

Health Care Compliance LETTER

Volume 12, Issue 17

health.cch.com

August 25, 2009

On The Front Lines 4

Has the IRS Met Its Goals with the New Form 990?

by Lisa A. Stegink, J.D.

False Claims 1

- **OIG Chief Counsel testifies on ensuring CME integrity**

Anti-Kickback/Physician Self-Referral 2

- **OIG: proposed physician, hospital joint venture permissible**
- **Reduced Medicare inpatient deductibles acceptable, OIG**
- **Free blood pressure screenings OK'd by OIG**

Trends 6

- **CMS needs agency-wide policy for translating written documents**

Health IT 7

- **Breach notification rule issued for e-health information**

Employment 7

- **Sex toy scandal did not affect doctor's application for privileges**
- **Billing manager's whistleblower, retaliatory discharge actions fail**

Tax-Exempt Organizations 8

- **Consolidation of nonprofit hospitals not *bona fide* sale**

In The News 8

OIG Chief Counsel testifies on ensuring CME integrity

The commercial sponsorship of continuing medical education (CME) poses a potential conflict of interest between patient welfare and the commercial interests of sponsors, according to the testimony of the Office of Inspector General (OIG) Chief Counsel, Lewis Morris. Sponsors that provide funding to CME providers are frequently manufacturers of drugs, biologics, or medical devices related to the topic of the CME program. Commercially-sponsored CME programs consequently tend to focus more on sponsors' products than do programs that are not commercially-sponsored. One study on pharmaceutical promotional strategies revealed that spending \$1 on physician events generated an average of \$3.56 in increased revenue.

ACCME authority. The Accreditation Council for Continuing Medical Education (ACCME) is the principal CME accrediting authority in the U.S. Its responsibilities include determining whether providers qualify to offer accredited CME programs, and overseeing the CME industry. Once a CME provider is accredited by ACCME, the provider can offer accredited CME programs without further review on the program's content. ACCME has enacted measures to mitigate commercial bias, such as prohibiting CME content from promoting a specific proprietary interest.

Limited oversight. However, the impact of ACCME's measures is limited. ACCME neither pre-approves content nor routinely monitors CME programs. Its oversight is complaint-driven, and in practice, several years may lapse before a noncompliant CME provider's accreditation is revoked. Under the current system, CME providers can seek commercial financial support by developing CME content to favor funders' economic interests. Some manufacturers publicize general topics they are willing to fund to solicit grant applications from CME providers that propose programs on those topics. As a result of these and other activities, industry-supported CME usually covers topics related to commercial products, rather than patient care.

Legal implications. Commercially-sponsored CME may implicate the Federal Food, Drug, and Cosmetic Act (FDCA). On at least two occasions, a pharmaceutical company was required to pay millions of dollars to resolve charges arising out of CME programs that allegedly promoted the off-label uses of its product in violation of the FDCA. The False Claims Act may be similarly implicated if a manufacturer knowingly collaborates with a CME provider to promote an off-label use and submit claims for that drug to federal health care programs. Industry-supported education may also implicate the criminal anti-kickback statute; for example, if a pharmaceutical manufacturer rewards a high-prescribing physician by directing a CME provider to pay that physician to be CME faculty, that payment may be a kickback.

Measures to preserve the integrity of CME. According to the OIG, the "surest way to eliminate commercial bias in CME is to eliminate industry sponsor-

False Claims (cont.)

ship by funders who have a significant financial interest in physicians' clinical decisions." CME providers should accept funds only from sources that have no commercial interest in the CME. A consequence, however, is that CME providers would have to find alternative funding. Toward that end, companies should take the following interim measures to permit industry funding but limit commercial bias in CME: (1) grant-making functions should be separated from sales and mar-

keting to ensure that grant funding is not influenced by marketing motivations; (2) objective criteria for making educational grants should be established to ensure that funded activities are for legitimate educational purposes; and (3) company control over speakers or content of CME should be eliminated to reduce the risk that payments are for speaker's referrals or promotion of "off-label" uses.

