Key Provisions for Health Care Providers in Historic Health Care Reform Bill

Late last month, in two historic pieces of legislation, President Obama signed into law the Patient Protection and Affordable Care Act of 2010 and the Health Care Education Affordability Reconciliation Act of 2010 (together, "Health Care Reform Bill"). The Health Care Reform Bill, which is hundreds of pages long, makes numerous changes to the operation of the health care system. While the extensive provisions of the Health Care Reform Bill impact health care providers both in their role as employers and in their role as providers, in this alert, we focus on several major compliance and regulatory provisions directly related to the provider role.

Return of Overpayments. The Health Care Reform Bill requires health care providers to return all known Medicare and Medicaid overpayments. This new requirement eliminates any prior uncertainties regarding whether providers had an affirmative obligation to return overpayments and now establishes a specific time frame for the return of overpayments. The overpayment amounts must be returned to the applicable Medicare Administrative Contractor by the later of (1) 60 days after the date on which the overpayment was identified, and (2) the date the applicable cost report is due. The failure to return an overpayment within the required time frame is a violation of the False Claims Act. This section is effective as of March 23, 2010.

Clarification of Federal Anti-Kickback Statute Knowing and Willfully Standard. The Federal Anti-Kickback Statute requires a defendant to commit a prohibited act "knowingly and willfully" in order to violate the law. The Health Care Reform Bill amends the Anti-Kickback Statute to clarify that under the "knowingly and willfully" standard, a defendant is required neither to have actual knowledge that his or her actions were prohibited by the Anti-Kickback Statute nor to have acted with the specific intent to violate the statute to be convicted of a violation of the Anti-Kickback Statute. This clarification resolves inconsistencies in the way various courts have interpreted the Anti-Kickback Statute's standard and expressly rejects the approach of some courts which have interpreted the standard to require the government to prove the defendant had "actual knowledge" and "specific intent." With this change, it may be easier for the government to obtain convictions for violations of the Anti-Kickback Statute in jurisdictions where courts have previously applied the more stringent knowledge and intent standards. This section is effective as of March 23, 2010.

Changes to Stark Law In-Office Ancillary Exception. The Health Care Reform Bill amends the Stark Law in-office ancillary exception to require a physician referring a Medicare or Medicaid patient to his or her practice for certain imaging services (e.g., MRI services, CT services) under the in-office ancillary services exception to (1) inform the patient in writing that the patient can obtain the imaging services from another provider, and (2) provide the patient with a list of alternative providers. This provision of the Health Care Reform Bill is retroactive to January 1, 2010, although providers obviously could not comply with this requirement until the Health Care Reform Bill was enacted on March 23, 2010.

Restriction on Physician Ownership of Hospitals. Currently, the Stark Law includes an exception that allows physicians to be investors in hospitals to which they refer Medicare and Medicaid patients if they hold an ownership interest in the entire hospital – commonly referred to as the "whole hospital" exception. In addition, physicians may also be investors in hospitals if the requirements of the rural entity exception to the Stark Law are met. The Health Care Reform Bill amends the Stark Law by prohibiting the establishment of new physician-owned hospitals. The Bill "grandfathers" physician-owned hospitals in existence as of December 31, 2010, but places certain limitations on the ability of

these hospitals to expand their capacity, such as number of beds and operating rooms.

Establishment of Stark Law Self-Disclosure Protocol. In 2009, the Office of Inspector General ("OIG") announced that it would no longer accept self-disclosures involving only liability under the Stark Law. This announcement left providers without a self-disclosure mechanism for Stark Law violations. The Health Care Reform Bill addresses this problem and calls for the Secretary of the Department of Health and Human Services ("HHS"), in coordination with the OIG, to establish a self-disclosure protocol for potential violations of the Stark Law by September 23, 2010. The Bill also stipulates that the new protocols are to be separate and apart from the OIG's advisory opinion process.

