



AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE

Administrative Office

1209 Montgomery Highway
Birmingham, Alabama 35216-2809
Tel 205/978-5000 • Fax 205/978-5005
Email: asrm@asrm.org • Web Sites: www.asrm.org
www.reproductivefacts.org

J. Benjamin Younger

Office of Public Affairs
409 12th Street S.W., Suite 203
Washington, D.C. 20024-2155
Tel 202/863-4985 • Fax 202/484-4039

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July 30, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1612-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Administrator Tavenner:

The American Society for Reproductive Medicine is writing to comment on proposed changes to “Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015” as specified in the July 11, 2014 Federal Register notice. ASRM is commenting specifically on proposed changes with respect to “continuing education exclusions of reports of payments or transfers of values to covered recipients” (beginning page 40383 of the Federal Register notice).

ASRM is a voluntary, non-profit organization devoted to advancing knowledge and expertise in reproductive medicine, including infertility, menopause, contraception, and sexuality. Founded in 1944, we are an organization of more than 8,000 physicians, researchers, nurses, technicians, and other professionals. We develop and organize an annual meeting at which Continuing Medical Education (CME) offerings for our member attendees is a priority.

First, it is our position that the process currently employed using specified accrediting organizations to determine the requirements and standards for continuing education works quite well. ASRM programming is certified by the Accreditation Council for Continuing Medical Education and we have been compliant with the requirements of the Sunshine Act and the Open Payment rules.

The proposed changes to continuing education exclusions of reports of payments or transfers of values to covered recipients would eliminate in its entirety section 403.904 (g). The stated reason for the elimination of this section is the redundant provisions in section 403.904(i)(1). However, the elimination of 403.904(g) poses a situation that will have a chilling effect on continuing medical education, which is not in the public interest.

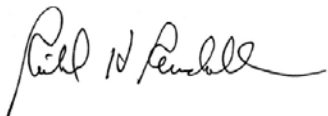
As defined in 403.902, an applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know the identity of the covered recipient *prior to the payment or transfer of value*. Section 403.904(i)(1), on the other hand, excludes indirect payments or other transfers of value when the manufacturer is unaware of the identity of the covered recipient *during the reporting year and the second quarter of the subsequent year*. We take issue with the definition of “know” in 403.902, which is somewhat ambiguous, whereas 403.904(g) provides more specifics. While the manufacturer would be unaware of the identity of speakers at the time the grant is given, they certainly could know the identity of speakers by the time the activity takes place. In practice, ASRM receives funding from manufacturers for continuing medical education, but the manufacturer has no part in determining the speakers or the attendees of such events. However, the manufacturer may become aware of the identity of speakers and/or attendees after such time the program is developed due to the fact that ASRM may post the identity of speakers in its programming and or on its website. Further, an attendee of an ASRM sponsored continuing medical education program may cross paths with a representative of a manufacturer/sponsor at some date past the event, at which time it is learned the attendee received value at the event.

We therefore recommend that the CMS modify the proposal to exclude CME activities where the industry donor is unaware of the speakers and other participants before committing to fund the activity. This accomplishes CMS’ goal while eliminating the potential for negatively impacting CME.

Sincerely,



Rebecca Sokol, MD, MPH
President



Richard H. Reindollar, MD
Executive Director