June 2, 2014

Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid 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:

The American Association of Orthopaedic Surgeons (“AAOS”), representing more than 18,000 Board-certified orthopaedic surgeons in the United States, appreciates this opportunity to comment on the implementation of the Physician Payment Sunshine Act (“Sunshine Act”) provisions of the Patient Protection and Affordable Care Act.

AAOS is concerned that the system proposed by the Centers for Medicare and Medicaid Services (“CMS”) for the collection and reporting of physician financial information under the Sunshine Act will not produce accurate reports as required by law and as intended by Congress. Despite these concerns, AAOS will continue to educate its membership about the Sunshine Act and its implementation and will appreciate any support CMS can give us in these efforts.

This letter offers several suggestions on how to enhance the proposed CMS data collection and reporting (“Open Payments”) program under the Sunshine Act.
Focus on Accurate Reporting

AAOS is concerned that the proposed CMS Open Payments program for data collection and reporting under the Sunshine Act has numerous shortcomings. The current proposal does not include an adequate period to upload the data, process physician registrations, generate aggregated individualized reports, and manage the disputed communications and updates. It also will probably not be ready prior to September 30, 2014, likely leading to the release of inaccurate, misleading, and false information. Based on reports from drug and device makers, each manufacturer has created an unique process for physicians to follow to dispute any of the information that will be (or has been) reported to CMS. Physicians will need to acquaint themselves with each of these unique processes and follow them diligently to correct inaccurate information. This will be cumbersome for physicians and may also lead to the reporting of inaccurate or incomplete information.

CMS has increased the complexity and potential for error in Sunshine Act data collection and reporting by requiring that manufacturers and Group Purchasing Organizations (“GPOs”) report transfers beyond those required by the Sunshine Act. For example, CMS has recently interpreted the Sunshine Act to require the inclusion of such items as scientific peer-reviewed journal reprints, supplements, and medical textbooks provided by manufacturers to physicians as reportable transfers. This will create a disincentive for manufacturers to provide, and physicians to receive, helpful peer-reviewed journals that could enhance patient care. AAOS has met with congressional staff regarding this issue, and is pleased that Senator Grassley, author of the Sunshine Act, raised this matter at a hearing in April with then-Health and Human Services Secretary Kathleen Sebelius. We share Senator Grassley’s concerns and urge CMS to modify the requirement to include educational items such as journal reprints, supplements, and medical textbooks as reportable transfers.

CMS intends to publicly release data concerning financial interactions, including in-kind transfers of value, between physicians and manufacturers and GPOs by September 30, 2014. CMS has allocated only a short period to inform physicians that they must register to review the information about themselves. The period for CMS to process anywhere from 200,000 to 500,000 physician registrations before the review and dispute process begins is also short. The number of physician registrations is likely to overwhelm the “Open Payments”
database. In addition, the tight timetable may result in too little time to adequately notify physicians of what is being reported about them through existing communication mechanisms.

AAOS’ concern is exacerbated by reported difficulties CMS has encountered in providing customer support for the hundreds of manufacturers and GPOs that have registered with the “Open Payments” database in the past two months. This raises significant concerns that when industry begins submitting detailed financial data to CMS in June—at the same time that thousands of physicians are registering to review those data—serious problems may be identified that CMS will struggle to correct prior to September 30, 2014. Any such massive data collection effort should undergo a pilot test period to work out all potential kinks prior to the public release of the information—something not included in the current timetable.

Proposed Dispute Resolution and Notification: Physician Due Process Concerns

AAOS believes the April 2014 proposed modifications to the dispute process and notifications in the CMS data collection and reporting system are inconsistent with the due process provisions of the Sunshine Act, are contrary to congressional intent and the Final Rule implementing the Sunshine Act (“Final Rule”), and violate physician due process rights.

As proposed in April 2014, the CMS data collection and reporting system authorizes applicable manufacturers and GPOs to dismiss disputes lodged by applicable physicians and teaching hospitals unilaterally and without resolution of the dispute. This is a new development and is inconsistent even with the Final Rule. In Open Payments System: Review and Dispute Email Notifications, Centers for Medicare & Medicaid Services, April 2014, CMS 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
Neither the Sunshine Act nor the Final Rule authorizes manufacturers or GPOs to dismiss disputes without both parties agreeing that the dispute is resolved. The Final Rule provides that the parties may resolve disputes, but if the parties are unable to resolve the dispute, the reported data from the manufacturer or GPO should be marked as disputed and flagged as such in the public database until the parties have reached a resolution. 42 C.F.R. Sect. 403.908(g)(3)(iv)

The April 2014 proposed notification under the CMS “Open Payments” data collection and reporting system violates the due process rights of physicians and may cause damages resulting from the publication of data that is false or inaccurate.