Another measure that may limit commercial bias is the creation of indepen-

dent CME grant organizations that would accept donations from the industry and distribute the funds to CME providers. Broad educational categories could also be established to allocate industry donations to ensure that grants are awarded for general topics such as "oncology," rather than specific, commercially motivated topics such as "injectable therapies for osteoarthritis of the knee." ■

Testimony before the Senate Special Committee on Aging, July 29, 2009

Anti-Kickback/Physician Self-Referral

OIG: proposed physician, hospital joint venture permissible

A proposed joint venture involving ownership of an ambulatory surgery center (ASC) by a hospital and a physician group could constitute unlawful remuneration; however, the safeguards put in place would lower the risk sufficiently and the joint venture would not be subject to administrative sanctions in connection with the anti-kickback statute.

Joint venture. Under the proposed arrangement, the hospital and physician group would enter into a joint venture to own and operate an ASC with two operating rooms in a medical office building owned by the hospital and located on its campus. The hospital would initially develop a single hospital operating room in a space within the building. Upon receipt of necessary regulatory approvals, the hospital would then contribute the assets used to operate the operating room to a separate corporate entity after which the operating room would be operated as a Medicare-certified ASC. The physician group would then purchase a 50 percent share in the corporate entity. At the conclusion of this transaction, the hospital and the physician group would jointly own the corporate entity, which in turn would own and operate the two-operating room ASC.

Proportional investment. Physician investors' ownership in the physician group would be proportional to his or her capital investment. Additionally, each physician received at least one-third of his or her medi-

cal practice income for the previous fiscal year or previous 12-month period from the performance of procedures payable by Medicare when performed in an ASC.

Referral limitations. Physicians employed by the hospital or its affiliates would not make referrals to the joint venture ASC; nor would the hospital undertake any actions requiring or encouraging its medical staff to refer patients to the ASC. In addition, the hospital will continue to operate its own facilities for outpatient surgery.

Minimal risk. Under the proposed arrangement: (1) certain commitments would limit the ability of the hospital to direct or influence physician referrals; (2) each of the physician investors is qualified to invest in the ASC directly without destroying its eligibility for safe harbor protection; and (3) the amount of payment to a physician in return for the investment would be directly proportional to the amount of capital invested by that physician. For these reasons, while the proposed arrangement would result in income to investors that would not be protected by any safe harbor, it involved minimal risk of fraud or abuse. ■

OIG Advisory Opinion, No. 09-09, July 22, 2009, Health Care Compliance Reporter, ¶500,214

Reduced Medicare inpatient deductibles acceptable, OIG

A proposed arrangement between an insurer's Medicare Supplemental

continued on page 3



Portfolio Managing Editor
Pamela K. Carron, J.D., LL.M.

Coordinating Editors
Susan Smith, J.D., M.A.
Harold M. Bishop, J.D.
Kristine Chung, J.D.

CCH Washington Bureau
Paula Cruickshank
SEC—Peter Feltman
Tax—Jeff Carlson, Steve Cooper,
Chandra Walker

Designer
Chris Tankiewicz

Requests for information about article submission and comments from readers are welcome and should be directed to Susan Smith at susan.smith@wolterskluwer.com, Tel. 847-267-2780, Fax 847-267-2514. Customer service inquiries should be directed to 800-449-9525.

CCH Health Care Compliance Letter is published 24 times a year by CCH, a Wolters Kluwer business, 4025 W. Peterson Avenue, Chicago, IL, 60646. Subscription rate is \$305 per year. First-class postage paid at Chicago, Illinois, and at additional mailing offices. POSTMASTER: SEND ADDRESS CHANGES TO CCH Health Care Compliance Letter, 4025 W. PETERSON AVENUE, CHICAGO, IL 60646. Printed in U.S.A. ©2009 CCH. All rights reserved.

No claim is made to original government works; however, the gathering, compilation, and arrangement of such materials, the historical, statutory and other notes and references, as well as commentary and materials in this Product or Publication are subject to CCH's copyright.

This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is sold with the understanding that the publisher is not engaged in rendering legal, accounting or other professional service. If legal advice or other expert assistance is required, the services of a competent professional should be sought.

For more information about the CCH Health Care Compliance Portfolio, please visit our online store at <http://health.cch.com>.

