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February 17, 2012

Marilyn B. Tavenner
Acting Administrator
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Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
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Re: Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests

Dear Acting Administrator Tavenner:

On behalf of American Society of Hematology (ASH), thank you for the opportunity to provide comments in response to the proposed regulation published on December 19, 2011, *Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests (CMS-5060-P)* (Proposed Rule).

ASH represents over 16,000 clinicians and scientists committed to the study and treatment of blood and blood-related diseases, including blood cancers such as leukemia, lymphoma, and myeloma and many nonmalignant illnesses such as anemia, thrombosis, and bleeding disorders. The Society supports the proposed rule's goal of discouraging inappropriate influence on clinical decision-making by increasing transparency, but offers the following comments and concerns about how the proposed rule reporting provisions will impact our members, relations between industry and medical professional societies, and our patients.

Reporting of In-direct Transfers of Value

ASH strongly urges CMS to modify the proposed rule to clarify that grants from applicable manufacturers to CME Providers for Accredited and Certified CMS activities do not constitute an indirect transfer of value, either to faculty independently selected and paid by the CME Provider or to participants in the Accredited and Certified CME activities. Neither faculty nor participants in Accredited and Certified CME activities have relationships established with applicable manufacturers by virtue of the manufacturer making an educational grant to the CME Provider under the ACCME Standards for Commercial Support of continuing medical education.

It is important to note the legislative intent and background concerning reporting on indirect transfers of value. When Congress passed the Physician Payment and Affordable

Care Act's Sec. 6002, it expressed an unambiguous intent to strike prior legislative language that would have required reporting on in-direct transfers of value except when manufacturers make a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a physician as specified in Section 6002(a)(1)(B). Earlier versions of what eventually became Sec. 6002, H.R. 5605, *Physician Payments Sunshine Act of 2008*, and S. 2029, *Physician Payments Sunshine Act of 2007*, would have explicitly required that manufacturers report a payment or other transfers of value made, "directly, indirectly, or through an agent, subsidiary, or other third party." This language was not included in the final version of the statute.

Sec. 6002 provides for reporting on direct transfers except as outlined in Sec. 6002(a)(1)(B). This latter subsection was added in the final statute in order to capture when reporting on in-direct payments and transfers would be required, specifically where manufacturers are transferring payment or value to a third party at the request of the physician or designated on behalf of the physician. When Congress conferred the agency with the authority to add additional reportable categories, it did not confer the agency with the authority to expand reporting to indirect payments or transfers except in this carefully prescribed area.

The proposed rule, however, interprets "payment or other transfer of value," Sec. 6002(e)(10)(A), to include instances where the manufacturer learns of the identity of a physician before, during, or after the manufacturer makes a payment or transfers value to a third party or when made through an "agent." CMS proposes to require reporting where a manufacturer has actual knowledge of, or acts in deliberate ignorance or reckless disregard of, the identity of a physician. ASH believes this interpretation is inconsistent with congressional intent, is unworkable, and could undermine the independence of certified CME and other activities where manufacturers make grants, but are barred from any control over how funds are used. This is amplified by the agency's overbroad proposal to make attribution of value even where there is little to no evidence that the physician receives any payment or value.

CMS proposes to expand the universe of detailed information manufacturers would demand to have about physicians where the manufacturer is reasonably expected to learn that a physician received a benefit from a transfer to a third party. This would add to the complexity of the reporting requirement because the third parties would have to report in detail back to all manufacturers the value attributed to each physician in their organization/company/conference after the indirect transfer is made.

Including the reporting of in-direct transfer of values would significantly affect ASH's educational sessions and meetings as well as other CME accredited programs. For example, ASH, like other professional medical societies, seeks industry support to expand its educational efforts, and the Society goes to great lengths to ensure that industry does not influence the selection, content or speakers at our meetings. Industry is not involved in the program planning. In addition, the Society collects conflict of interest disclosure information and the program committee works to resolve any cases where the disclosed conflict of interest might inappropriately prejudice a proposed speaker. Speakers must provide full conflict of interest disclosure at the beginning of their talk and session chairs are advised on how to manage any conflicts. Yet, according to the proposed rule, certified Continuing Medical Education (CME) activity faculty would have to be listed as receiving a payment from industry despite the fact that manufacturers are explicitly prohibited from having any control over the content, speakers, or attendees. While industry does not name the faculty, they could learn the identity of the faculty since this information is typically publicly available. Many conferences that physicians attend in order to earn certified CME credit (either developed by the American Academy of Family Physicians, the American Osteopathic Association or the AMA) also publish a list of the participants so the manufacturer could "know" or "should know" who potentially received an indirect transfer of value after the transfer is made to the third party. However, the manufacturer cannot accurately report how to make proper attribution

of value unless the CME provider or conference host provides a detailed attribution for all faculty and CME/conference attendees. The consequence of such an approach would be the transfer of an exhaustive amount of information to manufacturers about individual physicians participating in independent, certified CME. Congress never intended that transparency reports would become a gold mine of physician information for manufacturers.

