CCH Health Care Compliance LETTER

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Effect of Senate bill on insurance premiums analyzed by CBO/JCT

The Congressional Budget Office (CBO) and the staff of the Joint Committee on Taxation (JCT) have analyzed how the enactment of the Patient Protection and Affordable Care Act (HR 3590), as introduced in the Senate on November 18, 2009, might affect health insurance premiums. The CBO/JCT examined the key provisions of the proposed legislation and analyzed the effects on premiums for coverage purchased by individuals, small employers (less than 50 employees), and large employers.

Key elements of Senate bill. The proposal legislation includes many provisions that would affect insurance premiums:

- **2014 requirements.** New policies purchased from insurers individually or by small employers in 2014 would have to cover a specified set of services and have to pay, on average, at least 60 percent of the costs of providing covered services to a representative set of enrollees. Insurers also would have to accept all applicants during an annual open-enrollment period, and insurers could not limit coverage for preexisting medical conditions. Premiums, moreover, could not vary based on an enrollees' health condition or use of services and could only vary based on an enrollee's age to a limited degree.
- **2013 requirements.** In 2013, and thereafter, health insurance plans: (1) could not impose lifetime limits on the total amount of services covered; (2) could rescind coverage only for certain reasons; (3) would have to cover certain preventive services with no cost sharing; and (4) would have to allow unmarried dependents to be covered under their parents' policies up to age 26. These changes would also apply to new coverage by large employers, including firms that self-insure. Current policies, however, that had been purchased or offered by self-insured firms would be exempt from all of those changes if they were maintained continuously or "grandfathered" in.
- **Additional mandates.** The proposal legislation also would: (1) establish a mandate for most legal residents of the U.S. to obtain health insurance; (2) set up insurance "exchanges" through which individuals and families could receive subsidies reducing the cost of coverage; (3) make a public insurance plan available through those exchanges in certain states; (4) penalize certain individuals if they did not obtain insurance coverage; (5) penalize certain employers if their workers receive subsidies through the exchanges; (6) provide tax credits to small employers that offer coverage to their workers; (7) significantly expand Medicaid eligibility; (8) substantially reduce Medicare payment rate growth for most services; (9) levy an excise tax on insurance plans with relatively high premiums; (10) impose fees on insurers and manufacturers

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and importers of certain drugs and medical devices; and (11) make various other changes to the federal tax code and to Medicare, Medicaid, and other federal programs. Each of these mandates have the potential to increase or decrease premiums.

Findings. According to the CBO and JCT, the proposal legislation would affect premiums differently based on the respective markets. The largest effect would be seen in the individual (nongroup) market, which would grow in size, but would still consist of only 17 percent of the overall insurance market in 2016. The effects on premiums would be much smaller in the small employer and large employer markets, which would make up about 13 percent and 70 percent of the total health insurance market, respectively.

- **Individual (nongroup market).** The average premium per person covered for new individual policies would be about 10 percent to 13 percent higher in 2016 than the average premium for individual coverage in that same year based on the current law. About half of those enrollees would receive government subsidies that would reduce their costs below the premiums that would be charged under current law. Average premiums per policy in the individual market in 2016 would be about $5,800 for single policies and $15,200 for family policies, compared with $5,500 for single policies and $13,100 for family policies based on the current law. These figures indicate what enrollees would pay without accounting for the new federal subsidies. About 57 percent of individual enrollees would receive subsidies from the new insurance exchanges, and those subsidies would cover nearly two-thirds of the total premium.
- **Small employer market.** In the small employer market, the CBO and JCT estimate that the change in the average premium per person resulting from the proposed legislation could range from an increase of 1.0 percent to a reduction of 2.0 percent in 2016, as compared to the current law. The average premium per policy in the small employer market would be in the vicinity of $7,800 for single policies and $19,200 for family policies, compared with about $7,800 and $19,300 under current law.
- **Large employer market.** In the large employer market, defined as employers with more than 50 workers, the proposed legislation would yield an average premium per person that is zero to 3.0 percent lower in 2016, as compared to current law. These overall effects reflect the net impact of many small changes, some of which would increase premiums and some of which would reduce premiums. In the large employer market, average premiums would be roughly $7,300 for single policies and $20,100 for family policies, compared to about $7,400 and $20,300 under the current law.

