

Healthcare Practice Section
News, Notes and Articles for January 2018

NOTES:

I hope everyone had a wonderful holiday season and had time to spend with your family. This is a reminder that the Winter Meeting is rapidly approaching. The meeting will be held at Amelia Island from Sunday, February 25, 2018 until Wednesday, February 28, 2018. If you have never visited Amelia Island you should seriously consider attending. It is a wonderful destination and very relaxing!

The Healthcare Practice Section and Professional Liability Sections have joined up to co-present. The topic is "The Economics of Reasonable Value and the Valuation of Medical Losses" presented by John E. Schneider, PhD and Cara M. Scheibling. They are with Avalon Health Economics LLC, 26 Washington St., 3rd Floor, Morristown, NJ 07960. The break out session is scheduled for Tuesday, February 27th from 7:45 a.m. to 8:45 a.m. It should be a fantastic presentation.

ARTICLES:

The amount of healthcare false claims/qui tam cases continues to rise for what seems the previous five years. General healthcare litigation has also picked up, at least in my part of the country.

One of the big topics toward the end of 2017 that will pick up steam greatly in 2018 is all types of litigation surrounding opioids. These cases range from DEA/state regulators cracking down on perceived "pill mills," false claims/qui tam lawsuits against toxicology labs related to billing for the confirmation and/or screening tests for opioid use or diversion and more recent theories of liability against wholesale drug distributors for not reporting suspicious drug orders and pharmaceutical manufacturers for failure to warn or other tort types of claims.

The Healthcare Practice Section newsletter will run a multiple part series on the government's prosecution of pill mill practices as this area should see continued activity. A colleague of mine, Adam Overstreet, a former United States Assistant Attorney General for the Southern District of Alabama has graciously agreed to contribute the articles.

If you have any questions about the articles or would like to talk to Adam feel free to email him at aoverstreet@burr.com.

The New Department of Justice Initiative: Aggressively Investigating and Prosecuting Opioid-Related Cases

Before joining the Burr & Forman, LLP law firm, I was a federal prosecutor for a little over a decade specializing in health care fraud and general white collar matters. In that role, I was the member of a prosecution team that secured guilty verdicts earlier this year against two pain management doctors in Mobile, Alabama following a protracted jury trial. The doctors were convicted of a litany of federal crimes arising from their operation of a pain management clinic, including, among others, violations of the Controlled Substances Act and the Anti-

Kickback Statute. The doctors received substantial prison sentences of 20 and 21 years, respectively, and forfeited virtually all of their assets (including bank accounts, houses, and cars) to the government.

The doctors in this case were convicted of running what the government calls a "pill mill," a pain management clinic that allegedly prescribes narcotics for illegitimate purposes. Pain management professionals should be aware that this is just one example of what will likely be an onslaught of "pill mill" and other opioid-related prosecutions by the Department of Justice (DOJ) during the current administration. In fact, just a few months after the convictions in the Mobile case, Attorney General Jeff Sessions announced a nationwide takedown of 120 doctors, pharmacists, and nurses -- dubbed "Operation Pilluted" -- who were charged with various federal crimes related to their alleged "unlawful distribution of opioids and other prescription narcotics." In announcing the takedown, Sessions noted that the DOJ would continue to "aggressively pursue corrupt medical professionals," and that "the Department's work is not finished. In fact, it is just beginning."

On the heels of that announcement, in August of this year, Sessions heralded a new DOJ pilot program called the "Opioid Fraud and Abuse Detection Unit." According to Sessions, the unit "will focus specifically on opioid-related health care fraud using data to identify and prosecute individuals that are contributing to the opioid epidemic." Sessions warned, "If you are a doctor illegally prescribing opioids or a pharmacist letting these pills walk out the door and onto our streets based on prescriptions you know were obtained under false pretenses, we are coming after you." Sessions explained that the DOJ would be appointing a special federal prosecutor in twelve select districts across the country whose sole purpose will be to prosecute "pill mill" and other opioid-related cases.

One of the districts which has received one of the special "pill mill" prosecutors is the Northern District of Alabama, in Birmingham. The U.S. Attorney for that district, Jay Town, separately confirmed that the new prosecutor will spend "one hundred percent of their time working these types of cases. . . . What we're going after are the medical providers who are operating outside the boundaries of the law and the medical practice." Echoing the Attorney General's statements, Town vowed, "We're going to rid the Northern District of these pill mills."

Note that "pill mills" are not the only opioid-related cases on the DOJ's radar. In fact, it is also concentrating on the "diversion" of opioids in hospital settings. Such "diversion" schemes include, for instance, the theft of opioids from a hospital "Paxxis" machine (a device hospitals utilize to regulate the dispensing of controlled substances) by nurses, or the forgery or fraudulent creation of opioid prescriptions by hospital personnel.

In sum, the DOJ has fired a warning shot that physicians, pharmacists, and other medical professionals involved in the treatment of pain patients will be under intense scrutiny for the foreseeable future. This is especially true for physicians who operate pain management clinics. These doctors should, in general, prescribe opioids reasonably and carefully in the context of each patient's presentation and thoroughly document their treatment.

To that end, doctors should, among other things: maintain a thorough intake procedure which requires the patient to give a detailed medical history and provide previous diagnostic studies;

have the patient sign, if applicable, an "opioid treatment agreement" requiring the patient to abide by certain opioid use guidelines; perform exhaustive physical examinations during the initial visit and at regular intervals during the patient's treatment (which should be carefully documented); consider alternatives to opioid treatment, such as non-narcotics drugs, physical therapy, and surgery (and, where applicable, carefully document why alternative treatments would be ineffective); prescribe the lowest dosage and quantity of opioids possible to treat the patient's condition; closely monitor for signs of diversion and addiction by regularly ordering urine drug screens and reviewing the patient's prescription drug monitoring data; and have regular independent audits conducted by a billing consultant or another pain management specialist to ensure compliance with all regulations and laws. Implementing these practices should help doctors avoid government scrutiny as part of the DOJ's new initiate to crackdown on alleged "pill mill" operations.