June 2, 2014

Via Electronic Delivery and United States Mail

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulatory Development
Attention: CMS-10495
Room C4–26–05
7500 Security Boulevard
Baltimore, Maryland 21244–1850

Re: AdvaMed Comments on CMS-10495: Agency Information Collection Activities: Submission for OMB Review; Comment Request

Dear Administrator Tavenner:

The Advanced Medical Technology Association (“AdvaMed”) is pleased to comment on the Department of Health and Human Services, Centers for Medicare & Medicaid Services (“CMS”) above-referenced information collection request related to the dispute resolution and corrections process of Open Payments, the program implementing Section 6002 of the Affordable Care Act (“ACA”) and the final rule implementing the same (the “Final Rule”).

Below we include our comments and recommendations with respect to the dispute resolution and corrections process and the CMS website related to the same (the “System”).

Applicable manufacturers should be able to designate a dispute resolution and corrections contact person and such contact person should be notified of initiated disputes in real time.

We recommend that CMS allow applicable manufacturers to designate within the Open Payments system an individual or individuals to serve as the dispute resolution and corrections contact person. Such individual(s) should be notified if a covered recipient or physician owner or investor initiates a dispute and provided access to the information submitted by the disputing covered recipient or physician owner or investor. The same dispute resolution and corrections contact person should be allowed to serve as the contact person for affiliated applicable manufacturers. Just as some companies may opt to submit consolidated reports, some companies may also opt to centralize the dispute resolution and corrections process such that disputes related to payments or other transfers of value made by any affiliated applicable manufacturer will all be addressed by the same individual or department.

We also recommend that CMS immediately notify the dispute resolution and corrections contact person of disputes as they are initiated in the System by covered recipients and physician owners.
and investors. Given the limited time period available for dispute review, correction and resolution prior to the public release of the data, it is important that applicable manufacturers are notified of disputes as soon as they are initiated so that applicable manufacturers may begin the resolution process as soon as possible. Based on information released by CMS pursuant to the above-referenced CMS Form Number, it is our understanding that CMS intends to utilize email notifications.\(^1\) In addition, it is our understanding that the System will include a “Disputed and Commented Records Page,” which will allow applicable manufacturers to review all records that have been disputed or selected for comments by a physician or teaching hospital, regardless of status.\(^2\) We agree with these proposals. In order to ensure immediate notice, we recommend CMS provide notice of an initiated dispute to the appropriate contact person via email, as CMS has proposed. In addition, the System should allow applicable manufacturers to log in and view all disputes in real time, as CMS has proposed. All disputes initiated in the System should include a time stamp of when the dispute was initiated, with such detail visible to applicable manufacturers. Finally, we request that the System provide the means for applicable manufacturers to review not just pending disputes, but all initiated disputes, including those that have been resolved. This is necessary to ensure that applicable manufacturers have the opportunity to use this information to refine processes in hopes of avoiding future disputes of the same nature.

_The System should include specific electronic fields and should allow covered recipients to dispute only certain aspects of a transfer of value._

In the preamble to the Final Rule, CMS stated that if a covered recipient or physician owner or investor decides to initiate a dispute, he or she will be directed to fill out electronic fields detailing the dispute, including the proposed corrections.\(^3\) In contrast, information released by CMS pursuant to the above-referenced CMS Form Number, indicates that the only information covered recipients and physician owners or investors initiating a dispute will be directed to complete is a free-form text box.\(^4\) Further, covered recipients and physician owners or investors may choose to dispute one, multiple, or all records reported and may do so by completing a single free-form text box for all such disputed records.\(^5\)

We agree with CMS’ proposal in the preamble to the Final Rule to require covered recipients and physician owners and investors to provide detail regarding the dispute(s) at issue. Such detail should be sufficiently specific to assist applicable manufacturers in the resolution process. We believe it is highly unlikely that the proposed free-form text box will provide applicable

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\(^3\) 78 Fed. Reg. 9458, 9502 (Feb. 8, 2013).


\(^5\) Id.
manufacturers with sufficient information regarding initiated disputes, especially because covered recipients and physician owners or investors may submit a single explanation for all initiated disputes.

As noted in the electronic fields recommended below, covered recipients and physician owners and investors should be allowed to dispute only the existence of a transaction or the amount of a transaction. Covered recipients and physician owners and investors should not be allowed to dispute other fields of an applicable manufacturer’s report since CMS has recognized that applicable manufacturers have discretion with respect to some of the information that is reported.