Anti-Kickback/Physician Self-Referral

Health Insurance (Medigap) policyholders and in-network hospitals, offered in almost every state in the country, which would provide policyholders discounts of up to 100 percent on Medicare inpatient deductibles incurred at the “preferred” in-network hospitals, had sufficient safeguards that it presented a low risk of fraud and abuse. The arrangement also had the potential to lower costs for Medigap policyholders who select network hospitals, and because savings realized from the arrangement would be reported to state insurance rate setting regulators, it also would have the potential to lower costs for all policyholders.

Proposed arrangement. Although the deductibles would be covered under the insurers' Medigap plans, the discounts applied only to Part A inpatient hospital deductibles and not other coinsurance or cost-sharing amounts. No other benefits would be offered by the hospitals to the insurers or their policyholders. When policyholders utilized non-network hospitals, the insurers would have to pay the full Part A hospital deductible. As part of the agreement, the insurers would return a portion of the savings from the arrangement to any policyholder who had an inpatient stay at one of the in-network hospitals.

Low risk. The arrangement was found to represent a low risk of fraud or abuse because: (1) the waivers would not increase or affect per service Medicare payments and payments to hospitals under Part A for inpatient services that were fixed and unaffected by beneficiary cost-sharing; (2) the discounts would not increase utilization of the hospitals; (3) the arrangement did not unfairly affect competition because membership in the network would be open to any accredited hospital; and (4) professional medical judgment would not be affected because a patient's physician or surgeon would not be a recipient of remuneration. ■

OIG Advisory Opinion, No. 09-10, July 24, 2009, Health Care Compliance Reporter, ¶1500,215

Free blood pressure screenings OK'd by OIG

Civil monetary penalties would not be imposed by the Office of Inspector General (OIG) in connection with a small county-owned critical access hospital's provision of free blood pressure screenings to walk-in visitors during daylight hours, some of whom may be Medicare and Medicaid beneficiaries.

Facts presented. Under the proposed arrangement, the free blood pressure checks offered by the hospital are not conditioned on the use of any other goods or services from the hospital or any other particular practitioner or provider. Should a member of the public call in to inquire about the service, the hospital indicates that it provides the service to any visitor who enters requesting the service during daylight hours. The hospital does not advertise the service to the public. The service is provided in accordance with the hospital's own specific guidelines and procedural checklists by an on-duty staff nurse. The visitor receiving the blood pressure check is not directed to any particular health care practitioner or provider. Nor does the hospital offer the visitor any special discounts on follow-up services. Staff responds to an abnormal blood pressure reading by

advising the visitor to see his or her own health care professional. The hospital does not bill the blood pressure check service to any federal health care program or any other third-party payors.

Law. The hospital did not indicate the fair market value of the blood pressure screenings, but the OIG has previously taken the position that “incentives that are only nominal in value are not prohibited by the anti-kickback statute,” and has interpreted “nominal value to be no more than \$10 per item, or \$50 in the aggregate on an annual basis.” The statute also contains an exception for incentives given to individuals to promote the delivery of preventive care.

Analysis. The free blood pressure checks offered by the hospital will meet the definition of preventive care services if the free care does not promote the provision of other, nonpreventive care reimbursed by Medicare or Medicaid. In sum, the OIG found that the arrangement is crafted to avoid improper ties to the provision of other services. The free screenings, therefore, would not violate the prohibition on beneficiary inducements resulting in administrative sanctions or the imposition of civil money penalties. ■

OIG Advisory Opinion, No. 09-11, Aug. 3, 2009, Health Care Compliance Reporter, ¶1500,216

CCH Health Care Compliance Editorial Advisory Board

Timothy P. Blanchard, Esq.
McDermott Will & Emery

Patricia L. Brent, J.D., M.P.H.
President, Morgan Hill Associates

Michael E. Clark, J.D., LL.M.
Partner, Hamel Bowers & Clark LLP

Bill Dacey, MBA, MHA, CPC
President, The Dacey Group

Allan P. DeKaye, MBA, FHFMA
DeKaye Consulting, Inc.

Paul R. DeMuro, J.D., MBA
Partner, Latham & Watkins

Albert Y. Lin, Esq.
Partner, Brown McCarroll, LLP

Jeffrey B. Miller, Esq.
Chief Compliance Officer, Synthes Inc.

Stephen A. Miller, J.D.
Chief Compliance Officer, Capital Health System

Corrine Parver, J.D.
American University College of Law, Washington, D.C.

