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HEALTH INDUSTRY ALERT

REMINDER: JANUARY 1, 2007 IS DEADLINE FOR MEETING DEFICIT REDUCTION ACT COMPLIANCE-RELATED PROVISIONS

On February 8, 2006, the Deficit Reduction Act of 2005 (DRA) was signed into law, mandating, among other things, that certain entities participating in Medicaid institute policies regarding false claims, whistleblower protections and compliance measures and set forth those policies in employee handbooks. All affected entities should take steps to comply with this mandate before January 1, 2007.

In short, the DRA requires all entities that receive or make at least $5 million in annual Medicaid payments (including funding under waiver programs) to establish specific written policies for their employees, contractors and agents regarding various false claims-related laws (e.g., Federal False Claims Act (FCA)) and whistleblower protections under such laws as well as provisions regarding their "policies and procedures for detecting and preventing fraud, waste, and abuse" (in other words, the entities' compliance programs). Additionally, entities must include a specific discussion of these laws, whistleblower protections and compliance policies in any employee handbook. These requirements are a condition of receiving all future payments under the Medicaid program. *See* Pub. L. No. 109-171, § 6032, 120 Stat. 74 (2006).

One issue that has been met with uncertainty in the industry is what constitutes an "entity" under the DRA. For instance, many have questioned whether the law applies to a particular facility within a system where, although such entity does not receive $5 million in annual Medicaid payments, the system as a whole receives in excess of $5 million in Medicaid funds in a year. Although the DRA does not define "entity," it does make reference to "any entity . . . under a State plan." Thus, the answer to this question arguably turns upon how a particular state medical assistance plan defines "entity." As a practical matter, however, it is probably most prudent for any system that receives aggregate Medicaid payments of $5 million or more to implement the DRA requirements across the system.

In that regard, since compliance programs are typically implemented consistently across health care systems, it would be incongruous to not implement any additional policies required by the DRA at all of the system's facilities. Second, the system probably has one employee handbook that is distributed to all employees throughout the system. The DRA-modified handbook would naturally be distributed to all employees across the system.

Another issue worth noting relates to those entities (albeit probably few) that may not currently have employee handbooks. The DRA states that an entity should "include in any employee handbook" the policies at issue. In this way, the DRA apparently presupposes that all entities already have such handbooks. Arguably, an entity that does not already have an employee handbook could satisfy the DRA by distributing to employees a Code of Conduct and/or a Compliance Policy that incorporates all the relevant specific requirements of the DRA (e.g., discussion of false claims laws, whistleblower protections and compliance policies). To require otherwise would be to elevate form over substance. Should you need further guidance and assistance regarding this point, please contact us.

Other than to require that affected entities include "detailed information" and "specific discussion," the DRA is otherwise silent regarding how detailed and specific the policies and/or discussion of the laws and policies must be. However, prudence would dictate that affected entities include a meaningful and comprehensive treatment of the relevant laws and policies. For example, two or three bullet points on the FCA would probably not suffice. Indeed, given that the DRA, among other things, cites to the entire statute, i.e., 31 U.S.C. §§ 3729-3733, when requiring that "detailed information" about the FCA be included in the policies and the handbook, it is probably necessary not only to address the liability provisions of the FCA but the *qui tam* provisions as well. To do less could potentially expose the entity to the argument that it has not met the requirements of the DRA.

Affected entities must also be mindful of the potential consequences of failure to adhere to these DRA requirements. First, implementing these provisions is a "condition of receiving [Medicaid] payment." Thus, failure to take any action and/or adhere completely to the requirements could cause an entity to lose its Medicaid payments until it has satisfied the Centers for Medicare & Medicaid Services that its policies and handbook discussions fully satisfy the law. Second, although the DRA does not contain any other specific sanctions for noncompliance, failure to meet the DRA could potentially subject the affected entity to FCA liability predicated on alleged statutory noncompliance. Although this obviously would constitute a controversial and overreaching use of the FCA, the government, and more importantly, relators, have not hesitated to bootstrap the FCA onto other types of alleged statutory or regulatory violations where the underlying rule is arguably a condition of payment (e.g., Stark law violations).

Clearly, there are good and viable legal arguments to counter such a theory. Suffice it to say, however, that it would be tragically ironic if a provider became subject to a *qui tam* action for failing to notify sufficiently and adequately its employees of the *qui tam* provisions under the FCA or any other DRA requirements. Affected entities have a short time left to review their compliance policies and employee handbooks and modify them, as appropriate, to meet the DRA requirements and avoid such a disagreeable turn of events.

If you have questions about these DRA provisions, require assistance in conforming your policies and procedures to meet this statutory mandate, or have other questions about fraud and abuse or compliance issues as they relate to your organization, please contact us.

CONTACT INFORMATION

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