

Processing Manual (Pub. 100–4), Chapter 1, Sections 30.2.10 and 30.2.11) However, having a NPI or UPIN does not necessarily mean that the substitute physician is enrolled in the Medicare program. Without being enrolled in Medicare, we do not know whether the substitute physician has the proper credentials to furnish the services being billed under section 1842(b)(6)(D) of the Act or if the substitute physician is sanctioned or excluded from Medicare. The importance of enrollment and the resulting transparency afforded the Medicare program and its beneficiaries was recognized by the Congress when it included in the Affordable Care Act a requirement that physicians and other eligible non-physician practitioners (NPPs) enroll in the Medicare program if they wish to order or refer certain items or services for Medicare beneficiaries. This includes those physicians and other eligible NPPs who do not and will not submit claims to a Medicare contractor for the services they furnish. We solicited comments regarding how to achieve similar transparency in the context of substitute physician billing arrangements for the identity of the individual actually furnishing the service to a beneficiary.

2. Analysis of Comments

To help inform our decision whether and, if so, how to address the issues discussed in section III.H.1., and whether to adopt regulations interpreting section 1842(b)(6)(D) of the Act, we solicited comments on the policy for substitute physician billing arrangements. We noted that any regulations would be proposed in a future rulemaking with opportunity for public comment. Through this solicitation, we hoped to understand better current industry practices for the use of substitute physicians and the impact that policy changes limiting the use of substitute physicians might have on beneficiary access to physician services.

We received a few comments on the issues raised in this solicitation. We thank the commenters for their input, and we will carefully consider their comments in any future rulemaking on this subject.

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 of the Social Security Act (“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” 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, which 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 proposed a change to § 403.904(g) to correct an unintended consequence of the current regulatory text. Additionally, at § 403.904(c)(8), we proposed 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 proposed 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 proposed 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 proposed 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, for example, 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 solicited comments on both alternatives presented, including commenters' suggestions about what standards, if any, CMS should incorporate.

The following is summary of the comments we received regarding both alternatives presented, and what standards, if any, CMS should incorporate.

Comment: We received numerous comments addressing our proposal to remove the exclusion for compensation for speaking at a continuing education program. Some comments were in support to remove the exclusion stating it is an important step toward ensuring transparency. Supporting comments also agreed removing the exclusion will level the playing field with the medical education community. Numerous commenters questioned our proposal to remove the exclusion for compensation for speaking at a continuing education program. Commenters provided background regarding accrediting continuing education organizations stating that creating continuing education accreditation standards is a function of professional self-regulation and additional government regulation is not necessary.

Many commenters recommend modifying the indirect payment exclusion currently at § 403.904(i)(1) to specify a continuing education indirect payment should be excluded if the manufacturer did not know the identity of the covered recipient *before* providing the payment to a third party, such as a continuing education organization. This differs from the current indirect payment exclusion language which states the payment is excluded if the manufacturer did 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. Commenters stated it is not practical for a manufacturer to not know the identity of a physician speaker receiving compensation for speaking at a continuing education event during the reporting year or by the end of the second quarter of the following reporting year because manufacturers could learn the identities of physician speakers through brochures, programs and other publications. Therefore, commenters assert that the indirect payment exclusion is not applicable to exclude compensation provided to physicians at a continuing education event and recommend the indirect

payment exclusion is modified to accommodate indirect payments provided to a physician covered recipient through a continuing medical education organization.

Additionally, commenters suggested an alternative approach where CMS would adopt established criteria, such as the Standards for Commercial Support: Standards to Ensure Independence in CME Activities, in order to have payments provided to physicians at continuing education events excluded. Similar criteria suggested by commenters to modify the exclusion were: does not pay covered speakers or attendees directly, does not select covered recipient speakers or provide a third party with a distinct, identifiable set of individuals to be considered as speakers or attendees for the continuing education program, and does not control the continuing education program content.

Response: We appreciate commenters support to remove the exclusion for compensation for speaking at a continuing education program. We appreciate the comments stating that continuing medical education accrediting organizations is a function of professional self-regulation. We believe creating consistent reporting requirements for all continuing education events, by removing the language in § 403.904(g) in its entirety, will provide enhanced regulatory clarity for stakeholders. Manufacturers reporting compensation paid to physician speakers may opt to distinguish if the payment was provided at an accredited or certified continuing education program versus an unaccredited or non-certified continuing education program by selecting the appropriate nature of payment category at § 403.904(e).

