POLICY & MEDICINE
COMPLIANCE UPDATE
Volume 5.11 | November 2019

FEATURE

# Helio Patient Services Compliance Survey

## *The Latest Trends and Lessons Learned*

*By Minna Bak, Senior Manager, and John Poulin, Partner, Helio Health Group* [1]

**Summary:** Patient services programs are continuing to evolve as life sciences companies consider the associated risks, which have been highlighted by government investigations and regulations. This article highlights the major trends and lessons learned in the industry as seen through the third annual patient services compliance survey conducted by Helio Health Group.

In the February issue of the Policy & Medicine Compliance Update, we analyzed the results from the 2017 and 2018 Helio's survey on patient services compliance.[2] Helio's annual patient services compliance survey provides a benchmark as to how the industry is continuing to develop, evolve, and manage their patient services programs, considering the associated risks that are beginning to emerge as these programs become increasingly scrutinized. In this article, we report on 2019 results and analyze the trends and lessons learned over the past three years (2017 to 2019).

## The Overall Patient Services Compliance Landscape

Patient services programs and the ways in which the life sciences industry directly or indirectly interacts with patients is not only an interest for the commercial functions determining how best to reach their target patient populations and use patient data but for Government agencies as well. In 2019, there was an increase in the number of Corporate Integrity Agreements ("CIA") focused on patient services programs and activities between manufacturers and patients. The donations to third-party foundations and charities that provide patient assistance and allegations of violating the False Claims Act ("FCA") and the Anti-Kickback Statute ("AKS") were a particular focus of these CIAs.



## INSIDE

In addition to scrutinizing donations to independent charities, the Government also is investigating the use of patient data and how this data is stored by manufacturers. In 2017, one manufacturer entered into a Deferred Prosecution Agreement ("DPA") in the District of Massachusetts to resolve its "criminal liability" involving the Health Insurance Portability and Accountability Act ("HIPAA"), admitting it obtained patients' identifiable health information without patient consent for commercial purposes.[3] Data privacy has been a burning issue in terms of how companies broadly use personal data, even outside of the life sciences industry. HIPAA regulations, the General Data Protection Regulation ("GDPR"), the California Consumer Protection Act ("CCPA"), which is set to be fully implemented in January of 2020, and other state-specific data privacy laws have prompted companies to evaluate their patient data management practices.

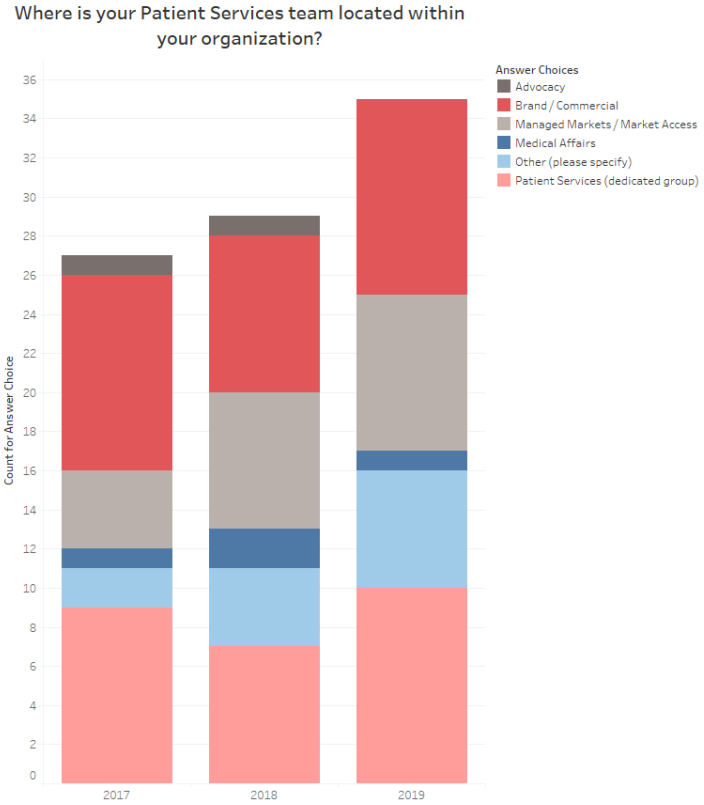
## Year over Year Trends: 2017-2019

The 2017 survey focused on compliance concerns relevant to setting up patient services programs. As the government started pursuing AKS, FCA, and HIPAA violations related to patient services, the 2018 survey included questions regarding monitoring and controls specific to areas where compliance challenges are emerging. In 2019, Helio expanded the survey to include a focus on data privacy and the use of patient data. The surveys included responses from compliance and patient services professionals across small, mid-size (top 21-50) and large (top 20) pharmaceutical and biologic companies.[4] The number of respondents by year is as follows:

| Year | # of Respondents |
|---|---|
| 2017 | 27 |
| 2018 | 28 |
| 2019 | 36 |

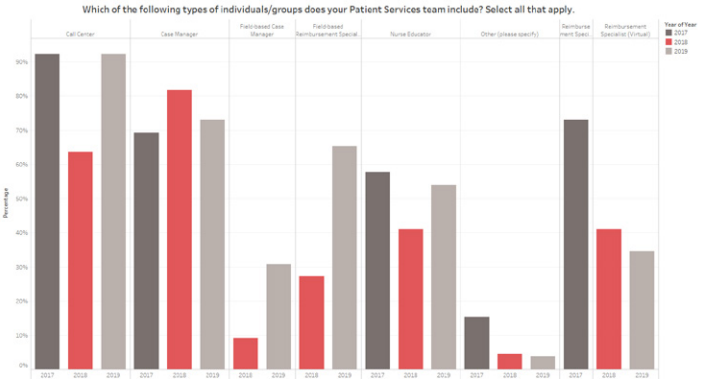
## Organizational Reporting Structure

Between 2017 and 2018, companies shifted their patient services team out from under Brand/Commercial operations into its own group or other functional areas. In 2019, companies continued to follow this trend in addition to "Other" categories where patient services reports to both Brand/Commercial and Managed Markets or have dotted lines between Brand/Commercial and Patient Services.



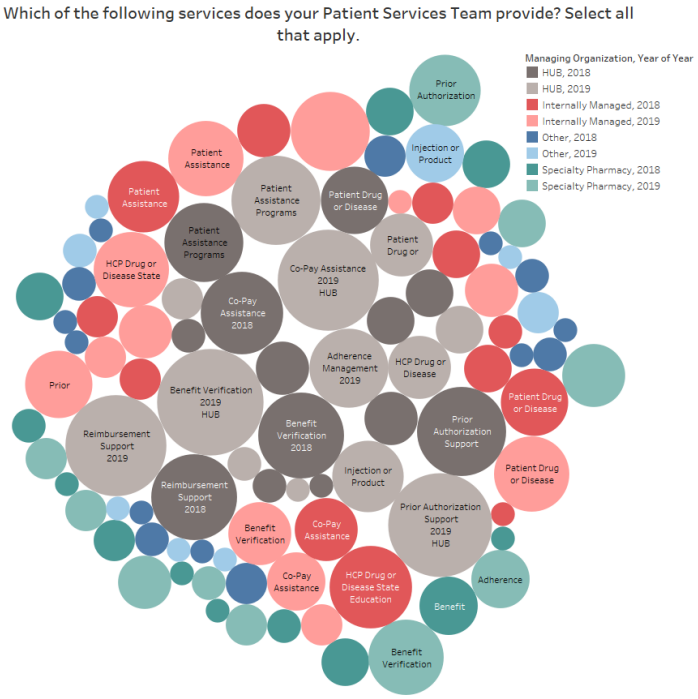

## The Makeup of the Patient Services Team

Over the last three years, companies have increased their field-based patient support teams, particularly with reimbursement specialists. Note that in 2017, the survey did not differentiate between field-based and virtual reimbursement specialists. However, the sum of field-based and virtual specialists in 2018 and 2019 was greater than that of 2017.



## Management of Services Provided by the Patient Services Team:

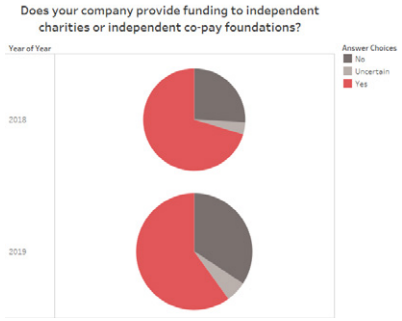
Between 2018 and 2019, there has been an increase in the outsourcing of financially related patient services (Benefit Verification, Co-Pay Assistance, Reimbursement Support, and Prior Authorization Support) to Hubs and Specialty Pharmacies. Also, there has been a slight decrease overall in HCP and Patient Disease and Product education services.

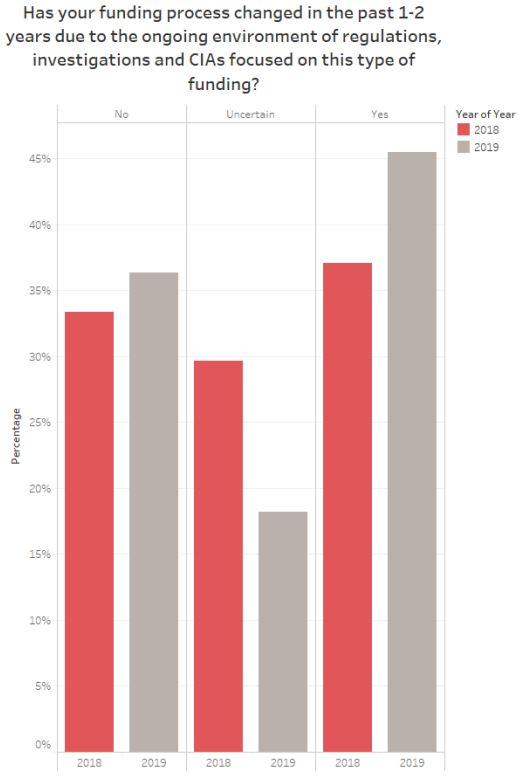



## Independent Charities and Co-pay Assistance Foundations

Over the last several years, the Government has launched various investigations into pharmaceutical manufacturers' donations to independent charities. In April of 2019, six pharmaceutical manufacturers settled with the Department of Justice ("DOJ") to resolve allegations of violating the FCA for paying through third-party foundations the copays for patients insured by federal healthcare programs to induce patients to purchase the manufacturers' drugs.[5] According to the Justice Department, "[u]nder the Anti-Kickback Statute, a pharmaceutical company is prohibited from offering, directly or indirectly, any remuneration — which includes paying patients' copay obligations — to induce Medicare patients to purchase the company's drugs." Each of these companies also entered into five-year CIAs with the Department of Health and Human Services, Office of the Inspector General ("OIG"), which included specific provisions to ensure that their interactions with and donations to independent patient assistance programs comply with federal requirements.

Interestingly, according to the survey, between 2018 and 2019, there was an 8% increase in manufacturers that stated that they did not provide funding to independent charities or co-pay foundations, which correlated to an 8% increase of manufacturers that claimed that their funding process has changed in the past 1-2 years due to the ongoing environment of regulations, investigations, and CIAs focused on this type of funding. Thus, clearly the Justice Department's activities in this area are having a deterrent effect.



As companies determine which charities and how to set up the donations to these organizations, specific and defined criteria are critical to ensure that these donations are not being used to incentivize the organizations to provide assistance to certain patients and to ensure that patients are not directed to specific organizations. However, challenges may arise in rare disease areas where there are limited foundations supporting these disease states, and thus underscores the importance that contracts have robust guidelines and that policies are clearly written regarding communication and any data received from the organizations.