Cynthia Reaves, Esq.
Deloitte Services LP

Fay A. Rozovsky, J.D., M.P.H.
President, Rozovsky Group

William P. Schurgin, Esq.
Seyfarth, Shaw, Fairweather & Geraldson

John E. Steiner, Jr., Esq.
*Chief Compliance Officer,
UK HealthCare of Lexington, Kentucky*

Sanford V. Teplitzky, Esq.
Ober, Kaler, Grimes & Shriver

Has the IRS Met Its Goals with the New Form 990?

by Lisa A. Stegink, J.D.

More than a year ago, tax-exempt organizations and their advisors started preparing for the new Form 990 – the IRS’s long overdue redesign of the annual information reporting form filed by tax-exempt organizations. The new 11-page “core” section for all tax-exempt organizations and 16 potential schedules incorporate major changes and significant additions. Organizations that have not yet been required to file the new Form 990 are holding their collective breath to see how the experience goes for the first round of filers.

The IRS articulated essentially three main goals with the overhaul of the Form 990: promoting tax compliance; enhancing transparency to provide the IRS and the public with a realistic picture of the organization; and minimizing the administrative burden on filing organizations. Organizations that have spent any time with the new Form 990 may wonder whether they are looking at the same form as the IRS, particularly when it comes to minimizing the burden on filing organizations.

“Invasive,” “traps for the unwary,” “data mining,” and “does little to increase compliance” are phrases that have been variously used by exempt organizations’ financial staff, chief staff officers, and attorneys to describe the newly revised Form 990. This article considers whether the IRS really is meeting its goals, based on input from individuals responsible for completing, reviewing, and advising various size organizations on how to complete the Form 990.

Goal 1: Increase Tax Compliance

Can the IRS really change behavior as aggressively as it seems to be trying to do? One CFO of a large national professional society does not think so. According to him, the IRS appears to be trying to close loopholes for a small percentage of groups and all the rest have to pay: “Rather than audit the two percent of organizations that need it, the IRS is asking all the audit questions and making every organization send it in.”

In other words, this CFO believes the level and type of questions asked are more appropriate as part of an audit than as standard tax information reporting. Moreover, organizations that are not compliant now are not likely to answer the questions any differently or be more likely to comply simply

because there are more, or more detailed, questions. Another CFO agrees that while the new form may make the organization more “transparent” by putting more information out to the public, it does little to increase tax compliance.

In addition to required reporting on finances and activities, many sections address relationships within the organization and policies and practices helpful to ensure good governance. When asked why it included questions on governance, the IRS conceded that many of the questions request information on practices or policies that are not required by the federal tax law. Nevertheless, it believes that good governance and accountability practices provide safeguards that the organization’s assets will

be used consistently with its exempt purposes. The Form 990’s Checklist of Required Schedules also is intended by the IRS to provide “a quick view of whether the filing organization is conducting activities that raise tax compliance concerns, such as lobbying or political campaign activities, transactions with interested persons, and major dispositions of assets.”

Despite these goals, the questions may create confusion and make it more difficult than before for organizations to comply. It is true that some obscure statutory references on the Form 990 were replaced with specific, directed questions. However, it is essential for each organization and its tax preparer to review the definitions and instructions carefully to unearth the real questions. In some cases, questions that appear clear on their face must be answered differently than a straightforward reading of the question would imply. Organizations may unintentionally over-disclose or simply answer questions incorrectly if they are not careful.

In other cases, the same information is required in multiple places (e.g., independent contractor compensation, deferred compensation), or the organization must report information

“'Invasive,' 'traps for the unwary,' 'data mining,' and 'does little to increase compliance' are phrases that have been variously used by exempt organizations' financial staff, chief staff officers, and attorneys to describe the newly revised Form 990.”

differently on the form than it does in practice. For example, some schedules require salaries and payments to vendors to be reported on a calendar year basis, even if the organization's financial reports are completed on a fiscal year basis. All those factors increase the likelihood that organizations will make inadvertent reporting and compliance mistakes.

