

Compliance Programs: Serious Business for Health Care Providers

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Compliance programs aimed at reducing fraud and abuse have for several years been strongly recommended, but not required, by the federal government. However, there has been an increasing trend at the federal and state level to pass legislation requiring the implementation of compliance programs, particularly by individuals who receive significant Medicaid payments. These new laws, as well as continuing investigations and penalties imposed by federal and state agencies, have moved compliance programs to the forefront of importance for health care providers. Even those providers who are not technically required by federal or state laws to adopt compliance programs need to recognize the important role a compliance program can play in defending against federal or state allegations of fraud and abuse. This article discusses the various laws, guidance, and considerations that health care providers should address when developing compliance programs.

MODEL COMPLIANCE PROGRAMS

No discussion of health care compliance programs would be complete without a review of the model compliance programs published by the US Department of Health and Human Services, Office of Inspector General (OIG). The OIG's model compliance programs have traditionally provided the framework for compliance programs. These programs are based on the Federal Sentencing Guidelines,

which establish 7 requirements that have become the hallmarks of an effective compliance program. Simply stated, a compliance program should include a discussion of the 7 essential elements that demonstrate due diligence to prevent and detect improper conduct and promote an organizational culture that encourages commitment to compliance with the law. These 7 elements are (1) standards and procedures to prevent and detect criminal conduct; (2) governing authority oversight of the implementation and effectiveness of the compliance program; (3) the appropriate delegation of authority; (4) the effective communication of standards through training and education, including training of the upper levels of the organization; (5) monitoring, auditing, and reporting systems, including mechanisms that allow for anonymity or confidentiality; (6) enforcement and discipline, including incentives for cooperation with compliance programs; and (7) appropriate and consistent response on the detection of an offense (eg, a corrective action plan, program modifications).

DEFICIT REDUCTION ACT

In addition to the recommendations made in the OIG's model programs, health care providers need to take into consideration the federal Deficit Reduction Act of 2005 (DRA) [1], which was signed into law on February 8, 2006. The DRA includes a requirement that all entities, which receive annual Medicaid payments of at least \$5

million (Medicaid providers), have in place various policies and procedures that address the prevention of fraud, waste, and abuse. As the largest health benefit program in the United States, Medicaid has seen a tremendous growth in payments over the last few years but still lacks federal oversight of the individual state program safeguards. To address this concern, the federal government, under the DRA, is requiring states to ensure that their Medicaid providers adopt compliance programs to prevent and combat Medicaid fraud and abuse. In addition, the DRA offers financial incentives to the states if they enact laws relating to false or fraudulent claims that, among other things, contain provisions for rewarding and facilitating *qui tam*¹ actions in a manner that is at least as effective as the same provisions under federal law [2].

Although, as noted above, the OIG has for several years recommended voluntary compliance programs for hospitals (as well as other types of health care providers), the DRA is the first federal law to expressly require Medicaid providers to have compliance programs as a "condition of payment." The requirements for a compliance program under the DRA are consistent with the OIG's model programs in that the DRA requirements focus

¹ A *qui tam* action is a lawsuit under a statute, which gives to the plaintiff bringing the action a part of the penalty recovered with the balance to the state. The plaintiff describes himself or herself as suing for the state as well as for himself or herself.

on policies describing the prevention of fraud, waste, and abuse; training; and the protection of employees who make good-faith reports of compliance violations to an entity's compliance officer or government officials (eg, compliance hotline reports, whistleblowers). However, the DRA also requires a detailed discussion of false-claims laws and whistleblower protections. Specifically, the DRA requires state Medicaid plans to compel Medicaid providers to have the following in place:

- Written policies and procedures for all employees (including management), contractors, and agents that provide detailed information on the federal false-claims laws, federal administrative remedies for false claims and statements, any state laws pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under such laws, and the role of these laws in preventing and detecting fraud, waste, and abuse in federal health care programs. Examples of laws that would be required to be included in such policies include the federal False Claims Act [3] and its whistleblower protections and the Fraud Civil Remedies Act [4].
- Written policies and procedures for all employees detailing the Medicaid Provider's methods for detecting and preventing fraud, waste, and abuse, similar to the policies already recommended in the OIG's model programs.
- A section in any employee handbook (including codes of conduct and compliance manuals) of the Medicaid provider that (1) provides a specific discussion of the laws described above, (2) highlights the right of employees to be protected as whistleblowers, and (3) summarizes the enti-

ty's policies and procedures for detecting and preventing fraud, waste, and abuse.

