



National Health Council

1730 M Street NW, Suite 500, Washington, DC 20036-4561 ■ 202-785-3910 ■ www.nationalhealthcouncil.org ■ info@nhcouncil.org

BOARD OF DIRECTORS

Chairperson

LaVarne A. Burton
American Kidney Fund

Chairperson-Elect

Nancy Brown
American Heart Association

Vice Chairperson

Randy Beranek
National Psoriasis Foundation

Secretary

John J. Castellani
PhRMA

Treasurer

Paul Pomerantz, FASAE, CAE
American Society of Anesthesiologists

Immediate Past Chairperson

Larry Hausner
American Diabetes Association

Margaret Anderson

FasterCures – The Center for
Accelerating Medical Solutions

Barbara Collura

RESOLVE: The National
Infertility Association

Tracy Smith Hart

Osteogenesis Imperfecta Foundation

Nina M. Hill, PhD

Pfizer Inc

Jennifer L. Howse, PhD

March of Dimes Foundation

Dan Leonard

National Pharmaceutical Council

Carolyn Levering

National Marfan Foundation

Eric Racine, PharmD

Sanofi

Amy Comstock Rick, JD

Parkinson's Action Network

J. Donald Schumacher

National Hospice and
Palliative Care Organization

John R. Seffrin, PhD

American Cancer Society

Stephen J. Ubl

Advanced Medical Technology
Association (AdvaMed)

Thomas W. Wallace

Eli Lilly and Company

John W. Walsh

Alpha-1 Foundation

Cynthia Zagieboylo

National Multiple Sclerosis Society

Ex Officio Member

Myrl Weinberg, FASAE, CAE
Chief Executive Officer
National Health Council

December 4, 2013

The Honorable Kathleen Sebelius

Secretary

Department of Health and Human Services

P.O. Box 8010

Baltimore, MD 21244-8010

Cc: The Office of Inspector General

Department of Health and Human Services

1500 Pennsylvania Ave NW

Washington, DC 20220

Re: Urgent Need for Clarity Surrounding Pharmaceutical Industry Provision of Direct Cost-Sharing Assistance to Patients

Dear Secretary Sebelius:

We are writing this letter today to raise concern about the lack of clarity surrounding the provision of direct cost-sharing assistance to patients enrolled in plans operating in the health insurance marketplace. Recent communications from the administration have muddled the issue rather than offered clear guidance. We urge you to deliver straightforward guidance to clarify whether cost-sharing assistance programs will be permitted for members of marketplace plans.

The NHC is the only organization that brings together all segments of the health community to provide a united voice for the more than 133 million people with chronic diseases and disabilities as well as their family caregivers. Made up of more than 100 national health-related organizations and businesses, its core membership includes approximately 50 of the nation's leading patient advocacy groups, which control its governance. Other members include professional societies and membership associations, nonprofit organizations with an interest in health, and major pharmaceutical, medical device, biotechnology, and insurance companies.

The NHC is addressing this letter to the Department of Health and Human Services (HHS) because of recent communications stemming from this agency. We are also addressing the Office of Inspector General (OIG) because it has direct jurisdiction over this policy issue.

Two communications in recent weeks have greatly increased the confusion surrounding the ability of industry groups to provide direct cost-sharing assistance to patients. The first was issued on October 30, when HHS sent a letter to

Representative McDermott (D-WA) indicating that the agency does not consider qualified health plans (QHPs) purchased through insurance exchanges to be federal health care programs. This letter implied that such plans will not be subject to federal anti-kickback rules, potentially allowing health care stakeholders, including drug manufacturers, to provide direct financial assistance to patients.

However, on November 4, HHS issued a Q&A publication stating that premium and cost-sharing assistance by providers and commercial entities is discouraged. This Q&A publication confounded the situation for pharmaceutical manufacturers providing cost-sharing programs to patients. The two documents have led to widespread confusion about the government's stance on this issue. Recent conversations with several manufacturers have indicated their likelihood of abandoning affordability programs for patients in marketplace plans.

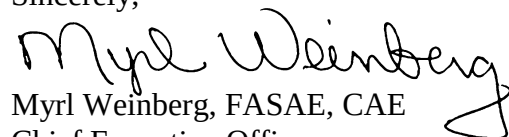
It is vital for patients living with chronic conditions and disabilities to have access to affordable care and prescription drugs offered through qualified health plans. Often, patients depend on financial assistance programs, such as cost-sharing assistance from pharmaceutical companies. This assistance is of particular importance for patients who take medications placed on the highest tiers of marketplace plans. Very often, these medications have no generic or less expensive alternative, forcing patients to make tough choices about paying rent, putting food on the table, or accessing their lifesaving medication.

Qualified health plans have nearly no limits to the cost sharing they may assign to any particular services. In fact, a review of more than 600 exchange plans revealed that patients will face high cost sharing amounts, which will contribute to patients reaching the out-of-pocket maximum faster regardless of income level. For example, an analysis of 145 benefit designs for silver plans' fourth tier showed copayments ranged from \$50 to \$500, while coinsurance ranged from 0% to 50%. These high cost-sharing requirements for specialty tier drugs will disproportionality affect people with chronic diseases and disabilities, and put in jeopardy their ability to afford life-saving branded prescription drugs that have no generic equivalents.

Therefore, we strongly encourage HHS/OIG to issue clear, unambiguous guidance allowing cost-sharing assistance programs sponsored by pharmaceutical manufacturers to operate with qualified health plans. Such a decision will allow patients with chronic conditions to be protected from the high cost-sharing benefit designs inherent in the qualified health plans.

Please do not hesitate to contact Eric Gascho, our Director of Government Affairs, if you or your staff would like to discuss these issues in greater detail. He can be reached by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org. You may also reach me on my direct, private line at 202-973-0546 or via e-mail at mweinberg@nhcouncil.org.

Sincerely,



Myrl Weinberg, FASAE, CAE
Chief Executive Officer