HOUSE BILL 592
Committee Substitute Favorable 4/15/25

Short Title: Toxic-Free Medical Devices Act of 2025. (Public)

Sponsors:

Referred to:

April 1, 2025

A BILL TO BE ENTITLED

AN ACT TO PROHIBIT THE MANUFACTURING, SELLING, AND DISTRIBUTING OF INTRAVENOUS SOLUTION CONTAINERS AND INTRAVENOUS TUBING THAT ARE INTENTIONALLY MADE WITH DEHP.

The General Assembly of North Carolina enacts:

SECTION 1. Chapter 130A of the General Statutes is amended by adding a new Article to read as follows:

"Article 19C.

"DEHP Hazard Management.

"**§ 130A-453.33. Legislative finding.**

The General Assembly finds all of the following:

(1) DEHP and other ortho-phthalates are toxic chemicals used primarily to produce flexibility in plastics, mainly polyvinyl chloride (PVC).

(2) DEHP is the most common plasticizer used in medical devices, including intravenous solution containers, which are also known as IV bags, and intravenous tubing.

(3) Over the course of its shelf life, DEHP leaches from IV bags and tubing made from DEHP into the solutions being held in the medical devices.

(4) DEHP is classified by the United States Environmental Protection Agency as an endocrine-disrupting compound since it can:

a. Interfere with the hormonal system in humans and animals.

b. Mimic or block the actions of hormones, leading to adverse effects on reproductive health, development, and metabolism.

(5) DEHP exposure has been associated with adverse effects on reproductive organs and fertility. DEHP can also disrupt normal reproductive development, reduce sperm quality, and affect hormone levels in both males and females.

(6) DEHP is metabolized in the liver and can accumulate in the body over time. Prolonged exposure to high levels of DEHP has been shown to cause liver and kidney damage in animal studies.

(7) Inhalation or ingestion of DEHP can cause respiratory irritation and allergic reactions in some individuals, particularly those with preexisting respiratory conditions or sensitivities.

(8) Studies have suggested a potential link between DEHP exposure and certain types of cancer, including breast, liver, lung, and testicular cancer.

(9) The United States Environmental Protection Agency has determined that DEHP is a probable human carcinogen.

(10) The leaching of DEHP from medical devices at varying concentrations has been linked to multidrug resistance in breast cancer cells, inhibiting the effectiveness of breast cancer drugs. This phenomenon has been observed at both high and low concentrations of DEHP, highlighting the potential impact of DEHP leaching on cancer treatment outcomes.

(11) Exposure to DEHP has been linked to multidrug resistance in triple-negative breast cancer cells, inhibiting the apoptosis mechanism induced by breast cancer drugs, such as tamoxifen, and increasing cell proliferation.

(12) DEHP has been suggested to serve as a mitogenic factor for estrogen receptor-positive breast cancer cells, potentially making them multidrug resistant.

"**§ 130A-453.34. Definitions.**

The following definitions apply in this Article:

(1) DEHP. – Di(2-ethylhexyl) phthalate.

(2) 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 State licensing agency or board.

(3) Intentionally added DEHP. – DEHP that a manufacturer has intentionally added to a product and that has a functional or technical effect on the product.

(4) 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.

(5) Intravenous tubing. – Tubing used to intravenously administer fluids, medication, or nutrients directly to an adult, child, or infant.

(6) 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).
g. Diisononyl phthalate (DINP).
h. Di-n-hexyl phthalate (DnHP).
i. Di-n-octyl phthalate (DNOP).
j. Di-n-pentyl phthalate (DnPP).
k. Diisoheptyl phthalate (DIHP).

(7) 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.

"**§ 130A-453.35. Prohibitions.**

(a) Intravenous Solution Containers. – Beginning January 1, 2030, a person or entity shall not manufacture, sell, or distribute into commerce in the State of North Carolina intravenous solution containers made with intentionally added DEHP.

(b) Intravenous Tubing. – Beginning January 1, 2035, a person or entity shall not manufacture, sell, or distribute into commerce in the State of North Carolina intravenous tubing made with intentionally added DEHP.

(c) Replacement. – A person may not replace DEHP, pursuant to this Article, with another ortho-phthalate in a new or revised medical device.

(d) Maximum Quantity. – 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).

(e) Exemptions. – 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) Apheresis and cell therapy blood kits and bags, including integral tubing.

(f) Delayed Compliance. – 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 subsection (a) of this section 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 October 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 subsection (a) of this section."

SECTION 2. G.S. 130A-22(b3) reads as rewritten:

"(b3) The Secretary may impose an administrative penalty on a person who violates ~~Article 19A or 19B~~ Article 19A, 19B, or 19C of this Chapter or any rules adopted pursuant to ~~Article 19A or 19B~~ Article 19A, 19B, or 19C of this Chapter. Each day of a continuing violation is a separate violation. The penalty shall not exceed five thousand dollars ($5,000) for each day the violation continues for Article 19A of this Chapter. The penalty shall not exceed five thousand dollars ($5,000) for each day the violation continues for Article 19B of this Chapter. The penalty shall not exceed five thousand dollars ($5,000) for each day the violation continues for Article 19C of this Chapter. The penalty authorized by this section does not apply to a person who is not required to be certified under Article 19A or 19B."

SECTION 3. Except as otherwise provided, this act is effective when it becomes law.