



## Client Alert

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### **SENATOR BAUCUS' AMERICA'S HEALTHY FUTURE ACT COULD ALTER THE FRAUD AND ABUSE LANDSCAPE**

America's Health Future Act of 2009, one of the six health care reform bills in Congress, contains significant revisions to fraud and abuse laws and procedures. These revisions are generally not in the spotlight, as the focus on the bill, which was sponsored by Senator Max Baucus of Montana, is on the health insurance issues. However, if the bill is passed into law, it would have the side effect of broadening liability under the federal anti-kickback statute and would allow for suspension of Medicare and Medicaid reimbursement during a government investigation of alleged fraud. On a positive note, the bill would also create new exceptions to the civil monetary penalties law for certain charitable programs.

#### **Expansion of Liability Under the Anti-Kickback Statute**

The federal anti-kickback statute provides for criminal sanctions against anyone who "knowingly and willfully" offers, pays, solicits, or receives remuneration to induce or reward referrals of Medicare or Medicaid business. In one of the more noteworthy anti-kickback cases of record, Hanlester v. Shalala, 51 F. 3d 1390 (9th Cir. 1994), the Ninth Circuit Court of Appeals interpreted the "knowingly and willfully" intent requirement as requiring proof that an individual knew that the anti-kickback statute prohibited a behavior and the individual engaged in that behavior with the specific intent to violate the law. This interpretation of the intent requirement made it more difficult to prosecute alleged violations of anti-kickback, as the government must provide proof that a defendant had knowledge of the anti-kickback's prohibition on rewarding or inducing referrals and proof that the defendant had a specific intent to violate the law.

The America's Health Future Act would void the Hanlester opinion's interpretation of the intent requirement by amending the anti-kickback statute to include the following language at the end of the statute:

"With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section."

In other words, a person may be found guilty of violating the anti-kickback statute without even knowing that the statute exists and without intending to violate the statute. In the Chairman's Mark of the bill, the change was described as defining "willfully" for purposes of the intent requirement as a person acting "voluntarily and purposefully to do what the law forbids and the person need not have actual knowledge of the law or specific intent to

violate that law.”

If this amendment is adopted into law, it will have the result of lessening the burden on the government when prosecuting under the anti-kickback statute. This change will be most significant in the jurisdictions that follow Hanlester or have adopted similar interpretations. Further, because the anti-kickback statute is often used to bootstrap a federal False Claims Act suit, the change would reduce the level of proof that a whistleblower would need to produce when filing a *qui tam* action under the False Claims Act.

### **Suspension of Reimbursement During Fraud Investigation**

The America’s Health Future Act would also allow the Medicare and Medicaid programs to suspend a provider or supplier’s reimbursement during an investigation of a credible allegation of fraud against the provider or supplier. The Office of Inspector General of the Department of Health and Human Services and the various state Medicaid programs will have the discretion to deem an allegation of fraud to be “credible,” thus resulting in suspended reimbursement during the investigation. The bill anticipates that there could be exceptions to the reimbursement suspensions for “good cause.”

If this provision of the America’s Health Future Act is adopted, the Department of Health and Human Services will be required to promulgate regulations governing the reimbursement suspensions. Those regulations will provide the detail on this potentially drastic measure.

### **Creation of New Exceptions to Civil Monetary Penalties Law**

Finally, the America’s Health Future Act would add four broad exceptions to the civil monetary penalty statute’s anti-inducement provision. Currently, the anti-inducement provision levies significant monetary penalties against a person or organization that offers or provides remuneration to a Medicare or Medicaid beneficiary when the person/organization “knows or should know” that the remuneration will likely influence the beneficiary’s choice of provider or supplier. There is a small number of existing exceptions to the provision, and the bill would add four more, as follows:

- An exception for remuneration that promotes access to care and poses a low risk of harm to patients and the Medicare and Medicaid programs.
- An exception for the offer or transfer of items or services for free or less than fair market value if the items or services consist of coupons, rebates or other rewards from a retailer, the items or services are offered on equal terms to the general public regardless of health insurance status, and the offer is not tied to the provision of other items/services reimbursable by Medicare or Medicaid.
- An exception for items or services provided for free or less than fair market value when the items or services are not offered as part of any advertisement or solicitation, are not tied to the provision of other items/services reimbursable by Medicare or Medicaid, there is a reasonable connection between the free items or services and the medical care of the recipient, and the free items or services

are only given after a good faith determination of the recipient's financial need.

- An exception for the waiver by a Medicare Part D plan sponsor of a beneficiary's copayment for a covered Part D drug when the individual elects a generic equivalent.

These exceptions are drafted in very broad terms and are aimed at programs described in the Chairman's Mark of the bill as "charitable and other innocuous programs currently covered by the broad reach" of the anti-inducement provision. If adopted, implementing regulations would be expected and would hopefully provide detail and examples for providers and suppliers wishing to pursue a program under one or more of the exceptions.

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We will continue to monitor the America's Health Future Act, as well as the other healthcare reform bills in Congress, and will provide updates in the future should any of the provisions be adopted into law. In the interim, if you have any questions, please contact Jennifer D. Burgar or Aaron M. Danzig.

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