



# Compliance TODAY

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Thank you  
**Roy Snell**





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by Ritu Kaur Cooper, Katherine Kuchan, and James Junger, CHC

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

- » The opioid crisis is an important priority for all providers, and compliance professionals should include appropriate education and auditing and monitoring activities in their 2019 work plans.
- » Harnessing all available data will help identify and reduce risk related to opioids and associated fraud and abuse risk.
- » Vulnerable populations, such as beneficiaries receiving hospice care, are an area of increased attention.
- » Changes to the ethical and religious directives are likely to impact both Catholic and non-Catholic institutions.
- » Beyond the opioid crisis, government efforts to reduce healthcare fraud and abuse continue apace.

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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



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of the actions taken by state and federal regulators to address this public health crisis.

Each year since at least 2010,<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> In addition, many of these new statutes place strict limits on the initial doses that patients can receive.<sup>4</sup>

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).<sup>5</sup> 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.

### Other enforcement priorities

Even though significant attention has been paid to the opioid crisis, other government enforcement efforts continue. This is evident even in the 2018 National Takedown: 439 of the 601 arrests made through the National Takedown were for violations unrelated to opioids. Compliance professionals should continue to look to traditional sources of guidance, including the OIG Work Plan and government statements regarding enforcement priorities, to determine where to focus proactive efforts in 2019.

### Vulnerable populations

In 2018, OIG continued to show an interest in protecting Medicare and Medicaid beneficiaries who are particularly vulnerable and the respective programs designed to serve them. This priority is evident in a presentation given at the 2018 HCCA Compliance Institute, where an OIG representative highlighted enforcement actions against home health and hospice providers and providers who faced enforcement actions for providing unnecessary therapy and substandard care.<sup>6</sup> Additionally, in January 2018, OIG, the Administration for Community Living, and the Office for Civil Rights (OCR) released a joint report focused on beneficiary health and safety in group homes.<sup>7</sup>

OIG sees hospice as a particular risk area, as demonstrated through its July 31, 2018 release of a media portfolio discussing perceived weaknesses in the hospice system.<sup>8</sup> The media portfolio represents a collection of OIG's work in the hospice area. OIG recommended that CMS take 15 specific actions to address seven weaknesses identified in the hospice system, which are outlined in the media portfolio.

Among other risks, OIG believes that the hospice *per diem* payment system creates incentives for providers to withhold care from beneficiaries. In its studies, OIG determined that in 31% of claims for services, hospice providers rendered less care than was called for in the patients' plans of care.<sup>9</sup> In addition, OIG

found that hospice physicians often fail to meet all the requirements for certifying that a patient is eligible for hospice care. Finally, OIG determined that hospices frequently charged for a higher level of care than was needed, leading to significant overpayments.

Compliance professionals can incorporate

a focus on vulnerable populations into their 2019 work plans through a few concrete steps. To identify potential FCA risks, the 2019 work plan could include audits of hospice claims. These audits could compare the items and services included in the claim to the patient's plan of care, ensure that the physician's certification meets all requirements, and determine whether the hospice billed for the appropriate level of care.

In addition, two Work Plan items are worthy of particular attention by participating entities, because OIG will be examining records that could lead to increased scrutiny

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for providers. Included in the January 2018 Work Plan update was a study to determine the extent to which Medicare beneficiaries are subject to abuse or neglect.<sup>10</sup> To complete this project, OIG will examine the diagnosis codes from Medicare claims to determine the prevalence of diagnoses indicating that a beneficiary may have been abused. An August 2018 Work Plan update includes a similar project focusing on children covered by Medicaid.<sup>11</sup>

OIG did not identify any particular providers that would be subject to review in these projects, but compliance professionals should consider including monitoring, auditing, and policy review activities in their 2019 work plans. For instance, compliance professionals can work with their counterparts in Patient Quality to audit medical records and claims or survey hospice patients and their families to identify potential instances of neglect or abuse. Although quality of care typically falls outside the Compliance umbrella, there is FCA risk where services provided fall below the standard of care, leading providers to submit claims for services the government considers worthless.

Compliance professionals could take their analysis one step further, asking what the organization's response has been to potential instances of abuse. All 50 states have laws requiring healthcare providers to report suspected abuse or neglect of children or vulnerable individuals. Compliance professionals can review their organizations' abuse reporting policies, update them to account for any changes in state law, and survey clinical staff to determine whether they are comfortable with the organization's handling of cases of suspected abuse or neglect.

### **Ethical and religious directives**

Although a significant portion of most compliance professionals' work is rooted in government health care program

requirements, the United States Conference of Catholic Bishops' *Ethical and Religious Directives for Catholic Health Care Services*<sup>12</sup> (ERDs) directly apply to all Catholic health institutions and many entities with which they enter into contracts. In many institutions, the ERDs are a part of a compliance professional's portfolio. Compliance professionals should be aware that changes to the ERDs could have a significant impact on existing and future arrangements between Catholic and non-Catholic providers.

Although a full description of the ERDs is beyond the scope of this article, one long-standing requirement is that Catholic institutions cannot condone or participate in abortion, sterilization, euthanasia, or assisted suicide (i.e., "immoral procedures"). Compliance professionals at Catholic and non-Catholic institutions should be aware that the revisions to the ERDs will expand the situations in which this restriction has to be met.