We understand commenters concern regarding learning the identity of the physician during the reporting year or by the end of the second quarter of the following reporting year. In the situation of an applicable manufacturer providing an indirect payment through a continuing education organization and learning the identity of the physician covered recipient in the allotted timeframe (during the reporting year or by the end of the second quarter of the following reporting year) the indirect payment would not meet the criteria of the indirect payment exclusion and would need to be reported. However, payments or other transfers of value, including payments made to physician covered recipients for purposes of attending or speaking at continuing education events, which do not meet the definition of an indirect payment, as

defined at § 403.902, are not reportable. For example, if an applicable manufacturer or applicable GPO provides funding to support a continuing education event but does not require, instruct, direct, or otherwise cause the continuing education event provider to provide the payment or other transfer or value in whole or in part to a covered recipient, the applicable manufacturer or applicable GPO is not required to report the payment or other transfer of value. The payment is not reportable regardless if the applicable manufacturer or applicable GPO learns the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year because the payment or other transfer of value did not meet the definition of an indirect payment. This approach is also consistent with our statement at (78 FR 9490), where we explained that “if an applicable manufacturer provided an unrestricted donation to a physician professional organization to use at the organization’s discretion, and the organization chose to use the donation to make grants to physicians, those grants would not constitute ‘indirect payments’ because the applicable manufacturer did not require, instruct, or direct the organization to use the donation for grants to physicians.” Therefore, because such payments are not indirect payments, we do not need to create an additional exclusion specific to continuing education indirect payments by modifying the indirect payment exclusion at § 403.904(i)(1).

Comment: Many commenters interpreted the removal of physician speaker compensation at continuing education events would also remove the reporting exclusion for attendees at accredited or certified continuing education events whose fees have been subsidized through the continuing medical education organization by an applicable manufacturer.

Response: We did not intend to remove the exclusion regarding subsidized fees provided to physician attendees by manufacturers at continuing education events. However, we intend for physician speaker compensation and physician attendees fees which have been subsidized through the continuing medical education organization by an applicable manufacturer to be reported unless the payment meets the indirect payment exclusion at § 403.904(i)(1). This allows for consistent reporting for physician attendees and speakers at continuing education events. We will provide sub-regulatory guidance specifying tuition

fees provided to physician attendees that have been generally subsidized at continuing education events by manufacturers are not expected to be reported. However, if a manufacturer does instruct, direct, or otherwise cause the subsidized tuition fee for a continuing education event to go to a specific physician attendee, the payment will not be excluded, since the indirect payment exclusion only applies if the manufacturer did not know the identity of the physician attendee.

Comment: Many commenters interpreted the proposed removal of § 403.904(g) to expand the exclusion to account for continuing education programs accredited or certified for nurses, optometrists, pharmacists, and others.

Response: We appreciate the comments, but the removal of § 403.904(g) was not intended to expand the exclusion. The intent is to 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.

Comment: A few commenters requested CMS provide clear and realistic timeframes regarding payments related to continuing education events to allow manufacturers to provide sponsor notice as it considers proposals to eliminate the current CME exclusion.

Response: We agree with commenters that manufacturers may need additional time to comply with reporting requirements; therefore, we are finalizing data collection requirements that would begin January 1, 2016 according to this final rule for applicable manufacturers.

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 manufacturers 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 aligning 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 proposed to revise § 403.904(c)(8) to require applicable manufacturers to report the marketed name for all 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.

Comment: We received a few comments regarding revising reporting requirements at § 403.904(c)(8). These comments mainly stated that the marketed name for a device or medical supply is not useful for the public because the public is not familiar with device or medical supply marketed names. We also received a few comments that supported requiring the reporting of marketed name for devices and medical supplies. Supporting commenters believe that reporting marketed name for all products will allow the public (including researchers and consumers) to search the data via the Open Payments public Web site for a specific device or medical supply. Commenters also stated that reporting marketed name for non-covered products is not required by the statute and therefore manufacturers should not be required to report marketed names for non-covered products. Additionally, some comments indicated reporting marketed name for devices and medical supplies for research payments is not practical because there is not a marketed name for every device or medical supply associated with research payments; rather there may only be a connection to an associated research study. A few commenters addressed that manufacturers will have an increased burden to modify reporting systems to accommodate reporting marketed name for devices and medical supplies.

Response: We appreciate the comments supporting our proposed revisions requiring reporting marketed name for devices and medical supplies.

