eliminating a major barrier to patients' access to care.

No changes are proposed for provisions in the final rule that give patients the right to inspect, copy and amend their medical records.

Reprieve For Business Associates

Currently, healthcare organizations must ensure that their business associates—including vendors, billing firms and consultants, among others—comply with federal privacy rule requirements. HHS would give providers and other covered entities up to an additional year to modify existing business associate contracts for this purpose.

Thompson says this added time should ease the burden of renegotiating contracts all at once. As a further aid, model provisions are proposed to help guide contract re-writes.

Most covered entities have until Apr. 14, 2003, to comply with the patient privacy rule; small health plans have an additional year.

Initial Reaction

"This does make it easier for providers to implement HIPAA by recognizing some of the practical difficulties with consents and research trials," says John Steiner, corporate compliance officer for the Cleveland Clinic Foundation (Cleveland, OH). "It's helpful to have the additional year to include the business associates provisions."

Peter Kazon, an attorney with Mintz Levin Cohn Ferris Glovsky & Popeo, PC (Washington, DC), calls the revisions "logical and reasonable" and thinks they will go a long way toward easing the compliance burden for providers. Laboratories in particular may benefit since many do not have "direct treatment relationships" with patients and thus might not even be subject to the "good faith effort" requirement on privacy notices, he says.

Labs should also benefit from other provisions that reduce what type of information is subject to use/disclosure tracking, Kazon adds. "One problem labs have faced under HIPAA has been the difficulty of accounting for different types of lawful disclosures. Now, neither TPO nor activities subject to an authorization would be subject to an accounting. This should make the tracking piece easier."

HIPAA Medical Privacy Rule: *Key Proposed Changes At A Glance*

- Eliminate prior written consent for use/disclosure of personal protected health information, but provider has option to obtain it.
- Require a "good faith" effort to inform patients of their privacy rights by covered entities that have a direct treatment relationship with the patient.
- Exempt authorized disclosures from "minimum necessary" and tracking requirements.
- Grant an extra year to providers to modify business associate contracts.
- Require prior authorization for "marketing" communications.
- Defer to state and other applicable law on parental access to their child's medical records.
- Simplify research use of protected health information.

Other Changes Sought

❖ **Maintain the "minimum necessary" rule while allowing treatment-related conversations**. Under the final rule, covered entities must make reasonable efforts to limit the use and disclosure of, and requests for, protected health information to the minimum necessary to accomplish the intended purpose, including during oral communications. The change proposed by HHS would keep the "minimum necessary" standard, but make clear that doctors may discuss a patient's treatment with other doctors and healthcare professionals involved in the patient's care without fear that their conversations could violate the rule.

❖ **Restrict use of medical records for marketing**. Based on consumer concerns that marketing provisions in the final rule were insufficient to protect patient privacy, the rule would be modified to explicitly require pharmacies, health plans and other covered entities to first obtain the individual's specific authorization before sending him/her any marketing materials. Doctors and other covered entities may still communicate freely with patients about treatment and other health information.

❖ **Establish a single consent for research**. HHS would eliminate the need for researchers to use multiple consent forms—one for informed consent to the research and one or more related to information privacy rights. It would also simplify other provisions so that the rule more closely follows requirements of the "Common Rule" which governs federally funded research.

❖ **Clarify parental rights to access a child's medical records**. HHS clarifies that state law governs this. Where state law is silent or unclear, a provider would have discretion to grant or deny a parent's access to such records, including information on abortions or treatment for mental illness or sexually transmitted disease.

❖ **Allow disclosure of enrollment/disenrollment information**. HHS clarifies that a group health plan or other issuer of health insurance coverage may disclose information about an individual's enrollment or disenrollment to a plan sponsor without amending plan documents.

Resources

- John Steiner: 216-444-1709
- Peter Kazon: 202-661-8739
- *Federal Register*, Mar. 27, '01. Online at *www.access.gpo.gov/su_docs*

COMPLIANCE PERSPECTIVES

A Practical Guide To Benchmarking Your Compliance Program
Tips & Strategies For Evaluation, Auditing

H. Guy Collier is an attorney with McDermott, Will & Emery in Washington, DC

Over the past five years, virtually every provider organization in the country has implemented a corporate compliance program, focused initially on key areas of risk under state and federal fraud & abuse laws. Clearly, most of these programs touch all the bases required under the Federal Sentencing Guidelines for Organizations. What's less clear is how well these programs actually function to prevent, as well as detect, violations of law.

