March 5, 2018

**Via Electronic Submission (www.regulations.gov)**

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

**Re: CMS-2017-0163; Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter – Proposal to Permit Substitution of Prescription Drugs with OTC Drugs and Dietary Supplements**

Dear Administrator Verma:

Mended Hearts wishes to offer our comments on the Part D provisions of the proposed draft Call Letter titled, “Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter,” and particularly the proposal by the Centers for Medicare and Medicaid Services (CMS) to permit Part D Plans (PDPs) to substitute dietary supplements for prescription drugs in the Medicare Prescription benefit. As a leading association representing heart patients across the lifespan, we are deeply troubled by the Agency’s proposal and urge CMS to withdraw any reference to dietary supplements from the Call Letter when it is finalized.

Mended Hearts is the largest peer to peer support network for cardiovascular patients in the world. We represent 20,000 members and provide support for over 200,000 patients every year. Our organization is located within 300 local communities across the country serving over 460 hospitals. Many of our patients rely on Medicare for their health care needs and we assert that the voice of the patient be protected in discussions, such as this determination presented.

The Draft Call Letter (Part II), page 197, proposes to allow PDPs: “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.” We object to this proposal, and urge CMS to withdraw it from the final Call Letter. As explained below, dietary supplements are not equivalent to, and cannot be substituted for, prescription drugs; and they cannot be used to treat, prevent, cure, or mitigate disease. Instead, dietary supplements are “food”[[1]](#footnote-1) not subject to any FDA approval and they have no place in the Part D Prescription Drug benefit.

Mended Hearts believes that protecting the patient from harm should be first and foremost at the top of all discussions. Making informed decisions are vital to our patients and this proposed rule change would open patients to a false sense of security when looking towards dietary supplements in their total health care equation. The current regulations regarding dietary supplements do not provide consumers or health care providers with sufficient information on safety and efficacy to make informed decisions about the use of such supplements. And therefore, Mended Hearts is against such a policy change.

Our position is not unique, and numerous other associations and societies have similarly issued clear statements against the use of supplements for treatment. For example, the American Society of Health System Pharmacists has written:

The American Society of Health-System Pharmacists (ASHP) believes that the widespread, indiscriminate use of dietary supplements presents substantial risks to public health and that pharmacists have an opportunity and a professional responsibility to reduce those risks. ASHP recognizes that patients may choose to use legally available dietary supplements, but believes that the decision to use substances that may be pharmacologically active should always be based on reliable information about their safety and efficacy. The current regulatory framework governing dietary supplements does not provide consumers or health care providers with sufficient information on safety and efficacy to make informed decisions. Furthermore, standards for product quality are currently inadequate.[[2]](#footnote-2)

The American Diabetes Association similarly warns against the use of supplements for treatment purposes:

There continues to be no clear evidence of benefit from herbal or nonherbal (i.e., vitamin or mineral) supplementation for people with diabetes without underlying deficiencies. Metformin is associated with vitamin B12 deficiency, with a recent report from the Diabetes Prevention Program Outcomes Study (DPPOS) suggesting that periodic testing of vitamin B12 levels should be considered in patients taking metformin, particularly in those with anemia or peripheral neuropathy. Routine supplementation with antioxidants, such as vitamins E and C and carotene, is not advised due to lack of evidence of efficacy and concern related to long-term safety. In addition, there is insufficient evidence to support the routine use of herbals and micronutrients, such as cinnamon and vitamin D, to improve glycemic control in people with diabetes.[[3]](#footnote-3)

Our statement, along with the statements of others noted above (which are only a selection of the numerous opinions warning against the use of supplements for anything more than dietary nutrition purposes) are clear, and we urge CMS to take note of them. We also urge CMS to acknowledge statements and studies by the National Institute of Health[[4]](#footnote-4) and the United States Justice Department[[5]](#footnote-5) to the same effect.

There is no requirement that dietary supplement manufacturers demonstrate that they are safe or effective, or even labeled appropriately before the products are marketed. Thus, if CMS were to treat dietary supplements as being substitutable for drugs, it would risk Plans harming beneficiaries instead of providing the treatment that beneficiaries count upon from their Medicare drug plans.

There are also important legal considerations here that require dietary supplements to continue to be excluded from the Part D program. Dietary supplements do not meet the definition of “covered Part D drug” or a “covered outpatient drug” in the Social Security Act. See 42 U.S.C. § 1395w-102(e). The term “covered part D drug” is defined in pertinent part as “a *drug* that may be dispensed only upon a *prescription* and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii), of [S]ection 1927(k)(2).” In turn, section 1927(k)(2)(A)(i) only includes “drugs” that have been approved by FDA pursuant to Section 505 of the Federal Food, Drug & Cosmetic Act (FDCA), 21 U.S.C. § 355, and the other two referenced provisions refer to “drugs” that are otherwise legally marketed under the FDCA. As mentioned, dietary supplements are “food” under the FDCA,[[6]](#footnote-6) not “drugs,” and therefore, they are excluded from that definition.

Moreover, FDA regulations specifically prohibit dietary supplements from making “disease claims” that they are a substitute for a “product that is a therapy for a disease,” which begs the question how a Part D Plan could require a dietary supplement in the first instance. In sum, and as a matter of law, supplements should be excluded from the Call Letter.

It may be the case that CMS intended only to permit OTC drugs to be substituted for prescription drugs – and not “dietary supplements” as well. Because both products can be bought off the shelf, others in the past have confused “OTCs and supplements.” They are not alike. Thus, however CMS decides to treat OTC drugs in the Part D program, we urge CMS to eliminate from the Call Letter any reference to dietary supplements.

Thank you for consideration of the above comments, and please contact the undersigned with questions that you may have.

Sincerely,



Andrea Baer

Director of Patient Advocacy and Program Management, Mended Hearts and Mended *Little* Hearts

1. 21 U.S.C. § 321(f), (ff). [↑](#footnote-ref-1)
2. https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/use-of-dietary-supplements.ashx?la=en&hash=51A155A1F5354D4B9145C5677E685F1590F5015C [↑](#footnote-ref-2)
3. http://care.diabetesjournals.org/content/41/Supplement\_1/S38 [↑](#footnote-ref-3)
4. Cohen PA. The Supplement Paradox: Negligible Benefits, Robust Consumption. JAMA. 2016;316(14):1453-1454. [↑](#footnote-ref-4)
5. Attorney General Lynch Discusses Department’s Efforts to Protect Consumers From Unsafe Dietary Supplements, Department of Justice, Office of Public Affairs, March 8, 2016, https://www.justice.gov/opa/pr/attorney-general-lynch-discusses-departments-efforts-protect-consumers-unsafe-dietary [↑](#footnote-ref-5)
6. 21 U.S.C. § 321(f), (ff). [↑](#footnote-ref-6)