The ability to dispute other categories might serve to only expend resources and raise frustrations among all stakeholders, without any real hope of resolution. For example, if covered recipients are permitted to dispute the nature of payment category or the date of payment as reported by an applicable manufacturer it would contravene the approach taken by CMS with respect to such information, specifically that applicable manufacturers have discretion to determine the appropriate information to report for these areas. Likewise, physicians should not be permitted to dispute accurately-reported state licensure or specialty information. Applicable manufacturers are required to report professional license numbers for at least one state where the physician maintains a license, but need not report multiple state license numbers if maintained. Similarly, applicable manufacturers need only report a single specialty for a physician, notwithstanding the fact that a physician may have multiple specialties. If an applicable manufacturer reports a single, valid state license number and specialty, a physician should not be able to initiate a dispute because he or she would prefer that a different state license or specialty was reported.

We recommend that the System include at least the following electronic fields, all of which must be completed/auto-filled for each individual record being disputed by the covered recipient, physician owner, or physician investor and shared with the applicable manufacturer:

- a) Unique identifier for payment, other transfer of value, or ownership or investment interest at issue;
- b) Physician NPI number or teaching hospital tax identification number, as appropriate;
- c) The nature of the dispute, specifically identifying whether the transaction is being disputed in its entirety (i.e., that the transaction did not occur) or if the amount of the payment, transfer of value, or ownership or investment interest is being disputed;
- d) Proposed alternative information for the amount of payment, transfer of value, or ownership or investment interest, if applicable;
- e) Description of the dispute/reasons for the dispute;

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6 See C.F.R. § 403.904(e)(2); 42 C.F.R. § 403.904(c)(5); 78 Fed. Reg. 9458, 9477 (“... we believe that the nature of payment categories are descriptors and that applicable manufacturers should select the most appropriate description.”); 78 Fed. Reg. 9458, 9473-9474 (“... applicable manufacturers have the flexibility to report payments made over multiple dates either separately or as a single line item for the first payment date. In addition, we will allow flexibility for what specific date to report for a nature of payment category.”).

7 C.F.R. § 403.904(c)(3)(iii).

8 C.F.R. § 403.904(c)(3)(i); 78 Fed. Reg. 9458, 9473 (“... we do not believe applicable manufacturers need to provide more information when reporting physician covered recipient specialty. We believe that a single specialty should be sufficient ...”).
f) Name of the individual with whom the applicable manufacturer should work with to resolve the dispute; and

g) Contact information for the individual with whom the applicable manufacturer should work with to resolve the dispute, including telephone number and email address.

Applicable manufacturers should be able to submit any updates to data via either the file upload process or manually via the Graphic User Interface (GUI).

It is our understanding that applicable manufacturers will be required to submit updated payment, transfer of value, and ownership and investment data to CMS and attest to the same using the Open Payments system. This is the case whether such updates relate to initiated disputes or are the result of an applicable manufacturer’s own review, and whether such updates are identified inside or outside of the 15-day correction period. Changes to the data can be made either through bulk file uploads or manually through the GUI, regardless of the original data entry method used.⁹

We agree with this approach. Applicable manufacturers that upload their initial data should be allowed to upload updated data or use the GUI to update their data. We recommend that CMS confirm that any updates arising from the dispute resolution and corrections process may be submitted to CMS via the same Open Payments mechanism through which initial data is submitted, and that manufacturers have the option of submitting the updated data either through bulk file uploads or through the GUI.

CMS should encourage covered recipients and physician owners and investors to initiate disputes in the System.

We recommend that CMS encourage covered recipients and physician owners and investors to use the System to initiate and resolve disputes with applicable manufacturers, as opposed to contacting applicable manufacturers directly regarding disputes. Our members expect some covered recipients and physician owners and investors may contact applicable manufacturers directly to discuss disputed payments, other transfers of value, or ownership or investment interests. While we expect these applicable manufacturers will take reasonable steps to address such concerns, we believe handling disputes through a centralized system, such as the System proposed by CMS in the preamble to the Final Rule, will ensure efficiency and consistency for applicable manufacturers as well as covered recipients and physician owners and investors.

The dispute resolution and corrections process and related System should remain consistent and available year-round.