For a number of very practical reasons, providers and other healthcare entities are well advised to evaluate the actual operation of their compliance program periodically

For a number of very practical reasons, providers and other healthcare entities are well advised to evaluate the actual operation of their compliance program periodically. To the extent possible, this should measure a program's effectiveness using articulated standards, or benchmarks. This article sets forth a practical approach to such a periodic evaluation, or benchmarking.

What Are The Benchmarks?

The most obvious benchmark for compliance program assessment is the compliance plan itself. When your organization adopted its plan, what were the key objectives? Was the plan designed to extend to all parts of the organization, cover all employees and address compliance with all applicable federal and state laws? Was it intended to foster a "top-down" culture of compliance throughout the organization?

More specifically, when your organization initiated its compliance program, there was likely a detailed implementation plan addressing the roll-out to employees, priorities for training and education, a schedule for periodic audits and the like. Has that original plan been updated, and have the action items set forth initially been re-prioritized after the first few years of experience? In short, does the implementation plan reflect the current reality of how your compliance program operates on a day-to-day basis?

Additional benchmarks for measuring program effectiveness can be found in the various compliance guidance documents issued by the HHS Office of Inspector General. Although your organization, and even your legal counsel and consultants, may not agree in all respects with this "guidance," the views of federal regulators charged with enforcing the fraud & abuse laws are nevertheless an important benchmark. This applies with equal force to the pronouncements of other state and federal regulators with jurisdiction over your operations.

Finally, what are the "best practices" across the healthcare industry regarding specific aspects of compliance program operation? In short, how does your program compare to those of other, similar organizations? Formal/informal networking and professional education through organizations such as the Health Care Compliance Association and the American Health Lawyers Association will often provide useful feedback on this question.

Why Evaluate Your Program?

Compliance programs essentially have two goals, one prospective and one retrospective. First, in the terms of Federal Sentencing Guidelines, is your program effective in prospectively preventing violations of law? Second, is it effective in retrospectively detecting violations that may have occurred? Is the general and the targeted training sufficiently broad-based and detailed to prevent both inadvertent and intentional violations of law? Similarly, are baseline and targeted audits sufficiently frequent and detailed to

identify violations that may have occurred?

Performing a detailed evaluation of your compliance program may confer another very real benefit on your organization. Over the past year, the OIG has shown a willingness to take a more flexible approach to the imposition of Corporate Integrity Agreements (also referred to by the OIG as "Institutional Integrity Agreements") when settling federal False Claims Act allegations. Previously, the OIG had routinely insisted on the imposition of a CIA, entailing a set of onerous audit and training requirements extending for 3-5 years. In response to intense industry pressure, and following discussions with industry representatives, the OIG has softened this position.

Now, when a provider or other organization can demonstrate to the OIG's satisfaction that it has a sufficiently detailed, comprehensive and viable compliance program, the government may accept the provider's agreement to file annual compliance "certifications" in lieu of an actual CIA. This benefit cannot be overstated. For example, rather than facing the prospect of retaining an Independent Review Organization to perform detailed annual audits, at substantial time and expense, the provider may now be permitted by the OIG simply to certify that it has conducted appropriate internal auditing and training to address the substantive issue(s) that gave rise to the False Claims Act allegations.

Thus, one of the clear benefits of a benchmarking exercise is to maximize the likelihood that the OIG will deem a compliance program to be sufficiently comprehensive to permit the waiver of the CIA requirement.

Though provider organizations often have internal audit functions and well-trained compliance staff to permit an internal review, you should ask how candid, thorough, and objective an internal review will be

Who Should Evaluate Your Program?

There are two fundamental considerations here: inside or outside review, and legal or non-legal review.

Though provider organizations often have internal audit functions and well-trained compliance staff to permit an internal review, you should ask how candid, thorough, and objective an internal review will be. Because the key to an effective evaluation will be true objectivity, there should be a strong presumption that the review will be conducted by personnel from outside the organization.

