Compliance and Program Integrity under Health Care Reform

Bills Currently Under Consideration Take Aim at Fraud, Waste, and Abuse

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As the health care reform debate continues on the "big stage," certain proposals focused on compliance and program integrity issues are being overlooked. Medicare and Medicaid fraud and abuse schemes have been reported to cost billions of dollars a year. Earlier this year, the Administration established a new Department of Justice (DOJ) and Department of Health and Human Services (HHS) task force to specifically focus on health care fraud and abuse — Operation HEAT. The President has noted his intention to eliminate at least $50 billion a year in wasteful spending in the Medicare program alone to assist in paying for expanded health care coverage.

The HHS Office of Inspector General (OIG) has highlighted several "principles" that should be considered in the context of health care reform to better address fraud, waste, and abuse, including (1) screening of providers and suppliers seeking to enroll governmental health care programs; (2) establishing payment methods that are responsive to changes in the marketplace; (3) improving program compliance policies and practices; (4) monitoring of health care delivery and financing for evidence of fraud, waste, and abuse; and (5) responding to detected violations.

Various provisions for addressing these principles can be found in the health care reform bill (H.R 3200) that is being considered by the House of Representatives. The bill includes a number of provisions that are aimed specifically at compliance and program integrity issues. Most of these have been reflected in the various compliance guidance documents issued over the last de-

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cade, and as noted below, all of the seven elements of a compliance program offered by the OIG and consistent with the United States Sentencing Guidelines for Organizations are also addressed in the legislation.

Under the proposed legislation, Medicare and Medicaid integrity contractors would be mandated to increase their efforts through additional audits and payment review activities, as well as regular evaluations of effectiveness. Thus, new Medicare contractors such as zone program integrity contractors (ZPICs) and recovery audit contractors (RACs) would be given additional impetus to expand their activities. Also, there would be a $100 million annual increase in funding for the existing Health Care Fraud and Abuse Control Fund to better address fraud, waste, and abuse in health care programs as well as increased penalties for perpetrators.

The legislation would create a "Medicare and Medicaid Provider/Supplier Data Bank" to improve oversight of suspect utilization and prescribing patterns and complex business arrangements. This would entail enhanced oversight in program areas determined to pose a significant risk for fraudulent activity. In addition, the legislation would mandate better screening of providers and suppliers before they are enrolled to participate in Medicare and Medicaid.

Further, in an effort to close what Congress believes are loopholes in the law that invite abusive practices, the legislation would specify that only Medicare-enrolled physicians could order durable medical equipment (DME) or home health services furnished to Medicare beneficiaries and for which Medicare payment is claimed. In addition, there would be new and enhanced sanctions for health care fraud and abuse, including penalties for Medicare Advantage (Part C) and prescription drug (Part D) plans that violate marketing requirements or submit false bids, rebate reports, or other submissions to the Centers for Medicare & Medicaid Services (CMS).

The health care reform bill approved by the Senate H.E.L.P Committee on July 15, 2009, "The Affordable Choices Act," also contains certain provisions aimed at program integrity, including a requirement that a "Health Care Program Coordinating Council" be established to "coordinate strategic planning among Federal agencies involved in health care integrity and oversight."

Of particular note is a provision in H.R. 3200 that would require providers and suppliers to adopt a compliance program as a condition of participating in Medicare and Medicaid. This new requirement would change the voluntary compliance guidance of the OIG into a legal mandate. This requirement is similar to one adopted in the State of New York that requires providers and suppliers participating in its Medicaid program to have a compliance program. Further, the House proposal would require the Secretary of HHS to further define the elements of a mandated compliance program.

Health care providers and suppliers would be required to have internal policies and procedures in place to ensure they are delivering medically necessary items and services to program beneficiaries in a compliant manner, consistent with program requirements. Failure to meet the compliance program requirement could subject a provider or supplier to disenrollment from Medicare or Medicaid, civil monetary penalties, or intermediate sanctions.

In conjunction with the compliance program requirement, it is likely that the chief executive officer (CEO) or other members of senior management would have to provide some sort of certification or attestation of compliance, as is usually required by the OIG as part of its integrity-related settlement agreements. Congress adopted a similar approach in enacting section 302 of the Sarbanes-Oxley Act of 2002, which requires certifications by a company's CEO and chief financial officer (CFO) with respect to "Corporate Responsibility for Financial Reports."

These requirements would change the entire context of health care compliance programs. Organizations and entities that have failed to make compliance a priority will need to reevaluate their priorities. Should the compliance program requirement survive the legislative process, senior management will be held accountable for a health care provider's or supplier's compliance.

Another provision in the House bill would require the reporting and repayment of an identified Medicare or Medicaid overpayment within 60 days after discovery. Failure to repay would "create an obligation" subject to liability under the False Claims Act (FCA). The FCA was amended earlier this year by the Fraud and Abuse Act of 2009 (FERA) to extend liability under the FCA to any misrepresentation made to knowingly avoid paying an "obligation" to the government. This has been characterized as a "reverse" false claim.

Regardless of the outcome of the "big picture" health reform debate, it is very likely that some legislation will emerge that will include new program integrity requirements. Addressing health care fraud, waste, and abuse is one area that has broad, bipartisan support. In light of such consensus, it would be wise for health care organizations and entities to reexamine their compliance programs and position themselves to meet new expectations and requirements.

This would be a more sensible approach than waiting on the sidelines until the passage of new health care reform legislation and creation of new legal obligations. Time may be more constructively spent preparing for the future rather than waiting to learn the consequences. It might be advisable to consider the following:

- CEOs and senior management carefully reexamine now, rather than after enactment, their compliance program efforts to date. Although ways for demonstrating accountability for compliance has not been made clear in the proposed legislation, it is very likely that senior management will bear increased responsibility for evidencing the effectiveness of a compliance program. Both OIG corporate integrity agreements and certification of compliance agreements require attestation and certification by senior management of compliance with the standards set forth in the agreements. Also, for a recent expression of congressional intent on this subject, one only has to refer to the Sarbanes-Oxley Act of 2002, which requires certifications by a company's CEO and CFO with respect to "Corporate Responsibility for Financial Reports." A similar requirement for health care provider/supplier compliance programs would raise the bar for compliance to a new level, above that of the designated compliance officer.
- Senior management should consider how it will prepare for an attestation or certification of a compliance program's effectiveness. Answers to that may be found by examining the OIG compliance guidance documents. There the OIG calls for two types of ongoing auditing and monitoring. The first is for high-risk areas, some of which are highlighted by the OIG. There are a variety of ways to accomplish this objective. It can be done through external auditors and consultants or performed "in house" by the compliance officer and other internal audit and review resources. The second type of ongoing auditing and monitoring is of the compliance program itself. For this, the compliance officer cannot objectively evaluate areas for which he or she is responsible. Accordingly, most organizations have come to rely upon an external review of compliance program effectiveness by a knowledgeable consultant, or special compliance committee, which reports results to senior management or the board. In light of

an impending congressional mandate, it may be advisable to have this kind of review performed with any identified deficiencies made part of a corrective action plan. It is this kind of independent review upon which senior management and a board of directors reasonably may rely in providing an attestation or certification of a compliance program's effectiveness.

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