In the preamble to the Final Rule, CMS stated that after registering with the CMS System, physicians, teaching hospitals, and physician owners and investors may sign into the System to

review or dispute officially submitted and attested transactions any time during the year.\textsuperscript{10} We recommend that the same dispute resolution and corrections process apply throughout the year, even outside of the 60-day review, correction, and resolution period. In addition, applicable manufacturers, like physicians, teaching hospitals, and physician owners and investors, should have access to the System and receive immediate notice of initiated disputes year-round so that the parties can continue to address and resolve disputes at any time during the year. This will be particularly important since we expect that, at least in the first year, many disputes may not be raised until after initial publication of the submitted data on the public website.

The applicability of a consistent process and the availability of the System year-round are important because applicable manufacturers may develop internal processes, procedures, and systems to address disputes, consistent with the process and System finalized by CMS. It will be difficult for applicable manufacturers, and confusing for covered recipients and physician owners and investors, if manufacturers are forced to create separate processes, procedures, and systems for inside and outside the 60-day review, correction, and resolution period.

Notwithstanding the availability of the System year-round, we agree with CMS’ determination that covered recipients and physician owners and investors will only be allowed to review in the System the previous year’s data (submitted in that year) and initiate disputes between the time that the 45 day review and correction period begins until the end of the calendar year.\textsuperscript{11} This time period allows for sufficient review and correction, while also ensuring applicable manufacturers are not forced to address indefinitely disputes related to past transactions.

\textit{CMS should acknowledge that there are certain disputes for which resolution may not be possible.}

In the preamble to the Final Rule, CMS noted that it plans to monitor the rate of disputes and resolutions, including whether an applicable manufacturer or applicable GPO has an abnormally high number of disputes or has an abnormally high rate of unresolved disputes.\textsuperscript{12}

Even using best and reasonable efforts to resolve disputes initiated by covered recipients and physician owners and investors, CMS should understand that there are certain disputes for which resolution may not be possible.

For example, an applicable manufacturer may report to CMS a transfer of value to a physician in the form of a meal, the value of which has been determined consistent with 42 C.F.R. § 403.904(h), the rule for reporting food and beverage. Nonetheless, if the physician does not understand or agree with the Open Payments regulations, he or she may dispute the value of the meal and may not be willing to accept the applicable manufacturer’s rationale for the value of the meal.

\textsuperscript{10} 78 Fed. Reg. 9458, 9503.
\textsuperscript{11} See 42 CFR § 403.908(g)(3)(v); 78 Fed. Reg. 9458, 9501; FAQ8268; FAQ8362.
\textsuperscript{12} 78 Fed. Reg. 9458, 9501.
Similarly, an applicable manufacturer may report to CMS a transfer of value to a physician, the value of which is based on the assumptions or methodologies that the applicable manufacturer has established for purposes of reporting consistently all such transfers of value under Open Payments. A physician may dispute the transfer of value because he or she does not agree with the established assumptions or methodologies used to determine the reported amount.

In either case, the result may be that the parties may be at an impasse, notwithstanding the fact that the applicable manufacturer has reported the transfer of value consistent with the Open Payment regulations or its own established assumptions and methodologies.

It is the applicable manufacturer that is required to attest to the accuracy and completeness of the data and the applicable manufacturers that is subject to penalties if such reports are not accurate and complete. CMS should acknowledge that in some cases resolution may not be possible, even after reasonable diligence, and applicable manufacturers should not be penalized for the same.

Following the first cycle to dispute resolution and collection, applicable manufacturer will likely have additional information regarding the types of disputes addressed, including those categories of disputes for which resolution was not possible. AdvaMed is willing to engage in discussions with CMS regarding these findings, to the extent CMS would find such a dialogue helpful.

Only the actual physician or a relevant representative affiliated with a teaching hospital should be able to initiate and resolve disputes in the System.

We understand that in the near future physicians and teaching hospitals will be able to register with CMS to review and dispute information about payments or other transfers of value and/or ownership or investment interests submitted on their behalf. Physicians and teaching hospitals will register in CMS’ Enterprise Portal, which will allow for secure user identification and authorization. In the preamble to the Final Rule CMS stated that “the secure user-based authentication requires that the actual individual register and interact with the system to ensure the utmost security of the data.”