With respect to legal vs. non-legal assistance, the key issue is maintenance of confidentiality under the attorney-client privilege. Depending on the law regarding privilege in a given state, it is possible that inside or outside counsel could retain non-legal consultants to perform the evaluation and attempt to preserve privilege. It is certainly clearer, however, that outside counsel retained specifically to conduct the evaluation will maximize the likelihood that the privilege can be maintained, permitting a full and frank discussion of all areas of concern.

How Do You Perform A Meaningful Evaluation?

There are essentially two major components to any compliance program benchmarking: a review of pertinent documents and interviews of key staff.

With respect to documents, it is obvious that the code of conduct, the compliance plan itself, and accompanying policies and procedures will be the starting point. Minutes of the organization's internal compliance committee or subcommittee, as well as those of the board-level committee with authority over the compliance process, should be reviewed.

Documents regarding the organization's hotline—call activity, intake reports, disposition forms and the like—should also be reviewed to assess how well this reporting function actually works. Finally, documentation pertinent to the organization's screening process for excluded and debarred persons and internal disciplinary mechanisms should be reviewed.

Key personnel whose functions touch the compliance process should be interviewed. They will include, for example, the chief compliance officer, chairperson of the internal compliance committee, chief legal officer, chief financial officer, other finance staff with significant responsibilities for billing and coding, chief information officer (with respect to HIPAA privacy rule concerns), director of research and key institutional review board personnel (if applicable), internal audit staff and the hotline coordinator. Other miscellaneous personnel with key regulatory functions, such as radiation safety, environmental protection and occupational safety, may be included as well.

What Substantive & Procedural Areas Should be Covered?

The key areas to be covered by a benchmarking exercise have been highlighted above. They include the review, updating and re-prioritization of the compliance plan

itself; educational efforts; audit activities; hotline functioning and results; internal disciplinary mechanisms and results; and the effectiveness of screening for persons excluded or debarred from participating in federal healthcare programs.

Also, internal reporting relationships should be examined closely, both in theory and in practice. To whom does the chief compliance officer report? Does he/she have ready access to the chief executive officer, board of directors or appropriate board committee or subcommittee? Is there periodic reporting on compliance activities to the board or appropriate committee or subcommittee? Is there an appropriate document retention policy, and is it generally adhered to?

Finally, there should be an assessment of the adequacy and organization of the overall documentation of the program.

For example, your organization may be doing a terrific job in training, auditing and other required compliance activities, but be failing to document these findings adequately. In the event of an external governmental investigation, full documentation will be critical to demonstrate to the OIG the comprehensive nature and actual working of your program. All the documents referenced above should be maintained for appropriate periods, be well organized, and be centrally located for ease of reference.

What Is The "Deliverable" Or Work Product?

At the conclusion of the benchmarking exercise, a privileged report should be made to the chief compliance officer and to internal legal counsel. It should describe fully the scope of the evaluation and the process employed. Interviews should be summarized. Most importantly, it should contain targeted recommendations for remedial action in areas found to be deficient. Prior to issuance of this final report, a draft should be reviewed by the chief compliance officer and by internal counsel for any factual inaccuracies.

If your organization is "on the radar screen" of regulatory agencies due to previous investigations or enforcement activities, it may be advisable to benchmark your program more frequently. In general, however, most organizations should consider some form of evaluation every 2-3 years

A final step in the process will be the presentation of the report to senior management and, in all likelihood, the board committee or subcommittee with jurisdiction over the compliance function in the organization. This is an important step to ensure that the board is meeting its fiduciary duty by being fully informed about the adequacy, and shortcomings, of the organization's compliance efforts.

Practical Considerations

A successful benchmarking exercise should be organized, simple yet thorough, objective and cost-effective. Utilizing experienced outside counsel or consultants with the professional judgment to know what to ask for, what to review and the appropriate level of detail will be a critical success factor.

At the outset, a realistic timeline should be established. For most organizations, a good rule of thumb is that the process should take roughly 6-8 weeks from the receipt of all pertinent documents for review. Professional fees will obviously vary, depending on the size and complexity of your organization. If the effort is well organized and carefully targeted, however, professional fees should not be extensive.

Similarly, the frequency of this type of benchmarking will vary, depending on the size and complexity of your organization, particular risk areas and previous experience with regulatory agencies. Providers with skilled nursing care, home care, rehabilitation services, psychiatric services and other substantive areas of historic concern to regulatory agencies may want to evaluate their compliance efforts more frequently. Providers with exceptionally large Medicare and Medicaid patient loads may choose to do so as well.

