



13034 Ballantyne Corporate Pl.  
Charlotte, NC 28277

T 704 357 0022  
F 704 357 6611

444 N Capitol Street NW  
Suite 625  
Washington, DC 20001-1511

T 202 393 0860  
F 202 393 6499

premierinc.com

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February 17, 2012

Ms. Marilyn Tavenner  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

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

Dear Administrator Tavenner:

On behalf of the Premier healthcare alliance serving more than 2,500 leading hospitals and health systems and 81,000-plus other healthcare sites, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule to implement section 6002 of the *Affordable Care Act* (ACA). This statute requires certain manufacturers to report on transfers of value to physicians and teaching hospitals and certain manufacturers and group purchasing organizations to submit reports on physician ownership or investment interests. Premier, a nationwide performance improvement alliance, is owned by nearly 200 hospitals and healthcare systems. Premier maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks.

The Premier healthcare alliance has consistently supported policies aimed at making financial relationships between pharmaceutical and medical device companies and physicians more transparent. It is essential that patients have a method to inform themselves of payments made by these companies to physicians in order to prompt candid discussions with their healthcare providers to learn if financial inducements might be influencing clinical decision making. While relationships between physicians and the industry are an important part of patient care and can aid in the development of better drugs and devices, as well as provide cross-educational opportunities that can benefit patient safety, greater transparency of the financial relationships between physicians and the industry is



needed, including relationships among other prescribing health professionals and applicable manufacturers and applicable group purchasing organizations. Premier offers the following specific comments to topics for which CMS seeks input.

Premier is generally supportive of the proposed rule and believes CMS has been responsive to the feedback it sought in a Special Open Door Forum session on implementation of section 6002 held on March 24, 2011. The proposed rule asks for a comment on a great number of issues, including alternative policy proposals, and this raises serious concerns with respect to implementation of the law consistent with the statutory deadline. Patients and healthcare consumers require sufficient and meaningful information to determine the existence and possible impact of potential conflicts of interest that may influence the decision making of the very healthcare providers on which these patients and consumers rely. Premier urges CMS to complete its rulemaking in a timely manner so that the requisite reports are first made available to the public in 2013 and patients may begin making more informed healthcare decisions sooner.

### **1) Reports on payment or transfers of value**

Premier continues to believe that the forms of payment or transfers of value listed in the statute are sufficient for implementation of the reporting requirements and concurs with CMS that at this time there is no need for additional categories. We support efforts to identify form and nature of each payment or transfer of value with as much specificity as possible and encourage CMS to require that payments be segregated so they can be identified by payment categories where possible. Simply listing aggregate payment or value amounts will serve to limit transparency; all parties are best served if public reporting reveals both form and nature of payments to covered recipients. With respect to the proposal to use dictionary definitions to define terms to categorize payments or transfers of value, we would encourage CMS to ensure that these definitions provide sufficient clarity to avoid underreporting and to monitor reports to determine whether entities required to report are in compliance with both the spirit and letter of the law. Where definitions are vague or subject to multiple interpretations, the very practice the statute seeks to preclude may well continue; further, these terms and definitions may also be interpreted differently by the public. **The statute will be most successfully implemented where CMS can provide greater specificity or guidance to the parties involved and the public.**

Premier agrees with the CMS proposal to exclude from reporting requirements those payments of applicable manufacturers made indirectly to a covered recipient through a third party in those cases where the applicable manufacturer is unaware of the identity of the covered recipient. An example of this type of third party payment is the case where an applicable manufacturer pays administrative fees to a group purchasing organization (GPO) that is a separate, independent legal entity. A GPO may make a payment or distribution of income to one or more covered recipients – for example, a teaching hospital. Under this type of arrangement, the applicable manufacturer is wholly unaware whether the GPO made any payment or distribution of income

at all, or, if the GPO made payments or distributions, the amount of the payments or distributions to the covered recipients involved. This type of arrangement is clearly not envisioned under the statute, and reporting of these payments or distributions presents the same difficulty on the applicable manufacturer as applies to other third party payments or distributions to covered recipients unknown to the manufacturer. **Premier urges CMS to clarify that this type of arrangement fits the criteria for the proposed exclusion of third party payments to unknown covered recipients.**

## **2) Applicable manufacturers**

Premier supports the proposed interpretation of the definition of applicable manufacturers and agrees that overseas manufacturers as well as entities that hold FDA approval, licensure or clearance for a covered drug, device, biological or medical supply that contract out with other entities to perform the actual manufacturing for sale or distribution in the United States should be required to report payments and other transfers of value to covered recipients. This scope is appropriate in carrying out congressional intent to curb inappropriate relationships or undue influence of manufacturers in relation to covered recipients. While we believe it is clear on the face of the language of the statute that a manufacturer of drugs dispensed on prescription is an applicable manufacturer, we are concerned that the definition could be construed to include pharmacies, which we believe is inconsistent with the intent of Congress. The goal of the statute is to deter undue influence or inappropriate relationships among those entities that manufacture a product and those who are in a position to influence the medical decisions of those for whom the products are intended to be sold. It is the prescribing of a product – not the site (often retail) where the consumer acquires the product – that is a focus of the statute. Congress elected not to include pharmacies as covered recipients because the discounts or rebates a pharmacy may negotiate from a manufacturer is to the benefit of the consumer; consistent with this policy, the statute also clearly excludes discounts or rebates from the definition of payments or other transfers of value where manufacturers make these available to covered recipients, because again this is of value to the patient. **CMS should clarify that pharmacies are excluded from the definition of applicable manufacturer under this provision of the law; it is consistent with treatment of pharmacies under other related provisions of federal law and with the goals of section 1128G of the *Social Security Act*.**

