Cassidy

AMENDMENT NO. 2 Calendar No._____

Purpose: To require reporting on prescription drug expenditures under group health plans and on prescription drug price changes, and for other purposes.

IN THE SENATE OF THE UNITED STATES—116th Cong., 1st Sess.

S. 1895

To lower health care costs.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

At the end of title II, add the following:

SEC. 2___. PRESCRIPTION DRUG PRICE REPORTING REQUIREMENTS.

(a) SUBMISSION OF DATA.—

(1) IN GENERAL.—Each manufacturer of a prescription drug shall submit to the Secretary, electronically, in such manner as the Secretary may require, by April 1 of each year, a list of each such drug that is marketed in the United States and, with respect to each such drug, all of the following information with respect to the previous year:

(A) Each applicable National Drug Code (or J-Code).

(B) Brand name.

(C) Generic name and chemical name, as applicable.

(D) Therapeutic class or classes, as applicable.

(E) Current wholesale acquisition cost per 30-day supply or typical course of treatment.

(F) Average wholesale acquisition cost for the drug per 30-day supply or typical course of treatment during the previous calendar year, or, in the case of a drug that has been marketed for only a portion of such year, during the portion of time in such year that the drug was marketed.

(G) Average net price per 30-day supply or typical course of treatment, during the previous calendar year, or, in the case of a drug that has been marketed for only a portion of such year, during the portion of time in such year that the drug was marketed, taking into account all discounts, rebates, and other fees or payments to health insurance plans or pharmacy benefit

managers with respect to sales of the drug to individuals covered by such a plan.

(H) Total rebates and other payments to health insurance plans or pharmacy benefit managers, per 30-day supply or typical course of treatment, with respect to individuals covered by such a plan, during the previous calendar year, or, in the case of a drug that has been marketed for only a portion of such calendar year, during the portion of time in such calendar year that the drug was marketed.

(2) TIMELINE FOR INITIAL SUBMISSION.—

(A) DRUGS MARKETED BEFORE DECEMBER 31, 2020.—Each manufacturer of a prescription drug that is marketed at any time during calendar year 2020, shall submit to the Secretary, not later than April 1, 2021—

(i) the information required under paragraph (1); and

(ii) in addition to the information required under subparagraphs (F), (G), and (H) of paragraph (1), such average wholesale acquisition cost, average net price, and total rebates and other payments, described in each of such subparagraphs, re-

spectively, with respect to the calendar year immediately preceding the calendar year for which such information is required to be reported under such subparagraphs (F), (G), and (H).

(B) SUBSEQUENTLY MARKETED DRUGS.—With respect to a prescription drug that is first marketed after December 31, 2020, each manufacturer of such a drug shall submit the information required under subparagraphs (A) through (E) of paragraph (1) not later than 60 days after the date on which the drug is first marketed, and shall submit annual reports of all of the information required under paragraph (1) beginning on the first annual reporting date that is more than 30 days after the date on which the drug is first marketed.

(b) ADVANCE NOTIFICATION OF PRESCRIPTION DRUG PRICING CHANGES.—

(1) IN GENERAL.—Each manufacturer of a prescription drug shall report to the Secretary, electronically, in such manner as the Secretary may require, any increase or decrease in the wholesale acquisition cost of a prescription drug not later than

30 days prior to the date on which the price change takes effect.

(2) CONTENT.—A price change report under paragraph (1) shall include—

(A) the information required under subparagraphs (A), (B), (C), (D), and (F) of subsection (a)(1);

(B) the wholesale acquisition cost per 30-day supply or typical course of treatment immediately prior to the price change;

(C) the new wholesale acquisition cost per 30-day supply or typical course of treatment, when the change takes effect; and

(D) financial and non-financial factors the manufacturer took into consideration when making the price change, including any changes or improvements to the drug.

(c) PUBLIC DATABASE.—

(1) IN GENERAL.—The Secretary shall establish an internet-based system to post prescription drug information reported under subsection (a) and price change reports required under subsection (b).

(2) CONSUMER SUBSCRIPTION OPTIONS.—The system established under paragraph (1) shall enable

consumers to subscribe to price change notifications—

(A) for—

(i) all drugs;

(ii) a particular drug; or

(iii) a particular therapeutic class of drugs; and

(B) that are limited to price changes that are at or over a specified amount.

(3) TIMING.—The prescription drug information reported under subsection (a) shall be made publicly available not later than 30 days after being reported to the Secretary. Price change reports required under subsection (b) shall be made publically available no later than 5 business days after submission to the Secretary.

(d) PRIVACY PROTECTIONS.—The information submitted under subparagraphs (A) through (F) of subsection (a)(1) and paragraph (2)(A)(ii) shall be publicly available through the database established under subsection (c). No other information submitted to the Secretary pursuant to subsection (a) or (b) that is proprietary, confidential, or trade secret information shall be included in such database.

(e) DEFINITIONS.—For purposes of this section—

(1) the term "manufacturer" has the meaning given such term in section 581 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee);

(2) the term "prescription drug" means a drug approved section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) that is subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1));

(3) the term "Secretary" means the Secretary of Health and Human Services; and

(4) the term "wholesale acquisition cost" has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).

(f) PREEMPTION.—Effective on the date that the public database under subsection (c) first becomes operational, no State or political subdivision of a State may establish or continue in effect any law requiring the manufacturer to report or make public prescription drug pricing information.