CCH Health Care Compliance LETTER

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OIG Final Rule clarifies data collection reporting requirements

by Gené Stephens Connolly, JD, Contributing Editor

The Office of Inspector General (OIG) released a Final Rule that clarifies one of the technical changes to the Health Care Integrity and Protection Data Bank (HIPDB) reporting requirements. HIPDB was designed to collect and disseminate information regarding final adverse actions against providers, suppliers and practitioners pursuant to section 221(a) of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and section 1128E(b)(2) of the Social Security Act (the Act).

Purpose of HIPBD. The HIPBD was designed to collect information regarding: (1) civil judgments against health care providers, suppliers or practitioners in federal or state courts that are related to the delivery of a health care item or service; (2) federal or state criminal convictions against a health care provider, supplier or practitioner related to the delivery of a health care item or service; (3) final adverse actions by federal or state agencies responsible for the licensing and certification of health care providers, suppliers or practitioners; (4) exclusion of a health care provider, supplier or practitioner from participation in federal or state health care programs; and (5) any other adjudicated actions or decisions that the Secretary of HHS establishes by regulation. The Act specifies a number of required elements and types of data for reporting information to the HIPBD.

Non-citizen physicians. As part of the required data, the Final Rule allows for the substitution of an individual taxpayer identification number (ITIN) in the limited cases where an individual does not have a social security number (SSN). The HIPBD regulations at 45 C.F.R. § 61 require an SSN on reports of adverse actions on individuals. The OIG believes that the inclusion of the ITIN is consistent with the statutory requirements of HIPAA and will also address cases of individuals who are non-citizens with permission to work in the United States, but who do not have an assigned SSN. Non-citizen physicians, for example, who do not practice in the United States but who desire to have a state license as a qualification of his or her ability to practice medicine may be assigned an ITIN for tax purposes.

The regulations amending 45 C.F.R. § 61 of the HIPBD provisions became effective on July 19, 2004. ■

CCH Chicago Bureau, September 24, 2004

Hospitals should use both in-house and outside counsel when facing investigations

by Catherine Hubbard, MA, Contributing Editor

Deciding whether to use in-house counsel or hire outside lawyers to defend your facility is not an either/or determination. It's often best to use both. While in-house counsel knows the internal workings of the organization and understands management concerns better, outside counsel may be more experienced with particular types of regulatory issues. "Both have strengths," according to Howard Burde, an attorney with Blank Rome LLP, Philadelphia, who has served as both inside and outside counsel. "It's important that in-house and outside counsel recognize each other's strengths," he said during a Sept. 14 American Health Lawyers Association teleconference, "Legal and Other Crises: How Can Outside Counsel Help? (Why In-House Counsel Can't and Shouldn't Do It All)".

Both sides need to work together and use their combined strengths to help the organization through a lawsuit or government query. "It has to be a collaborative relationship," said Burde, adding that the decisions outside counsel makes will have implications the organization will have to live with in the future.

In most cases, Burde said, it is difficult for general counsel to take on the investigation while handling day-to-day tasks. "If the in-house counsel is going to take a major role, then other things won't get done," he said.

Kimarie Statos, general counsel for Miami Children's Hospital, recommended organizations hire outside counsel at least on a limited basis. She noted that respect for the lawyer's opinion lowers when he or she is in house. "Your opinion is not viewed as objective," she said, noting that in-house lawyers often attend executive meetings.

Brent Henry, vice president and general counsel for Partners HealthCare System, Boston, provided some tips for handling a government investigation, particularly one that involves a search warrant. "First, find out what the government is looking for," he recommended. "Find out what documents they want." One way to find out is by asking the people involved in the document production. "Then you begin to get a picture of it," he said.

Statos emphasized that hospitals should have the proper policies and procedures in place that specify personnel should contact in-house counsel before handing documents over. "A lot of damage can be done at the forefront before it ever gets to counsel if there's not an appropriate policy in place."

"While in-house counsel knows the internal workings of the organization and understands management concerns better, outside counsel may be more experienced with particular types of regulatory issues."

