CCH Health Care Compliance LETTER

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House and Senate unveil health care reform legislation

Comprehensive health care reform legislation passed two significant milestones last week as the Senate Health, Education, Labor and Pensions (HELP) Committee passed the "Affordable Health Choices Act" out of committee and House democrats introduced the "America's Affordable Health Choices Act of 2009" (HR 3200). At the same time, comments from the head of the Congressional Budget Office (CBO), Republican leaders, and Democrats on the Senate Finance Committee put a damper on the potential progress of the legislation.

Senate bill. While the HELP Committee's measure has passed out of committee, the heavy lifting, or how to pay for it, has been left up to the Senate Finance Committee. Finance Committee Chairman Max Baucus (D-Mont.) and key members have yet to forge an agreement on the best way to raise revenue to fill an estimated $320 billion gap that remains after all reforms are in place and the final cost nears $1 trillion. Even after the Finance Committee produces a markup, lawmakers will face the hurdle of melding it with the HELP committee version.

Play or pay mandate. Approved 13-10 on party lines, the HELP Committee's measure provides a public insurance option and a play-or-pay mandate for most employers that would require them to provide health insurance for their employees or face a stiff penalty. The reform reportedly would cover 97 percent of the currently estimated 46 million uninsured and place greater emphasis on preventative care and wellness programs.

House bill. The House bill (HR 3200) would reportedly raise taxes approximately $581.1 billion over 10 years, mostly through a progressive tax on upper income individuals. The 1,018 page bill is expected to cut Medicare spending by at least $500 billion. The measure includes penalties for employers with payrolls exceeding $250,000 that do not provide health insurance, a tax credit to help small businesses provide coverage for their employees, and surtaxes for high-income earners.

High-income surtax. Under HR 3200, approximately $544 billion in revenues would be raised through a surtax of 5.4 percent on married individuals with adjusted gross income over $1 million beginning in 2011, a 1.5 percent surtax on incomes between $500,000 and $1 million, and a one percent surtax on incomes from $350,000 to $500,000. The lowest two tax rates would be increased to two percent and three percent, respectively, if health care cost savings are not achieved by the bill.

Employer surtaxes, tax credits. HR 3200 also would require that employers with annual payrolls exceeding $250,000 pay a payroll penalty of two percent

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if they do not provide health insurance. Firms with annual payrolls above $400,000 would pay an eight percent penalty. Some small businesses would be eligible for a new small business tax credit to help them provide coverage for their employees.

Early opposition. House Minority Leader John Boehner (R-Ohio) immediately criticized the health care bill. "During a deep economic recession, it is criminal malpractice for Democrats to push a government takeover of health care and a new small business tax that will destroy more American jobs," Boehner stated.

CBO estimates. A preliminary estimate from the CBO and the Joint Committee on Taxation indicated that passage of the health reform measure would result in a net increase in federal deficits of $1.042 trillion for fiscal years 2010 through 2019. Most of the increased deficit comes from $438 billion in additional federal outlays for Medicaid and $773 billion in federal subsidies that would be provided to purchase coverage through the new insurance exchanges. The other main element that would increase federal deficits is the tax credit for small employers who offer health insurance, which is estimated to reduce revenues by $53 billion over 10 years. CBO Director Douglas Elmendorf warned lawmakers that the reform measures introduced to date will significantly expand the federal spending on health care.

Senate reaction. The House plan to raise revenue through a surtax on the wealthy may be a nonstarter in the Senate as several members of the Senate Finance Committee let it be known that the provision had little support. "The House is the House. We in the Senate are a different institution," said Baucus when asked if he could back a surtax on the wealthy. Baucus also was unwilling to commit to a expedited markup deadline. Instead he promised to have a bill completed before the Senate leaves for its summer recess. ■

CCH Washington and Chicago Bureaus, July 17, 2009

Antitrust

Physician fails to show denial of privileges impacted interstate commerce

Antitrust claims against a medical center were dismissed because the denial of a physician's reappointment to the hospital staff did not have an effect on interstate commerce.