Goal 2: Enhance Transparency

The IRS believes that “well-governed and well-managed organizations are more likely to be transparent organizations with regard to their operations, finances, fund raising practices, and use of assets for exempt and unrelated purposes.” Opinions differ on whether the IRS, donors, members, and others interested in an organization will get a “realistic” and more transparent picture of any organization, or whether more confusion will result from the redesigned Form 990.

Some believe the new form will help unsophisticated readers understand an organization's activities and financial position. Others find transparency is not improved. A CFO from an international trade association said, “With all of the requirements, any layman trying to get a feel for the organization will in all likelihood be very confused or give up!”

Many organizations already are “transparent” in their reporting. For example, Code Sec. 501(c)(3) organizations have been required to disclose information, such as key employee compensation, and to take steps to avoid excess benefit transactions for some time, so the changes do not enhance transparency for them.

Yet, much has changed in the new form. Schedule O is a new schedule for providing further detail on questions answered, and for voluntary disclosure of anything not covered elsewhere. A tension can arise between fully describing the organization and its most important activities, and saying too much. The IRS generally encourages adding descriptions on schedules to supplement answers on the form. Organizations often desire to use the Form 990 as a public relations piece and a way to showcase the organization in a nutshell. However, they must remember that Form 990 is signed under penalty of perjury and the organization will be held accountable for all statements made. From a legal perspective, organizations must answer truthfully and fully, but also should suppress the urge to say everything that could possibly be said about the organization.

One CFO noted a potentially unintended result of “enhanced transparency.” Because names and salaries of the five highest compensated employees paid more than \$100,000 must now be disclosed publicly, tensions among employees could increase. Describing the question as “invasive,” this CFO believes such salary disclosures could force employee

salaries up or down from existing levels for no reason other than the required IRS disclosure. Organizations might reduce salaries to avoid disclosure, or raise salaries in response to perceived inequity among employees at a particular job level.

Goal 3: Minimize Administrative Burden

The consensus is clear that the IRS not only failed to minimize the administrative burden on reporting organizations, but it increased the burden substantially. The CFO of a large national trade association said, “Let me put it this way. Not in all my years have I had to consult an attorney in order to complete the Form 990—until now.” The IRS reorganized the layout of the form in an apparent effort to make it easier for someone who is not an accounting or legal professional to understand what is reported. However, organizations completing the form are having more difficulty and needing much more time to figure out how to report accurately.

Another CFO was very concerned that the association's valuable resources—including member dues and volunteer time—must be spent on additional consulting and legal fees, and board review necessary to complete the Form

990. “Not only do these efforts draw us away from the organization's mission, but obtaining governing body review may take weeks of time in our case, and cause significant levels of frustration among board members.”

Moreover, for many organizations, such as Code Sec. 501(c)(6) trade and professional organizations, the reporting requirements go beyond what the law requires for tax compliance. For example, Code Sec. 4958 imposes intermediate sanctions for excess benefits transactions on 501(c)(3) and 501(c)(4) organizations. Yet, all organizations now are required to answer questions regarding how they determine compensation, and whether their process for compensation decisions includes review and approval by independent persons, comparability data, and contemporaneous substantiation of decisions. Those are the three elements of a “safe harbor” for 501(c)(3) and 501(c)(4) organizations, but are not required by law for other types of exempt organizations.

In the current economic climate, the timing is bad for expending additional resources, particularly to answer operational questions that are not required by law or, some would argue, not appropriate for the IRS to ask. Many small organizations, in particular, could potentially be more at risk for answering incorrectly, especially if they need outside review but do not seek it for resource reasons.

“All those factors increase the likelihood that organizations will make inadvertent reporting and compliance mistakes.”

Private Foundations and Form 990-PF

How the changes in Form 990 will flow through to private foundations is currently unknown. Although speculation is that agents may start applying similar principles to private foundations, the IRS recently indicated it anticipates no changes to the Form 990-PF in the near future. In any event, private foundations, for which the rules are more restrictive than for public charities, should consider themselves “on notice” of potential changes.

Final Thoughts and Recommendations

To many, the redesigned Form 990 does not meet the IRS’s goals to increase compliance and transparency and minimize the administrative filing burden. Improvements to the Form 990 are needed to meet those goals. One approach the IRS could take is to apply the “80/20 rule.” Under the 80/20 rule, the IRS could obtain 80 percent of the information it needs and achieve 80 percent of its goals with only 20 percent of the questions it asks on the Form 990. For example, by focusing on the top five problem situations from the IRS perspective, such as business transactions with interested persons, the IRS could craft detailed, audit-like

questions that would give the IRS the critical information it needs to address major concerns.