## **3) Applicable group purchasing organizations**

Premier fully supports the CMS proposal to include physician-owned distributors in the definition of the term “applicable group purchasing organization.” It is these entities that Congress envisioned when vesting discretion in CMS to define the term “applicable GPO” to expand its application beyond what CMS refers to as the traditional GPO model. The influence of this type of entity is growing. The Senate Finance Committee findings clearly demonstrate a significant role and influence of physician-owned distributorships in the country. For example, in

California alone there are more than 40 of these entities. Thus the proposal to include physician-owned distributors along with applicable GPOs should curb undue influence of these entities through requisite transparency of the relationships of the physicians involved and the healthcare services and products they prescribe.

#### **4) Covered drug, device, biological, or medical supply**

Premier supports the proposed exclusion from the definition of covered drugs, devices, biologicals, and medical supplies of over-the-counter drugs and biologicals as well as those medical devices and medical supplies for which premarket approval by or premarket notification to the Food and Drug Administration is not required. The proposed reporting requirements properly focus on prescription drugs and FDA-approved medical devices and supplies because those products play a significant role as drivers of healthcare costs and with respect to which the likelihood of inappropriate relationships that adversely affect the healthcare consumer, both patients and payers, is significantly higher. Additionally, CMS correctly expects large volumes of data for these covered products. To include reporting requirements for an enormous quantity of additional medical products for which concerns of inappropriate influence are mitigated by market forces runs the risk of providing too much information which may obscure the goals for transparency as well as imposing significant additional burdens on manufacturers, and may well be confusing to the public.

#### **5) Public reporting**

Premier supports CMS' intention to structure the information reported to the public for ultimate usability; this is consistent with our earlier comments that the data be presented in an easily comprehensible and fully meaningful manner. To implement this, reports must, at a minimum, be organized and searchable by physician name (and by NPI or state identifier number if required), by applicable manufacturer, by applicable GPO, including physician-owned distributorship, and other enumerated entities. To the maximum extent possible, the information should be specified individually; the aggregation of information on payments for multiple products is less informative and subject to manipulation than individual payment information by product. We urge CMS to both require specificity of information from applicable manufacturers and applicable GPOs and to display that information with sufficient specificity to afford the public meaningful information on a product by product, and payment by payment, basis. Premier supports the proposal to require use of the name of the drug or device in a form that is recognizable to the public. Again, the public data must reference the specific drug or device associated with any reported payment or transfer of value; CMS should not permit reporting of multiple covered products as related to a single payment as it will make aggregating payments by product more difficult and the resulting information less useful.

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Premier urges CMS to ensure that members of the public have opportunities to test the website prior to its launch and periodically thereafter as they will be the best judges of whether the site and report format are user-friendly and provide adequate information for the average and reasonable person to comprehend and use. To achieve the ultimate usability CMS seeks, the agency should regularly seek input from the public and make adjustments to accommodate legitimate concerns.

With respect to the period for review and correction of data collected by CMS as reported by applicable manufacturers and applicable GPOs, Premier supports the proposed 45-day review period as well as the agency's evident desire that disputes among applicable manufacturers and covered recipients be settled promptly. We believe that two opportunities to correct information contained in reports submitted to CMS is sufficient. In those cases where disputes are not resolved before the date the information is made available to the public, both the data as reported by the manufacturer and by the covered recipient should be included; aggregation functions should then be available by applicable manufacturer or by covered recipient. Disputes among the parties must neither interfere with the prompt provision of data to the public nor permit avenues for noncompliance by manufacturers and others through delay or dispute. Premier also supports the proposed descriptive material that would accompany the information on the website and encourages the inclusion of information on penalties imposed for reporting violations under the statute.

Premier reiterates its commitment to work with CMS as it implements section 6002 of the ACA to ensure full transparency to the public of meaningful information on financial relationships among applicable manufacturers, applicable group purchasing organizations, and covered recipients. If you have any questions, please do not hesitate to contact me at 202.879.8009 or [blair\\_childs@premierinc.com](mailto:blair_childs@premierinc.com).

Sincerely,

A handwritten signature in black ink, appearing to read "Blair Childs". The signature is fluid and cursive, with a large initial "B" and "C".

Blair Childs  
Senior Vice President, Public Affairs