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Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Agency Information Collection Activities: Submission for OMB Review; Comment Request
[Document Identifier: CMS–10495]

Dear Administrator Tavenner:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the U.S. Department of Health & Human Services (HHS) Agency Information Collection Activities: Submission for OMB Review. **The AMA strongly urges the Centers for Medicare & Medicaid Services (CMS) and the Office of Management and Budget (OMB) to implement immediate modifications to the proposed system for the collection of information as the provisions governing disputes violate the Administrative Procedures Act (APA), the Paperwork Reduction Act (PRA), the Physician Payments Sunshine Act (Sunshine Act) provision of the Affordable Care Act (ACA), and the due process rights of physicians.**

The agency is not permitted by law or regulation to authorize and facilitate the unilateral dismissal of disputes between manufacturers and group purchasing organizations (GPOs) and physicians as proposed in this notice and supporting documentation. The AMA has additional concerns that the proposed system for the collection of information and overall implementation of the Sunshine Act will not produce accurate reports as required by law and as intended by Congress. We offer the following recommendations in order to remedy the current program shortcomings and ensure accurate reports are issued.

PROPOSED DATA COLLECTION SYSTEM & DISPUTES

The proposed dispute process and notifications detailed in the proposed system for collection of information, are contrary to the express dispute provisions contained in the final rule implementing the Sunshine Act program (dubbed the "Open Payments Program" by the agency), contravene the express due process provisions of the Sunshine Act, are contrary to congressional intent, and violate well-settled

rights and principles governing due process. As a result, the information collected will lack clarity—since disputed data will not be flagged as such—increase the paperwork burden as physicians will have to repeatedly initiate disputes to revive disputes that remain unresolved, and be of limited usefulness since self-serving attestation of one party to a dispute cannot be reasonably relied upon by the general public where the other party (physician or teaching hospital) dispute the data. It will also increase significantly the likelihood of litigation that will call into question the quality and reliability of the information gathered and published. Therefore, the proposed dispute specifications are inconsistent with PRA considerations for the collection of information by the government.

The proposed system for information collection to implement the Open Payment Program provides that applicable manufacturers and GPOs are authorized to dismiss disputes lodged by applicable physicians (and teaching hospitals) unilaterally and without resolution of the dispute. In the supporting document, branded with the CMS logo and titled, *Open Payments System: Review and Dispute Email Notifications, Centers for Medicare & Medicaid Services, April 2014*, on page 2, the agency proposes to provide the following notification to manufacturers after a physician or teaching hospital has initiated a dispute:

> You [the manufacturer or GPO] 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.

(Emphasis added.) **The final rule does not authorize manufacturers or GPOs to dismiss disputes without both parties agreeing that the dispute is resolved. The final rule implementing the Sunshine Act provides that the parties to the dispute are authorized to resolve disputes**. If the parties are unable to resolve the dispute, the manufacturer's/GPO's reported data will be marked as disputed and it will be flagged as such in the public database until resolution has been reached between the parties. Unilateral dismissals not only violate the PRA and APA, they also violate physicians' due process rights. The manufacturer/GPO, CMS, and the contractor responsible for the Open Payments system of information collection that permits unilateral dismissals of disputes are liable for denying a physician his or her due process rights as well as damages resulting from the publication of data that is false or inaccurate.

CMS cannot use the PRA comment period as a stand-in for APA proposed rulemaking; therefore, the proposal to permit manufacturers/GPOs to dismiss disputes without the parties resolving a dispute violates the APA. The final rule provides:

> If a covered recipient or physician owner or investor disagrees with the information reported, the covered recipient or physician owner or investor can initiate a dispute, which is sent to the appropriate applicable manufacturer or applicable group purchasing organization **to be resolved between the parties**.

42 C.F.R. section 403.908(g)(3)(iv) (emphasis added). The regulation further provides:

> If the 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**.