Excise tax effects. The reduced premiums described above would not include the effects of the excise tax on high-premium insurance policies offered through employers, which would significantly increase premiums for the affected workers, but which would affect only a portion of the market in 2016. An estimated 19 percent of workers with employment-based coverage would be affected by the excise tax in 2016. Individuals who keep their high-premium policies would pay a higher premium than under current law, with the difference in premiums roughly equal to the amount of the tax. The CBO and JCT, however, estimate that most people would avoid the cost of the excise tax by enrolling in plans that had lower premiums; the reductions resulting from choosing plans that either pay a smaller share of covered health care costs, manage benefits more tightly, or cover fewer services.

Uncertainty of estimates. The degree of uncertainty that surrounds the CBO and JCT's estimates of the impact that the proposed legislation would have on insurance coverage rates and the federal budget also exists in their analysis of the effects on premiums. Estimates depending on how enrollees, insurers, employers, or other key actors respond to changes in the market rules for individual policies or the excise tax on high-premium policies contain great uncertainty, according to the CBO and JCT, as are the projections of average premiums in each market under current law. ■

CBO/JCT Report, An Analysis of Health Insurance Premiums Under the Patient Protection and Affordable Care Act, Nov. 30, 2009

CCH Health Care Compliance Letter

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OIG reports $20.97 billion in FY 2009 savings and recoveries

In its *Semiannual Report to Congress*, HHS' Office of Inspector General (OIG) has reported savings and expected recoveries of $20.97 billion for fiscal year (FY) 2009, including $16.48 billion in implemented recommendations to put funds to better use, $4 billion in investigative receivables, and $492 million in audit receivables.

In FY 2009, the OIG also excluded 2,556 individuals and organizations from participation in federal health care programs; reported 671 criminal actions against individuals or organizations that engaged in crimes against HHS programs; and reported 394 civil actions, including False Claims Act and unjust enrichment suits filed in federal district court, civil monetary penalties law settlements, and administrative recoveries related to provider self-disclosure matters.

OIG accomplishments during the semiannual reporting period (April 1, 2009 to September 30, 2009) include the following:

Medicare Fraud Strike Force. Seven employees of a Miami infusion clinic were ordered to pay $19.8 million in restitution and sentenced to prison terms ranging from 37 to 97 months for a fraud scheme involving manipulation of patients' blood samples to generate false medical records, ordering and administering medications to treat conditions that were falsely documented with fraudulent test results, and billing Medicare for services that were medically unnecessary or never provided.

The Medicare Fraud Strike Force investigations resulted in the filing of charges against 138 individuals or entities, 44 convictions, and $40.7 million in investigative receivables.

Pandemic influenza preparedness. During the semiannual reporting period, the OIG issued two reports relating to states' and localities' pandemic influenza preparedness.

In one review the OIG found that although the majority of selected localities had begun planning to distribute and dispense vaccines and antiviral drugs, more needs to be done to improve localities' ability to respond to an influenza pandemic.

In a second review, the OIG found that although selected states and localities were making progress in preparing for a medical surge, they needed to do more to improve their ability to respond to an influenza pandemic.

Pfizer settlement. Pfizer Inc. entered into a $1 billion civil False Claims Act settlement with the U.S. in connection with its marketing and promotion of the anti-inflammatory drug Bextra and several other drugs. The settlement agreement is part of a global criminal, civil, and administrative settlement with Pfizer and its subsidiary, Pharmacia & Upjohn Company, Inc., which also includes a comprehensive five-year corporate integrity agreement between Pfizer and the OIG.

Pfizer and Pharmacia & Upjohn agreed to pay a total of $2.3 billion in this case, the largest health care fraud settlement in history, to resolve both the civil and criminal liability arising from the illegal promotion of certain pharmaceutical products.

The criminal portion of the settlement was not included in the OIG's semiannual report because it became effective after September 30, 2009.

Medicaid personal care claims. The OIG estimated that New York state improperly claimed $275.3 million in federal Medicaid reimbursement for some personal care claims submitted by providers in New York City during calendar years 2004 through 2006. The improper claims occurred because the state did not adequately monitor New York City's personal care services program for compliance with federal and state requirements.