The physician had a standard two-year appointment for admitting privileges at the medical center that was set to expire. The medical center sought additional information not previously provided by the physician in connection with his prior reappointments, including information that would permit the medical center to evaluate his competency. The physician eventually had his application for reapplication denied by the medical center because of questions regarding his clinical competence. During this timeframe, the physician had a concurrent, pending application for staff privileges at another community hospital. The community hospital requested information that the physician alleged was outside of its standard credentialing application. Soon after his denial for reappointment at the medical center, the physician's community hospital application was denied because he did not have privileges at another hospital within 50 miles as required by its bylaws.

Conspiracy claims. The physician alleged that the medical center's credentialing board and community hospital conspired to exclude his privileges at both facilities in violation of antitrust laws. The physician alleged that between the time he applied to and was denied admitting privileges at the local hospital, the credientialing board at the medical center was influencing the decision-making process. The physician claimed that the community hospital intentionally delayed taking action on his application so that a decision would not be made until his medical center privileges expired.

Court rationale. Following precedent of the U.S. Supreme Court, the U.S. District Court for the District of Delaware noted that the parallel actions of the medical center and community hospital did not suggest a conspiracy. Without further evidence, it was plausible that the medical center and community hospital were each acting in

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their best economic interests. Although specific examples of interstate commerce were not necessary, the physician needed to provide allegations regarding his interstate dealings to support the notion that his exclusion from the medical staff affected interstate commerce.

According to the court, the physician failed to demonstrate that: (1) the medical services provided by the medical center were regional; (2) federal funds were accepted by the medical center; or (3) the physician, himself, frequently treated out of state patients. The physician's allegations were limited in geographic scope to the county in which both facilities were located. Therefore, the medical center's motion to dismiss was granted. ■

Villare v. Beebe Medical Center, Inc., D. Del., July 1, 2009, Health Care Compliance Reporter, ¶800,688

Anti-Kickback/Physician Self-Referral

Sharing of cost savings, free supplements for dialysis patients OK'd

The Office of Inspector General (OIG) has issued advisory opinions stating that (1) an existing arrangement by a hospital to share its cost savings arising from a number of physician-implemented cost-reduction measures with three medical specialty groups would not be subject to administrative sanctions under the anti-kickback statute, and (2) it would not seek sanctions against a dialysis facility providing dialysis services to patients with end stage renal disease (ESRD) that proposed to furnish free nutritional supplements to patients.

Sharing hospital cost savings. A hospital sharing its cost savings arising from a number of physician-implemented cost-reduction measures with a cardiology group, a vascular surgical group, and an interventional radiology group requested that OIG review the existing arrangement. The cost savings were measured based on the physicians' use of specific medical devices and supplies during designated cardiac catheterization procedures. Individual physicians made a patient-by-patient determination of the most appropriate device or supply for use. The physicians had available the same selection of devices and supplies after implementation of the arrangement. Quality care indicators were tracked and the hospital did not allocate any cost-sharing amounts to the physician groups if the cardiac catheterization procedures performed involved reductions in the hospital's quality.

In approving the arrangement, the OIG noted that a number of safeguards reduced the risk of fraud or abuse, including: (1) a transparent process that identified and separated cost-saving actions and resulting savings, (2) credible support that cost-saving measures did not adversely affect patient care, (3) amounts to be paid were calculated based on all procedures performed, (4) objective historical and clinical measures were used to establish baseline thresholds beyond which no savings accrued to the physician groups, (5) protections ensured that individual physicians had available the same selection of devices and supplies, (6) written disclosures of the arrangement were provided to patients, (7) financial incentives were limited in duration and amount, and (8) profit distribution was on a *per capita* basis.

Free nutritional supplements. A dialysis facility providing services to ESRD patients proposed furnishing free nutritional supplements to patients whose blood albumin levels were below a specified target and whose physicians ordered the supplements. Although the provision of free items or services ordinarily would implicate the anti-kickback statute and the prohibition of remuneration to beneficiaries, the OIG found that the following safeguards minimize the risks: (1) the supplements would be provided only to ESRD patients with blood albumin levels below a specified target and would be stopped when the patient attained the target, (2) the supplements would be furnished only on a physician's order, (3) the availability of the supplements would not be advertised, (4) the provider would not include the cost of the supplements in any cost report, and (5) the patients would receive only one dose at a time and would be required to consume it during that visit to the facility. ■

