

What's New in GCP? CMS Proposed Rule on Payment Disclosure Details Research Fee Requirements and Delayed Posting

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The Center for Medicare and Medicaid Services' (CMS) long-awaited proposed rule on disclosure of industry payments to physicians and institutions spells out the requirements for research payment disclosure, as well as for delayed publication of the information on a public website.

The proposed rule, released Dec. 19, implements the requirements in the 2010 Patient Protection and Affordable Care Act that medical product manufacturers covered by Medicare, Medicaid or the Children's Health Insurance Program file annual reports with CMS detailing payments and other transfers of value (including gifts) to physicians and teaching hospitals, as well as physicians' ownership or investment interests in a manufacturer.

"Disclosure of these relationships will discourage the inappropriate influence on clinical decision-making that sometimes occurs while still allowing legitimate partnerships," Peter Budetti, CMS deputy administrator for program integrity, said in announcing the proposed rule. The increased transparency is intended to help reduce the potential for conflicts of interest that physicians or teaching hospitals might face as a result of their relationships with manufacturers.

Defining Bona Fide Research

CMS wants to limit the research category "to bona fide research activities, including clinical investigations that are subject to both a written agreement or contract between the applicable manufacturer and the organization conducting the research, as well as a research protocol."

CMS noted that reporting research payments or other transfers of value "may be complicated, since many research activities include large payment amounts, which are spread across numerous activities and parties." In addition, the payments "are often not provided directly to a covered recipient, but to a clinic, hospital or institution administering the research that is often led by a physician covered recipient(s) as the principal investigator(s)." And the research scenario "is further complicated" because many manufacturers use contract research organizations (CROs) and site management organizations to manage their clinical research.

CMS proposed separating the classification of research payments to clarify whether the payment or other transfer of value went indirectly or directly to the covered recipient. The indirect research category would be used when a research payment is made to a clinic, hospital (other than a teaching hospital), or institution conducting the research (either by a manufacturer or a CRO) and that organization in turn pays the physician covered recipient (or multiple physician covered recipients) serving as a principal investigator(s).

A direct research category would be used when a research payment is provided directly to a physician or teaching hospital covered recipient by a manufacturer or CRO.

“When reporting indirect or direct research, we propose that the payment or other transfer of value should be reported individually under the names and [National Provider Identifiers] of physician covered recipients serving as principal investigators. For indirect payments, this includes the physician covered recipient(s) serving as principal investigator(s) who would ultimately receive payments from the clinic, hospital or other research institution, assuming the applicable manufacturer is aware of the identity of the principal investigator(s).”

CMS wants comment on whether the proposed method is viable and not overly burdensome, and whether an alternative method would be better.

Teaching Hospital Concerns Detailed

Teaching hospitals also are defined as covered recipients, and may conduct research led by physician covered recipients acting as principal investigators. “While these payments could be reported as direct research to the teaching hospital covered recipient, we do not want to establish different reporting requirements for physician covered recipients acting as principal investigators at teaching hospitals versus other research institutions,” the agency said. “To maintain consistency, we propose that research payments provided to teaching hospitals and ultimately to physician covered recipients must be reported for both the teaching hospital covered recipient and the physician covered recipient(s). The payment or other transfer of value to the teaching hospital covered recipient should be reported as a direct research payment, whereas the payment or other transfer of value for the principal investigator(s) (physician covered recipient(s)) should be reported as indirect research.”

CMS added that “reporting the amount of the payment or other transfer of value may be difficult because neither the applicable manufacturer nor the CRO generally know how the research payment is distributed because the payment includes all items and activities associated with the research project, not only the physician’s time and services. This is particularly important for indirect research, since a principal investigator(s) may be receiving his/her usual salary from the institution for conducting the study.”

In addition, CMS said “the total costs should be attributed personally to the principal investigator(s). However, we do believe it would be burdensome for applicable manufacturers to accurately determine the exact amount a physician covered recipient received. Finally, we also believe that reporting the total research payment amount provides additional transparency to end users about the applicable manufacturers’ total research payments.”

CMS proposed that for both direct and indirect research, manufacturers report the entire payment amount for each research payment (whether to the covered recipient or research institution), rather than the specific amount that was provided to the covered recipient. However, on the public website, CMS would report the payment amounts separately and not aggregate it into the total for physician covered recipients.

“For teaching hospitals, we believe end users would understand that the research payment covered all aspects of the research, so we believe it is appropriate to aggregate this into the teaching hospital’s total payment amount. However, for physician covered recipients we believe attributing the full research payment to the physician could be misleading, due to the nature of research payments as described.” The agency wants comment on this proposal.

CMS also is considering attributing the total payment to the covered recipient for direct research. “We believe this may be necessary because in direct research, the covered recipient is individually receiving the payment, so the specific amount the covered recipient is receiving is clearly defined and available to the applicable manufacturer.”

The agency noted that proposed reporting requirements “may not cover all circumstances in which applicable manufacturers make payments or other transfers of value to covered recipients for research-related activities (for example, post-marketing research or other research or studies not conducted pursuant to a written contract between the applicable manufacturer and the organization conducting the research, and those studies without a research protocol).” CMS wants comments about which existing nature-of-payment category would apply to these other types of research, whether the scope of the “research” nature of payment should be broadened, and/or whether another nature-of-payment category should be added to address such research.

The agency also noted that “some of the reporting requirements will duplicate requirements already required under FDA regulations at 21 C.F.R. Part 54.”

Delayed Public Disclosure Addressed

CMS noted that the Affordable Care Act provides for delayed publication of payments “made pursuant to product research or development agreements or clinical investigations.” Delayed public disclosure “aims to maintain confidentiality for proprietary information relating to development” of new medical products.

