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September 2, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1612-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave. SW
Washington DC 20201

RE: Comments on Physician Sunshine and the CME safe harbor in the Medicare Physician Fee Schedule Proposed Rule for CY 2015

Dear Ms. Tavenner:

On behalf of Mercy Health (Mercy) and Summa Health System (Summa), we write today to comment on the proposed changes to the Physician Sunshine Act, section 6002 of the Patient Protection and Affordable Care Act (ACA), that the Centers for Medicare and Medicaid Services (CMS) proposes in the CY 2015 Medicare Physician Fee Schedule rule CMS 1612-P which was published in the *Federal Register* on July 11, 2014.[1] **We urge you to both further extend the deadline for which physicians can review and contest information posted on the Open Payments website and NOT to adopt the proposed changes to the continuing medical education (CME) exception to the Physician Sunshine Act as it makes an already complex area even more difficult to comply with and does not serve the transparency intent that the law tries to achieve.**

As a mission-driven, nonprofit Catholic health system meeting the healthcare needs of people in Ohio and Kentucky, Mercy operates 22 acute care hospitals, long-term care facilities, housing sites for the elderly, home health agencies, hospice programs, wellness centers and other healthcare organizations including dozens of physician group practices. Throughout Mercy, we combine advanced medical technology and innovative healthcare treatment with a caring, holistic tradition that focuses on the

[1] This proposed rule, *Medicare Program; 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; Proposed Rule*, 79 Fed. Reg. 40,318 (July 11, 2014) is available at http://www.gpo.gov/fdsys/pkg/FR-2014-07-11/pdf/2014-15948.pdf.

whole person – body, mind and spirit. We also place a high priority on giving back to our communities through community benefit, which consists of programs that help more people access the healthcare they need, as well as programs that improve the health of communities – particularly the most vulnerable members of those communities. During 2013, the $374.7 million in community benefit that we provided placed us among the top quartile of Catholic health systems. We provide more than $1 million in charity care and community benefit every single day. Mercy is also the largest provider of Medicaid services in the state of Ohio. Moreover, as a large employer with more than 32,000 employees and as the fourth largest employer in Ohio, we are strongly committed to providing an outstanding work environment for our employees.

Summa is an integrated healthcare delivery system that provides coordinated, value-based care across the continuum for the people and populations we serve in Northeastern Ohio. Summa integrates the resources of six owned, affiliated and joint venture hospitals, a regional network of ambulatory centers, a network of more than 1,000 physicians that includes more than 290 employed multi-specialty groups, a 230,000+ member health plan, a system-level foundation and 9,500 employees, nurse and healthcare professionals in order to provide the right care at the right time at the right place for our patients.

Summa and Mercy affiliated in 2013 to become the largest provider of healthcare in the State of Ohio. The organizations are collaborating on four major initiatives at Summa that will result in an increase in revenue cycle efficiencies, reducing the length of stay in acute care visits, and creating improvements in both supply chain and labor productivity, respectively.

Background and Proposed Changes to the Physician Sunshine Act

CMS terms the Physician Sunshine Act law as the Open Payments program. This program establishes a system for annually reporting and increasing public awareness of financial relationships between drug and device manufacturers and certain health care providers.

Open Payments is a national disclosure program that promotes transparency by publishing information about these financial relationships on a publicly accessible website developed by CMS. The Open Payments program requires applicable manufacturers of covered drugs, devices, biologicals, and medical supplies to report payments or other transfers of value they make to physicians and teaching hospitals to CMS. It also requires applicable manufacturers and applicable group purchasing organizations (GPOs) to report certain ownership or investment interests held by physicians or their immediate family members, and payments or other transfers of value made to physician owners or investors if they held ownership or an investment interest at any point during the reporting year.

Delay the Deadline for Physicians to Review and Contest Data Posted on the Open Payments Website

First and foremost, Mercy and Summa have continued concerns about the integrity of the Open Payments system. In the interest of ensuring that the information that is posted by the abovementioned manufacturers has been adequately vetted and accurately attributed, we would ask that an additional 45 days be added to the September 25th deadline (November 9th) for physicians to review and contest information found on the Open Payments website. In addition, so as to allow for CMS to ensure any additional concerns or extenuating circumstances are addressed, we believe an additional 45 days after the new deadline, or December 24th, should be added to the timeline as the new date on which the Open Payments data will be released.

Reinstate the CME exclusion

In response to questions and experience administering the program, in the CY 2015 Medicare Physician Fee Schedule Rule, CMS proposes four changes to Open Payments, one of which is very troubling to Mercy and Summa. ***CMS proposes to delete the CME Exclusion in its entirety.*** CMS justifies eliminating the safe harbor because the agency believes it will create a more consistent reporting requirement, and will also be more consistent for consumers who will ultimately have access to the reported data.

CMS believes that the CME exclusion is redundant with the exclusion for "indirect payments or other transfers of value where the applicable manufacturer is ''unaware'' of, that is, ''does not know,'' the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year." 79 Fed Reg. 40384. CMS continues that "[w]hen an applicable manufacturer or applicable GPO provides funding to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting under § 403.904(i)(1)." *Id.* CMS proposes that "when an applicable manufacturer conditions its financial sponsorship of a continuing education event on the participation of particular covered recipients, or pays a covered recipient directly for speaking at such an event, those payments are subject to disclosure."

Mercy and Summa believe this proposal is unworkable. It just muddies the water further. We are concerned that your recent proposal would instead eliminate the current CME "safe harbor" from reporting by redefining CME payments as "indirect payments" which may be reportable.

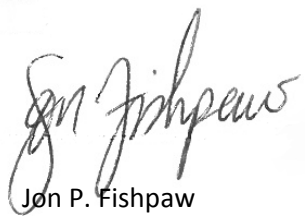
We ask that you ensure indirect commercial support for CME programs, where the accredited provider exercises complete discretion on the content, remains exempted from reporting under the Open Payments system. We believe retaining the CME safe harbor as originally written will further this goal. It is vital to America's patients that their healthcare providers remain well educated and informed on the latest medical science in their field, and therefore, we must encourage, rather than discourage, participation in CME.

Finally, it is important to America's doctors that they have clear rules that provide a safe harbor from Open Payments reporting when they participate in accredited CME. Mercy and Summa appreciate the opportunity to submit comments for your consideration in an effort to cooperatively work toward improving access, consistency in policy, and continued quality in health services.

Please direct any questions to Michael Dalton at 234-312-5259 or at daltonm@summahealth.org.

Sincerely,

William A. Powel, III
Senior Vice President & General Counsel
Summa Health System



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