OIG Advisory Opinions, No. 09-06, June 23, 2009, Health Care Compliance Reporter, ¶500,211; and No. 09-07, June 23, 2009, Health Care Compliance Reporter, ¶500,212

On The Front Lines

How The American Recovery and Reinvestment Act of 2009 Changed HIPAA's Privacy Requirements

by Corrine P. Parver, Esq. & Savannah Thompson-Hoffman

The 2009 economic stimulus bill, known as the American Recovery and Reinvestment Act (ARRA),[1] significantly affects the health care industry by imposing more stringent and expansive requirements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA)[2] privacy and security provisions, most especially on key players in the health care industry while simultaneously strengthening the enforcement of such provisions. Title XIII of Division A and Title IV of Division B of ARRA collectively are known as the "HITECH Act." Because the majority of ARRA's changes to HIPAA appear in Subtitle D of Title XIII of ARRA, entitled "Privacy," Subtitle D will be the primary focus of this article, which highlights ARRA's major changes to the HIPAA privacy and security provisions and explores the implications of these sweeping changes for the health care industry.

Direct Application of HIPAA's Privacy and Security Provisions to Business Associates

Perhaps the most sweeping change made by ARRA is its imposition of HIPAA obligations and liability on business associates. Section 13401 of ARRA makes a major change in the treatment of business associates by extending the application of the HIPAA physical,[3] technical,[4] and administrative security[5] provisions to business associates, provisions that previously applied only to covered entities.[6] Section 13404 further restricts the ability of business associates to use and disclose protected health information by extending the application of HIPAA privacy provisions[7] to business associates.

Covered entities are health plans, health care clearinghouses, and health care providers that transmit electronic health information.[8] Business associates contract with covered entities to perform functions or services on behalf of the covered entities "involving the use or disclosure of individually identifiable health information,"[9] such as: "legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services."[10]

Prior to the enactment of ARRA, HIPAA privacy and security rules applied only to covered entities.[11] Business associates were not directly covered by HIPAA but were obligated to comply with privacy rules to the extent required in their contracts with covered entities.[12] If a business associate breached the terms of the contract, known as the business associate agreement, thereby violating HIPAA, the business associate was liable only to the covered entity for breach of contract and was not subject to federal penalties.

Sections 13401 and 13404 impose direct liability on business associates for violations of HIPAA security and privacy provisions, respectively, and erase an important distinction between business associates and covered entities by subjecting business associates to the same civil and criminal penalties that apply to covered entities for HIPAA violations. Thus, all business associate agreements between business associates and covered entities must be updated to reflect ARRA's new privacy and security requirements.

Expanded Definition of Business Associate

Section 13408 broadens the definition of business associate for the purposes of HIPAA to include organizations that "provid[e] data transmission of protected health information" to covered entities and that "requir[e] access on a routine basis to such protected health information."[13] Health Information Exchange Organizations, Regional Health Information Organizations, E-prescribing Gateways, and vendors that "contrac[t] with a covered entity to allow that covered entity to offer a personal health record to patients as part of its electronic health record" are examples of business associates under ARRA's expanded definition.[14] One implication of this expanded definition of business associate is that, under ARRA, these organizations are now required to enter into business associate agreements with covered entities and are subject to the same penalties as covered entities.

Stricter Breach Notification Requirements

Section 13402 imposes federal breach notification requirements on both covered entities and business associates. Section 13402(a) requires a covered entity to notify an individual if there has been a breach or reasonably suspected breach of that individual's unsecured protected health information (PHI). Section 13402(b) requires a business associate to notify a covered entity in the event of a breach or suspected breach of an individual's PHI.

A breach is defined as "the unauthorized acquisition, access, use, or disclosure of protected health information which compromises the security or privacy of such information."[15] Three main exceptions exist to this definition. First, a breach does not occur when an unauthorized person who receives PHI is unable to reasonably retain the information. Second, a breach does not occur if an "unintentional acquisition, access, or use" of PHI occurs within the scope of employment of an employee of a covered entity and the information is "not further acquired, access, used, or disclosed by any person."[16] Finally, a breach does not occur if the disclosure of PHI is both inadvertent and is from "an individual who is otherwise authorized to access protected health information at a facility operated by a covered entity or business associate" to a "similarly situated individual at the same facility."[17] Importantly, the information must not be "further acquired, accessed, used, or disclosed by any person."[18]

A breach is considered "discovered" on the first day it is known or should reasonably have been known to have occurred.[19] Breach notifications are required to be made "without unreasonable delay" and not later than 60 days after discovery of the breach.[20] The burden of proof is on the covered entity to demonstrate that all required notifications of breach were made and explain the reasons for any delay in notification.