Once general counsel has a pretty good idea of what the investigation involves, the hospital should consider hiring outside counsel, said Henry. He recommended in-house lawyers call both hometown lawyers, who are more convenient, and contact lawyers nationally who have expertise in the areas under investigation. "They don't have to be in your hometown," he emphasized.

Statos added that even a small hospital with a small budget "shouldn't hesitate to look nationally for the right representation," particularly if the issue is more obscure areas of the law, like the Health and Human Services Department's Office for Human Resource Protections for hospitals that have research institutes, as opposed to Stark and Office of Inspector General issues, where there's a broad knowledge base.

If general counsel wants to be involved in the case, routine matters, such as contract review, can be handed over to local counsel, Statos said, adding that for routine work her organization tries to find a solo practitioner or lawyer at a small firm who has worked

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at a large firm. "We can be a bigger fish in their pond," she said. She looks to the large firms for expertise on particular regulatory issues, unless the small firm or solo practitioner happens to have experience in the area.

Finding lawyers with past employment and current contacts at the National Institutes of Health, the OHRP or the Food and Drug Administration might help in the investigation, Statos said. This can be useful, said Henry, particularly if the government "has caught you red-handed and you need someone to plead your case and try to get you off without paying too much of a penalty." On the other hand, he said, "If you think it's a bogus investigation, you want a bulldog type attorney who will defend you vigorously," noting that people who have been inside government may not want to take such an aggressive approach.

Although the decision about whether to retain outside counsel and who to use should ultimately rest with the general counsel, it's important to get buy-in from colleagues and the board, said Henry and Statos. "It's important to select counsel that will give the board a comfort level and the CEO a comfort level that the matter is being handled by top-notch folks," said Statos.

Henry added that the organization should meet with the outside lawyers and conduct performance reviews so that they "know you're looking over their shoulder in terms of results."

Pricing. Once the organization decides to hire outside counsel, it should try to negotiate discounts on billing, Henry said. "Find out what discounts you can muster from the outside counsel. Send the message that you have to stay within a budget," he said. Statos also suggested hiring contract paralegals and investigators and to negotiate rates for document production.

"Once the organization decides to hire outside counsel, it should try to negotiate discounts on billing."

Since the workload may grow as the case develops, the organization should hold periodic meetings with the outside counsel and review proposed expenditures for each stage, said Henry. "Keep the communication going, so that you, the inside counsel, have a sense every step of way of how much this thing is costing," he advised.

Statos added that it's worth the investment to find the right lawyer. "Being penny-wise and pound foolish could result in disaster in terms of the reputation of you organization and monitory fines that are waged against your organization," she said.

"Don't be a slave to your budget," Henry added. "Spend what it takes to get the job done because at the end of the day, it's more important to have a success." ■

CCH Washington Bureau, September 24, 2004

Letters to the Editor

The CCH Health Care Compliance team welcomes comments or questions regarding articles published in the CCH Health Care Compliance Letter. Send comments to Sharon Sofinski, Coordinating Editor, at sofinsks@cch.com. For more information about the CCH Health Care Compliance Portfolio visit our online store at http://health.cch.com.

Becoming an effective compliance officer: Thoughts from HCCA President, Al Josephs

by Catherine Hubbard, MA, Contributing Editor

In this article, Catherine Hubbard, a reporter in CCH Incorporated's Washington, D.C. office, talks with the HCCA president about what it takes to become an effective compliance officer.

One of the biggest assets for compliance professionals, regardless of their work experience or educational background, is their ability to work well with others. "That is a have to have asset," according to Health Care Compliance Association (HCCA) president Al Josephs, who is the corporate compliance director for Hillcrest Health System, Waco, Texas. "If you take on the position as a sheriff, you're going to be very ineffective, but if you look to be a collaborator or facilitator, that's what this position calls for," he said during a recent interview.

Compliance officers must understand the structure of their organization, determine specific areas they need to watch and create a strong internal network, Josephs said. "You have to have a blueprint of the organization and know where you need to have circuit breakers," he advised.

