

November 16, 2012

Marilyn B. Tavenner
Acting Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Ms Tavenner:

We are writing to urge you to fully implement Section 1128G of the Social Security Act, the Physician Payments Sunshine Provision, which was added as Section 6002 of the Patient Protection and Affordable Care Act (PPACA).

This provision requires that manufacturers of drugs, devices, biologics or medical supplies, or their subsidiaries that sell these products in the United States, report to Health and Human Services (HHS) certain payments made to physicians and teaching hospitals. It reflects the recommendation by major medical, consumer and industry groups, as well as MedPAC and the Institute of Medicine, that Congress pass federal legislation to bring transparency to the financial relationships between pharmaceutical and medical device companies, and health professionals and teaching hospitals.

This federal transparency provision has support from diverse stakeholders, including consumer and patient groups, professional medical associations, provider organizations, and industry.

As you move forward to implement this provision, we ask you to work quickly. The legislation required HHS to establish, by October 1, 2011, reporting procedures for applicable manufacturers to submit information to you, as well as procedures for making such information available to the public. Over one year later, these final regulations have not yet been released.

Many companies have already invested significant resources in preparing to comply with the Sunshine provision. The original statute required covered entities to begin collecting payment information as of January 1, 2012, and to submit to HHS the required information on March 31, 2013. However, delays in establishing procedures for the submission and public reporting of the required information have made these deadlines unfeasible.

We request that final regulations be released no later than December of this year, so that manufacturers can begin implementing procedures in order to begin collecting payment information.

This provision had bipartisan champions in Congress and has the support of both consumer groups and industry. Full implementation of this law will protect patients and help restore trust in our health care system.

Sincerely,



Thomas J. Schumacher
Vice President, Chief Ethics and Compliance Officer
Medtronic, Inc.

Allan Coukell
Director, Medical Programs
The Pew Charitable Trusts