

CMS Issues Proposed Revisions to Open Payments/Sunshine Act Reporting Requirements

August 2, 2019

Key Points:

- On July 29, 2019, CMS released its proposed 2020 Physician Fee Schedule rule, which includes the much anticipated proposed regulatory changes to the Sunshine Act/Open Payments program (“Open Payments”).¹ The proposed regulations incorporate the SUPPORT Act’s expansion of the Sunshine Act to include advanced practice registered nurses, nurse practitioners, and other nonphysician health care professionals.² Companies are required to start tracking this information on January 1, 2021.
- CMS has also proposed to consolidate certain nature of payment categories associated with educational grant funding and to add three new payment categories for debt forgiveness, product evaluations/loans and acquisition-related payments.
- CMS reaffirmed its requirement to disclose NDCs (for drugs) and incorporated a proposal to require medical device makers to include a device identifier derived from UDI for each disclosure.
- Comments are due September 27, 2019, at 5:00 p.m. Eastern.

What Is the Open Payments Program?

Created by the U.S. Physician Payments Sunshine Act (as included in the Affordable Care Act of 2010), The Centers for Medicare and Medicaid Services (CMS) Open Payments program is responsible for regulatory oversight of pharmaceutical, biologics and medical device companies’ annual Sunshine disclosures of payments and transfers of value made to physicians and teaching hospitals in the United States.³ Put simply, the Sunshine Act requires 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), and requires CMS to make this information available to the public.⁴

Contact Information

If you are interested in filing comments in response to CMS’s proposed updates to the Open Payments regulations or if you would like to discuss the proposals in more detail, Akin Gump is ready to assist. Please reach out to one of the following for support:

Matthew Wetzel

Senior Counsel
mwetzel@akingump.com
Washington, D.C.
+1 202.887.4221

Taylor Jones

Senior Counsel
tjones@akingump.com
Washington, D.C.
+1 202.887.4278

Marlee Gallant

Associate
mgallant@akingump.com
Washington, D.C.
+1 202.887.4252

Adam Axler

Associate
aaxler@akingump.com
Washington, D.C.
+1 202.887.4256

What Changes Did CMS Propose?

CMS proposed three changes to the program: (1) updating the definition of covered recipients; (2) adding new payment categories for reporting; and (3) requiring inclusion of device identifiers for medical devices in reports.

1. Updating definition of covered recipient to align with the SUPPORT Act

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) expanded the statutory definition of “covered recipient” to include a number of nonphysician health care professionals, with respect to reports submitted on or after January 1, 2022.⁵ **This means that applicable manufacturers and GPOs must report payments and transfers of value made in 2021 to the expanded list of covered recipients.** The proposed rule would expand CMS’ existing Open Payments regulations to include these provider types in the definition of a “covered recipient.”

The expanded list of covered recipients will include, in addition to physicians and teaching hospitals, the following health care professionals:

- Physician assistants (PAs)
- Nurse practitioners (NPs)
- Clinical nurse specialists (CNSs)
- Certified registered nurse anesthetists (CRNAs)
- Certified nurse midwives (CNMs).

CMS did not provide guidance as to whether the agency will offer a list of these covered recipients for applicable manufacturers and GPOs to use in preparing their Sunshine data. Nor did CMS provide information about the data set it plans to use in validating manufacturers’ submissions associated with these new covered recipients.

2. Adding new payment categories for reporting

As part of the Sunshine Act’s requirements, for each payment or transfer of value, manufacturers must include the “nature of payment.”⁶ The statute and the regulations promulgated by CMS both include several payment categories for companies to use in disclosing this information. If a payment or transfer of value does not have a specifically assigned category, CMS has instructed manufacturers to use their best judgment. Although the “gift” category is not intended to serve as a miscellaneous reporting category, manufacturers have occasionally used it as such, which can be misleading.

In the proposed 2020 Physician Fee Schedule, CMS offered to combine two existing payment categories and add three new categories to provide greater clarity for industry in submitting Open Payments data.

- First, CMS proposed to combine reporting categories for “accredited/certified” and “unaccredited/non-certified continuing education programs.” CMS stated that although they “defined separate categories at the inception of the Open Payments program [they] no longer believe that the distinction in this category is necessary.”
- Second, CMS proposed to add the following reporting categories:

- A. *Debt forgiveness*: This new category would cover transfers of value related to forgiving the debt owed a manufacturer by a covered recipient. CMS has long required disclosure of debt forgiveness,⁷ but has not provided an adequate disclosure category.
- B. *Long-Term Medical Supply or Device Loan*: The Open Payments program currently excludes 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 transfers of value.⁸ CMS has stated that, for evaluations over 90 days in length, the manufacturer must report the evaluation, starting on day 91.⁹ Despite CMS' requirement, the agency did not provide an adequate category for manufacturers to use in making these disclosures. This new category would cover loans of devices or provision of supplies for greater than 90 days, which therefore do not qualify for the short-term exclusion.
- C. *Acquisitions*: This new category would cover buyout payments in exchange for a physician's ownership interest in a company acquired by the reporting manufacturer. Although the moniker "acquisitions" may require amendment to include any kind of payment made to a physician owner in the course of a corporate transaction, the addition of this new payment category should serve to add better clarity and context for Open Payment reporting.

3. Requiring inclusion of device identifiers in reporting

The Open Payments program also currently requires applicable manufacturers and GPOs to report the name of the product and the National Drug Code (NDC) when payments or transfers of value relate to specific drugs and biologicals.¹⁰ CMS has proposed to extend this practice to device manufacturers, **requiring them to include the device identifier (DI) (i.e., the fixed portion of the Unique Device Identifier (UDI) assigned to a device)**. 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.

What Should Companies Know?

- *Effective Dates*: If CMS finalizes these proposals they would be effective for transfers made on January 1, 2021, and after. Additionally, CMS explicitly stated that its clarification of the obligation to include NDCs for both research and nonresearch payments would take effect 60 days after publication of the final rule.
- *Guidance on Enforcement*: CMS did not provide any clear guidance on how it plans to validate company reports on the expanded covered recipient list, or whether CMS would plan to publish a comprehensive list of individuals who qualify as part of this expansion. This may prove to be a practical and administrative challenge for the agency, but one that would appropriately serve manufacturers as they seek to comply with the Sunshine Act.
- *Deadline for Comment*: Comments on the proposed rule are due at 5:00 p.m. Eastern on September 27, 2019.

¹ CMS, CY 2020 Revisions to Payment Policies under the Physician Fee Schedule; Proposed Rule (issued July 29, 2019), available at <https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-16041.pdf> (to be published in the Federal Register on August 14, 2019).

² Pub. L. No. 115-271, § 6111(a)(1), (b), 132 Stat. 3894, 4006-07 (2018).

3 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6002, 124 Stat. 119, 689-96 (2010).

4 See 42 U.S.C. § 1320a-7h.

5 Pub. L. No. 115-271, § 6111(a)(1), (b), 132 Stat. 3894, 4006-07 (2018).

6 See 42 U.S.C. § 1320a-7h(a)(1)(A)(vi); 42 C.F.R. § 403.904(e).

7 CMS, Open Payments: Frequently Asked Questions 11, <https://www.cms.gov/OpenPayments/Downloads/open-payments-general-faq.pdf> (updated June 28, 2019).

8 42 U.S.C. § 1320a-7h (e)(10)(B)(iv).

9 Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9487 (Feb. 8, 2013) (final rule).

10 See 42 C.F.R. § 403.904(f)(1)(iv).

akingump.com