SECOND REGULAR SESSION

HOUSE BILL NO. 3357

103RD GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE DEAN.

7257H.01I JOSEPH ENGLER, Chief Clerk

AN ACT

To amend chapter 191, RSMo, by adding thereto one new section relating to the safety of medical devices.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Chapter 191, RSMo, is amended by adding thereto one new section, to be known as section 191.647, to read as follows:

191.647. 1. As used in this section, the following terms mean:

(1) "DEHP", di(2-ethylhexyl) phthalate;

(2) "Intentionally added DEHP", DEHP that a manufacturer has intentionally added to a product and that has a functional or technical effect on the product;

(3) "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;

(4) "Intravenous tubing", tubing used to intravenously administer fluids, medication, or nutrients directly to an adult, child, or infant;

(5) "Ortho-phthalate", a class of chemicals that are esters of ortho-phthalic acid, including DEHP or any of the following:

(a) Benzyl butyl phthalate (BBP);

(b) Dibutyl phthalate (DBP);

(c) Dicyclohexyl phthalate (DCHP);

(d) Diethyl phthalate (DEP);

(e) Diisobutyl phthalate (DIBP);

(f) Diisodecyl phthalate (DIDP);

EXPLANATION — Matter enclosed in bold-faced brackets **[**~~thus~~**]** in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

(g) Diisononyl phthalate (DINP);

(h) Di-n-hexyl phthalate (DnHP);

(i) Di-n-octyl phthalate (DNOP);

(j) Di-n-pentyl phthalate (DnPP); or

(k) Diisoheptyl phthalate (DIHP);

(6) "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.

2. Beginning January 1, 2030, a person or entity shall not sell or distribute into commerce in this state intravenous solution containers made with intentionally added DEHP.

3. Beginning January 1, 2035, a person or entity shall not manufacture, sell, or distribute into commerce in this state intravenous tubing made with intentionally added DEHP.

4. A person or entity subject to the prohibitions in this section shall not replace DEHP with another ortho-phthalate in a new or revised medical device.

5. An intravenous solution container or intravenous tubing product shall not have unintentionally added DEHP present at a quantity at or above one-tenth of one percent weight per weight.

6. The following items, as described in Title 21 of the Code of Federal Regulations, shall be exempt from the requirements of this section:

(1) Human blood collection and storage bags; and

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

7. The date of January 1, 2030, by which compliance is required for a person or entity under subsection 2 of this section shall be extended to January 1, 2032, if all of the following conditions are met:

(1) The need for an extension is 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;

(2) The person or entity notified its Missouri customers, before October 1, 2026, that it has commenced development of the DEHP-free intravenous solution container to meet the requirements of this section; and

(3) The person or entity provides notice to its customers and posts to its official internet website, before January 1, 2028, that it will not meet the deadline imposed under subsection 2 of this section.

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