Establishing and maintaining key contacts in the organization is an important talent of successful compliance officers. "You have to make sure you develop those and cultivate them so that there's good communication," Josephs said. "If you can work with people, that's going to be the biggest part of it," Josephs said. "There's going to be conflicts, it's not always easy, but you have to manage those well," he added.

"Compliance is not just about interpreting laws and rules and regulations. It's about processes and sometimes the skill set of the individuals drive more their ability to work in the organization."

Also important, Josephs emphasized, is staying in touch with personnel in all the key areas of an organization, including the business office, billing staff and coding staff. "I know quite a few people and they are comfortable approaching me," he said. "They feel they can discuss their concerns and know that I'll act on it and do it in a very effective way."

Compliance officers should become a useful resource that department leaders will want to consult, Josephs said. "If you become a resource, then people are going to want to involve you in new processes so that you can make sure it goes correctly," he said.

In fact, Josephs said he's often invited to meetings in various departments of Hillcrest and he feels comfortable requesting to sit in on meetings. "When I find issues I want to be involved in, they don't mind if I sit in," he added. "Everyone has a strong desire to do things right, and oftentimes they just need help," he said.

Josephs also suggested compliance officers not take ownership of the particular issues they become involved in. "It's not your issue," he explained. "You're just managing how you respond to it, how you fix it or how you bring about the change to make it better," he said.

Eventually, organizations will consider the compliance profession as crucial to their operations as the legal and accounting professions, said Josephs. "We're going to establish ourselves as a profession on a level with an accountant or lawyer," he predicted.

"Organizations have recognized over time that while we don't necessarily generate revenue, we can certainly prevent negative revenue by helping to make sure that we do things right the first time in terms of billing errors and other processes," Josephs said. "Any time that you spend time looking at the processes you have in an organization, you're going to improve outcomes of everything," he added.

Josephs pointed out that nearly 90 percent of health care organizations have a compliance program in place, a program born out of the regulatory environment yet maturing to become an active part of management. The trend "speaks well of the industry," Josephs said. "We're really an effective management tool, rather than an enforcement tool."

Results of 2004 survey

In its 2004 compliance survey, the HCCA found that only 17 percent of compliance officers have law degrees. In contrast, 62 percent have completed either a bachelor's or master's degree.

Noting that compliance officers come from all sorts of backgrounds, Josephs said the job doesn't require a particular degree or work experience. Success "depends more on the individual and their skill set," he said.

For instance, Josephs said, a law degree can be useful for interpreting laws, but it is not necessarily a prerequisite. "Compliance is not just about interpreting laws and rules and regulations. It's about processes and sometimes the skill

set of the individuals drive more their ability to work in the organization," he said.

Compliance certification

The survey also highlights the increasing demand for compliance officers certified in health care compliance (CHC), said Josephs, noting that the certification helps auditors to understand compliance issues and their implications for the organization. The CHC may be a coder or a RN, for instance, said Josephs, who is certified himself. "Certification for those folks is critical in that they need to understand what compliance programs are and what they're about," he said. "Obtaining certification for those individuals is very important so that people doing those compliance audits have a clear understanding of what needs to go on and why compliance programs are important to an organization."

Sarbanes-Oxley

The survey also shows that even though the law technically doesn't apply to nonprofits, many tax-exempt health care organizations are interested in complying with Sarbanes-Oxley. "That's a regulation that's worthy of adhering to," said Josephs, adding, "It's just a matter of time before most nonprofits governed by [Code Sec.] 501(c)(3) anticipate the IRS will follow along," he said.

"Whether you report to the SEC or not, it's important that you have good controls in place," Josephs said. "Most boards of nonprofit organizations see [Sarbanes-Oxley] as an opportunity to kick their level of knowledge about the organization high," he said, adding that compliance with the law "is good business." ■

Al Josephs is the Director of Corporate Compliance and Privacy Officer for Hillcrest Health System in Waco, Texas. He is responsible for the development and operation of the compliance program for all Hillcrest System entities, including one acute care hospital and six primary care physician clinics employing 30 physicians. In addition to his compliance responsibilities, Al coordinates all activities related to the JCAHO accreditation process. Prior to assuming responsibilities for compliance Al worked in the area of finance for Hillcrest and Baylor Health Care System in Dallas, Texas.