Finally, if your organization is "on the radar screen" of regulatory agencies due to previous investigations or enforcement activities, it may be advisable to benchmark your program more frequently. In general, however, most organizations should consider some form of evaluation every 2-3 years.

Conclusion

If structured correctly and performed by experienced personnel, compliance program benchmarking will be cost-effective, timely and concise. It offers significant benefits to your organization.

In general, it should indicate whether or not your compliance program is actually functioning as intended and is effective in preventing as well as detecting violations of law. In particular, it should indicate whether your program is sufficiently viable and comprehensive to avoid the imposition of a burdensome Corporate Integrity Agreement if your organization has the misfortune to be targeted by a False Claims Act lawsuit or other enforcement action.

Mr. Collier can be reached at McDermott, Will & Emery, 600 13th St., NW, Washington, DC 20005-3096. Tel: 202-756-8009. E-mail: gcollier@mwe.com

California's Phlebotomy Certification Law Touted As Model
Push Is On For Uniform Standards, Improved Training

While there are no federal standards for phlebotomy training and certification, several states reportedly are considering following the lead of California, which in 1999 enacted legislation that greatly expands education and training requirements for phlebotomists employed in clinical laboratories.

California's law was passed in response to an incident in which a SmithKline phlebotomist allegedly reused needles when drawing blood specimens (*GCR, May '99, p. 1*). It could become a model for other states, says Sheila Clover, BS CPT. Clover is executive director of Phlebotomy West, a not-for-profit advocacy group based in Brentwood, CA, that is working to raise phlebotomy standards and improve training.

"There are a few states we know of that are considering similar legislation," says Clover, who is also a phlebotomy instructor at Ohlone College in Fremont. "We've heard from New York and Florida." They're waiting to see what happens as California implements its law, she adds.

No Universal Standards

While several organizations—including the American Society of Clinical Pathologists, the National Credentialing Association and the National Phlebotomy Association—offer training and certification programs, most states do not require certification, relying instead on labs to set the standards for phlebotomists.

A few states have developed guidelines for phlebotomist training, but only California and Louisiana require phlebotomists to be certified, says Clover. Tennessee is currently working on standardizing the scope of practice for phlebotomists.

This lack of universal training and education standards is dangerous, she believes, noting that in some instances phlebotomists can begin drawing blood with as little as 10 hours of training. A shortage of qualified lab personnel also means that many labs are hiring personnel to work as phlebotomists with scant training and experience.

"We've created a situation in which we are accepting less qualified personnel because we have not clearly and judiciously provided national guidelines for experienced and knowledgeable phlebotomy personnel," Clover contends. "This puts patients at risk."

Lobbying For Federal Standards

As individual states consider adopting their own standards for phlebotomists, a coalition of phlebotomy and certification groups—led by Phlebotomy West—is lobbying Congress for national standards.

Clover met this month with staff of Rep. Pete Stark (D-CA) to discuss what might be included in such legislation. While Phlebotomy West believes California's regulatory plan to implement the phlebotomist certification law can serve as a model for national standards, there are certain requirements it would like to see modified. For example, says Clover, experienced phlebotomists should not have to return to school to obtain 20 hours of classroom training, but should be allowed to obtain the didactic training through continuing education or by passing a national certification exam.

Phlebotomy West also believes the number of skin—or capillary—punctures required for certification are too high. The California proposal calls for 50 venipunctures and 25 skin punctures prior to certification.

"In California, phlebotomists are not allowed to do point-of-care testing, and that's where you're going to get most of your skin punctures," Clover explains. "Some of the smaller hospitals don't do 25 skin punctures in an entire year, so it's unlikely they would have enough for several students to do that many."

Sheila Clover
Phlebotomy West

Richard Nicholson
Westcliff Medical Labs

In fact, she adds, the California Laboratory Technology Advisory Committee, which advises the state on lab issues, recommended that phlebotomy students only be required to perform five skin punctures prior to certification.