We agree that only the actual physician or a relevant representative affiliated with a teaching hospital should be able to initiate disputes in the System. There will only be 60 days to review, correct, and resolve disputed information before the information is initially published on the public website. In order to ensure that as many disputes as possible can be addressed and resolved prior to publication, it is important that the individual disputing a payment is sufficiently familiar or informed regarding the payment or other transfer of value and the reason for the dispute so that he or she is qualified to work with an applicable manufacturer to address or resolve the dispute. This will be particularly important in the context of large organizations that qualify as teaching hospitals, where an affiliated representative may not have specific knowledge regarding the payment or transfer of value at issue so that resolution is inefficient or impossible.

13 Id. at 9500.
The System should only be available to covered recipients, physician owners and investors, applicable manufacturers, and applicable group purchasing organizations.

It is our understanding that the System will only be accessible and available to covered recipients, physician owners and investors, applicable manufacturers, and applicable group purchasing organizations.\textsuperscript{14} Third parties, such as non-covered recipient individuals who receive payments or other transfers of value from applicable manufacturers on behalf of or at the direction of a covered recipient, will not have access to the System or the ability to initiate a dispute within the System. We agree with this limitation. Covered recipients and physician owners and investors on whose behalf applicable manufacturers have submitted information regarding payments, other transfers of value, and ownership and investment interests, and not third parties, are in the best position to resolve disputes regarding the same with applicable manufacturers.\textsuperscript{15}

The background information and context included on the Open Payments website should address the dispute resolution and corrections process.

We have commented before on the critical importance of CMS furnishing, in any future Open Payments disclosures, clear background information and context regarding industry relationships and the data being publicly disclosed.\textsuperscript{16} In order to ensure that those reviewing the publicly available data, including patients and covered recipients, understand the information, such background and context information should also include a discussion of the Open Payments dispute resolution and corrections process.

We recommend that the Open Payments website clearly detail the finalized dispute resolution and correction process, including CMS’s intention to publish as “disputed” payments, other transfers of value, or ownership or investment interests that cannot be resolved by the end of the 15-day resolution period, according to information reported by applicable manufacturers,\textsuperscript{17} and CMS’s intention to update the public data only at least once annually, beyond the initial data publication following the submission of the data.\textsuperscript{18}

In addition, the background and context information should provide examples of the reasons disputes may arise and address the fact that there are certain disputes for which resolution may not be possible, including for the reasons discussed above. For example, a dispute may arise for the following reasons:

\textsuperscript{14} See 42 C.F.R. § 403.908(g); 78 Fed. Reg. 9458, 9500.
\textsuperscript{15} We also agree with the limitation that covered recipients and physician owners and investors will only be granted access to data regarding payments or other transfers of value and/or ownership or investment interests submitted on their behalf. \textit{Id.}
\textsuperscript{16} \textit{See}, e.g., AdvaMed’s letter dated July 12, 2011 to Dr. Berwick regarding implementation of Section 6002 of the ACA; AdvaMed’s letter dated February 17, 2012 commenting on the proposed rule implementing Section 6002 of the ACA; AdvaMed’s letter dated April 9, 2013 commenting on the final rule implementing Section 6002 of the ACA; AdvaMed’s letter dated May 8, 2014 regarding background/context information to be included on the Open Payments public website.
\textsuperscript{17} 78 Fed. Reg. 9458, 9502.
\textsuperscript{18} \textit{Id.} at 9503.
• A covered recipient disputes that a reported transaction occurred
• A covered recipient disputes the dollar amount of a reported payment
• A covered recipient does not agree with the valuation methodology CMS has established for purposes of reporting certain types of transfers of value
• A covered recipient does not agree with the valuation methodology that an applicable manufacturer has established for purposes of reporting consistently certain types of transfers of value

Providing examples of the types of disputes that may occur will enable consumers and the public to more fully appreciate the data presented on the public website, including payments, other transfer of value, and ownership or investment interests that are marked as “disputed.” An acknowledgment by CMS that it may not be possible to resolve certain disputes will also ensure that consumers and the public do not incorrectly assume that disputes necessarily indicate inaccurate data submission by an applicable manufacturer or a lack of reasonable resolution efforts on the part of an applicable manufacturer.

Finally, background and context information regarding the dispute resolution process should note that the period during which covered recipients and physician owners and investors may initiate disputes is not indefinite and is limited to the time period after the 45 day review and correction period begins for the previous year’s data through the end of the calendar year.

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We thank you for your consideration of these comments and recommendations as you work towards finalizing the dispute resolution and corrections process.

Sincerely,

Christopher White, Esq.
Senior Executive Vice President, General Counsel

cc: Stephen J. Ubl, AdvaMed
Andrew Van Haute, AdvaMed