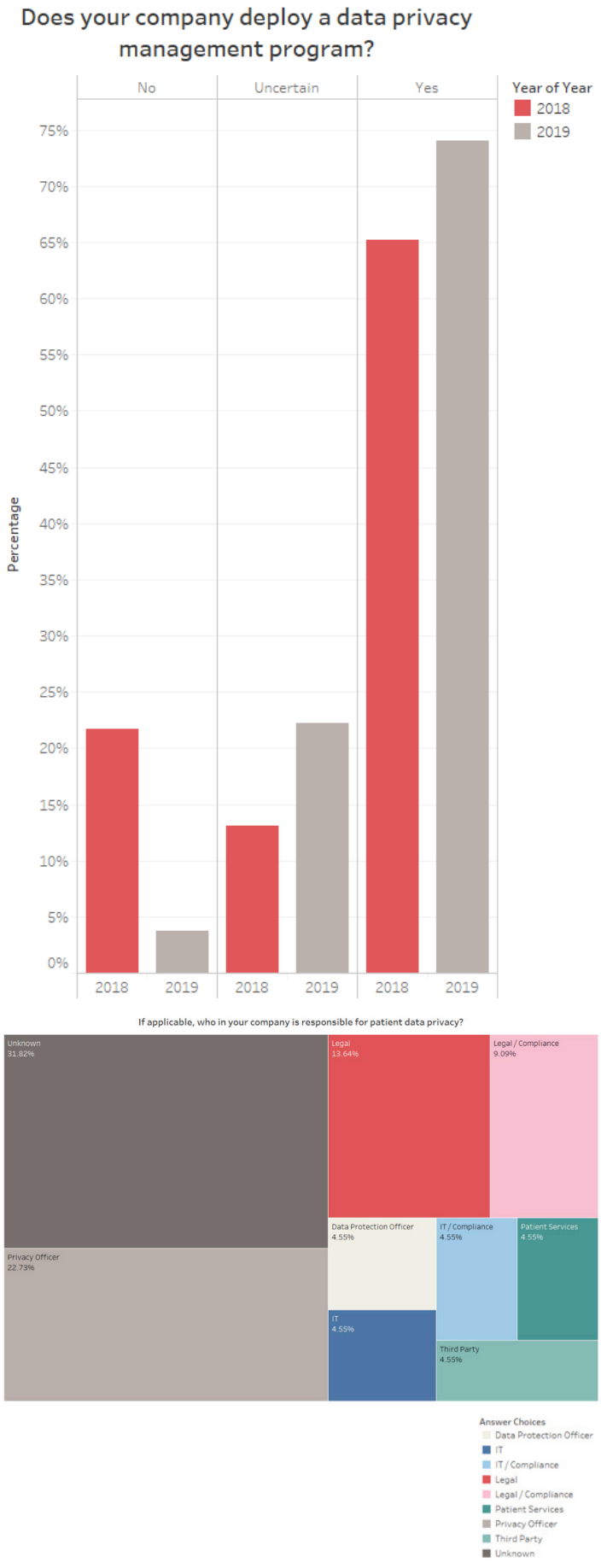
## Patient Data and Data Privacy

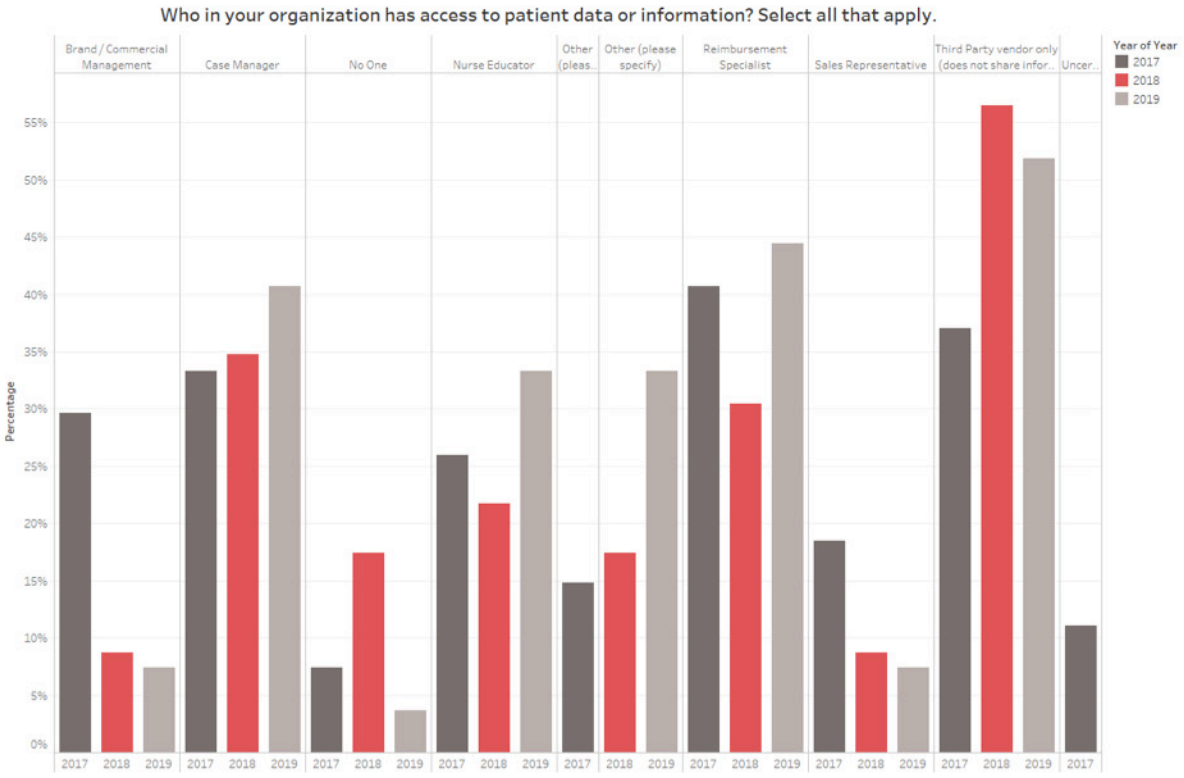
Various government investigations and regulations have caused companies to examine aspects of their data service programs for compliance and risk mitigation. These investigations are a result of data breaches and the discovery of previously unknown use of personal data. Some of the largest data breaches in the past year include MyHeritage – 92 million people,[6] Facebook – 50 million users,[7] and Salesforce – an outage that led to data access irrespective of permissions.[8]

Data breaches also plagued the healthcare industry, as well. In June 2019, Quest Diagnostics, one of the nation's largest providers of clinical laboratory testing services, left the personal records of 12 million customers exposed to an unknown party, when the American Medical Collection Agency ("AMCA") of New York, a billing collections vendor, was hacked.[9] The hackers gained illicit access to personally identifiable information ("PII") such as social security numbers and protected health information ("PHI"). In August 2019, another data breach at Massachusetts General Hospital in the neurology department exposed PHI of nearly 10,000 people via computer programs used by researchers.[10]

In 2019, there was a 9% increase in respondents that stated that their company deployed a data privacy management program.

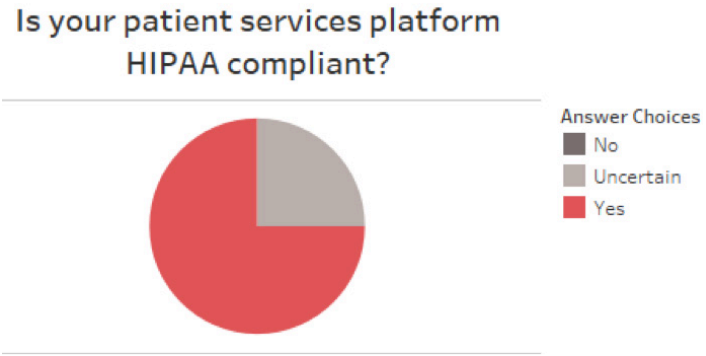
When looking at the responsibility of patient data privacy, 23% of respondents stated that they had a dedicated Privacy Officer, while 14% stated that Legal was responsible. The rest was a mix of IT, Compliance, Patient Services, and Data Protection team.






From 2017 to 2019, there was a significant decline (-20%) in the usage of data by Brand / Commercial Management and Sales Representatives (-11%), but an increase in sharing data with third-party vendors.

Although manufacturers are not directly regulated by HIPAA as they are not considered a covered entity ("CE") or a business associate ("BA"), manufacturers often must structure their data to meet HIPAA standards to ensure that their partnerships with CEs and BAs meet their data regulation. When building patient services programs and platforms, 75% of respondents noted that their platforms were HIPAA compliant.




Manufacturers have been known to repurpose existing CRM Platforms as patient service platforms in order to reduce implementation costs and simplify their IT Infrastructure. This does, however, introduce other complexities beyond poor optics, such as managing access roles to these systems and fire-walling the brand and commercial teams from the patient data. Many CRM systems are designed for massive-scale and not necessarily data privacy. For example, as mentioned earlier, the Salesforce CRM Cloud Platform had a recent high-profile failure where a broad amount of data was being shared between customers accidentally regardless of login or access controls.

## Conclusion

Prosecutorial action and regulations continue to shape how Patient Services Programs and patient data are managed by manufacturers. While donations to independent charities continue to be scrutinized heavily, there also are a large number of inquiries focused on the management of patient data and data privacy. As companies continue to create and modify their patient services programs, they must ensure that effective controls and protections are in place to ensure that these programs purely benefit the patient and provide appropriate access to treatments they otherwise would be unable to obtain, while simultaneously protecting the sensitive asset they have in managing patient data.

### References

1 Helio Health Group is a management consulting and small data engineering-centric firm that specializes in providing consulting services across compliance and patient services areas of life sciences organizations.
2 See M. Bak, et al., Patient Services Compliance Survey – Trends and Insights into this Highly Scrutinized Area, 5.2 POLICY & MEDICINE COMPLIANCE UPDATE 1 (2019).
3 See U.S. Dept. of Justice Press Release, Drug Maker Aegerion Agrees to Plead Guilty; Will Pay More Than $35 Million to Resolve Criminal Charges and Civil False Claims Allegations, (Sep. 22, 2017), https://www.justice.gov/opa/pr/drug-maker-aegerion-agrees-plead-guilty-will-pay-more-35-million-resolve-criminal-charges-and.
4 See Pharm Exec's Top 50 Companies 2019, PHARMACEUTICAL EXECUTIVE (Jul. 12, 2019), http://www.pharmexec.com/pharm-execs-top-50-companies-2019.
5 See U.S. Dept. of Justice Press Release, Pharmaceutical Company Agrees to Pay $17.5 Million to Resolve Allegations of Kickbacks to Medicare Patients and Physicians, Department of Justice (Apr. 30, 2019), https://www.justice.gov/opa/pr/pharmaceutical-company-agrees-pay-175-million-resolve-allegations-kickbacks-medicare-patients.
6 See Kanishka Singh, Security breach at MyHeritage website leaks details of over 92 million users, REUTERS (Jun. 5, 2018), https://www.reuters.com/article/us-myheritage-privacy/security-breach-at-myheritage-website-leaks-details-of-over-92-million-users-idUSKCN1J1308.
7 See Mike Issac and Sheera Frenkel, Facebook Security Breach Exposes Accounts of 50 Million Users, THE NEW YORK TIMES (Sep. 28, 2018), https://www.nytimes.com/2018/09/28/technology/facebook-hack-data-breach.html.
8 See Savia Lobo, Salesforce suffers major outage providing data access irrespective of the permission settings, PACT PUBLISHING (May 20, 2019, 8:12 a.m.), https://hub.packtpub.com/salesforce-suffers-major-outage-providing-data-access-irrespective-of-the-permission-settings/.
9 See Jeremy Hill, Debt Collector Goes Bankrupt After Health Care Data Hack, BLOOMBERG (Updated Jun. 17, 2019, 6:35 p.m. EDT), https://www.bloomberg.com/news/articles/2019-06-17/american-medical-collection-agency-parent-files-for-bankruptcy.
10 See THE BOSTON GLOBE, MGH reports data breach that exposed information of nearly 10,000 people, (Aug. 22, 2019), https://www.boston.com/news/local-news/2019/08/22/mgh-reports-data-breach-that-exposed-information-of-nearly-10000-people.


# When Having a Monopoly Is Not Enough

## *Avanir Comes Under Fire for Inappropriate Marketing Practices*

By Kaitlin Fallon Wildoner, Esq., Senior Staff Writer


**Summary:** In September 2019, the United States Department of Justice announced a settlement with Avanir resolving allegations that the company paid kickbacks to physicians and engaged in false marketing, promotion, and billing of Nuedexta. On the same date, two doctors and two pharmaceutical representatives were indicted on federal charges for their roles in a kickback conspiracy. This article outlines those resolutions and new charges. Thus, Avanir serves as an important case study for all compliance professionals.


Over the past 18 months, both the *Policy & Medicine Daily Edition* and the *Policy & Medicine Compliance Update* have covered numerous enforcement actions by the U.S. Department of Justice ("DOJ") charging various pharmaceutical and medical device manufacturers with engaging in inappropriate sales and marketing activities including kickbacks and illegal promotional practices that resulted in false reimbursement claims being submitted to the Government. Avanir Pharmaceuticals ("Avanir"), a subsidiary of Otsuka America, Inc., is just the latest to face these allegations. Avanir's story, however, is unusual in that the company allegedly engaged in these activities despite having the only treatment approved by the U.S. Food and Drug Administration ("FDA") in the space.

## Background

Readers of the *Policy & Medicine Daily Edition* may remember the early October article, which highlighted Avanir's issues involving its prescription drug, Nuedexta.[1] Nuedexta is the first and only FDA-approved treatment for PsuedoBulbar Affect ("PBA"), a neurologic condition that causes sudden, frequent, and uncontrollable episodes of crying or laughing that are exaggerated and do not match how the patient actually feels.[2] Avanir came under fire from the Justice Department for its alleged illegal promotional practices.

In late September 2019, the DOJ and Avanir announced a settlement that totaled $116 million to resolve federal and state claims over the company's alleged payment of kickbacks to physicians and its alleged false marketing, promotion, and billing of Nuedexta.[3] In addition to paying the fines and penalties, the company entered into a three-year Deferred Prosecution Agreement ("DPA") and a five-year Corporate Integrity Agreement ("CIA") with the Department of Health and Human Services, Office of Inspector General ("OIG").[4] Additionally, at the time the company settlement was announced, the Justice Department also announced that two doctors and two Avanir employees were indicted federally for engaging in a kickback conspiracy. Since these matters are ongoing not all the case documents have been unsealed.

## The Criminal Information & Deferred Prosecution Agreement

As a result of a wide-ranging investigation conducted by multiple federal and state agencies,[5] the Justice

Department filed a one-count criminal information in the United States District Court for the Northern District of Georgia. That information charged Avanir with violating the federal Anti-Kickback Statute ("AKS") because it provided financial incentives to a physician in an attempt to get him to write more Nuedexta prescriptions for beneficiaries of federal healthcare programs and recommend to other physicians that they should do the same.[6]

To resolve the criminal information, Avanir and the Justice Department agreed to a three-year DPA under which Avanir made certain admissions, including that it paid the doctor to maintain – and increase – his Nuedexta prescription volume.[7] Under the DPA, Avanir will pay a $7.8 million penalty and forfeiture in the amount of $5,074,895, and the DPA is final until it is accepted by the court.[8]

A major factor in the DOJ agreeing to the DPA involved Avanir's "substantial and ongoing" cooperation with the investigation. According to the Justice Department, this cooperation included:

> capturing and producing text messages from employee cell phones, [as well as] the extensive remedial measures taken by the company, including terminating, or permitting to resign in lieu of termination, multiple employees, at various levels of the organization, including senior executives, and its enhanced compliance program.[9]

Also, the DOJ considered the fact that:

> Avanir has agreed to resolve all civil claims relating to federal health care programs arising from its conduct; and a conviction (including a guilty plea) would likely result in the Office of the Inspector General of the Department of Health and Human Services imposing mandatory exclusion of Avanir from all federal health care programs under 42 U.S.C. § 1320a-7 for a period of at least five years, which would result in substantial consequences, including to American consumers.[10]

By using the DPA remedy, the Government in essence could have "its cake and eat it to," because as the Justice Department noted in its announcement, the agreement "ensures that integrity has been restored to Avanir's operations and preserve its financial viability while preserving the United States' ability to prosecute it should material breaches occur." This "carrot and stick" approach also preserved access to the only FDA-approved treatment available to U.S. patients suffering from PBA.

