I. Reports of Payments or Other Transfers of Value to Covered Recipients

1. Background

In the February 8, 2013 **Federal Register** (78 FR 9458), we published the "Transparency Reports and Reporting of Physician Ownership or Investment Interests" final rule which implemented section 1128G to the Act, as added by section 6002 of the Affordable Care Act. Under section 1128G(a)(1) of the Act, manufacturers of covered drugs, devices, biologicals, and medical supplies (applicable manufacturers) are required to submit on an annual basis information about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Section 1128G(a)(2) of the Act requires applicable manufacturers and applicable group purchasing organizations (GPOs) to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. The implementing regulations are at 42 CFR Part 402, subpart A, and Part 403, subpart I. We have organized these reporting requirements under the "Open Payments (Sunshine Act)" program.

The Open Payments program creates transparency around the nature and extent of relationships that exist between drug, device, biologicals and medical supply manufacturers, and physicians and teaching hospitals (covered recipients and physician owner or investors). The implementing regulations describe procedures for applicable manufacturers and applicable GPOs to submit electronic reports detailing payments or other transfers of value and ownership or investment interests provided to covered recipients and physician owners or investors are codified at §403.908.

Since the publication and implementation of the February 8, 2013 final rule, various stakeholders have provided feedback to CMS regarding certain aspects of these reporting

requirements. Specifically, §403.904(g)(1) excludes the reporting of payments associated with certain continuing education events, and §403.904(c)(8) requires reporting of the marketed name for drugs and biologicals but makes reporting the marketed name of devices or medical supplies optional. We are proposing a change to §403.904(g) to correct an unintended consequence of the current regulatory text. Additionally, at §403.904(c)(8), we are proposing to make the reporting requirements consistent by requiring the reporting of the marketed name for drugs, devices, biologicals, or medical supplies which are associated with a payment or other transfer of value.

Additionally, at §403.902, we propose to remove the definition of a "covered device" because we believe it is duplicative of the definition of "covered drug, device, biological or medical supply" which is codified in the same section. We also propose to require the reporting of the following distinct forms of payment: stock; stock option; or any other ownership interests specified in §403.904(d)(3) to collect more specific data regarding the forms of payment.

2. Continuing Education Exclusion (§403.904(g)(1))

In the February 8, 2013 final rule, many commenters recommended that accredited or certified continuing education payments to speakers should not be reported because there are safeguards already in place, and they are not direct payments to a covered recipient. In the final rule preamble, we noted that "industry support for accredited or certified continuing education is a unique relationship" (78 FR 9492). Section 403.904(g)(1) states that payments or other transfers of value provided as compensation for speaking at a continuing education program need not be reported if the following three conditions are met:

- The event at which the covered recipient is speaking must meet the accreditation or certification requirements and standards for continuing education for one of the following organizations: the Accreditation Council for Continuing Medical Education (ACCME); the American Academy of Family Physicians (AAFP); the American Dental Association's

Continuing Education Recognition Program (ADA CERP); the American Medical Association (AMA); or the American Osteopathic Association (AOA).

- The applicable manufacturer does not pay the covered recipient speaker directly.
- The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

Since the implementation of §403.904(g)(1), other accrediting organizations have requested that payments made to speakers at their events also be exempted from reporting. These organizations have stated that they follow the same accreditation standards as the organizations specified in §403.904(g)(1)(i). Other stakeholders have recommended that the exemption be removed in its entirety stating removal of the exclusion will allow for consistent reporting for compensation provided to physician speakers at all continuing education events, as well as transparency regarding compensation paid to physician speakers. Many stakeholders raised concerns that the reporting requirements are inconsistent because certain continuing education payments are reportable, while others are not. CMS' apparent endorsement or support to organizations sponsoring continuing education events was an unintended consequence of the final rule.

After consideration of these comments, we propose to remove the language in §403.904(g) in its entirety, in part because it is redundant with the exclusion in §403.904(i)(1). That provision excludes 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. When 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). This approach is consistent with our discussion in the preamble to the final rule, in which we explained that if an applicable manufacturer conveys "full discretion" to the continuing education provider, those payments are outside the scope of the rule (78 FR 9492). In contrast, 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.

We considered two alternative approaches to address this issue. First, we explored expanding the list of organizations in §403.904(g)(1)(i) by name, however, we believe that this approach might imply CMS's endorsement of the named continuing education providers over others. Second, we considered expansion of the organizations in §403.904(g)(1)(i) by articulating accreditation or certification standards that would allow a CME program to qualify for the exclusion. This approach is not easily implemented because it would require evaluating both the language of the standards, as well as the enforcement of the standards of any organization professing to meet the criteria. We seek comments on both alternatives presented, including commenters' suggestions about what standards, if any, CMS should incorporate.

3. Reporting of Marketed Name (§403.904(c)(8))

Section 1128G(a)(1)(A)(vii) of the Act requires applicable manufacturers to report the name of the covered drug, device, biological or medical supply associated with that payment, if the payment is related to ''marketing, education, or research'' of a particular covered drug, device, biological, or medical supply. Section 403.904(c)(8)(i) requires applicable manufacturers to report the marketed name for each drug or biological related to a payment or

other transfer of value. At §403.904(c)(8)(ii), we require an applicable manufacturer of devices or medical supplies to report one of the following: the marketed name; product category; or therapeutic area. In the February 8, 2013, final rule, we provided applicable manufactures with flexibility when it was determined that the marketed name for all devices and medical supplies may not be useful for the general audience. We did not define product categories or therapeutic areas in §403.904(c). However, since implementation of the February 8, 2013 final rule and the development of the Open Payments system, we have determined that making the reporting requirements for marketed name across drugs, biologics, devices and medical supplies will make the data fields consistent within the system, and also enhance consumer's use of the data.

Accordingly, we propose to revise §403.904(c)(8) to require applicable manufacturers to report the marketed name for all covered and non-covered drugs, devices, biologicals or medical supplies. We believe this would facilitate consistent reporting for the consumers and researchers using the data displayed publicly on the Open Payments. Manufacturers would still have the option to report product category or therapeutic area, in addition to reporting the market name, for devices and medical supplies.

Section 403.904(d)(3) requires the reporting of stock, stock option or any other ownership interest. We are proposing to require applicable manufacturers to report such payments as distinct categories. This will enable us to collect more specific data regarding the forms of payment made by applicable manufacturers. After issuing the February 8, 2013 final rule and the development of the Open Payments system, we determined that this specificity will increase the ease of data aggregation within the system, and also enhance consumer's use of the data. We seek comments on the extent to which users of this data set find this disaggregation to be useful, and whether this change presents operational or other issues on the part of applicable manufacturers.

4. Summary of Proposed Changes

As noted above in this section, we propose the following changes to Part 403, subpart I:

- Deleting the definition of "covered device" at §403.902.
- Deleting §403.904(g) and redesignating the remaining paragraphs in that section.
- Revising §403.904(c)(8) to require the reporting of the marketed name of the related covered and non-covered drugs, devices, biologicals, or medical supplies, unless the payment or other transfer of value is not related to a particular covered or non-covered drug, device, biological or medical supply.
- Revising §403.904(d) to require the reporting of the reporting of stock, stock option or any other options as distinct categories.

Data collection requirements would begin January 1, 2015 according to this proposed rule for applicable manufacturers and applicable group purchasing organizations.