Al is a graduate from the University of West Florida, with a Bachelor Degree in Accounting and is certified in Healthcare Compliance (CHC). He is a member of the Healthcare Financial Management Association and a past board member of the Lone Star Chapter of HFMA, Past-President of the Texas Association of Hospital Financial Administration, one of the founding members of HCCA Region VI and active in the VHA-Southwest Compliance Officer Group. He is currently a member of the Healthcare Compliance Certification Board and has been active in the development of the certification exam for compliance professionals. He has been a member of the HCCA Board since 2000 and served as Secretary, 2nd Vice President and 1st Vice President prior to becoming President in 2004.

CCH, HCCA announce partnership

CCH Incorporated and the Health Care Compliance Association (HCCA) have teamed up to bring you the new *Health Care Compliance Professional's Manual.*

The *Manual*, also referred to as the "Blue Book," is considered a bible for health care professionals—in fact, HCCA uses it for all of its training academies, both regular and advanced. According to HCCA President Al Josephs, "The book contains a wealth of information useful to someone who is new to the compliance field and a useful reference tool for those who are experienced." The updated *Manual*, set for a Fall release, will include all of the key compliance documents, including best practices and changes in the sentencing guidelines, he said. "It's an extremely useful tool." Regular updates will ensure compliance officers stay current, he noted. Josephs said he looks forward to a successful partnership with CCH. He added, "We're excited about this opportunity for CCH. It's really going to be a good partnership."

The new *Health Care Compliance Professional's Manual* will replace the *CCH Healthcare Compliance Guide*; customers receiving the *Guide* will receive their new *Manual* this Fall.

The release of the *Health Care Compliance Professional's Manual* coincides with major enhancements CCH is making to its electronic *Health Care Compliance Reporter.*

Effective October 4, subscribers will notice significant content, organizational, and design changes to the Reporter. We have reorganized the content in the Reporter to make research sessions more intuitive. In the past, the information was organized by topic and is now organized by document type and by government agency. The content is broken down further by topic for enhanced search capabilities.

We have added invaluable content, including: Departmental Appeals Board decisions; selected CFR titles, EEOC decisions, NLRB decisions; Public Laws including the Sarbanes Oxley Act, Medicare Prescription Drug and Improvement Act and Administrative Simplification Compliance Act of 2001; several USC titles in their entirety; and 5,500 new health law cases with their official citations. Customers can now search for these documents—and cases—not only by their CCH paragraph number, but by their official citation as well. Pinpoint citations are also available.

For more information or to order the *Health Care Compliance Professional's Manual* or *CCH Health Care Compliance Reporter*, contact CCH Customer Service at 1-800-449-9525 or visit health.cch.com.

Technology

GAO releases report on barriers to health IT initiatives

by Gené Stephens Connolly, JD, Contributing Editor

The United States General Accounting Office (GAO) released a report to the Senate Committee on Health, Education, Labor, and Pensions concerning the Department of Health and Human Services' (HHS) efforts to promote health information technology (IT) among health care providers. The GAO report focuses on the ways in which health IT mechanisms are used within clinical health care delivery systems. The findings address the legal barriers that affect the adoption of health IT initiatives in public and private health care settings, as well as describe the financial, technical and cultural barriers to health IT provider advancement.

According to the GAO, six legal areas present barriers to the nationwide adoption of health IT initiatives: (1) fraud and abuse; (2) antitrust; (3) federal income tax; (4) intellectual property; (5) liability and provider malpractice insurance; and (6) state licensing requirements. The report suggests, however, that HHS has done little to combat these legal barriers. In addition, the GAO identified the following financial, technical and cultural barriers to health IT access and usage:

Financial barriers

- Inability to access high-quality IT services at affordable prices
- Need for greater access to capital
- Inability to provide evidence of return on investment

"According to the GAO, six legal areas present barriers to the nationwide adoption of health IT initiatives."

