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Director  
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U.S. Department of Health and Human  
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7500 Security Boulevard  
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Re: Sunshine Act Final Rule Recommended Guidance on Reprints

Dear Mr. Brennan and Dr. Agrawal:

On behalf of the physician and medical student members of the American Medical Association (AMA), I urge you to provide additional guidance consistent with our recommendations below related to the application of the Physician Payments Sunshine Act (Sunshine Act) final regulation on reprints of peer-reviewed articles in scientific medical journals and the valuation of such reprints. The AMA recommends that the Centers for Medicare & Medicaid Services (CMS) clarify that the Sunshine Act final regulations do not apply to reprints where large numbers of physicians: (1) have a subscription to the journal in which the article is published; (2) are able to obtain the reprint for free through an institutional, organizational, or employment affiliation; or (3) have free access to the article along with the public. In brief, in the foregoing circumstances, physicians are not receiving a payment or transfer of value; therefore, such reprints are not subject to reporting under the Sunshine Act.

The preamble of the Sunshine Act final regulation provides that reprints are subject to reporting. Presumably, CMS has concluded that where physicians do not have free access to articles in peer-reviewed medical journals and would have to purchase them, the articles are subject to reporting under the Sunshine Act. However, articles that are available to physicians for free because the physician has a subscription to the journal in which the article is published, or the article may be accessed for free by physicians through affiliations or employment, do not constitute a payment or transfer of value to a physician. An article that a physician already has or may obtain easily for free cannot be characterized a "transfer of value" and does not constitute a "payment."

While a manufacturer may incur a cost to obtain a reprint, a physician does not receive a transfer of value when the article is already available or free to the physician independent of the manufacturer. The only thing of value transferred to the physician would, at most, be the convenience of having the

reprint—which is a paper copy or electronic PDF of an article the physician may already have in a printed journal or can access online. Identifying an appropriate and reasonable valuation would be highly speculative, difficult to attribute, and certainly de minimis. The Sunshine Act provides that only payments and transfers of value are subject to reporting. Therefore, only reprints where physicians would incur a cost to obtain the article should be subject to reporting.

Furthermore, articles that are made available to the public without charge, for a minimum period of time, cannot be assigned a fair market value beyond what it would cost the public to obtain the article. Therefore, on this basis alone we urge CMS to provide guidance that establishes a bright line rule specifying that where publishers of a journal provide free public access to articles, manufacturers are not required under the Sunshine Act to track, assign a valuation, and report on such reprints.

### *Background*

In general, physicians typically are able to obtain access to peer-reviewed medical journals through personal subscriptions, institutional site licenses, and free online access. Similar to other established medical journals such as the *New England Journal of Medicine* (NEJM), we estimate that a substantial number of physicians have access to the *Journal of the American Medical Association* (JAMA) and the *JAMA Specialty Journals* either through personal subscriptions or free access through a parent organization's site license.

The full text of *JAMA* and the *JAMA Specialty Journals* from 1998 forward is available to subscribing institutions, paid subscribers, and AMA members. The *JAMA Network Websites* include the full text of *JAMA* and the *JAMA Specialty Journals*, published by the AMA. All of the journals publish Online First content.

Institutions are able subscribe to journals in the *JAMA Network* through a site license. A site license offers the broadest possible access to research, medical news, and commentary published from 1998 forward. **Organizations that have a site license typically provide access to all physicians affiliated with the organization. This means affiliated physicians have free access to all of the journals to which the organization subscribes.**

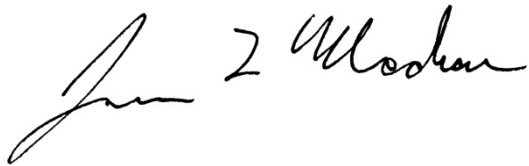
Research articles are freely available to the public (including physicians) after six months for *JAMA* and 12 months for the *JAMA Specialty Journals* from 1998 forward. Patient education features such as the *JAMA Patient Page* and *JAMA Pediatrics for Patients* are freely available.

Finally, reprints from scientific peer reviewed medical journals are not marketing materials, but are essential for improved patient care. This is why *JAMA*, and other medical journal publishers, provide free public access to research articles to ensure that physicians are equipped with new information to provide appropriate patient care. Furthermore, the Food and Drug Administration regulates manufacturer distribution of reprints to physicians to prevent inappropriate promotion or marketing. The paperwork requirements associated with fairly and accurately reporting on reprints for articles that are widely available for free to physicians could chill such exchanges of information.

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The Sunshine Act final regulations provide in the preamble that reprint articles from medical journals would be subject to reporting, but clarification is needed that articles for which physicians already have free access, do not have a fair market value subject to reporting under the Sunshine Act. We welcome the opportunity to provide additional information on the issue of reprints and the Sunshine Act. If you have questions, please contact Margaret Garikes, Director, Division of Federal Affairs, at 202-789-7490 or [margaret.garikes@ama-assn.org](mailto:margaret.garikes@ama-assn.org).

Sincerely,

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

James L. Madara, MD