FDA warning letter signals move to tighten oversight

A warning letter sent to a Johns Hopkins University researcher may be a sign that the government is tightening a loophole that has exempted some research from federal oversight, according to Adil Shamoo, PhD, professor at the University of Maryland, in Baltimore. Shamoo says it could mean that hundreds of research studies operating outside the boundaries of federal oversight may now need to apply for Investigational New Drug (IND) applications—and could be subject to FDA review.

The warning letter, sent to Alkis Togias, MD, on March 31, was written in response to a study in which the drug hexamethonium bromide was used to induce asthma symptoms in a study at Johns Hopkins Asthma and Allergy Center in Baltimore. Ellen Roche, 24, a healthy study volunteer, died after inhaling the substance, which damaged her lungs. Her family later reached a settlement agreement with the university.

In the letter, FDA officials conclude that the Hopkins’ researcher violated the law by failing to apply for an IND and failing to follow the regulations that govern those.

Forerunners in accreditation: Meet two AAHRPP-approved institutions

In May, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) awarded two organizations with full accreditation status.

The University of Iowa, in Iowa City, and the Western Institutional Review Board in Olympia, WA, became the first nongovernmental research organizations in the nation to be accredited. Representatives from both organizations said their leaders are strong supporters of voluntary accreditation, which is why they moved so quickly to begin the process.

At the time these organizations chose AAHRPP, it was the only organization offering accreditation to private research organizations. Since that time, the National Committee for Quality Assurance has partnered with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to form an accreditation program. (See related story on p. 5.)

“We were eager to have our program reviewed,” says Trish > p. 3
applications. “You failed to submit an IND for the conduct of a clinical investigation with an investigational new drug as required by 21 CFR 312.20,” states the letter. “A clinical investigation is defined as ‘any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects . . . except for the use of a marketed drug in the course of medical practice.’ You conducted a study in which you administered a drug not approved for marketing (hexamethonium bromide) to human subjects, and accordingly, conducted a clinical investigation.”

In the works
According to Robert Temple, MD, associate director for medical policy at the Center for Drug Evaluation and Research, a division of the FDA in Rockville, MD, the agency currently has an internal group exploring the question of when, under FDA regulations, an IND is necessary and how the regulations apply to the range of situations in which investigators use “off-the-shelf” chemicals. Though the FDA warning letter does not constitute a change in the rules, the agency wants to clarify the guidelines for when investigators need to apply for an IND in cases in which they are conducting clinical investigations using drugs that are not lawfully marketed, he says.

If a lawfully marketed drug is used in the course of medical practice, an IND is not needed. However, if a marketed drug is used in a clinical investigation, an IND may be required, although there are a number of exemptions. If the clinical investigation meets all the criteria for an exemption under the regulations detailed in 21 CFR 312.2(b), then you’re not required to submit an IND. For example, “If you’re using a marketed drug in an investigational setting—and the use does not increase risk to the subject—you may not need to submit for an IND.”

The situation is different when a clinical investigation involves the use of a substance or substances that are not lawfully marketed drugs. Although most investigators realize they must submit an IND for a clinical investigation involving a drug with the potential for commercial development, they have not consistently realized that the use of “shelf chemicals” (e.g., the hexamethonium used in the Togias case) for physiology studies can be subject to IND requirements. “We know there are people who use shelf chemicals for tests who are not getting INDs, and we were forcibly reminded of this from the Togias case,” says Temple.

Widening oversight
Many sites operate without government regulation, which is something Shamoo says is a problem he has been working with the government to address. He says the government has taken a step toward addressing that issue with this letter, which appears to broaden the FDA’s jurisdiction.

If this is the case, says Shamoo, “there will be hundreds of experiments that have to apply for an IND.” Temple doesn’t have real numbers but says Shamoo’s estimate could be accurate.

“We know academics are worried about the implications [of clarified rules regarding INDs],” Temple says.

Although the agency does not want to impose unnecessary burdens on researchers, the protection of human subjects remains its highest priority. The FDA plans on releasing further guidance on INDs for public comment.

In the meantime, investigators should follow the rules on the FDA Web site (www.fda.gov) regarding when INDs are required. If the answer is still in question, they should contact the FDA directly, Temple recommends. ■
Wasek, CIP, director of the human subjects office at the University of Iowa. “I think for us it was a validation of what we always believed to be very sound practices in human subject protections.”

Angela Bowen, MD, president of the Western Institutional Review Board, believes the accreditation will reflect well on the board’s work. She hopes more organizations will embrace accreditation in the future.