AAOS strongly believes that the CMS “Open Payments” data collection and reporting system must not include a mechanism that allows manufacturers or GPOs to dismiss disputes unilaterally. Further, it must contain a mechanism whereby the manufacturer or GPO can notify CMS that both parties have resolved the dispute and provide an electronic notification to the physician, though it currently does not. In addition, AAOS believes the physician should have the option to notify CMS and the manufacturer or GPO that the dispute is not resolved and should continue to be marked disputed. This is consistent with the Sunshine Act and the Final Rule, and ensures that physician due process rights are protected.

Potential Harm to Physicians if Inaccurate Reporting Occurs

AAOS strongly disagrees with the notion that physicians should be less concerned with inaccuracies in information reported through the Open Payments system because the physicians are not subject to penalties. Physicians are uniquely positioned and motivated to ensure that Sunshine Act reports about them are accurate because inaccurate reporting potentially may result in loss of employment, disciplinary action, reputational harm, loss of associations and affiliations, other financial sanctions, and possibly 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 hospital committees...
Employers who wish to initiate disciplinary action, terminate a physician’s employment, remove the physician from a committee(s), or terminate grants could easily use the inaccurate reporting by a manufacturer or GPO that is ultimately reported by CMS as part of their actions.

Nonetheless, CMS representatives have repeatedly dismissed the notion that harm could occur to physicians as a result of the Sunshine Act “Open Payments” data collection and notification program because physicians are not subject to the civil monetary penalties under the program. This view of the consequences that flow from inaccurate reporting will not excuse manufacturers, GPOs, or CMS when the government facilitates the defamation of individual physicians through publishing inaccurate Sunshine Act information and the harm was reasonably foreseeable—as it is here.

CMS has declined to specifically require manufacturers or GPOs to take reasonable and prudent steps to avoid the publication of false, misleading, and incorrect information. AAOS urges CMS to take appropriate steps to ensure that the initial publication of Sunshine Act data does not become mired in controversy and litigation.

Need to Help Educate Physicians

There is less than four months before CMS will make physician financial information publicly available and yet physicians have received limited information and guidance about the Sunshine Act Open Payments program. While AAOS has been educating our members about the Sunshine Act through articles, alerts, conversations, and a website specifically to deal with Sunshine Act inquiries (http://www.aaos.org/govern/public/sunshine.app), AAOS and other provider education and professional groups need more time to prepare and educate physicians about the Sunshine Act data collection and notification program.

In the preamble to the Final Rule, CMS stated that it would not provide actual notification to physicians, nor require manufacturers or GPOs to notify physicians, of any financial information that will be reported about them. We are aware that some manufacturers have voluntarily provided this information to physician and plan to continue this practice, but they are not required to do so.
Instead, CMS stated that it would “work with physician professional societies” to provide physicians with information concerning the registration, review, and correction process. To date, AAOS has not received this support.

We stand ready to assist in this major educational effort. However, the efforts of AAOS and other medical societies to educate members about the Sunshine Act data collection and notification program have been hampered because CMS has been unable to provide firm dates and information concerning registration, review, and correction processes. CMS has not undertaken a reasonable outreach effort to the physician community concerning the Sunshine Act provisions, registration, and dispute process. It has not provided effective notification to physicians, nor has it provided a reasonable amount of time for physician organizations like AAOS to engage and educate members on the registration and dispute process.

AAOS strongly believes there must be very clear guidance and timelines from CMS for disputing questionable disclosures and resolving them in a timely manner, and physicians must clearly understand how to track these disclosures throughout the reporting period. We cannot provide this education until CMS has issued clear guidance and physicians are registered in the “Open Payments” database.

Given the lack of pilot testing, the lack of guidance from CMS, and the impending September 30th date, the AAOS suggests that CMS consider at least a 90-day delay in implementation through the end of 2014 and possibly beyond if these multiple concerns cannot be adequately addressed. Alternatively, a rolling schedule of implementation might be considered once these serious issues are appropriately addressed.

# # # #

The American Association of Orthopaedic Surgeons appreciates this opportunity to comment on CMS’ implementation of the Sunshine Act. We are aware that much more physician education remains to be done and we pledge that, although there is little time, we will provide educational resources regarding the Sunshine Act and its implementation to the extent we can.
If you have any questions regarding these comments, please do not hesitate to contact Graham Newson, AAOS Director of Government Relations at newson@aaos.org or Richard N. Peterson, AAOS General Counsel at peterson@aaos.org.

Sincerely,

Frederick M. Azar, MD
President
American Association of Orthopaedic Surgeons

cc: Karen L. Hackett, FACHE, CAE, Chief Executive Officer
    William Shaffer, MD, Medical Director