Organizations that have not yet filed should continue to learn as much as they can about the new form and ask questions of their legal and tax advisors. They should ensure that governance policies are in place, and they should answer questions and describe activities with care and attention. If possible, they should do a “dry run” well in advance of the tax deadline to give the organization and its leadership time to work through the form and ask additional questions of attorneys and accountants. By identifying potential issues now, there is time to take thoughtful action, as necessary or appropriate, to minimize scrutiny and avoid leaving misimpressions with the IRS, members, donors, or the public.

If an organization already has filed the new Form 990, now is the time to provide feedback to the IRS. The IRS has specifically asked for comments on the redesigned Form 990 and the experience of filers with the new form. By providing feedback, the collective experiences and learning of numerous organizations could potentially contribute to improvements in the form and to the IRS’s approach to tax-exempt organization information reporting. ■

Lisa A. Stegink, J.D., is a partner in the Chicago law firm of Neal Gerber Eisenberg LLP. The author wishes to thank Amy Dering, a third-year law student at the University of Chicago Law School, for her contributions to this article.

“By providing feedback, the collective experiences and learning of numerous organizations could potentially contribute to improvements in the form and to the IRS’s approach to tax exempt organization information reporting.”

Trends

CMS needs agency-wide policy for translating written documents

To improve the consistency and transparency of translation decisions by the Centers for Medicare and Medicaid Services (CMS), the Government Accountability Office (GAO) recommends that CMS develop a written, agency-wide policy that includes criteria for the translation of written documents as part of its limited English proficiency (LEP) plan.

This matter was addressed in depth in the article “Title VI of the Civil Rights Act of 1964: A Compliance Primer for Health Care Providers” by Bruce L. Adelson, Esq., which appeared in the May 19, 2009 issue of the *Health Care Compliance Letter*.

Legal authority. Pursuant to the 2000 Executive Order 13166, federal agencies were required to develop a plan for how LEP individuals would be provided with

meaningful access to their programs, and the Department of Health and Human Services (HHS) in turn developed an LEP strategic plan that spelled out how its agencies would ensure that LEP beneficiaries were provided with language assistance services. Providers have noted that the cost of translating documents for themselves and of providing interpreters has increased as the number of languages spoken in the United States has increased.

Investigation request. CMS documents were reviewed by the GAO, at the request of the House Committee on Small Business, to determine whether the necessary forms and guidance are translated for beneficiaries with LEP.

The GAO interviewed various officials and staff from federal agencies, organizations interested in LEP issues, and provider representatives to assess the extent to which CMS provides translated documents and to study the difficulty providers encounter in communicating with LEP beneficiaries.

GAO findings. Specifically, the GAO examined a sample of 134 Medicare documents and found that 87 percent were translated into Spanish, but only some were translated into other languages such as Chinese, Korean, and Vietnamese. While HHS officials noted that its LEP plan provides a “road map” for addressing HHS’ goal of ensuring that LEP beneficiaries were provided with translations, CMS officials were not aware of an agency-wide translation policy for Medicare documents.

CMS has taken the step to appoint an individual to create just such an agency-wide policy so that vital information is consistently translated to LEP beneficiaries in the future. Furthermore, such a policy would be a cost-effective measure for providers who would not have to translate documents themselves and would reduce the need for bilingual staff and interpreters for oral translations. ■

GAO Letter to the House of Representatives Committee on Small Business, GAO-09-752R, July 30, 2009

Health IT

Breach notification rule issued for e-health information

On August 17th, the Federal Trade Commission (FTC) issued a final rule requiring certain web-based businesses to notify consumers when the security of their electronic health information is breached. The rule applies to both vendors of personal health records, which provide online repositories that people can use to keep track of their health information, and entities that offer third-party applications for personal health records.

Examples. These applications could include, for example, devices such as blood pressure cuffs or pedometers whose readings consumers can upload

into their personal health records. Many entities offering these types of services are not subject to the privacy and security requirements of the Health Insurance Portability and Accountability Act (HIPAA), which applies to health care service providers such as doctors' offices, hospitals, and insurance companies.