## The Civil Settlement

As the Justice Department noted, Avanir's civil settlement was a substantial factor in avoiding an actual criminal prosecution. Under the terms of the civil settlement, Avanir agreed to pay over $95 million to the United States and over $7 million to resolve state Medicaid claims.[11]

The civil settlement was based upon two lawsuits filed by three *qui tam* whistleblowers surrounding Avanir's sales and marketing practices.[12] The three whistleblowers, Kevin Manieri, Duane Arnold, and Mark Shipman were all former employees of Avanir and will share in $17.8 million of the recovery.[13]

### *Remuneration to HCPs*

According to the Government, between October 29, 2010 and December 31, 2016, Avanir provided remuneration to certain physicians and other healthcare professionals ("HCPs") to encourage them to write prescriptions for Nuedexta. This included remuneration in the form of money, honoraria, travel, and food, as wells as payments to various HCPs for speaker's programs about Nuedexta that the Government alleged "were primarily social, with no educational value."[14]

### *Preying on the Elderly*

Although the remuneration allegations could be considered almost "normal" by seasoned compliance professionals and attorneys familiar with DOJ enforcement actions, the Government also alleged a more insidious effort on the part of Avanir and its employees that targeted the elderly in nursing homes, a vulnerable patient population.

According to the Government, Avanir worked to expand the use of Nuedexta beyond its approved indication for PBA by engaging in an off-label marketing strategy. The Justice Department contends that Avanir attempted to

capitalize on efforts by the Centers for Medicare and Medicaid Services ("CMS") to reduce the use of antipsychotics to treat dementia patients in LTC facilities by instructing its sales force to initiate discussions in LTCs regarding antipsychotic use and how Nuedexta could be used to reduce the LTC facility's reliance on anti-psychotics. As part of these directions, Avanir instructed its sales representatives to provide false and misleading information that commonly-observed symptoms of dementia, including crying without tears, moaning, or making other inarticulate sounds, could actually be PBA even though the company's own studies had determined that the actual population of patients with PBA was limited.[15]

Demonstrating the extent to which Avanir's efforts paid dividends for the company while corrupting independent medical judgment, the DOJ recounted a story allegedly reported by an Avanir employee of one doctor, who was also a paid speaker for Nuedexta, had "entire units" of the LTC facility where he worked on Nuedexta, each of which contained a large number of dementia patients with behavioral issues. According to the story, while another doctor in the facility who was a geriatrician would routinely discontinue the use of Nuedexta of patients, the Avanir speaker "constantly re-initiat[ed]" the treatment.[16]

## The Corporate Integrity Agreement

In addition to the DPA and civil settlement prongs of the resolution, the third prong involves a CIA between Avanir and the OIG. Under the terms of the CIA, which lasts five-years, Avanir will appoint a Compliance Officer within 90 days, and under terms like those seen earlier this year in the Insys CIA,[17] the Compliance Officer:

1. Must report to CEO;
2. Must not report to the General Counsel or Chief Financial Officer;
3. Must not have any responsibilities that involve acting in any capacity as legal counsel or in a supervisory role over legal counsel functions for the company; and
4. Must not have any additional noncompliance job duties that could interfere with the CO's ability to do his or her compliance job.[18]

Also, like the Insys CIA, the Board of Directors must include independent, non-executive members.

In a departure from the Insys CIA, the Avanir agreement does not contain a financial recoupment clause or "claw¬back" provision to retain an independent Compliance Expert to assist it.[19] Thus, it appears that even the "boilerplate" in a CIA is negotiable.

While the Avanir CIA focuses on field force activities and medical education, for the most part, the remainder of the CIA is straight-forward. Avanir was required to notify healthcare providers about the settlement and inform them how to report any questionable practices by Avanir's representatives that they see either to Avanir's Compliance department or to the FDA. That notification was published on Avanir's website in the form of a "Notice to Healthcare Providers and Entities" by Wa'el Hashad, President and CEO of Avanir.[20]

## The Kickback Conspiracy

The day Avanir's global settlement was announced, the U.S. Attorney's Office for the Northern District of Ohio announced that two doctors (Drs. Deepak Raheja and Dr. Bhupinder Sawhny) and two Avanir employees (Gregory Hayslette and Frank Mazzucco) were indicted on 83 counts for their roles in a kickback conspiracy related to Nuedexta.[21]

The conspiracy involved using the Avanir speakers' bureau to allow sales representatives not only to have physicians to speak about and promote Nuedexta but to reward them for writing Nuedexta prescriptions.[22] This is not a new potentially violative activity, but one that frequently made headlines in the late 1990s and early 2000s. Now it appears to have made somewhat of a resurgence despite multiple enforcement actions and voluntary industry guidelines.

### *The Role of the Doctors*

In this situation, the indicted doctors, Drs. Raheja and Sawhny both allegedly wrote Neudexta prescriptions for patients that did not have PBA and also submitted materially false and fictitious prior authorizations to Medicaid MCOs that showed PBA diagnoses for patients that did not have PBA.[23]

Dr. Raheja also joined the speakers' bureau in February 2011 and gave more than 200 presentations at various restaurants and doctors' offices between October 2011 and April 2016. He allegedly received $1,500 for each of those presentations for total compensation of $331,500, and also wrote the highest number of Nuedexta prescriptions in the country during that same time period (an estimated 10,088).[24]

Dr. Sawhny, on the other hand, in addition to writing off-label prescriptions and then submitting false prior authorizations to federal programs, also allegedly allowed unauthorized access to protected health information ("PHI").[25]

### *The Role of Avanir's Employees*

The two indicted Avanir employees, Gregory Hayslette , a sales representative, and Frank Mazzucco , a regional business manager and Hayslette's supervisor, were accused of arranging the speakers' programs and paying the honoraria and other expenses for Raheja and other clinical speakers.[26] Hayslette also allegedly submitted false and fictitious sign-in sheets for those speaking events to justify and maximize the payments that were made to the participating doctors.[27]

Part of his alleged objective in arranging these programs was that the programs provided an opportunity to promote off-label uses and dosages of Nuedexta through the speakers' programs and literature provided at the programs. He also accessed PHI without authorization and helped to submit false authorizations to federal MCOs, which is something we have seen before with Warner Chilcott and Insys in 2016.[28]

## Conclusion

We believe that the Avanir indictments and settlement has much to teach compliance professionals. First, just because a company has a monopoly product, the drive to sell even more is a powerful corrupting influence, but DOJ also will factor the monopoly situation into any settlement to avoid, as much as possible, harming innocent patients. Also, where vulnerable patient populations are at risk, the Justice Department likely will take a keen interest in a company's sales and marketing campaigns and the individuals who run them.

We also should be mindful that, in many respects, the activities of which Avanir stands accused are very similar to those in the recent opioid cases (e.g., Insys, Indivior, J&J), which illustrates that the lessons in the opioid cases are not unique. They also involve promotional practices that are not new, but rather are playing out with a new generation of defendants. The bottom line, therefore, is compliance professionals must learn from prior cases, and never let their guard down.

### References


1 *See Thomas Sullivan, Avanir Settles One Kickback Suit, Agrees to Cooperate in Another, POLICY & MEDICINE, https://www.policymed.com/2019/10/avanir-settles-one-kickback-suit-agrees-to-cooperate-in-another.html (last visited Oct. 17, 2019).*

2 *See NUEDEXTA, What is PBA?, https://www.nuedexta.com/could-i-have-pba (last visited Oct. 17, 2019).*

3 *See Press Release U.S. Dep't of Justice, Pharmaceutical Company Targeting Elderly Victims Admits to Paying Kickbacks, Resolves Related False Claims Act Violations (Sep. 26, 2019), (hereinafter "DOJ Press Release Targeting Elderly Victims"). https://www.justice.gov/usao-ndga/pr/pharmaceutical-company-targeting-elderly-victims-admits-paying-kickbacks-resolves; see also AVANIR, Notice to Healthcare Providers and Entities,, https://www.avanir.com/responsibility/notice-healthcare-providers-and-entities (last visited Oct. 17, 2019).*

4 *See id.*

5 *The investigation was conducted by the FBI, HHS-OIG, the Department of Defense Criminal Investigative Services, the Office of Personnel Management Office of Inspector General, the Department of Veteran's Affair Office of Inspector General, and the Ohio Medicaid Fraud Control Unit with assistance from the Consumer Protection Branch of the Department of Justice, HHS Office of Counsel to the Inspector General and the National Association of Medicaid Fraud Control Units. See DOJ Press Release Targeting Elderly Victims, supra (Sep. 26 2019).*

6 *See DOJ Press Release Targeting Elderly Victims, supra (Sep. 26 2019).*

7 *See DOJ Press Release Targeting Elderly Victims, supra (Sep. 26 2019).*

8 *See DOJ Press Release Targeting Elderly Victims, supra (Sep. 26 2019).*

9 *See DOJ Press Release Targeting Elderly Victims, supra (Sep. 26 2019).*

10 *See DOJ Press Release Targeting Elderly Victims, supra (Sep. 26 2019).*

11 *See Department of Justice, Pharmaceutical Company Targeting Elderly Victims Admits to Paying Kickbacks, Resolves Related False Claims Act Violations (Sept. 26, 2019), https://www.justice.gov/usao-ndga/pr/pharmaceutical-company-targeting-elderly-victims-admits-paying-kickbacks-resolves (last visited Oct. 17, 2019).*

12 *See DOJ Press Release Targeting Elderly Victims, supra (Sep. 26 2019); see also United States ex rel. Kevin Manieri v. Avanir Pharmaceuticals, Inc. and Deepak Raheja, Action No. 5:15-cv-611 (N.D. Ohio); United States ex rel. Duane Arnold and Mark Shipman v. Avanir Pharmaceuticals, Inc., Action No. 1:15-cv-01250 (N.D. Ga.).*

13 *See DOJ Press Release Targeting Elderly Victims, supra (Sep. 26 2019).*

14 *See DOJ Press Release Targeting Elderly Victims, supra (Sep. 26 2019).*

15 *See DOJ Press Release Targeting Elderly Victims, supra (Sep. 26 2019).*

16 *See DOJ Press Release Targeting Elderly Victims, supra (Sep. 26 2019).*

17 *See C. Greene, Insys as a Compliance Cautionary Tale, 5.7 POLICY & MEDICINE COMPLIANCE UPDATE 9, 12 (2019).*

18 *See Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Avanir Pharmaceuticals, Inc. at 4 (Sep. 25, 2019) (hereinafter Avanir CIA); https://oig.hhs.gov/fraud/cia/agreements/Avanir_Pharmaceuticals_Inc_09252019.pdf.*

19 *See Avanir CIA at 5.*

20 *See AVANIR, Notice to Healthcare Providers and Entities,, https://www.avanir.com/responsibility/notice-healthcare-providers-and-entities (last visited Oct. 17, 2019).*

21 See Press Release U.S. Dep't of Justice, Physicians and pharmacy sales reps indicted for kickback conspiracy in which doctors allegedly received money in exchange for writing unnecessary prescriptions of Nuedexta (Sep. 26, 2019) (hereinafter "DOJ Kickback Conspiracy Press Release")., https://www.justice.gov/usao-ndoh/pr/physicians-and-pharmacy-sales-reps-indicted-kickback-conspiracy-which-doctors-allegedly (last visited Oct. 17, 2019)
22 See DOJ Kickback Conspiracy Press Release (Sep. 26, 2019), supra.
23 See DOJ Kickback Conspiracy Press Release (Sep. 26, 2019), supra.
24 See DOJ Kickback Conspiracy Press Release (Sep. 26, 2019), supra.
25 See DOJ Kickback Conspiracy Press Release (Sep. 26, 2019), supra.
26 See DOJ Kickback Conspiracy Press Release (Sep. 26, 2019), supra.
27 See DOJ Kickback Conspiracy Press Release (Sep. 26, 2019), supra.
28 See DOJ Kickback Conspiracy Press Release (Sep. 26, 2019), supra.

# Drug Importation Experiences a Rebirth

*By Gwendolyn Ball, Staff Writer*

**Summary:** Although drug importation has been a topic of debate for more than 15 years, the continuing struggle to contain rising drug prices has rekindled interest in pursuing importation as a possible remedy. This article explores the recent state efforts in Vermont, Colorado, Maine and Florida and how those efforts once more are shaping Federal policy.

Although the issue of drug importation dates to 2003, only recently as the ongoing debate about the rising costs of pharmaceuticals continues occupying center stage have various state governments begun seriously considering drug importation as a viable alternative to contain health care costs for their citizens. This article explores these state proposals and their possible impact on the federal authority of the U.S. Food and Drug Administration ("FDA") to regulate what drug products are available to the American public.

## The Origins of Drug Importation

Patient advocacy groups and other experts have discussed the notion of drug importation (allowing U.S. citizens to purchase pharmaceutical products directly from other countries) since 2003. Those discussions centered around two distinct, but intertwined legs. The first leg focuses on patient access to new therapies and centers around the perception that the FDA is too slow when it comes to approving new therapies for the U.S. market, especially cancer treatments.[1]

The second leg focuses on actual market prices and the position that U.S. prices are significantly higher than those prices for the same drugs in other countries. For example, the National Academy for State Health Policy ("NASHP") has cited a 2013 Canadian Price Board study that determined prices for brand name prescription drugs are about twice as high in the U.S. as in the Canadian market.[2] NASHP also compared wholesale acquisition cost ("WAC") prices in CMS' National Average Drug Acquisition Cost ("NADAC") database for specific drugs. By doing so, the NASHP determined the price of Lyrica, a common treatment for nerve damage is $6.04 in the United States and 63 cents in Canada;[4] one tablet of Xarelto, used to prevent and treat blood clots, lists at $12.44 in the U.S. and $2.11 in Canada.[4]

### *Congressional Authorization for Limited Importation*

In 2003, Congress, under Subtitle C of Title XI (entitled: "Access to Affordable Pharmaceuticals") of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,[5] authorized the Secretary of the Department Health and Human Services ("HHS") to permit the importation of drugs from Canada, but only if HHS could confirm the imports do not pose any additional risks to public health and safety and generate cost-savings for consumers.[6]

The statute directed the Secretary to promulgate regulations permitting pharmacists and wholesalers to import prescription drugs,[7] including specified provisions respecting: (1) importer and foreign seller recordkeeping and information requirements; (2) qualified laboratory drug testing; (3) registration with the Secretary of Canadian sellers; and (4) approved labeling.[8] Only "small molecule" drugs, and not biologics or biosimilars, can be imported.[9] Thus, under current legislation, any state program to import drugs can only do so from Canada and only with the approval of HHS.