“I think it’s a way that you can bring some level of competence to the entire world of IRBs,” she says.

Moving through the accreditation process

Step 1: Self-assessment
The first step in the AAHRPP accreditation process is a self-assessment, which is submitted as a program description, according to AAHRPP. The two organizations tackled this process in different ways.

• University of Iowa—“We were very fortunate because we had just hired a full-time IRB co-chair, Martha Jones,” says Wasek. Jones, who reports directly to the assistant vice president for research, was able to work on the self-assessment as soon as she began her new position.

There was no formal committee, but Wasek and others met regularly with Jones as she put together the application, says Wasek.

“My background is as a research assistant and this process was similar to putting together a grant application,” she says. “There were other people who had to be consulted who may have had to contribute small sections of information, and that’s kind of how we approached it.”

Wasek says it would be difficult to say how much time it took to complete the self-assessment. “Martha was hired in June, started working on this in June, and submitted it in September. She worked on it in addition to her full-time IRB duties.”

In total the self-assessment was between 400 and 500 pages long. But much of that bulk consisted of copies of the university’s forms, such as reports, applications, and templates used in the office.

• Western Institutional Review Board—Western Institutional Review Board formed a committee to pull together its application. It began the process last fall by creating a committee composed of a team leader and three others. They worked to gather all the necessary documents and write the narrative.

The process took about six months, says Bowen.

Western IRB consists of 11 IRB panels and serves as an IRB for 83 research institutions, which range from community hospitals to clinics to major academic institutions, such as Johns Hopkins and Boston University.

“We have a review panel in Santiago, Chile, another in Vancouver, British Columbia, and the remainder are here in Washington state,” says Bowen.

The self-assessment was “quite intensive,” says Bowen. They ended up submitting thousands of pages of meeting minutes, policies, and procedures. “[AAHRPP representatives] were good auditors,” says Bowen.

Step 2: The site visit
After submitting their self-assessments and documentation, each organization was able to schedule a site visit. At Western IRB the site visit lasted four days. At the University of Iowa it took three days, which Wasek says was probably based on the size of the
During the site visit the audit team also reviewed records. “I wasn’t really surprised along the way, simply because it’s similar to having a site visit after submitting a grant to the National Institutes of Health [NIH] and a team of NIH reviewers comes out to do a site visit,” says Wasek.

Accreditation status
Both organizations say the process was worth the time and effort. As to whether it will improve their standing among sponsors or subjects, “that’s something we’ll have to see,” says Wasek. Accreditation is valid for three years and these organizations must now submit annual reports on the status of their human research protection programs, according to AAHRPP.

Other organizations planning to go through the process should be certain they are in compliance before moving forward. “I can’t imagine going through such a thorough process if you’re not,” says Bowen. “It would be apparent right away.”

The organizations found the process was also educational and they have made small improvements as a result. “It was a very valuable experience, and as I said, while I believed we had a strong program, I think there is always room for improving the process,” says Wasek.

Go to www.aahrpp.org for more information about AAHRPP accreditation.

• Western Institutional Review Board—At Western Institutional Review Board, “[AAHRPP] sent six people out . . . and interviewed board members, employees, our clients, our investigators,” says Bowen. It was very similar to a federal audit visit, she says, but the team was a bit friendlier and very cordial.

“After the site visit, they sent us a written summary and we sent them back what we thought might have been misperceptions on a point or two,” says Bowen. Then they waited for word. They were confident “without being cocky” that they would receive full accreditation, she says.

• University of Iowa—At the University of Iowa, the site visit was scheduled in January. “I wouldn’t describe it as difficult—it was busy,” says Wasek. There were many individual meetings with members of the human subjects office staff. A number of the chairs, co-chairs, vice chairs, and probably half of the IRB members were interviewed. Then the team also spoke with other researchers around campus. “We told people [to] be honest, explain what you do, and answer questions the best you can,” Wasek says. “We did have a meeting of the full IRB to explain to them what AAHRPP was, it was a really new body at the time—and give people some background.”
NCQA, JCAHO release human research protection accreditation standards

In May, the National Committee for Quality Assurance (NCQA) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) planned to release the final standards for their human research protection accreditation program.

The standards will be available in hard copy this month, according to Jessica Briefer French, assistant vice president of human research protection for the combined program.

