

114TH CONGRESS
2D SESSION

S. 2994

To amend the Federal Food, Drug, and Cosmetic Act to prevent the abuse of dextromethorphan, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 26, 2016

Mr. CASEY (for himself and Ms. MURKOWSKI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to prevent the abuse of dextromethorphan, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “DXM Abuse Preven-
5 tion Act of 2016”.

1 **SEC. 2. SALES OF OVER-THE-COUNTER DRUGS CONTAINING**
 2 **DEXTROMETHORPHAN.**

3 (a) PROHIBITED ACT.—Section 301 of the Federal
 4 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
 5 ed by adding at the end the following:

6 “(eee) The failure of a retailer to implement a
 7 verification system as required by section 506G (relating
 8 to sales of over-the-counter drugs containing
 9 dextromethorphan).”.

10 (b) VERIFICATION SYSTEM.—The Federal Food,
 11 Drug, and Cosmetic Act is amended by inserting after sec-
 12 tion 506F of such Act (21 U.S.C. 356f) the following:

13 **“SEC. 506G. SALES OF OVER-THE-COUNTER DRUGS CON-**
 14 **TAINING DEXTROMETHORPHAN.**

15 “(a) VERIFICATION SYSTEM.—Any retailer selling or
 16 offering for sale in interstate commerce dextromethorphan
 17 shall implement a verification system to ensure compliance
 18 with this section. Such a system may ensure such compli-
 19 ance by means of—

20 “(1) an electronic point-of-sale system coded to
 21 prompt for verification of the age of all purchasers
 22 of drugs described in subsection (b) and deny sales
 23 to those under the age of 18;

24 “(2) training manuals or materials instructing
 25 employees to verify the age of all purchasers of such
 26 drugs and deny sales to those under the age of 18;

1 “(3) signage in and around the sales counter
2 outlining the age restriction on sales of such drugs;

3 “(4) designating one on-duty employee to ap-
4 prove all sales of such drugs; or

5 “(5) any other verification measure deemed
6 valid by the Secretary.

7 “(b) PROHIBITION.—Except as provided in sub-
8 section (c), each retailer shall verify that no individual is
9 under 18 years of age who purchases any drug that—

10 “(1) contains dextromethorphan; and

11 “(2) is not subject to section 503(b)(1).

12 “(c) EXCEPTIONS.—

13 “(1) INDIVIDUALS OVER 26.—Subsection (b)
14 does not require verification of the age of any indi-
15 vidual over the age of 26.

16 “(2) VALID PRESCRIPTION.—Subsection (b)
17 does not apply to any sale made pursuant to a val-
18 idly issued prescription.

19 “(3) VALID MILITARY IDENTIFICATION CARD.—
20 Subsection (b) does not apply to any sale to an indi-
21 vidual under 18 years of age if such individual sup-
22 plies proof at the time of such sale that such indi-
23 vidual is actively enrolled in the military and pre-
24 sents a valid military identification card.

1 “(d) AFFIRMATIVE DEFENSE.—It shall be an affirm-
2 ative defense to an alleged violation of subsection (b) that
3 the individual selling a drug containing
4 dextromethorphan—

5 “(1) examined the purchaser’s identification
6 card; and

7 “(2) based on that examination, reasonably con-
8 cluded that the identification was valid and indicated
9 that the purchaser was not less than 18 years of
10 age.

11 “(e) DEFINITION.—In this paragraph, the term
12 ‘identification card’ means an identification card that—

13 “(1) includes a photograph and the date of
14 birth of the individual; and

15 “(2) is issued by a State or the Federal Govern-
16 ment or is considered acceptable for purposes of sec-
17 tions 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B)(1)
18 of title 8, Code of Federal Regulations (including
19 any successor regulations).”.

20 “(c) CIVIL PENALTIES.—Section 303 of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amend-
22 ed by adding at the end the following:

23 “(h) Notwithstanding subsection (a), the following
24 provisions shall apply to violations of section 301(eee):

1 “(1) A person who violates section 301(eee)
2 shall—

3 “(A) receive a violation notification from
4 the Secretary for the first such violation; and

5 “(B) be subject to a civil penalty in an
6 amount—

7 “(i) not more than \$1,000 for the sec-
8 ond such violation by a person;

9 “(ii) not more than \$2,000 for the
10 third such violation by a person; and

11 “(iii) not more than \$5,000 for the
12 fourth such violation, or a subsequent such
13 violation, by a person.