As the Pharmaceutical Research and Manufacturers of America ("PhRMA") noted:

> To date, not a single [HHS] Secretary, from democratic and republican administrations, has been able to make this certification,[and while] [o]ver the years, a handful of states have piloted drug importation programs as a way to provide access to drugs

from outside the United States, but there has yet to be a successful program. For example, six states tried a contracted importation program with a Canadian operator of online pharmacies that cost $1 million to implement. Four years later, the program was deemed a failure and terminated.[10]

## The Debate Over Drug Safety

Due to these alleged difficulties in maintaining the safety of the drug supply, drug importation has been opposed at the highest levels of the health regulatory establishment. In 2017, the last four former FDA commissioners urged Congress that routine importation was "likely to harm patients and consumers and compromise the carefully constructed system that guards the safety of our nation's medical products."[11] PhRMA, for example, highlights the following statistics to support those concerns including:

- 1 in 10 medicines are counterfeit,
- 96% of internet drug outlets were found not to be compliant with U.S. pharmacy laws in 2014, and
- 1,050+ websites have been the subject of FDA and Interpol drug and device seizures from 2015.[12]

In an address made on the occasion of the release of the White House Blueprint on Drug Pricing, HHS Secretary Alex Azar expressed his agreement with the former FDA commissioners that "there is no effective way to ensure drugs coming from Canada really are coming from Canada, rather than being routed from, say, a counterfeit factory in China."[13]

Critics of efforts to import prescription drugs also contend the importation programs will undermine the new, meticulously-built system to electronically "track and trace" the source of all prescription drugs in the United States as mandated by the Drug Quality and Security Act (DQSA) of 2013.[14] Although Health Canada also has a drug tracing system, the critics contend that it is neither identical to nor compatible with the U.S. system.[15] Therefore, systematic importation of prescription drugs will undermine the system,[16] or even revert to a "patchwork" of inconsistent state regulation.[17]

Supporters counter that state importation programs will be manufactured in the same FDA-inspected facilities:

> "The imported drugs, which will be made in the FDA-approved facilities, will be repackaged and relabeled by FDA-registered re-packagers and re-labelers to ensure drug labeling matches US requirements. The same carriers, freight forwarders, customs house brokers, and trucking companies that currently provide the United States with most of its pharmaceuticals will move these imported drugs..."[18]thereby "extending DSCSA requirements deeper into the international supply chain, the same regulatory mechanism currently used for ensuring proper labeling, safety, and effectiveness of drugs will be used to ensure the safety and quality of drugs."[19]

Supporters argue that as long as state-level importation is a limited, closed system, states can be easily integrated into the "track and trace" system by giving them their own identifier code.[20] In addition, importation advocates argue that state programs require wholesalers to test their imported supply, thereby enhancing patient protection.[21]

### *Growing Frustration with Federal Efforts*

As the *Policy & Medicine Compliance Update* has detailed, Congress has entertained several bills designed to curb drug price increases, while the White House developed a "Blueprint" to do the same.[22] However, frustration has grown as there is a sense that the Federal Government is moving too slowly on the issue. Legislation addressing drug pricing is seen as too often mired in party politics,[23] and in recent months the White House has walked back several of its more aggressive proposals.[24]

However, while the White House is still exploring drug importation under its drug pricing "blueprint;"[25] and drug importation has growing support in Congress,[26] impatient state legislatures have shown a willingness to move more rapidly and radically to address the prescription drug price problem.

### *State Setbacks Trigger Renewed Interest in Importation Legislation*

To date, many of the local initiatives to directly tackle the drug pricing issue have encountered obstacles.[26] For

example, Maryland passed legislation banning price gouging, only to see it negated on Constitutional grounds.[28] A California proposal demanding transparency in drug pricing is currently under attack by PhRMA in the courts.[29] These setbacks have led states to pursue other options, including importation.[30]

One such possibility seems to be state legislation regarding the importation of prescription drugs. However, once again, this policy initiative brings state efforts to combat high drug prices fall under the purview of federal authority, launching another round of conflict around "pharmaceutical federalism." Whether these initiatives can get off the ground will depend on whether they can harmonize the state programs with federal laws and regulations. And if they do advance, they may be more of a stopgap, relieving some of the pressure on state and patient budgets, rather than a real solution.

## The State Drug Importation Push

Currently, eighteen state legislatures have explored drug importation through a series of recent bills.[31] As shown in Table 1, most of these proposals have been allowed to die at the end of legislative sessions or are still under review in state legislature committees.

However, in four states—Vermont, Colorado, Florida, and Maine—drug importation proposals have been approved by the legislature and signed into law by the governor. These laws are detailed below.

### VERMONT

On May 16, 2018, Vermont became the first state in the nation to enact a law allowing the importation of wholesale prescription drugs with the signing of S 175.[32] The Act Relating to the Wholesale Importation of Prescription Drugs Into Vermont authorizes the Vermont Agency of Human Services to designate a state agency or outside contractor to serve as a wholesaler for purposes of importation.

Under the program, only FDA approved drugs that "provide significant prescription drug cost savings to Vermont consumer"[33] and where the benefits are shared with consumers are eligible for importation.[35] The program also mandates that importation must be in compliance with all federal regulations, and the State must develop procedures to prevent diversion to other states.[36]

The statute also requires that a request for certification must be presented to the Secretary of HHS by July 2019,[37] but since that deadline has already passed, Vermont officials have asked to meet with HHS to discuss how to move forward.[38]

### COLORADO

Exactly one year after Vermont enacted its importation statute, the Governor of Colorado signed SB19-005 into law, creating the "Canadian Prescription Drug Importation Program."[39] This legislation authorizes the Colorado Department of Health Care Policy and Financing to contract with one or more vendors to import drugs from Canada.[40]

**TABLE 1:** *State Drug Importation Bills*

| Bill | State | Status |
|---|---|---|
| SB 5 | CO | Enacted, 2019 |
| SB 85, 142 | CT | Failed upon adjournment |
| HB 19/SB 1452 | FL | Enacted, 2019 |
| HB 1441 | IL | Referred to House Rules Committee |
| LD 1252 | ME | Enacted 2019 |
| HB 1228 | MA | Referred to House Public Health Committee |
| SF 495, 1184 | MN | Referred to Senate State Government Finance and Policy and Elections Committee |
| HB 667 | MO | Passed House Professional Registration and Licensing Committee; referred to House Rules Committee |
| AB 7588/SB 5682 | NY | Referred to Assembly Higher Education/Referred to Senate Health Committee |
| SB 940 | OK | Referred to Senate Health and Human Services Committee |
| HB 2680, SB 409 | OR | Failed on adjournment |
| HB 267 | UT | Failed on adjournment |
| H 542 | VT | Enacted 2018 |
| HCR 24, HB 2428, SB 250 | WV | Failed on adjournment |
| HB 287 | WY | Not considered for introduction |

Source: National Academy for State Health Policy, Legislative Tracker

Eligible vendors include state-licensed pharmacists supplying Medicaid participants or the general public, certified drug wholesalers, or commercial health plans. Each eligible vendor wishing to import drugs from Canada must establish a wholesale prescription drug importation list, in consultation with the Department, that identifies the prescription drugs that have the highest potential for cost savings to the state.[41] Biologics and biosimilars are not covered.[42]

The program also specifically mandates that eligible vendors are responsible for compliance, and their participation in the program will be suspended if they are found to be in violation of any federal regulation or law.[43] Finally, the vendors in the program are required to import generic drugs when available, and limits are set on their profit margins.[44]

Like Vermont's program, Colorado requires that any imported drugs must be FDA approved and their importation must comply with all federal laws and regulations, including supply chain tracing and patent law.[45] The program also requires that Colorado will seek approval from HHS by September 2020.[46]

### FLORIDA

On June 11, 2019, Florida enacted legislation[47] that has a broader scope than Vermont and Colorado. The Florida statute creates two separate but interrelated programs for the importation of foreign drugs. The first program, which is similar to Vermont and Colorado, is the Canadian Prescription Drug Importation Program ("CPDI Program"), while the other is the International Prescription Drug Importation Program ("IPDI Program").[48]

The CPDI program will be regulated by Florida's Agency for Health Care Administration ("AHCA"). Like Colorado, the CPDI program allows pharmacists and other registered suppliers serving Medicaid patients, public clinics, the Department of Corrections, and county health departments to import drugs from Canada.[49] The imported pharmaceuticals must be FDA approved, and biologics and biosimilars are not covered. Florida is required to seek approval for the program from HHS by July of 2020.[50]

The IPDI Program, on the other hand, is regulated by the Florida Department of Business and Professional Regulation, will focus on more commercial use and consumer access.[51] It establishes a procedure for granting importation permits to "international prescription drug wholesale" distributors.[52] FDA approved drugs other than biologics may be imported;[53] all federal laws and regulations, including drug testing procedures, must be followed.[54]

Despite the lack of any federal law laying the foundation for imports from any nation other than Canada, these distributors can import from any "foreign nations with which the United States has current mutual recognition agreements, cooperation agreements, memoranda of understanding, or other federal mechanisms recognizing their adherence to current good manufacturing practices for pharmaceutical products."[55] Florida, recognizing the lack of federal authority to import drugs from these countries, calls for a pilot project, the design of which will be negotiated with HHS.[56]

### MAINE

On June 24, 2019, the governor of Maine signed "An Act to Increase Access to Low-cost Prescription Drugs" to begin importation of drugs from Canada.[57] This program mirrors Vermont's program.

The Maine Department of Health and Human Services will designate a state agency to become a licensed wholesaler to import drugs from Canada that are FDA approved and will lead to cost savings for Maine residents.[55] The agency is charged with designing procedures to prevent drugs from being diverted to other states. The State also must obtain approval for the program from HHS by May 2020.[56]

## *State Efforts Appear to Trigger Federal Action*

Despite the apparent opposition from Secretary Azar,[60] the White House has instructed HHS to lend support to efforts to import prescription drugs—at least from Canada. Drug importation is still being considered under the White House "Blueprint" for Drug pricing[61] and it has become administration policy to support state efforts to import drugs from Canada.

In July 2018, the FDA created a working group "to examine how to safely import prescription drugs from other countries in the event of a dramatic price increase

for a drug produced by one manufacturer and not protected by patents or exclusivities."[62] Moreover, it appears that the President directed Secretary Azar to cooperate with Florida in the development of its drug importation plan, reportedly instructing the state "to be prompt in production of the plan, and for the secretary to be prompt in the review of the plan.[63]

At the end of July 2019, HHS and FDA released the "Safe Importation Action Plan."[64] The Action Plan lays out two pathways for implementing drug importation.[65] The first pathway directly addresses state initiatives to import prescription drugs.[66] Under Pathway I, FDA will promulgate a Notice of Proposed Rulemaking ("NPRM"), relying on its authority under the Federal Food, Drug, and Cosmetic Act ("FFDCA") to authorize demonstration projects importing drugs from Canada[67] allowing States, wholesalers, or pharmacists to submit plans for demonstration projects for HHS to review.[68] The drugs eligible for importation must be drugs authorized for sale in Canada that are versions of FDA-approved prescription drugs.[69] The projects are required to detail how they will comply with all federal laws and regulations, including[70]

- track and trace requirements to allow drug tracing from manufacture to pharmacy;
- all labeling requirements of the FD&C Act;
- requirements to ensure foreign sellers engaged in the distribution of the imported drugs are registered;
- importation entry requirements (e.g., providing certain electronic information demonstrating that each shipment should be allowed into the U.S.);
- and post-importation requirements such as adverse event reporting, procedures to
- facilitate recalls, and CGMP for certain manufacturing activities such as relabeling.

Thus, rather than objecting to state importation programs, HHS and the FDA apparently are now committed to facilitating them.

### *Assessing the Impact of Importation*

It is too early to tell what the impact of these drug importation programs will have on the pharmaceutical prices paid by U.S. patients. However, as currently structured, the programs and HHS policy have some significant limitations.

First, while it is possible to construct state drug importation programs that are compliant with federal laws and regulations and which will meet HHS expectation, it is unclear whether wholesalers will be able to import drugs under their existing contracts. Most drug wholesaler contracts contain clauses specifically baring the wholesaler from importing drugs from outside the U.S., precisely to avoid the type of "price arbitrage" that state importation programs hope to exploit.[71] It is unclear if these firms would be willing to tear up and renegotiate their contracts.

Second, the programs under development can only cover "small molecule" drugs; expensive biologics cannot be imported under federal law. Thus, importation cannot be used as a systematic cure for high prices of biologic and biosimilar products such as insulin.

Finally, current statutes[72] only authorize importation from Canada, and it appears that the Canadian drug market is not large enough to supply any meaningful portion of U.S. drug needs. Canada represents about 2% of the global market, while the U.S. accounts for 44%.[73] One 2018 study found that if 20% of U.S. prescriptions were filled in Canada, the Canadian drug supply would be depleted in 183 days.[74]

Canadian stakeholder organizations are already arguing that their government protect the Canadian drug supply through imposition of tariffs or application of government power to put prescription drugs on the "export control list" that would bar U.S. importation.[75] And some compliance professionals warn that market shortages create precisely the environment in which drug counterfeiters flourish.[76] Thus, in the absence of authority to import from countries other than Canada, drug importation can never be more than a stopgap measure.

However, proponents of importation still believe it can help lessen the pressure on U.S. drug prices. If nothing else, the possibility of accessing cheaper foreign markets may improve the bargaining position of both public and private purchasers in negotiations with drug manufacturers.[77]

Regardless of the actual outcomes, there remains strong public, and hence political, support for importation with nearly eighty percent of recent survey respondents supporting the idea.[78] Thus, it appears the push for importation will continue, and compliance professionals need to be prepared to address the compliance challenges associated with these programs.

