

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

June 9, 2011

Donald Berwick, M.D., M.P.P.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Administrator Berwick:

We are writing to you in our roles as Chairman and Ranking Members of the Senate Finance, Special Committee on Aging and Judiciary Committees to raise an issue which is an area of mutual concern given our collective mandate to protect Medicare beneficiaries and the Federal health care programs. We are increasingly concerned about the proliferation over the past few years of what are known as physician owned distributorships (PODs), also sometimes known as physician owned intermediaries, and the lack of guidance being provided to physicians, patients and the health care community on how these arrangements square with existing federal law. Specifically, with respect to the Centers for Medicare & Medicaid Services (CMS), we are writing regarding the Physician Payments Sunshine Act (Sunshine Act) and the provisions of the Patient Protection and Affordable Care Act dealing with Accountable Care Organizations (ACOs).

A POD is an arrangement where a physician investor purchases ownership shares in an entity that then purchases or serves as a medical device distributor for the products the physician utilizes in surgery. There are a variety of models which are utilized, some of which may indeed be appropriate, but the potential for conflicts of interest in this physician ownership model, the safety concerns for patients, and the potential impact on costs to the healthcare system raise a number of troubling issues about PODs and other similar arrangements which we believe merit consideration as CMS finalizes its rulemaking process.

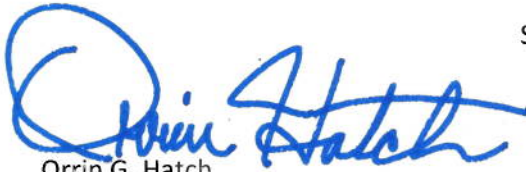
Congress passed the Sunshine Act in response to growing concerns over medical device and pharmaceutical company payments to physicians, and their potential negative effects on the effort to restrain the healthcare cost spiral. Under the provisions of this law, manufacturers are required to report to the Secretary of the Department of Health and Human Services (HHS) all manner of payments to physicians, including consulting fees, honoraria, travel and entertainment, for public disclosure by the Secretary on the Internet to include the identity of the manufacturer, the physician, and the drug or device associated with the payment. An additional provision requires manufacturers and GPOs (which could include many PODs, depending on their structure) to report all ownership or investment interests held by physicians or members of their family, also for public reporting by the Secretary. It is our understanding that the Secretary has delegated implementation of this provision to CMS.

The POD model at its basic level is exactly the type of entities envisioned by the Sunshine Act, which would require disclosure of the financial interests of their physician investors. Therefore, CMS needs to closely examine the physician ownership and investment interests presented by PODs and ensure that those are addressed as you finalize the reporting requirements of the Sunshine Act. This would mean that the distribution model of these physician owned companies would need to be included as CMS develops a final definition of "applicable manufacturers" and "applicable Group Purchasing Organizations (GPOs)." This would ensure consistent treatment of the three business models (physician-owned manufacturers, GPOs and distributors) that present similar policy and legal risks.

Another facet of the growth in PODs which needs to be taken into consideration is the extent to which the recently released ACO regulations issued by CMS will provide an inadvertent loophole allowing the less reputable POD models to fall under the Stark and Anti-Kickback law waivers envisioned for ACOs. CMS should take into account the POD models when developing its final regulation to ensure that qualification and oversight of ACOs protect against potential abuses posed by PODs. The final rule should prohibit ACOs from purchasing products or services from entities that are owned by physicians participating in the ACO. Ownership would be deemed to exist if the physician receives any remuneration (cash, equity, options, profits, dividends, etc.) from the entity supplying the product or service. It should also be made clear that waivers of Stark and Anti-Kickback laws should not extend to PODs.

We look forward to hearing from CMS by July 15, 2011, about how you will be addressing our concerns as you work to implement both of these provisions. Recognizing that both of these provisions are under potential rulemaking, the update can be provided in an in person staff briefing. Thank you for your prompt attention to this important issue.

Sincerely,



Orrin G. Hatch
Ranking Member
Finance Committee



Max Baucus
Chairman
Finance Committee



Herb Kohl
Chairman
Special Committee on Aging



Bob Corker
Ranking Member
Special Committee on Aging



Charles E. Grassley
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