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Why are so many DLA Piper employees certified in compliance?

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For skilled nursing and nursing facilities, compliance counts

» The ACA requires compliance programs in exchange for receiving federal funds.
» As of March 23, 2013, nursing facilities must have compliance programs in place.
» Past guidance provides eight key elements for effective compliance programs.
» The ACA lists components required for nursing facilities' compliance programs.
» Recommendations for implementing effective compliance programs.

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Under the Affordable Care Act (ACA), medical service providers and suppliers must now enact compliance programs in order to participate in federal health care programs. Although the statute does not provide an implementation timeline for providers and suppliers generally, skilled nursing facilities (SNFs) and nursing facilities had to establish compliance programs by March 23, 2013. The ACA requires the Secretary of the Department of Health and Human Services (HSS) and the Office of the Inspector General (OIG) to establish core elements for these mandatory compliance programs. The Secretary also must promulgate regulations for effective compliance programs for nursing facilities. HHS/OIG will likely base these core elements and regulations on elements of compliance programs found in the Federal Sentencing Guidelines, prior OIG compliance guidance, and existing Corporate Integrity Agreements (CIAs). These resources provide guidance on how to develop effective compliance programs that will meet the requirements of the ACA. Given the increase in funds dedicated to combatting legal violations in the health care industry, the time to implement compliance programs for players in the health care sector is now.

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Background

The Federal Sentencing Guidelines have long provided that effective compliance programs can mitigate the penalties associated with corporate legal violations. An effective compliance program consists of exercising due diligence to prevent and detect criminal conduct and promoting an organizational culture that encourages employees to act ethically.[1]

Since 1998, the OIG has encouraged medical service providers and suppliers to voluntarily adopt compliance programs, developing tailored compliance program guidance over the years for eleven sectors of the health care industry: nursing facilities, hospitals, individual and small group physician practices, pharmaceutical manufacturers, ambulance suppliers, Medicare+ choice programs, hospices, durable medical equipment manufacturers, third-party medical billing companies, and clinical laboratories. However, the OIG did not require providers and suppliers to implement these suggestions.

For medical services suppliers and providers subject to government investigations, compliance

programs often become a facet of the settlement. OIG generally negotiates CIAs that incorporate compliance programs or accommodate pre-existing programs in exchange for allowing the supplier or provider to continue participating in federal health care programs.

Although stated slightly differently in each resource, the Sentencing Guidelines, OIG compliance guidance, and CIAs all generally require organizations to implement some variation of eight fundamental elements to achieve an effective compliance program:

- Adopt written compliance standards and procedures
- Appoint compliance personnel
- Conduct compliance training and education
- Establish confidential reporting mechanisms for violations
- Conduct internal monitoring and auditing
- Enforce the compliance program through appropriate disciplinary measures
- Restrict employment of individuals who have engaged in illegal activities
- Respond appropriately to detected offenses

Despite the guidance described above, the government has never required members of the health care sector to implement compliance programs, absent the existence of a CIA, until now. Under the ACA, compliance programs are a mandatory condition of enrollment in Medicare, Medicaid and CHIP.

A recent case against Life Care Centers of America (Life Care), a company that manages and owns over 200 skilled nursing facilities nationwide, highlights the HHS/OIG's increasing emphasis on effective compliance programs, especially given the existence of the OIG compliance guidance. In November 2012, OIG civilly charged Life Care under the False Claims Act for allegedly overcharging federal health care programs by setting aggressive Ultra High level billing targets "that were completely unrelated to its beneficiaries' actual conditions, diagnoses, or needs."[2] Medicare's Ultra High level provides the greatest reimbursements to facilities. Prosecutors allege that Life Care punished facilities that did not meet these targets, ignored numerous complaints, and chastised or fired the complainants.

The government contends that Life Care knew, since at least September 2008, that the HHS/OIG was concerned with facilities providing "medically unnecessary rehabilitation therapy," and cites the OIG Supplemental Compliance Program Guidance for Nursing Homes, published in September 2008, as the source of this knowledge. The complaint states, "HHS-OIG 'strongly advise[d] nursing facilities to develop policies, procedures and measures to ensure that residents are receiving medically appropriate therapy services."[3] The complaint's reference to the OIG's compliance guidance emphasizes the HHS/OIG's already enhanced expectations of skilled nursing facilities when it comes to implementing compliance programs.