## References


1 See, e.g., CEI Staff, FDA Too Slow to Approve New Medical Drugs and Devices, Competitive Enterprise Institute (Apr. 30, 2002) ("61% of cancer specialists polled believe the FDA is too slow to approve new medical drugs."), https://cei.org/content/fda-too-slow-approve-new-medical-drugs-and-devices.
2 State Wholesale Importation Program Explained , National Academy for State Health Policy (May 2017) https://nashp.org/wp-content/uploads/2017/05/Wholesale-Importation1.pdf.
3 Id.
4 Id.
5 Public Law No: 108-173, 108th Congress (2003-2004), striking and replacing Section 804 of the Food, Drug and Cosmetics Act (21 U.S.C. 381 et seq.) https://www.congress.gov/bill/108th-congress/house-bill/1.
6 Id.
7 The statute also outlines limited conditions under which an individual may directly import drugs from Canada. Id.
8 Id.
9 Id.
10 See PHRMA, The History of Drug Importation, https://www.phrma.org/advocacy/safety/drug-importation (last visited Aug. 24, 2019), see also Katelyn R. Brubaker and Joseph L. Fink III, States Act to Address Issues of Drug Prices, PHARMACY TIMES (April 2019) https://www.pharmacytimes.com/publications/issue/2019/april2019/states-act-to-address-issues-of-drug-prices.; Policy Proposal: Importation of Prescription Drugs, the Pew Charitable Trusts (Apr. 2017) https://www.pewtrusts.org/-/media/assets/2017/04/policy-proposal-importation-of-prescription-drugs.pdf
11 Ed Silverman, Four former FDA commissioners urge Congress to reject importing drugs, STAT (March 16, 2017) https://www.statnews.com/pharmalot/2017/03/16/fda-drug-prices-canada-importation/.
12 See PHRMA, Medicine Safety – Drug Importation, https://www.phrma.org/advocacy/safety/drug-importation (last visited Aug. 24, 2019).
13 Alex Azar, Secretary of Health and Human Services, Remarks on Drug Pricing Blueprint, May 14 2018 Az://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html.
14 Public Law No: 113-54 (11/27/2013) https://www.congress.gov/bill/113th-congress/house-bill/3204/cosponsors.
15 Id.
16 Id.
17 See, e.g., Adam Fein and Dirk Rodgers, State drug importation laws undermine the process that keeps our supply chain safe, STAT (July 11, 2019) https://www.statnews.com/2019/07/11/state-drug-importation-laws-undermine-supply-chain-safety/. See also Joe Lawlor, Critics take aim at plan to allow prescription drug imports from Canada, PORTLAND PRESS HERALD (April 24, 2019) (quoting a past president of the Maine Pharmacists Association as stating that "to start a wholesale purchasing program from Canada, there would need to be "robust" state oversight in Maine, and he's not sure that can be done and still provide a cost savings.")
18 Fein and Rodgers, supra n. 17.
19 National Academy for State Health Policy, Wholesale Importation Legislation Q&As, https://nashp.org/wp-content/uploads/2019/04/Final-updated-Importation-QA-4_1_2019.pdf.
20 See Jane Horvath, State drug importation programs will work with the FDA, not outside of it, STAT (July 16, 2019) https://www.statnews.com/2019/07/16/state-drug-importation-programs-fda/.
21 NASHP, Q&A, supra n. 19.
22 See G. Ball, Congress Enters the Drug Pricing Fray, 5.5. POLICY & MEDICINE COMPLIANCE UPDATE 12 (2019); G. Ball, The Executive Bran Perspective on Drug Pricing, 5.6 POLICY & MEDICINE COMPLIANCE UPDATE 8 (2019); see also S. Whitelaw, N. Fiorentino, J. O'Leary, Drug Pricing—The Next Compliance Waterloo, MITCHELL HAMLINE LAW REVIEW: Vol. 44: Iss. 4, Article 2 (2018), https://open.mitchellhamline.edu/mhlr/vol44/iss4/2.
23 Adam Cancryn, Liberals fight their own party over drug prices, POLITICO (Jun. 6, 2019) https://www.politico.com/story/2019/06/06/democrats-prescription-drug-prices-1497676.
24 Sarah Owermohle, et al., Trump leaning on Sanders-style ideas to save his drug plan, POLITICO (Jul. 11, 2019) https://www.politi co.com/story/2019/07/11/white-house-drug-rebate-rule-1405884.
25 Nicholas Florko, Everything (or almost everything) you need to know about importing drugs from Canada STAT (JULY 31, 2019) https://www.statnews.com/2019/07/31/everything-about-importing-drugs-from-canada/.
26 Id.
27 As one analyst described it, the "limitations on other state action to manage drug costs" include "patent case law, dormant commerce clause case law, Medicaid rules, the Constitution's Supremacy clause, trade secrets law, and potentially, FDA rules on dissemination of drug information by manufacturers." See Jane Horvath, Prescription Drug Importation: New Federal Initiatives And The Case for State Action, HEALTH AFFAIRS (November 14, 2018) https://www.healthaffairs.org/do/10.1377/hblog20181113.552343/full/.
28 Lev Facher, Supreme Court deals a fatal blow to Maryland drug 'price gouging' law STAT (February 19, 2019) https://www.statnews.com/2019/02/19/supreme-court-declines-case-on-maryland-drug-price-gouging-law/.
29 David C. Gibbons, et al., PhRMA Revives its Lawsuit against Enforcement of California Drug Pricing Transparency Bill SB 17, FDA Blog (October 14, 2018) http://www.fdalawblog.net/2018/10/phrma-revives-its-lawsuit-against-enforcement-of-california-drug-pricing-transparency-bill-sb-17/.
30 Lev Facher, States, eager to lower drug prices, regroup after courts strike down Maryland 'price-gouging' law, STAT (March 1, 2019) https://www.statnews.com/2019/03/01/state-drug-pricing-after-scotus-on-maryland/
31 See State Legislative Action to Lower Pharmaceutical Costs, National Academy of State Health Policy https://nashp.org/rx-legislative-tracker-2019/.
32 https://legislature.vermont.gov/Documents/2018/Docs/ACTS/ACT133/ACT133%20Act%20Summary.pdf.
33 Id. Sec. 1.
34 Id.
35 Id.
36 Id.
37 Id.
38 Wilson Ring, Vermont seeks meeting with feds to talk drug importation, AP NEWS (August 15, 2019) https://www.apnews.com/e35a8891fc5344aab2e10b4972a590c6.
39 https://leg.colorado.gov/bills/sb19-005.
40 Id.
41 Id.
42 Id.
43 Id.
44 Id.
45 Id.
46 Id.
47 CS/HB 19 https://www.flsenate.gov/Session/Bill/2019/19`
48 Id.
49 CS/HB 19 Section 1 https://www.flsenate.gov/Session/Bill/2019/19.
50 Id.
51 CS/HB 19 Section 2 https://www.flsenate.gov/Session/Bill/2019/19.
52 Id.
53 Id.
54 Id.
55 Id.
56 Id.
57 SP0392 LD 1272 https://legislature.maine.gov/legis/bills/bills_129th/billtexts/SP039201.asp.
58 Id.
59 Id.
60 See, e.g., Dan Diamond, et al., 'Two teams with two visions': Health friction worsens between Trump aides and HHS, POLITICO (June 18, 2019) https://www.politico.com/states/florida/story/2019/06/18/two-teams-with-two-visions-health-friction-worsens-between-trump-aides-and-hhs-1066998; In prepared statements, Secretary Azar has merely stated that "Over that time, the landscape and the opportunities for safe linkage between drug supply chains has changed." See Secretary Azar, Remarks on the Safe Importation of Certain Prescription Drugs (July 31, 2019). https://www.hhs.gov/about/leadership/secretary/speeches/2019-speeches/remarks-safe-importation-certain-prescription-drugs.html.
61 See Florko, supra n. 25.
62 Press Release, U.S. Department of Health and Human Serivces, HHS Secretary Azar Directs FDA to Establish Working Group on Drug Importation to Address

Price Spikes (July 19, 2018) https://www.hhs.gov/about/news/2018/07/19/hhs-secretary-azar-directs-fda-establish-working-group-drug-importation-address-price-spikes.html.

63 Alexandra Glorioso, Trump directs Azar to work on Florida drug import plan, POLITICO (05/06/2019) https://www.politico.com/states/florida/story/2019/05/06/trump-directs-azar-to-work-on-florida-drug-import-plan-1008710?utm_source=POLITICO.EU&utm_campaign=89703b26c9-EMAIL_CAMPAIGN_2019_07_31_03_21&utm_medium=email&utm_term=0_10959edeb5-89703b26c9-189723457.

64 Press Release, U.S. Department of Health and Human Services, HHS Announces New Action Plan to Lay Foundation for Safe Importation of Certain Prescription Drugs (July 31, 2019) https://www.hhs.gov/about/news/2019/07/31/hhs-new-action-plan-foundation-safe-importation-certain-prescription-drugs.html.

65 U.S. Food and Drug Administration, Safe Importation Action Plan (July 31, 2019) https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf.

66 Id. Pathway II, which is somewhat less detailed, allows manufacturers of FDA-approved drug products would be able to import versions of these FDA-approved drugs that they sell in foreign countries into the U.S. Id.

67 Id.

68 Id.

69 Id.

70 Id.

71 Nicholas Florko and Lev Facher, Canadians are hopping mad about Trump's drug importation plan. Some of them are trying to stop it, STAT (August 12, 2019) https://www.statnews.com/2019/08/12/canadians-are-hopping-mad-about-trumps-drug-importation-plan-some-of-them-are-trying-to-stop-it/.

72 See supra n. 5.

73 Ed Silverman, As Bernie Sanders neared, Canadian officials were urged not to allow U.S. to import medicines, STAT (July 29, 2019) https://www.statnews.com/pharmalot/2019/07/29/bernie-sanders-canada-importation-insulin/.

74 Marv Shepherd, U.S. Drug Importation: Impact on Canada's Prescription Drug Supply, 4 Health Econ Outcome Res Open Access 146 (2018) https://www.omicsonline.org/open-access/us-drug-importation-impact-on-canada8217s-prescription-drug-supply-2471-268X-1000146-99116.html.

75 Florko and Facher, supra n. 71.

76 Fein and Rodgers supra n. 17.

77 Id.

78 Kaiser Foundation, KFF Health Tracking Poll – February 2019: Prescription Drugs (February 2019) https://www.kff.org/report-section/kff-health-tracking-poll-february-2019-prescription-drugs-findings/.

# Shifting the Landscape

## *HHS Proposes Modifications to the Anti-Kickback Statute & the Stark Law*

*By Gwendolyn Ball, Staff Writer*

**Summary:** In October 2019, HHS published two new proposed rules, which will significantly change the current landscape governed by the Anti-Kickback Statute and the Stark Law. This article discusses the details and potential impact of these proposals. **The comment period on the proposed rules closes on December 31st.**

The Government has made the drive towards value-based payment systems ("VBPs") an important focus of its efforts to control the expansion of healthcare costs and improve patient outcomes. In fact, in September, the Administrator for the Centers for Medicare and Medicaid ("CMS"), Seema Verma, issued a stern pronouncement before a meeting of the American Hospital Association.[1] Verma told the attendees that it was time for hospitals to "get on board" with value-based payment systems or face increased regulatory burdens and lower Medicare fees.[2]

Despite the Government's efforts, providers have been slow to adopt the new model out of fear that the breadth of the current legal framework surrounding kickbacks and self-referrals prohibits such arrangements.[3] In early October, the Department of Health and Human Services ("HHS") published two new proposed rules to "modernize and clarify the regulations that interpret the Physician Self-Referral Law (the 'Stark Law') and the Federal Anti-Kickback Statute ... [to] provide greater certainty for healthcare providers participating in value-based arrangements and providing coordinated care for patients."[4]

## Sweeping Breadth Limits Innovation

Healthcare payers, providers, and manufacturers have struggled with both the Anti-Kickback Statute ("AKS") and the Stark Law for decades. The sweeping breadth of both laws has resulted in numerous enforcement actions by the Justice Department. In the case of the AKS, by 2017, the HHS has established 23 safe harbors and issued 369 advisory opinions to clarify its scope.[5] Under the Stark Law, while the statute always allowed "bona fide employment relationships," in 1993 the law was expanded to prohibit self-referrals by physicians to designated health services ("DHSs") in which the physician has a "compensation arrangement."[6]

Based on current interpretations of these laws, compensation arrangements that distribute cost savings generated by referrals could be prohibited under the AKS and the Stark Law.[7] For example, as the American Hospital Association pointed out, a hospital's financial support to establish a shared Electronic Health Records ("EHR") system creates a financial relationship under Stark that can be considered remuneration under the AKS.[8]

Under the current legal landscape, any new value-based arrangements must fit within the protections afforded both by the statutory and regulatory AKS "safe harbors" as well as the Stark Law exceptions. The attempts by the OIG to draft AKS safe harbors to cover incentive-based structures have run up against the requirement under the

Stark Law that financial relationships must "pose no risk of program or patient abuse."[9] The OIG has stated that it was impossible to craft a flexible exception to address the breadth of alternative payment models ("APMs') under this standard, and only a more narrow and detailed exception would guarantee "no risk."[10]

The OIG's task has been further complicated by the fact that many exceptions to the Stark Law do not allow for the volume or value of a physician's referrals to be used in determining physician compensation. Since the VBPs inherently link compensation to the "value" of referrals, they inherently run afoul of the Stark Law.[11] Other safe harbors and exceptions require the amount of any payment be specified in advance—an impossibility in a value-based incentive arrangement.[12]

## HHS Moves to Remove the Regulatory Barriers

Before providers move forward with implementing value-based payment models, they want certainty that their actions, viewed in hindsight, will not subject them to AKS or Stark Law liability. This reasonable position has prompted HHS to undertake significant efforts to clarify the landscape and remove the perceived regulatory barriers.

For example, early last year, CMS announced the formation of an inter-agency task force with the U.S. Department of Justice ("DOJ") and the HHS Office of Inspector General ("OIG") to address the problems created by anti-fraud statutes.[13] Later in the year, CMS initiated the "Regulatory Sprint to Coordinated Care" to "determine how [laws and their regulatory interpretations] may be impeding care coordination, as part of Secretary Azar's effort is to build a value-based healthcare system [and] engage in rulemaking to empower clinicians and other providers to coordinate and deliver value."[14]

These efforts were followed by Requests for Information ("RFIs") seeking comments on how CMS might modify exceptions under the Stark Law, and OIG HHS might modify the "safe harbors" under the AKS to remove regulatory barriers to coordinated care.[15] The comments submitted in response to these requests provided much of the basis for the current draft regulations published on October 17th.[16] As these regulations were drafted in concert with one another, practitioners interested in new arrangements should review both proposals and their interconnections.[17]

## Modifying the Stark Law

The CMS proposal to update and modify the Stark Law starts with a conceptual framework that defines a "value-based arrangement" that is eligible for protection.

