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# Congress of the United States
## House of Representatives
## Washington, DC 20515

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May 18, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Room 314 G Humphrey Building
Washington, DC 20201

Dear Ms. Tavenner,

We are writing to voice our concerns over the Centers for Medicare and Medicaid Services (CMS) proposed rule pertaining to Title VI, Section 6002 of Public Law 111-148 entitled *Transparency Reports and Reporting of Physician Ownership or Investment Interests.*

The rule, issued on December 14, 2011, requires that all drug, medical device, and medical supply manufacturers disclose every payment or object valued above $10 allocated to physicians or teaching hospitals. The rule also calls for additional reporting of pharmaceutical payments to groups including Continuing Medical Education (CME) providers, professional medical associations, patient advocacy groups, and non-profits. Should manufacturers fail to report payments, they face fines of up to $150,000 a year.

While the law and subsequent rule may attempt to provide transparency in areas where potential conflicts-of-interest can arise, the regulation as written could cause a number of unintended consequences. If unaddressed, these issues will negatively impact patient care and the practice of medicine in this country.

Requiring that manufacturers report any payment or transfer of value over $10, or exceeding $100 in a calendar year, creates several problems including:

1. **Overwhelming administrative burden for companies and providers.** Complexities such as third party payments, global companies with multiple affiliates, and accounting requirements that call for companies to track the actions of providers during meetings – such as how much food an individual ate when in a group setting in order to calculate the foods worth – will force companies and providers to spend limited resources on compliance lawyers and administrative staff rather than strategies to improve patient care and outcomes. In addition, there is nothing in the statute or rulemaking that prohibits

drug and device manufacturers from passing the data collection requirements on to medical providers. Placing this kind of administrative burden on medical providers, on top of all other administrative requirements required under the Public Law 111-114, would redirect valuable time from the care of patients and place a financial strain on medical practices that some may not be able to manage.

2. **Continuing Medical Education of Medical Providers.** Currently, thousands of continuing education seminars and other provider workshops are funded by grants from various sources, including private companies. These seminars are a valuable source of medical education for providers and support their efforts to provide the highest quality health care to their patients. We are concerned that the failure to exempt accredited CME events and non-CME speaking engagements in the proposed rule will end company participation in CME events, especially when the focus of the seminar relates to advancements in medical technology. We fear that if this were to occur, the primary means by which medical providers keep abreast of advancements in patient care will no longer exist. With no equitable alternative available, it is not difficult to imagine the negative impacts on patients this kind of change will have. This is especially true for rural providers, whose CME opportunities are more limited than those practicing in urban areas.

3. **The impact on medical research in this country**. An Association of Clinical Research Organizations survey found that roughly 24% of current physicians who conduct research and clinical trials for industry would be less likely to participate if their payments from such work were made public. One reason given for these numbers is the simple fact that compliance with the regulation would provide a distorted view of provider compensation resulting from this type of work. As the regulation reads now, CMS would require each maker of a drug or device to submit the total dollar amount a researcher is paid to run the clinical trial, including operational costs. As medical providers only receive a percentage of the total payments supplied to them as compensation, with the rest going toward the cost of running the trial, the rules as written could lead to a distorted view of drug and device research in this country and stifle innovation due to the appearance of impropriety.

   Small manufacturing, medical device and pharmaceutical companies will also face a challenge that could result in job loss and operations moving overseas as companies cut back on new research and development. CMS estimates that small manufacturers would need to dedicate 50 percent of their employee's time just to comply with reporting requirements created under this rule.

4. **Billions in compliance costs for industry and federal government**. Another consequence of the strict, low-dollar amount disclosure requirement is the threat of a large fine to manufacturers deemed to be out of compliance with the law. The potential for high penalties will cause over reporting—most of which will be trivial in nature – rather than face a $150,000 fine. As it stands, estimates suggest it will cost CMS as much as $500 million to develop and maintain a database capable of sharing these transparency reports with the public. However, if over reporting were to occur, the cost of maintaining this database could easily stretch into the billions.

The threat of fines and the additional resources required of industry to be in compliance with the rule will have a dramatic impact on medical innovation as well. Accounting changes and internal controls necessary to track the actions of individual providers will create an estimated $200 million dollar burden per applicable manufacturer – costs that directly threaten medical innovation and job creation in this country.

We believe it would be unwise for the Centers for Medicare and Medicaid Services to move forward with this rule without a closer examination of the areas outlined in this letter. We therefore ask that you delay implementation of the rule until the appropriate congressional committees of jurisdiction have had a chance to review the proposed rule and its impact on patients and the U.S. health system.

Respectfully,