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On Your Mark, Get Set, Go: Life Science Companies Face A Challenging Year For Compliance With New Open Payment Program Data Collection And Reporting Requirements

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The Physician Payment Sunshine Act (the "Sunshine Act") – a federal law first adopted as Section 6002 of the Patient Protection and Affordable Care Act of 2010 ("PPACA") – requires the Centers for Medicare and Medicaid Services ("CMS") to collect and display information reported by applicable manufacturers and group purchasing organizations about the payments and other transfers of value these organizations have made to physicians and teaching hospitals. Currently, CMS fulfills its Sunshine Act obligations to collect and report data to the public through the "Open Payments" program.

On October 24, 2018, President Trump signed into law the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act ("SUPPORT Act"). The SUPPORT Act impacted the Sunshine Act by making significant changes to the Open Payments data collection and reporting requirements that go into effect on January 1, 2021 – *N.B.*, the reporting requirements will not be implemented until 2022 when data collected in 2021 is reported through Open Payments. On November 15, 2019, CMS issued the CY 2020 Medicare Physician Fee Schedule Final Rule ("Final Rule") which includes the regulatory enactment of the Open Payments provisions in the SUPPORT Act.

The changes to the Open Payments program as promulgated in the Final Rule will have a significant – and likely challenging – impact on life science companies that are subject to the Sunshine Act's requirements. The following is a review of these changes and some observations regarding the looming Sunshine Act implementation challenges that life science companies will face in 2021.

BACKGROUND

As noted above, the Sunshine Act was signed into law on March 23, 2010 as part of PPACA. According to the Sunshine Act, manufacturers, including certain distributors, of medical devices, drugs, biologicals, and medical supplies (collectively known as "Reporting Entities") are required to

track and report certain payments and transfers of value to physicians[1] and teaching hospitals (collectively known as "Covered Recipients.") Reported data is then made available by CMS to the public online through the Open Payments Data website.

As described by CMS on the Open Payment homepage, Open Payments is designed to promote a, "more transparent and accountable health care system by making the financial relationships between applicable manufacturers and group purchasing organizations (GPOs) and health care providers (physicians and teaching hospitals) available to the public."

In 2018, the Office of Inspector General ("OIG") of the U.S. Department of Health and Human Services conducted an Open Payments audit and issued its audit report, "Open Payments Data: Review of Accuracy, Precision, and Consistency in Reporting," in August 2018. As described in its audit report, the OIG recommended that CMS take a number of "practical steps" to, "improve the accuracy, precision, and consistency of the [Open Payments] data to better help consumers use the information." The steps include: (1) ensure that records contain all required data; (2) strengthen validation rules and revise data-element definitions so that actual drug and device names must be reported; (3) revise the definition of the device-name data element so that the information reported is required to be more specific; and (4) ensure that manufacturers and group purchasing organizations report valid NDCs for drugs.

In significant part, the SUPPORT Act was a response to the OIG's findings and recommendations. However, the SUPPORT Act and, in turn, the Final Rule go further by expanding the scope of "Covered Recipients" to include certain non-physician practitioners ("NPPs"). As some have suggested, the expansion was promulgated as a response to several factors including: (i) early criticism of the Sunshine Act and its failure to require Reporting Entities to publicly report payments to nurse practitioners or physician assistants, even though they are allowed to write prescriptions in most states,[2] (ii) state action requiring manufacturers to report their transfers of value made to those APRNs who can prescribe medications within the scope of their licenses,[3] (iii) data showing that NPPs write a substantial and increasing percentage of prescriptions nationwide,[4] and (iv) federal investigations and enforcement activity focused on the financial arrangements between pharmaceutical manufacturers and healthcare practitioners including APRNs.[5]

FINAL RULE CHANGES TO OPEN PAYMENT PROGRAM

1. **Expansion of the Definition of "Covered Recipient."** As noted above, under the Final Rule, CMS expanded the definition of "Covered Recipients," which originally encompassed only physicians and teaching hospitals, to include NPPs. As defined by the Final Rule, NPPs include physician assistants and four categories of advanced practice registered nurses ("APRNs") – Nurse Practitioners ("NPs"), Certified Nurse Specialists ("CNSs"), Certified Registered Nurse Anesthetists ("CRNAs"), and Certified Nurse Midwives ("CNMs"). According to the Final Rule, the existing Open Payments reporting exception that applies to physicians who are employed by the reporting manufacturer also applies to NPPs employed by the reporting manufacturer.