The exceptions for value-based arrangements are based on CMS' definition of a "value-based purpose" which include

1. Coordinating and managing the care of a target patient population;
2. Improving the quality of care for a patient population;
3. Appropriately reducing costs, or growth in, expenditures of, payors without reducing the quality of care for a target patient population; or
4. Transitioning from health care delivery and payment based on the volume of items and services provided to mechanisms based on the quality of care and the control of costs of care for a target patient population.[18]

"Value-based activities," which do not encompass referrals, therefore, are the provision of a good or service, or the taking or not taking of an action in pursuit of one or more of the value-based purposes.[19] "Value-based enterprises" ("VBEs") are defined as being comprised of individuals or entities collaboratively engaging in value-based activities.[20] To be legitimate, VBEs must have a governing document and governing structure for conducting these activities, but CMS notes that VBEs can be legal entities (such as ACOs) or two parties engaged in a value-based activity formalized in a legal document.[21] CMS anticipates that most of the protected arrangements "will involve activities that coordinate the care of a target population."[22]

However, not all entities may ultimately qualify as VBEs. Concerned with protecting program integrity, CMS is considering excluding from its allowable exceptions, arrangements with laboratories, suppliers of durable medical equipment, pharmaceutical manufacturers,

pharmacy benefit managers, and wholesalers.[23] CMS's rationale is that these types of firms are unlikely to contribute to coordination under value-based models and also raise concerns from the perspective of law enforcement agencies.[24]

### *Proposed Exceptions for Value-Based Arrangements*

Using these definitions, CMS is considering several potential exceptions that the agency believes should cover any CMS sponsored model.[25] However, CMS is seeking comments on the desirability of any or all of these proposed exceptions.

#### The full financial risk exception[26]

This exception would protect value-based arrangements in which the remuneration to the physician exposes the physician to full financial risk for reimbursable services, such as a capitated payment system. CMS believes that exposure to such risk will be a better check on excessive charges than could be provided by fraud and abuse laws.

#### The meaningful downside risk exception[27]

Since not all physicians may be able to assume full downside financial risks in a value-based arrangement, CMS is also considering arrangements in which "the physician [has a] meaningful downside financial risk from the failure to achieve the value-based purpose." CMS proposes that "meaningful downside financial risk" be defined as putting at least 25% of the physician's remuneration at risk. Obviously, the full financial risk exception could fall under this exception, and so a separate exception may not be necessary.

#### Value-based payments, without a financial risk requirement[28]

CMS recognizes that some physicians, particularly those in small practices, may not be willing or able to participate in arrangements that involve serious downside financial risk. Thus, it may be necessary to have an exception that protects value-based arrangements without the requirement of risk-sharing. However, more specific limitations on the arrangement may be necessary to substitute for the incentives supplied by financial risk-sharing. For example, physician remuneration under the value-based arrangement exception and any other arrangement between the physician and other participants in the VBE cannot be based on the volume or the value of referrals. Alternatively, CMS is considering whether only nonmonetary remuneration of physicians is protected under this exception.

#### Other proposed exceptions[29]

Of particular interest to value-based models are modifications to allow physicians to receive donations of EHR software and hardware. The draft regulation asks for comments on whether the requirement that physicians cover 15% of the cost be dropped. It also responds to comments in the RIF, suggesting that donations of cybersecurity software and training be covered under the exception.

## Modifying the AKS Safe Harbors

The new safe harbors proposed by the HHS OIG are built around the same conceptual framework used by CMS.[30] Thus the new safe harbors apply to value-based arrangements, which are arrangements between participants in value-based enterprises to conduct value-based activities (not including referrals) using the same four value-based purposes outlined by CMS.[31] Like the CMS Stark Law proposal, the OIG believes that some entities--pharmacies, pharmaceutical companies, producers of durable medical devices, etc.—should be precluded from qualifying as a "participant" in a VBE and therefore from protection under a safe harbor.[32] The OIG, however, is more specific than CMS on some of the details that value-based arrangements must fulfill to be covered by a safe harbor. For example, it provides more detail on the documentation and governance structure value-based enterprises must employ.[33]

As proposed, there are three possible safe harbors corresponding to the level of downside financial risk assumed by the parties to the arrangement. Since assumption of risk is assumed to be a check on overcharging, the greater the financial risk assumed, the greater the flexibility.

#### Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor[34]

Value-based arrangements that do not subject the provider to any downside financial risk are vulnerable to the same kind of abuses the OIG has experienced with

fee-for-service arrangements. Thus, the OIG is proposing several "safeguards" to qualify for this safe harbor. For example, remuneration cannot be based on the volume or value of referrals. Nonmonetary remuneration must be "commercially reasonable," that is, necessary to provide a value-based activity. Finally, all aspects of the value-based arrangement must be set forth in writing.

### Value-based Arrangements with Substantial Downside Financial Risk[35]

When the payment recipient shares some of the downside financial risk, such as in the sharing of savings and losses that occur between a provider and an ACO, there is less incentive for abuse, and the OIG correspondently proposes imposing fewer requirements. The OIG also is seeking comments on how to establish and measure the amount of risk-sharing.

### Value-based Arrangements with Full Financial Risk[35]

This safe harbor covers arrangements where the recipient is fully responsible for the cost of care, such as capitation and bundled payment payments. The OIG is looking for comments on what kind of payment structures would qualify for this safe harbor, and some restrictions still would apply to these arrangements, including the prohibition on payments based on the volume or value of referrals.

### Other ancillary safe harbors related to value-based arrangements

Three other proposed safe harbors that support the administration of value-based arrangements were also proposed. These include:

1. **Cybersecurity Technology and Related Services**[38] In response to "overwhelming support" in the RFI, OIG proposes a safe harbor for donations of cybersecurity technology. The OIG is requesting comments on the appropriate definitions and specific parameters for this safe harbor.

2. **Electronic Health Records**[39] OIG favors keeping the current 15% mandatory contribution requirement. However, it is requesting comments on possibly reducing the mandatory contribution for small or rural practices or eliminating it.

3. **Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency**[40] The draft regulation also included a lengthy discussion of the possibility of creating a safe harbor for patient engagement programs.

OIG also proposes amendments and changes to some existing safe harbors covering:

- Personal Services and Management Contracts and
- Outcome-Based Payment Arrangements;[41]
- Warranties;[42]
- Expansion of Mileage Limit for Patients Residing in Rural Areas;[43] and
- The ACO Beneficiary Incentive Program safe harbor.[44]

## Conclusion

Together, the two proposals represent one of the most significant revisions to the limitations to the AKS and Stark Law, representing the changing healthcare landscape and the need to balance costs and risk. Until the comment period closes on December 31st, and the final rules are issued, it remains to be seen how far these revisions will go or what the ultimate impact will be on current healthcare activities. But ultimately, it is a sign that HHS is listening to those it regulates and is trying to make suitable adjustments. Therefore, all compliance professionals should take note and carefully monitor these developments.

### References


1 *See Michael Brady, Americans 'fed up' with high healthcare costs, surprise billing, Verma says, MODERN HEALTHCARE, (Sep. 11, 2019), https://www.modernhealthcare.com/payment/americans-fed-up-high-healthcare-costs-surprise-billing-verma-says.*
2 *Id.*
3 *See, e.g., Carlton Fields, Provider Beware: MACRA Implementation Fraught with Fraud and Abuse Implications, JDSUPRA (Apr. 6, 2017), https://www.jdsupra.com/legalnews/provider-beware-macra-implementation-74494/.*
4 *Press Release, Centers Medicare and Medicaid Services, HHS Proposes Stark Law and Anti-Kickback Statute Reforms to Support Value-Based and Coordinated Care (Oct. 9. 2019), https://www.hhs.gov/about/news/2019/10/09/hhs-proposes-stark-law-anti-kickback-statute-reforms.html.*
5 *See Rebecca Olavarria, MACRA and Stark: Strange Bedfellows at the Heart of Health Care Reform, 62 WAYNE L. REV., 131 147 (2017).*
6 *Id. at 156.*
7 *See C. Field, supra n. 3.*
8 *See American Hospital Association, Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them, (2017) https://www.aha.org/system/files/content/16/barrierstocare-full.pdf.*
9 *U.S. GOV'T ACCOUNTABILITY OFF., GAO 12-355, MEDICARE IMPLEMENTATION OF FINANCIAL INCENTIVE PROGRAMS UNDER FEDERAL FRAUD AND ABUSE LAWS, 18-19 (2012).*

10 Id.
11 Fields, supra. n. 3.
12 Under the AKS "personal services" Safe Harbor (which is primarily used for directorship and management contracts), compensation must be set out in advance, consistent with "fair market values," and not based on the volume or value of referrals. See Corbin Santo, Walking a Tightrope: Regulating Medicare Fraud and Abuse and the Transition to Value-Based Payment, 64 CASE W. RES. L. REV. 1377, 1402 (2014)
13 https://www.youtube.com/watch?v=vrtey7QPAYg&feature=youtu.be.
14 Press Release, Dept. of Health and Human Services, Secretary Azar Highlights Recognition of HHS as Top Agency for Regulatory Reform (Oct. 17, 2018), https://www.hhs.gov/about/news/2018/10/17/secretary-azar-highlights-recognition-of-hhs-as-top-agency-for-regulatory-reform.html.
15 See 83 Fed. Reg. 29524 (Jun. 25, 2018) and 83 Fed. Reg. 43607 (Aug. 27, 2018).
16 See Centers for Medicare and Medicaid Services, Medicare Program: Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. 55766 (Oct. 17, 2019); Department of Health and Human Serv's, Office of the Inspector General, Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbor under the Anti-Kickback Statute, and Civil and Monetary Penalty Rules Regarding Beneficiary Inducement, 84 Fed. Reg. 55694 (Oct. 17, 2018).
17 See 84 Fed. Reg. at 55696; 84 Fed. Reg. at 55771.
18 Id. at 55773
19 Id.
20 Id.
21 Id. at 5577
22 Id.
23 Id.
24 Id. at 55775
25 Id. at 55778
26 Id. at 55779-81
27 Id. at 55781-83
28 Id. at 55783-86
29 Id. at 55822-25
30 See 84 Fed. Reg. at 55700
31 Id. at 55701-55706.
32 Id. at 55703-08
33 Id. at 55701-02
34 Id. at 55708-16
35 Id. at 55716-19
36 Id. at 55719-21
37 Id. at 55720
38 Id. at 55733-39
39 Id. at 55739-44
40 Id. at 55721-33
41 Id. at 55744
42 Id. at 55748
43 Id. at 55750
44 Id. at 55752

# Tinkering with Open Payments

## *CMS Proposes New Changes in Response to Comments & Legislation*

*By Nicodemo Fiorentino, Associate Editor, Policy & Medicine Compliance Update*[1]

**Summary:** Centers for Medicare & Medicaid Services recently published proposed revisions to the Open Payments program in its annual Physician Fee Schedule proposed rule. The proposed revisions expand the definition of covered recipient and make changes to the nature of payment categories, standardize data on reported covered products and updates the national drug code reporting requirements for drugs and biologicals.

An ongoing challenge for compliance professionals charged with ensuring compliance with the Physician Payments Sunshine Act or Open Payments, is that the Centers for Medicare & Medicaid Services ("CMS") keep tinkering with the rules. This year was no exception as CMS released its annual Physician Fee Schedule ("PFS") and proposed even more changes to the Open Payments regulations.[2]

## Responding to Legislation and Comments

The impetus for the proposed changes announced in August is being driven by new legislation and previously submitted comments. On the one hand, the expansion of the definition of "covered recipients" was triggered by Section 6111 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act").[3]

The SUPPORT ACT mandated that the term "covered recipient" be expanded to include physician assistants ("PAs") and nurse practitioners, certified nurse midwives, certified registered nurse anesthetists, and certified nurse specialists (collectively "advanced practice registered nurses" or "APRNs").[4]

On the other hand, CMS, responding to comments received during the CY 2017 PFS rule proposal,[5] CMS intends to expand the nature of payment categories, standardize data on reported covered drugs, devices, biologicals, or medical supplies, and correct the national drug code ("NDC") reporting requirements for drugs and biologicals.[6]

### *Effective Date of the Changes*

All proposed changes, with the exception of correcting the NDC reporting requirements, will become effective for data collected beginning during the 2021 program year (January 1, 2021 through December 31, 2021) and apply to reports for the 2022 program year (reports are due by March 31, 2022). The NDC reporting requirements for drugs and biologicals will be effective sixty (60) days following the publication of the final rule.[8]

## Expanding the Term "Covered Recipient"

Perhaps the most straightforward revision to the Open Payments regulations is the expansion of the term

"covered recipient" to include PAs and APRNs. These definitions, like the original definition of physician, will incorporate the same meaning given those terms by section 1861 of the Social Security Act.[10]

Somewhat complicating matters is how CMS intends to add the definition "non-teaching hospital covered recipients" by replacing the term "physician" found throughout the regulations with this new version.[11] It is unclear why CMS chose "non-teaching hospital covered recipients" instead of something simpler like "healthcare practitioners" or even "physicians and mid-level practitioners." Additionally, CMS proposes to add the following new terms:

- "long-term medical supply or device loan,"
- "short-term medical supply or device loan" (redesignated to the definition section),
- "device identifier," and
- "unique device identifier."[12]

The definitions, except for "non-covered teaching hospital covered recipients," can be found in Table 1.