Technical barriers

- Complex and lengthy implementation processes
- Lack of uniform standards for data submission and reporting
- Inability to sufficiently integrate and incorporate changes to business processes

Cultural barriers

- Need for better understanding of best practices for IT adoption
- Lack of leadership support from the public and private sectors
- Resistance by health care providers

The report further revealed that in previous GAO studies, cost savings and other benefits from 20 health IT initiatives were reported across the country, including an $8.6 million annual savings at a teaching hospital that replaced outpatient paper medical charts with electronic health records, and a rural community hospital's administrative prevention of over 1200 wrong drug dosages over a one-year period by switching to bar coded wireless scanners to identify patient medications. Additionally, the report contains comments and responses from HHS, as well as describes HHS' current major health IT initiatives, goals, and results through IT programs within the National Institutes of Health, the Centers for Medicare and Medicaid Services, the Food and Drug Administration, the Indian Health Service, and the Health Resources and Services Administration. ■

CCH Chicago Bureau, September 2, 2004

Fraud and Abuse

OIG will not object to malpractice insurance subsidy program in atypical shortage area

by Suzanne Szymonik, JD, Contributing Editor

A medical center's plan to offer malpractice insurance subsidies to obstetricians who practice in a health professional shortage area (HPSA) did not fit squarely into an anti-kickback statute safe harbor for such subsidies, but the plan's extra safeguards protect against fraud and abuse, and the Office of Inspector General (OIG) decided in OIG Advisory Opinion No. 04-11 not to subject the program to sanctions.

Under 42 C.F.R. §1001.952(o), safe harbors are available for obstetrical malpractice insurance subsidies given to doctors in HPSAs if seven standards are satisfied: (1) there must be a written contract between the premium payer and the doctor; (2) 75 percent of the doctor's patients must reside in certain underserved areas such as HPSAs; (3) there can be no referral deal requirement; (4) there can be no staff privileges restrictions; (5) the subsidy amount cannot be based on previous or expected volumes of referrals; (6) the doctor must treat patients in a nondiscriminatory manner; and (7) the insurance must be a *bona fide* policy. In this case, the second standard was not met because the doctors do not practice in a primary care HPSA, but rather, in an area with a HPSA designation due to low-income populations, migrant agricultural workers, and homeless individuals.

"The medical center's failure to fit into the safe harbor was not fatal to its program."

The medical center's failure to fit into the safe harbor was not fatal to its program. The failure was mitigated by the center's careful structuring of an arrangement that benefits an underserved community, while providing these fraud safeguards: (1) subsidies will be temporary and tied to premium increases; (2) subsidies will not create windfalls for doctors because doctors still must pay as much as they had previously for such coverage; and (3) doctors will be covered

even when they perform services away from the medical center.

The OIG observed that the intent of the safe harbor regulations is to ensure access to needed obstetrical care, including expert care for high-risk and complicated deliveries, in places and for populations that do not have sufficient access to such care. Thus, it decided to evaluate and approve this nonconforming arrangement on a case-by-case basis. As with all OIG advisory opinions, the OIG cautioned that the opinion is applicable only to the requestor. ■

OIG Advisory Opinion 04-11, September 9, 2004

Physician self-referral advisory opinion rules reinstated

by Suzanne Szymonik, JD, Contributing Editor

CMS corrected a technical error in the March 26, 2004, interim final rule regarding physician self-referral prohibitions, commonly known as "Stark II," that had caused the deletion of physican self-referral advisory opinion regulations from 42 C.F.R. Part 411, by issuing a new interim final rule with an effective date retroactive to the original effective date of July 26, 2004. The mere omission of an ellipsis at the end of regulatory text caused the problem. The deleted advisory opinion rules had been in effect since their publication on January 9, 1998. CMS had never proposed to remove or revise the rules. The rules cover procedures for submitting advisory opinion requests as well as the applicability of CMS opinions. The March 26, 2004, interim final rule codified provisions of the Medicare Modernization Act of 2003 (MMA, PubLNo 108-173) that placed an 18-month moratorium on physician referrals to specialty hospitals they own.

