

January 14, 2013

Jeffrey Zients, Acting Director
The Office of Management and Budget
725 17th Street N.W.
Washington, D.C. 20503

Email: ombdirector@omb.eop.gov

Dear Mr. Zients:

We, the undersigned organizations, respectfully urge the Administration to release the long-delayed final regulations for the Physician Payments Sunshine Act (“the Sunshine Act”, CMS-5060-P, RIN 0938-AR33) as soon as possible.

Collectively, we represent tens of millions of Americans and consumers of health care, and we are deeply concerned that additional delay in implementation will undermine the original Congressional intent behind these key consumer protection and transparency provisions. The intent of the Sunshine Act, passed in March 2010 as part of the Patient Protection and Affordable Care Act (“Affordable Care Act”) – is to protect patients and to guard the publicly funded Medicare and Medicaid programs from fraud and abuse, which in turn drive up costs for the health care system as a whole. Regulations to implement the Sunshine Act are now 15 months overdue.

There is a significant consequence for health care system costs associated with the ongoing delay in implementation because of the practice by some physicians of over-prescribing certain drugs, or by otherwise prescribing medically unnecessary and expensive treatments. The drug and medical device industries invest significant dollars to influence a physician’s choice of products, and the influence of this marketing is well established. A major Institute of Medicine (IOM) report emphasized that some financial relationships between physicians and industry raise concerns about the risk of bias in clinical decisions. The IOM concluded that conflicts of interest may present the risk of undue influence on professional judgments and the quality of patient care.

The Sunshine Act requires pharmaceutical and medical device companies to publicly report their gifts and payments to physicians and teaching hospitals. It is essential that the use of pharmaceutical products and medical devices be guided by sound clinical evidence and practice, rather than marketing. Every patient deserves the safest, most effective treatment.

As recently as six months ago, GlaxoSmithKline (GSK) finalized a record-breaking \$3 billion settlement with the Department of Justice because GSK's representatives were charged with bribing physicians to prescribe and promote the company's products for off-label uses. The Sunshine Act provides patients with the right to know about potential conflicts of interest between their physician and industry, and will help to protect patients from payments or financial relationships that could compromise the quality or cost of their health care. On behalf of millions of Americans and health care consumers, we ask that the Administration release the Sunshine Act regulations as soon as possible.

Sincerely,

AARP
AFL-CIO
AFSCME
Alliance for Retired Americans
American Medical Women's Association (AMWA)
American Medical Student Association (AMSA)
Annie Appleseed Project
Center for Science and Democracy at the Union of Concerned Scientists
Community Catalyst
Connecticut Center for Patient Safety
Families USA
Health Care for America Now! (HCAN)
National Research Center for Women & Families
National Women's Health Network
Prescription Policy Choices
The TMJ Association
U.S. PIRG
UAW Health Benefits Trust
Woodymatters