

> Specialty Drugs Trend Increases Fraud Risk, OIG Officials Say

> 2015-11-18 23:11:13.188 GMT

>

>

> By James Swann

> Pharmaceutical Fraud

> Key Takeaway: Drug manufacturers increasingly turn to high-cost specialty drugs, increasing fraud risks, government officials say.

> Additional Information: Overall drugs costs are rising, including the prices of generic drugs.

> Nov. 18 (BNA) -- The pharmaceutical industry is moving toward a new business model emphasizing the production of high-cost specialty drugs, which is increasing fraud and drug diversion risks, two government officials said Nov. 18.

> "These high-dollar drugs are like bright, shiny objects for fraudsters," Michael Cohen, an operations officer with the Department of Health and Human Services Office of Inspector General said at the National Health Care Anti-Fraud Association's annual training conference in San Diego.

> Under the evolving business model, Cohen said, pharmaceutical manufacturers are looking to produce drugs that hit the "sweet spot" between treating very common conditions and extremely rare conditions, such as multiple sclerosis. The goal is then to find off-label uses for the drugs to further increase revenue, he said.

> For example, Cohen said a number of newly approved diabetes drugs have been touting a weight-loss side effect.

> Victoza, a diabetes treatment from Novo Nordisk, can cause roughly a 10 percent weight loss, Cohen said, and weight loss has also been seen in users of Farxiga, another diabetes drug marketed by Bristol-Myers Squibb and AstraZeneca.

> The drugs are very expensive, and Cohen said there was a concern they could be abused for their weight-loss effect, with the drugs billed to Medicare Part D.

>

> Part D Spending

>

> Cohen was joined by Shimon Richmond, the OIG's special agent in charge of the Miami office, who said Medicare Part D spending continues to expand at a fast clip. In 2006, Medicare Part D spending was \$51 billion, compared with \$121 billion in 2014, Richmond said.

- > While opiates such as OxyContin are still an issue for the OIG, Richmond said they accounted for only \$7.8 billion of the
- > \$121 billion in 2014 Medicare Part D spending, compared with \$113 billion in non-controlled drugs.
- > The increase in overall Medicare Part D spending has coincided with an increase in the price of generics, Richmond said.
- > One in five generics had price increases of at least 50 percent in 2013, and among drugs covered by Medicare Part D, one-half of all generics rose in price in 2014, Richmond said.
- > “Many generics have exclusive market share, like brand-name drugs,” Richmond said, noting that the pharmaceutical manufacturers are increasing generic prices “because they can.”
- > Looking to the future, Richmond said the OIG is concerned about tiered pricing among generics. With domestic generic prices increasing, Richmond said many pharmaceutical companies are selling much cheaper versions of the drugs overseas.
- > “Now we have to look for illegal importation of generics,”
- > Richmond said.
- > In some cases, fraudsters could illegally import the cheaper overseas generics, then bill Medicare Part D for the more expensive domestic versions, Richmond said.
- >
- > High-Cost Drugs
- >
- > Beyond drug price increases, Richmond also touched on some high-cost drugs the OIG is monitoring that could be involved in both fraudulent billing schemes and illegal drug diversion, such as Pfizer's Lyrica, a schedule V drug (a lower level of controlled substances) intended for seizures and neuropathy.
- > Lyrica accounted for \$400 million in Medicare Part D spending in the first quarter of 2015, Richmond said, and is commonly abused by addicts.
- > PCSK9 drugs, which lower LDL cholesterol, are also on the OIG's radar screen, Richmond said.
- > Sanofi had a PCSK9 drug approved by the Food and Drug Administration this past spring, Richmond said, and Amgen had another approved by the FDA in August.
- > The PCSK9 drugs are very expensive, Richmond said, and must be taken indefinitely, increasing the chances of fraud.
- > Richmond also mentioned Subsys, which is a schedule II narcotic intended only for cancer pain. The drug costs \$10,000 a month, and Richmond said only 1

percent of Subsys prescriptions were written by oncologists, an indication of potential fraud.

> Schedule II drugs are considered to have a high potential for abuse that may lead to severe psychological or physical dependence.

> To contact the reporter on this story: James Swann in Washington at jswann1@bna.com

> To contact the editor responsible for this story: Brent Bierman at bbierman@bna.com