Under the new Directive #73, Catholic institutions are required to ensure that they will not "manage, carry out, assist in carrying out, make...facilities available for, make referrals for, or benefit from the revenue generated by immoral procedures."<sup>13</sup> Catholic institutions are also prohibited from establishing another entity that would oversee, manage, or perform such procedures. In the past, Catholic organizations could partner with providers who performed these services by creating contractual firewalls between the Catholic organization and the prohibited services. In light of the updated ERDs, both existing and new arrangements may be subject to additional scrutiny by the clergy.

Compliance professionals should be aware of the updated ERDs and educate their business leaders as appropriate. Additionally, compliance professionals should consider reviewing agreements between Catholic and non-Catholic institutions to identify the

obligations of each party, then auditing operations to ensure that these obligations are being upheld. Compliance professionals working with a board that oversees a joint venture between a Catholic and a non-Catholic institution should inform the board of any negative audit findings. In advising the board, these compliance professionals should be aware that the new ERDs do not mandate that an agreement be terminated if it constitutes a prohibited relationship. Instead, the leader of the organization is to immediately inform the local bishop and work to resolve the situation as soon as reasonably possible.<sup>14</sup>

### **Evolving enforcement tools**

In a constantly changing enforcement environment, compliance professionals should work to understand the tools that regulators use to fight fraud and abuse. The year 2018 saw developments in the government's use of data analytics and the creation of two new groups focused on fighting fraud and abuse and the opioid crisis.

### **Use of data analytics**

For years, compliance professionals have heard that the government is utilizing "Big Data" to augment its enforcement efforts. This year has proven to be no different.

The opioid crisis has provided a window into the ways in which regulators use data in their enforcement efforts. In a presentation at the 2018 Compliance Institute, an OIG representative demonstrated the agency's use of data in identifying at-risk patients and providers who prescribe dangerous levels of opioids.<sup>15</sup> In 2016, there were 44 million Medicare Part D beneficiaries. From this population, OIG determined that 14.4 million received opioids, and half of these beneficiaries received high amounts of opioids. OIG's analysis found that 90,000 of these beneficiaries were at serious risk of opioid misuse or

overdoses, and 70,000 beneficiaries received extreme amounts of opioids (i.e., more than 240 morphine-equivalent milligrams per day for more than 12 months). OIG further determined that 678 beneficiaries received more than 1,000 morphine-equivalent milligrams each day for over a year. Perhaps most striking, OIG identified one beneficiary, from the full population of 44 million, who received 134 prescriptions for opioids in a single 12-month period. Although the government's use of data analytics is well known, the example above is a stark demonstration of the government's capabilities in 2018.

In 2019, compliance professionals should use whatever tools they have available to analyze data from their organizations to aid in their compliance efforts. Additionally, examples such as the one described above are valuable education tools; employees should understand that healthcare claims are continually monitored by regulators. When one beneficiary can be identified from 44 million, there should be little doubt that one provider with non-compliant practices can be identified from the thousands who participate in the Medicare and Medicaid programs.

### **New federal task forces**

In 2018, the federal government created two new task forces focused on combating fraud and abuse and the opioid crisis. In February 2018, Attorney General Jeff Sessions announced the DOJ's creation of the Prescription Interdiction & Litigation Task Force (PIL Task Force).<sup>16</sup> The PIL Task Force includes officials from across the DOJ who are using criminal and civil enforcement tools to reduce the harm associated with the opioid crisis, with particular focus on opioid manufacturers and distributors. These distributors include pharmacies, pain management clinics, drug testing facilities, and individual physicians.

The PIL Task Force has been specifically identified as contributing to a number of significant or novel enforcement actions since its creation. For instance, in August of this year, the U.S. Attorney's Office in the Northern District of Ohio filed first-of-their-kind motions against two physicians accused of illegally distributing opioid drugs.<sup>17,18</sup> At the outset of the case, the DOJ asked the court to issue temporary restraining orders prohibiting them from prescribing controlled substances. These orders were issued before the providers even knew they had been accused of wrongdoing.

In addition to the PIL Task Force, the DOJ created a new Medicare Strike Force on August 12, 2018, with jurisdiction over the Newark, New Jersey and Philadelphia, Pennsylvania region. Although Medicare Strike Forces are a known component of the government's enforcement strategy, the creation of a new Strike Force is a signal for all providers working in the area. In the past, Medicare Strike Forces have contributed significantly to the annual National Takedowns, and we can expect that the 2019 National Takedown will include providers operating in this newly covered region.

In planning for 2019, compliance officers should be aware of the government's new enforcement tools. In particular, the PIL Task Force's use of temporary restraining orders is a teaching point for prescribers: although those accused of criminal conduct are presumed innocent until proven guilty, these temporary restraining orders are civil tools, and their successful deployment in Ohio is likely to lead to attempts in other jurisdictions as well. Practitioners should be aware that, if they engage in egregious conduct, they may lose the ability to earn an income while they defend themselves against civil and criminal charges levied by

experienced prosecutors with a vast pool of resources from which to draw.

## Conclusion

Although nobody can predict what 2019 will bring, we advise that the past should be considered prologue. None of the developments described above occurred in isolation, and we think that compliance professionals can expect most of these trends to continue on into the next year. 🍷

*This article is educational in nature and is not intended as legal advice. Always consult your legal counsel with specific legal matters.*

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