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HealthCare Appraisers' Industry Insight

CMS PROPOSED UPDATES TO OPEN PAYMENTS PROGRAM

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The Centers for Medicare and Medicaid Services' (CMS) Proposed Rule for the 2022 Physician Fee Schedule (as of July 2021)¹ includes updates to the Open Payments Program to require additional information with respect to the relationships between providers and various pharmaceutical and life sciences companies. The proposals are intended to provide more and higher quality information to the general public in relation to these payments.

As part of the proposals, CMS sets forth a specific definition of a Physician Owned Distributor (POD) and POD reporting requirements. Under the Proposed Rule, CMS defines a POD as an entity that meets the definition of an applicable manufacturer or applicable group purchasing organization (GPO). Furthermore, the POD must meet at least one of two additional conditions, as follows:

- The POD has a minimum of 5% direct or indirect ownership or investment interest in the applicable manufacturer or GPO held by a physician or a physician's immediate family member.
- A physician or a physician's immediate family member receives direct or indirect compensation or remuneration from the applicable manufacturer or GPO, derived from the sale or distribution of devices by the applicable manufacturer or GPO in which the physician or physician's immediate family member has ownership.

With regards to organizations under common ownership with PODs that report on a consolidated report, CMS expands on the above conditions in the Proposed Rule. Such organizations are only required to register as a POD if the organization meets the 5% ownership requirement when ownership of all entities in the disclosure is calculated, regardless as to whether a physician has a controlling interest in the reporting entity, and inclusive of indirect ownership interests. Furthermore, organizations that meet the definition of a POD must identify as PODs within a disclosure. These changes expand upon the quantity of covered organizations required to disclose physician-owner payment information. The net effect of these changes may translate to an increase in enforcement actions.

In addition to expanding upon the quantity of covered organizations, CMS is further modifying the Open Payments Program to increase the quantity of reported payments. CMS is proposing language within the rule that will prevent organizations from deleting or modifying disclosures that have been submitted unless an error is discovered in the disclosure. Furthermore, CMS will no longer allow organizations to delay payment disclosures. Currently, organizations may delay the disclosure of payment information if the payment relates to research and development or clinical investigation

¹ CY 2022 Medicare Physician Fee Schedule Proposed Rule, 86 Fed. Reg. 39104 (July 23, 2021), last accessed August 18, 2021 from: <https://www.federalregister.gov/documents/2021/07/23/2021-14973/medicare-program-cy-2022-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part>



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activities for new drugs, devices and biologicals. CMS indicates that reporting delays may occur as a result of ancillary payments (e.g., airfare travel) not specifically outlined in a compensation arrangement. However, CMS has taken the position that payments related to the primary purpose of the agreement should not be held up by ambiguity surrounding ancillary payments.

Last, CMS is now requiring organizations to ensure that their contact information remains current provided that the organization has made reportable payments within the past two (2) calendar years. CMS is proposing this change to ensure that organizations may be contacted for irregularities or non-compliance in connection with the Open Payments Program.

KEY TAKEAWAYS

The above proposals are intended to increase the quantity of open payment information released to the general public. They reflect the continued and increasing scrutiny that the government places on payments from life science companies to providers. For these reasons, it is even more important that reporting entities ensure that payment relationships are commercially reasonable and consistent with FMV.

HealthCare Appraisers has extensive experience valuing the services that physicians and other providers supply to life science companies. Additionally, we have utilized the insights reported by the Open Payment Program datasets to render defensible opinions of commercial reasonableness and fair market value. **Contact us with any questions you may have.**