Retroactive effective date. The agency may issue rules with retroactive effective dates without notice and comment opportunity in extraordinary circumstances to protect the public's interest. CMS already had issued two advisory opinions since the July 26, 2004, effective date and it currently is reviewing 30 advisory opinion requests regarding the MMA-mandated moratorium on physician referrals to specialty hospitals in which they have an ownership interest. The agency believes it would be contrary to the public interest to issue any more opinions or review any more requests without rules to guide the process. The agency will accept comments, submitted by November 23, 2004, only on the reinstatement of the advisory opinion rules, but not on the substance of the regulations themselves. ■

69 FR 57226, September 24, 2004

Preemption and alcohol and substance abuse treatment programs

by Harris Beach, LLP

Since the early 1970s, the confidentiality of patient information generated by alcohol and substance abuse treatment programs has been regulated by the privacy protections set forth at 42 C.F.R. Part 2 ("Part 2"). Following their enactment, many alcohol and substance abuse treatment programs are also subject to the requirements of Privacy Rules. In many circumstances, therefore, alcohol and substance abuse treatment programs are left to determine whether the Privacy Rules preempt the provisions of Part 2, whether Part 2 is more stringent and therefore controlling, or whether compliance with both the Privacy Rules and Part 2 is required.

Preemption analysis. Assuming that a specific alcohol or substance abuse treatment program falls within the definition of a "covered entity" as established by the Privacy Rules, that program is generally required to comply with both the provisions of Part 2 and the Privacy Rules. There are, however, some fundamental differences between the provisions of these two regulations which must be noted:

Protected information. Part 2 protects information that identifies a person as a drug or alcohol abuser, directly or through other publicly available information or by verification of identity by a third person. Further, the protections of Part 2 only extend to information obtained for the purpose of treating drug or alcohol abuse, making a referral for treatment or making a diagnosis. The Privacy Rules protect PHI. Generally, the list of that information which is deemed to constitute identifying information is the same under Part 2 and the Privacy Rule. One exception, however, is that Part 2 does not deem a patient identifying number assigned by a treatment program to be an identifier, provided that it does not consist of, or include, numbers that could be used to identify that patient from sources external to the program such as social security number or driver's license number. The Privacy Rules deem any unique identifying number to make information individually identifiable. As such, alcohol and substance abuse treatment programs now are required to treat any unique identifying number issued to a patient as something that would make information individually identifiable.

When protections arise. The protections of Part 2 apply to information relating to any individual who has applied for or been given a diagnosis or treatment for alcohol or substance abuse in a federally assisted program. The Privacy Rules apply to all PHI which is created, received or maintained by a covered entity, no matter when it was received. Generally, therefore, an alcohol or substance abuse program should continue to protect information in accordance with Part 2, except that the program must now protect information which is received in advance of a patient applying to a program.

Disclosure of Information

Part 2 consents and HIPAA authorizations. The disclosure rules of Part 2 and the Privacy Rules are very different. Therefore, before making a disclosure, an alcohol or substance abuse program must first determine whether

the disclosure is permitted by Part 2. Assuming that the disclosure is permitted by Part 2, the program must then determine whether the disclosure is permitted under the Privacy Rules. Generally, alcohol and substance abuse treatment programs make disclosures pursuant to a consent from the patient. The signed consent form must conform to the requirements set forth at 42 C.F.R. § 2.31 and § 2.32. With minor exceptions, the requirements for a patient consent set forth in Part 2 mirror those set forth in the Privacy Rule. Alcohol and substance abuse treatment programs should note, however, that in addition to the Part 2 requirements, the Privacy Rules require a statement setting forth the ability or inability to condition treatment on the patient signing the authorization. Additionally, the Privacy Rules require that the authorization be written in plain language. Therefore, whenever an alcohol or substance abuse program discloses information in a manner in which the Privacy Rules require the authorization of the patient, that program must use a HIPAA compliant authorization. If the Privacy Rules do not require an authorization prior to making the disclosure, when necessary the program may continue to use a consent which only complies with the requirements of Part 2.

