

COMPLIANCE TODAY

MAGAZINE

FEBRUARY 2019

NIURKA ADORNO

REGIONAL COMPLIANCE OFFICER
MOLINA HEALTHCARE OF SOUTH CAROLINA &
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PROVIDERS AND THE OPIOID CRISIS: COMPLIANCE OFFICERS NEED TO BE AWARE

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On October 24, 2018, the President signed into law the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT for Patients and Communities Act, or the Act), a comprehensive law that requires efforts across federal agencies to mitigate the opioid epidemic. The Act is another recent government action among many laws, regulations, policies, and enforcement actions taken to curb the national epidemic. The opioid epidemic has touched and devastated nearly every community in the U.S., with 46 people dying every day from prescription opioid-involved overdoses in 2016.¹ Healthcare compliance officers and committees should be particularly aware, because the agencies that regulate the healthcare space have focused heavily on the opioid epidemic over the last few years, with consistently increasing efforts to reduce its effects. Compliance officers should be aware of government agency efforts and enforcement initiatives and work with their operational departments to ensure that oversight and proper controls are in place within their facilities to

deter inappropriate overprescribing, drug diversion, and potential risks to patients.

The SUPPORT for Patients and Communities Act

The Act is the most comprehensive law to address the opioid crisis since the passage of the 21st Century Cures Act and the Comprehensive Addiction and Recovery Act in 2016.² The Act includes a variety of new utilization controls, prescription reviews, and data analytics and monitoring provisions to help prevent unnecessary prescribing and opioid diversion, and increase access to alternative pain management and opioid use disorder (OUD) treatments. Additionally, it instructs the Department of Health and Human Services (HHS) to implement new requirements for services such as Medication-Assisted Treatment (MAT), pre-authorization, and e-prescribing of opioids for Medicare Part D providers.³ Many of the new provisions are meant to lower barriers to treatment and prevent future overprescribing and drug diversion. The government uses strong monitoring and enforcement tools to achieve these goals, which in turn require healthcare organizations

to be aware of changes to billing procedures, payment coverage, monitoring requirements, and enforcement trends.

Beyond the components of the Act that touch on greater access to treatment, alternative pain management methods, and reconstruction of payment mechanisms to make treatment and recovery more accessible, the Act also contains increased fraud and abuse enforcement tools. The Act created the Eliminating Kickbacks in Recovery Act (EKRA), a criminal statute separate from other federal and state anti-kickback statutes, which makes it illegal for providers paid by either federal healthcare programs or private insurers to solicit, receive, induce, or offer to pay remuneration in return for referring patients to a recovery home, clinical treatment facility, or laboratory.⁴ A provider that takes part in a transaction that triggers EKRA, and where the transaction does not fall under one of the statutory exceptions, could face up to \$200,000 in fines or up to 10 years in prison, or both. In addition, the Act creates enforcement mechanisms intended to remove incentives to use opioids over evidence-based, non-opioid alternatives for outpatient facilities and ambulatory surgical centers.⁵

Agency action

Compliance officers should also be aware of the regulations and guidance materials released by federal agencies. In October 2018, the Office for Civil Rights (OCR) released two fact sheets emphasizing the civil rights of patients seeking treatment for OUD. OCR previously released a 2017 guidance clarifying when a provider can disclose opioid treatment-related information without violating the HIPAA Privacy Rule. One 2018 fact

sheet provides guidance on the applicability of federal disability rights laws to those experiencing OUD. The fact sheet outlines when an individual with OUD may fit into the legal definition of a person with a disability and, therefore, be protected under the Americans with Disabilities Act (ADA) and other federal disability laws.⁶ The second 2018 fact sheet outlines the prohibition against discriminatory barriers to health services based on race, color, national origin, age, disability, exercise of conscience, religion, or sex. These health services include OUD treatment and recovery programs. OCR provides the following best practices for those entities that may treat these patients:

1. Examine program eligibility and admission criteria to ensure there are no discriminatory barriers in the organization's practices;
2. Ensure individuals who primarily speak, write, read, or understand a language other than English have meaningful access to health and treatment programs, including MAT;
3. Ensure individuals with physical or mobility disabilities have access to OUD treatment programs and critical healthcare services, and auxiliary aids and services are provided when necessary at no additional cost; and
4. Ensure that qualified individuals recovering from OUD have access to health and human service programs, such as child welfare programs.⁷

OCR emphasized that if a patient is protected by civil rights laws such as the ADA, or falls under another protected class, the fact that the patient chooses to seek treatment for or is recovering

...an individual with OUD may fit into the legal definition of a person with a disability and, therefore, be protected under the Americans with Disabilities Act...

from OUD does not diminish the applicability of the laws' protections. In some circumstances, OUD may be the reason an individual is provided with protection under the ADA and other federal disability rights laws. Therefore, it is important for an organization and providers to have proper policies in place to prevent discriminatory practices against patients with OUD.

