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The opioid epidemic: What compliance officers should know

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It is not news to anyone that the opioid epidemic is a critical public health issue, in addition to being an area of heightened scrutiny by various government agencies and regulators. Due to increased enforcement, physicians and other healthcare providers who prescribe opioid medications to help their patients manage pain are becoming ever more cautious about overprescribing those medications. The concern for prescribers of opioids is legitimate, based on the litany of settlements and government actions against providers/prescribers, pharmacies, and drug companies. The quandary for physicians, of course, is that their first priority is to take care of their patients, which often includes managing chronic pain. The focus of this article will be to provide compliance guidance for physicians and prescribers, although other healthcare players bear risk as well.

Many types of providers are impacted by the challenges presented in this public health crisis: family physicians (who are responsible for about half of the opioid pain relievers dispensed),[1] physicians who specialize in pain management, neurologists, orthopedic and other surgeons, hospitals, and pharmacies all have potential exposure in this very visible risk area. Other specialties can be impacted as well, due to patients who see multiple specialists to seek relief from various health problems.

The government's concern relating to the opioid epidemic is twofold. First, of course, is the alarming increase in deaths and health consequences related to opioid misuse and abuse, which has become a public health crisis and is the subject of countless news programs and other media attention. According to The New England Journal of Medicine,[2] the opioid epidemic has claimed more than 300,000 lives since the year 2000 in the United States alone. Secondly, issues of drug diversion, "pill mills," and other illegal activities increase the cost of healthcare drug spending and raise concerns from regulators who investigate healthcare fraud and abuse. Federal agencies focusing on this crisis include Health and Human Services (HHS), the Drug Enforcement Agency (DEA), the Food and Drug Administration (FDA), and the Centers for Disease Control (CDC). At the state level, Medicaid fraud task forces, health departments, law enforcement, and licensing and pharmacy boards all have a role in monitoring the prescribing, use, and abuse of opioids.

Several types of cases have been frequently brought in the battle against the opioid epidemic. The most visible and large-dollar cases involve pharmaceutical companies and off-label or deceptive marketing. Off-label marketing cases typically occur when drug companies market a drug for purposes other than what the FDA approved the drug for. These cases often involve physicians as well, when there are financial benefits provided to prescribers for not only prescribing the drug for the unapproved use, but also for conducting marketing activities for that same drug and unapproved usage. These cases are often significant. Purdue,[3] as only one example, paid a settlement of $600 million for misbranding OxyContin® and misleading physicians and patients about the product's addictive qualities. Cardinal Health[4] ,[5] paid $44 million for violating the Controlled Substances Act, specifically by failing to report suspicious drug orders to the DEA.