Minors. The Privacy Rules and Part 2 require that authorization for disclosure be given by that person who has the capacity to make decisions regarding health care. Specifically, if state law permits a minor to enroll in an alcohol or substance abuse treatment program without the consent of his or her parent or guardian, then the program must obtain the consent or authorization of the minor prior to any disclosure for which a Part 2 consent or HIPAA authorization is required.

Disclosures for which the provisions of Part 2 remain applicable. In many circumstances, alcohol and substance abuse treatment programs may continue to make disclosures in accordance with the familiar provisions of Part 2. Specifically, programs may continue to disclose information in accordance with Part 2 in the following instances:

(a) internal program communications or communications made to individuals within the treatment program who have a need to know;
(b) to report crimes or threats to commit crimes on the program premises or against program personnel. These reports must be made to law enforcement officials, and the information disclosed must be limited to the circumstances of the incident and the patient's status, name, address and last known whereabouts;
(c) child abuse reporting, provided such disclosure is limited to making the initial report;
(d) medical emergencies, provided that such disclosure is made to medical personnel and is limited to that information which is necessary to treat the medical condition. Following any disclosure made during a medical emergency, the alcohol or substance abuse treatment program must document in the patient's file the following information relating to such disclosure: (i) the name and affiliation of the medical personnel to whom the disclosure was made; (ii) the name of the person making the disclosure; (iii) the date and time the disclosure was made; and (iv) the nature of the medical emergency which necessitated such disclosure; and
(e) information disclosed pursuant to a subpoena, provided that the program obtains a Part 2 compliant consent prior to making the disclosure.

Disclosures requiring new procedures. The following disclosures are permissible pursuant to Part 2 but may no longer be made by alcohol and substance abuse treatment programs without first ensuring compliance with the Privacy Rules:

(a) "Non-patient identifying disclosures" or disclosures that do not reveal any information that identifies the patient as an alcohol or substance abuser or as the recipient of assessment or treatment for alcohol or substance abuse. The provisions of Part 2 are only applicable to information that would identify the patient as an alcohol or substance abuser. Therefore, alcohol and substance abuse treatment programs are permitted by Part 2 to make disclosures that do not identify the patient as an alcohol or substance abuser or as a person who is in or has sought assessment or treatment for alcohol or substance abuse. For example, Part 2 permits an alcohol or substance abuse treatment program to make certain disclosures which identify the treating entity only as a hospital and not as a treatment program. Following the enactment of the Privacy Rules, before making any non-patient identifying disclosure of PHI, an alcohol or substance abuse treatment program must first ensure that such disclosure is made in accordance with the Privacy Rules.
(b) Disclosures to qualified service organizations. Part 2 requires that an alcohol or substance abuse treatment program enter into a qualified service organization agreement prior to making any disclosure to a qualified service organization. Under the Privacy Rules, a covered entity is required to enter into a business associate agreement with any outside party who provides services that require the disclosure of PHI to the covered entity. Since the required contents of a qualified service organization agreement and a business associate agreement are different, alcohol and substance abuse treatment programs are required to enter into agreements which satisfy both the provisions of Part 2 and the Privacy Rule prior to making disclosures to qualified service organizations.
(c) Disclosures to accreditation bodies. Part 2 permits an alcohol or substance abuse program to disclose patient information to an accreditation agency, provided that either a qualified service organization agreement is in place or the disclosure is made in accordance with the audit and evaluation provision of Part 2. The Privacy Rule, however, deems accreditation agencies to be business associates and requires that there be a business associate agreement in place prior to PHI being disclosed to any such accreditation agency. Therefore, an alcohol and substance abuse treatment program must comply with the business associate provisions of the Privacy Rules and with either the audit and evaluation provision or the qualified service organization provisions of Part 2 prior to making disclosures to accreditation bodies. ■

Adapted from the CCH HIPAA Privacy Guide, by Harris Beach, LLP. For information or to order the Guide, call 1-800-449-9525, or visit health.cch.com.