HHS's department-wide approach to the opioid crisis includes:

- ◆ A focus on better access to treatment, prevention, and recovery;
- ◆ Better use of data to understand the causes, effects, and treatments of OUD and improving the use of prescription drug monitoring programs (PMDPs);
- ◆ Better pain management techniques;
- ◆ Better targeting of overdose-reversing drugs; and
- ◆ Better research regarding OUD.

In June 2018, the HHS Office of Inspector General (OIG) released a Toolkit that provides steps for public

and private healthcare prescribers to identify patients who are at risk of opioid overdose or misuse by analyzing prescription claims data. The Toolkit includes technical steps to help providers calculate a patient's daily morphine equivalent dose (MED) and analyze and program code to apply to the user's own data.⁸ Additionally, the OIG independently and in conjunction with other agencies, has heavily focused on enforcement in recent years on federal healthcare fraud and abuse involving prescription opioids.⁹

DOJ and OIG are bringing actions against those committing blatant abuses, as well as organizations with insufficient compliance controls.

Enforcement

The Department of Justice (DOJ) and OIG have aggressively enforced federal healthcare fraud and abuse laws in order to combat prescription opioid diversion and improper billing and prescribing of opioids. In recent years, the DOJ has pursued a number of cases directly related to opioid prescribing that resulted in large settlement agreements.

In 2014, Dignity Health agreed to pay \$1.55 million to resolve claims that the hospital system had

deficiencies in its policies and procedures for the handling of controlled substances.¹⁰ The U.S. government initiated an investigation after Dignity Health allegedly failed to prevent the loss of more than 20,000 tablets from one of its pharmacies. More recently, a CEO pleaded guilty to a scheme involving harmful and unnecessary prescriptions, totaling 6.6 million dosage units and over \$300 million worth of fraudulent claims.¹¹ The CEO gave unnecessary prescriptions to Medicare beneficiaries, including beneficiaries who were addicted to narcotics. These two cases alone provide a snapshot of the large net DOJ is casting when bringing fraud and abuse cases involving prescription opioids. DOJ and OIG are bringing actions against those committing blatant abuses, as well as organizations with insufficient compliance controls.

Furthermore, the government has used the Controlled Substances Act (CSA) as a basis for False Claims Act (FCA) cases in this area, which has led to monetary penalties under both the CSA and FCA and compliance agreements with both the Drug Enforcement Agency (DEA) and the OIG.¹² For example, PharMerica Corporation, a pharmacy that dispenses medication for long-term care facilities, entered into a \$31.5 million settlement for alleged violations of the CSA and FCA. The qui tam-initiated suit alleged that PharMerica dispensed and billed for Schedule II drugs without a valid prescription, which violated the CSA. Because the prescriptions were not valid under CSA requirements, the government argued it would not have paid if the government knew of the invalid prescriptions; therefore, PharMerica allegedly also violated the FCA.

The OIG and DOJ were also involved in large national healthcare

fraud and abuse takedowns that include individuals who improperly prescribed or diverted opioids. For example, in June 2018, as part of a \$2 billion fraud takedown, the DOJ filed charges against a doctor, nurse practitioner, and surgical technician who allegedly conspired to distribute unnecessary opioid prescriptions and defraud Medicare and Medicaid.¹³ The physician pre-signed prescriptions, which were then distributed by the surgical technician, and in return the conspirators received cash kickbacks. For hospitals and other providers, monitoring prescribing is a significant mechanism to prevent a similar occurrence, or the possible recreational use of opioids by workforce members.