In the event of a breach, there are a variety of methods of notice under Section 13402(e) that are required depending upon the circumstances and the number of individuals affected. Generally, an individual must be notified by first-class mail if his or her unsecured PHI has been breached.[21] If notification by mail is not possible, a substitute form of notice shall be provided such as a phone call or email. If the PHI of ten or more individuals has been breached and there is insufficient contact information, the covered entity must post a conspicuous notice on its web site or place a notice in the local media.[22] In addition to notifying the affected individual of the breach, the covered entity also must keep a log of all breaches and submit annual documentation of such breaches to the Secretary of the Department Health and Human Services (HHS).[23]

If the PHI of more than 500 individuals of a state is breached, the covered entity responsible for the breach must provide notice to prominent media outlets as well as immediate notice to the Secretary of HHS. In such a situation, the Secretary is required to list the covered entities involved in the breach on HHS's website.[24]

The breach notification should include five pieces of information – (1) a brief summary of what happened, (2) a description of the types of unsecured PHI involved in the breach, (3) a description of what the covered entity is doing to investigate the breach and prevent further breaches, (4) the steps the affected individual should take to mitigate the harm resulting from the breach, and (5) contact information to allow the individual to learn more information about the breach incident.[25] Vendors of personal health records also must notify an individual if there has been a breach of that individual's unsecured personal health record. Additionally, vendors must notify the Federal Trade Commission in the event of a breach.[26]

Encryption and Data Destruction Provide Safe Harbor from Breach Notification Requirement

The breach notification requirement is only triggered when the PHI that is breached is unsecured. Health information is "secured" if it is rendered "unusable, unreadable, or indecipherable to unauthorized individuals" using a methodology that the HHS Secretary approved.[27]

On April 27, 2009, HHS published guidance, as required by Section 13402(h) of ARRA, specifying the technologies and methodologies that render PHI secured.[28] Under the guidance, covered entities and business associates may use encryption or data destruction, among other methods, to secure PHI so that the notification requirement is not triggered if the information is breached. "While covered entities and business associates are not required to follow the guidance, the specified technologies and methodologies, if used, create the functional equivalent of a safe harbor and, thus, result in covered entities and business associates not being required to provide the notification otherwise required by Section 13402 in the event of a breach."[29] Covered entities and business associates nevertheless must comply with applicable state regulations regarding the breach of PHI as well as HIPAA's requirement that any harmful effects of the breach be reasonably mitigated.[30]

Expanded Individual Rights

ARRA greatly expands the rights of individuals under HIPAA. For the first time, covered entities have an obligation to comply with an individual's request to restrict the disclosure of PHI if the disclosure is not for the purposes of treatment, and the information "pertains solely to a health care item or service for which the health care pro-

vider involved has been paid out of pocket in full."[31] Prior to ARRA, individuals could request restrictions on the disclosure of their PHI, but covered entities were under no obligation to comply.[32] This new provision imposes an administrative burden on health care providers by requiring them to separate certain information (for services which have been paid for out of pocket in full by an individual) from the rest of an individual's record.

Section 13405(c) further expands the rights of individuals by giving them the right to request a description of all disclosures of their PHI stored in an electronic health record made during the three years prior to the request.[33] Prior to ARRA, individuals had the right to request an accounting of the disclosures of their PHI by a covered entity or its business associates during the six years prior to the accounting request, but covered entities were not obligated to account for disclosures for treatment, payment, or health care operations. While Section 13405(c) imposes a burden on covered entities to adopt a new accounting method to track each disclosure of PHI, including disclosures for treatment, payment, and health care operations, it "represents a major change in the transparency of health data uses and flows."[34]

Section 13410(c) reinforces the rights of individuals by requiring the establishment of a methodology to distribute to an "individual who is harmed by an act that constitutes an offense [under Subtitle D]... a percentage of any civil monetary penalty or monetary settlement collected with respect to such offense."[35] While individuals do not have a private cause of action to vindicate their own rights under HIPAA, ARRA now recognizes harmed individuals by allowing them to share in part of the monetary penalty collected.