Ten organizations have already said they will seek accreditation through this program, called the Partnership for Human Research Protection, Inc. (PHRP), and are scheduled to undergo surveys. The 10 include two independent review boards.

The other eight are as follows:

- Aurora Health Care, Milwaukee
- Baylor Research Institute, Dallas
- Chesapeake Research Review, Columbia, MD
- Essex Institutional Review Board, Lebanon, NJ
- Hartford (CT) Hospital
- National Jewish Medical and Research Center, Denver
- Patient Advocacy Council, Mobile, AL
- University of Rochester, Rochester, NY

The formation of PHRP was announced in January. In 2001, the NCQA designed the nation's first human research protection accreditation program for research within the Department of Veterans Affairs (VA). This new program created in conjunction with JCAHO is based on the standards developed for the VA.

This will be the JCAHO's first foray into human subjects research. It currently accredits nearly 17,000 health care organizations and programs including 9,000 hospitals and home care organizations.

“We commend these organizations for seeking accreditation and serving as examples for the human research community,” said NCQA President Margaret O’Kane in a written release.

“We look forward to other organizations joining them in making a public commitment to quality improvement and safety.”

PHRP has designed a Web-based evaluation tool, which the 10 applicants will use to complete readiness evaluations by October 31. The surveys will take place after those evaluations are complete.

The accreditation process involves the evaluation, followed by a review of supporting documentation, and the on-site review.

Editor’s note: Go to www.phrp.org to purchase a copy of the standards or call customer service at 866/787-7477. The standards can be purchased in hard copy ($160) or Web-based versions ($142.20). An interactive survey tool is also available for $475.
Strategies for IRBs in addressing conflicts of interest

Problems arising from conflicts of interest in research can harm human subjects and damage reputations. Many institutions have taken steps to address this issue, but IRBs need to be very active in addressing conflicts to ensure subjects are adequately protected.

This means that many IRBs will need to develop their own sets of policies regarding conflicts and design them to ensure that human subject protections are not compromised, says Patrick Taylor, associate general counsel for Children’s Hospital in Boston. Keep in mind that IRBs need to examine conflicts from a different perspective than institutions. They should look deeper at the conflicts, examining how they could affect the development of protocols, eligibility criteria, and the informed consent process, he says.

Conflicts of interest in research are currently subject to added scrutiny by the federal government. In March, a draft guidance aimed at addressing conflicts of interest was published in the Federal Register. This document makes it even more critical for your IRB to take action so that conflicts aren’t eroding the integrity of research at your institution.

When your IRB begins to look at conflicts of interest, it is best to start with existing policies. Most likely your institution already has a conflict of interest policy in place. But IRB members shouldn’t automatically assume that the institutional policy is designed to address subject safety and protection, says Taylor.

Also, instead of just looking at whether a conflict exists, they need to examine what potential impact that conflict might have on the design and conduct of research—for example, on the investigator’s protocol design.

One of the key issues an IRB might look at when it comes to a conflict is how it affects the researcher’s clinical obligations toward the subject, says Taylor. For example, if a researcher has a conflict and is also designing the protocol, the IRB may need to put some additional scrutiny on issues such as the frequency of sample collection and how inclusion and exclusion criteria will be implemented, he says.

If you find the institutional policy wasn’t written with the IRB in mind, you should consider drafting your own policy.

Writing a conflict of interest policy
To draft a new conflict of interest policy, your IRB should form a group to look at the issue. It’s a good idea to include investigators, legal counsel, research administrators, and other members of the facility. “You want to make sure the IRB doesn’t create a policy that is unrealistic or impossible to administer,” says Taylor. “Intellectual-property office staff can help educate you to a whole new vocabulary and set of issues involving equity, licenses, and commercial relationships.”

The first step in developing any policy is to first define the topic: What is a conflict of interest? The FDA, American Association of Medical Colleges, Association of American Universities, and National Institutes of Health, as well as other organizations, have solid definitions you can use as a starting point, says Taylor.

IRBs also should identify examples of conflicts, and consider the specific situations in their institutions that the FDA and Office of Human Research Protections mention. Also be sure to look at past and current guidance issued on the topic, says Taylor.

The next task is to think systematically about how those conflicts might affect human subjects. Some areas potentially affected by conflicts of interest include

- study design
- informed consent—particularly the representation of risks and benefits of the study
- subjects’ clinical burdens
- data collection and adverse event reporting
- eligibility criteria
how protocol deviations are determined and reported

It’s critical to examine how conflicts can affect each of these areas and determine ways to manage or eliminate any potential problems.

