November 10, 2022

Jen Dickman

Pronouns: she/her/hers

Product Stewardship Program Analyst

Urban Sustainability Administration

Department of Energy & Environment

Government of the District of Columbia

1200 First Street, NE, 5th Floor
Washington, DC 20002

**RE: DOEE Battery Stewardship Regulation Comments**

Dear Ms. Dickman and the District of Columbia Department of Energy & Environment,

The Advanced Medical Technology Association (AdvaMed) submits this letter to provide comments on the proposed rule that establishes requirements to implement the battery producer responsibility provisions of the Zero Waste Omnibus Amendment Act of 2020. AdvaMed is the largest national trade association representing nearly 450 of the world’s leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. Medical devices made by AdvaMed members help patients stay healthier longer, expedite recovery, allow earlier detection of disease, and improve effectiveness and efficiency of treatment.

The law includes an exemption for medical devices, however the lack of clarity as to its applicability within the home when a product is not directly purchased by the consumer provided by home medical equipment specialists (HMEs), and safety concerns relating to the disposal of battery powered medical devices is what we hope to address with our clarified amendment language. California’s recently enacted [Electronic Waste Recycling Act](https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202120220SB1215) for covered battery-embedded products includes this proposed exemption clause in order to provide more clarity between medical devices that are prescribed, rather than the setting in which patients use them. We respectfully request the DOEE to consider including the following clarification to the exemption as guidance or in rulemaking:

(2) “Covered battery-embedded product” does not include any of the following:

(A) A medical device, as defined in Section 321(h) of Title 21 of the United States Code, if either of the following applies:

(i) It is a Class I device as defined in Section 360c of Title 21 of the United States Code, and either of the following applies:

(I) It is a device described in Section 414.202 of Title 42 of the Code of Federal Regulations.

(II) Either of the following applies:

(ia) The device is predominantly used in a health care setting by a provider.

(ib) The device is predominantly prescribed by a health care provider.

Medical devices and technology with embedded batteries are not a typical consumer product and are much more complex. These products and their batteries aren’t disposed of in the same way as consumer products and often have their own process for recycling that a hospital, health system, or original manufacturer handles.

This clarification would ensure that all battery containing products that are medical devices as defined in the amendment would be exempt. Some examples include blood pressure cuffs and thermometers and other essential battery powered devices. Electric toothbrushes, which are a class 1 device that contain batteries but that are not prescribed or predominantly used in a health care setting, would be the only category of device that is not exempt.

We thank both agency staff at the Department of Energy and Environment for discussing our concerns over the course of the last several weeks and we hope to continue working with you to ensure that the DC Battery Recycling program works smoothly and achieves its intent.

Sincerely,

Roxy Kozyckyj

Director, State Government and Regional Affairs

AdvaMed