Provisions of the ACA concerning compliance programs

The obligation to develop compliance programs to continue participating in federal health care programs stems from Section 6102 and Section 6401 of the ACA. Section 6102 of the ACA requires skilled nursing facilities and nursing facilities to implement a compliance program "that is effective in preventing and detecting criminal, civil, and administrative violations" and that promotes quality of care in line with HSS/OIG regulations as of March 23, 2013. Section 6102 directed the HHS/OIG to promulgate regulations by March 23, 2012, but the HHS/OIG failed to meet this deadline.[4] In fact, when this article was submitted for publication, HHS/OIG had not promulgated these regulations. However,

the OIG's 2012 Work Plan directed nursing facilities to implement compliance programs based on the elements identified in the relevant OIG compliance guidance.[5] Accordingly, as the March 23, 2013 deadline has passed, nursing facilities that do not already have compliance programs should develop and implement them immediately. Interestingly, HHS/OIG was also required to submit an evaluation of the compliance programs by March 23, 2013.

Despite the absence of the HHS/OIG regulations, Section 6102 itself enumerates eight minimum required components for effective nursing facility compliance programs. The required components obligate organizations to:

- establish compliance standards and procedures that are "reasonably capable of reducing the prospect of criminal, civil, and administrative violations";
- designate a specific high-ranking individual with sufficient resources and authority to oversee compliance with the standards and procedures and take responsibility for the program;
- use due care to avoid delegating discretionary authority to individuals with a propensity to engage in criminal, civil, and administrative violations;
- effectively communicate its standards and procedures to all personnel by requiring participation in training programs or by disseminating documents explaining the requirements of the program;
- take reasonable steps to achieve compliance by using monitoring and auditing systems designed to detect violations and by implementing and publicizing a reporting system that allows employees to report violations without fear of retribution;
- consistently enforce appropriate disciplinary mechanisms, including discipline for failure to detect an offense;
- take reasonable steps to respond appropriately to detected offenses and to prevent further offenses, including modifying the compliance program as necessary to prevent and detect violations; and
- periodically reassess the compliance program to identify necessary changes.[6]

Section 6401 of the ACA applies to all health care providers and suppliers, including skilled nursing facilities and nursing facilities, and makes compliance programs mandatory as a condition of enrollment in Medicare. Unlike Section 6102, Section 6401 does not establish an implementation timeline for compliance programs. Rather, it directs HHS/OIG to establish the implementation timeline for providers and suppliers within particular industries or categories. In setting the timelines, the statute mandates HHS/OIG to consider the extent to which a particular provider or supplier industry or category has already adopted compliance programs. To date, HHS/OIG has not announced any implementation deadlines.

> …[HHS/OIG] intends to establish core elements that closely resemble the required compliance program components under Section 6102.

Section 6401 also instructs HHS/OIG to establish core elements for compliance programs for each "particular industry or category."[7] Thus, HHS/OIG may tailor the core elements for each type of provider or supplier. HHS/OIG has not yet established the core elements for any industry or category. However, it has advised that it intends to establish core elements that closely resemble the required compliance program components under Section 6102. It has also indicated that it will look to the seven elements of compliance programs

in the Federal Sentencing Guidelines in establishing the core elements.[8] Thus, suppliers and providers have an adequate roadmap to begin developing effective compliance programs now.

Consequences of failing to implement an effective compliance program

Failing to implement an effective compliance program may result in exclusion from participating in federal health care programs. Moreover, the ACA provides HHS and the Department of Justice with additional funds for combatting health care fraud. It also establishes stricter standards under pre-existing rules. For example, the ACA eliminates the bar against *qui tam* actions based on public disclosure,[9] clarifies that actual knowledge is not required to violate the Anti-Kickback standard, and expands civil monetary penalties.[10] Given the heightened stringency of the laws and the enforcement trend in the health care industry, an effective compliance program may protect providers and suppliers from incurring substantial liability for violations of the civil False Claims Act, the Anti-Kickback Statute, the Stark Physician Self-Referral Law, the Civil Monetary Penalties Law, and the Criminal Health Care Fraud Statute. The existence of a compliance program previously served as a mitigating factor for punishment, but the absence of a compliance program after the ACA is implemented may provide an additional basis for severe sanctions.

