BY ELECTRONIC SUBMISSION

February 17, 2012

Marilyn Tavenner
Acting Administrator and Chief Operating Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Comments by AARP; American Federation of State, County and Municipal Employees (AFSCME); American Medical Student Association (AMSA); Community Catalyst; Consumer Union; Families USA; and the National Women's Health Network.

RE: CMS 5060–P: Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests

Dear Ms. Tavenner:

Thank you for the opportunity to submit comments regarding the Centers for Medicare & Medicaid Services (CMS) proposed rule for Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests.[1]

We are national consumer advocacy, labor, senior, women's, and physician organizations that strongly support the goals of the Physician Payments Sunshine Act (PPSA), codified as Section 1128G of the Social Security Act. We have been involved in the development and advocacy for these provisions, and many of us have worked with state advocates and medical professionals to support state disclosure laws as well. We appreciate the efforts of CMS to implement this important provision in a timely and effective manner and offer our support in this process.

Section 1128G will address a critical problem. The Institute of Medicine (IOM) has concluded that conflicts of interest in medicine "present the risk of undue influence on professional judgments and thereby may jeopardize the integrity of scientific investigations, the objectivity of medical education, the quality of patient care, and the public's trust in medicine." Financial relationships between physicians and industry have been found to be associated with reduced generic prescribing; prescribing patterns inconsistent with evidence-based guidelines; increased drug costs; and requests for additions to hospital formularies.[2] Section 1128G will discourage these inappropriate relationships between industry and physicians and between industry and teaching hospitals by allowing patients and the general public to examine potential conflicts of interest, as well as recognize those medical professionals and institutions that have avoided inappropriate relationships. We believe that such transparency and a critical examination of the required industry data, available in a public CMS database, by patients, public officials, researchers and the media will help ensure

that medical care is based on sound medical science rather than industry influence. This will contribute to improving quality of care and reducing unnecessary costs to patients and the overall health care system, whose financial sustainability and ethical standards are critical to the well-being of all consumers.

COMMENTS

1. Comment re expeditious implementation of these rules:

We respectfully call upon CMS to implement Section 1128G as soon as possible.
We propose that required data collection from applicable manufacturers and Group Purchasing Organizations (GPOs) begin as soon as possible after the final rule is published, but no later than 90 days. Partial data for 2012 should be submitted to CMS by March 31, 2013 and made public by CMS on September 30, 2013, as provided in the statute. In our view, manufacturers should be well prepared to meet these deadlines given that most have already designed and implemented data collection systems to comply with comparable state disclosure laws, and many companies record and publish similar data in compliance with Corporate Integrity Agreements negotiated with the Department of Justice.

2. Comment re segregating payments into component parts:

We applaud CMS's proposal that payments be divided into component parts, (if appropriate) which are then described under just one best descriptor.
Clarity and consistency in the data reported by applicable manufacturers is essential to the end-users of the resulting CMS database, including patients, the general public, researchers, and state and federal agencies concerned about conflicts of interest. If lump-sum payments include both appropriate compensation – research – and inappropriate forms of compensation – travel to exotic locations – then the public will not be able to discern the extent of appropriate interactions. CMS has proposed an effective solution to this problem, which is to require manufacturers to describe a payment that is segregable into different purposes as separate payments.

3. Comment on the need for regulatory definitions of payment categories:

We respectfully urge CMS to promulgate specific definitions of categories for "nature of payment" rather than leave industry without clear and consistent definitions.
We suggest that to meet CMS's goal of encouraging clarity in reporting, it is essential that the regulations provide specific definitions of the categories for nature of payment rather than allowing manufacturers to use "dictionary definitions." We urge CMS to promulgate specific definitions for all fourteen "nature of payment" categories, as well as guidance on how potentially overlapping categories (e.g. 'research' and 'grant') should be applied. We offer the following proposals for several key categories:

> **Gifts.** We propose that a gift includes but is not limited to promotional items, computers, software, membership fees and dues, subscriptions and journal reprints, textbooks, free services, and any other payment or transfer of value not meeting

criteria for other payment categories. In addition, any other cash, item or in-kind contributions given to an entity at the request of a physician (with the exception of 'charitable contributions') should be defined to be gifts. As required under the statute, such a designated gift is to be reported in the physician's name.

Food and beverage. We propose that this category include, but not be limited to, food or beverages (including alcoholic beverages), provided at restaurants, at professional or educational conferences, meetings, or events; food or beverages provided in an office setting or to teaching hospital physicians or other staff; food or beverages associated with prospective product purchases and demonstrations; food or beverages provided at marketing or promotional events; or payments to a teaching hospital fund for meals or beverages.

Travel and Lodging (including the specified destinations). We propose that travel includes, among other things, contributions to teaching hospital travel funds for conferences and events; the direct purchase, reimbursement, or provision of travel or accommodations associated with speaking at or attending a meeting, conference or event; or travel associated with prospective product purchases and demonstrations, consulting, research, other services, or with entertainment.