The preamble to the final rule discusses the dispute resolution process in a number of places and the following excerpts are representative:

> We [CMS] appreciate the comments and agree that effective and accurate resolution of disputes is essential to the program. After reviewing the comments, we believe that we do have a responsibility to facilitate the capability for correcting the data and resolving disputes among the parties. However, we maintain that we should not be actively engaged in mediating dispute resolutions. The relationship exists between the applicable manufacturer or applicable GPO, and the covered recipient or physician owner or investor, **so these parties should be involved in the resolution of the dispute, not CMS**. We believe that we are not the appropriate party to mediate the disputes. However, we do plan to provide the opportunity for covered recipients, or physician owners or inventors to review and correct the data submitted on their behalf. **We also plan 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.**
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> **If a dispute cannot be resolved in this time, the parties may and should continue to work to reach resolution and update the data. However, we will continue to move forward with publishing the original and attested data, but will mark it as disputed**.

Federal Register, Vol. 78, No. 27, February 8, 2013, 9501-2 (emphasis added). As the foregoing excerpts demonstrate, the final rule provides that the parties to the dispute are required to work with physicians to resolve disputes over reported data and that the agency will monitor whether or not a manufacturer/GPO has a high rate of disputes and resolved disputes. The final rule does not authorize manufacturers/GPOs to dismiss disputes unilaterally, but requires the parties to reach a mutually agreeable resolution and, when that is not possible, mark the data as disputed. The foregoing is underscored in presentations by CMS officials describing the dispute resolution process, including agency PowerPoints and Fact Sheets for Manufacturers and GPOs that detail the dispute process and highlight that a resolution must be achieved between the two parties to the dispute and do not include a provision outlining a unilateral dismissal.

CMS proposes to notify physicians that they are able to repeatedly submit notifications disputing data after it is dismissed by the manufacturer/GPO. Requiring physicians and their staff to re-direct scarce time and resources away from providing direct patient care in order to keep flagging disputed data is patently unreasonable and contrary to this Administration's stated goal of minimizing administrative burdens on the regulated and small businesses. Even if physicians and their staff had the time and resources to continue to lodge disputes that a manufacturer/GPO unilaterally dismisses, the CMS final rule precludes physicians from filing a new dispute after the close of the calendar year. Therefore, CMS has attempted, contrary to law and regulation, to undermine the ability of physicians to protect their employment and other economic interests as well as their reputational standing when manufacturers/GPOs submit false, inaccurate, and misleading information. The agency has already substantially abridged the due process rights of physicians by limiting the review and dispute process until the end the calendar year, and now proposes to further dilute these rights through the creation of a mechanism that permits unilateral dismissal of disputes without the agreement or consent of the physician

who initiated the dispute. A manufacturer or GPO can simply wait until January 1 of each year and dismiss any disputes filed by physicians, thereby skirting around the express intention of Congress that physicians would be able to secure corrections to reports.

We are further concerned that the agency has attempted to substantially modify the rights of physicians to challenge inaccurate reports by including a heretofore undisclosed right of manufacturers/GPOs to unilaterally dismiss disputes in a relatively obscure section of a PRA supporting document. This is contrary to what we expect in terms of fair notice and transparency.

In light of the foregoing, the proposed information collection should exclude the mechanism that allows manufacturers/GPOs to dismiss disputes. The information collection system must provide a mechanism whereby the manufacturer/GPO notifies CMS that the parties have resolved the dispute and provides the physician with an electronic copy of the notification. **The physician must be provided the option to notify CMS and the manufacturer/GPO that the dispute is not resolved and should continue to be marked as disputed. The foregoing is consistent with the statute, the regulation, PRA considerations, and does not violate the APA or physician due process rights.**

ACCURATE REPORTING SHOULD BE AGENCY PRIORITY

The agency has increased the complexity and potential for error in the Open Payments Program by exceeding the statutory scope of reportable transfers to include such items as reprints, for example, while simultaneously placing excessive restrictions on a physician's ability to receive timely information on what is being reported and the opportunity to seek correction. The foregoing substantive modifications to physician due process rights, combined with the missed deadlines and compressed timeframes for physician registration, violate the agency's obligation to implement the program in a manner that produces accurate reports.