The statute requires public disclosure “on the first publication date after the earlier of either: (1) the approval, licensure or clearance by the FDA of the covered drug, device, biological or medical supply; or (2) four calendar years after the date of payment.”

CMS proposed that manufacturers indicate on their annual reports whether or not the disclosure should be delayed. “In the absence of notification by an applicable manufacturer that a payment or other transfer of value is subject to delayed publication, we would have no way of knowing that such a payment or other transfer of value should not be published. In addition, we propose that payments or other transfers of value subject to delayed reporting need to be reported each year with a continued indication that publication should remain delayed and any updated information on the payment or other transfer of value, as necessary.”

Up to Manufacturers to Indicate When Publication Delay Is Over

CMS also proposed that following FDA approval, licensure or clearance, manufacturers must indicate in their next annual submission that the payment should no longer be granted a delay and should be published in the current reporting cycle. “Failure to indicate to CMS in a timely fashion that a payment or other transfer of value should no longer be granted a delay in publication, due to FDA approval, licensure or clearance, may be subject to penalties.”

The Affordable Care Act provides that violators of the reporting requirements will be subject to civil monetary penalties capped at \$150,000 annually for failing to report, and \$1 million for knowingly failing to report.

And if a report includes a date of payment four years prior to the current year, then the payment would be automatically published, “regardless of whether the applicable manufacturer indicates that the payment should be delayed.”

CMS noted that with annual publication, “it is difficult to grant each payment an exactly four-year delay and we recognize that payments made early in the year would be granted more than a full four-year delay period under this proposal. We believe that this method is preferable because it allows all payments, even those made late in the year, a full four-year delay.” Again, CMS wants comments on this proposal.

"To ensure that the payments or other transfers of value granted a delay are for bona fide research, we propose that the 'product research or development agreement' referenced in the statute include a written statement or contract between the applicable manufacturer and covered recipient, as well as a written research protocol," the agency said. Additionally, the statute defines "clinical investigation" as "[a]ny experiment involving one or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed or used." "We propose that in the context of this definition, a clinical investigation is limited to one that is memorialized in a written research protocol between the covered recipient and the applicable manufacturer."

In cases where a CRO is involved, "as long as the applicable manufacturer has a written agreement with the CRO, we propose that the CRO may have the written research agreement with the covered recipient, rather than the applicable manufacturer."

What Is Medical Technology?

Noting the statute provides for delayed publication of payments for services furnished in connection with research on "medical technology" with regard to both research on potential new medical technologies and new applications of existing medical technologies, as well as for services furnished in connection with the development of, or a clinical investigation for, a new medical product but not for a new application of an existing product, "we propose to consider 'medical technology' broadly, as any drug, device, biological or medical supply. We propose this interpretation because we believe that the rationale underlying the statutory inclusion of the delayed publication provision — protecting an applicable manufacturer's legitimate proprietary and competitive interests in research and development — should apply to all applicable manufacturers under this statute. Moreover, it is difficult to fairly carve out certain applicable manufacturers or certain products for differing standards of delayed publication. Alternatively, we are considering defining 'medical technology' more narrowly as a subset of drugs, devices, biologicals and medical supplies." CMS wants comments on both approaches, including suggestions for a narrower definition of "medical technology."

The statute also distinguishes between the scope of delayed publication permitted for payments related to "research" and those for "development" or "clinical investigations."

"Delayed publication is allowed for payments or other transfers of value for research-related services for both new medical technologies and new applications of existing medical technologies, whereas, delayed publication for development and clinical investigations are limited solely to new drugs, devices, biologicals and medical supplies. It is difficult to meaningfully separate research and development due to the overlap in the activities associated with them, and the fact that they are commonly used synonymously," CMS said.

"Given this close association between the terms, we propose to treat them similarly," the agency said. "However, we are also considering the possibility of assigning different meanings to 'research' and 'development,' and we seek comments on this approach and suggestions for meaningful distinctions for the two terms."

The agency added that it believes "clinical investigations," has a distinct meaning in the statute that "is separate from both 'research' and 'development,'" in that the statute provides that clinical investigations involve human subjects or materials derived from human subjects. "We note that this definition may differ from those that applicable manufacturers may be familiar with in 21 C.F.R. §312.3 and §812.3."

Given these interpretations, CMS proposed that delayed publication should apply to payments to covered recipients for services in connection with research on, or development of new products, as well as new applications of existing products. "Conversely, we propose

limiting delayed publication for payments in connection with clinical investigations for new drugs, devices, biologicals or medical supplies, and not new applications of existing drugs, devices, biologicals or medical supplies.”

The agency wants comments on this proposal and “whether there are better ways to distinguish among these categories for the purposes of delayed publication, including treating payments and transfers of values made in connection with clinical investigations the same as those made in connection with research and development.”

CMS noted that the information subject to delayed publication “shall be considered confidential and shall not be subject to disclosure under 5 U.S.C. 552, or any other similar federal, state or local law, until after the date on which the information is made available to the public.”

A final rule is expected to be released sometime in 2012. Depending on when a final rule is released, CMS proposed that manufacturers be required to submit a partial year report on Mar. 31, 2013. Once the data is submitted, CMS will aggregate the submissions at the individual physician and teaching hospital levels, provide them with 45 days for review and, if necessary, data correction, and make the data publicly available by Sept. 30, 2013.

Under the proposal, electronic records would be due annually on the 90th day of each year. Manufacturers are exempt from reporting if they made no reportable payments or transfers of value for the previous calendar year.

To Find Out More

The proposed rule is available at <http://www.gpo.gov/fdsys/pkg/FR-2011-12-19/pdf/2011-32244.pdf>.

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