The experience at Children’s Hospital

Children’s Hospital recently began the process of revising the conflict of interest policy in use by its IRB, says Taylor. The process took between four and five months from beginning to end and consisted of four meetings and discussions with the IRB and medical staff executive committee.

While Children’s Hospital already had a strong institutional conflict of interest policy that required conflict disclosure, the examination process was designed to strengthen it and add to the list of conflict remedies the IRB would consider.

Under the revised policy, the disclosure became shorter and more focused. The process of conflict review was more explicitly articulated. The group also came up with a menu of potential conflict-of-interest remedies that could be handed out to investigators and IRB members.

Managing conflict can be difficult. Although disclosure is an important element in managing conflicts of interest, it seldom will be enough to simply address how a conflict may affect an investigator or the IRB’s review, says Taylor.

Remedying conflicts of interest

IRBs should use a disclosure form as part of their process. However, the institutional disclosure form may or may not meet the IRB’s needs. For example, an institutional form might not include information about whether an investigator was paid by a company to write the protocol, but the IRB might consider that information important.

It’s important to review your institution’s disclosure form and adapt it to your IRB’s needs, says Taylor. IRBs also should be certain that conflicts of interest are disclosed to everyone involved with the study, including the sponsor’s study monitors. Letting the monitors know about the conflict will add another layer of protection.

IRBs also should look at other options when it comes to managing conflicts. Classic remedies you might see in an institutional policy include certain kinds of disclosures, divestiture issues, and outright prohibitions, says Taylor. The IRB might want to take it a step further. For example, in a situation in which an investigator has a financial interest in a device that is being developed, the IRB would not only need to determine that a conflict exists, but decide how it might affect the review process for that study.

The IRB would need to verify the description of risks and benefits provided to subjects, which is the basis for the IRB’s review. It’s also critical for the IRB to examine the protocol to ensure that the existing conflict of interest will not have an adverse impact on the clinical care that the subjects receive, says Taylor.

In very unusual cases in which the research should be undertaken, but there is a serious conflict, IRBs can require limited recusal for some of the particular functions in which subject safety would depend solely on clinical judgments made by the investigator with a substantial conflict of interest, says Taylor.

Another issue on which IRBs should focus is ensuring that subjects know they have the right to withdraw from the study at any time. “We all know that subjects must be told they have the right to withdraw, but it’s critical to maintain the viability of those rights when a conflict exists,” says Taylor.

Consent and data monitoring are other tools that IRBs may use in some cases “so that interim information can reveal that a protocol that was a close question is getting to be an even closer question,” Taylor adds. “IRBs should consider requiring collection of data that would show whether a conflict is having an impact.”

And finally, education is critical, he says. “Everyone wants to do the right thing,” says Taylor. Education allows everyone to work together.
Getting it right with adverse event reporting

When it comes to adverse event reporting, both too much and too little can be a problem. Underreporting can lead to subject injuries and federal penalties. Overreporting can result in flooding your IRB with too much information and make the critical adverse events more difficult to ferret out.

Tamara Norton-Smith, MT (ASCP), RAC, CCRA, president and senior consultant of Norton Audits, Inc., in South Carolina and Adil Shamoo, PhD, a research scientist and professor at the University of Maryland, Baltimore, offered a number of tips on how to get reporting just right during a recent audioconference sponsored by CTC called “Clinical Trials Adverse events: How to Identify Document and Report.”

“Adverse event reporting is probably one of the most serious practices that you actually do,” said Norton-Smith. So it’s important to ensure it is done correctly. This can be difficult, however, because federal regulations and reporting timelines are vague, said Shamoo. In addition, if your systems aren’t good, adverse events can be missed or go unreported.

The top reason for underreporting is that reporting creates additional work, said Norton-Smith. “It’s a lot of effort to report adverse events,” she said. Poor monitoring and misunderstandings about what constitutes an adverse event are also factors, she says.

While underreporting is an established problem, overreporting is also becoming more of an issue.

According to Shamoo, the number of adverse event reports has skyrocketed in the past few years as government scrutiny has increased in this area. For example, between 1990 and 2000, reporting to the Office of Human Research Protections was abysmal. During that period only 386 adverse events were reported nationwide. That number has increased dramatically in recent years.

Where to begin
Before a study begins, it is critical to understand the investigator’s brochure in order to understand the drug. It is essentially the starting point from which you can determine whether an adverse event is expected or unexpected. It’s the unexpected events that are of most concern.