Furthermore, the AMA and other physician organizations need at least six months to prepare physicians for the review and dispute process. In the preamble to the final regulation the agency states that it will not provide actual notification to physicians, nor require manufacturers/GPOs to do so either. Instead, the agency stated that it would "work with physician professional societies" to provide physicians with information concerning the registration, review, and correction process. The AMA's efforts to implement an outreach program for physicians has been repeatedly hamstrung because the agency has been unable to provide firm dates and information concerning registration, review, and correction processes.

In addition to the foregoing, there are widespread concerns that the implementation of this new system for data collection—without minimally a six month period to upload the data, process registrations, generate aggregated individualized reports, and manage the dispute communications and updates—will not be ready and will likely lead to the release of inaccurate, misleading, and false information. These irregularities and shortcomings will be further exacerbated as the agency has not undertaken a reasonable outreach effort to the physician community concerning the Sunshine Act provisions, registration, and dispute process. The agency has not provided effective notification to the vast majority of physicians, nor provided a reasonable amount of time for organizations such as the AMA and other physicians' organizations to engage and educate physicians on the registration and dispute process. Early in 2014 the AMA informed the agency that a minimum of six months would be needed to ensure an adequate amount of time for registration and outreach on the dispute process. **The AMA has continually expressed support for efforts to establish meaningful and accurate transparency; however, we have been**

repeatedly disappointed and increasingly concerned that the implementation of the Sunshine Act will not lead to the publication of accurate information and appropriate context.

The agency has created a system that accommodates the concerns of manufacturers and GPOs and dismisses recommendations from physician stakeholders that would ensure the accuracy of the final reports and minimize and mitigate potential reputational and economic harm from inaccurate, false, or misleading reports. **As such, the AMA strongly urges CMS and OMB to delay for six months, until March 31, 2015, the publication of the information collected under the Open Payments Program, as the agency has denied physicians the ability to register for the Open Payment Program for the past six months (since January 1, 2014) despite representing that physicians would be permitted to do so beginning in 2014 in agency communications throughout 2013.**

COMPRESSED TIMEFRAMES COMPROMISE ACCURACY AND FAIRNESS

The implementation of the Open Payments Program has been marked by missed deadlines mandated by statute and regulation, as well as by moving target dates, inadequate and unreasonable registration and data submission timeframes, and poor methods and platforms for providing basic and essential information concerning the Open Payments Program. There are approximately four months left before CMS intends to publicly publish data concerning financial interactions including in-kind transfers of value between physicians and manufacturers and GPOs. The repeated delays and general confusion with the status of the implementation and key elements of the program have compounded the last minute rush the agency now proposes in order to meet the September 30, 2014 publication date—sacrificing outreach and reasonable notice requirements. The agency has:

- Prevented manufacturers and GPOs from meeting the deadline for submission of detailed reports on these interactions to the Open Payments Program database even though industry was required by regulations promulgated by CMS to do so approximately two months ago;[1]
- Not permitted physicians to begin registering with the Open Payments Program database on January 1, 2014, and kept the actual physician registration period a moving target undermining the ability to conduct outreach and education;
- Allocated a mere two months to inform physicians that registration is permitted and to process anywhere from 200,000 to 500,000 physician registrations before the review and dispute process begins—even with the lower number an improbable possibility given it is likely to overwhelm the database and leaves too little time to adequately notify physicians through existing communication mechanisms;
- Just issued the proposed database mechanism to process disputes even though the database has to be operational to process disputes in approximately two to three months;
- Maintained an Open Payments Program webpage that has not provided clear guidance or information on timelines concerning registration and the dispute process or even accessible and rationally organized sub-regulatory guidance; and
- Reportedly had difficulty providing customer support for the couple hundred manufacturers and GPOs that have registered with the Open Payments Database in the past two months which raises significant concerns that when industry begins submitting detailed data to the government during the

[1] 42 CFR section 403.908(a). Reports required by the Open Payments Program "must be electronically submitted to CMS by March 31, 2014."

month of June there may be additional problems that the agency will struggle to correct during this compressed timeframe.

