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Marilyn Tavenner
Administrator
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare and Medicaid Services
Department of Health and Human Services

Office of Information and Regulatory Affairs
Office of Management and Budget
Executive Office of the President
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Document Identifier: CMS-10495, Agency Information Collection Activities Relating to the Revision of Registration, Attestation, Dispute & Resolution Assumptions Document and Data Retention Requirements for Open Payments, 79 FR 25596
Submitted at www.regulations.gov

Dear Administrator Tavenner,

The Association of American Medical Colleges (AAMC) appreciates that the Centers for Medicare and Medicaid Services (CMS) has called attention to and invited specific comments on the dispute resolution and corrections processes in the collection activity in the above referenced announcement. The AAMC is a not-for-profit association representing all 141 accredited U.S. and 17 accredited Canadian medical schools, nearly 400 major teaching hospitals and health systems, and 90 academic and scientific societies. Through these institutions, the AAMC represents 128,000 faculty members, 83,000 medical students, 110,000 resident physicians, and thousands of graduate and post-doctoral trainees in the biomedical sciences.

The AAMC recognizes that the dispute resolution and corrections processes, as described in the supplemental documents to the request for comment, have been fleshed out significantly since the original proposed information collection was submitted to OMB. The AAMC focuses its comments here on those specific dispute initiation and resolution processes. The process for notifying physicians and teaching hospitals about the availability of records to review, and for initiating and resolving disputes about the information to be made publicly available, is critical to the accuracy and utility of the Open Payments Program. **The AAMC strongly encourages CMS to revise and clarify the process for initiating and resolving disputes through the Open Payments Program and to ensure that the publicly available database accurately reflects whether each disputed payment has been resolved to the satisfaction of both the applicable manufacturer or applicable group purchasing organization (GPO) and the physician or teaching hospital initiating the dispute.**

As described in the notice, the “Sunshine” provisions in Section 6002 of the Affordable Care Act (ACA) reflect Congress’ intent that pharmaceutical, device or other manufactures of covered products annually

report to CMS payments or transfers of value made to physicians and teaching hospitals (“covered recipients”). CMS is required to make that information available to the public after the physicians and teaching hospitals have had an opportunity to review the reported information and dispute any listed payments that appear to be incorrect. The final rule (78 FR 9458) further specifies that if an initiated dispute “is not resolved by 15 days after the end of the 45-day review and correction period, CMS publicly reports and aggregates the applicable manufacturer’s or applicable group purchasing organization’s version of the payment or other transfer of value, or ownership or investment interest data, but marks the payment or other transfer of value or ownership or investment interest as disputed.” Thus, any record not marked as “disputed” is presumed to be either accurate as originally submitted or resolved after communication between the parties (i.e., the manufacturer and the covered recipient).

Supplemental material provided by CMS in association with this Comment Request includes drafts of email notifications that would be sent to applicable manufacturers or applicable GPOs 1) when a covered recipient makes a comment about a payment or other transfer of value or ownership or investment interest, 2) when a covered recipient initiates a dispute, or 3) when a dispute is withdrawn by a physician or teaching hospital. The supplemental material also includes draft email notifications that would be sent to a covered recipient when an applicable manufacturer or applicable GPO has: 1) acknowledged that a dispute has been initiated, 2) **dismissed** a dispute, or 3) resolved a dispute.

The AAMC is deeply concerned that these draft notifications suggest that applicable manufacturers or applicable GPOs may simply *dismiss* an initiated dispute without resolution or the express agreement by a covered recipient.¹ This jeopardizes the accuracy of the reported information and could lead to serious negative consequences for physicians, teaching hospitals, manufacturers and CMS. We recommend the following changes or clarifications to the process and email notification text so that the Open Payments Program is more accurate, useful, and meets the requirements of the program as set forth in the ACA and in the final rule implementing the provisions.

- **CMS should remove the ability to “dismiss” a dispute from the proposed system and leave the options to acknowledge the dispute and then to report a resolution between the parties.** The draft notification to covered recipients following a dismissal of a dispute states, “If you disagree with this dispute dismissal, you may dispute this transaction again.” The burden of determining whether there is an error in the information and understanding why reported information was disputed should lie with the reporting entity, not with a physician or teaching hospital. Without further communication from an applicable manufacturer, we would expect that each unilaterally dismissed record should be disputed again. The need to communicate this additional step to every individual who disputes a record decreases the likelihood that legitimately disputed records will be resolved or correctly presented to the public. Further, the short timeline for reviewing and correcting the information does not allow for multiple rounds of disputing dismissed records. If a covered recipient disputes a payment within the 45-day review window and an applicable manufacturer dismisses the dispute in the 15-day resolution window, a physician or teaching hospital cannot timely dispute the record before publication of the data that year.

¹ The draft notification entitled Dispute Initiated by the Physician of Teaching Hospital, intended to be sent to the applicable manufacturer or GPO reads in part: “You may resolve the dispute by submitting and attesting to the corrected data. After reviewing the disputed information, if you determine that no change is required to the data, you may dismiss the dispute or request that physician or teaching hospital who initiated the dispute to withdraw it.”

- **CMS should ensure that “dismissed” records (if that option is retained) and those marked as “resolved” by an applicable manufacturer or GPO but *not* by the subject of the record are marked in the Open Payments database as “disputed” and thus unresolved.** A physician or teaching hospital should expect that once a dispute is initiated, the only two possible results are 1) that the dispute is resolved to the satisfaction of both parties (with or without a change in the information presented on the database) or 2) that the information is marked in the public database as disputed. The data collection process through Open Payments should make this clear to all parties. We are concerned, given the potentially large number of disputes and volume of email, that this system depends on physicians and teaching hospitals assertively following up on information they believe to be incorrect to ensure that it is not misrepresented as correct in the database. This presumption not only threatens the accuracy of the information in Open Payments, it greatly increases the administrative burden on physicians and teaching hospitals.
- **CMS should make explicit that an applicable manufacturer or GPO cannot unilaterally dismiss or resolve a dispute and expect that the information will be reported as fact without qualification.** This information should be made clear in FAQs and other documents on the Open Payments website as well as in the email notifications presented in draft form in the supplemental materials. It is essential that the public be able to see if manufacturers and recipients continue to disagree about the veracity of information posted.

The key to transparency is ensuring that the information in question is accurate and presented in a meaningful and useful context. The dispute initiation and resolution process within Open Payments is the only check on the accuracy of the reported information. Although the rule itself includes penalties for failure to report accurate information, the consequences of having inaccurate information in the database are potentially much greater for physicians and teaching hospitals. Erroneous or misleading records about payments made by manufacturers can have serious repercussions to an individual’s reputation and career. A miscategorized payment or one that is reported as larger than the actual amount can place an individual at risk of appearing to have violated institutional policies, professional standards, or other legal or ethical requirements. Congress, individuals and institutions who will be listed in the database, and the American public need to know that the information ultimately presented has been reviewed by those who are the subjects of the reports and that CMS has taken every opportunity to confirm that the database more faithfully represents transparency into the relationships between manufacturers and health care providers.

The AAMC is again grateful for this opportunity to comment and we look forward to working with CMS as it moves toward the launch of the complete Open Payments Program. Please contact Heather H. Pierce, J.D., M.P.H. at hpierce@aamc.org with any questions or for further information.

Sincerely,



Ann C. Bonham, Ph.D.
Chief Scientific Officer