Although not expressly stated in the DRA, it is implied that any Medicaid provider that does not comply with these compliance requirements will not be entitled to submit Medicaid claims, and if a Medicaid provider does submit claims without having complied, it could potentially be liable for submitting false claims under the federal (and state, if applicable) False Claims Act. For Medicaid providers that receive Medicaid revenues of \$5 million or more, this means that they must have compliance programs with written policies and procedures for detecting and preventing fraud, waste, and abuse (eg, a compliance program that addresses the 7 elements from the Federal Sentencing Guidelines discussed on the previous page), as well as a summary of federal and state laws regarding false claims.

Furthermore, the policies and procedures regarding the federal and state false-claims laws must be made available to agents and contractors, in addition to all employees. For the purposes of the DRA, the Centers for Medicare and Medicaid Services has defined a "contractor" or an "agent" to include any contractor, subcontractor, agent, or person that or who, on behalf of a Medicaid provider, furnishes or authorizes the furnishing of Medicaid health care items or services, performs billing or coding function, or is involved in the monitoring of health care provided by the Medicaid provider.

STATE LAWS

The DRA also provides financial incentives to states to pass their own laws that establish liability for

false or fraudulent claims with respect to payment by the states' Medicaid plans. For a state to avail itself of such incentives, individual state law must have, at a minimum, provisions that (1) are at least as effective in rewarding and facilitating *qui tam* actions and (2) civil penalties that are not less than the amount of the civil penalty authorized under the DRA. Because the DRA establishes only minimum requirements, states may adopt laws that are applicable to a broader range of health care providers or that have requirements above and beyond those required under DRA. Many states have already passed, or are in the process of passing, laws that address *qui tam* actions and false claims. For example, New York recently passed legislation requiring certain health care providers that receive Medicaid payments (eg, hospitals and individual providers with significant Medicaid receivables) to adopt compliance programs that include, among other things, written policies on compliance issues and nonretaliation against whistleblowers, a compliance officer, training, good-faith reporting, a system for addressing reported compliance concerns, and policies on disciplinary actions [5]. When developing compliance programs, health care providers need to be aware of any requirements under their applicable states' laws and not simply review the applicability of, and compliance with, the DRA.

For more information on the individual state laws, the OIG [6] posts on its Web site analysis of some of the state false-claims laws. However, it is important to note that states not listed on this Web site may still have compliance requirements. Health care providers should conduct their own assessments of state laws.

CONCLUSION

Increasingly, laws are being enacted to require certain covered health care providers to develop compliance programs to prevent against fraud and abuse. Therefore, the first step health care providers need to take is to understand whether they are covered by any of these laws. If they are, the requirements to be met are generally described in the applicable law, such as the DRA. Even those providers that are not legally required to adopt compliance programs should nevertheless strongly consider developing them.

A functioning compliance program can, among other things, be very important when responding to government allegations of billing improprieties or other similar allegations of wrongdoing. Regardless of the reasons for developing the compliance program, strong consideration should be given to the framework established by the Federal Sentencing Guidelines, as well as other legal requirements, if any. Health care providers with strong compliance programs are in a position to better prevent against fraudulent or erroneous billing and business practices and

more readily defend themselves against any suggestions of impropriety.

REFERENCES

1. Deficit Reduction Act, Pub. L. No. 109-1711, Chap. 3, § 6032.
2. Deficit Reduction Act, Pub. L. No. 109-1711, Chap. 3, § 6031.
3. 31 U.S.C. 3729 et seq.
4. 31 U.S.C. 3801, 3802.
5. New York Social Services Law 363-d.
6. US Department of Health and Human Services, Office of Inspector General. State false claims act reviews. Available at: <http://oig.hhs.gov/fraud/falseclaimsact.html>.

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