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AdvaMed

Advanced Medical Technology Association

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September 3, 2015

Via Express Mail and Electronically

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1631-P
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850
www.regulations.gov

Re: CMS-1631-P: AdvaMed Comments on Open Payments Data Considerations

Dear Acting Administrator Slavitt:

The Advanced Medical Technology Association (“AdvaMed”) is pleased to comment on the Physician Compare Website provision of the Department of Health and Human Services, Centers for Medicare & Medicaid Services (“CMS”) 2016 Medicare Physician Fee Schedule Proposed Rule (“Proposed Rule”) related to Open Payments data.¹

The Proposed Rule includes several new policies related to the Physician Compare website, a website established by CMS pursuant to Section 10331 of the Affordable Care Act (“ACA”) that provides searchable information to consumers regarding physicians and other healthcare professionals who provide Medicare services. In addition, the Proposed Rule seeks public comment for possible future rulemaking related to Physician Compare, including with respect to Open Payments data. This letter responds to CMS’ request for comment regarding Open Payments data as it relates to Physician Compare².

In particular, the Proposed Rule seeks comment about the following with respect to Open Payments data: (1) including Open Payments data on individual eligible professional (“EP”) profile pages; and (2) adding Open Payments data to Physician Compare, to the extent it is feasible and appropriate. CMS notes in the Proposed Rule that prior to considering a formal proposal, it will continue to test Open Payments data with consumers to “establish the context

¹ 80 Fed. Reg. 41686, 41815 (July 15, 2015).

² Separately, AdvaMed provides comments regarding other provisions of the proposed rule. Our comments here are limited to Open Payments and Physician Compare issues only.

and framing needed to best ensure these data are accurately understood and presented in a way that assists decision making.”

1. Physician Compare

We first address CMS’ call for comments on adding Open Payments data to Physician Compare. We commend CMS for its careful consideration of the best way to present background and context information and frame Open Payments data. It is of critical importance that CMS furnish in conjunction with any Open Payments data (wherever it is published) clear background information and context regarding industry relationships. As we have noted before,³ we believe providing context – giving consumers understandable, meaningful information concerning industry relationships – is extremely important in ensuring that the legislative intent of Open Payments is met, without discouraging beneficial interactions critical to the development and safe and effective use of innovative medical technologies. We reiterate our recommendations regarding website context information as it relates to any public release by CMS of information submitted by manufacturers pursuant to Open Payments, and comment specifically regarding the possible future inclusion of Open Payments data on the Physician Compare Web Site and/or individual EP profile pages. In addition to working with consumers to “establish the context and framing needed to best ensure these data are accurately understood and presented in a way that assists decision making,” we recommend that CMS also continue to work with industry to ensure appropriate and complete context information.

CMS has invested great time and resources to ensure that the Open Payments website is functional for both those reporting information and those reviewing reported information. With respect to consumers reviewing the reported information, the Open Payments website currently includes background information on industry-physician relationships.⁴ As we noted in our previous comments, such background ensures the reported data is meaningful and helpful in patient decision-making. Further, providing context for reported payments and other transfers of value is critical to ensuring consumers do not form mistaken impressions that all payments to physicians are suspect. Indeed, CMS recognized the importance of context in the Proposed Rule when it confirmed that “consumer testing has . . . indicated that additional context, wording, and display considerations can help consumers better understand the information.”

CMS should not make Open Payments data or information available on the Physician Compare website, or anywhere else, without also providing immediate and direct access to necessary context information. In order to ensure that consumers evaluate complete Open Payments data and information in direct conjunction with necessary and appropriate context information and

³ 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 to Shantanu Agrawal, M.D., Deputy Administrator and Director.

