



February 17, 2012

Marilyn Tavenner, Acting Administrator and Chief Operating Officer
Centers for Medicare & Medicaid Services
Department of Health & Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests (CMS-5060-P)

Dear Acting Administrator Tavenner,

The American College of Physicians (ACP) appreciates this opportunity to comment on the above referenced Proposed Rule, which has also been referred to as the Physician Payment Sunshine Provisions of the Affordable Care Act. ACP is the largest medical specialty society and second largest physician membership organization in the United States, representing 132,000 internal medicine physicians who specialize in primary and comprehensive care of adolescents and adults and medical students who are considering a career in internal medicine.

Background and Overall Comment

This proposed rule, while recognizing that collaboration among physicians, teaching hospitals and industry is important to continued innovation and improvement of health care, also recognizes that payments made to physicians and teaching hospitals can introduce conflicts of interests that may influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care, and may lead to increased health care costs. The rule requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by federal health care programs to report annually to the Secretary single transfers of value or payments of \$10 or more, or aggregated yearly transfers of value or payments valued at greater than \$100 to (covered) recipient physicians and teaching hospitals. These values would be indexed by the Consumer Price Index. In addition, applicable manufacturers and applicable group purchasing organizations (GPOs) are required to report annually specified physician ownership or investment interests. The Secretary is required to publish applicable manufacturers’ and applicable GPOs’ submitted payment and ownership information on a public, searchable website.

The ACP has long had policy about physician-industry relations reflected in the College’s ethics, continuing education, and publication policies. For example, ACP policy states: “The acceptance by a physician of gifts, hospitality, trips, and subsidies of all types from the health care industry that might diminish, or appear to others to diminish, the objectivity of professional judgment is strongly discouraged. Even small gifts can affect clinical judgment and heighten the perception and/or reality of a conflict of interest. Physicians must gauge regularly whether any gift relationship is ethically appropriate and evaluate any potential for influence on clinical judgment.” ACP supports disclosure, stating: “Physicians who have potential financial conflicts of interest, whether as researchers,

speakers, consultants, investors, partners, employers, or otherwise, must not in any way compromise their objective clinical judgment or the best interests of patients or research subjects. Physicians must disclose their financial interests to patients, including in any medical facilities or office-based research to which they refer or recruit patients. When speaking, teaching, and authoring, physicians with ties to a particular company should disclose their interests in writing.” (ACP Ethics Manual, sixth edition, Ann Intern Med 2012; 156: 73-104

http://www.acponline.org/running_practice/ethics/manual/manual6th.htm#conflict).

Therefore, ACP supports the concept of making transparent relationships that the health care industry has with physicians and teaching hospitals, and the overall intent of this rule to reduce the adverse effects of instances of conflict of interest within health care. However, there are parts of the proposed rule that we think require further clarification and reconsideration.

These concerns, as well as some additional supportive comments, are indicated below.

Implementation

The College strongly supports the proposal to delay reporting, which is required under the Affordable Care Act to begin January 1, 2012, until a final rule has been issued by CMS to ensure that physicians have adequate notice of final transparency report requirements and provide CMS and manufacturers/GPOs an adequate opportunity to establish a reporting process that is consistent with the statute and congressional intent.

Covered Drug, Device, Biological or Medical Supply

We agree with the limitation in the definition of covered drug, device, biological and medical supply to those that require a prescription (excluding over-the-counter drugs and biologicals) and the limitation of the definition of devices and medical supplies to those that require premarket approval or notification to the FDA. We concur that manufacturers of the excluded items have not been demonstrated to have relationships that are of primary concern here and that they would be unlikely to influence clinical judgment and patient medical care.

Nature of Payment Categories

The Affordable Care Act provides categories for the “nature of payment or other transfer of value” that manufacturers must use in describing payments. **The proposed rule notes that “if a payment could conceivably fall into more than one category, we ask applicable manufactures to make reasonable determinations about the nature of payment reported for the payment or transfer of value.” We believe this is more than just conceivable, and therefore further clarification/definition of these categories is requested. The goal should be to define each category in a manner that promotes clarity and uniformity in reporting.**

The issue of proper categorization becomes more problematic in the situation of payment or transfer of value that includes “a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.” This language has been interpreted in the rule as requiring that payments provided by a third party must be reported if the manufacturer is aware of the covered recipient’s identity. How does all of this apply, for example, to faculty for a medical education program? This concern will be discussed further below.

