



PHARMACEUTICAL LAW & INDUSTRY



REPORT

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Fraud and Abuse

Regulators Looking More at Payments To Providers, New York Official Says

NEW YORK—Regulators at the state and federal level are increasingly looking into financial relationships between providers and pharmaceutical and medical device manufacturers as an area of potential abuse, a New York Medicaid official said Jan. 28.

Speaking at a session on off-label prescribing at the Food, Drug, and Cosmetic Law Section of the annual meeting of the New York State Bar Association, state Deputy Medicaid Inspector General Michael E. Little said that his office takes seriously its mandate to determine whether physician payments affect health care quality, patient safety, or cost.

If a doctor's prescribing patterns are creating a quality-of-care issue and are found to be inconsistent with sound medical or professional practice, he said that "we will take action."

Little, a former deputy inspector general at the federal Department of Health and Human Services, is responsible for investigations and enforcement in the state Office of the Medicaid Inspector General. He was standing in for state Medicaid Inspector General James G. Sheehan, who was in Washington attending an HHS health care summit.

As a federal prosecutor in Philadelphia, Sheehan was a pioneer in the application of fraud and abuse statutes to quality of care issues, panelists at the meeting noted. While at HHS, Little worked in the Philadelphia regional office and often collaborated with Sheehan on investigations.

Pressure to Disclose. Little pointed to increasing pressure on companies to disclose their financial relationships with providers, whether voluntarily or as a requirement of a legal or regulatory settlement.

State disclosure laws, such as a measure enacted by Massachusetts in 2008 that takes effect this July, also

are playing a role, Little said. New York Gov. David A. Paterson (D) has proposed a similar law in his budget request recently (8 PLIR 136, 1/29/10), and Congress is also looking at the issue, he added.

A federal provider payment settlement with Pfizer announced in September 2009 (7 PLIR 1047, 9/11/09), which provided for a record \$2.3 billion in fines and penalties (including a \$1.2 billion criminal fine), is emblematic of a growing trend toward the use of criminal penalties to deter companies from making improper payments, Little said.

The accompanying corporate integrity agreement required Pfizer to publicly disclose information on provider financial relationships, and other companies have done the same, he noted.

"We take a look at this information and look for patterns," he said. "This information is increasingly being made public."

Fraud and abuse regulators can use data-mining techniques to analyze the financial relationships, he said. While payments to physicians are not prohibited in the absence of a kickback arrangement, the presence of a financial relationship is nonetheless "an indicator that we will look into," he said.

Antipsychotic Rx Probe. New York Medicaid investigators, for instance, are looking into prescriptions of atypical antipsychotics for Medicaid nursing home patients despite a Food and Drug Administration black box warning against their use by elderly patients with dementia-related psychosis, Little reported.

They have found that the atypicals have been prescribed for 8,879 nursing home patients in the state, although 3,589 of the patients had no prior diagnosis of psychosis, he said. In 2007 and 2008, 330 patients had a reported diabetes diagnosis since being prescribed atypicals, he added, a negative outcome suggesting a quality of care or patient safety issue.

Investigators look to whether the prescriptions meet the standard of "sound medical or professional practice" in drug therapy, Little said. Issues include whether patient selection, prescribing, and monitoring were ap-

propriate, as well as coordination and communication among patients, physicians, and pharmacists, he indicated.

“We want to know why they were prescribed,” he said of the atypicals.

Industry Concerns. Bethany J. Hills, an attorney with the firm Hodgson Russ in Buffalo who participated in the session panel with Little, expressed concerns that state fraud and abuse cases for off-label prescribing of

drugs with black box warnings could run counter to the FDA regulatory process.

“Once you have met all the FDA requirements,” she said, “you might still face a different standard for prescribing at the state level.”

Companies themselves need to scrutinize their own communications practices to make sure that they are not promoting off-label prescribing, Hills suggested. “If the government is monitoring this, so should companies,” she said.

BY JOHN HERZFELD