Competency A Concern For Labs

Phlebotomist competency is a growing priority for laboratories, many of which are facing a shortage of qualified phlebotomists. Richard Nicholson, president and CEO of Westcliff Medical Laboratories (Newport Beach), which operates 40 patient service centers in southern California, welcomes efforts to raise phlebotomy standards and improve training.

"I think [the California proposal] will benefit both the lab industry and phlebotomists. It will raise the status of phlebotomists, and I think they deserve that. It also will likely attract more people to the field because of the increased status and certification involved."

Westcliff employs about 50 phlebotomists and requires new, inexperienced hires to undergo 80 hours of practical and didactic training and pass an exam before being certified to work in the lab. Phlebotomists who are certified when hired by Westcliff go through an observation

Proposed Phlebotomy Certification Requirements

Phlebotomists in California would have to undergo 40 hours each of didactic (classroom) and practical training, perform 50 supervised punctures and pass a state-approved certification exam in order to be certified under regulations expected to take effect this summer.

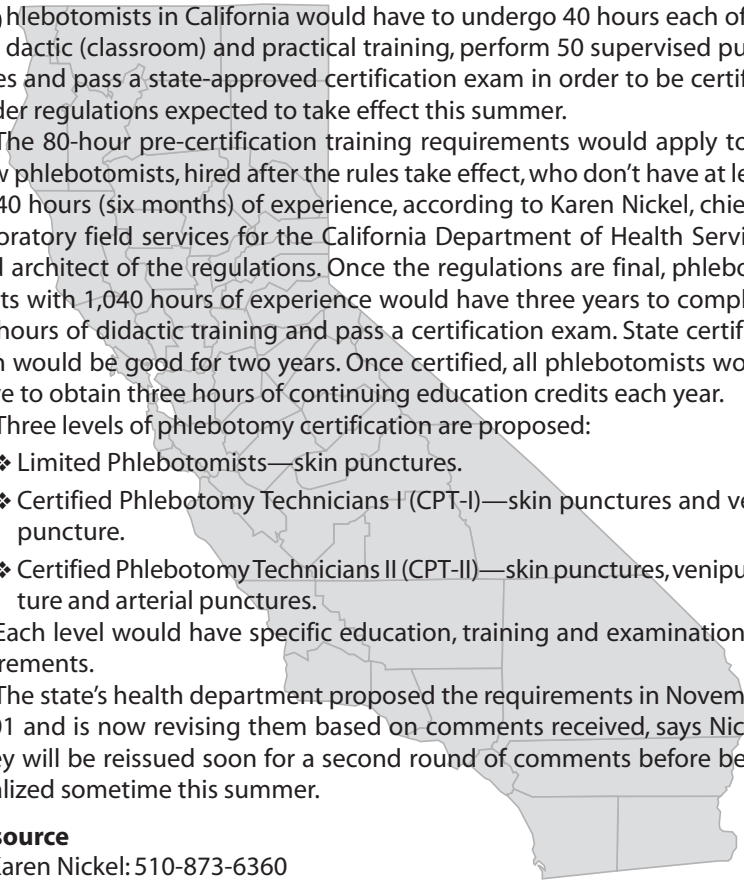
The 80-hour pre-certification training requirements would apply to all new phlebotomists, hired after the rules take effect, who don't have at least 1,040 hours (six months) of experience, according to Karen Nickel, chief of laboratory field services for the California Department of Health Services and architect of the regulations. Once the regulations are final, phlebotomists with 1,040 hours of experience would have three years to complete 20 hours of didactic training and pass a certification exam. State certification would be good for two years. Once certified, all phlebotomists would have to obtain three hours of continuing education credits each year.

Three levels of phlebotomy certification are proposed:

- Limited Phlebotomists—skin punctures.
- Certified Phlebotomy Technicians I (CPT-I)—skin punctures and venipuncture.
- Certified Phlebotomy Technicians II (CPT-II)—skin punctures, venipuncture and arterial punctures.

Each level would have specific education, training and examination requirements.

The state's health department proposed the requirements in November 2001 and is now revising them based on comments received, says Nickel. They will be reissued soon for a second round of comments before being finalized sometime this summer.



Resource

- Karen Nickel: 510-873-6360

period during which they perform different types of venipuncture on different patients under the supervision of a senior phlebotomist.