## Changing Nature of Payment Categories

CMS intends to add three new nature of payment categories and consolidate two categories into one. The three new categories are:

- debt forgiveness,
- long-term medical supply or device loan, and
- acquisitions.[13]

In an effort to "streamline the reporting requirements," the categories for "compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program" and "compensation for serving as faculty or as a speaker for an accredited or certified continuing education program" will be consolidated into a single category entitled "medical education programs."[14] CMS's rationale for this change is that CMS recognized that it had originally provided separate categories for these payment types, but now believes the distinction is no longer necessary.[15]

**TABLE 1:** *Proposed Definitions*

| |
|---|
| **Physician Assistant and Nurse Practitioner** |
| A physician assistant or nurse practitioner who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations. 42 U.S.C. 1395x(aa)(5)(A). |
| **Clinical Nurse Specialist** |
| An individual who—(i) is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and (ii) holds a master's degree in a defined clinical area of nursing from an accredited educational institution. 42 U.S.C. 1395x(aa)(5)(B). |
| **Certified Registered Nurse Anesthetist** |
| A certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists. Such term also includes, as prescribed by the Secretary, an anesthesiologist assistant. 42 U.S.C. 1395x(bb)(2). |
| **Certified Nurse-Midwife** |
| A registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary or has been certified by an organization recognized by the Secretary. 42 U.S.C. 1395x(gg)(2). |
| **Device Identifier** |
| A mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device. 21 C.F.R. 801.3. |
| **Unique Device Identifier** |
| An identifier that adequately identifies a device through its distribution and use by meeting the requirements of 830.20 of this chapter. 21 C.F.R. § 801.3. |
| **Long-Term Medical Supply or Device Loan** |
| The loan of supplies or a device for 91 days or longer. 84 FED. REG. 40713, 40715. |
| **Short-Term Medical Supply or Device Loan** |
| The loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient. 42 C.F.R. § 403.904(h)(5). |

## Standardizing Reported Data

### *Device Identifiers*

Currently, applicable manufacturers and group purchasing organizations ("GPOs") are not required to provide specific information about supplies and devices. Instead, CMS allows them to report either the device's therapeutic area or its product category. However, with the advent of the unique device identifier ("UDI") requirements, CMS believes the time is ripe for the reporting of more specific information. To support its proposal, CMS references regulations issued by the U.S. Food and Drug Administration ("FDA") and the U.S. Health and Human Services Office of the National Requirements that require the use of UDIs on most medical devices distributed in the United States.[16]

CMS also relies upon the HHS Office of Inspector General's ("OIG") recommendation that Open Payments require more specific information about medical devices.[17] In their report, the OIG pointed out the inconsistency between reporting by drug manufacturers, who report the actual names of the products, whereas device manufacturers and GPOs report either the device's therapeutic area or its product category.[18] As a result, the OIG noted how there were "hundreds of thousands of records" where device manufacturers and GPOs reported information based solely on broad product categories such as "hips," "spine," and "knees" (these three devices accounted for $153 million in reportable spend).[19]

Thus, CMS is proposing that applicable manufacturers and GPOs report the device identifiers ("DI"), a subcomponent of UDIs for supplies and devices.[20] CMS believes the DIs would be used by CMS to validate submitted device information and allow the public to obtain "more precise information" about supplies and devices.[21]

### *National Drug Codes*

Reporting NDCs is a requirement for payments or other transfers of value associated with drugs and biologicals, although, from a regulatory standpoint, reporting NDCs is only specifically mentioned under the rules for research-related payments.[22] However, CMS stated that it erroneously removed the NDC reporting requirement for non-research related payments in the CY 2015 PFS final rule.[23] Thus, CMS intends to address the regulatory error by making it clear that NDCs must be reported for non-research and research-related payments.[24]

## Comments to the Proposed Rule

During the sixty (60) day comment period, over forty thousand (40,000) comments were submitted, but only thirty (30) comments concerned the proposed revisions to Open Payments.[25] Notable stakeholders included Advanced Medical Technology Association ("AdvaMed"), Biotechnology Innovation Organization ("BIO"), Pharmaceutical Research and Manufacturers of America ("PhRMA"), the Medicare Payment Advisory Commission ("MedPAC"), and the American Medical Association ("AMA"). Table 2 provides a complete list on the individuals and organizations that submitted comments.

AdvaMed, BIO, and PhRMA all expressed concern about validating covered recipients. AdvaMed also believed the standardization of data by requiring applicable manufacturers and GPOs to add the device identifier would not be meaningful to the public and would be a burden on company resources.

**TABLE 2:** *Who Commented?*

| | |
|---|---|
| Ad Hoc Sunshine and State Law Compliance Group (submitted by King & Spalding) | Association of American Medical Colleges |
| AdvaMed | Barbara McAneny MD MACP FASCO[26] |
| Alliance of Specialty Medicine | BIO |
| Allina Health | Biocom |
| American Academy of Neurology | Continuing Medical Education ("CME") Coalition |
| American Academy of PAs | CONMED Corporation |
| American Association of Nurse Practitioners | Lilly USA, LLC |
| American College of Osteopathic Surgeons | National Association of Pediatric Nurse Practitioners |
| American College of Physicians | National Comprehensive Cancer Network |
| AMA | MedPAC |
| American Nurses Association | Pew Charitable Trusts |
| American Society of Plastic Surgeons | PhRMA |
| American Urological Association | Sanofi US |
| Amgen, Inc. | Unity Point Health |
| Anonymous (1) | University of Pittsburgh Medical Center |

## Conclusion

With comment period now closed, CMS will soon release the final rule. CMS will likely take into consideration the comments it received, but it is unlikely CMS will delay the effective dates for collecting and submitting data in 2021 and 2022. Hopefully CMS will address industry concerns with validating data and reconsider requiring impacted companies from reporting device identifiers. Regardless of the outcome, compliance departments will be busy in 2020 updating policies and procedures, educating and training impacted departments and employees, and reviewing their data collection efforts and systems (internal and external).

### References

1 *Mr. Fiorentino is Associate Editor and a Member of the Policy & Medicine Compliance Update Editorial Board. The views expressed in this article are solely those of the author.*
2 *84 Fed. Reg. 40713, available at https://www.govinfo.gov/content/pkg/FR-2019-08-14/pdf/2019-16041.pdf (hereinafter Open Payments Proposed Rule). The Open Payments regulations can be found at 42 C.F.R. part 403.*
3 *H.R. 6, 115th Cong. § 6111 (2018), available at https://www.congress.gov/bill/115th-congress/house-bill/6/text#toc-H77564108ED994D18885D621E5404482C.*
4 *Id.. Section 6111 also revised the Sunshine Act by sunsetting the exclusion of a covered recipient's National Provider Identification ("NPI") in information made publicly available.*
5 *81 FED. REG. 46395. CMS published a summary of the solicited comments in the CY 2017 PFS final rule 81 FED. REG. 80428–80429.*
6 *See Open Payments Proposed Rule, supra note 2 at 40714.*
7 *Id.*
8 *Id.*
9 *Id.*
10 *Id. The definitions for PAs and APRNs can found under sections 1861(aa)(5)(A), 1861(aa)(5)(B), 1861(bb)(2), and 1861(gg)(2) of the Social Security Act.*
11 *Id. at 40714-15. For example, CMS intends to revise the following: (1) in § 403.904(c)(1), (f)(1)(i)(A), and (h)(7), to replace the term "physician" (replacing the term "physician" in § 403.904(c)(1), (f)(1)(i)(A), and (h)(7), to replace the term "physician" with the phrase "non-teaching hospital;" (2) in § 403.904(c)(3), to replace the term "physician" in the title with the phrase "non-teaching hospital," add the phrase "non-teaching hospital" after "In the case of a," and remove the phrase "who is a physician" from the text; (3) in § 403.904(c)(3)(ii) and (iii), (f)(1)(i)(A)(1), (f)(1)(i)(A)(3) and (5), and (f)(1)(v), to change the term "physician" to the phrase "non-teaching hospital covered recipient;" (4) in § 403.904(h)(13), to remove the phrase "who is a physician" and add the phrase "non-teaching hospital" after "In the case of;" (5) in § 403.904(f)(1), to remove the phrase "(either physicians or teaching hospitals);" and (6) in § 403.908(g)(2)(ii), to change the words "physicians and teaching hospitals" to the term "Covered recipients."*
12 *Id. at 40715-16.*
13 *Id. at 40715*
14 *Id.*
15 *Id.*
16 *Id.*
17 *See DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL, OEI-03-15-00220, "OPEN PAYMENTS DATA: REVIEW OF ACCURACY, PRECISION, AND CONSISTENCY IN REPORTING" (Aug. 2018), https://oig.hhs.gov/oei/reports/oei-03-15-00220.asp.*
18 *Id.*
19 *Id.*
20 *Id.*
21 *Id.*
22 *See 42 C.F.R. § 403.904(f)(1)(iv).*
23 *See Open Payments Proposed Rule, supra note 2 at 40716.*
24 *Id.*
25 *The docket was last accessed on October 1, 2019. The term "Open Payments" was used to search for relevant comments.*
26 *Dr. McAneny noted her comments were submitted as her own opinion and "do not reflect [her] position as the Immediate Past President of the American Medical Association, but do reflect [her] position as the CEO of an Independent Multi-disciplinary Oncology Practice, New Mexico Oncology Hematology Consultants practicing at New Mexico Cancer Center and a participant in the Oncology Care Model, OCM."*
27 *Hyperlinks to the complete letters submitted by the trade associations are available here:*
*AdvaMed (https://www.regulations.gov/document?D=CMS-2019-0111-36422);*
*BIO (https://www.regulations.gov/document?D=CMS-2019-0111-37929);*
*PhRMA (https://www.regulations.gov/document?D=CMS-2019-0111-38049).*

# Spreading the Blame

## *DEA Criticized for Its Role in the Opioid Crisis*

*By Dr. Seth B. Whitelaw, Editor*

**Summary:** The DOJ OIG in October released a report sharply critical about the DEA's efforts to address the use and diversion of opioids. This article takes an in-depth look at what the report found.

**"[I]n my humble opinion, everyone shares some of the responsibility, and no one has done enough to abate it."**

With these words, Judge Dan Aaron Polster, the judge presiding over the Opioid MDL litigation, cast a wide net of responsibility to include "the manufacturers, the distributors, the pharmacies, the doctors, the federal government and state government, local governments, hospitals, third-party payors, and individuals."[1] For the most part, however, the U.S. Drug Enforcement Agency ("DEA") has avoided the scrutiny and criticism leveled against the manufacturers and distributors, but the recently released report by the United States Department of Justice, Office of Inspector General ("JOIG") is sharply critical of the DEA and its efforts to address the opioid crisis.[2]

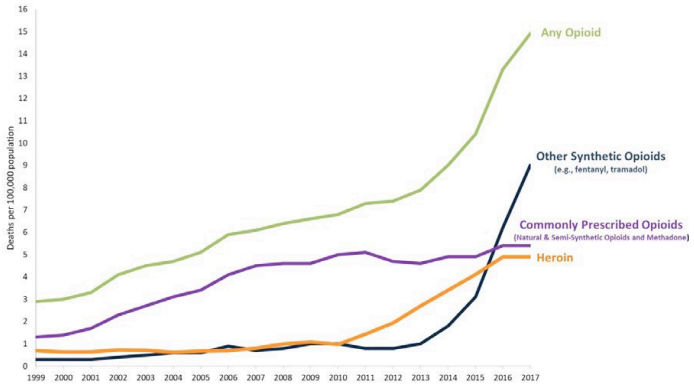
## Background

Both the opioid overdose epidemic and the accompanying litigation are not something that only has recently emerged but has been ongoing over several decades (see Figure 1). Nor is this the first oversight report examining the DEA's opioid diversion efforts. In fact, since September 2002, the JOIG and the U.S. Government Accountability Office ("GAO") have conducted eight previous reviews of DEA's opioid efforts.[3]

However, not only have the JOIG and GAO been critical of DEA's opioid diversion efforts, but various defendants in the Opioid MDL have maintained that any failure on their part to have "effective controls against diversion"

is the direct result of DEA's lack of specificity and guidance on what registrants were required to do.

**FIGURE 1:** *The Three Waves in the Rise of Opioid Overdose Deaths*[4]




## The Major Findings

At the outset, it is important to understand the concept of diversion as it pertains to legal medicinal products made with a controlled substance, including prescription opioids. As the JOIG noted in its report, "controlled [substance containing] pharmaceuticals can be diverted from legitimate channels through theft or **fraud during the manufacturing and distribution process** by anyone involved in the process."[6] This includes "medical and pharmacy staff and individuals involved in selling or using pharmaceuticals."[7] Thus, the false or misleading product promotion, the filling of excessive or medically unnecessary prescriptions, and the failure to report suspicious orders for these products to the DEA can all constitute diversion.

The Inspector General's report highlighted four major shortcomings with the DEA's efforts to control the diversion of opioids. Specifically, JOIG found that:

1. The DEA "was slow to respond to the significant increase in the use and diversion of opioids since 2000;"
2. The DEA "did not use its available resources including its data systems, and strongest administrative enforcement tools" effectively;
3. The DEA's "policies and regulations did not adequately hold registrants accountable;" and
4. While the DEA has taken recent steps to improve its response, "more work is needed."[8]

The remainder of the Inspector General's 71-page report was spent expanding on each of the four major findings.

### *The Report's Inherent Limitation*

At the outset, the report contains an inherent limitation that hampers its overall usefulness. In conducting its review, the JOIG limited its review to Fiscal Years 2010 to 2017 (October 1, 2009, to September 30, 2017).[9] However, by starting the review with the third quarter of 2009, the JOIG examined DEA operations when the opioid crisis was already in full swing as illustrated by Figure 1. Thus, the report does not address squarely what the DEA could or should have done to prevent the crisis in the first place.

In addition, the Controlled Substances Act ("CSA") and its accompanying regulations, including the key provisions around diversion and suspicious order monitoring ("SOM") date to 1971.[10] Therefore, clarifications and guidance provided by the DEA prior to 2009 were not factored in this review.[11] These clarifications and guidance are central points of contention in the current Opioid MDL litigation.

## Meat and Potatoes

The JOIG highlighted numerous specific policy and practices deficiencies by the DEA that undermined the DEA's ability to confront "one of the worst drug epidemics in [American] history."[12] These specific deficiencies form the "meat and potatoes" of the Inspector General's report.

### *A Slow Response to the Epidemic*

As shown in Figure 1, beginning in 2000, there was a precipitous rise in the number of overdose deaths attributed to commonly prescribed opioids. Under the CSA, the DEA is charged with setting an annual Aggregate Production Quota ("APQ"), which is the total amount of a given Schedule I or II product (which includes opioids) that can be manufactured each year.[13]

According to the JOIG report, the opioid overdose rate grew approximately 8% per year from 1999 to 2013, but during the four years from 2013 to 2017, it grew an average of 71%. However, in case of oxycodone alone from 2002 to 2013, the DEA approved a 400% increase in the APQ. Furthermore it was not until 2017 that DEA made any meaningful reduction (25%) to the APQs for opioids.[14] This failure to set appropriate APQs was compounded by the fact that it was not until 2018 that the DEA finalized regulations explicitly authorizing the Agency to take diversion into account when setting those quotas.[15] As a result, it can be argued that the DEA aided

and abetted the crisis by not fully using its quota authority to contain the rapid growth of opioid usage despite evidence suggesting widespread diversion was occurring.

