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Same Targets, Different Firing Squad: New York Authorities Pursue Off-Label and Federal Fraud and Abuse Recoveries from Healthcare Industry

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Recent pronouncements from the New York Office of the Medicaid Inspector General (OMIG) confirm the OMIG will likely join federal prosecutors and the New York Attorney General's Office in aggressively pursuing off-label and other alleged fraud and abuse recoveries from healthcare providers and pharmaceutical and medical device companies. On January 28, 2010 at a New York State Bar Association meeting, Michael E. Little, Deputy Medicaid Inspector General for Investigations and Enforcement, stated that the OMIG will closely scrutinize pharmaceutical and medical device companies' relationships with and payments to providers. Little also stated that the OMIG is currently investigating off-label prescribing to nursing home and assisted living patients.

The OMIG was created in 2006 as part of New York's effort to crack down on Medicaid fraud. The OMIG quickly became part of a triple enforcement threat—along with federal prosecutors and the State Attorney General—that healthcare providers and pharmaceutical and medical device companies that operate in New York must face. The number of OMIG staff has been increased by nearly 200 since 2006 and 2007, with the most significant hire being the Medicaid Inspector General himself, former Assistant United States Attorney James G. Sheehan, a career prosecutor specializing in healthcare fraud enforcement and recovery matters. Although the OMIG's mandate is to look for fraud, waste, and abuse in New York State's Medicaid program, its modus operandi has been to seek to recover full payment for noncompliance with technical and administrative rules. The OMIG has been criticized for imposing draconian measures and carrying out burdensome audits that often result in stiff penalties for technical violations and administrative errors that have no impact on the fiscal integrity of the Medicaid program.

Little's pronouncements make clear that the OMIG will not only continue but expand its efforts to obtain substantial sums for what it alleges are fraud and abuse issues. If the OMIG's past practices are an indicator, it will continue to seek to turn alleged regulatory violations into punitive financial recoveries. The OMIG will also likely rely on New York's recently proposed healthcare legislation that, if enacted, would regulate marketing and promotional practices by pharmaceutical and medical device companies.

New York's Proposed Heathcare Legislation

Introduced by Governor David Paterson on January 19, 2010, the proposed legislation is part of the Fiscal Year 2010-11 Executive Budget and sounds much like a "me too" law under which New York will prohibit the same kind of conduct prohibited by federal law—the provision of inappropriate gifts and payments to prescribers and the provision of misleading information—including information inconsistent with FDA regulations—regarding the companies' products. The proposed legislation would, for example:

- Set forth strict criteria for consulting and speaking contracts
- Prohibit companies from providing meals, tickets, or financial support for provider attendance at healthcare conferences
- Prohibit companies from sponsoring continuing medical education unless certain criteria are met, including separation of a company's medical education and grant-making function from its sales and marketing department
- Prohibit companies from providing to prescribers promotional materials that are inconsistent with FDA regulations

These measures are purportedly aimed at reducing the utilization of higher-cost drugs. The proposed legislation is also unabashedly part of the New York's broader effort to close its budget deficit, which the State projects will grow to $193 billion in 2010. Indeed, according to the Executive Budget Presentation, New York will increase its target Medicaid fraud recovery from $870 million for Fiscal Year 2010 to $1.2 billion for Fiscal Year 2011.

The promotional practices legislation goes hand-in-hand with the New York Attorney General's off-label investigations, as authorities in off-label investigations zero in on companies' financial relationships with prescribers as well as the information companies provide to them. New York has already reaped millions from off-label settlements in 2008 and 2009.

Impact on Healthcare Providers and Pharmaceutical and Medical Device Companies

The New York State Attorney General's Office is likely to continue its focus on lucrative off-label investigations. Moreover, if the proposed legislation passes, the Attorney General's Office also can be expected to scrutinize relationships between prescribers and pharmaceutical and medical device companies.

Little's comments suggest that the OMIG will try to use the legislation or the existing Medicaid regulations to pursue the very same kind of investigations. Pursuant to the regulations governing Medicaid audits, the OMIG can seek recoupment of "overpayments" resulting from false statements or levy sanctions for "unacceptable practices," which include violations of certain federal and state laws having a nexus to a person's involvement in the medical assistance program. In short, healthcare providers and pharmaceutical and medical device companies that operate in New York must be prepared for a new wave of aggressive enforcement by the OMIG.

Morgan Lewis's White Collar Litigation practice already has experience in defending against the OMIG's enforcement and audit proceedings.

If you have any questions regarding this LawFlash or healthcare fraud and abuse laws and regulations, or require assistance with any other issue relating to the defense of any other government enforcement matters, please contact the authors, Eric W. Sitarchuk, Kelly A. Moore, and Alison Tanchyk Dante (listed below), or any of our White Collar Practice attorneys:

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