2. **New "Nature of Payment" Categories**. Pursuant to 42 CFR 403.904(e)(2), "Nature of Payment" categories are categories that must be used to describe why a payment or other transfer of value was made by a Reporting Entity to a Covered Recipient. Per the Final Rule, the Nature of Payment categories are updated to include three new categories: debt forgiveness, long term medical supply or device loan, and acquisitions.

3. **Consolidation of Nature of Payment Categories Related to Education Programs**. Pursuant to the Final Rule, CMS has consolidated the two current payment categories for continuing education programs – accredited/certified and unaccredited/non-certified – into one payment category – "Compensation for serving as faculty or as a speaker for medical education programs" – for all continuing education programs provided to Covered Recipients.

4. **New "Device Identifier" Reporting Requirements for Medical Device and Supply Product Manufacturers**. The Open Payments program requires that when Reporting Entities report payments and transfers of value related to drugs and biologics, the Reporting Entities are required to report both the name of the product as well as the associated national drug code ("NDC") number. Based, in part, on the OIG recommendations referenced above, the Final Rule will now make it mandatory for reporting device and supply product manufacturers to report the device identifier ("DI") part of the device's or supply product's applicable unique device identifier ("UDI") along with the name of the device or supply product name. The DI is a mandatory, fixed portion of the UDI that identifies the labeler and the specific version or model of the device or supply.

5. **National Drug Code Reporting Correction**. In the 2015 Medicare Physician Fee Schedule Final Rule, CMS says that it inadvertently struck a reference in the regulations that required NDCs to be reported for non-research payments. In the Final Rule, CMS states that its policy has always been to require NDCs for drugs and biologicals for both research and non-research payments in the Open Payments reports. To reflect this policy, the Final Rule adds text to the Open Payments regulations to clarify that NDCs are required for both research and non-research payments for drugs and biologicals. Unlike the other portions of the Final Rule which are effective as of January 1, 2020. The NDC correction went into effect in December 2018.

IMPLEMENTATION CHALLENGES

Per the SUPPORT Act, the changes listed above apply to data submitted on or after January 1, 2022, which will have been collected beginning January 1, 2021. As such, applicable Reporting Entities have been advised by CMS and many sources to update their policies and systems for capturing and tracking payments and transfers of value to this expanded list of providers and for reporting in compliance with the new reporting requirements – particularly those relating to medical device and supply manufacturers.

Although most Reporting Entities have likely undertaken compliance steps to update their Open Payments data collection and reporting procedures to get ready for the new rules that go into effect on January 1, 2021, it is worth noting the challenges that Reporting Entities will likely face in the implementation and operation of their updated procedures.

The following highly abridged list of challenges includes some of the obstacles that Reporting Entities will face as they seek to comply with the new Open Payments requirements:

1. **Medical Device Identifier Reporting Requirements.** It is anticipated that the new DI-reporting requirements will pose a significant challenge for device manufacturers because a single device with multiple components may have a lengthy list of related DIs.

   In FAQs issued by CMS regarding the Open Payments device data reporting requirements

(updated by CMS as of July 30, 2021), CMS left it to the reporting entity's discretion to identify the representative DI for the device/product at issue. As part of its data confirmation process, CMS will validate reported brand names and DIs against the information from the Global Unique Device Identification Database. According to CMS, reporting entities are, "responsible for making a determination about which combination(s) of brand names and device identifiers to report, but are encouraged to note any assumptions made or methodologies used to determine which device brand names and device identifiers to report in the assumptions statement."

Given the possible application of multiple DIs to a single device or product supply and the discretion that CMS is leaving with reporting entities to determine which DIs and brand names that they should report, the development and implementation of processes and procedures for identifying and reporting the appropriate DIs will be a significant challenge for device manufacturers.