Monitoring

The DOJ will use data analytics and other tools to support its enforcement actions. Created in August 2017, the Opioid Fraud and Abuse Detection Unit focuses solely on opioid-related healthcare fraud cases, and uses data to identify those who are contributing to the opioid crisis through either improper overprescribing or illegal actions like running a "pill mill."¹⁴ The Unit also created pilot offices in regions across the country to specifically focus on fraud and abuse involving opioids. In February 2018, the DOJ announced the Prescription Interdiction and Litigation Task Force, which will be made up of DOJ attorneys and DEA officials tasked with prosecuting manufacturers, pharmacies, pain management clinics, drug testing facilities, and individual physicians who contribute to the epidemic through illegal actions.¹⁵

Similar to the DOJ, the OIG will use various tools, other than enforcement, to identify those who

Compliance officers may consider working with internal task force(s) or compliance committees to initiate or support internal data monitoring that specifically targets opioid fraud and abuse.

may have violated federal healthcare fraud and abuse laws due to drug diversion or overprescribing. The Deputy Inspector General, Gary Cantrell, testified in January 2018 before the House Subcommittee on Oversight about the OIG's and the Centers for Medicare & Medicaid Services' (CMS) efforts to use data analysis tools already in place to detect fraud, abuse, and overprescribers.¹⁶ The agencies use these analytical tools to identify mitigation strategies and follow-up with prescribers and at-risk beneficiaries.

Further, the OIG emphasized the use of monitoring and data analytics in a June 2018 Data Brief. The brief focused on the concerning opioid use patterns in Medicare Part D and addressed how to mitigate such troubling patterns.¹⁷ For example, the brief notes that a doctor-shopping patient (i.e., a patient who receives high amounts of opioids from multiple prescribers) may indicate a need for greater care coordination or prescriber monitoring through tools like the states' PDMP. As such, organizations need to have sufficient policies and procedures in place that use monitoring systems, such as PDMP, and prevent drug diversion by doctor-shopping patients.

Additionally, the OIG notes that it will work with the DOJ's Opioid Fraud and Abuse Detection Unit to review "identified prescribers," who are outliers in the number of

opioids they prescribe based on their respective practice and geographic area. The OIG will monitor areas and prescribers associated with high volumes of prescriptions to determine the potential occurrence of medically unnecessary prescribing.¹⁸ If the OIG identifies unnecessary prescribing, it may use it as the basis for an FCA action. Therefore, organizations should have robust auditing and monitoring practices in place to identify potential outlier prescribers, correct unnecessary provider prescribing, and reduce the potential of FCA violations.

CMS has also prioritized monitoring and alternative treatment options to reduce the effects of the opioid crisis. Since 2017, CMS has prioritized opioid prescribing practices and the expansion of the use of MAT to reduce OUD, as well as the use and distribution of naloxone.¹⁹ As a result, providers and Part D prescribers should implement effective monitoring mechanisms to track opioid prescribing, and ensure treatment options like MAT, alternative pain management, and naloxone are properly coded and billed for, especially if these treatment options are relatively new for a provider.

Starting January 1, 2019, CMS was originally planning to enforce a new requirement for Medicare Part D providers prescribing opioid prescriptions. In a continued effort

to reduce the volume of opioids prescribed under Medicare Part D, CMS wanted to require that the majority of prescribers writing prescriptions for Medicare Part D beneficiaries to be enrolled in Medicare or have opted out to ensure the coverage of the drug.

Also, CMS's National Benefit Integrity Medicare Drug Integrity Contractors (NBI MEDICs) will provide increased data analysis of opioid prescribing trends to CMS and the OIG.²⁰ NBI MEDICs will conduct proactive analysis to find trends, outliers, and questionable pharmacy or physician practices. These findings will be reported to plan sponsors who will have the discretion to take further action, up to and including termination of a physician or pharmacy.

Compliance officer actions: Policies/procedures/monitoring

Compliance officers most importantly need to stay informed about what is happening on the regulatory front with regards to opioids so that they can work together with internal operation departments, patient advocacy groups, clinical experts, and others to develop strategies to handle risk areas related to opioid fraud and abuse. Also, privacy officers and compliance officers need to be familiar with OCR specific guidance and noted best practices.

Compliance officers may consider working with internal task force(s) or compliance committees to initiate or support internal data monitoring that specifically targets opioid fraud and abuse. For example, compliance officers may setup an "Internal Opioid Fraud and Detection Unit," emulating the government's activities. The internal unit may require recruiting experts in clinical treatment, data mining and analysis, as well as reimbursement fields to

have an effective strategy. It would demonstrate an aggressive and proactive stance in the matter, as well as combat fraud, waste, and abuse. In addition, compliance officers may want to update their internal policies and procedures, including policies regarding privacy and civil rights laws, as well as those pertaining to physical safeguards, inventory management, and risk identification.