Recommendations:

ASH urges CMS to replace the proposed standard with a regulation that provides that in all instances where a manufacturer would not necessarily know the identities of the specific recipients (who eventually receive a benefit) and the transfer is not made at the request of a covered recipient or designated on behalf of covered recipient, an indirect transfer is not reportable. In addition, ASH opposes the effort to expand this provision to the agents of manufacturers and, moreover, Congress specifically rejected this approach.

ASH recommends that the final rule distinguish between direct compensation for serving as a speaker in a promotional educational program offered by an applicable manufacturer, which should be reportable, from faculty serving as speakers in Accredited and Certified CME programs, in which the faculty are independently selected and paid by the CME Provider and have no relationship with any applicable manufacturer supporting the CME activity through an educational grant, which should not be considered a transfer of value and should not be reportable.

ASH recommends that the final rule explicitly state that attending an industry supported educational session is not a transfer of value and not reportable.

ASH urges CMS to exclude from reporting certified CME as this is a reasonable interpretation of both congressional intent and the legislative history of this provision.

Importantly, the Proposed Rule's overbroad interpretation of the statutory language is inconsistent with the Administration's stated goal of reducing regulatory burdens on physicians. CMS has significantly understated the paperwork burden that would be imposed on all physicians if indirect reporting is required, as this would dictate that physicians track any activity that could conceivably have any indirect transfers of value.

Reporting the Portion of the Transfer of Value/Payment

The Physician Payment and Affordable Care Act mandates that manufacturers are required to specify and report the portion of the transfer of value/payment made directly to a physician or an indirect transfer made at their request or designated on the physician's behalf. ASH believes that CMS's proposal to estimate or impute attribution even where there is no direct transfer or a qualifying indirect transfer is beyond its statutory authority and is inconsistent with congressional intent. Congress did not direct CMS to develop reports that provide an approximation of the value transferred by manufacturers to physicians nor did Congress intend that transfers of value made by manufacturers to an organization or entity that employ physicians would be attributed to a physician without regard to whether they received the transfer, requested the transfer, or it was designated on their behalf. CMS has proposed that where an organization receives a payment or transfer of value, it will be apportioned among the physicians in the organization or institution. This is simply not feasible and will result in misleading reporting. A physician employed by a large organization or institution could have funding and transfers imputed to their report that he/she cannot reject, does not receive directly (or even indirectly but in the most attenuated sense), and for which he/she has no knowledge so is unable to effectively challenge it.

ASH also strongly opposes CMS's proposal to attribute to a physician transfers of value or payment that are made to other individuals where the physician personally did not request the transfer, it was not designated on their behalf, and did not receive it.

Recommendation:

The final rule should require manufacturers to document and report only those payments and transfers made directly to physicians or those specified indirect transfers/payments requested by the physician or designated on his/her behalf.

Exemption for Educational Materials that Benefit Patients

ASH believes the exemption for educational materials that directly benefit patients is important. The Society notes that the proposed rule invites input on what educational materials are not necessarily intended for patient use. ASH believes that reprints of peer reviewed articles meet the spirit of the educational material reporting exemption and should be explicitly included in the final rule.

Like many medical professional societies, ASH's peer-reviewed journal, *Blood*, publishes original research articles and clinical practice information. Some of the peer-reviewed articles update clinical practice recommendations for the diagnosis and management of hematologic conditions or expand the available treatment options for treating hematologic disease. Frequently, companies that have products impacted by research articles or clinical practice information purchase reprints of these articles for distribution to physicians as educational material. In most cases, the reprints are intended to educate the physician on how to diagnose or treat a condition and are not necessarily intended for patient use. ASH, however strongly believes that patients ultimately benefit from the distribution of these peer-reviewed articles and that distribution of reprints should qualify under the exemption for educational materials.

Recommendation:

ASH recommends that the final rule explicitly state that reprints of peer-reviewed articles intended for physician education and that are not necessarily given to patients but provide information to increase a physician's medical knowledge meet the educational materials reporting exemption.

Implementation

Because the proposed rule was issued later than expected and contains several significant issues needing further clarification, ASH believes it should not be implemented in calendar year 2012. The final rule will have significant impact on medical professional societies, industry partners and physicians. While the Society appreciates the enormous pressure CMS staff has been under to complete a wide range of implementation regulations called for by health care reform, late promulgation will complicate the initial year collection and reporting of data. ASH and many medical societies like us will not have the necessary lead time and resources to make changes in our data system to comply with the reporting requirements in 2012.

Recommendation:

ASH strongly supports the proposal to delay reporting until a final rule has been issued by CMS to ensure that affected organizations have adequate time to put reporting mechanisms in place.

Again, ASH appreciates the opportunity to provide our comments. The Society hopes that CMS will agree with our recommendations. If you need any additional information that the Society can provide, please have your staff contact ASH Senior Director for Government Relations, Practice, and Scientific Affairs Mila Becker at <a href="majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-majorage-major

Sincerely,

Armand Keating President

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