Manufacturers should report the "specified destinations" of any travel, as per statute, and we recommend that this include the Country, State, City traveled to; and the name of any event, educational conference or gathering.

Education. We propose that education should be limited to payments to support accredited continuing or graduate medical education events or activities. Accreditation ensures that commercial support has minimal sales and marketing influences.[3]

Direct compensation for serving on the faculty or as a speaker for a medical education program. We propose that this category only be used only for payments for speaking engagements at ***non-accredited*** programs, including activities termed ***"speakers bureaus."*** This definition would be consistent with the standards of the Accreditation Council for Continuing Medical Education (ACCME) standards.

Consulting Fees. We propose that the definition of 'consulting fee' should require that such fees are paid at fair market value under a written agreement that meets the criteria adopted in voluntary industry codes of conduct [4] and subsequently codified under the Massachusetts disclosure law.[5] These criteria ensure that consulting fees are not inflated and do not function as disguised gifts.[6]

Research. We applaud the CMS proposal to limit the definition of research to "bona fide research activities, including clinical investigations that are subject to both a written agreement….as well as the research protocol." For further clarity, we propose that CMS adopt the definition of research in the Public Health Service Act.[7] We further support CMS's proposed method for separately classifying research payments

into indirect or direct payments. This system would capture critical information, including the names of physicians receiving payments through research projects; the total research payments; and the entities initially receiving the payments, including teaching hospitals, universities or contract research organizations.

4. Comment re the need for narrow definition of medical technology:

We express our strong support for the narrowest possible definition of 'existing medical technology' so that payments related to research on unapproved 'off-label' uses of drugs, biologicals, and invasive implanted devices are not delayed.

The statute allows the delayed disclosure of payments for "research on… a new application of an existing medical technology…." CMS has asked for comment on a broad definition of medical technology (i.e. "any drug, device, biological, or medical supply") or a more narrow one that limits delayed disclosure for research on new uses of "a subset of drugs, devices, biologicals, and medical supplies." (Draft rule at 60.)

We believe the most important criteria for defining the scope of this delay of public disclosure is not whether the proprietary interests of drug or device makers are treated unequally, but rather how these asserted proprietary interests are balanced against the potential for public harm of not disclosing payments for up to 4 years.

Some proprietary interests are protected by the manufacturer's patent(s) on a drug or device. But the risk is that delayed disclosure would help mask inappropriate payments, made in the guise of 'research' on such new, i.e. 'unapproved' or 'off-label' uses, designed to promote off-label prescribing. The widespread consumer harm from off-label prescribing, fostered in part by inappropriate financial relationships, has been well documented by federal investigations and prosecutions of most of the largest drug manufacturers.[8] In light of these concerns, we strongly support CMS adopting a narrow definition of medical technology so that payments for research on off-label or unapproved uses of drugs and devices are not delayed.

The term 'medical technology' should be defined to exclude all drugs and biologicals, but it could also exclude any invasive or implantable medical devices. This would leave only those devices operated by "medical technologists" that scan or image patients for assistance with diagnosis, which pose fewer risks to patients and to the public integrity of prescribers.

5. Comment re the definition of applicable manufacturers:

We applaud CMS's proposed definition of 'applicable manufacturer' that is broadly inclusive of manufacturers, regardless of where products are physically made, or how they are purchased by Medicare or Medicaid.

In light of the increasingly global market for the manufacturing and development of covered products, and the multinational nature of most drug and device manufacturers, we think the proposed rule -- that a manufacturer must report if any of their products are available for payment by Medicare and Medicaid -- is a straightforward, common sense approach that will provide clarity to industry. In addition, we support CMS's interpretation that a manufacturer

meets this definition if it manufactures only a single product (Draft rule at 11); or if it merely holds the patent, license, or clearance for the product and contract out the physical manufacturing to another entity (Draft rule at 11); or if the product is purchased individually or in bundled reimbursement (Draft rule at 14).

6. Comment re the definition of subsidiaries, etc. as an entity 'under common ownership':

We support CMS's broad definition of subsidiaries that must report.
A subsidiary of a manufacturer is described by statute as an "entity under common ownership." CMS has proposed that such 'common ownership' exists when "the same individual… or entity . . . own any portion of two or more entities." (Draft rule at 12) We support this proposal because it will help prevent attempts to circumvent the statute through complicated corporate ownership structures.

7. Comment on reporting of payments via third parties:

We strongly support the CMS interpretation that a manufacturer must report its payments made via third parties if it has knowledge of the identity of the recipient.
CMS has proposed that manufacturers must report payments that are made to a covered recipient through a third party, if the manufacturer is aware of the identity of the recipient. CMS has defined this to include when the manufacturer "has actual knowledge of" the identity of the recipient, or "acts in deliberate ignorance or reckless disregard of, the identity of the covered recipient." This interpretation will help prevent industry from funneling payments through third parties in order to evade the reporting requirements.