Restrictions on the Sale of Protected Health Information and Marketing Communications

Section 13405(d) prohibits the sale of electronic health information without patient authorization except in certain circumstances. These circumstances include when the exchange of information is for: public health activities, research, treatment of the individual, the health care operation, or to provide the individual with a copy of his or her PHI. This provision effectively "shut[s] down the secondary market that has emerged around the sale and mining of patient health information by prohibiting the sale of an individual's health information without [his or her] authorization."[36]

ARRA "clarifies that a marketing communication by a covered entity or business associate about a product or service that encourages the recipient to purchase or use the product or service may not be considered a health care operation unless the communication is for a health-care related product or service, or relates to the treatment of the individual."[37] Section 13406 requires written fundraising communications to "provide an opportunity for the recipient of the communications to elect not to receive any further such communication."[38]

Penalties and Protections: Strengthened Enforcement of HIPAA with Increased Penalties

ARRA sharpens the teeth of HIPAA provisions by increasing civil penalties and expanding the scope of enforcement opportunities. Section 13410 amends HIPAA by "replacing the existing civil monetary penalties with four tiers of penalties, the highest of which would impose a fine of $50,000 per violation and up to $1,500,000 for all such violations of an identical requirement or prohibitions during a calendar year."[39] The four tiers are differentiated based upon the knowledge and intent of the person who violated the provision. Persons who "did not know (and by exercising reasonable diligence would not have known) that they were violating a provision, fall into the first tier. The second tier includes persons whose violations were "due to reasonable cause and not willful neglect." Persons who engage in violations due to willful neglect but who correct the violation within a specified time fall into the third tier. Finally, the fourth tier includes persons whose violations are due to willful neglect and who fail to correct the violation within a specified time.[40]

Various members of the health law bar have expressed some puzzlement over the meaning of ARRA's tiered penalty provisions. While some have interpreted Section 13410(d)(1)(A) to ascribe the maximum 1.5 million dollar penalty to unwitting violations, logic dictates that it would be inconsistent with the plain meaning of the statute to apply the same penalty to unwitting violations as those violations resulting from willful neglect.[41] If a violation is due to "willful neglect," the Secretary is required to investigate formally the situation and impose a civil monetary penalty. Moreover, the Secretary is required to "perform periodic audits to ensure compliance with the HIPAA privacy and security standards" and the requirements of Subtitle D.[42]

Finally, ARRA amends HIPAA by authorizing state attorneys general to bring a civil action in federal court on behalf of individuals who were "threatened or adversely affected by any person who violates a provision of HIPAA against individuals who threaten" an interest of one or more of the residents.[43] This change will likely contribute to greater attention to enforcement of HIPAA at the state level.

Enhanced Guidance and Education

Section 13401 requires the Secretary, in consultation with stakeholders in the health care industry, to issue annual guidance on "the most effective and appropriate technical safeguards" for protecting electronic health information.[44] Section 13403 requires the Secretary to appoint an individual in each HHS regional office to "offer guidance and education to covered entities, business associates, and individuals on their rights and responsibilities" related to health information privacy and security.[45]

Because the Office for Civil Rights (OCR) currently provides guidance, it is likely that a regional contact will be able to provide more personalized and tailored guidance and advice to local entities. Section 13403 requires OCR to create a national

education initiative to teach individuals about the permissible uses of their PHI and their rights under HIPAA. This initiative will "enhance public transparency" and empower individuals to ensure that their PHI remains secure.[46]

Ramifications of ARRA's Changes to HIPAA for the Health Care Industry

ARRA increases the rigor and broadens the scope of HIPAA compliance. These broad new requirements necessitate a variety of expensive and time-consuming changes by covered entities, business associates, and vendors to ensure compliance.

Covered entities, business associates, and vendors will need to update their HIPAA policies and procedures to address the changes made by ARRA. In addition, they will need to train their employees on these important changes. The contracts between business associates and covered entities will need to be updated and amended to reflect ARRA's changes. Health Information Exchange Organizations, Regional Health Information Organizations, E-prescribing Gateways, and other organizations not previously included within HIPAA's definition of "business associate" will have to enter into business associate agreements for the first time with covered entities.