Compliance officers may need to structure independent audits to align with the DOJ and OIG’s monitoring efforts and changes in billing, particularly if the organization increases use of MAT or alternative pain management practices. Compliance officers may have to compile an interdisciplinary team to look at prescriber analysis and treatment protocols. Hotlines should be closely monitored for anonymous reporting, as well as calls to patient complaint lines.

Conclusion

Ultimately, compliance officers need to work within their set budgets that are driven by their work plans. Therefore, compliance

budgets may need updates and additional resources to accommodate any additional monitoring and reprioritizing in light of this explosively growing risk area. Most importantly, compliance officers should get their governing boards involved and, at the very least, ensure that the board or board compliance committee receives an overview and regular updates of

the new opioid-related regulations and changes in the law. If the board members better understand how the opioid epidemic affects the organization, as well as the expectations from government agencies, they are more inclined to allocate funds to monitoring and education for the Compliance department doing its part to fight the epidemic. It is all about knowledge. CT

Endnotes

1. Centers for Disease Control and Prevention, “Opioid Overdose” (last modified August 30, 2017). <https://bit.ly/2rKhG75>
2. Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018, Public Law No. 115-271 (2018). <https://bit.ly/2L7Tzuo>
3. Idem at §§2003, 6032, 6062.
4. Idem at § 8121.
5. Idem at § 6082.
6. U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR), *Drug Addiction and Federal Disability Laws*, 2018. <https://bit.ly/2GF1P4e>
7. HHS, OCR, *Nondiscrimination and Opioid Use Disorder*, 2018. <https://bit.ly/2rHEHro>
8. HHS, Office of Inspector General (OIG), Toolkit: Using Data Analysis to Calculate Opioid Levels and Identify Patients at Risk of Misuse or Overdose, OEI-02-17-00560, 2018. <https://bit.ly/2Eyoza8>
9. HHS, *5-Point Strategy to Combat the Opioid Crisis*, 2017. <https://bit.ly/2ECtaC9>
10. U.S. Department of Justice (DOJ), Justice News press release: “Dignity Health Agrees To Pay \$1.55 Million In Civil Penalties To Resolve Controlled Substances Act Claims” July 16, 2014. <https://bit.ly/2CoJ54C>
11. DOJ, Justice News press release: “Health Care CEO Pleads Guilty to \$150 Million Health Care Fraud Scheme Involving Harmful Injection and Unnecessary Prescriptions of Millions of Opioids” October 15, 2018. <https://bit.ly/2QdkQLa>
12. Edward A. Baker and Stacey Gerber Ward, “Pursuing False Claims Act Liability for Controlled Substances Act Violations” *United States Attorney’s Bulletin* 64, no.6, November 2016:102-105. <https://bit.ly/2SbjFgq>
13. DOJ, Justice News press release: “National Health Care Fraud Takedown Results in Charges Against 601 Individuals Responsible for Over \$2 Billion in Fraud Losses” June 28, 2018. <https://bit.ly/2SchBES>
14. DOJ, Justice News press release: “Attorney General Session Announces Opioid Fraud and Abuse Detection Unit” August 2, 2017. <https://bit.ly/2ukVRdf>
15. DOJ, Justice News press release: “Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force” February 27, 2018. <https://bit.ly/2GQrwtH>
16. U.S. Congress, House of Representatives, Committee on Ways and Means, *The Opioid Crisis: The Current Landscape and CMS Actions to Prevent Opioid Misuse* January 17, 2018. Transcript at <https://bit.ly/2POkf1B>
17. HHS, Office of Inspector General, Opioid Use in Medicare Part D Remains Concerning, OEI-02-18-00220, 2018. <https://bit.ly/2NdpbwG>
18. Idem.
19. HHS, Centers for Medicare & Medicaid Services, *Opioid Misuse Strategy*, 2016. <https://go.cms.gov/2MxydDE>
20. *Ibid*, Ref #2, §§ 2003-4, 5042, 6062.

Takeaways

- ◆ 42 CFR Part 2’s purpose is to protect those who seek substance abuse treatment.
- ◆ Part 2 programs are subject to use and disclosure restrictions.
- ◆ Applicability of Part 2 can be determined through a two-factor test.
- ◆ The recent revisions modified Part 2 consent form requirements.
- ◆ Part 2 programs and other lawful holders must implement security policies.