Recommendations for establishing an effective compliance program

Medical service providers and suppliers should develop a compliance program that incorporates the required components under Section 6102 and the eight fundamental elements found in the Federal Sentencing Guidelines, OIG compliance guidance, and CIAs, which largely match Section 6102's requirements.

Providers and suppliers should establish written standards of conduct and procedures that indicate the organization's commitment to complying with relevant federal and state statutes, and policies and procedures that are designed to prevent and detect violations of these statutes. To create adequate standards, organizations should identify and address risk areas in their particular industry. An organization should also designate a compliance officer or compliance committee to oversee and implement the compliance program. The organization should provide the compliance officer with sufficient resources to operate the compliance program, and the compliance committee may report directly to the board of directors of an organization.

Organizations should also implement mandatory compliance training and education, providing new employees with an introduction to the compliance program and requiring annual or bi-annual training for all employees. The training program should be tailored to an employee's specific job function and cover the risk areas each class of employee is most likely to encounter. In addition, organizations should conduct internal self-monitoring and audits, and periodically review policies and procedures and claim submissions. If an issue arises from an internal audit, the organization should take appropriate action as soon as possible. Organizations should develop open lines of communication and avenues for employees to report potential problems without fear of retaliation, such as anonymous hotlines. Organizations must also develop appropriate response mechanisms for identified or reported issues, such as documenting any investigative measures taken and deciding how to handle individuals involved in the incident. Finally, organizations should enforce the compliance program with adequate disciplinary measures, implementing a full range of disciplinary actions while still maintaining sufficient flexibility to account for varied circumstances.

The Life Care case discussed above emphasizes the importance of taking steps to ensure that compliance programs function effectively, beginning with the tone at the top. Although Life Care had a compliance office that purportedly received multiple complaints about Life Care's Ultra High billing targets through a hotline and otherwise, prosecutors allege that Life Care did not adequately address these complaints. Although Life Care's compliance manual directed the chief compliance officer to investigate hotline complaints, in practice, the same Life Care executives that implemented the Ultra High billing targets allegedly conducted these investigations. Furthermore, although the compliance manual stated that Life Care would keep hotline complaints confidential and not retaliate against complainants, prosecutors allege that Life Care's investigations often focused on identifying the complainant rather than addressing the complaint, and that Life Care purportedly terminated 57% of complaining employees who provided their names. Prosecutors also allege that top Life Care executives frustrated compliance efforts by interfering with investigations, impeding access to data, pressuring the Compliance Office to close complaint cases, and preventing the Compliance Office from visiting Life Care facilities unannounced. Due in part to these alleged compliance failures, despite the existence of a compliance program, Life Care now potentially faces hundreds of millions of dollars in fines and other penalties.

Conclusion

Although the HHS has not set final deadlines for the adoption and implementation of compliance programs for medical service providers other than nursing facilities, it is only a matter of time before continued participation in federal health care programs will hinge on the existence of an effective compliance program. Medical service providers and suppliers should act now to implement the mandates of the ACA to avoid potential future exclusion from Medicaid and Medicare or additional liability for allegations involving health care fraud.

1. Federal Sentencing Guidelines Manual, Section 8B2.1(a) (2011).
2. *U.S. ex rel. Martin v. Life Care Centers of America, Inc.*
3. *Id*.
4. Patient Protection and Affordable Care Act § 6102(b).
5. 2012 OIG Work Plan, p. 1-10.
6. ACA § 6102(b)(4)(A-H).
7. ACA § 6401(a).
8. 76 Fed. Reg. 5862 at 5942 (Feb. 2, 2011)
9. ACA § 1303(j)(2).
10. ACA § 6402.