14 “(2) In determining the amount of a civil pen-
15 alty under this subsection for a person who is a re-
16 tailer, the Secretary shall consider whether the re-
17 tailer has taken appropriate steps to prevent subse-
18 quent violations, such as the establishment and ad-
19 ministration of a documented employee training pro-
20 gram to ensure all employees are familiar with and
21 abiding by the provisions of section 506G, where
22 such program includes—

23 “(A) educating employees regarding prod-
24 ucts containing dextromethorphan;

1 “(B) instruction on the correct method of
2 checking a purchaser’s identification card; and

3 “(C) notifying employees of the civil pen-
4 alties under this subsection.

5 “(3) If a person who is a retailer transacts
6 sales of products containing dextromethorphan at
7 more than one physical location, for purposes of de-
8 termining the number of violations by that person
9 under this subsection, each individual physical loca-
10 tion operated by that retailer shall be considered a
11 separate person.

12 “(4) The Secretary shall notify persons found
13 to have violated section 301(eee) as soon as prac-
14 ticable after the Secretary discovers such violation.
15 Such notification shall include the date and time
16 when the violation was observed to occur.

17 “(5) Notwithstanding any other provision of
18 this subsection or section 301(eee), an employee
19 shall not be subject to penalties under this sub-
20 section unless such employee knowingly and willfully
21 participates in a conspiracy to violate section
22 301(eee). For purposes of this paragraph, a con-
23 spiracy shall consist of an agreement between 2 or
24 more persons with the intent to violate section

1 301(eee) and the commission of at least one overt
2 act in furtherance of the agreement.

3 “(6) In this subsection—

4 “(A) the term ‘employee’ means an indi-
5 vidual who is employed by a retailer in a cler-
6 ical or other non-managerial position; and

7 “(B) the term ‘retailer’ means a grocery
8 store, general merchandise store, drug store,
9 pharmacy, convenience store, or other entity or
10 person whose activities as a distributor relating
11 to products containing dextromethorphan are
12 limited almost exclusively to sales for personal
13 use, both in number of sales and volume of
14 sales, including any sales made by the Internet
15 or other means.”.

16 **SEC. 3. RESTRICTIONS ON DISTRIBUTION OF BULK**
17 **DEXTROMETHORPHAN.**

18 The Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 321 et seq.) is amended—

20 (1) in section 501, by adding at the end the fol-
21 lowing:

22 “(k) If it is unfinished dextromethorphan and is pos-
23 sessed, received, or distributed in violation of section
24 506H.”;

1 (2) by inserting after section 506G, as added by
2 section 2(b), the following:

3 **“SEC. 506H. RESTRICTIONS ON THE DISTRIBUTION OF**
4 **BULK DEXTROMETHORPHAN.**

5 “(a) IN GENERAL.—No person shall—

6 “(1) possess or receive unfinished
7 dextromethorphan, unless the person is registered
8 under section 510 or otherwise registered, licensed,
9 or approved pursuant to Federal or State law to en-
10 gage in the practice of pharmacy, pharmaceutical
11 production, or manufacture or distribution of drug
12 ingredients; or

13 “(2) distribute unfinished dextromethorphan to
14 any person other than a person registered under sec-
15 tion 510 or otherwise registered, licensed, or ap-
16 proved pursuant to Federal or State law to engage
17 in the practice of pharmacy, pharmaceutical produc-
18 tion, or manufacture or distribution of drug ingredi-
19 ents.

20 “(b) EXCEPTION FOR COMMON CARRIERS.—This
21 section does not apply to a common carrier that possesses,
22 receives, or distributes unfinished dextromethorphan for
23 purposes of distributing such unfinished
24 dextromethorphan between persons described in sub-
25 section (a) as registered, licensed, or approved.

1 “(c) DEFINITIONS.—In this section:

2 “(1) The term ‘common carrier’ means any per-
3 son that holds itself out to the general public as a
4 provider for hire of the transportation by water,
5 land, or air of merchandise, whether or not the per-
6 son actually operates the vessel, vehicle, or aircraft
7 by which the transportation is provided, between a
8 port or place and a port or place in the United
9 States.

10 “(2) The term ‘unfinished dextromethorphan’
11 means dextromethorphan that is not contained in a
12 drug that is in finished dosage form.”; and

13 (3) by amending section 303, as amended by
14 section 2(c), by adding at the end the following:

15 “(i) Notwithstanding subsection (a), a person who
16 violates section 506H shall be subject to a civil penalty
17 of not more than \$100,000.”.

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