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September 6, 2016

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1656-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave. SW,
Washington, DC 20201

RE: CMS 1654-P

Medicare Program; Revisions to the Payment Policies under the Physician Fee Schedule and other Revisions to Part B for CY 2017 Comments Submitted by the Academy for Radiology Research specifically related to CMS questions regarding the Open Payments Final Rule which implemented section 1128G of the Act, as added by section 6002 (Sunshine Act) of the Affordable Care Act.

Dear Administrator Slavitt:

As part of the comments for the Revisions to the Payment Policies under the Physician Fee Schedule and other Revisions to Part B for CY 2017, CMS has requested feedback regarding the Open Payment database.

The Academy is honored to respond to three of the questions CMS asks regarding Open Payments Rule. The Academy for Radiology Research (Academy) is a non-profit advocacy organization representing scientific research for more than 20 years. The Academy advocates to increase federal funding for imaging research and to promote the translation of that research to improve health care outcomes. We have been engaged in discussions about the Sunshine Act legislation and the Open Payment Rules since the legislation was being written. Our engagement stems from the fact that academic and industrial collaboration is vital to scientific innovation. In our comments, we seek to preserve the positive aspects of this law and lend our collective voice to the areas where we see unintended consequences and undue burden. We hope CMS will consider our views in further rulemaking.

Are the payment categories inclusive enough to facilitate reporting of all payments or transfers of value to covered recipient physicians and teaching hospitals?

The Academy does not feel that the current categories accurately facilitate reporting. The current categories can be misleading and can create compliance burdens for physicians and teaching hospitals. CMS should also provide more context on the Open Payment database website to help the public understand the information being presented regarding transfers; otherwise, the data will be misleading and counter-productive. The Academy has identified four major problems with the current reporting schema.

First, some categories are far too broad (ie “gift” category), and do not reflect the nature of the transfer and can be misleading. The Academy recommends that CMS focus on better defining the current terms used for each of the categories to ensure accurate data collection and transparency. CMS should also add additional categories as needed for clarity. For example, industry support does not always come in the form of cash payments linked to salary support for researchers, but may include in-kind contributions of expensive equipment required for a research project, software that is not commercially available or other types of non-cash support. Among our membership the use of and having access to medical equipment and/or software is a standard practice that demonstrates the collaboration between industry and physicians that benefits patient care. The Academy recommends that CMS consider additional categories such as “equipment loan” or “software for testing.” CMS could also consider categories that reflect that the use of the equipment or software as a “work in progress” or “already released for the purposes of evaluation” and categories to reflect “in-kind expert support.” Each of these examples would be better reflections of the nature of the transfer and demonstrate better what actually is occurring in practice.

Second, the Academy continues to be concerned about reports in the ‘research grant’ category. The vast majority of these grants are from industry to teaching hospitals, NOT to individual physicians as principal investigators or “PI’s”. When the awarded funds cover personnel expenses, they typically only pay for the time each of the project’s researchers (both the PI and other personnel) spend doing a project and do not add to their total compensation. When the awarded funds cover supplies or other non-personnel expenses, again there is no personal financial benefit to the PI. Current reporting practices would have the public believe that the entire value of a research grant is given directly to the PI. This is highly misleading. In fact, the Academy has serious concerns about the impact of this misleading reporting on academic-industrial collaborations which have clinical value and accelerate the time to discovery and cures, and should be fostered and streamlined to advance patient care. Individual researchers believe that there is a stigma attached to receiving an equipment loan from industry or that being listed as the personal recipient of a research grant will mislead the public when in fact, it is the institution who is the beneficiary. These factors discourage fruitful collaborations. The Academy would recommend that research grants are listed as being awarded to an institution and not to an individual PI.

Third, the reporting in the category food and beverage is for manufacturers and researchers. Sometimes an interaction as simple as two long-term colleagues sharing a taxi to the airport (one industry/one academia) does not create an issue that does not benefit the public good. The Academy would recommend that CMS not require the reporting of these small amenities at all and only require reporting of individual food, beverage and travel costs that are above a de-minimis amount, such as \$100.

Finally, the Academy has concerns about compliance burdens among multiple-jurisdictions including but not limited to state/federal and institutional policies. For example, academic departments have compliance rules that are sometimes stronger than what is in current regulations. CMS should make recommendations to Congress that express the challenges faced by researchers in complying with multiple laws over many jurisdictions. CMS can help encourage Congress to develop more common sense streamlined statute that would create great efficiencies in reporting.

Whether response to these concerns requires a statutory or an administrative change, we believe that the Open Payment database should be updated to avoid serious unintended consequences.

How many years is the open payment data relevant to stakeholders to help determine the number of years to publish and refresh as well as archive or download annually on the website?

The intent of the Open Payment database is to allow for public review and disclosure. This goal although laudable has created burdens and unintended consequences. Key members of industry and academia tell us that data collection, reporting and accurate review requirements in the Open Payment database have caused large financial burdens on both parties. The cost of compliance can be several million dollars per year for large organizations. Certainly, CMS wants to minimize the burden of compliance, which only increases health care costs.

The Academy can appreciate the interest of CMS to ensure that the data is open to the public and fully disclosed but again we would ask that rules of record retention and publications be consistent and not overly burdensome to academia and industry. CMS should work with stakeholders to ensure that information is published in a reasonable amount of time and that archives are available for public use. It may also be reasonable to keep archives/download files on the website for a few years past the record retention requirements.

Definition of covered recipient teaching hospitals and the fact that it makes reporting of value difficult for applicable manufacturers. What are those challenges that the current definition presents. They also want proposed alternative definitions or definitional elements of a covered recipient teaching hospital.

The Academy recommends that CMS consider the Association of University Radiologist (AUR) definition of a teaching hospital. AUR defines a teaching hospital as a hospital "with an accredited residency program." In closing, the Academy of Radiology Research appreciates the opportunity to share our recommendations on these important issues as part of the current request for comments to CMS. In asking these questions CMS may be able to identify additional ways that can help meet the goals of the Open Payment database while ensuring the scientific enterprise and research community can continue finding cures and treating disease.

The Academy stands ready to work with you and other stakeholders on this issue. If you have any additional questions, issues or concerns please do not hesitate to contact Maria Spencer, Senior Director of Legislative Affairs and Advocacy/Vice President of Public Policy at m Spencer@acadrad.org or at 202.347.5870.

Respectfully Submitted,

A handwritten signature in black ink that reads "Renee Crua". The signature is written in a cursive, flowing style.

**Reneé L. Crua, MPA
Executive Director
Academy of Radiology Research**