It’s also important to get a good medical history from the patient prior to beginning the trial. “While a verbal report of the history is a good thing, you need to augment it with records from the subject’s primary physician,” said Norton-Smith.

TIP: It is crucial that when you are asking patients for the release of medical records that you do not use undated presigned medical release forms. Make sure they are signed on the day the request is made, said Norton-Smith.

Use the subject’s condition at the time the informed consent is signed as your starting point. Anything that happens to change the subject’s condition from that point on—whether it is a car crash, a subject passing out, or a stubbed toe—should be considered an adverse event.

Look for trends when it comes to adverse event reports. Reports should not only be examined per patient, but also for patient groups. This can be critical in detecting problems. For example, in one drug study, patients with normal blood pressure saw remarkable increases after they took the drug. If you do not examine trends between patients, you would not see that blood pressure is increasing studywide.

It’s also important to update records to include infor-
mation when a potential diagnosis for an adverse event is ruled out. Sometimes a patient will be evaluated and theories about his or her condition can make it into the medical record. Be certain to note a particular theory that later was discounted, said Norton-Smith.

Any changes to that patient have to be evaluated by a physician. Most sponsors require that a physician evaluate adverse events. It’s your job to seek a determination as to whether an incident qualifies as an adverse event.

“It’s a concern when the sponsor says this is not a serious adverse event, or this is an adverse event,” said Norton-Smith. “Make sure your responsibility is not taken from you.”

Identifying adverse events
It’s critical to understand that no medicine or drug product is risk-free, said Norton-Smith. People are willing to take trial drugs believing that the treatment will outweigh the inherent risks, but even if a study involves a very safe product there is always the prospect of an adverse event.

“If a facility tells me ‘we have no [serious adverse events],’ we become very concerned that there is something wrong with the system,” said Norton-Smith. This is also true if there are very low numbers of adverse events.

Be aware that staff members play a critical part in spotting and reporting adverse events. “A facility is only as good as its best monitor,” said Norton-Smith.

“On the other side, research is only as good as its best study coordinator.” Some principal investigators (PIs) are very good at adverse event reporting. Generally, the more involved the PI, is the better the reporting will be, said Norton-Smith.

“If you have a weaker study coordinator and a weaker monitor, and the principal investigator is not involved in the study, that’s when the most damage can be done to sponsor organizations,” she said. “So what you want to do within the industry is make sure that these trends and behaviors are not occurring.”

As a general rule it’s better to overreport than underreport, said Shamoo.

Working with sponsors
Under federal law, the sponsor has the largest share of responsibility when it comes to reporting adverse events. Therefore, it is critical that you report any event as quickly as possible to help your sponsor meet its requirements. This is particularly true when it comes to unexpected adverse events not outlined in the investigator’s brochure.

“Generally sponsors want to know as soon as you have the [adverse event] information so they can start reporting to the FDA,” said Norton-Smith.

Sponsors often use large databases to track trends in medications and medical devices. These databases can be an important tool for spotting rare and unexpected risks that might otherwise go undetected. Be sure to report to these databases as precisely as you can.

Avoiding overreporting
In recent years, many organizations fearful of increased government scrutiny have chosen to err on the side of caution and are overreporting adverse events.

“While you should be certain to report to your IRB, most IRBs will only want to know about unexpected adverse events,” Norton-Smith said. “What you don’t want to do is inundate IRBs with noise in the system.”

Go to your institution and find out what their requirements are. Do they require you to report expected events or just unexpected ones? Cutting down on reporting expected adverse events can reduce the number of adverse event reports your IRB will need to sort through.

Editor’s note: To purchase a copy of the audioconference tape “Clinical Trials Adverse Events: How to Identify, Document, and Report,” call customer service at 800/650-6787.
HIPAA happenings

Guidance dismisses concerns regarding IRB review of HIPAA documents
IRBs do not need to review HIPAA authorization forms as many organizations mistakenly believe, according to recent guidance issued by the Department of Health and Human Services (HHS).

Many organizations determined that IRBs needed to review authorizations because of guidelines established by the International Conference on Harmonisation (ICH), a group seeking to unify international guidelines for product registration. Under ICH guidelines, IRBs would be required to review any documents related to a clinical trial, including HIPAA forms.

The federal government said in its guidance that this step is not required, however, because it does not view these guidelines as mandatory, says Demetrios Kouzoukas, an attorney for Gardner, Carton & Douglas, LLC, in Washington, DC.