Food emergencies. In two separate reviews, the OIG addressed the Food and Drug Administration's (FDA) responsibilities for overseeing the safety of food in both the human and pet food supply.

In the first review, the OIG found that in the event of a food emergency, the FDA would likely have difficulty tracing food products through the food supply chain. Specifically, the OIG was only able to trace five of the 40 products reviewed through each stage of the food supply chain. For 31 of the 40 products, the OIG could identify the facilities that likely handled the products, and for the remaining four products, the OIG could not identify the facilities. Fifty-nine percent of the facilities reviewed did not meet the FDA's requirements to maintain

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On The Front Lines

The Role of the Board in Hospital Compliance: A Checklist to Analyze Your Board's Performance - Part 1

by Seth M. Lloyd, J.D., Howard E. O'Leary, J.D., and Thomas J. McGraw, J.D.

What is the appropriate role for the governing body of a health care organization (its "board") in its attempts to comply with the wide variety of laws and regulations to which it is subject regarding the submission of claims, fraud and abuse, and Stark?

In Part 1 of this two-part article, the authors address this question, setting forth four specific issues and providing a brief history of government pronouncements on compliance, including some recent pronouncements. In Part 2, the authors will set forth a practical guide to compliance, including a discussion of organizational education, compliance program structure, and evaluation of compliance within the organization. Part 2 will also provide a checklist on compliance for the board and a draft resolution for delegating compliance responsibilities to a committee of the board.

To begin, the four specific issues dealt with in this article include the following:

- To what extent does the board need to understand why the organization needs a compliance program?
- To what extent does the board need to understand the compliance program which the organization has in place?
- To what extent does the board need to evaluate the effectiveness of the compliance program and the adequacy of the resources devoted to it, and how frequently should such an evaluation be made?
- What relationship, if any, should the board have with those in charge of compliance matters, particularly the "compliance officer"?

A Brief History of Governmental Pronouncements on Compliance

While compliance plans or programs for health care organizations have been in existence since the mid-1990s, the first "formal" guidance about this subject came in 1998, when the Office of Inspector General of the Department of Health and Human Services (HHS-OIG) published the agency's initial guidance on compliance. This twelve-page "notice" appeared in the Federal Register of February 23, 1998 and was jam-packed (three columns per page of small print, accompanied by 62 footnotes) with guidance directed particularly to the hospital community.[1] An earlier "program guidance" had been directed toward clinical laboratories.[2]

The hospital guidance of 1998 had two goals. First, the notice devoted a few pages to advocacy for the proposition that hospital compliance programs were of significant value for the hospital community, as well as discussing the general principles on which such programs should be built. Second, the notice discussed – while disclaiming that the notice itself could be adopted as a compliance program – rather specific guidelines regarding the content of such a program.

In the course of addressing these twin goals, the notice had many general comments about the role of the board, although it contained little specific guidance. Citing the *Caremark* decision,[3] the HHS-OIG noted that the failure of a board member to attempt to institute a compliance program "in certain situations" might breach the member's fiduciary obligations to the corporation.[4] What the board member's responsibility was regarding an existing compliance program was less clear. To be sure, the notice talked about the "substantial commitment" required of the board if an effective compliance program were to be in place; and it expressed the OIG's belief that "...every effective compliance program must begin with a formal commitment by the hospital's governing body to include *all* of the applicable elements" listed in that portion of the notice containing the specific guidelines.[5] The nature of the "substantial" and "formal" commitment was less than clear. The compliance officer and compliance committee should report "directly" to the CEO and the board. The compliance officer should have "direct access" to the board and CEO. The "guidance" recommended that the compliance officer should report to the board "on a regular basis" on compliance matters. The program should be regularly (i.e., not less than annually) reviewed in a written report distributed to, among others, the board. Apart from these general injunctions, the notice said precious little about the precise role of the board.

On January 31, 2005, the HHS-OIG issued its Supplemental Compliance Program Guidance for Hospitals.[6] While

offering, again, general comments about the importance and benefits of compliance programs for hospitals, this Supplemental Guidance was noteworthy for its discussion of particular topics on which a hospital might focus its compliance efforts. For example, the document noted the importance of following the National Correct Coding Initiative guidelines and the dangers of improper claims for cardiac rehabilitation services. It contained a detailed discussion of anti-kickback rules, Stark Law prohibitions, and gainsharing arrangements, among many other specific compliance topics.