Recovery Act provisions. The American Recovery and Reinvestment Act of 2009 (ARRA) required the FTC to issue a rule requiring these entities to notify consumers if the security of their health information is breached. The FTC issued a proposed rule in April 2009, and collected public comments until June 1, 2009.

Requirements. The rule requires vendors of personal health records and related entities to notify consumers fol-

lowing a breach involving unsecured information. If a service provider to one of these entities has a breach, it must notify the entity, which in turn must notify consumers. The rule also specifies the timing, method, and content of notification, and in the case of certain breaches involving 500 or more people, requires notice to the media. Entities covered by the rule must notify the FTC, and they may use a standard form, which can be found along with additional information about the rule on the FTC web site at www.ftc.gov/healthbreach.

Effective date. The rule will take effect 30 days after publication in the *Federal Register*. The FTC will begin enforcement 180 days after publication. ■

FTC Press Release, August 17, 2009

Employment

Sex toy scandal did not affect doctor's application for privileges

Insufficient evidence existed to conclude that a doctor's professional references resulted in negative evaluations and interfered with his application for privileges with an association of doctors at a university hospital.

Facts. The case involved a scandal at the university's hospital where a female doctor received a sex toy from an adult store and the invoice clearly named the doctor as the purchaser. Although the doctor claimed his identity was stolen and that he was framed, and he remained under a cloud of suspicion, the university never took any formal disciplinary action against him.

Claims. The doctor argued that the university and the negative references interfered with his expectation of employment and induced the doctors' association to deny his application.

Findings. The U.S. Court of Appeals for the Seventh Circuit found no evidence that the defendants "prevented" him from obtaining clinical privileges at the association; in fact, four of the five references swore they never provided evaluations to the credential committee. The court also found no evidence that the association relied on

a conversation with the fifth reference because the doctor never took discovery from the association. The court stated that "only when the actions of a third party cause an employer to fire an ... employee, the third party is liable in tort." In addition, the information about the scandal was not privileged under the Illinois Medical Studies Act because it did not relate to the doctor's "professional competence." Finally, the doctor voluntarily signed a "Release and Immunity" by which he "extend[ed] absolute immunity to, release[d] from any and all liability, and agree[d] not to sue" any party for any matter relating to the application for privileges. ■

Botvinick v. Rush University Medical Center, 7th Cir., July 24, 2009, Health Care Compliance Reporter, ¶1800,698

Billing manager's whistleblower, retaliatory discharge actions fail

A former employee who brought suit against the radiology practice that terminated his employment failed to carry his burden of proof as to his state whistleblower and common law retaliatory discharge claims, according to the U.S. District Court for the Western District of Tennessee.

Facts. The employee was contracted to manage the business operations of the practice, including billing practices, which were handled by an outside billing service. He alleged that he repeatedly urged the board of directors to address the possibly illegal billing activities of the outside billing service, but that he was instead discharged in retaliation for raising these billing issues.

Whistleblower claim. The state whistleblower claim failed because the employee did not actually discover the alleged illegal billing activities, but rather, when he was asked to bring some structure and organization to the practice and to the outside billing company, the activities were pointed out to him, according to the testimony of one of the physicians. He was also unable to show that the billing issues were the sole reason for his termination. Furthermore, the court noted evidence that clearly indicated he was terminated due to his verbal abuse of another employee.

Retaliatory discharge claim. The employee's retaliatory discharge claim was also dismissed by the court because he was not an at-will employee as required for the Tennessee law to apply, but instead was employed pursuant to an employment contract. ■

McDonough v. Memphis Radiological Professional Corporation, W.D. Tenn., July 22, 2009, Health Care Compliance Reporter, ¶1800,695

Tax-Exempt

Consolidation of nonprofit hospitals not *bona fide* sale

There was no *bona fide* sale of assets between two nonprofit hospitals that consolidated and therefore no recognizable loss on disposition of assets that would trigger a reimbursement adjustment, according to the U.S. Court of Appeals for the Third Circuit.

Assets and liabilities. The first hospital had approximately \$47 million in monetary assets, \$107 million in other business assets, and \$27 million in debt. The second hospital had \$122 million in monetary assets, \$25 million in other business assets, and debts of approximately \$93 million.

