



# HOUSE BILL 592: Toxic-Free Medical Devices Act of 2025.

2025-2026 General Assembly

<b>Committee:</b>	House Rules, Calendar, and Operations of the House	<b>Date:</b>	April 15, 2025
<b>Introduced by:</b>	Reps. Reeder, Rhyne	<b>Prepared by:</b>	Stewart Sturkie
<b>Analysis of:</b>	Second Edition		Committee Co-Counsel

**OVERVIEW:** *House Bill 592 would add Article 19C to Chapter 130A of the General Statutes. The bill would prohibit the manufacture, sale, and distribution of intravenous (IV) solution containers and IV tubing made with Di(2-ethylhexyl) phthalate (DEHP) in North Carolina.*

## BILL ANALYSIS:

**Section 1** of the bill would:

- Present legislative findings.
- Introduce definitions for: DEHP, health care practitioner, intentionally added DEHP, IV solution container, IV tubing, ortho-phthalate, and unintentionally added DEHP.
- Prohibit:
  - Manufacture, sale, or distribution of IV solution containers made with intentionally added DEHP on or after January 1, 2030.
  - Manufacture, sale, or distribution of IV tubing made with intentionally added DEHP on or after January 1, 2035.
  - Replacement of DEHP with another ortho-phthalate in a new or revised medical device.
  - The unintentional addition of DEHP into an IV solution container or tubing at a quantity at or above 0.1 percent weight per weight.
  - Compliance will be delayed until January 1, 2032 for people or entities that are waiting for FDA approval of DEHP-free IV solution containers or that do not have adequate equipment to make DEHP-free IV solution containers, if:
    - The person or entity notifies its North Carolina customers no later than October 1, 2025, that it has begun development on a DEHP-free IV solution container.
    - The person or entity provides notice to its customers that it will not meet the deadline and posts that it will not meet the deadline to its official website no later than January 1, 2028.
- Exempt from the prohibitions:
  - Human blood collection and storage bags.
  - Apheresis and cell therapy blood kits and bags, including integral tubing.

Kara McCraw  
Director



Legislative Analysis  
Division  
919-733-2578

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**Section 2** of the bill would impose an administrative penalty on a person who violates the Article. The penalty would not exceed \$5,000 for each day the Article is violated.

**EFFECTIVE DATE:** Except as otherwise provided, the act would be effective when it becomes law.

**BACKGROUND:** DEHP has been linked to health concerns that include interference with hormonal systems in humans and animals, adverse effects on reproductive organs and fertility, and respiratory irritation. Studies have suggested a potential link between DEHP and certain types of cancers.