

117TH CONGRESS  
1ST SESSION

# H. R. 1026

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

---

## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 11, 2021

Mr. STANTON introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

## A BILL

To amend the Controlled Substances Act to require dispensers of certain opioids and opiates to affix on the container or package thereof a clear, concise warning that the opioid or opiate 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”.

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 through the period and inserting the following: “which  
7 shall provide that—

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

13 “(2) the label of any container or package con-  
14 taining an opioid or opiate listed in schedule II, III,  
15 IV, or V (other than a drug that is approved or au-  
16 thorized by the Food and Drug Administration for  
17 the treatment of addiction or an opioid use disorder)  
18 shall, when dispensed to or for a patient, contain a  
19 clear, concise warning that the opioids or opiates  
20 dispensed can cause dependence, addiction, and  
21 overdose.”;

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

25 (c) REGULATIONS.—

1           (1) REGULATIONS.—Not later than 1 year after  
2           the date of enactment of this Act, the Secretary of  
3           Health and Human Services shall prescribe final  
4           regulations to implement the amendments made by  
5           subsections (a) and (b), which regulations shall be  
6           effective beginning on the date that is 2 years after  
7           the date of enactment of this Act.

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

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

○