Compounding Pharmacy's Pricing Drives $1.2M False Claims Pact

- • Unusual for DOJ to pursue False Claims case based on price alone
- • Feds say in some cases, pharmacy billed TRICARE up to 100 times more than cash-paying customers
- • Practices corrected in 2014, but overpayments not refunded

Related documents:

- Settlement agreement
- December 2013 complaint

By Chris Marr

A steep price difference between what a compounding pharmacy charged TRICARE and its cash-paying customers proved sufficient for federal prosecutors to negotiate a $1.2 million settlement—in what one health-care attorney called a novel civil prosecution strategy.

The now-defunct Florida pharmacy, RS Compounding LLC, and its owner Renier Gobea agreed to pay $1.2 million to settle allegations originally brought in a 2013 whistleblower lawsuit. The federal government intervened on some of the allegations in 2017.

The case shows "the government is willing to bring aggressive enforcement action just based on a price differential," said Ryan Stumphauzer, a white-collar crime attorney at Stumphauzer & Sloman in Miami and a former federal prosecutor.

Most False Claims Act cases against compounding pharmacies involve allegations of kickbacks to physicians or patients or prescribing of medically unnecessary drugs, or both. In this case, the final allegations detailed in the settlement agreement don't mention any of those, Stumphauzer told Bloomberg Law on Oct. 3.

"If I was the operator of a compounding pharmacy, this is concerning. But from the government's perspective, it's really smart," he said, adding that proving a price difference is much more straightforward than proving a kickback scheme.

By allegedly misrepresenting its "usual and customary" prices, the company charged TRICARE at least 20 times the price it charged cash-paying customers for its compounded drugs from 2012 to 2014, and in some cases charged as much as 100 times more, the Justice Department said in a Sept. 28 announcement of the settlement.

The allegations of massive pricing differences might have helped pique federal prosecutors' interest in a below-the-radar case, according to T. Mills Fleming, a health-care attorney with HunterMaclean in Savannah, Ga.

“The fact that there was such an egregious upcharge on this is what got the government’s attention,” Fleming told Bloomberg Law on Oct. 3. The Justice Department tends to be more interested in False Claims Act cases involving hospitals, doctors, and larger dollar amounts, he said. But perhaps in this case, “they wanted to send a message.”

No Refund of Overpayments

Another key piece of the government’s case was that RS Compounding didn’t refund TRICARE’s overpayments after discovering its error, according to Scott Grubman, a health-care attorney at Chilivis Cochran Larkins & Bever LLP in Atlanta.

TRICARE is the Defense Department’s health insurance program for members of military, veterans, and their families.

The company determined in January 2014 that its billing practice violated TRICARE policy, after which it changed its billing, the Justice Department said.

An attorney for RS Compounding and Gobea confirmed the company changed its billing practices in January 2014 to comply with TRICARE rules, and added, “Mr. Gobea was not advised to refund any amounts to the TRICARE program.”

The defendants didn’t admit any liability or wrongdoing as part of the settlement. “It is simply a business decision by Mr. Gobea to put this issue behind him,” Kevin Darken, an attorney at Kevin Darken Law Group in Tampa, Fla., told Bloomberg Law in an emailed statement Oct. 3.

This aspect of the case is a good reminder for all health-care providers who bill Medicare, because that program requires providers to report and refund any overpayments within 60 days of discovering them, said Grubman, who’s also a former assistant U.S. attorney.

If a provider doesn’t refund overpayments, “the government will raise the argument they violated the False Claims Act for that reason, regardless of the other behavior,” he said.

High Profit Margins

Selling compounded drugs at substantial profit margins, often 95 percent or more, is typical of the compounding pharmacy industry, Stumphauzer said. It’s possible the pharmacy agreed to mark down the prices it would normally charge TRICARE for cash-paying customers who came in requesting a certain pain cream, he added.

“No one is their right mind is going to pay 12 grand for a jar of pain cream,” Stumphauzer said.

TRICARE largely shut off its reimbursements to compounding pharmacies in 2015 after a few years of exponential growth in that market. The Justice Department said TRICARE’s reimbursements to compounding pharmacies grew from $5 million in 2004 to $514 million in 2014 and then jumped to $1.75 billion in fiscal year 2015.

“That’s not coincidence. That’s pure fraud,” Stumphauzer said.

The whistleblower in the case, McKenzie Stepe, was a former sales representative for RS Compounding. She died in February 2018, and her estate is due to receive 22 percent of the settlement proceeds, according to the settlement agreement.

The case is *United States ex rel. Stepe v. RS Compounding LLC*, M.D. Fla., No. 8:13-cv-03150, settlement announced 9/28/18.

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