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New Open Payments Reporting Requirements Effective January 1, Are You Ready to Comply?

As of January 1, 2021, life sciences companies should be prepared to comply with new reporting requirements under the Open Payments program.

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act ("SUPPORT Act"), signed in 2018, expanded the reporting obligations under the Physician Payments Sunshine Act, or Open Payments program, for data collected in calendar year 2021 and reported on or after January 1, 2022.

The SUPPORT Act extends the definition of "covered recipient" to include five new provider types: (1) physician assistants; (2) nurse practitioners; (3) clinical nurse specialists; (4) certified registered nurse anesthetists and anesthesiologist assistants; and (5) certified nurse-midwives. It also expands the nature of payment categories to include: (1) debt forgiveness; (2) long-term medical supply or device loans; and (3) acquisitions. Covered entities will also be required to report device identifiers, which is intended to standardize reported data between drugs and devices.

The expansion to non-physician practitioners will require industry stakeholders to collect data and report on substantially more covered recipients and will create data collection and reporting challenges. For example, some states do not have separate licensing for the categories of non-physician practitioner types included in the expanded definition (e.g. PA, NP, CNS, CRNA, CNM), and these practitioners may not have National Provider Identifiers.

Reporting entities should carefully monitor the implementation of updated policies and their tracking capabilities to ensure data is collected and reported accurately, and they will need to determine, on a case-by-case basis in some instances, whether certain non-physician practitioners must be included in reported data. Preliminary resources prepared by CMS to aid reporting entities can be found [here](#).

CMS describes the Open Payments program, which requires applicable manufacturers and group purchasing organizations to report information about certain transfers of value made to covered recipients, as promoting a more transparent and accountable health-care system. The changes to the Open Payments program reflect increasing scrutiny from regulators regarding the potential for conflicts of interest arising from payments from drug and medical device companies to prescribers.

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