While the level of specificity in the 2005 guidance was considerably greater than that found in its 1998 predecessor, only the last three pages of the eighteen page document addressed matters of direct board concern. Here, the OIG made a number of recommendations, some specific and some not. The board should make a formal commitment to compliance. The board should participate in the development of all aspects of the compliance program. The board should ensure that a review of the program's effectiveness is conducted annually, including checking to see that the compliance officer has "direct access" to the governing body, that he/she has the authority to retain legal counsel, and that he/she makes "regular reports" to the board. With regard to communication between the compliance function and the board, the OIG also recommended that internal investigations be shared with the board and that the board be involved in attempting to remedy "institutional or recurring [compliance] problems" identified by the compliance officer. The OIG recommended that the board receive training on fraud and abuse laws. In short, while the notice made additional recommendations for the interaction between the board and the compliance function, and while some of those recommendations were more specific than those in the 1998 notice, there was still substantial ambiguity about those things which the board should do, particularly without intruding into areas properly the responsibility of the organization's administration.

In 2003, the HHS-OIG teamed up with lawyers from the American Health Lawyers Association, a nationwide organization of lawyers whose practice focuses on health care law, to produce a document which provided far more guidance to the industry. This document, *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors*,[7] focused much more practically on the board's appropriate concerns and, more importantly, what it should do regarding compliance.

The HHS-OIG/AHLA publication first discussed the basic legal underpinnings for the board's responsibility for compliance – a corporate director's obligation to act in good faith with the care an ordinarily prudent person would exercise under similar circumstances. This obligation, the publication explained, arose in two general situations. First, in the context of making a decision on a specific transaction or matter, members of a board were obligated to ask whether the "deal" improperly enriched the other party to the health care organization's detriment. It was, the publication noted, the obligation of a board to ask this question in the course of its "decision-making" function. Second, in fulfilling the board's "oversight" function, the board also had obligations, these more general. Does the organization have in place, the publication suggested the board should ask, a system which will bring to the board's timely attention, and as part of its normal operations, any compliance matter of which the board should be aware? This oversight function did not require that each director play detective, looking to "ferret out" wrongdoing. Rather, the board members simply needed to assure that an appropriate system was in place. When something came to their attention which raised the possibility of a compliance issue, a so-called "red flag," the report concluded, the board had an obligation to address the problem head on until it received a satisfactory explanation from management. Without this "red flag," however, the directors were entitled to rely on senior leadership of the organization.

The report did not stop there. Instead, it suggested many questions the board should pose, both to establish to its satisfaction that an appropriate system existed and that it contained all of the essential elements necessary to be effective.

With regard to the compliance system itself, the report advocated the board should take at least the following actions:

(1) Establish a compliance committee of the board, with appropriate authority.
(2) Receive regular reports from that board committee at board meetings.
(3) Understand the rationale and objectives of the compliance program put into place by senior leadership.
(4) Determine the adequacy of resources devoted to the compliance program.
(5) Ask senior leadership how it will measure the program's effectiveness.

With regard to whether the compliance system had the components necessary to be effective, the report suggested that its operation should be characterized by at least the following:

(6) A "code of conduct" for the organization.
(7) Appropriate policies and procedures relating to compliance.
(8) A compliance officer possessing adequate authority and appropriate access to the highest levels of the senior leadership and of the board.
(9) Clear accountability for the compliance program's implementation.
(10) Appropriate education and training regarding compliance.
(11) Identification of the significant risk areas in compliance for health care organizations.

(12) Completion of internal compliance audits.
(13) Timely responses to violations discovered.
(14) A policy for disclosing violations, where appropriate.
(15) A policy prohibiting retaliation against those who uncovered violations.

Thus, the HHS-OIG and AHLA took a major step to assist the industry in understanding the hallmarks of an effective compliance program and a board's oversight responsibilities with regard to it. What even this report did not do, however, was to provide very practical guidance for members of the boards of health care organizations, to which we will turn in a moment.