⁴ AdvaMed maintains that this critical information function can be improved. For example, we have recommended that the background text include specific information regarding the various common arrangements between industry and physicians and teaching hospitals, and that the Open Payments background information should incorporate existing industry codes of conduct and guidance, such as AdvaMed’s Code of Ethics on Interactions with Health Care Professionals.

background, AdvaMed recommends that if CMS decides to include any reference to Open Payments data on the Physician Compare website, it should include general information regarding Open Payments, or reference to the Open Payments website, as opposed to the actual Open Payments data. For example, CMS could include a statement on the Physician Compare website that Open Payments data is available elsewhere, and even include a link to the Open Payments website. This will ensure that consumers are viewing the Open Payments data in the format in which it was intended to be viewed, and with proper and necessary context information. In addition, we believe this approach – a reference or link to the Open Payments website – is more feasible, given the large amount of data associated with Open Payments and the fact that the Open Payments data is much more detailed than the high-level data included on the Physician Compare website.⁵

Further, including on Physician Compare a reference or a link to the Open Payments website, as opposed to Open Payments data, is appropriate because the Physician Compare website and the Open Payments website are separate programs created for different purposes. As a result, information and data from the two websites cannot and should not be combined after the fact.

As one example of how the programs are not easily comingled, consider payments made to an entity other than a covered recipient on behalf of or at the request of a covered recipient (*e.g.*, a physician provides consulting services to an applicable manufacturer, for which the applicable manufacturer makes payment to the physician’s group practice on behalf of or at the request of the physician). Under the Open Payments program, such payment would be reported to the Open Payments program and published on the Open Payments website. However, the Open Payments website would also include information sufficient to confirm the true nature of the payment (*i.e.*, that the physician did not receive the payment). It would be inaccurate and misleading to include on the Physician Compare website information that suggests that the physician received the payment reported to Open Payments on his or her behalf. Instead, providing a reference or a link to Open Payments would ensure that the payment, and all relevant information and context, can be viewed completely and accurately. The Open Payments website was developed after careful consideration of “the intricacies of disclosure and the importance of discouraging inappropriate relationships without harming beneficial ones.”⁶ The same consideration was not evident in developing the Physician Compare website.

2. Eligible Professional Profile

⁵ The Physician Compare website includes the following information for physicians and other health care professionals (“HCPs”): (i) name, address, phone number, specialty, clinical training, and gender; (ii) whether the physician/HCP speaks languages other than English; (iii) hospitals with which the physician/HCP is affiliated; (iv) whether the physician/HCP accepts Medicare; and (v) group practice information. In contrast, for Open Payments, manufacturers are required to report, and CMS publishes, very detailed information regarding payments and transfers of value, and ownership interests. The 2014 data recently published on the Open Payments website includes information about 11.4 million financial transactions attributed to over 600,000 physicians and more than 1,100 teaching hospitals. According to CMS, this amounts to 5.3 GB of data, including 10,818,054 rows of data and 63 columns of data, for general payments detail; 446 MB of data, including 585,079 rows of data and 164 columns of data, for research payment detail; and 1.8 MB, including 4,785 rows of data and 28 columns of data, for physician ownership detail. Open Payments Public Use Files: Methodology Overview & Data Dictionary (June 2015).

⁶ 78 Fed. Reg. 9458, 9459 (Feb. 8, 2013).

Next, in response to CMS' call for comments regarding linking Open Payments data to Eps, we offer the following recommendations. Even if CMS includes reference or a link to the Open Payments on the Physician Compare website, it should not include Open Payments information, data, or references on the individual EP profile pages. To include such information may be misleading to consumers and suggest that the proper financial relationships a physician has with an applicable manufacturer are necessarily a conflict of interest or otherwise improper. As CMS has recognized, "disclosure alone is not sufficient to differentiate beneficial financial relationships from those that create conflict of interests or are otherwise improper. Moreover, financial ties alone do not signify an inappropriate relationship."⁷

In the alternative, if CMS decides to include Open Payments data on EP profile pages and/or the Physician Compare website, it should also include directly on the EP profile pages and/or the Physician Compare website necessary and appropriate context information and background regarding the Open Payments data. Viewed simply as numbers and categories, Open Payments data tells very little in terms of real world impact, and is subject to a wide variety of positive and negative interpretations and assumptions. It is not sufficient for the EP profile pages and/or the Physician Compare website to include Open Payments data and simply reference or direct consumers to the Open Payments website for context information. Such an arrangement would allow, or even encourage, consumers to view Open Payments data without the benefit of context, which may result in the data being misleading or confusing to consumers, contrary to the legislative intent of the Open Payments program.

