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June 2, 2014

Marilyn Tavenner, Administrator
Centers for Medicare and 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 Ms. Tavenner:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) we appreciate the opportunity to provide comments on the above referenced document regarding the process the Centers for Medicare and Medicaid Services (CMS) will use to manage inaccuracies in manufacturer reports of payment to physicians in the newly established CMS Open Payment System. We echo the comments from the American Medical Association (AMA) and other specialty societies in urging the Office of Management and Budget (OMB) and CMS to review and reconsider its plan to publish disputed information regarding industry payments to physicians. We have confidence that the following recommendations to modify the proposed procedures are in keeping with the original intent of Congress, respect the due process rights of physicians, and will make the Open Payment system stronger for physicians, manufacturers, CMS and the public.

Additional Time for Review

The AANS and CNS urge CMS to allow more time for physicians to register in the Open Payment system before their information is made public. The agency delayed publication of the regulations and attempted to expand the purview beyond the strict limits of the law and is now rushing to have the data published by September 30, 2014. The two-step physician registration is confusing and the dispute process unclear. Despite several years of Sunshine Act information in the lay press and specialty society education efforts, the reality is that physicians are increasingly inundated with regulatory requirements and other paperwork unrelated to direct patient care and need adequate time to register, review, and correct their data. We believe allowing this additional time now will maximize physician registration. A reasonable delay for increased education is better than having many physicians discover their data only when they see their name and potentially inaccurate information published in the local newspaper. The idea of a small window for review, only 45 days, is unrealistic and unworkable. CMS has stated that they would not be contacting individual physicians to notify them when industry submits information of payments in their name and has instead said they would provide specialty societies with information to educate their members. **As such, we join the AMA and the physician community in strongly urging CMS and OMB to delay for at least six months the publication of any physician data.**

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Notification to Physicians Prior to Reporting

The AANS and CNS recommend that CMS require manufacturers to notify the physician prior to submitting data to the Open Payment system. In fact, a notification to the physician soon after the payment itself, within 30 days of the transfer of value, especially for smaller items such as dinners, would be useful for the physician and the manufacturer. Payment for larger items such as consulting arrangements should be readily known to physicians, but smaller items such as dinners may not be. Early notification by the manufacturer would give physicians additional time to review and correct data and would encourage physicians who had not yet done so to register with the Open Payment system. It would also foster useful discussion between the manufacturers and physicians and prevent the need for dispute resolution. Presumably most discrepancies are merely honest mistakes. For example, an individual may have written down the wrong name of a physician at a dinner, something that could easily be cleared up if the physician was made aware. The consequence of inaccurate reporting can have serious repercussions for physicians, many of whom are required to submit financial and conflict of interest disclosures as conditions of employment, to hold specialty society office, or as a recipient of a grant. A requirement that the manufacturer notify a physician prior to submitting data would improve efficiency and prevent other serious unanticipated consequences.

Dismissal of Disputes

Both physicians and industry should be required to agree that a dispute has been resolved before the information is posted. As currently written, the CMS proposal would allow a manufacturer to report that a dispute was resolved without proof that the physician is in agreement. This substantially diminishes the due process rights of physicians. We are concerned that the agency proposes to substantially modify the rights of physicians to challenge inaccurate reports by permitting manufacturers to unilaterally dismiss disputes. This is contrary to fair notice and transparency. The information collection system must provide a mechanism whereby the manufacturer notifies CMS that the parties have resolved the dispute and provides the physician with an electronic copy of the notification. The physician must be provided the option to notify CMS and the manufacturer that the dispute is not resolved and should continue to be marked as disputed. Furthermore, we recommend that in the cases where both parties have not agreed that the dispute is resolved, the item not only be marked as disputed, but be omitted from publication until both parties have agreed to its inclusion.

Follow-up

Stakeholders can know neither the degree of actual disruption nor the unintended consequences of the Open Payment system until it is implemented. We believe CMS should closely monitor the burden placed on physicians, including the actual amount of time it takes to register and track their own information, the type and number of disputes, and the degree to which potentially inaccurate data is disseminated to patients, the general public, and the press. Clearly, publishing disputed data is worse than holding the information until a full and fair review can be made, and we urge CMS to heed the comments from the AMA and the physician community to fulfill the intent of Congress in the least burdensome way possible.

Conclusion

The AANS and CNS believe that teamwork between industry and physicians has led to many significant clinical improvements for patients. We firmly support transparency in physician interaction with biopharmaceutical and medical technology companies, but believe the information must be accurate and presented in the appropriate context for it to be useful to patients. America's health policy leaders must educate the public about why collaborations between physicians and industry are a very important part of advancing the health and well-being of patients. Advancements in drugs and devices has helped

neurosurgery to become safer, more effective, and better able to successfully treat diseases for which there were few options to address patient mortality, morbidity, and pain in the not too distant past. Collaboration between industry and neurosurgeons has been responsible for most of these improvements in neurosurgical care. This system, like any system, can be abused and it is essential that the abuses be recognized and reported. We believe that the recommendations that we have made, along with those from the AMA and other physician specialty societies, will help to prevent unnecessary confusion in the Open Payment system and allow for effective oversight in the least restrictive way.

Thank you for your time and attention.

Sincerely,



Robert E. Harbaugh, MD, President
American Association of Neurological Surgeons



Daniel K. Resnick, MD, President
Congress of Neurological Surgeons

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