Recent Governmental Pronouncements

Two additional and more recent sources of guidance are also available. First, the HHS-OIG deals regularly with those organizations whose boards have not adequately fulfilled their obligation to ensure that an effective compliance system is in place. These are organizations whose failure to comply with laws or regulations have led as part of the remedy to the imposition by the OIG of a corporate integrity agreement (a "CIA"). What do these CIAs say about the appropriate role for the boards of such entities? A review of those imposed on hospitals through August 2009 reveals that the CIAs say quite little about the precise role of the board. Rather, they impose various education and training programs on the organization as a whole, and require regular audits by outside auditing organizations. While such requirements carry with them the inference that the board "missed the boat" by failing in its oversight of these areas, the only real practical advice contained in these CIAs, and it appears in each 2009 CIA on the HHS-OIG website,[8] is that the compliance officer have "direct access" to the board. Nowhere is "direct access" defined.

Second, the New York State Medicaid Office of Inspector General has spoken at length about that state's additional emphasis on compliance. Part of this emphasis is new regulations to go into effect in the Fall of 2009.[9] These regulations require that a health care organization doing business with the New York Medicaid program in the amount of at least $500,000 per year certify annually that it has in place a compliance program meeting the requirements of the regulations. Those regulations, in turn, set forth many of the typical elements in compliance plans.

Of particular relevance to this article are the portions of the regulations that address the relationship between the compliance program's operation and the governing body. These portions add the following to our list above:

(16) A compliance officer reporting directly to the CEO or other senior administrator designated by the CEO who, on a periodic basis, "report[s] directly to the governing body on the activities of the compliance program."
(17) A training and education program on "compliance issues, expectations and compliance program operation" that includes governing body members.
(18) A reporting system that allows all employees and agents of the organization, including members of the governing body, to report compliance issues.

Based on all this guidance over the past 11 years, we know that the governing body of a health care organization has responsibilities in the area of compliance. Clearly, it needs to ensure that the organization has a written program, that the governing body understands the program and the compliance challenges faced by the organization, that the program contains the elements deemed important by those in the government who may someday review it, that the governing body provides it sufficient resources, and that the program is "effective" in that it deals effectively with compliance issues. All that being said, however, what are the very specific steps that a board should take to accomplish these general goals? It is to those steps that we will turn in Part 2. ■

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1 63 FR 8987 (Feb. 23, 1998).
2 62 FR 9435 (March 3, 1997).
3 *In re Caremark International Inc. Derivative Litigation*, 698 A.2d 959 (Del. Ch. 1996). In the settlement of *Caremark*, Chancellor William P. Allen of the Delaware Court of Chancery pointed out that, under the Federal Sentencing Guidelines, fines are reduced for entities that have corporate compliance programs. "A director's obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the board concludes is adequate, exists, and that a failure to do so under some circumstances may, in theory at least, render a director liable for losses," according to Allen.
4 *Supra* n. 1 at 8988.
5 *Supra* n. 1 at 8989 (emphasis in original).
6 70 FR 4658 (Jan. 31, 2005).
7 The Office of Inspector General of the U.S. Department of Health and Human Services and the American Health Lawyers Association, April 2003.
8 http://oig.hhs.gov/fraud/cias.asp.
9 www.omig.state.ny.us; for the regulations, see 18 N.Y.C.R.R. §521.1.

records about their sources, recipients, and transporters, and 25 percent were unaware of these requirements.

In the second review, the OIG found that the FDA did not have statutory authority to require pet food manufacturers or importers to initiate recalls of contaminated food or to assess penalties for recall violations. Furthermore, the FDA's existing regulations were issued as nonbinding recall guidance for firms. The OIG found that the FDA's lack of authority, coupled with its sometimes lax adherence to its recall guidance and internal procedures, limited its ability to ensure that contaminated pet food was promptly removed from retailers' shelves.

Permanent exclusion. Emmanuel Bernabe, President and Chairman of the Board of Pleasant Care Corporation, agreed to be permanently excluded from federal health care programs following an investigation of substandard care at nursing homes formerly operated by Pleasant Care. For example, the OIG alleged that Pleasant Care failed to maintain adequate staffing levels, properly administer medication, provide adequate hydration and nutrition, and prevent accidents.

