

PUBLICATION

Medicare Spreads Sunshine Act Coverage to New Categories of Payments, Recipients

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On November 15, 2019, the Centers for Medicare and Medicaid Services ("CMS") finalized changes to the Open Payments Program as part of the CY 2020 Physician Fee Schedule Final Rule.

The Open Payments program, also known as the Sunshine Act, is a statutorily mandated program that promotes transparency by providing information to the public about the financial relationships between the pharmaceutical and medical device industry, and certain types of health care providers. CMS has required applicable manufacturers and group purchasing organization ("GPOs") to report most payments and transfers of value to specified covered recipient types (U.S. physicians and teaching hospitals). CMS publishes this data in a searchable online database accessible by the general public.

The new rule expands CMS' existing Open Payments regulations to include additional practitioners in the definition of a "covered recipient." Starting with data collection for CY 2021 (reporting deadline is 2022), manufacturers will be required to track and report payments made to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives.

CMS also added three additional payment categories for reporting purposes:

- **Debt forgiveness:** This new category would be used to report transfers of value related to forgiveness of debt owed a manufacturer by a covered recipient. CMS has long required disclosure of debt forgiveness but had not previously provided a specific disclosure category.
- **Long-Term Medical Supply or Device Loan:** The Open Payments program currently excludes short-term loans of medical devices for less than 90 days or provision of less than a 90-day supply of medical supplies from the definition of reportable transfers of value. This new category would be used to categorize loans of devices or provision of supplies for greater than 90 days, which therefore do not qualify for the short-term exclusion.
- **Acquisitions:** This new category would apply to payments made in exchange for a physician's ownership interest in a company acquired by the reporting manufacturer.

CMS consolidated the two payment categories for continuing education programs – accredited/certified and unaccredited/non-certified – into one payment category for all continuing education programs.

The Open Payments program has required manufacturers and GPOs to report the National Drug Code ("NDC") when payments or transfers of value relate to specific drugs and biologicals. There was a lack of federally recognized medical device identifiers ("Dis") when CMS started the Open Payments program. Since then, the Food and Drug Administration established and continues to implement a system for the use of standardized unique device identifiers ("UDIs") for medical devices. Based upon OIG's recommendation, CMS proposed that the DI component, the mandatory fixed portion of the UDI assigned to a device, should be incorporated into Open Payments reporting. CMS also confirmed that NDCs are required for all payments that relate to drugs and biologics not just research payments; an earlier edit to the regulatory text had erroneously

deleted this requirement. CMS stated that its clarification of the obligation to include NDCs for both research and non-research payments would take effect 60 days after publication of the final rule.

The expansion of Sunshine reporting will mean greater tracking obligations for providers, suppliers and manufacturers. It closes a few loopholes and makes clear that transactions outside of conventional compensation arrangements are no longer outside the spotlight.