

117TH CONGRESS
2D SESSION

H. R. 7653

To amend the Federal Food, Drug, and Cosmetic Act to modernize the methods of authenticating controlled substances in the pharmaceutical distribution supply chain, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 3, 2022

Mr. MULLIN (for himself and Mr. O'HALLERAN) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to modernize the methods of authenticating controlled substances in the pharmaceutical distribution supply chain, 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 “Modern Authentication
5 of Pharmaceuticals Act of 2022”.

1 **SEC. 2. MODERNIZING THE AUTHENTICATION OF CON-**
2 **TROLLED SUBSTANCES IN THE PHARMA-**
3 **CEUTICAL DISTRIBUTION SUPPLY CHAIN.**

4 (a) IN GENERAL.—Section 582(a)(9) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 360eee–
6 1(a)(9)) is amended—

7 (1) in subparagraph (A)(ii), by striking “and”
8 at the end;

9 (2) by redesignating subparagraph (B) as sub-
10 paragraph (C); and

11 (3) by inserting after subparagraph (A) the fol-
12 lowing:

13 “(B) a physical chemical identifier shall be
14 included in or on each dose of a product that
15 is—

16 “(i) a controlled substance (as defined
17 in section 102 of the Controlled Sub-
18 stances Act);

19 “(ii) in solid oral dosage form; and

20 “(iii) manufactured on or after Janu-
21 ary 1, 2026; and”.

22 (b) CONFORMING CHANGES.—

23 (1) Section 581(14) of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 360eee(14)) is amend-
25 ed to read as follows:

1 “(14) PRODUCT IDENTIFIER.—The term ‘prod-
2 uct identifier’ means—

3 “(A) a standardized graphic that includes,
4 in both human-readable form and on a ma-
5 chine-readable data carrier that conforms to the
6 standards developed by a widely recognized
7 international standards development organiza-
8 tion, the standardized numerical identifier, lot
9 number, and expiration date of the product; or

10 “(B) a physical chemical identifier, pos-
11 sessing a unique physical or chemical substance
12 or combination of substances, that—

13 “(i) is in or on a product;

14 “(ii) is machine-readable; and

15 “(iii) is intended to authenticate the
16 product or a dosage form thereof.”.

17 (2) Section 581(28) of the Federal Food, Drug,
18 and Cosmetic Act (21 U.S.C. 360eee(28)) is amend-
19 ed to read as follows:

20 “(28) VERIFICATION OR VERIFY.—The term
21 ‘verification’ or ‘verify’ means—

22 “(A) determining whether the product
23 identifier affixed to, or imprinted upon, a pack-
24 age or homogeneous case corresponds to the
25 standardized numerical identifier or lot number

1 and expiration date assigned to the product by
2 the manufacturer or the repackager, as applica-
3 ble in accordance with section 582; or

4 “(B) determining whether a product or a
5 dosage form thereof is authentic using a phys-
6 ical chemical identifier described in paragraph
7 (14)(B).”

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