

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1301 Session of
2024

INTRODUCED BY BOSCOLA, FONTANA, COSTA, BREWSTER AND MILLER,
AUGUST 20, 2024

REFERRED TO HEALTH AND HUMAN SERVICES, AUGUST 20, 2024

AN ACT

1 Amending Title 35 (Health and Safety) of the Pennsylvania
2 Consolidated Statutes, providing for medical devices.

3 The General Assembly of the Commonwealth of Pennsylvania
4 hereby enacts as follows:

5 Section 1. Title 35 of the Pennsylvania Consolidated
6 Statutes is amended by adding a chapter to read:

7 CHAPTER 58A

8 MEDICAL DEVICES

9 Subchapter

10 A. Preliminary Provisions (Reserved)

11 B. Prohibited Chemicals in Medical Devices

12 SUBCHAPTER A

13 PRELIMINARY PROVISIONS

14 (Reserved)

15 SUBCHAPTER B

16 PROHIBITED CHEMICALS IN MEDICAL DEVICES

17 Sec.

18 58A11. Scope of subchapter.

1 58A12. Legislative findings and declarations.

2 58A13. Definitions.

3 58A14. Prohibitions.

4 58A15. Notice.

5 § 58A11. Scope of subchapter.

6 This subchapter relates to prohibited chemicals in medical
7 devices.

8 § 58A12. Legislative findings and declarations.

9 The General Assembly finds and declares as follows:

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

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

16 (3) Over the course of its shelf life, DEHP leaches from
17 plastic containers such as medical devices into a simulant.

18 (4) DEHP is classified as an endocrine-disrupting
19 compound since it can:

20 (i) Interfere with the hormonal system in humans and
21 animals.

22 (ii) Mimic or block the actions of hormones, leading
23 to adverse effects on reproductive health, development
24 and metabolism.

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

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

30 (7) DEHP exposure:

1 (i) Has been associated with adverse effects on
2 reproductive organs and fertility.

3 (ii) Can disrupt normal reproductive development,
4 reduce sperm quality and affect hormone levels in both
5 males and females.

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

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

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

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

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

28 § 58A13. Definitions.

29 The following words and phrases when used in this subchapter
30 shall have the meanings given to them in this section unless the

1 context clearly indicates otherwise:

2 "DEHP." Di(2-ethylhexyl) phthalate (Chemical Abstracts
3 Service Registry Number 117-81-7).

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

8 "Intentionally added DEHP." Either of the following:

9 (1) DEHP that a manufacturer has intentionally added to
10 a product and that has a functional or technical effect on
11 the product.

12 (2) DEHP that is an intentional breakdown product of an
13 added chemical.

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

18 "Intravenous tubing." Tubing used to administer fluids,
19 medication or nutrients directly to an individual.

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

22 (1) Benzyl butyl phthalate (BBP) (Chemical Abstracts
23 Service Registry Number 85-68-7).

24 (2) Dibutyl phthalate (DBP) (Chemical Abstracts Service
25 Registry Number 84-74-2).

26 (3) Dicyclohexyl phthalate (DCHP) (Chemical Abstracts
27 Service Registry Number 84-61-7).

28 (4) Diethyl phthalate (DEP) (Chemical Abstracts Service
29 Registry Number 84-66-2).

30 (5) Diisobutyl phthalate (DIBP) (Chemical Abstracts

1 Service Registry Number 84-69-5).

2 (6) Diisodecyl phthalate (DIDP) (Chemical Abstracts
3 Service Registry Number 26761-40-0).

4 (7) Diisononyl phthalate (DINP) (Chemical Abstracts
5 Service Registry Number 28553-12-0).

6 (8) Di-n-hexyl phthalate (DnHP) (Chemical Abstracts
7 Service Registry Number 84-75-3).

8 (9) Di-n-octyl phthalate (DNOP) (Chemical Abstracts
9 Service Registry Number 117-84-0).

10 (10) Di-n-pentyl phthalate (DnPP) (Chemical Abstracts
11 Service Registry Number 131-18-0).

12 (11) Diisoheptyl phthalate (DIHP) (Chemical Abstracts
13 Service Registry Number 71888-89-6).

14 "Patient." An individual who is under the medical care of a
15 health care practitioner, in addition to the following, as
16 applicable:

17 (1) The parent or legal guardian of the individual if
18 the individual is under 18 years of age.

19 (2) The health care agent, as defined in 20 Pa.C.S. §
20 5422 (relating to definitions), of the individual.

21 (3) The health care representative, as defined in 20
22 Pa.C.S. § 5422, of the individual.

23 (4) The guardian of the individual if the individual is
24 deemed an incapacitated person in accordance with 20 Pa.C.S.
25 (relating to decedents, estates and fiduciaries).

26 § 58A14. Prohibitions.

27 (a) Intravenous solution containers.--Beginning January 1,
28 2026, a person may not manufacture, sell or distribute
29 intravenous solution containers made with an intentionally added
30 DEHP.

1 (b) Intravenous tubing.--

2 (1) Beginning January 1, 2026, a person may not
3 manufacture, sell or distribute intravenous tubing made with
4 an intentionally added DEHP for use in neonatal intensive
5 care units or for the purpose of nutrition infusions or
6 oncology treatment infusions.

7 (2) Beginning January 1, 2031, a person may not
8 manufacture, sell or distribute intravenous tubing made with
9 an intentionally added DEHP.

10 (c) Replacement.--A person may not replace DEHP with another
11 ortho-phthalate in a new or revised medical device.

12 § 58A15. Notice.

13 (a) Requirement.--A health care practitioner shall notify a
14 patient prior to use of an intravenous solution container or
15 intravenous tubing that contains DEHP or other ortho-phthalate
16 in the course of treatment.

17 (b) Contents.--Notice under subsection (a) shall include, at
18 a minimum, information relating to:

19 (1) The risks associated with exposure to DEHP and other
20 ortho-phthalates.

21 (2) The patient's right to request an intravenous
22 solution container or intravenous tubing that is free from
23 DEHP and other ortho-phthalates.

24 Section 2. This act shall take effect in 90 days.