Increased Importance of Effective Compliance and Ethics Programs

Legal Alert
August 23, 2007

Garvey Schubert Barer Legal Update, August 23, 2007.

Historically, an effective compliance and ethics program has been viewed by the government as merely one factor to be considered when determining culpability. The outcome of a recent case involving the federal Anti-Kickback Statute demonstrates the increased value you may realize from a robust compliance program. The case is *States v. Bruens, et al*., No. 05-10102 (D. Mass.) The jury in Bruens acquitted former employees of Serono Laboratories Inc. of all criminal charges for allegedly violating the Anti-Kickback Statute, after the company had settled with the government and agreed to pay $704 million.

As you are aware, the Anti-Kickback Statute makes it illegal to knowingly and willfully charge, solicit or accept any remuneration in exchange for referrals of items or services that are paid in whole or in part by a federal healthcare program. The jury in *Bruens* decided that the federal prosecutors failed to prove a willful violation of the law.

Significantly, the acquittals came about because the court instructed the jury that "a defendant's good faith belief that his or her conduct was lawful is an absolute defense to a charge of conspiring to violate - or violating - the Anti-Kickback Statute, because good faith is inconsistent with willfulness." The jury instruction is reminiscent of a footnote in the 1995 decision of *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995), which stated that "Congress, by use of the phrase 'knowingly and willfully' to describe the type of conduct prohibited under the anti-kickback laws, intended to shield from prosecution only those whose conduct 'while improper, was inadvertent'." *Footnote 16*.

Healthcare lawyers have long debated the importance of the *Hanlester* decision, pointing out that the decision was issued by three judges from the "liberal" United States Court of Appeals for the Ninth Circuit and arguing that the *Hanlester* case cannot be easily reconciled with decisions from other circuit courts.

The *Bruens* court's emphasis on good faith (if followed by other circuits) bodes well for healthcare providers who are actively working to monitor and evaluate their business practices. Demonstrating good faith may difficult for providers who do not have robust compliance programs, and may be particularly problematic for providers who, as discussed below, were required beginning January 1, 2007, to provide compliance training to employees, contractors and agents, but who are not doing so.

Action Advised: Because good faith may now be an absolute defense to a criminal charge of violating the Anti-Kickback Statute, we believe you, your officers, directors and your employees may realize a clear and significant benefit from having in place an effective and comprehensive compliance program. A well designed compliance plan may help you demonstrate that your healthcare business activities are conducted in good faith.

Compliance Training is Now Required for Many Medicaid Providers and Suppliers.

Effective January 1, 2007, certain healthcare entities are now required to provide compliance training. Section 1902(a) of the Social Security Act requires healthcare entities receiving $5 million or more in annual Medicaid payments to establish written policies and procedures for employees, contractors, and agents detailing the entity's fraud prevention efforts and providing information about federal and state false claims and whistleblower laws, as well as certain other specific content elements required by new provisions of Section 1902(a) of the Social Security Act.

This new provision makes compliance a "condition of payment." Each organizational unit, unless part of a health system, is considered to be separate for purposes of the $5 million threshold. In the case of a health system, the entire organization is the entity. In terms of contractors, the guidance indicates that "contractors furnishing Medicaid healthcare items or services include, but are not limited to, all contract therapists, physicians (including, but not limited to, house staff, hospitalists, and independent contractors), and pharmacies."

Action Advised: You should determine if the new law applies to your organization (Do you meet the $5 million threshold?) If so, you should ensure that your organization has implemented the changes required by Section 1902(a) of the Social Security Act. In the event that your organization is later embroiled in an Anti-Kickback Law investigation, it may be difficult to show that you have acted in good faith if you fail to meet the new requirements of Section 1902(a).

Strong Compliance Programs Make Great Business Sense Too.

Not only will a strong compliance program likely help you to avoid criminal liability under the Anti-Kickback Statute, but a strong compliance program makes great business sense as well. In our experience, healthcare providers who discover, correct and report compliance issues are better positioned to work with regulatory agencies.

For example, our office recently assisted a client with voluntary disclosure of a potential Medicare overpayment and an administrative appeal concerning repayment of the Medicare monies received. Our client's compliance officer discovered a billing anomaly that resulted in more than $1 million in Medicare funds that might possibly be deemed an overpayment. The administrative law judge ruled that our client is entitled to keep the $1 million payment, concluding that not only were the Medicare billing rules unclear, but that our client acted in good faith by bringing the issue to the regulator's attention. Medicare had made offsetting

underpayments which masked the overpayment; absent the overpayment the provider would have repositioned itself in a way that would have increased Medicare funding.