AdvaMed
The Medtech Association

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January 29, 2026

Senate Committee on Natural Resources and Energy
Vermont State House
115 State Street
Montpelier, VT 05633-5301

Re: Oppose S 247 Unless Amended

Dear Chair Watson, Vice Chair Williams, and Members of the Committee:

On behalf of AdvaMed, the MedTech Association, we are writing in respectful opposition to and concerns with S 247, *An act relating to the regulation of the disposal of plastics and the sale of consumer products containing microplastics*.

AdvaMed is the largest medical technology association, representing the innovators and manufacturers transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our nearly 650 members range from emerging companies to large multinationals, and include traditional device, diagnostic, medical imaging, and digital health technology companies.

As introduced, this legislation would prohibit the manufacture, sale and distribution of intravenous solution containers made with intentionally added DEHP beginning January 1, 2030. AdvaMed believes that if enacted as currently drafted, this legislation could have a negative impact on and create challenges in market continuity for these necessary products to the many patients and health systems across Vermont and the United States who rely on these critical products.

Similar bills addressing DEHP were enacted in California in 2024 and in North Carolina in 2025. Additional states have pending legislation that has been introduced or amended to align with the enacted bills in California and North Carolina. These bills reflect the inputs of many stakeholders to arrive at an agreement, and we would ask the same of this bill in Vermont.

Medical devices like intravenous solution containers must meet stringent regulations set forth by the United States Food and Drug Administration (FDA). These regulations cover the entire lifecycle of products – from design to manufacture to distribution – to ensure that patients have access to safe, effective, and high-quality devices and/or drugs. As part of this process, manufacturers must establish and maintain a comprehensive "quality system" to ensure that their

devices are manufactured consistently to specifications and have in place reporting mechanisms to detect, identify, and mitigate device-related issues.

Changing or substituting product materials is a highly complex process and subject to strict regulatory requirements and lengthy approval times. We respectfully request your consideration of three amendments that would help alleviate concerns around patient safety and access.

We propose the following edits to SB 247 to align with what has been enacted in other states:

Under § 1514. MEDICAL DEVICES amend the following to align with California and North Carolina laws:
(3) "~~Medical~~ **Intravenous** solution container" means a container used to house medicine, fluid, or nutrition therapy that is administered intravenously ~~or through the mouth, nose, stomach, or intestines~~ to patients in a hospital, outpatient, or other health care facility.

(4) "~~Medical~~ **Intravenous** tubing" means any tubing used to administer fluids, medication, **or nutrients directly to an adult, child, or infant.**~~, or oxygen, including:~~
~~(A) intravenous tubing used to administer fluids, medication, or parenteral nutrition directly into the bloodstream of an adult, child, or infant;~~
~~(B) medical tubing used to deliver enteral nutrition or medication to the digestive system for an adult, child, or infant; or~~
~~(C) respiratory tubing and nasal cannulas delivering oxygen to an infant or child.~~

(6) "Unintentionally added DEHP" means DEHP in an intravenous ~~or specified medical~~ solution container or ~~medical~~ **intravenous** tubing product that is not used for a functional or technical effect on the product.
(b) Beginning on January 1, 2030, no person shall manufacture, sell, or distribute in commerce in Vermont a ~~medical~~ **intravenous** solution container made with intentionally added DEHP.
(c) Beginning on January 1, 2035, no person shall manufacture, sell, or distribute in commerce in Vermont ~~medical~~ **intravenous** tubing made with intentionally added DEHP.
(d) No person shall replace DEHP prohibited in a product under this section with other ortho-phthalates.
(e) **An** ~~medical~~ **intravenous** solution container or ~~medical~~ **intravenous** tubing product shall not have unintentionally added DEHP present in a quantity at or above 0.1 percent by weight.

Additionally, we propose the addition of an extension with the following language to align S 247 to the California and North Carolina laws (text from California):

> (f) A person or entity, due to pending United States Food and Drug Administration approval for the DEHP-free intravenous solution container or due to the manufacturer not having adequate equipment to manufacture the DEHP-free intravenous solution container, shall meet the requirement in subdivision (a) by January 1, 2032, if all of the following conditions are met:
>
> > (1) The person or entity notified its North Carolina customers, no later than July 1, 2025, that it has commenced development of the DEHP-free intravenous solution container to meet the requirements of this section.
> >
> > (2) The person or entity provides notice to its customers and posts to its official internet website, no later than January 1, 2028, that it will not meet the deadline imposed pursuant to subdivision (a).

These proposed edits mirror the enacted language in California and North Carolina and reflect was agreed upon by stakeholders. We believe that the amendments proposed above will help Vermont meet its goal of removing intentionally added DEHP but also provide time for manufacturers to meet these requirements while not impacting patient access to necessary medical devices.

Sincerely,

Adrienne Frederick
Director, State Government & Regional Affairs
AdvaMed