Nicholson hopes Westcliff can serve as a certified phlebotomy training site once the California standards are finalized. "Labs and hospitals should help the state provide this training, so it does not put a burden on the taxpayer. I hope we'll be able to provide training, submit information to the state and have them approve it."

While Nicholson supports efforts to improve phlebotomist competency, he thinks standards and certification requirements are best addressed by individual states. "It would be difficult to set national standards for everyone because there are labs in rural states that may not get the volume needed for the level of training required. I think it should be done on a state-by-state basis."

Resources

- Sheila Clover: 925-240-0770
- Richard Nicholson: 949-646-0216

FTC Takes Lead Antitrust Role For Healthcare Industry

Under a new agreement between the U.S. Department of Justice and the Federal Trade Commission, the FTC will take primary responsibility for civil enforcement of federal antitrust laws in the healthcare, pharmaceutical and biotech industries.

For decades, the two agencies have shared enforcement authority under the federal antitrust laws, but a Mar. 5 Memorandum of Agreement (MOA) streamlines the clearance process for antitrust investigations by allocating civil enforcement to FTC.

Nothing in the MOA alters the jurisdiction or authority of either agency since this would require statutory changes. But the revised clearance system means, in effect, that Justice will decline to pursue civil enforcement actions in the healthcare arena, except in unusual circumstances.

"This agreement will improve our law enforcement efforts," said Charles James, assistant attorney general in charge of Justice's antitrust division. "Allocating industry sectors in a more rational manner will enable the department to investigate more efficiently possible anti-competitive conduct affecting consumers and will provide greater certainty to the business community, all of which is good for consumers."

The agreement is both good and bad for healthcare providers, thinks attorney Robert Enders with Foley & Lardner (Los Angeles, CA).

"The good news is that the MOA presumably will result in more efficient use of limited government antitrust resources [and should] result in a reduction in the waiting time involved in the clearance process, offer predictability concerning which agency will investigate and afford clarity as to which agency one should submit antitrust proposals or complaints."

The downside Enders sees is that businesses subject to FTC oversight are likely to incur multiple reviews, more policy-oriented scrutiny and the concomitant greater costs in responding to FTC investigations and civil enforcement actions. "The often more deliberate and more comprehensive evaluation of a matter subject to FTC investigation or litigation will mean that healthcare businesses will likely incur greater time delay and expense."

OIG Revises Fraud & Abuse Enforcement Powers
More Leeway Allowed In Setting EMTALA Sanctions

The HHS Office of Inspector General has announced a host of revisions to its enforcement powers, including expanding its authority in determining sanctions for violations of the Emergency Medical Treatment & Active Labor Act (EMTALA) and modifying what is considered an aggravating factor in extending a provider's exclusion from Medicare.

In a final rule in the Mar. 18 *Federal Register*, the OIG also made a number of changes and technical corrections to its policies on imposing penalties for healthcare fraud and abuse. Some of these were part of a rule proposed on Oct. 20, 2000.

EMTALA Sanctions

According to the final rule, when determining sanctions under EMTALA, the OIG and administrative law judges (ALJs) may consider not only the alleged violation, but also other instances when the provider failed to furnish appropriate medical care for patients coming to a hospital's emergency department. The proposed rule had permitted only consideration of other "offenses," not other "instances."

The OIG decided not to use the term "offenses" because it believes the term "restricts consideration of incidents that are relevant to provider culpability, but have not resulted in convictions or judicial or administrative decisions.

"Because these prior similar incidents generally become known during the administrative appeals process, we believe the term 'offense' is too limiting, and the revision … will allow the OIG and the ALJs a broader range of conduct and options to consider in their determinations," the OIG said.

Financial Loss Threshold

In other changes, the OIG:

- Increased from $1,500 to $5,000 the financial loss considered to be an aggravating factor in determining when to lengthen a period of exclusion from federal healthcare programs. The OIG also will consider as an aggravating factor—and a basis for lengthening an exclusion period—acts "that caused, or reasonably could have been expected to cause, a financial loss" to a government healthcare program of $5,000 or more. This modifies the original proposal to allow "intended loss" to be considered as an aggravating factor.
- Modified the definition of "item or service" to clarify that, in addition to itemized claims or cost reports, the term includes any item or service reimbursed through any healthcare payment mechanism, such as prospective payment.
- Refrained from making proposed changes to the safe harbor for discounts. The OIG says it is evaluating comments and will address specific changes at a future date through separate rulemaking.