Food and Beverage

The proposed method of reporting cost per covered recipient seems like a reasonable way to encourage transparency and accountability. The exclusion of modest food offered at conference booths or in similar settings where it would be difficult to establish the identities of individuals accepting the food also seems reasonable.

Research

We agree with the approach of limiting the research category to bona fide research activities. We also agree with the reporting methods specifying whether payments are direct research (to a physician-principal investigator or teaching hospital) vs. indirect research (to an institution that then pays the physician-principal investigator).

Direct Compensation for Serving as Faculty or as a Speaker for a Medical Education Program

We agree with the rule's proposal to interpret this category broadly. We see no principled distinction that justifies different treatment of payments for speakers or faculty in different settings or who receive payments directly versus indirectly. If the faculty member has knowledge of where the funding originated, there is a basis for a possible conflict of interest.

However, we believe this category is somewhat confusing, given the additional categories that speaker/faculty payments could fall under. Conceivably, a payment for speaking could be direct compensation for serving as a speaker; honoraria; or compensation other than for consulting. If the payment is through a third party and the speaker's identity is known, would that be in the category of honoraria? Or would it fall under compensation other than consulting; but not direct compensation for serving as a speaker? Furthermore, while we understand that the term "direct" and the explanation of "indirect payments through third parties" is contained in Section 6002 of the Affordable Care Act, and must be included in the proposed rule, they add to the confusion within this context.

One suggestion to help clarify this area, in line with the proposed rule's broader interpretation based on the grant of authority to add additional nature of payment categories, would be to have two categories within the nature of a payment section: direct compensation for serving as faculty or as speaker for a medical education program and indirect compensation for serving as faculty or as a speaker for a medical education program (with an accompanying definition of medical education program). This approach would parallel the direct and indirect reporting requirements for research.

Exclusion: Educational Materials that Directly Benefit Patients or are Intended for Patient Use

Defining as an exclusion from reporting "educational materials that directly benefit patients or are intended for patient use" as including, for example, written or electronic materials (and not services or other items) is reasonable. Per the request for comment, we do not view the provision of a medical textbook to a clinician—which is a gift—as educational material that directly benefits patients or is intended for patient use and would thus not include it in this exclusion.

Exclusion: Indirect Payments through a Third Party

We have discussed this provision previously as it applies to speakers/faculty. The Affordable Care Act states that the term “payment or other transfer of value means a transfer of anything of value” but that term “does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.” The proposed rule says that this exclusion “hinges on whether an applicable manufacturer is ‘unaware’ of the identity of the covered recipient” and must report if the identity is known through actual knowledge, and does not exclude reporting in cases of acts of deliberate ignorance or reckless disregard of the identity of the covered recipient. One example is given—that identities are known if they are publicly available, as with department chairs at a hospital. This leads us to believe that, for example, attendees at a conference would not be known to a manufacturer unless there was a publicly available registration list. But even if there were such a list, it might not be accurate as to who actually attended the meeting (vs. registering for the meeting) and a list might have the unintended effect of giving manufacturers potential marketing opportunities without the consent of the individual physicians. **This provision, in general, would benefit from further examples and clarification. Furthermore, we would strongly recommend explicit language that attendees at accredited and certified Continuing Medical Education (CME) events be excluded from the reporting requirement whether or not the registration list is publicly available. Finally, we do not see consideration in the rule of payments through third parties where funding is received from a number of companies to support a program, thereby potentially “diluting” the influence of any one company. Clarification on the handling of this sort of pooled funding arrangement would be helpful.**

Payment or Other Transfers of Value: Reporting and Review

The proposed rule notes that in instances when a covered recipient requests a payment or other transfer of value be transferred by the manufacturer to another individual or entity that such payments are to be reported under both the name of the covered recipient and the individual or entity that actually received the payment. **We agree this maximizes transparency and accountability. However, we do not agree that it is sufficient to only allow the covered recipient to review the information before it is made public. Fundamental fairness requires that anyone (or any entity) named in a report have the opportunity to review the report for accuracy before the information is made available on the CMS website.**