Covered entities will need to revise their HIPAA privacy notice to incorporate changes to an individual's right to request a restriction on the disclosure of some PHI. Covered entities will need to review their liability insurance contracts and make changes to ensure that they are covered for potential HIPAA violations given the increased requirements and penalties. Covered entities also will need to develop and institute new breach notification procedures that comply with ARRA's federal breach notification requirements. They will need to work with a team of information security specialists to adopt new and potentially very costly technologies such as encryption or data destruction methods to ensure that all PHI they handle is considered "secure" and, thus, not subject to the breach notification requirements.

Finally, covered entities will need to develop a new accounting method to track disclosures of PHI to comply with the increased rights of individuals to know when their PHI has been disclosed. While these changes will burden covered entities because they will be expensive and disruptive to implement, the benefits outweigh the burdens. Congress should be commended for using the stimulus bill as an opportunity to improve the health of all Americans by investing in health information technology that will result in fewer medical errors and efficient health care delivery while simultaneously taking broad sweeping steps to ensure greater protection of personal health information.

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1 American Recovery and Reinvestment Act of 2009 (ARRA)(PubLNo 111-5).
2 HIPAA (PubLNo 104-191).
3 45 C.F.R. §164.310.
4 45 C.F.R. §164.312.
5 45 C.F.R. §164.308.
6 *Supra* n. 1 at §13401(a).
7 45 C.F.R. §164.504(e).
8 45 C.F.R. §160.103.
9 45 C.F.R. §160.103(i)(A).
10 45 C.F.R. §160.103(ii).
11 *Supra* n. 8.
12 Center for Democracy and Technology, Policy Post 15.2: *Improvements and Challenges in Health Privacy Law*, http://www.cdt.org/publications/policyposts/2009/2, March 27, 2009.
13 *Supra* n. 1 at §13408.
14 *Id.* at §13408.
15 *Id.* at §13400(1)(A).
16 *Id.* at §13400(1)(B)(i).
17 *Id.* at §13400(1)(B)(ii).
18 *Id.*
19 *Id.* at §13402(c).
20 *Id.* at §13402(d)(1).
21 *Id.* at §13402(e)(1)(A).
22 *Id.* at §13402(e)(1)(B).
23 *Id.* at §13402(e)(3).
24 *Id.* at §13402(e)(2).
25 *Id.* at §13402(f).
26 *Id.* at §13407(a).
27 *Id.* at §13402(h)(1)(B).
28 Guidance Specifying the Technologies and Methodologies That Render Protected Health Information Unusable, Unreadable, or Indecipherable, Final rule, 74 FR 19006, 19009 (April 27, 2009) (to be codified at 45 C.F.R. parts. 160, 164).
29 *Id.* at 19008.
30 *Id.*
31 *Supra* n. 1 at §13405(a).
32 Office for Civil Rights, *OCR Privacy Brief: Summary of the HIPAA Privacy Rule*, May 3, 2009.
33 *Supra* n. 1 at §13405(c)(1)(B).
34 Center for Democracy and Technology, Policy Post 15.2: *Improvements and Challenges in Health Privacy Law*, http://www.cdt.org/publications/policyposts/2009/2, March 27, 2009.
35 *Supra* n. 1 at §13410(c).
36 Majority Staff of the Committees on Energy and Commerce, *Ways and Means, and Science and Technology, Title IV - Health Information Technology for Economic and Clinical Health Act*, Jan. 16, 2009.
37 *Id.* at 21.
38 *Supra* n. 1 at §13406(b).
39 C. Stephen Redhead, *CRS Report for Congress: The Health Information Technology for Economic and Clinical Health (HITECH) Act*, at 22, Feb. 23, 2009.
40 *Supra* n. 1 at §13410(d)(3).
41 *Id.* at §13410(d)(1)(A).
42 *Id.*
43 *Id.* at §13410(e).
44 *Id.* at §13401.
45 *Id.* at §13403(a).
46 *Id.* at §13403(b).

