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The past is prologue: Reviewing compliance landmarks from 2018 to plan for 2019

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Compliance professionals live in a world of constant change. As new laws are passed, new regulations are finalized, and public health crises emerge, compliance professionals are expected to guide their organizations through uncharted territory to the destinations chosen by other leaders.

Although predicting the future is impossible, compliance priorities rarely develop in isolation. This article surveys significant compliance landmarks from 2018 to help compliance professionals plan for the next year. To be certain, the expected, steady flow of rulemaking, guidance updates, and day-to-day enforcement actions has not abated. Compliance issues involving physician compensation, documentation, coding and billing, and HIPAA, among others, continue to garner government scrutiny and, in many cases, significant monetary settlements. However, such issues are likely already included in a compliance professional's plans for 2019. The events highlighted in this article are significant new topics that could alter the compliance landscape over the long term, requiring compliance professionals to adapt their practices to inform and protect their organizations.

Opioid crisis

The opioid crisis began before 2018, but this year saw substantial government resources dedicated to fighting the overuse and overprescribing of opioid drugs. Compliance professionals should be aware of the actions taken by state and federal regulators to address this public health crisis.

Each year since at least 2010,^[1] the Department of Justice (DOJ) and the Department of Health and Human Services have collaborated with state and federal partners to conduct an annual National Health Care Fraud Takedown (National Takedown). The National Takedown has become a marquee tool for fighting fraud and abuse, resulting in charges against more than 2,200 individuals, including at least 386 medical professionals, who are tied to more than \$7 billion in false billings since 2010.

In 2018, the government expanded the focus of the National Takedown to include actions against those contributing to the opioid crisis, and the DOJ billed it as the National Health Care Fraud and Opioid Takedown.^[2] Through the 2018 National Takedown, 601 defendants, including 165 doctors, nurses, and other medical professionals, were charged in connection with healthcare fraud schemes. Of these defendants, 162 were charged for their roles in prescribing and distributing opioids and other dangerous narcotics. Additionally, although the National Takedown is often thought of as a tool for criminal enforcement, the Office of Inspector General (OIG) announced in conjunction with the takedown that it excluded 2,700 individuals from participation in federal healthcare programs from July 2017 through June 2018 and that 587 of these individuals were excluded for conduct related to opioid diversion and abuse. Given these results, the government has demonstrated that exclusion, one of its most effective tools against healthcare fraud, will be used in the fight against opioids as well.

Compliance professionals should be aware that state governments are also taking action to address the opioid crisis. Many states have enacted new laws to place strict limits on opioid prescriptions. In many states, these laws require prescribers and pharmacists to check the state's prescription drug monitoring database at the beginning of a course of treatment.^[3] In addition, many of these new statutes place strict limits on the initial doses that patients can receive.^[4]

In all likelihood, opioid enforcement will continue to be a high priority in 2019. As seen in the results of this year's National Takedown, prosecutors are apt to charge those who contribute to the opioid crisis with offenses under the nation's criminal drug laws, and OIG has used its exclusion authority against providers who it suspects of contributing to the opioid crisis. Importantly, these individuals, and, potentially, organizations that employ or contract with them, could also be subject to criminal and civil enforcement actions under the False Claims Act (FCA) and the Civil Monetary Penalties Law. At the root of these enforcement actions are the basic Medicare requirements that providers only submit claims for medically necessary services and for services provided in accordance with applicable state laws. As states further restrict the ways in which opioids may be prescribed, these standards must be considered when determining whether a claim for opioids is medically necessary and appropriate. Finally, providers who do not heed these new restrictions may face professional disciplinary actions, potentially leading to suspension or revocation of their professional licenses.

Compliance professionals should prepare for 2019 by familiarizing themselves with prescribing requirements in their states and developing education for their practitioners. Additionally, targeted audits can be included on 2019 compliance work plans with the goal of identifying problematic practice patterns in time to allay significant risk to patients or the organization. Compliance professionals should also be aware that in January 2018, OIG published a Toolkit to Identify Patients at Risk of Opioid Abuse (Toolkit).^[5] The Toolkit was prepared to assist Medicare Part D providers, private insurers, and Medicaid Fraud Control Units. We recommend that compliance professionals use the Toolkit as a useful reference, as appropriate.

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