We have finalized a modified approach to accommodate concerns regarding reporting related covered drug, device, biological or medical supply information. We agree manufacturers should not be required to report marketed names for non-covered products; therefore, we are finalizing the proposal that reporting marketed names for non-covered drugs, devices, biologicals, or medical supplies will continue to be optional. We also agree a payment or other transfer of value associated with a research payment regarding a device or medical supply may not have a marketed name. Therefore, we are finalizing the proposal that manufacturers will continue to have an option to report either a device or medical supply marketed name, therapeutic area or product category when reporting research payments.

After consideration of comments received, we agree that displaying therapeutic areas or product categories are useful for the public reviewing data on the Open Payments public Web site because the public is not familiar with marketed names for devices and medical supplies. We agree therapeutic areas and products categories are more recognizable by the public. Yet, reporting marketed names for all covered products is necessary to achieve consistent reporting and to have the ability to aggregate all payments or other transfers of value associated with a specific device or medical supply. Therefore to achieve consistent reporting by manufacturers, we will require manufacturers to report marketed name and therapeutic area or product category for all covered drugs, devices, biologicals or medical supplies. We also agree with commenters that complying with this reporting requirement will require a change in manufacturers' reporting systems; therefore, data collection for this reporting requirement would begin January 1, 2016.

4. Reporting of Stock, Stock Option, or Any Other Ownership Interest

Section 403.904(d)(3) requires the reporting of stock, stock option, or any other ownership interest. We proposed 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

solicited 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.

The following is summary of the comments we received regarding the extent to which users of this data set find this disaggregation to be useful, requiring reporting of marketed name for covered devices and medical supplies, and whether this change presents operational or other issues on the part of applicable manufacturers.

Comment: Commenters agreed that requiring reporting of stock, stock option or any other ownership interest in distinct categories is useful.

Response: We agree the disaggregation of reporting stock, stock option or any other ownership interest in distinct categories. Therefore, we have finalized this provision as proposed, which requires reporting stock, stock option, or any other ownership interest form of payment or other transfer of value in distinct categories.

J. Physician Compare Web Site

1. Background and Statutory Authority

Section 10331(a)(1) of the Affordable Care Act, requires that, by no later than January 1, 2011, we develop a Physician Compare Internet Web site with information on physicians enrolled in the Medicare program under section 1866(j) of the Act, as well as information on other eligible professionals (EPs) who participate in the Physician Quality Reporting System (PQRS) under section 1848 of the Act.

CMS launched the first phase of Physician Compare on December 30, 2010 (<http://www.medicare.gov/physiciancompare>). In the initial phase, we posted the names of EPs that satisfactorily submitted quality data for the 2009 PQRS, as required by section 1848(m)(5)(G) of the Act.

Section 10331(a)(2) of the Affordable Care Act also requires that, no later than January 1, 2013, and for reporting periods that began no earlier than January 1, 2012, we implement a plan for making publicly available through Physician Compare information on physician performance that provides comparable information on quality and patient experience measures. We met this requirement in advance of January 1, 2013, as outlined below, and plan to continue addressing elements of the plan through rulemaking.

To the extent that scientifically sound measures are developed and are available, we are required to include, to

the extent practicable, the following types of measures for public reporting:

- Measures collected under the Physician Quality Reporting System (PQRS).
- An assessment of patient health outcomes and functional status of patients.
- An assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use.
- An assessment of efficiency.
- An assessment of patient experience and patient, caregiver, and family engagement.
- An assessment of the safety, effectiveness, and timeliness of care.
- Other information as determined appropriate by the Secretary.

As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan, we must include, to the extent practicable, the following:

- Processes to ensure that data made public are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary.
- Processes for physicians and eligible professionals whose information is being publicly reported to have a reasonable opportunity, as determined by the Secretary, to review their results before posting to Physician Compare. We have established a 30-day preview period for all measurement performance data that will allow physicians and other EPs to view their data as it will appear on the Web site in advance of publication on Physician Compare (77 FR 69166 and 78 FR 74450). Details of the preview process will be communicated directly to those with measures to preview and will also be published on the Physician Compare Initiative page (<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/>) in advance of the preview period.
- Processes to ensure the data published on Physician Compare provides a robust and accurate portrayal of a physician's performance.
- Data that reflects the care provided to all patients seen by physicians, under both the Medicare program and, to the extent applicable, other payers, to the extent such information would provide a more accurate portrayal of physician performance.
- Processes to ensure appropriate attribution of care when multiple physicians and other providers are involved in the care of the patient.
- Processes to ensure timely statistical performance feedback is