The OIG decided against going ahead with several previously proposed changes, including implementation of a policy that there would be no time limit on the OIG's imposition of a program exclusion.

Resource

- *Federal Register*, Mar. 18, '02. Available online at *www.access.gpo.gov/su_docs*

APC Rates Revised For Hospital Outpatient Departments

The Centers for Medicare & Medicaid Services has promulgated a revised final rule establishing new payment rates, effective Apr. 1, 2002, to hospitals for services performed in outpatient departments.

The rule, released Mar. 1, 2002, corrects technical errors in the final payment rule issued last Nov. 30. For virtually every service, it sets payment rates equal to or slightly higher than the November rule.

The only services that will see a significant change are 13 Ambulatory Payment Classifications (APCs) where errors had been found Among them are PET scans, certain electrophysiological evaluations and placement of certain intracoronary stents.

Pass-Throughs Corrected

The Nov. 30 rule had called for a pro rata reduction in pass-through payments for new drugs and devices to bring Medicare expenditures within the limit required by law. After it was published, CMS discovered errors in the assignment of certain pass-through devices to several APCs, causing the payments for some APCs to be set inaccurately.

The Mar. 1 rule revises the estimate of total transitional pass-through payments in 2002 for services furnished on or after Apr. 1. As a result, hospitals will get slightly higher payments for transitional pass-through items than had been projected in the Nov. 30 rule.

For more information, see the Mar. 1 *Federal Register*, available online at *www.access.gpo.gov/su_docs*.

New Medicare Charts Explain Proper Use Of ABN Modifiers

New charts illustrating how to use modifiers on Medicare claims in conjunction with Advance Beneficiary Notices (ABNs) are now available online at the Centers for Medicare & Medicaid Services' ABN Quick Reference Guide (*www.hcfa.gov/medlearn/refabn.htm*).

ABNs alert beneficiaries that Medicare probably will not pay for a certain Part B item or service. By signing the ABN, the beneficiary agrees to be responsible for payment if Medicare denies the claim.

GA Modifier

Use this on a claim you think will be denied because the item or service does not meet Medicare standards for medically necessary care.

This modifier helps protect the provider/supplier financially. For example, if a provider uses the GA modifier and Medicare denies the claim, the beneficiary (who has either signed the ABN or refused to sign but has demanded the service) will be fully liable to pay the provider for the service, either personally or through insurance.

However, if a provider fails to use the GA modifier in situations where the provider expects a medical necessity denial and the claim is in fact denied, the provider—not the beneficiary—will be held liable and may not collect payment from the beneficiary.

Failure to use the GA modifier on a consistent basis could raise concerns about abusive billing practices, warns CMS.

GY Modifier

Use this on a claim when the item or service is excluded by law from coverage or does not meet the definition of any Medicare benefit. Examples include routine physicals, lab tests in the absence of signs or symptoms, hearing aids, services in a foreign country, services to a family member and surgery by a physician not legally authorized to perform surgery in the state.

If you don't use the GY modifier, the claim will be reviewed by Medicare and probably will be denied; however, the review may take longer than if you had used the GY modifier.

GZ Modifier

Use of this modifier is optional on a claim when you expect the item or service will be denied as not reasonable and necessary and there is no signed ABN on file. It typically would be used when a lab gets a specimen from a physician but cannot get an ABN signed.

While using this modifier will not affect Medicare review of the claim, the modifier is provided, CMS says, for physicians and suppliers who want to submit a claim to Medicare, know that an ABN should have been signed but was not, and do not want any risk of alleged fraud or abuse for claiming services that are not medically necessary.

"By notifying Medicare, by the GZ modifier, that you expect Medicare will not cover the service, you can greatly reduce the risk of a mistaken allegation of fraud or abuse," the agency notes.

Medicare has approved standard formats for a general-use ABN and a lab-specific ABN. Providers may start introducing them now. CMS is expected to require their use later this year after instructions have been finalized and sent to carriers and intermediaries

Medicare Secondary Payer Timeline Eased For Hospital Reference Labs

In a policy change effective Mar. 31, 2002, hospital laboratories performing testing on referral must collect or update Medicare secondary payer (MSP) information on beneficiaries once every 90 days, instead of once every 60 days.

