



NATIONAL HEMOPHILIA FOUNDATION

www.hemophilia.org

August 27, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore MD 21244-1850

Attention CMS-1612-P

Dear Ms. Tavenner:

The National Hemophilia Foundation (NHF) is pleased to offer comments on the proposed rule on the *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 (CMS-1612-P)* as published in the Federal Register on July 11, 2014.

The National Hemophilia Foundation advocates on behalf of individuals with hemophilia and related bleeding disorders, leading the nationwide fight to ensure access to affordable medical care and services. We are writing to express our concerns with CMS's proposal to eliminate the exemption in §403.904(g)(1) ("the CME Exemption") of 42 CFR Part 403, Subpart 1, Transparency Reports and Reporting of Physician Ownership or Investment Interests, also commonly referred to as the "Open Payments Program" and included in proposed rule under the section: Reports of Payments or Other Transfers of Value to Covered Recipients.

NHF offers hematologists committed to serving the hemophilia community accredited continuing education opportunities to receive up-to-date information about hemophilia and related bleeding disorders and available treatment modalities. We do this by offering Accreditation Council for Continuing Medical Education (ACCME) accredited continuing education at many of our conferences for physicians. We offer similar opportunities for accredited continuing education for nurses, pharmacists, physical therapists, and social workers serving the hemophilia community, which often include physician speakers. Funding for these activities is often supported, in whole or in part, by educational grants from manufacturers of FDA-approved blood clotting factor therapies used to treat patients with bleeding disorders. However, commercial supporters do not determine the program's content, the speakers or provide an identifiable set of individuals to serve as speakers or attendees of these programs, nor do they pay speakers or attendees directly.

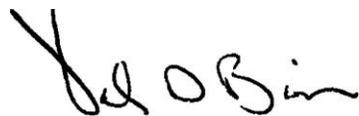
NHF is very concerned with CMS' proposal in the Medicare Physician Fee Schedule proposed rule to eliminate the explicit Open Payments Program regulatory exclusion for continuing medical education (CME) that is applicable to certified and accredited CME activities that meet the criteria for independence. We disagree with CMS that the provisions of §403.904(g)(1) are redundant of those in §403.904(i)(1) and, therefore, unnecessary. We believe that the CME exemption is a much-needed, clear exemption in the Open Payments Program and it should be maintained.

Moreover, while the hemophilia and related bleeding disorders community is small, the pool of hematologists dedicated to treating patients with non-malignant bleeding disorders like hemophilia is even smaller, particularly when compared to the physician population for general practice or other disease groups. While commercial supporters do not play a role in identifying speakers for a particular NHF CME or other certified continuing education (CE) program, the field of potential speakers is small enough that without a clear exemption for certified continuing education, we believe it will be difficult for commercial supporters not to "know" the identity of a physician speaker "during the reporting year or by the end of the second quarter of the following reporting year."¹ Furthermore, NHF's advance planning and marketing of our CME/CE programs makes it highly unlikely that this information would not be "known" to our commercial supporters during the relevant reporting period. Therefore, eliminating the CME exemption will likely open up all physician speakers at our CME/CE events to manufacturer reporting, which could create a chilling effect on recruiting quality, expert speakers.

NHF recognizes CMS' concerns with recognizing only a limited number of CME certification bodies. For that reason, we suggest that the exemption for certified continuing education programs be maintained and that CMS set forth specific standards that a CME or CE event must meet in order to qualify for the exemption. The medical profession has been self-regulating in this area since 2004 to ensure that the continuing education process is free from commercial influence. Thus, endorsing key standards by which a potential accreditor should be judged would meet the desired purpose and avoid potentially adversely impacting training programs for dedicated medical professionals, serving patients with rare diseases such as hemophilia and other bleeding disorders.

Thank you for considering the comments of the National Hemophilia Foundation. Please direct any questions to Ellen Riker, NHF's Federal Policy Advisor at eriker@dc-crd.com or Nicole Quinn-Gato, NHF Senior Policy Analyst at ngato@hemophilia.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Val Bias". The signature is fluid and cursive, with the first name "Val" being more prominent and the last name "Bias" following in a similar style.

Val Bias, CEO

¹ 42 CFR §403.904(h)(i)(1)