Further, any presentation of Open Payments data, on the EP profile pages, the Physician Compare website, or elsewhere, must be complete and include all data points so consumers have the detail necessary to develop informed opinions and decisions. It would not be appropriate to include something less than the complete Open Payments data on the Physician Compare website. For example, "third party payees" and "dispute status" are Open Payments data points that may be more specific than the information otherwise provided on the Physician Compare website. However, these Open Payments data points are important for ensuring that consumers understand the true nature of payments at issue and also represent information that physicians want consumers to have.

In addition, if CMS decides to include Open Payments data on EP profile pages and/or the Physician Compare website, CMS must take great care to ensure that the data matches precisely and accurately that which is included on the Open Payments website. The Open Payments program includes a disputes and corrections process. Even outside of that process, manufacturers are contacted by physicians about reported and/or published Open Payments data. Manufacturers should not be responsible or accountable for inaccuracies in the Open Payments data as a result of migrating data from the Open Payments website to the Physician Compare website. Applicable manufacturers attest to the data submitted to CMS for publication on the Open Payments website; that attestation does not apply to the Physician Compare website. If Open Payments information and/or data are included on EP profile pages and/or the Physician Compare website, CMS should make clear that manufacturers are not responsible for Physician

⁷ *Id.*

Compare data and physicians can only log complaints about Open Payments data through the dispute and correction process applicable to the Open Payments program.

3. Other Open Payments Recommendations

AdvaMed supports the appropriate disclosure of relationships between medical technology companies and covered recipients and remains committed to working closely with CMS and legislators to ensure the effective implementation and operation of the Open Payments program, and the use and further publication of data related to the same. To that end, and as previously discussed in correspondence with CMS, AdvaMed remains willing to work with CMS to refine and strengthen the background information and context language regarding relationships between the drug and device industry and physicians and teaching hospitals that accompanies Open Payments data included on the Open Payments and any other public website.

AdvaMed also recommends that CMS establish additional nature of payment categories for (i) stock option buy outs and (ii) transfers of value not otherwise covered by the existing nature of payment categories (*i.e.*, a new “miscellaneous” nature of payment category separate and apart from the “gift” nature of payment category). Currently, CMS defines the gift nature of payment category as “a general category, which will often include anything provided to a physician or teaching hospital that does not fit into another category.” The examples CMS includes for this category are promotional items such as clocks or flash drives that have the company’s name printed on them. However, manufacturers currently must include in the gift nature of payment category a much broader array of payments and transfers of value than those identified in CMS’ examples. For example, according to CMS guidance, manufacturers should be reporting as a “gift” a stock option buy out and a device loan that exceed 90 days, neither of which is properly considered a gift. It is inappropriate and misleading to consumers to categorize as a “gift” something that is by definition a “miscellaneous” payment or transfer of value, especially given the connotations of a gift in the fraud and abuse context.

If CMS does not create such additional nature of payment categories, at a minimum, the Open Payments context language related to “gifts” must be revised so that consumers are not misled about the types of payments and transfers of value captured by this nature of payment category. This is particularly important to the extent CMS decides to include Open Payments data or information on the Physician Compare website, or anywhere else. It is misleading to consumers to suggest that a physician received a “gift” from a manufacturer, when in fact the payment or transfer of value was not a “gift” as the consumer will understand the term and as CMS has defined it by the current gift examples on the Open Payments website.

* * *

We thank you for considering these comments, and AdvaMed looks forward to continuing to engage in active dialogue with CMS regarding Open Payment issues.

Sincerely,

A handwritten signature in blue ink, appearing to read "Chris White".

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

cc: Stephen J. Ubl, AdvaMed President and CEO