

Commenter	Comment	Response
PhRMA	1. Overall Burden of Compliance. The actual burden imposed on applicable manufacturers is significantly higher than the estimates provided by CMS.	This comment is outside the scope for CMS-10495, Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments. The overall burden of compliance commented by PhRMA relates to CMS-10419, Data Collection and Submission of Transparency Reports and Reporting of Physician Ownership or Investment Interests, with OMB control number 0931-1173.
	2. Burden Associated with Dispute Resolution. PhRMA comments the current CMS dispute resolution period is inadequate. Additionally, the cost of reviewing disputes could be more labor intensive because researching a disputed transaction could involve reviewing the original transaction and supporting documentation and contacting employees.	The Open Payments system will facilitate the process between covered recipients, physician owners and investors, applicable manufacturers and applicable group purchasing organizations, however, CMS does not estimate an additional burden imposed on applicable manufacturers and applicable group purchasing beyond collecting and submitting payments or other transfers of value to CMS. There is no additional burden estimated because CMS is not involved in the dispute resolution process between applicable manufacturers, applicable group purchasing organizations and covered recipients or physician owners or investors.
	3. Limitation of CME Organizations to Five Enumerated Organizations.	This comment is outside the scope for CMS-10495, Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments.

	4. CMS Should Exclude All Meals at Accredited CME Events from Reporting.	This comment is outside the scope for CMS-10495, Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments.
	5. Provision of Reprints to Covered Recipients Should be Excluded from Reporting.	This comment is outside the scope for CMS-10495, Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments.
	6. Recruitment Expenses Should be Excluded from Reporting.	This comment is outside the scope for CMS-10495, Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments.
	7. Payments to Physician Board of Directors at Applicable Manufacturers Should be Excluded from Reporting.	This comment is outside the scope for CMS-10495, Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments.
ACCME	8. ACCME requests CMS explicitly state that payments or other transfers of value provided as compensation for speaking at a continuing education program emanating from: (1) organizations directly accredited by the ACCME, (2) organizations directly accredited by the state medical societies recognized by the ACCME as accreditors of CME within the ACCME system, (3) organizations accredited by the Accreditation Council for Pharmacy Education, and (4) organizations accredited by the American Nursing Credentialing Center (ANCC) under the terms and conditions of the	This comment is outside the scope for CMS-10495, Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments.

	Joint Accreditation offered jointly by the ACPE, the ACCME and ANCC are not required to be reported under this final rule.	
AHCJ	9. The Association of Health Care Journalists requests CMS release the data with unique identifiers allowing the public and journalists to more easily aggregated payments to individual doctors. AHCJ urges CMS to assign a random unique identifier to each individual payee.	This comment is outside the scope for CMS-10495, Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments.
PEW	10. The current estimate of three hours of total support staff time for physician registration should be reduced to 30 minutes.	The estimate for physicians and teaching hospitals registration is reduced to thirty minutes.
	11. The number of physicians who will register is likely closer to 224,425 than to the current estimate of 448,850.	The number of physicians registering is reduced to 224,425.
	12. The number of physicians who, after review, will dispute the reported information will be a fraction of the currently estimated 224,425. CMS should reduce the number of physicians expected to dispute information to 10,000 or fewer to reflect the historically low levels of such disputes.	The number of physicians reviewing payments of other transfers of value is based on public comments received during the rulemaking process.
Fred Trotter	13. Requesting CMS use a unique identifier for each record. This should be a simple hash from the NPI.	This comment is outside the scope for CMS-10495, Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments.
AMA	14. Requests a justification for requiring physicians to register in Enterprise Identity Management (EIDM) system prior to registering in Open Payments.	Registration in EIDM prior to registering for Open Payments is necessary for identity proofing users in Open Payments. Individuals with EIDM credentials (because they accessed other application, which required EIDM registration) are only

		required to request access to Open Payments.
	<p>15. Requests CMS to clarify that the submission of phone numbers (business or personal) or emails (business or personal), is voluntary, and is not required to review Sunshine Act consolidated reports, dispute the contents of such reports, or secure corrections. Furthermore, to the extent that physicians (or their representatives) elect to receive notifications, they should not be compelled to provide more than one email or phone number for such notifications. Further, CMS must notify physicians in advance if the agency takes the position that voluntarily submitted information, such as email and phone numbers, will be disclosed to the public based on FOIA request or used for the other agency government activities. The agency is also required to notify physicians if it intends to use such contact information for any purpose other than the Sunshine Act Program.</p> <p>To the extent physicians want to have CMS notify or communicate with the physician or the physician’s representative, CMS should specify that physicians (and/or their representatives) have the option of: (1) logging into the online portal to obtain information without notification (via email, phone, or mail); or (2) selecting a method or method(s) of notification. Further, CMS</p>	Physicians are required to register in the Open Payments system prior to reviewing payments or other transfers of value submitted to CMS by applicable manufacturers or applicable group purchasing organizations. The information collected by physicians is necessary to ensure payments or other transfers of value submitted by applicable manufacturers or applicable group purchasing organizations are attributed to appropriate physicians. CMS is only using contact information submitted by physicians during registration for purposes of Open Payments.

	should urge physicians to carefully select the method of communication or contact with the agency.	
	16. CMS has underestimated the resources and burden imposed on physicians to ensure reports are accurate and fair.	The burden imposed on physicians during the review period is based on public comments received during the rulemaking process.
	17. The AMA strongly urges CMS to give physicians the opportunity, through the public registry, to provide physicians with the option to provide comments on their public reports similarly to reporting manufacturers and group purchasing organizations.	This comment is outside the scope for CMS-10495, Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments.