

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2013

H

D

HOUSE BILL 644
PROPOSED COMMITTEE SUBSTITUTE H644-PCS80362-TK-37

Short Title: Prevent Hazardous Drug Exposure.

(Public)

Sponsors:

Referred to:

April 10, 2013

1 A BILL TO BE ENTITLED
2 AN ACT RELATING TO THE HANDLING OF HAZARDOUS DRUGS TO PREVENT
3 DISEASE AND INJURY CAUSED BY EXPOSURE.

4 Whereas, according to the National Institute for Occupational Safety and Health
5 (NIOSH), early concerns about occupational exposure to antineoplastic drugs first appeared in
6 the 1970s; and

7 Whereas, antineoplastic and other hazardous drugs may cause skin rashes,
8 infertility, miscarriage, birth defects, and have been linked to a wide variety of cancers; and

9 Whereas, NIOSH published an alert on preventing occupational exposures to
10 antineoplastic and other hazardous drugs in health care settings in 2004 with an update in 2010;
11 and

12 Whereas, in this alert, the NIOSH presents a standard precautions or universal
13 precautions approach to handling hazardous drugs safely, meaning that it recommends that all
14 hazardous drugs be handled as outlined in the alert; Now, therefore,
15 The General Assembly of North Carolina enacts:

16 **SECTION 1.** The General Assembly finds that health care personnel who work
17 with or near hazardous drugs in health care settings may be exposed to these agents in the air,
18 on work surfaces, clothing, and medical equipment, or through patient contact. It is the intent of
19 the General Assembly to require health care facilities to follow rules requiring compliance with
20 all aspects of alerts from the National Institute for Occupational Safety and Health in order to
21 protect health care personnel in this State from hazardous exposure to such drugs.

22 **SECTION 2.** G.S. 95-127 reads as rewritten:

23 **"§ 95-127. Definitions.**

24 ~~In this Article, unless the context otherwise requires:~~ As used in this Article, the following
25 definitions apply:

26 (1) ~~The term "Advisory Council" shall mean the~~ Advisory Council. – The
27 Advisory Council or body established under this Article.

28 (2) Antineoplastic drug. – A chemotherapeutic agent that controls or kills
29 cancer cells.

30 (2)(3) ~~The term "Commission" means the~~ Commission. – North Carolina
31 Occupational Safety and Health Review Commission established under this
32 Article.

33 (3)(4) ~~The term "classified service" means a~~ Classified service. – A position
34 included in the State Merit System of Personnel Administration subject to
35 the laws, rules and regulations of the State Personnel Board as administered



* H 6 4 4 - P C S 8 0 3 6 2 - T K - 3 7 *

1 by the State Personnel Director and as set forth in Chapter 126 of the
2 General Statutes.

3 ~~(4)(5) The term "Commissioner" means the Commissioner.~~ – The Commissioner of
4 Labor of North Carolina.

5 ~~(5)(6) The term "days" shall mean a Day.~~ – A calendar day unless otherwise noted.

6 ~~(6)(7) The term "Department" means the Department.~~ – The North Carolina
7 Department of Labor of North Carolina.

8 ~~(7)(8) The term "Deputy Commissioner" means the Deputy Commissioner.~~ – The
9 Deputy Commissioner of the North Carolina Department of Labor, who is
10 appointed by the Commissioner to aid and assist the Commissioner in the
11 performance of his duties. The Deputy Commissioner shall exercise such
12 power and authority as delegated to him or her by the Commissioner.

13 ~~(8)(9) The term "Director" means the Director.~~ – The officer or agent appointed by
14 the Commissioner of Labor for the purpose of assisting in the administration
15 of the Occupational Safety and Health Act of North Carolina.

16 ~~(9)(10) The term "employee" means an Employee.~~ – An employee of an employer
17 who is employed in a business or other capacity of his or her employer,
18 including any and all business units and agencies owned and/or controlled
19 by the employer.

20 ~~(10)(11) The term "employer" means a Employer.~~ – A person engaged in a
21 business who has employees, including any state or political subdivision of a
22 state, but does not include the employment of domestic workers employed in
23 the place of residence of his or her employer.

24 ~~(11)(12) The term "established federal standard" means any Established federal~~
25 ~~standard.~~ – Any operative occupational safety and health standard
26 established by any agency of the United States and presently in effect, or
27 contained in any act of Congress in force on the date of enactment of this
28 Article, and adopted by the Secretary of Labor under the Occupational
29 Safety and Health Act of 1970.

30 ~~(12)(13) The term "federal act," as referred to in this Article, means the Federal~~
31 ~~Act.~~ – The Occupational Safety and Health Act of 1970 (Public Law 91-596,
32 91st Congress, Act of December 29, 1970, 84 Stat. 1950).

33 ~~(14)~~ Hazardous drug. – Any drug identified by the National Institute for
34 Occupational Safety and Health at the Centers for Disease Control as a
35 hazardous drug or any drug that meets at least one of the following six
36 criteria: (i) carcinogenicity; (ii) teratogenicity or developmental toxicity; (iii)
37 reproductive toxicity in humans; (iv) organ toxicity at low doses in humans
38 or animals; (v) genotoxicity; or (vi) a new drug that mimics existing
39 hazardous drugs in structure or toxicity.

