HOUSE DOCKET, NO. 4615 FILED ON: 4/29/2025

HOUSE . . . . . No. 4298

The Commonwealth of Massachusetts

PRESENTED BY:

James J. O'Day

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to toxic-free medical devices.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
James J. O'Day	*14th Worcester*	*4/29/2025*
Joan B. Lovely	*Second Essex*	*7/10/2025*

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By Representative O'Day of West Boylston, a petition (subject to Joint Rule 12) of James J. O'Day relative to the manufacture and sale of toxic-free medical devices. Public Health.

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Fourth General Court
(2025-2026)

An Act relative to toxic-free medical devices.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

Section 1. Chapter 111 of the General Laws is hereby amended by inserting after Section 244 the following section:-

Section 245. (a) For the purposes of the section, unless the context clearly requires otherwise, the following words shall have the following meanings:-

"DEHP." Di(2-ethylhexyl) phthalate

"Health care practitioner." An individual who is authorized to practice some component of the healing arts by a license, permit, certificate or registration issued by a Commonwealth licensing agency or board.

"Intentionally added DEHP." Either of the following:

(1) DEHP that a manufacturer has intentionally added to an intravenous solution container or intravenous tubing product and that has a functional or technical effect on the product.

"Intravenous solution container." A container used to house medicine, fluid or nutrition therapy that is intravenously delivered to a patient in a hospital, outpatient facility or other health care facility.

"Intravenous tubing." Tubing used to intravenously administer fluids, medication or nutrients directly to an adult, child, or infant.

"Ortho-phthalate." A class of chemicals that are esters of ortho-phthalic acid, including DEHP and any of the following:

(1) Benzyl-butyl phthalate (BBP)

(2) Dibutyl phthalate (DBP)

(3) Dicyclohexyl phthalate (DCHP)

(4) Diethyl phthalate (DEP)

(5) Di-isobutyl phthalate (DIBP)

(6) Di-isodecyl phthalate (DIDP)

(7) Di-isononyl phthalate (DINP)

(8) Di-n-hexyl phthalate (DnHP)

(9) Di-n-octyl phthalate (DNOP)

(10) Di-n-pentyl phthalate (DnPP)

(11) Diisoheptyl phthalate (DIHP)

"Unintentionally added DEHP." DEHP in an intravenous solution container or intravenous tubing product that is not used for functional or technical effect on the product.

(b) Beginning January 1, 2030, a person or entity shall not manufacture, sell or contribute into commerce in the Commonwealth intravenous solution containers made with intentionally added DEHP.

(c) Beginning January 1, 2035, a person or entity shall not manufacture, sell or distribute into commerce in the Commonwealth intravenous tubing made with intentionally added DEHP.

(d) A person or entity may not replace DEHP, pursuant to this section, with another ortho-phthalate in a new or revised medical device.

(e) An intravenous solution container or intravenous tubing product shall not have unintentionally added DEHP present at a quantity at or above 0.1 percent weight per weight (w/w).

(f) The following items, as described in Title 21 of the Code of Federal Regulations, are exempt from these provisions:-

(1) human blood collection and storage bags

(2) aspheresis and cell therapy blood kits and bags, including integral tubing

(g) A person or entity, due to pending United States Food and Drug Administration approval for the DEHPfree intravenous solution container or due to the manufacturer not having

adequate equipment to manufacture the DEHPfree intravenous solution container, shall meet the requirement in subsection (b) by January 1, 2032, if all of the following conditions are met:

(1) The person or entity notified its Massachusetts customers, no later than Oct 1, 2025, that it has commenced development of the DEHPfree 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 subdsection (b).".