

**AMENDMENT TO  
RULES COMMITTEE PRINT 117-51  
OFFERED BY MR. STANTON OF ARIZONA**

Page 135, after line 21, insert the following:

1 **SEC. 264. LESSENING ADDICTION BY ENHANCING LABEL-**  
2 **ING 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

1 dispensed can cause dependence, addiction, and  
2 overdose.”;

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

6 (c) REGULATIONS.—

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

14 (2) INTERIM RULES.—The Secretary of Health  
15 and Human Services may issue the regulations re-  
16 quired under paragraph (1) by interim rule to the  
17 extent necessary to comply with the timing require-  
18 ment in paragraph (1).

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

