

August 30, 2018

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Administrator Verma:

On behalf of our physician and medical student members, the American Medical Association (AMA) urges the Centers for Medicare & Medicaid Services (CMS) to make significant changes to the Open Payments Review and Dispute process such that physicians who dispute an industry payment can be assured of a fair, transparent, and equitable process.

As currently structured, the Open Payments Review and Dispute process is not fair for physicians because no reporting option exists when there is not a mutually agreed upon resolution to a disputed payment with an applicable manufacturer or Group Purchasing Organization (GPO). The reporting options—Resolved, Resolved No Change, and Withdrawn—and the definition of “Resolved” appear to heavily favor industry by assuming that all disputes will be resolved to the satisfaction of both parties when that is not always the case. This appears related to CMS’ decision, at the inception of the Open Payments Program, to leave the dispute resolution process up to the parties—applicable manufacturers and GPOs and physicians—to resolve. Unfortunately, this approach was not designed to guarantee physicians an equitable, transparent, or fair process but rather to process disputes as quickly as possible, allowing applicable manufacturers and GPOs to unilaterally dismiss disputes lodged by applicable physicians and teaching hospitals. The AMA has heard from members that some manufacturers and GPOs are not, in fact, acting in good faith to resolve disputes. This is contrary to what one would expect in terms of fair notice and transparency.

The final rule implementing Open Payments does not authorize applicable manufacturers or GPOs to dismiss disputes without both parties agreeing that the dispute is resolved. In fact, it requires both parties to reach a mutually agreeable resolution and, when that is not possible, to mark the payment as disputed.<sup>1</sup> Given the intent of the final rule, CMS should, at a minimum, amend its reporting options to reflect the reality that payment disputes are not always resolved. In addition to the three previously mentioned reporting options, a fourth option for “Disputed” payments should be added. This simple addition should not require additional rulemaking since the reporting options were defined in subregulatory guidance. More broadly, the AMA believes that any payment or transfer of value reported in Open Payments should

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<sup>1</sup> 78 Fed. Reg. 9458, 9502 (Feb. 8, 2013) (“If a dispute cannot be resolved [by the end of the 15-day resolution period], the parties may and should continue to work to reach resolution and update the data. However, [CMS] will continue to move forward with publishing the original and attested data, but will mark it as disputed.”).

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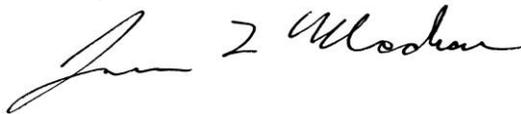
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indicate whether the physician acknowledged receipt of the payment or transfer of value and whether the payment was verified during the review and dispute process. Moreover, while the payment is under dispute, it should be removed from the Open Payments website until the applicable manufacturer or GPO validates the compensation with verifiable documentation. Physicians should not have to repeatedly refile disputes for these items. As discussed earlier in this paragraph, CMS should indicate that the removed payment is “Disputed” until it is validated.

Importantly, CMS’ decision to leave the review and dispute process up to the parties has meant there is no standardization with how the reporting entities determine which payments are reportable or how they collect and aggregate reportable payments. This lack of standardization has downstream consequences to the review and dispute process since the data reported to CMS will be based on the individual processes, each reporting entity uses to define, collect, and aggregate their data. The AMA urges CMS to establish and oversee a standardized system, which is based on a standardized set of definitions on what constitutes reportable payments, through which applicable manufacturers and GPOs can report their Open Payments data.

Effective and accurate resolution of disputes is essential to Open Payments. The AMA believes that the changes outlined above would help to ensure that the Open Payments Review and Dispute process adjudicates disputes fairly by giving physicians appropriate recourse and recognizing that not all disputes are “Resolved” to the mutual satisfaction of both parties. Should you have any questions or to arrange a meeting, please contact Jason Scull, Assistant Director Federal Affairs, at [jason.scull@ama-assn.org](mailto:jason.scull@ama-assn.org) or 202-789-4580.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large, sweeping initial "J".

James L. Madara, MD