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Pharma Manager Excluded From Medicare In a Case Showing Risks of Drug Samples

The risks of drug samples came into sharp focus with the Medicare exclusion of a pharmaceutical company district sales manager. Due to potential conflicts of interest and patient safety issues, free drug samples may require greater oversight, experts say. The exclusion also is a reminder that the government has vowed to hold individuals accountable when resolving corporate fraud cases.

Thomas C. Valentine, a former Sanofi sales representative and district sales manager in Orange County, Calif., will not be able to participate in federal health care programs for five years, according to an exclusion agreement with the HHS Office of Inspector General. The exclusion stems from free samples of Hyalgan, an injectable drug for knee pain. Between early 2006 and 2009, Valentine "delivered or supervised the delivery to physicians of samples of Hyalgan…with knowledge that the physicians would bill Federal health programs for the samples," OIG alleged.

The free Hyalgan samples reduced the per-unit price for the physicians, who were reimbursed by federal programs as if they had paid for the drug, OIG alleges. Because there was a reduction in the per-unit price of Hyalgan, physicians increased the spread between their acquisition costs and their reimbursement.

"OIG alleges that the provision of these samples with the knowledge that physicians would bill Federal health care programs for the samples constituted remuneration to induce the physicians to use or continue using Hyalgan instead of a competing product," the exclusion agreement says.

Last year, Sanofi settled a false claims lawsuit with the Department of Justice over Hyalgan samples.

In coming after Valentine, OIG exercised its "affirmative" exclusion authority because the exclusion was not derivative or mandatory, OIG spokeswoman Janna Raudenbush says. That means OIG must convince an HHS administrative law judge of its merits instead of just dropping the exclusion bomb. Valentine, however, settled the case before that was necessary and did not admit wrongdoing. His attorney, Kate Corrigan, says Valentine was never properly trained on samples. "This thing blindsided him," says Corrigan, with Corrigan & Welbourn in Newport Beach, Calif. Valentine apparently is the only individual to face an administrative or enforcement action in connection with the Sanofi case. "He is the only guy who goes down on this. It seems to be categorically unfair," she says.

Under the terms of the exclusion settlement, no federal health programs will pay Valentine for goods or services, including administrative and management services, furnished, ordered, or prescribed by Valentine. The ban on payment also applies to all "other individuals and entities (including, for example, anyone who employs or contracts with Valentine, and any hospital or other provider where Valentine provides services)."

Some physician groups and hospitals restrict the use of free drug samples, which raise conflict-of-interest, safety and billing issues. "Samples continue to be a tough issue and we take a hard line on it," says Gary Wimsett, director of the conflict-of-interest program at the University of Florida College of Medicine in Gainesville, which is part of UF Health. "Like many institutions, we took a look at how sampling was happening because it is one of the pharmaceutical industry's prime marketing tools. We struggled with it because there are some patient advocates here who are doctors serving vulnerable populations and they were adamant that we provide the samples. The patients have economic hardships, so there are real reasons to have samples."

But there are so many risks associated with drug samples that the faculty practice plan decided to more or less ban them, Wimsett says. However, physicians can request permission to dispense free samples if they have a compelling reason. They make their case to a patient safety committee, which considers the medical necessity of handing out samples. "There is a healthy debate about whether the drug is something that needs to be provided as a sample," Wimsett says.

The use of drug samples in hospitals is complex, says the head of a hospital's pharmacy policies, who prefers to not be identified. In addition to conflicts of interests and compliance with state laws, hospitals face the challenge of monitoring the safety and quality of drugs that are outside the traditional supply chain. "If samples are

given to individual physicians and they aren't dispensed by the pharmacy, that can lead to problems with drug interactions, therapeutic duplication, and allergic reactions with patients who are more critically ill," the pharmacist says. Hospitals also have to worry about proper labeling and secure storage of drug samples and ensure they haven't expired. There are also risks around so-called "lookalike" drugs. If two drugs have similar names or sound alike, "you don't want to store them on the same shelf. You want to separate them somehow."

Hospitals should have policies and procedures governing samples, including who gives and receives them and how to account for them, says San Francisco attorney Judy Waltz, with Foley & Lardner LLP. Billing also can trip up hospitals. Samples are less of an issue on the Part A side because drugs are bundled into prospective payments. But under Part B, CMS says that if physicians charge for drugs, they should bill them as a supply under the Part B incident-to provisions. According to *MLN Matters* SE0441, incident-to services include non-self-administrable drugs and other biologicals.

Free Samples Require Many Safeguards

OIG also draws a distinction between dispensing free samples and billing for them. In its "Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse," OIG says that "Many drug and biologic companies provide physicians with free samples that the physicians may give to patients free of charge. It is legal to give these samples to your patients for free, but it is illegal to sell the samples….If you choose to accept samples, you will need reliable systems in place to safely store the samples and ensure that samples are not commingled with your commercial stock."

OIG's focus on samples is manifested in the corporate integrity agreements with pharmaceutical manufacturers that require them to have policies and procedures on samples, Waltz says. "OIG considers this a pretty high risk area," she contends. However, drug samples are not reportable under the Physician Payments Sunshine Act. The new law requires drug and medical device manufacturers to report their physician payments to CMS, which will make the reports available online by Sept. 30, 2014 *(RMC 2/11/13, p. 4)*. Drug samples may be exempt because lawmakers view them as a patient benefit more than a physician perk, Waltz says. But free drug samples are gifts to physicians, the hospital pharmacist says. Prescribers benefit in various ways. Patients are grateful for the free meds, which helps cement their loyalty to the physician. And "a fairly high percentage of samples get diverted," he says. Physicians or employees may take them home for personal use or sales reps may dump a competitor's product if they are not supervised.

Some medical centers flat-out forbid the dispensing of drug samples. The hospital pharmacist prefers a moderate approach. If physicians want to dispense them, they have to abide by all of the rules and regulations on samples. Most don't because it's a hassle, he says.

The pushback on drug samples has had a ripple effect, Wimsett says. Pharmaceutical manufacturers now offer other perks, such as coupons and vouchers that reduce the cost of the drugs for patients, but not insurers. And sales reps are less likely to request time with physicians who work at entities that frown on samples.

The exclusion agreement with Valentine is another sign the government is holding more individuals accountable when their organizations are accused of fraud. OIG excluded three senior executives from the drugmaker Purdue Frederick Company, a move that was upheld by the U.S. Court of Appeals for the District of Columbia Circuit in July 2012. However, the judges ordered a lower court to reconsider the length of the 12-year exclusions, which were based on the executives' misdemeanor convictions under the "responsible corporate officer doctrine" *(RMC 8/6/12, p. 1)*.

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