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

Page 135, after line 21, insert the following:

SEC. 264. LESSENING ADDICTION BY ENHANCING LABELING OF OPIOIDS.

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

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

“(2) the label of any container or package containing an opioid or opiate listed in schedule II, III, IV, or V (other than a drug that is approved or authorized by the Food and Drug Administration for the treatment of addiction or an opioid use disorder) shall, when dispensed to or for a patient, contain a clear, concise warning that the opioids or opiates
dispensed can cause dependence, addiction, and overdose.”;

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

(c) REGULATIONS.—

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

(2) INTERIM RULES.—The Secretary of Health and Human Services may issue the regulations required under paragraph (1) by interim rule to the extent necessary to comply with the timing requirement in paragraph (1).

(d) APPLICABILITY.—The amendment made by subsection (b) applies beginning on the date that is 2 years after the date of enactment of this Act.