### *Poor Due Diligence on New Applicants*

Two key anti-diversion controls that are at the heart of the opioid litigation are the need for controlled substances manufacturers and distributors to perform adequate due diligence surrounding the sales of controlled substances (e.g., suspicious order monitoring),[16] and the ancillary concept to "know your customer."[17] Thus, registrants are expected to vet their customers and monitor their purchases for signs (e.g., "red flags") of suspicious activity.

However, in its report, the Inspector General determined that the DEA neither followed its own policies nor adhered to the same standards it expected of registrants. For example, the JOIG concluded that:

> DEA did not conduct background checks on all new applicants and relied instead on the good faith of applicants to disclose relevant information, even in cases in which the applicant had previously engaged in criminal activity.[18]

This was especially egregious in the case of pharmacy applicants as only two DEA field divisions routinely conducted pharmacy background checks, while the others simply "issued a registration if a pharmacy applicant had a valid state license." Nor did the DEA routinely investigate to see if an applicant was truthful if it told the DEA it has not been subject to any allegations of misconduct involving any required state license.[19] Thus the DEA simply trusted but did not verify.

The JOIG also noted that:

> DEA policy allowed, and still allows, registrants that have had their registration revoked, or that have surrendered it, to reapply for registration the day after a revocation is enforced or a surrender occurs.[20]

Furthermore, "[i]f someone buys the legal entity in its entirety and the legal entity has not ceased to exist, in effect nothing has changed, [] [the] DEA does not need to be notified."[22] With these policies and practices, the DEA created a kind of "revolving door" such that a registrant could surrender its license with one hand and obtain a new one with the other. This revolving door also offered the unscrupulous registrant-owner the opportunity to continue operating out-of-bounds by continuing to do business by simply buying another existing business.

### *Failure to Use Enforcement Tools Wisely*

To police registrant behavior, the DEA primarily employs two enforcement tools – an Order to Show Cause ("OTSC") or an Immediate Suspension Order ("ISO"). Of the two tools, the ISO is the strongest measure the DEA can employ.

#### Understanding Orders to Show Cause & Immediate Suspension Orders

An Order to Show Cause, as the name suggests is an order from the DEA to a registrant to demonstrate to the DEA why the DEA should not revoke the registrant's license to sell controlled substances. Upon receipt of the OTSC, the registrant must either file a written response within 30 days or request a full hearing before an Administrative Law Judge ("ALJ").[24] Typically, OTS's are resolved by settlement and submission of a corrective action plan.[25]

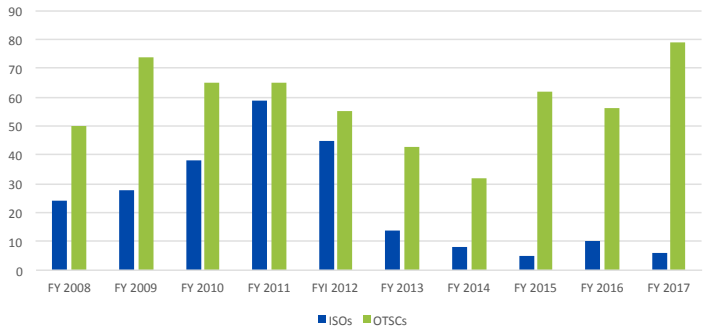
The ISO, on the other hand, is an immediate revocation or suspension of the registrant's license before the registrant has the opportunity for a response or a hearing.[26] Therefore, the registrant immediately must suspend all handling of controlled substances until the underlying OTSC is resolved.[27] To issue an ISO, the DEA must determine that there is "an imminent danger to public health and safety" if the registrant is allowed to continue controlled substances operations.[28] As clarified in 2016, an "imminent danger" means that:

> due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant... there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.[29]

In reviewing the number of OTSCs and ISOs issued by the DEA, the JOIG found that from FY 2010 to FY 2017, the number of ISOs issued declined by over 80% with an almost 70% decline in the last four fiscal years alone (see Figure 2).[24] However, during the same time period, the number of overdose deaths attributed to commonly prescribed and synthetic opioids continued to climb.

Although the JOIG could not attribute the decline in ISOs to a single factor, they did note that in 2012 during a second enforcement action against Cardinal Health, Inc. ("Cardinal"), one of the big three national distributors, a U.S. District Court Judge initially blocked DEA from executing the ISO for lack of evidence.[25] The same judge later allowed the DEA to proceed with the ISO, but only after DEA presented the full extent of its evidence against Cardinal. The DEA and Cardinal ultimately entered into a settlement agreement,[26] but the Inspector General found that the initial rejection by the District Court made the DEA "gun shy" in aggressively pursuing the ISO remedy.

**FIGURE 2:** *ISOs and OTSCs Issued By DEA (FY 2008 to FY 2017)*




The Inspector General also noted a significant delay by the DEA in implementing ALJ recommendations issued at the conclusion of OTSCs. Specifically, the JOIG report "determined that from FY 2010 through FY 2017, on average, the former acting DEA Administrator took nearly 10 months (302 days), and in a few cases approximately 2 years, to render a final decision after an ALJ issued a recommendation."[27] Thus, the JOIG concluded the DEA's inability to adjudicate enforcement actions in a timely manner is a challenge that has persisted for several years," and concluded that the "continuing failure to render a timely final decision is particularly concerning as registrants may continue to do business and potentially divert pharmaceutical opioids until [the] DEA revokes their registrations."[28]

### *Poor Use of Available Data*

The Inspector General also was critical of two of the DEA's primarily data systems: ARCOS and SORS. The Automation of Reports and Consolidated Orders System ("ARCOS") dates back to the 1970s, and it requires manufacturers and distributors of controlled substances to "report inventories, acquisitions, and dispositions of schedule I and II substances, and narcotic substances in schedule III as well as other selected substances such as Gamma-Hydroxybutyric Acid ("GHB")."[29]

Although ARCOS contains ordering information from about 1,100 manufacturers and distributors, data is uploaded inconsistently with some companies reporting monthly and other quarterly as permitted by the DEA. This inconsistency in reporting, according to the JOIG "forces [the] DEA to wait a full year before ARCOS contains all of the ordering information needed to fully analyze the data and develop leads and trends."[30] The database also does not capture data for Schedule III, IV, and V products, and thus, ARCOS does not present a full picture of potential diversion patterns.

By contrast, the DEA's consolidated Suspicious Order Reporting System ("SORS") only came into being in 2008 or the mid-point of the current crisis.[39] The main limitation to SORS as a tool comes from the fact that it only contains data from those registrants required to submit their suspicious order reports to DEA headquarters as opposed to the registrant's DEA Field Office. To put this into perspective, only 0.5% of the registered manufacturers' and distributors' suspicious order reports, as of August 2017, were contained in SORS (see Figure 3), essentially rendering SORS useless as a reporting tool.

**FIGURE 3:** *Total Registrants vs. Number of Entities Reporting in ARCOS & SORS*[31]


The JOIG also highlighted that the current suspicious order monitoring regulation allows registrants to use their own standards and thresholds when evaluating controlled substances orders.[32] Under the existing suspicious order monitoring regulation, an order must be reported to:

> the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.[33]

Thus, key concepts such as an "unusual size, pattern or frequency," as well as when a suspicious order is discovered, are left to each individual manufacturer's and distributor's discretion to define what is appropriate.

## Recommendations

The Inspector General also made numerous specific recommendations to improve the DEA's opioid diversion control efforts. These included:

1. Creating a national opioid enforcement strategy to harmonious the work of all the DEA field divisions;

2. Requiring criminal background investigations for all new license applicants;
3. Creating ways to ensure that DEA staff have all the necessary information concerning a renewing applicant's history including registration revocations, loss of state medical licenses and any other conduct that would render the applicant unfit to have a license;
4. Implementing electronic prescribing for all controlled substances prescriptions;
5. Increasing targeting flexibility and state agency cooperation;
6. Increasing the number of federal prosecutors dedicated to opioid prosecutions;
7. Creating regulations, policies, and procedures to define what constitutes a suspicious order;
8. Requiring ARCOS reporting for all controlled substances; and
9. Mandating all suspicious order reports be provided to DEA headquarters and included in SORS.[34]

## Conclusion

The release of the Inspector General's report roughly coincides with the start of the first trial in the Opioid MDL litigation. While some of the findings mirror positions taken by the defendants, it is unclear what the impact on the trial will be, as manufacturers and distributors ultimately retain responsibility for controlled substances compliance. It also is unclear when or if the JOIG's recommendation will be implemented as many of them require either new notice and comment rulemaking or even new grants of statutory authority from Congress. While addressing the opioid crisis may have bipartisan support, negotiating Congress's clogged legislative pipeline will be challenging. However, one thing is clear, and that is Judge Polster was correct when he said there is enough blame for the opioid crisis to go around.

### References

1 *See Defendants' Memorandum in Support of Motion to Disqualify Pursuant To 28 U.S.C. § 455(a) at 7, In re: National Prescription Opiate Litigation, MDL No. 2804 (N.D. Ohio, E.D., Sept. 14, 2019*
2 *See U.S. Dept. of Justice, Office of Inspector Gen'l, Review of the Drug Enforcement's Regulatory and Enforcement Control Efforts to Control the Diversion of Opioids 19-05 (Sep. 2019) (hereinafter "JOIG Report").*
3 *See JOIG Report at 53 (Appendix 3).*
4 *See JOIG Report at 6 (citing CDC Nat'l Center for Health Statistics, National Vital Statistics System, Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000–2017).*
5 *The term "registrants" refers to the requirement that the DEA requires everyone involved in the controlled substances supply chain (e.g., prescribers, pharmacists, manufacturers, distributors, and importers) to register with the DEA, obtain a license, and follow the regulatory requirements imposed on them by the DEA. This is essence of the so-called "closed loop system."*
6 *See JOIG Report at 1 (emphasis added).*
7 *See JOIG Report at 1 (citations omitted).*
8 *See JOIG Report at i (Executive Summary).*
9 *See JOIG Report at 12.*
10 *See 21 U.S.C. § 801 et seq., see also 36 Fed. Reg. 7778 (Apr. 24, 1971) codified at 21 C.F.R. part 1301.*
11 *See, e.g., U.S. DEP'T OF JUSTICE, DRUG ENFORCEMENT ADMINISTRATION CHEMICAL HANDLER'S MANUAL, (Jan. 2004) at https://www.justice.gov/sites/default/files/open/legacy/2014/05/09/2004-chemical-handlers-manual.pdf; Letters from J. Rannazzisi to All Registrants (Sep. 27, 2006, Feb. 7, 2007, Dec. 27, 2007), but see Letter from J. Rannazzisi to All Registrants (Jun. 12, 2012). The final Rannazzisi letter was within the scope of this report, but not discussed in detail.*
12 *See JOIG Report at 45.*
13 *See 21 C.F.R. §1303.11; see also Lee Rosebush and Marc Wagner, The DEA Quota System, FOOD AND DRUG LAW INSTITUTE UPDATE MAGAZINE (Aug. 2018), https://www.fdli.org/2018/08/update-the-dea-quota-system/.*
14 *See JOIG Report at 13.*
15 *See Controlled Substances Quotas, 83 Fed. Reg. 32,784 (Jul. 16, 2018) (codified at 21 C.F.R. pt. 1303); JOIG Report at 14; Rosebush and Wagner, supra.*
16 *See 21 C.F.R. § 1301.74; see also Letter from J. Rannazzisi to All Registrants (Jun. 12, 2012) (Joseph Rannazzisi was Deputy Assistant Administrator of the Office of Diversion Control for DEA at the time); DEA, Masters Pharmaceuticals, Inc.; Decision and Order, 80 Fed. Reg. 55418 (2015).*
17 *See Presentation by James Arnold, Effective Controls Against Diversion, Manufacturer/Importer/Exporter Conference, (Jun. 2013) (James Arnold, Unit Chief, Regulatory Unit, DEA HQ in June 2013), https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/conf_2013/); see also HDMA, Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, 13 (2008).*
18 *See JOIG Report at 15.*
19 *Id. at 16.*
20 *Id. at 15.*
21 *Id. (alterations added).*
22 *See 21 C.F.R. § 1314.150 and 1314.155; see also Andrew Hull, What to do When You Receive a DEA Order to Show Cause, FDA LAW BLOG (Nov. 16, 2017), http://www.fdalawblog.net/2017/11/what-to-do-when-you-receive-a-dea-order-to-show-cause/; see also Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. 114-145 (Apr. 19, 2016*
23 *See 21 C.F.R. § 1314.155(a).*
24 *See JOIG Report at 21-22. Figure 2 reproduced from original report.*
25 *See JOIG Report at 22-23. Cardinal was the target of a prior series of OTSCs and ISOs, which led to a settlement in 2008. See Administrative Memorandum of Agreement between the U.S. Department of Justice, Drug Enforcement Administration and Cardinal Health, Inc., 1 (Oct. 2, 2008).*
26 *See Administrative Memorandum of Agreement between the U.S. Department of Justice, Drug Enforcement Administration and Cardinal Health, Inc., (May 14, 2012),*
27 *See JOIG Report at 26.*
28 *Id. at 27.*
29 *See John Gilbert and Larry Houck, About Time: DEA Acknowledges that Long-Collected ARCOS Data is an Effective Enforcement Tool That Can Assist Manufacturers and Distributors, FDA LAW BLOG (Feb. 21, 2018), http://www.fdalawblog.net/2018/02/about-time-dea-acknowledges-that-long-collected-arcos-data-is-an-effective-enforcement-tool-that-can-assist-manufacturers-and-distributors/; see also 21 C.F.R. § 1304.33(b).*
30 *See JOIG Report at 28 and 29. ARCOS does not capture data about the following nine opioid compounds: dextropropoxyphene, difenoxin, tramadol, codeine preparations, difenoxin preparations, dihydrocodeine preparations, diphenoxylate preparations, ethyl morphine preparations, and opium preparations.*
31 *See JOIG Report at 31.*
32 *See JOIG Report at 31.*
33 *21 C.F.R. 1301.74(b).*
34 *See JOIG Report at 29, 31, 46-47.*

***THANK YOU*** to Policy & Medicine Compliance Update.

We currently are accepting submissions for future issues.

To submit an article or for questions about the submission process,

please contact our Editor, Dr. Seth B. Whitelaw at

***editorial@policymed.com***

or visit our website at

***www.complianceupdate.policymed.com***



## Editorial Board





Contents