2. **NPP Data Collection and Reporting.** The addition of NPPs to the list of Covered Recipients will significantly increase the number of Covered Recipients that will be reported through the Open Payments system. For example, as reported by CMS in its 2020 Open Payments Data Summary published on June 30, 2020, 2019 data covered 615,000 physicians. With the addition of NPPs to the ranks of Covered Recipients, MedPro Systems has estimated that roughly 450,000 additional healthcare practitioners with potentially reportable transactions will be added to the Open Payments 2021 data capture. This substantial increase in Covered Recipients and reportable data may put significant strain on an ill-prepared data collection and reporting program.

3. **Identification of APRN as Covered Recipients.** In its September 27, 2019 Comment Letter ("Comment Letter") to the Final Rule, the Advanced Medical Technology Association ("AdvaMed"), the leading trade association for medical device manufacturers, expressed its concern that it will be difficult for Reporting Entities to determine which APRNs should be treated as Covered Recipients for Open Payments reporting purposes. As described in the Comment Letter, the difficulty comes from the following facts:

    1. a number of NPs, CNSs, CRNAs, and CNMs do not currently have a National Provider Identifier (NPI) number;

    2. the licensing framework for these APRNs roles vary by state; and

    3. the proposed definitions may deem some APRNs as covered recipients without an advanced practice license, based only on Registered Nurse ("RN") licensure with some types of certification or education.

According to AdvaMed, the above state-to-state variations described in the Comment Letter result in more than 400 variations of state license credentials for APRNs. As a result, the Comment Letter requested that CMS revise the APRN definitions to provide greater specificity and guidance for Reporting Entities. In response, CMS stated in its commentary to the Final Rule (See, https://www.federalregister.gov/d/2019-24086/p-3137) that the Support Act mandates the use of those definitions included in the Final Rule. Therefore, CMS concluded that it does not have the authority to amend the definitions.

Notwithstanding CMS' conclusion that it could not modify and/or clarify the new NPP definitions, CMS committed to working with industry stakeholders to develop technical guidance for Reporting Entities in relation to the identification of NPPs for purposes of Open Payments reporting. To date, such guidance includes the issuance of "Open Payments Frequently Asked Questions: Covered Recipient Definition Expansion." Although these FAQs provide substantially more specificity than is provided in the Final Rule, the FAQs still leave a level discretion to Reporting Entities in the determination as to which NPPs are properly treated as Covered Recipients. As a result, Reporting Entities that have applicable financial arrangements with NPPs may have challenges in the navigation of the expanded definition of Covered Recipients.

FOOTNOTES

[1] For purposes of the Sunshine Act, the term "physician" includes doctors of medicine or osteopathy practicing medicine or surgery, doctors of dental medicine or dental surgery practicing dentistry, doctors of podiatric medicine, doctors of optometry, or chiropractors, all legally authorized to practice by their state.

[2] "Transparency Program Obscures Pharma Payments to Nurses, Physician Assistants," by Charles Ornstein, ProPublica (July 6, 2015) at https://www.propublica.org/article/transparency-program-obscures-pharma-payments-nurses-physician-assistants.

[3] In 2014, the Connecticut Legislature passed and the Governor signed Senate Bill 36, "*An Act Concerning the Governor's Recommendations to Improve Access to Health Care,"* that, effective October 2014, requires pharmaceutical and device manufacturers to report payments and transfers of value to nurse practitioners, clinical nurse specialists, nurse anesthetists, and nurse midwives.

[4] According to an IMS Health study as cited in a PLoS One Research Article, the number of prescriptions written by NPs and PAs in the U.S. more than doubled between 2010 and 2015; in 2015, NPs and PAs wrote 676 million of 4.4 billion (15.4%) prescriptions in the U.S. "Influence of pharmaceutical marketing on Medicare prescriptions in the District of Columbia," by Susan F. Wood, Joanna Podrasky, Meghan A. McMonagle, Janani Raveendran, Tyler Bysshe, Alycia Hogenmiller, and Adriane Fugh-Berman6, PLoS ONE 12(10): e0186060 (October 25, 2017) at https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0186060&type=printable.

[5] In a June 23, 2015 Press Release, the U.S. Attorney's Office of the District of Connecticut announced that an APRN practicing in the Connecticut admitted to receiving $83,000 in kickbacks—mostly as a speaker at dinner programs—from a drug manufacturer that made an oncology drug prescribed by the APRN. The U.S. Attorney's Office announced sentencing in a November 26, 2019 Press Release.

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