



March 5, 2018

The Honorable Seema Verma, M.P.H.  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attn: CMS-2017-0163  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Administrator Verma:

The Endocrine Society wishes to offer our comments on the Part D provisions of the proposed, “Advance Notice of Methodological Changes for Calendar Year 2019 for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter”. We are specifically concerned about the provision that would enable dietary supplements to be substituted for prescription drugs in Medicare Part D plans. We urge CMS to remove references to dietary supplements in finalizing this proposal and to clarify the distinction between non-FDA regulated dietary supplements and over the counter (OTC) medications.

Endocrinologists are at the core of solving the most pressing health problems of our time, from diabetes and obesity to infertility, bone health, thyroid conditions, and hormone-related cancers. Our more than 18,000 members care for patients and are dedicated to advancing hormone research and excellence in the clinical practice of endocrinology. We promote policies to help ensure that all individuals with endocrine diseases have access to high quality, specialized care and adequate, affordable health insurance.

We are concerned that CMS’s proposal would allow Part D plans “to include additional OTC products such as dietary supplements and cough medicines, without the requirement that either product offset the use of a Part D drug.” Dietary supplements are not equivalent to, and cannot be substituted for, prescription drugs. These supplements should not be used to treat, prevent, cure, or mitigate disease and can interfere with prescribed medications. We believe that, if covered under the Part D benefit, patients may believe that they can substitute their medications and achieve comparable treatment. Physicians should advise patients on what supplements should be taken, and in what amount, to avoid negative outcomes.

Dietary supplements are not subject to FDA approval and should not be included in the Part D Prescription Drug benefit. There is no requirement that dietary supplement manufacturers demonstrate that they are safe or effective, or even labeled appropriately before the products are marketed. Therefore, if CMS were to treat dietary supplements as substitutable for drugs, it could risk harm to patients. FDA regulations specifically prohibit dietary supplements from claiming to be a substitute for a “product that is a therapy for a disease,” which in conflict with CMS’s proposal. We urge you to continue prohibiting dietary supplements from being substitutes to prescription drugs and to distinguish between over the counter medication and dietary supplements in the final Call Letter.

Thank you for consideration. We would be happy to provide further information to your staff. Please contact Meredith Dyer, Director of Health Policy, at [mdyer@endocrine.org](mailto:mdyer@endocrine.org) if we can help.

Sincerely,

A handwritten signature in black ink, appearing to read "Grazia Aleppo" with a stylized flourish at the end.

Grazia Aleppo, MD  
Chair, Clinical Affairs Core Committee  
Endocrine Society