

115TH CONGRESS
2D SESSION

S. 3428

To amend the Controlled Substances Act to require warning labels for prescription opioids, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 12, 2018

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

A BILL

To amend the Controlled Substances Act to require warning labels for prescription opioids, 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 “Lessening Addiction
5 by Enhancing Labeling Opioids Act of 2018” or the
6 “LABEL Opioids Act”.

7 **SEC. 2. AMENDMENT.**

8 (a) IN GENERAL.—Section 305(c) of the Controlled
9 Substances Act (21 U.S.C. 825(c)) is amended—

1 (1) by inserting “(1)” before “The Secretary”;

2 and

3 (2) by adding at the end the following:

4 “(2) The label of any container or package containing
5 an opioid or opiate listed in schedule II or III shall, when
6 dispensed (other than administered) to or for a patient,
7 contain a clear, concise warning, in a manner specified by
8 the Secretary by regulation, that the opioids or opiates
9 dispensed can cause dependence, addiction, and over-
10 dose.”.

11 (b) REGULATIONS.—

12 (1) REGULATIONS.—The Secretary of Health
13 and Human Services shall prescribe regulations
14 under section 503(b) of the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 353(b)) to implement
16 the amendment made by subsection (a) and such
17 regulations shall be effective not later than 2 years
18 after the date of enactment of this Act.

19 (2) INTERIM RULES.—The Secretary of Health
20 and Human Services may issue the regulations re-
21 quired under paragraph (1) by interim rule to the
22 extent necessary to comply with the timing require-
23 ment in paragraph (1).

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