8. Comment on CEO certification of accuracy:

We applaud CMS for requiring that each report must be accompanied by a 'certification' of truthfulness by corporate CEOs.
CMS has stated a requirement that each annual report be accompanied by a certification "by the Chief Executive Officer, Chief Financial Officer, or Chief Compliance Officer of the applicable manufacturer or applicable group purchasing organization that the information submitted is true, correct, and complete to the best of his or her knowledge and belief." In light of the widespread failures by corporate governance bodies[9] of drug and device manufacturers to ensure marketing staff comply with federal laws banning promotion of unapproved uses of products, we feel this requirement will help promote compliance with the requirements of this statute.

9. Comment on public availability of the website, and further consumer engagement:

We ask that CMS take other opportunities to engage consumers and consumer advocates on the nature and usefulness of the public website, and the public availability of the disclosed data.
We understand that CMS and HHS are implementing many new provisions enacted in the Affordable Care Act, along with section 1128G. And we have expressed our support for implementing section 1128G quickly, in order to capture as many industry payments in 2012 as possible. Nevertheless, after CMS finalizes and publishes record keeping rules for

industry, we ask that the agency engage consumers and consumer advocates in further discussion of ways to make the public website accessible, useful, and understandable to consumers. In addition, to help integrate the federal data with other reporting systems maintained by Massachusetts and Vermont, we ask that the annual disclosure data be available in user-friendly format(s), as well as formats such as Comma-Separated Values (CSV), that are readily downloadable, searchable, and aggregable, so that those states can help further inform consumers, and researchers can readily examine the data.

Sincerely,

AARP
American Federation of State, County and Municipal Employees (AFSCME)
American Medical Student Association (AMSA)
Community Catalyst
Consumers Union
Families USA
National Women's Health Network

---

[1] 76 Fed. Reg. 78742 (December 19, 2011).

[2] Institute of Medicine. *Conflict of Interest in Medical Research, Education and Practice*. IOM Report Brief. April 2009.

[3] Accreditation Council for Continuing Medical Education. *ACCME Standards For Commercial Support*. 2007; see also Accreditation Council for Graduate Medical Education. *Policies and Procedures*. 2010.

[4] PhRMA Code of Interactions with Health Care Professionals, at 8. http://www.phrma.org/files/attachments/PhRMA%20Marketing%20Code%202008.pdf. Accessed Jan. 24, 2011; see also the *AdvaMed Code of Ethics on Interactions with Health Care Professionals*, stating that "[c]onsulting agreements should be written and describe all services to be provided. When a company contracts with a consultant to conduct clinical research services, there should also be a written research protocol." at 5-6, http://www.advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf. Accessed Feb. 11, 2011.

[5] Massachusetts 105 CMR 970.000: *Pharmaceutical and Medical Device Manufacturer Conduct*. Defining consulting arrangements as "compensation for bona fide services."

[6] Under Massachusetts regulation 105 CMR 970.004, consulting fees must be "formalized in a written agreement specifying the services to be provided, based on the fair market value of the services" and which meet the following criteria: "a legitimate need for the services clearly identified in advance; . . . a connection between the competence and expertise of the health care practitioner and the purpose of the arrangement; . . . the number of health care practitioners retained is not greater than the number reasonably necessary to achieve the identified purpose; . . . the retaining pharmaceutical or medical device manufacturing company maintains records concerning the arrangement and makes appropriate use of the services provided by the health care practitioner; . . . the venue and circumstances of any meeting with the health care practitioner is conducive to the services and activities related to the services are the primary focus of the meeting; . . . the decision to retain a health care practitioner is not unduly influenced by a pharmaceutical or medical device manufacturing company's sales personnel."

[7] 42 CFR 50.603 entitled "Responsibility of applicants for promoting objectivity in research for which Public Health Service funding is sought" which defines research relative to the significant financial interests of investigators.

[8] "The practice of illegal off-label promotion of pharmaceuticals has been responsible for the largest amount of financial penalties levied by the federal government over the past 20 years." Sammy Almashat, M.D., M.P.H, et. al., Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010, Public Citizen's Health Research Group, December 16, 2010, available at http://www.citizen.org/documents/rapidlyincreasingcriminalandcivilpenalties.pdf.

[9] David Evans, *Pfizer Broke the Law by Promoting Drugs for Unapproved Uses*, Bloomberg.com, available at http://www.bloomberg.com/apps/news?pid=email_en&sid=a4yV1nYxCGoA, last accessed 2-15-2012, noting that Pfizer illegally promoted Bextra, Geodon, Lyrica, and Zyvox for off-label uses, in clear violation of a Corporate Integrity Agreement that had created an internal monitoring and accountability program in resolution of earlier civil and criminal charges related to the illegal off-label promotion of Neurontin.