



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

AUG 10 2011

Administrator  
Washington, DC 20201

The Honorable Orrin G. Hatch  
United States Senate  
Washington, DC 20510

Dear Senator Hatch:

Thank you for your letter regarding physician-owned distributorships (PODs). The Centers for Medicare & Medicaid Services (CMS) is actively engaged in developing proposed regulations to support implementation of section 6002 of the Affordable Care Act. As you know, section 6002 of the Affordable Care Act requires applicable manufacturers of covered drugs, devices, biological, or medical supplies to report payments or other transfers of values to physicians and teaching hospitals. In addition, both applicable manufacturers and applicable group purchasing organizations (GPOs) are required to report ownership or investment interests held by physicians and their immediate family members in such entities. We appreciate your suggestions regarding defining GPOs as potentially including PODs, and will consider this issue carefully as we work to develop our proposed regulations.

Your letter also raises concern that the Medicare Shared Savings Program final rule could provide an inadvertent loophole allowing the less reputable POD models to benefit from waivers of the physician self-referral law ("Stark Law") and Anti-Kickback Statute. You stated that the final Medicare Shared Savings Program rule should prohibit Accountable Care Organizations (ACOs) from purchasing products and services from entities owned by ACO physicians, and that the fraud and abuse waivers should not extend to PODs.

On April 7, 2011, we published a notice of Waiver Designs in connection with the Medicare Shared Savings Program (76 FR 19655). Comments on the Waiver Designs notice, as well as the Medicare Shared Savings Program proposed rule, were due by June 6, 2011. We are currently reviewing the comments we received, and developing our final policies regarding the exercise of our waiver authority.

Thank you again for your letter and your continued support of CMS initiatives. We appreciate your input regarding this important issue. I will also provide this response to the cosigners of your letter.

Sincerely,

A handwritten signature in black ink, appearing to read "Donald M. Berwick".

Donald M. Berwick, M.D.