Report Submission and Correction

The proposed rule calls for CMS to aggregate submissions from applicable manufacturers/GPOs, and provides for a 45-day review period for covered recipients/physician owners or investors to review the reported information and correct inaccuracies. Covered recipients/physician owners or investors are expected to contact the applicable manufacturer/GPO directly to resolve inaccuracies—those expressed inaccuracies that remain outstanding would be flagged by CMS in the public database. **The proposed rule indicates that the agency would consider using the physician’s disputed aggregated total as the flagged amount—the College, at a minimum, supports using the aggregated total specified by the physician as the flagged amount. CMS might want to also provide a comment section on the public database that allows physicians to include a rebuttal for the flagged information in narrative form.**

The College also supports the implementation of a process that allows for the earlier **resolution of any conflicts between manufacturer/reporters and covered recipients/physician owners or investors through a correction process to ensure accuracy prior to submission of information to CMS, especially if there is only going to be a 45-day review period after submission of data but before information is made public. Manufacturers/reporters should be required to share information that they will report on some regular basis prior to the actual reporting to CMS with a method for correction.** It is our understanding that the technology exists that would allow manufacturers/GPOs to provide real-time as well as regular cumulative reports to physicians in multiple formats.

Public Availability of Reports

The rule notes that beyond the information required by statute, it is proposed that the website clearly state that disclosure of payments or other transfers of value “does not indicate that the payment was legitimate nor does it necessarily indicate a conflict of interest or any wrongdoing.” ACP agrees with including such a statement and would suggest that reference also be made to ethics guidelines on these topics with appropriate links to organizations with such guidelines including the American College of Physicians (see http://www.acponline.org/running_practice/ethics/manual/manual6th.htm#conflict and http://www.acponline.org/running_practice/ethics/issues/relations/); the American Medical Association; the Council of Medical Specialty Societies and others.

Information Collection Requirements (ICRs) Regarding Review and Correction by Physicians and Teaching Hospitals

CMS has provided a very limited estimate and analysis of the burden associated with the information collection requirements for physicians and teaching hospitals of the Proposed Rule. **The College believes that the analysis employed reflects a significant underestimate of the number of physicians/teaching hospital representatives who would be interested in monitoring the reported information and engage in efforts to correct inaccuracies. In addition, the time estimated to engage in these processes is also underestimated. Inaccurate reporting can significantly adversely affect the reputation of a physician or teaching hospital and efforts will be made by a majority of physicians and teaching hospitals to monitor and correct such events. Physicians also already have substantial reporting requirements as part of participation as providers within any of the federal health programs, and it should be a goal of CMS to implement this important provision in a manner that minimizes such burden. Thus, the College recommends the following steps to facilitate this goal:**

- **Re-evaluate the impact analysis conducted under this proposed rule.**
- **Require applicable manufacturers/GPOs to provide ongoing notifications to physicians of all transfers of value/ownership interests with an opportunity to correct reports as well as a cumulative report before the manufacturer/GPO transmits a report to CMS.**
- **Clarify and modify as outlined above the “Indirect Payment through Third Party” reporting category.** In particular, excluding participants attending certified and accredited CME presentations would significantly reduce the reporting burden.

- **Include in the final rule a requirement for a formal review and analysis of the report review and correction process implemented in the final rule that includes participation of all relevant stakeholders. This should occur no later than one year after implementation and have the goal of developing any necessary modifications to the process.**

The College commends CMS for the proposed rule's largely successful attempt to balance how to implement disclosures to discourage conflicts of interest and inappropriate relationships without damaging beneficial collaborations in health care. Please direct any questions regarding our recommendations to Lois Snyder, JD, Director of ACP's Center for Ethics and Professionalism at 215/351-2835 or lsnyder@acponline.org or Neil Kirschner, Ph.D at 202/261-4535 or nkirschner@acponline.org.

Respectfully,



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