Authority to Reduce Penalties for Stark Law Violations. In conjunction with the requirement that the government establish a self-disclosure protocol for Stark Law violations, the Health Care Reform Bill also expressly authorizes HHS to reduce the amount of sanctions assessed for self-disclosed violations of the Stark Law based on (1) the nature and extent of the violation, (2) the timeliness of self-disclosure, (3) the level of cooperation in providing additional information related to a self-disclosure, and (4) other factors considered appropriate by HHS.

Compliance Programs for Participation in Medicare and Medicaid. The Health Care Reform Bill requires providers and suppliers to establish a compliance program as a condition of enrollment in Medicare or Medicaid. It is unclear how HHS will apply this requirement to providers and suppliers already enrolled in Medicare and Medicaid. The Secretary of HHS is charged with identifying the core elements of the required compliance programs and the effective date of this new requirement.

New Transparency Reports by Manufacturers of Drugs, Devices, Biologicals and Medical Supplies and Group Purchasing Organizations. The Health Care Reform Bill generally requires applicable drug, device, biological and medical supply manufacturers to electronically file an annual report with the Secretary of HHS identifying certain payments made to physicians and teaching hospitals during the preceding calendar year. The Health Care Reform Bill further requires these manufacturers, along with group purchasing organizations, to electronically file an annual report with the Secretary of HHS identifying for the preceding calendar year (1) any physician ownership or investment in such entities, and (2) any payments made by such entities to its physician owners or investors. These requirements become effective as of March 31, 2013 for the 2012 calendar year.

New Civil Monetary Penalties. The Health Care Reform Bill expands the use of civil monetary penalties when a provider (1) orders or prescribes a medical item or service while excluded from participating in the Federal health care programs and the provider knows that a claim will be submitted to the programs for payment for the item or service, (2) knowingly making a false statement, omission or misrepresentation of a material fact on an application for participation in the Federal health care programs (this violation is subject to civil monetary penalties up to $50,000 per statement and penalties equal to three times the amount claimed), (3) knows of an overpayment and does not report and return the overpayment, (4) makes a false or fraudulent claim for payment (each violation is subject to civil monetary penalties up to $50,000), and (5) fails to grant timely access to OIG investigators who request access for the purpose of conducting audits and investigations (the provider is subject to $15,000 in civil monetary penalties for each day of delay). These provisions are currently in effect.

Termination of Medicaid Provider Participation. The Health Care Reform Bill requires that a State's Medicaid plan must provide that a participating provider will be terminated if such provider is also terminated under Medicare or another Medicaid plan. This section is effective as of January 1, 2011, but may be delayed if State legislation is required in order to comply with this amendment.

Increased Enforcement Funding. Along with the new fraud and abuse provisions comes an increase

in funding for enforcement efforts. The Health Care Reform Bill appropriates $10 million each year to the Health Care Fraud and Abuse Control Account, which finances the operation of the health care fraud and abuse program, from 2011 through 2020. The Reconciliation Act appropriates an additional $250 million to the Account from 2011 through 2016.

Please contact one of the attorneys in our Health Care Practice Group if you have questions about the recent Health Care Reform Bill.

Allen D. Allred	View Resume	aallred@thompsoncoburn.com
James L. Fogle	View Resume	jfogle@thompsoncoburn.com
Evan Raskas Goldfarb	View Resume	egoldfarb@thompsoncoburn.com
A. Jay Goldstein	View Resume	agoldstein@thompsoncoburn.com
Milada R. Goturi	View Resume	mgoturi@thompsoncoburn.com
James F. Gunn	View Resume	jgunn@thompsoncoburn.com
Joyce Harris Hennessy	View Resume	jhennessy@thompsoncoburn.com
Robert N. Kamensky	View Resume	rkamensky@thompsoncoburn.com
Richard J. Lang	View Resume	rlang@thompsoncoburn.com
Jan Paul Miller	View Resume	jmiller@thompsoncoburn.com
Tonya Oliver	View Resume	toliver@thompsoncoburn.com
Claire M. Schenk	View Resume	cschenk@thompsoncoburn.com

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