

117TH CONGRESS
1ST SESSION

S. 2353

To amend the Controlled Substances Act to require dispensers of certain opioids to affix on the container or package thereof a clear, concise warning that the opioid can cause dependence, addiction, and overdose, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 15, 2021

Mr. MARKEY (for himself, Mr. BRAUN, and Mr. MANCHIN) 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 dispensers of certain opioids to affix on the container or package thereof a clear, concise warning that the opioid can cause dependence, addiction, and overdose, 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 2021” or the
6 “LABEL Opioids Act of 2021”.

1 **SEC. 2. LESSENING ADDICTION BY ENHANCING LABELING**
2 **OF OPIOIDS.**

3 (a) IN GENERAL.—Section 305(c) of the Controlled
4 Substances Act (21 U.S.C. 825(c)) is amended by striking
5 “which shall provide that the label” and all that follows
6 and inserting the following: “which shall provide that—

7 “(1) the label of a drug listed in schedule II,
8 III, or IV shall, when dispensed to or for a patient,
9 contain a clear, concise warning that it is a crime
10 to transfer the drug to any person other than the
11 patient; and

12 “(2) the label of any container or package con-
13 taining an opioid listed in schedule II, III, IV, or V
14 (other than a drug that is approved, or authorized
15 for emergency use, by the Food and Drug Adminis-
16 tration for the treatment of addiction or an opioid
17 use disorder) shall, when dispensed to or for a pa-
18 tient, contain a clear, concise warning that the
19 opioid dispensed can cause dependence, addiction,
20 and overdose.”.

21 (b) PROHIBITED ACT.—Section 402(a)(3) of the
22 Controlled Substances Act (21 U.S.C. 842(a)(3)) is
23 amended by inserting “or dispense” after “distribute”.

24 (c) REGULATIONS.—

25 (1) REGULATIONS.—Not later than 1 year after
26 the date of enactment of this Act, the Secretary of

1 Health and Human Services shall prescribe final
2 regulations to implement the amendments made by
3 subsections (a) and (b), which regulations shall be
4 effective beginning on the date that is 2 years after
5 the date of enactment of this Act.

6 (2) INTERIM RULES.—The Secretary of Health
7 and Human Services may issue the regulations re-
8 quired under paragraph (1) by interim rule to the
9 extent necessary to comply with the timing require-
10 ment in that paragraph.

11 (d) APPLICABILITY.—The amendment made by sub-
12 section (b) applies beginning on the date that is 2 years
13 after the date of enactment of this Act.

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