Fraud & Abuse

Lack of direct knowledge, prior disclosure defeats whistleblower action

A federal district court properly dismissed a whistleblower's (relator) *qui tam* action against a wound care clinic for allegedly submitting false claims to Medicare and Medicaid because (1) the relator lacked direct or independent knowledge of the clinic's billing practices, and (2) the clinic's questionable billing practices were apparently disclosed when CMS began its investigation.

The relator was a patient at the wound care clinic, but her only knowledge of the alleged fraud was seemingly provided to her by her attorney. The allegations in the relator's complaint were substantially similar to publicly disclosed information. A false claim relator's complaint may not be based upon publicly disclosed allegations. Because both the relator and her attorney pleaded the Fifth Amendment, the court was unable to determine how and where the relator and her attorney gained knowledge of the wound care clinic's billing practices.

According to the court, the allegations in the relator's complaint were publicly disclosed by CMS when the agency began an active investigation into the clinic's billing practices a month before the relator filed her suit. The public disclosure by CMS warned the government that there may have been a potential fraud being perpetuated against it. Because the government agency had already begun an investigation, the relator's information was essentially useless to the government because it had been warned of the potential fraud. Given the unanswered questions of how and where the relator gained personal knowledge of the potential fraud and the previous public disclosure by CMS, the Seventh Circuit decided that the district court's dismissal of the case was correct. ■

Glaser v. Wound Care Consultants, 7th Cir., July 2, 2009, Health Care Compliance Reporter, ¶800,687

In the News

Obama nominates U.S. Surgeon General

The President has nominated Dr. Regina Benjamin for the position of U.S. Surgeon General. Dr. Benjamin is the founder and Chief Executive Officer of the Bayou La Batre Rural Health Clinic in Alabama. She previously served as Chair of the Federation of State Medical Boards of the United States, and as the Associate Dean for Rural Health at the University of South Alabama College of Medicine. She was chosen as President of the Medical Association of Alabama in 2002, becoming the first African-American woman to be president of a state medical society. She was also the first African-American woman and physician under 40 to be elected to the American Medical Association Board of Trustees. She received the Nelson Mandela Award for Health and Human Rights in 1998. In her remarks, Dr. Benjamin stated that: "...As we work toward a solution to this health care crisis, I promise to communicate directly with the American people to help guide them through whatever changes may come with health care reform."

White House Press Briefing, July 13, 2009

OIG concerned about ultrasound overuse

In a study of ultrasound services furnished during 2007, the Office of Inspector General (OIG) found that 20 high-use counties accounted for 16 percent of Part B spending on ultrasound despite having only 6 percent of Medicare beneficiaries. In 2007, Medicare Part B covered about 17 million ultrasound services in ambulatory settings at a cost of over $2 billion. Previous OIG work has raised concerns about the growth in imaging services covered under Part B and found that high geographic concentrations of providers or services may indicate weaknesses in Medicare's program safeguards. Nearly one in five ultrasound claims nationwide has characteristics that raise concerns about whether the claims were appropriate. The OIG recommends that CMS (1) monitor ultrasound claims data to detect questionable claims, and (2) take action when providers bill for high numbers of questionable claims for ultrasound services. CMS concurred with both of the OIG recommendations and intends to take actions to address them.

OIG Report, No. OEI-01-08-00100, July 1, 2009

Growth in health care sector jobs predicted

The President's Council of Economic Advisers predicts a continuation of the long-term trend toward more employment in health care, with the subsectors of nursing homes, physician offices, and private hospitals growing strongly. "Other medical services and dentists," which is a broad category including the ever-expanding home health care, outpatient care, and medical and diagnostic laboratories subsectors, is expected to add the most jobs. Jobs for medical records and health information technicians also are projected to increase, especially with government investment in health information technology mandated by the HITECH Act. The increased demand in health care support occupations are projected to experience even faster growth. The increased demand stems largely from an aging population. Health care reform, however, is expected to slow the growth rate of health spending as efficiency is improved. Even with a slower growth rate of spending, the expected expansion of health coverage could lead to an increased demand for workers – including physicians, nonphysician clinicians, health care support workers and nurses – to cover the newly insured population.

President's Council of Economic Advisors Report, "Preparing the Workers of Today for the Jobs of Tomorrow," July 2009