40 ~~(13)(15) The term "imminent danger" means any Imminent danger.~~ – Any
41 conditions or practices in any place of employment which are such that a
42 danger exists which could reasonably be expected to cause death, or serious
43 physical harm immediately or before the imminence of such danger can be
44 eliminated through the enforcement procedures otherwise provided by this
45 Article.

46 ~~(14)(16) The term "issue" means an Issue.~~ – An industrial, occupational or hazard
47 grouping.

48 ~~(15)(17) The term "occupational safety and health standards" means~~
49 ~~aOccupational safety and health standard.~~ – A standard which requires
50 conditions, or the adoption or use of one or more practices, means, methods,
51 safety devices, operations or processes reasonably necessary and appropriate

1 to provide safe and healthful employment and places of employment, and
2 shall include all occupational safety and health standards adopted and
3 promulgated by the Secretary which also may be and are adopted by the
4 State of North Carolina under the provisions of this Article. This term
5 includes but is not limited to interim federal standards, consensus standards,
6 any proprietary standards or permanent standards, as well as temporary
7 emergency standards which may be adopted by the Secretary, promulgated
8 as provided by the Occupational Safety and Health Act of 1970, and which
9 standards or regulations are published in the Code of Federal Regulations or
10 otherwise properly promulgated under the federal act or any appropriate
11 federal agencies.

12 ~~(16)~~(18) ~~The term "person" means one~~Person. – One or more individuals,
13 partnerships, associations, corporations, business trusts, legal
14 representatives.

15 ~~(17)~~(19) ~~The term "Secretary" means the~~Secretary. – The United States Secretary
16 of Labor.

17 ~~(18)~~(20) ~~A "serious violation"~~Serious violation. – A violation that shall be
18 deemed to exist in a place of employment if there is a substantial probability
19 that death or serious physical harm could result from a condition which
20 exists, or from one or more practices, means, methods, operations, or
21 processes which have been adopted or are in use at such place of
22 employment, unless the employer did not know, and could not, with the
23 exercise of reasonable diligence, know of the presence of the violation.

24 ~~(19)~~(21) ~~The term "State" means the~~State. – The State of North Carolina."

25 **SECTION 3.** G.S. 94-133(a) reads as rewritten:

26 "(a) There is hereby created and established in the North Carolina Department of Labor
27 a division to be known as the Occupational Safety and Health Division. The Commissioner
28 shall appoint a Director to administer this division who shall be subject to the direction and
29 supervision of the Commissioner. The Director shall carry out the responsibilities of the State
30 of North Carolina as prescribed under the Occupational Safety and Health Act of 1970, and any
31 subsequent federal laws or regulations relating to occupational safety and health, and this
32 Article, as written, revised or amended by legislative enactment and as delegated or authorized
33 by the Commissioner. The Commissioner shall make and promulgate such rules, amendments,
34 or revisions in rules, as ~~hethe~~the Commissioner may deem advisable for the administration of the
35 ~~office, he~~office. The Commissioner shall also accept and use the services, facilities, and
36 personnel of any agency of the State or of any subdivision of State government, either as a free
37 service or by reimbursement. The Director shall devote full time to his or her duties of office
38 and shall not hold any other office. The Director, subject to the approval of the Commissioner,
39 shall select a professional staff of qualified and competent employees to assist in the statewide
40 administration of the Article. All of the employees referred to herein shall be under the
41 classified service, as herein defined in G.S. 95-127, subdivision (3).service."

42 **SECTION 4.** Article 16 of Chapter 95 of the General Statutes is amended by
43 adding a new section to read:

44 "**§ 95-156. Handling of dangerous drugs.**

45 (a) The Commissioner of Labor shall adopt rules to establish requirements for the
46 handling of antineoplastic and other hazardous drugs in health care facilities.

47 (b) The rules adopted pursuant to this section shall be consistent with, but not exceed,
48 the recommendations issued by the National Institute for Occupational Safety and Health
49 (NIOSH) of the Centers for Disease Control and Prevention (CDC), as contained in the Alert:
50 Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health

1 Care Settings, as updated in 2010. The Department's adoption of the rules may incorporate
2 updates and changes to NIOSH's guidelines as made by CDC.

3 (c) Rules adopted pursuant to this section shall not apply to an entity that has obtained a
4 permit pursuant to G.S. 90-85.21 or G.S. 90-85.21A, or that is accredited by the Joint
5 Commission on Accreditation of Healthcare Organizations or other recognized hospital
6 accreditation body, and has filed with the Department written documentation of the process,
7 developed for that accreditation, for managing high-alert and hazardous materials consistent
8 with the NIOSH recommendations specified in subsection (b).

9 (d) The Commissioner shall enforce these rules and investigate complaints in
10 accordance with the provisions of this Article."

11 **SECTION 5.** The Commissioner of Labor shall adopt the rules to implement this
12 act no later than January 1, 2015. When developing rules as required by this act, the
13 Commissioner of Labor shall consider input from hospitals, organizations representing health
14 care personnel, and other stakeholders. Consideration shall be given to what constitutes a
15 reasonable time frame for facilities to implement new requirements.

16 **SECTION 6.** This act is effective when it becomes law.