As detailed in a prior AMA comment letter (attached), CMS has systematically elected to curtail and otherwise limit the due process rights of physicians by: (1) denying them an opportunity to review manufacturer and GPO data before it is submitted to the federal government; (2) denying physicians an adequate period of time to register for the Open Payment Program system for collection of information in order to obtain and dispute individualized reports; (3) establishing a three step process for obtaining reports that is time consuming and confusing; and (4) revising the final rule to permit manufacturers and GPOs to unilaterally dismiss disputes even though such disputes are to be "resolved by the parties involved."

Not only must there be very clear guidance and timelines for disputing questionable disclosures and resolving them in a timely manner, but physicians must clearly understand how to track these disclosures throughout the reporting period. However, this guidance cannot be issued until physicians have begun to register in the Open Payments Program. Not providing sufficient time for physicians to register in the system and understand the rules of the road will squander an opportunity to build trust among physicians. In the worst case scenario, this will result in vastly more disputes than the new system is designed to handle and destroy credibility.

ECONOMIC, FINANCIAL AND REPUTATIONAL HARM

A number of CMS officials have suggested that physicians are not subject to any penalties under the Open Payments Program and, thus, should not be concerned about inaccurate reports. This is troubling since the whole point of the Open Payments Program is to give the public an accurate picture of the financial interactions between physicians and industry. Congress did not intend that the agency would simply rubber stamp and publish reports submitted by manufactures/GPOs that may or may not be accurate, and that could be, in fact, defamatory. Physicians are uniquely positioned to be highly motivated to ensure that their report is accurate since inaccurate reporting may result in loss of employment, disciplinary action, reputational harm, loss of associations and affiliations, other financial sanction, and even civil and criminal liability. Many physicians are required to submit financial or conflict of interest disclosures as condition of employment or when serving on formulary committees or as recipient of grants. A manufacturer's/GPO's inaccurate reporting foreseeably would be relied upon by employers to initiate disciplinary action or terminate a physician's employment or removal from committees or termination of grants. Agency representatives have repeatedly dismissed the notion that harm could inure to physicians as a result of the Open Payment Program, because they have stated physicians are not subject to the civil monetary penalties under the program. This view of the consequences that flow from inaccurate reporting will not obviate liability for the manufacturers/GPOs, the agency, and the contractor administering the Open Payments Program database when the government facilitates the defamation of individual physicians and the harm was reasonably foreseeable as it is here. The agency has repeatedly declined to require manufacturers/GPOs to take reasonable and prudent steps to avoid the publication of false, misleading, and incorrect information. We urge CMS to take appropriate steps to ensure that the initial publication of reporting data does not become mired in controversy and litigation.

ADDITIONAL PRA CONSIDERATIONS

The AMA also strongly recommends that the proposed system for information collection:

- has notices clarifying that physicians should minimize the amount of information they disclose;
- clearly identifies information that will be disclosed to the public through the public database and in response to FOIA requests so that physicians can take steps to minimize identity theft risks;
- includes special safeguards for physicians who have been the victim of identity theft;
- includes a notification option where a manufacturer/GPO or physician notifies CMS that an error is the result of inaccurate attribution done by the database—not the manufacturer/GPO;
- provides physicians the ability to flag inaccurate reports that are a result of incorrect attribution by the Open Payments Database so these disputed reports are published with dispute notation; and
- includes information to public on the dispute percentage and rate for each GPO/manufacturer.

The foregoing modifications and recommendations are designed to increase the clarity and quality of information that is shared with the public while minimizing the burden on physician practices, many of which are small businesses.

CONCLUSION

The AMA appreciates the opportunity to comment and would like to work closely with CMS and OMB to put in place an Open Payment Program that produces accurate and fair reports on interactions and ownership interests as provided for in the Sunshine Act. There is a great deal of educational outreach that remains to be done and too little time to have a meaningful impact on the physicians who will be affected. If you have questions, please contact Jason Scull, Assistant Director, Division of Federal Affairs, at jason.scull@ama-assn.org or (202) 789-4580.

Sincerely,

James L. Madara, MD

Attachment