



October 14, 2013

Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Sebelius:

On behalf of the American Medical Group Association, I am writing today to express concern about a provision in the final rule implementing the Physician Payment Sunshine Act found in section 6002 of the Affordable Care Act. This provision requires manufacturers of drugs, devices, biological, or medical supplies covered under Medicare or Medicaid/CHIP to report annually to the Secretary certain payments or other transfers of value to physicians and teaching hospitals. After aggregation, and allowing for review and correction, the Centers for Medicare and Medicaid Services (CMS) will then publish the findings online, at the physician level.

Several statutory exceptions are included in the Physician Sunshine Act, notably one that excepts "educational materials that directly benefit patients or are intended for patient use" (1128G(e)(10)(B)(iii)). In the final rule (78 Fed Reg 9486), CMS states that medical textbooks and journal reprints do not fall within this exception, making use of these resources a reportable event in the regulatory framework. By not excepting use of such resources, patients could be put at risk, given that physicians often consult textbooks and journal articles for the most up-to-date information that is then used immediately to inform their clinical decision-making when they are presented with an unusual clinical picture. We believe that the current regulatory framework could have a chilling effect on the use of medical textbooks and journal reprints by physicians, which in turn, could produce unintended consequences for patient care. Physicians should have unfettered access to the most current information to help inform their clinical decision-making process without concern for the future ramifications of doing so.

The information contained in peer-reviewed medical journals and textbooks meets the highest standards of medical review. Peer review standards are continuously maintained through rigorous review, and each journal works diligently to protect the integrity of its scientific articles by adhering to strict standards for reprints and dissemination, and to ensure that published content remains uninfluenced by outside forces such as manufacturers.

Moreover, CMS exempted certified and accredited continuing medical education programs from the reporting requirements under the law because this information is critical to the education of clinicians and to quality patient care. Reprints of article abstracts from peer reviewed medical journals and textbooks serve the same purpose, and should therefore be excepted from the reporting requirements.

In addition to the burden of reporting, there are logistical difficulties inherent in tracking such activity, given that many scientific peer reviewed medical journals are available online at no cost for long periods

of time after their publication. CMS has chosen to value such reprints at the price paid by industry to acquire the reprints, which is contrary to the intent of the Physician Sunshine Act, the purpose of which is to determine the transfer of value to physicians. We recommend that CMS reconsider the valuation of such reprints to more accurately reflect the ways in which this information is used and disseminated.

We therefore ask CMS to use its administrative discretion to consider expansion of the exception that would permit peer-reviewed journal articles and medical textbooks to fall within the exception that covers “educational materials that directly benefit patients or are intended for patient use,” because physician use of these materials is of great direct benefit to patients. Alternatively, CMS could regard peer-reviewed journal articles and medical textbooks as continuing medical education materials. Either of these approaches would permit physicians to use these materials to inform clinical decision-making, the purpose for which they were intended.

Thanks for your serious consideration of our request. Please contact Karen Ferguson of my staff at kferguson@amga.org, with any questions you may have.

Sincerely,

A handwritten signature in black ink, appearing to read "Donald W. Fisher".

Donald W. Fisher, Ph.D.
President and CEO

Cc: Marilyn Tavenner, Administrator