

Marilyn B. Tavenner  
Administrator  
U.S. Department of Health & Human Services  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW, Room 445-G  
Washington, DC 20201

Re: Open Payments Program

Dear Administrator Tavenner:

The **sixty-four** undersigned organizations write on behalf of the more than 133 million Americans living with chronic diseases and disabilities and their family caregivers. We respectfully urge you to create an exclusion under the Open Payments Program that would exempt reporting for indirect payments to voluntary health agencies (VHAs) in cases when an applicable manufacturer grants full and independent discretion to VHAs in selecting recipients for funding.

CMS recently relied on this argument with respect to exempting certain funding granted to a certified continuing medical education (CME) provider. Specifically, CMS states that if “an applicable manufacturer or applicable [group purchasing organization] provides funding to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting ...” and that “if an applicable manufacturer conveys ‘full discretion’ to the continuing education provider, those payments are outside the scope of the rule.”<sup>1</sup>

To support research programs and other activities, VHAs will often pool funding from a variety of sources, including, but not limited to, manufacturers. Revenue from a particular grant or sponsorship is indistinguishable from revenue provided from other sources. Additionally, VHAs maintain full discretion in how the funding is allocated. While a VHA may receive funding for a specific grant program such as research, VHAs have rigorous processes in place to determine grant recipients within the program that are completely independent of the funders.

Requiring the disclosure of physicians who receive funding will create substantial administrative burden, as entire programs will need to be restructured to determine which researchers are receiving funding that came from a corporate sponsor as opposed to other sources of funding. If these programs are not restructured in such a fashion, VHAs will risk the loss of important funding streams, limiting their ability to fund research or conduct other activities that further their mission on behalf of the patients they serve.

Because VHAs maintain full discretion over whom they will fund, and corporate funders are unaware of the recipients of such funding, we urge CMS to implement an approach toward

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<sup>1</sup> “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Notice of proposed rulemaking,” 79 Federal Register 133 (July 11, 2014), pp. 40384.

VHAs that is consistent with your rationale for exempting indirect payments for continuing medical education.

We are deeply troubled by the negative impact that the Open Payments Program can have on the ability of VHAs to fulfill their missions and goals by supporting research and other activities that are vital to furthering the understanding and development of treatments, cures, and services for the patients that they represent.

We look forward to your agency's appropriate action on this matter to ensure that the nation's leading voluntary health agencies can maximize their resources to meet the needs of the growing number of people with chronic diseases and disabilities. Please do not hesitate to contact Eric Gascho, the National Health Council's Assistant Vice President of Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at [egascho@nhcouncil.org](mailto:egascho@nhcouncil.org).

Sincerely,

**\*Signature List as of September 10, 2014\***

ADAP Advocacy Association (aaa+)  
Aimed Alliance  
Alliance for Prostate Cancer Prevention  
Alpha-1 Foundation  
The ALS Association  
American Association for Respiratory Care  
American Autoimmune Related Diseases Association  
American Diabetes Association  
American Foundation for Suicide Prevention  
American Heart Association  
American Kidney Fund  
American Liver Foundation  
Amputee Coalition  
Arthritis Foundation  
Asthma and Allergy Foundation of America  
Cancer Support Community  
Caregiver Action Network  
Center for Lawful Access and Abuse Deterrence  
Colon Cancer Alliance  
Community Access National Network (CANN)  
COPD Foundation  
Crohn's and Colitis Foundation of America (CCFA)  
Cutaneous Lymphoma Foundation  
Epilepsy Foundation  
Foundation for Ichthyosis and Related Skin Types  
GBS/CIDP Foundation International  
Huntington's Disease Society of America (HDSA)  
Immune Deficiency Foundation

Kidney Cancer Association  
The LAM Foundation  
LIVESTRONG Foundation  
Lupus Foundation of America  
March of Dimes Foundation  
The Marfan Foundation  
Mesothelioma Applied Research Foundation  
Myasthenia Gravis Foundation of America  
National Alliance on Mental Illness  
National Alopecia Areata Foundation (NAAF)  
National Down Syndrome Society  
National Eczema Association  
National Health Council  
National Hispanic Council on Aging (NHCOA)  
National Multiple Sclerosis Society  
National Osteoporosis Foundation  
National Psoriasis Foundation  
The Neuropathy Association  
Osteogenesis Imperfecta Foundation  
Ovarian Cancer National Alliance  
Parkinson's Action Network  
Pennsylvania Prostate Cancer Coalition  
Prevent Blindness  
Prevent Cancer Foundation  
Pulmonary Hypertension Association  
RESOLVE: The National Infertility Association  
Scleroderma Foundation  
Sjogren's Syndrome Foundation  
Society for Women's Health Research  
Spina Bifida Association  
Us TOO International Prostate Cancer Education and Support Network  
The Veterans Health Council  
Vietnam Veterans of America  
Women Against Prostate Cancer  
Xeroderma Pigmentosum (XP) Family Support Group  
ZERO-The End of Prostate Cancer

\*Signature List as of September 10, 2014\*