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A bit more Sunshine: CMS proposes collecting additional information on manufacturer payments under the Open Payments program

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Device and drug manufacturers got a small surprise in the annual Physician Fee Schedule proposed rule[1] issued late in July by the Centers for Medicare & Medicaid Services (CMS) – among many other things, the proposed rule would make a few changes to manufacturer reporting requirements under the Open Payments program. Although the proposed changes would require manufacturers to capture new covered recipients and (for device manufacturers) report an additional device identifier, many companies should be able to leverage existing systems to respond to the new requirements. Manufacturers may want to build the new device identifier and nature of payment categories into their systems for calendar year (CY) 2020, and consider using CY 2020 as a practice year for tracking payments to new covered recipients before those requirements take effect in CY 2021.

Open Payments 1.0

Enacted as part of the Affordable Care Act, the Open Payments program requires manufacturers of drugs and medical devices for which payment is available under Medicare or Medicaid to report most payments and transfers of value that they make to covered recipients, currently defined as U.S. licensed physicians and teaching hospitals, as well as ownership interests held by physicians and their immediate family members. To comply with the law, applicable manufacturers have been tracking payments and ownership interests since August 2013 and submitting disclosure reports to CMS each March.[2]

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[1] Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations, CMS-1715-P (August 14, 2019), available at https://www.govinfo.gov/content/pkg/FR-2019-08-14/pdf/2019-16041.pdf at 40,713-16.

[2] See Hogan Lovells client alert available at https://www.hoganlovells.com/en/publications/the-sunshine-act-takes-effect-key-provisions-of-the-final-rule.

New covered recipients

CMS proposes to expand the definition of covered recipient as required by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act, a wide-ranging opioid bill enacted in 2018. Beginning with payments and transfers of value made in CY 2021, applicable manufacturers must report payments and transfers of value to:

- Physician assistants, nurse practitioners, and clinical nurse specialists, each as defined in Social Security Act (SSA) § 1861(aa)(5).
- Certified registered nurse anesthetists, as defined in SSA § 1861(bb).
- Certified nurse midwives, as defined in SSA § 1861(gg).

Manufacturers would continue to report payments and transfers of value to physicians and teaching hospitals. Payments to the new categories of practitioners would be reported in the same way and under the same rules and exclusions as payments to current covered recipients. The law does not require companies to report ownership interests held by these practitioners or their families.

CMS's proposal is a narrow implementation of the legislation enacted by Congress and manufacturers will have the next year to prepare their systems for compliance. Many companies do not have significant interactions with these allied professionals and will not need to make major changes to their reporting systems, but all manufacturers should take a look at previous years' reports to consider whether changes are needed. For example, employees giving group meals will need to be sure that new covered recipients' names are recorded, and companies that contract with nurse advisers or provide training to nurses or other licensed technicians will need to report those payments. Applicable manufacturers may want to use CY 2020 as a test year for tracking such payments and transfers of value to ensure complete reporting beginning in CY 2021.

New device identifier

For payments or transfers of value that are related to a covered product, CMS proposes to require manufacturers to report the Device Identifier (DI) for devices and the National Drug Code (NDC) for drugs and biologicals in both the research and non-research context. The more significant change is the DI requirement. U.S. Food and Drug Administration (FDA) rules already require device manufacturers to label each device with a DI, but in many cases a single brand of device may carry multiple DIs (for different sizes, configurations, and so forth). In those cases, device manufacturers may need to choose a default DI to report when a payment relates to a specific device but not a specific DI. Companies also should ensure that line extensions, updates, or other modifications that result in replacement of the DI on packaging are carried through to their Open Payments reporting systems.

New "nature of payment" categories

Finally, CMS proposes to create new "nature of payment" categories for debt forgiveness, long-term medical supply or device loans, and acquisitions. The proposed rule does not purport to expand manufacturers' reporting obligations and most payments or transfers of value that would fit these categories are currently reportable under Open Payments. Rather, the proposed revisions allow covered manufacturers to more accurately describe the nature of these payments instead of using a workaround category that may mischaracterize what are often substantial payments.

- "Debt forgiveness" would be used for transfers of value related to forgiving the debt of a covered recipient, a physician owner, or an immediate family member of a physician who holds an ownership or investment interest.
- "Long-term medical supply or device loan" would be used for loans of covered devices and medical supplies for longer than 90 days (and therefore not eligible for the 90-day device loan exclusion).
- "Acquisitions" would be used for buyout payments made to covered recipients related to the acquisition of a company in which the covered recipient has an ownership interest.

CMS will accept comments on the proposed rule until September 27, 2019.

If you have any questions about the Open Payments program or any related topic, please contact the authors of this alert or the Hogan Lovells lawyer with whom you work regularly.

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