He adds that this may be a moot point because many organizations are going to require this step anyway.

Many sponsors require sites to follow ICH guidelines. Therefore, even if the federal government says IRB review of HIPAA authorizations is not mandatory, it may be for many.

In addition, many IRBs are not going to be willing to give up this portion of oversight, he says. IRBs already are required to review HIPAA authorizations if they are included as part of the study’s informed consent.

Go to www.bricker.com/legalservices/practice/hcare/hipaa/hipaaresearch.pdf to see a copy of the booklet.

HHS issues HIPAA enforcement document
Facilities that are found to be in violation of the privacy rule now can be fined up to $100 for each violation and as much as $25,000 per year for similar violations of the same requirement.

This is according to, “Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings,” which was published in the Federal Register.

This rule will be in effect from May 19 to September 16, with HHS accepting public comment through June 16.

Go to www.clinicaltrialscompliance.com/content/Enforcement.pdf to view the enforcement document.

For permission to reproduce part or all of this newsletter for external distribution or use in educational packets, please contact the Copyright Clearance Center at www.copyright.com or 978/750-8400.
Ask the expert: Questions about the HIPAA security rule

This month’s expert is Margret Amatayakul, MBA, RHIA, FHIMSS, president of Margret A Consulting, LLC. She has more than 30 years experience in the health care industry, including in hospitals, health informatics education, association management and advocacy, and information systems consulting.

Question #1: If an organization has taken a more decentralized approach to health care databases, rather than a centralized one, do you think the HIPAA security rule will make it necessary to centralize? Will it become too onerous having so many people involved in different databases trying to implement the rule? Or can the standardization and implementation be completed by dozens of different groups?

Answer: It would certainly be nice to centralize your systems, but it may not be something your organization is willing to do. In that case, I think you’d have to go back to the security rule and highlight the risk analysis, the information security review, the evaluation of risk management, and all the areas that have an ongoing monitoring responsibility. And it may come down to having to prove that each and every one of those independent areas meets the baseline criteria for the organization as a whole.

Question #2: We’re wondering how many facilities have an information security officer already in place?

Answer: I’m not sure that there is any hard and fast data to give you, but I can share from my own experience that probably 50%-75% of my personal clients have identified an information security official. I would also mention that this position should be filled with more than a security analyst. It needs to be someone who is out there with the work force, spotting incidents.

Question #3: The security rule requires security awareness training. Have you seen any unique or innovative approaches to this?

Answer: In health care we can become so inundated with reminders about every regulation that we become desensitized to them.

Work to create a culture that promotes awareness. Everyone should be aware, although we don’t want to create a culture of being suspicious of everybody. If you see something, take action.

I’ve been doing privacy assessments for the past few years, and one of the things I’ve always done is to go into the emergency room and literally walk behind the nursing station and poke around in the trash to find any protected health information. I also look at the monitors.

I can’t tell you how many times I have not been challenged. I know people can see me, and I don’t belong there. I don’t have a badge from the hospital and somebody should have said, “May I help you?” So it’s definitely about raising awareness among staff.

You can do reminders and quips every once in a while for HIPAA security rule training as long as they are not too regular.

Question #4: The HIPAA privacy > p. 12
rule was modified before it was finalized. Will this happen with the security rule?

Answer: Anything is possible, but I would say the substantive nature of the rule is really unchanged from the proposed rule. You can look back—and the preamble does look back—to see what the government removed. But the things it removed were not taken out because they were controversial; they were removed because they were basically redundant. I think that the level of controversy is not as great with the security rule. So I don’t know that we’re going to have the major changes we saw with the privacy rule.

Question #5: How does this security piece relate to business associates and should it be addressed in the business associate agreement?

Answer: Fortunately, the rule-makers did reconcile the privacy and security rules. When looking at the business associate contract, look at it from the point of security as well as privacy. But the security rule doesn’t include any expansive descriptions of items to cover, so you can basically take the business associate contract that you used for privacy and make sure that there are no “chain of trust issues” or those kinds of things. There’s really not a lot of difference. If you have a good structure already, you’re probably in good shape for security.

Editor’s note: The questions above were adapted from a recent audioconference, “Final HIPAA Security Rules: How to Comply.” If you are interested in purchasing a copy of the audioconference tape, call customer service at 800/650-6787.

Have a question for our experts? E-mail Managing Editor Kelly Bilodeau at kbilodeau@hcpro.com. Questions can be on any topic related to clinical trials compliance.