Reimbursement adjustment. The hospitals argued they were entitled to an adjustment because CMS had improperly denied their claim based on *Program Memorandum (PM) A-00-76*, which the hospital argued was inconsistent with previous regulations.

The memorandum said that the "unrelated parties" and "bona fide sale" provisions in Medicare regulations apply with equal force to both statutory mergers and to consolidations. However, the Third Circuit in *Albert Einstein Medical Center v. Sebelius*, recently held that PM A-00-76 "offered a clarification of the Bona Fide Sale Provision that was not inconsistent with previous agency policy."

Arms length negotiations. The hospitals' second argument was that they fulfilled the "bona fide sale" requirement, even if it applies to both mergers and consolidations. Under the provision, however, a *bona fide* sale requires arms length negotiation and reasonable consideration. Here, there was no evidence to support a finding of arms length negotiation and reasonable consideration (i.e., a *bona fide* sale) because the hospitals' assets were not on the open market, there was no pre-consolidation appraisal, and there were no negotiations over price, assets, or debts. ■

Sewickley Valley Hospital v. Sebelius, 3rd Cir., July 24, 2009, *Health Care Compliance Reporter*, ¶800,697

In the News

Over \$1.3 billion recovered by MFCUs in FY 2008

In FY 2008, State Medicaid Fraud Control Units (MFCUs) recovered more than \$1.3 billion in court-ordered restitution, fines, civil settlements, and penalties. MFCUs also obtained 1,314 convictions and reported a total of 971 instances in which civil settlements and/or judgments were achieved. Of the 3,129 exclusions from participation in the Medicare, Medicaid, and other federal health care programs in FY 2008, 755 exclusions were based on referrals made to the Office of Inspector General (OIG) by the MFCUs. During this FY 2008 reporting period, 49 States and the District of Columbia participated in the Medicaid fraud control grant program through their established MFCUs. The mission of the MFCUs is to investigate and prosecute Medicaid provider fraud and patient abuse and neglect. MFCUs' authority to investigate and prosecute cases varies from state to state. Forty-three of the MFCUs are located within Offices of State Attorneys General. The remaining seven MFCUs are located in various other state agencies.

OIG's Annual Report on State Medicaid Fraud Control Units, FY 2008

Denials for pre-existing conditions examined

An HHS report examines the insurance company practice of denying coverage to or discriminating against Americans who have pre-existing medical conditions. According to the report, a recent national survey found that 12.6 million non-elderly adults were discriminated against in the past three years because an insurance company deemed them ineligible for coverage because of a pre-existing condition, charged them a higher premium, or refused to cover their condition. Another survey found 10 percent of cancer patients said they could not get health coverage, and six percent said they lost their coverage because of their diagnosis. The report states that some insurance companies respond to an expensive condition such as cancer by initiating a thorough review of the patient's health insurance application. If the company discovers that any medical condition was not reported on the application, it could revoke coverage retroactively for the patient and possibly his family. The report claims that companies can do this even if the condition found is not related to the expensive condition or if the person wasn't aware of the condition at the time. The report is available at www.HealthReform.gov.

HHS Report, August 11, 2009

\$13.4 million in nurses aid released

HHS has announced the release of \$13.4 million for loan repayments to nurses who agree to practice in facilities with critical shortages and for schools of nursing to provide loans to students who will become nurse faculty. The awards come from two programs administered by HHS' Health Resources and Services Administration (HRSA): the Nurse Education Loan Repayment Program (NELRP) and the Nurse Faculty Loan Program (NFLP). Funding under NELRP totals \$8.1 million. Those funds will help 100 registered nurses pay their nursing education debts. The program repays 60 percent of the loan balance of registered nurses in exchange for two years of service at facilities with a critical shortage of nurses. Funds under NFLP total \$5.3 million. Those funds go to schools of nursing to support the training of 500 masters and doctoral nursing students who plan to become nurse faculty after completing their education. Following graduation, loan recipients may cancel up to 85 percent of the loan principal and interest in exchange for four years of service as a full-time nursing faculty at a school of nursing. For additional information see <http://bhpr.hrsa.gov/recovery/>.

HHS News Release, August 12, 2009