The full *Semiannual Report to Congress* is available at http://oig.hhs.gov/publications/docs/semiannual/2009/semiannual_fall2009.pdf. ■

OIG's Semiannual Report to Congress, Dec. 3, 2009, Health Care Compliance Reporter, ¶530,737

GAO finds pervasive deficiencies in CMS's contract management

The Government Accountability Office (GAO) conducted a study of a random sample of CMS's 2008 contract actions and found that, in fiscal year 2008, CMS had significant internal deficiencies in its contract management "internal control." "Internal control" consists of plans, methods and procedures used to meet goals and objectives, and serves as the first line of defense in safeguarding assets and preventing fraud and errors. The GAO found that CMS had neither (1) implemented effective control procedures over contract actions, nor (2) established a strong control environment for contract management.

Contract level deficiencies. The GAO estimated that at least 84.3 percent of Federal Acquisition Regulation (FAR)-based contract actions in fiscal year 2008 contained at least one instance in which a key control was inadequately implemented. The GAO identified and evaluated eleven key controls; examples include: evidence that a contracting officer reviewed the contractor's proposals for price reasonableness, and the inclusion of documentation that supports the determination that the contractor was "responsible" to perform under the contract.

The control deficiencies were primarily caused by a lack of agency-specific policies requiring that the applicable FAR requirements and other control objectives were met. To the extent policies were in place, CMS did not always comply with the policies. For instance, standards for internal control require CMS to clearly document transactions and other significant events, and to have such documentation readily available for examination. The GAO discovered, however, that CMS's contract files did not always contain all the required documentation to support the contract actions.

Weak control environment. CMS's contract management was additionally impaired by a weak control environment. The GAO noted a lack of strategic planning to identify necessary staffing and funding, and a lack of reliable data for effectively carrying out contract management responsibilities. For instance, while CMS generally had reliable information on each contract action, CMS lacked reliable management information on other key aspects of its contracting operations, such as the number of certain contract types awarded and total contract value. In the absence of accurate data, CMS program managers would be unable to identify or monitor areas that pose a high risk of improper payments or waste.

Moreover, CMS took little to no action on the GAO's 2007 recommendations related to contracting and payments to contractors. Of the nine recommendations, CMS had completed only two recommendations: (1) develop policies that clarify roles and responsibilities during the invoice review process, and (2) develop a centralized tracking mechanism for employee training. CMS, however, did not complete the remaining seven recommendations: (1) develop policies for pre-award contract activities, (2) develop policies regarding cognizant federal agency responsibilities, (3) develop guidelines regarding sufficient detail to support contractor invoices, (4) establish criteria for negative certification for payment of invoices, (5) provide training on the invoice review policies, (6) develop a plan to reduce the backlog of contracts eligible for closeout, and (7) review the questionable payments identified in the GAO's 2007 report.

In its 2009 report, the GAO reiterated these seven recommendations to CMS and made ten additional recommendations for developing policies to ensure that FAR requirements and other control objects were met.

Congressional response. Senate Finance Committee Chairman Max Baucus (D-Mont.) stated, "These problems are unacceptable, and CMS's failure to implement prior recommendations to correct the problems is even more troubling. Fraud, waste and abuse cost our system billions of dollars each year."

"CMS is relying on contractors more than ever," Sen. Chuck Grassley (R-Iowa) said. "By failing to do a good job of overseeing them, CMS is increasing the risk that taxpayer dollars will be lost to fraud. Fraud in Medicare and Medicaid already costs the taxpayers more than $60 billion every year. CMS doesn't have a choice other than keeping a better eye on contractors," Grassley added. ■

GAO Report, No. GAO-10-60, Oct. 23, 2009; CCH Chicago Bureau, Nov. 24, 2009

False Claims

Qui tam settlement did not preclude third party claims

The False Claims Act (FCA) did not preclude contractual indemnity and independent claims for recovery against a third party by a *qui tam* defendant who settled with the government and the relator.

The manufacturer, Cell Therapeutics, Inc. (CTI), on the mistaken advice of an outside consultant, informed Medicare carriers and providers that one of its cancer drugs, Trisonex, was Medicare reimbursable for off-label uses. A CTI salesperson brought a *qui tam* action against CTI and its outside consultant, with only one of four claims being for indemnification, and CTI settled with the government and the salesperson.