The new policy was set forth by the Centers for Medicare & Medicaid Services in a recent program memorandum to carriers and fiscal intermediaries (Transmittal A-02-021, Mar. 22, 2002). It also changes the MSP data collection cycle for recurring outpatient services from once every 30 days to once every 90 days.

Under MSP rules, providers must determine whether Medicare is the primary payer or whether other insurers should be billed first. Other health insurance that may be responsible to pay first includes group health plans, no-fault insurance, liability insurance and workers' compensation.

Medicare officials say the new 90-day cycle is intended to lessen paperwork and administrative burdens on hospitals and patients. Previously, for hospital reference lab work, MSP information had to be collected or updated once every 60 days, but prior to the first of this year, each time an outreach test was run on a beneficiary.

In an earlier, separate relaxation of MSP policy, CMS stipulated that the MSP questionnaire had to be completed for lab outpatient and non-patient claims only at outpatient registration but before claims submission, instead of at every encounter with the beneficiary.

Transmittal A-02-021, which implements the new 90-day cycle policy, is posted online at *www.hcfa.gov/pubforms/transmit/memos/comm._date_dsc.htm.*

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

HCA Convictions Up-Ended: A federal appeals court on Mar. 22 overturned fraud convictions against two former executives of HCA-The Healthcare Company (formerly Columbia HCA) on grounds the government failed to prove that they had knowingly and willingly made false statements in cost reports to Medicare.

Jay Jarrell, president of HCA's southwest Florida division, and Robert Whiteside, director of reimbursement, were convicted in 1998 on six of seven counts of Medicare fraud. Jarrell was sentenced to 33 months in prison and $1.7 million in fines and restitution; Whiteside got a two-year sentence.

At the core of the convictions just overturned were allegations that the two men had defrauded Medicare by inflating the amount of interest expense to be reimbursed by the program. But the appeals court found that in light of experts' conflicting views on applicable Medicare policy, it was not unreasonable for the two to conclude that this expense was reimbursable. "The case confirmed that in the cost-reporting process, the applicable rules and regulations are frequently unclear, ambiguous and subject to conflicting interpretations," HCA lawyer Pat Loughlin said in a written statement.

HCA has already paid more than $800 million to settle criminal fraud charges and some civil charges. The company still faces additional civil fraud charges by the Justice Department and by private attorneys representing whistleblowers who are former HCA employees.

Stark II/Phase II Debut: Look for this by August, said an official with the HHS Office of Inspector General. James Kopf, director of the program investigations branch, recently disclosed that the Centers for Medicare & Medicaid Services should have this last leg of the physician self-referral rule ready for a 90-day public comment period at the end of this summer. Phase II is expected to deal with physician recruitment and retention issues, financial ownership concerns and exceptions that labs rely on, such as payments to physicians for services and office space/equipment rental. It also will address comments on Phase I of the Stark II final rule. That rule took effect Jan. 4, 2002, though the "set in advance" compensation requirement has been delayed till Jan. 6, 2003 (*GCR, Jan. '02, p. 2*).

Exclusions Extra: The Centers for Medicare & Medicaid Services is developing a new mechanism to ensure that providers excluded from federal healthcare programs don't get reimbursement. The Medicare Exclusion Database (MED) will give users access to the names of organizations and individuals not eligible for Medicare reimbursement because they have been barred from the program. For more information, see the Feb. 26 *Federal Register* or contact Angela Brice-Smith, 410-786-4340.

MD Fraud Conviction: A federal jury recently convicted Felix Vasquez-Ruiz, MD, on 27 counts of healthcare and mail fraud. He was found guilty of performing medically unnecessary nerve conduction tests. Evidence at the trial showed that the doctor defrauded various private medical insurers of at least $2.5 million by submitting false bills from 1996 through 1999. Vasquez-Ruiz faces a maximum of 15 years in prison and fines of $250,000 for each of the 27 counts. Sentencing is scheduled for June 27.

G-2 Compliance Report (ISSN 1524-0304). © 2002 Washington G-2 Reports, 1111 14th St, NW, Suite 500, Washington DC 20005-5663.

Tel: (202) 789-1034. Fax: (202) 289-4062. Order Line: (212) 629-3679. Website: www.g2reports.com.