CTI sued the consultant seeking contractual indemnity for damages related to the government's investigation and the related settlement and other independent claims, including breach of the service agreement, breach of contract, breach of implied warranty, and negligence. The district court ruled that *qui tam* defendants may not seek indemnification or contribution from other participants in a scheme to defraud the government based on the 9th Circuit's holding in *Mortgages, Inc. v. U.S. Dist. Ct.* (Sept. 28, 1990). However, the 9th Circuit's decision in *United States ex rel. Madden v. Gen. Dynamics Corp.* (Sept. 14, 1993), which differentiated claims for independent damages from those for indemnification or contribution, was more applicable here.

Further, under *Madden*, the manufacturer may bring its independent claims without regard to the finding of FCA liability. The text of the settlement agreement explicitly stated that it was not a final judgment on the manufacturer's FCA liability and should not be construed as an admission of liability, and thus, actions against third parties for independent claims were not barred. ■

Cell Therapeutics, Inc. v. Lash Group Inc., 9th Cir., Nov, 18, 2009, Health Care Compliance Reporter, ¶800,770

In the News

FTC accepts consent agreement with Pfizer

The Federal Trade Commission (FTC) has accepted, subject to final approval, a consent agreement with Pfizer Inc., which is designed to remedy the anticompetitive effects of its proposed acquisition of Wyeth. Under the agreement, Pfizer must divest to Boehringer Ingelheim Vetmedica, Inc. (BI) Wyeth's U.S. animal health business (Fort Dodge) in all areas of product overlap, except for equine tapeworm parasiticides and equine herpesvirus vaccines. In the area of equine tapeworm parasiticides, Pfizer must return to Virbac S.A. (Virbac) Pfizer's exclusive distribution rights for these products. In the area of equine herpesvirus vaccines, Pfizer must divest to BI Pfizer's equine herpesvirus products. According to the FTC, the proposed acquisition would cause significant competitive harm to consumers in the relevant U.S. markets for cattle, companion animal, and equine health products by eliminating actual, direct, and substantial competition between Pfizer and Wyeth.

Notice of Acceptance of Consent Agreement, 74 FR 62310, Nov. 27, 2009, Health Care Compliance Reporter, ¶760,404

Iowa first to receive EHR program funds

Iowa's Medicaid program is the first to receive federal matching funds for planning activities necessary to implement the electronic health record (EHR) incentive program established by the American Recovery and Reinvestment Act of 2009 (PubLNo 111-5). Cindy Mann, director of the Center for Medicaid and State Operations, said, "While Iowa is the first state to receive approval of its plan for implementing the Recovery Act's EHR incentive program, a number of other states have submitted plans as well. Meaningful and interoperable use of EHRs in Medicaid will increase health care efficiency, reduce medical errors and improve quality-outcomes and patient satisfaction within and across the states." Iowa's Medicaid program will receive approximately $1.16 million in federal matching funds and use the funds to (1) determine the state's current status of health information technology (HIT) activities; (2) gather information on issues such as existing barriers to use of EHRs, provider eligibility for EHR incentive payments, and the creation of a State Medicaid HIT Plan; and (3) assess expectations of its incentive payment recipients and their need for personal health records.

CCH Chicago Bureau, Nov. 24, 2009

Amendment to strip Medicare cuts rejected

On December 3, the U.S. Senate took action on certain proposed amendments to the Affordable Health Care for America Act (H.R. 3962). An amendment by Sen. John McCain (R-Ariz.) was rejected by a margin of 42 to 58 preserving nearly $500 billion in Medicare spending cuts. Sen. Ben Nelson (D-Neb.) and Sen. Jim Webb (D-Va.) joined with all 40 Republicans in supporting the failed amendment. Another amendment offered by Sen. Bennet (D-Colo,), clarifying that the Medicare cuts would not affect guaranteed benefits, was passed unanimously. An amendment by Sen. Mikulski (D-Md.), providing the Secretary of HHS with the authority to require health care plans to provide preventive services such as mammograms to women, was passed by a vote of 61-39. Finally, Sen. Nelson introduced an amendment requiring the drug industry to contribute $106 billion to close the coverage gap for Medicare Part D beneficiaries, which would increase the $80 billion industry contribution previously negotiated by the Obama Administration.

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