AMENDMENT NO. 1 Calendar No. _____

Purpose: To require reporting on drug pricing.

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, insert the following:

SEC. 2___. REPORTING ON DRUG PRICE INCREASES.

(a) DEFINITIONS.—In this section:

(1) MANUFACTURER.—The term "manufacturer" means the person—

(A) that holds the application for a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or the license issued under section 351 of the Public Health Service Act (42 U.S.C. 262); or

(B) who is responsible for setting the price for the drug.

(2) QUALIFYING DRUG.—The term "qualifying drug" means any drug that is approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262)—

(A) that has a wholesale acquisition cost of $100 or more per month supply, or per a course of treatment that lasts less than a month, and is subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)); and

(B) for which, during the previous calendar year, at least 1 dollar of the total amount of sales were for individuals enrolled under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or under a State Medicaid plan under title XIX of such Act (42 U.S.C. 1396 et seq.) or under a waiver of such plan.

(3) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(4) WHOLESALE ACQUISITION COST.—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)).

(b) REPORT.—

(1) REPORT REQUIRED.—Not later than 1 year after the date on which data is first submitted under subsection (c), and annually thereafter, the Secretary, acting through the Assistant Secretary for Planning and Evaluation, shall publish a comprehensive report on prescription drug prices and pricing trends.

(2) CONTENT.—The comprehensive report under paragraph (1) shall include—

(A) aggregate trends in the list and net prices of prescription drugs;

(B) trends in list and net prices of prescription drugs within particular categories or therapeutic classes;

(C) usage of advance price notifications, based on data from subscriptions to the public database under subsection (e), and other feedback from the public;

(D) primary justifications cited by manufacturers in price change reports filed pursuant to subsection (c);

(E) a list of all drugs and the manufacturers of such drugs for which prices increased and decreased more than 10 percent over the previous year; and

(F) information with respect to costs on marketing and advertising expenses, research and development expenses, and litigation expenses related to the manufacturer of any drug listed pursuant to subparagraph (E).

(3) FORMAT.—In developing the format of the reports under this subsection the Secretary shall consult stakeholders, including beneficiary groups, and shall seek feedback on the content and format of such reports from consumer advocates and readability experts to ensure such public reports are user-friendly to the public and are written in plain language that consumers can readily understand.

(c) SUBMISSION OF DATA.—

(1) IN GENERAL.—Each manufacturer of a qualifying 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) The brand name.

(C) The generic name and chemical name, as applicable.

(D) The 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) After the initial submission, for any drugs for which a change report was submitted under subsection (d) in the previous year:

(i) The initial launch price for such drug.

(ii) The total revenue generated from the qualifying drug for each calendar year since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or the issuance of the license for the drug under section 351 (42 U.S.C. 262), or since the manufacturer acquired such approved application or license.

(I) The aggregate expenditures of the manufacturer related to research and development.

(J) The total costs associated with marketing and advertising by the manufacturer.

(K) The total revenue and the net profit of the manufacturer.

(L) Executive compensation policies used by the manufacturer, consistent with informa-

tion that is already required to be disclosed to the Securities and Exchange Commission.

(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, respectively, 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 infor-

mation 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.

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

(1) IN GENERAL.—Each manufacturer of a qualifying drug shall report to the Secretary, electronically, in such manner as the Secretary may require, any increase 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 (c)(1);

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

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

(e) PUBLIC DATABASE.—

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

(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) PUBLIC AVAILABILITY.—

(A) IN GENERAL.—The information submitted under subparagraphs (A) through (F) of subsection (c)(1) and subsection (c)(2)(A)(ii) and the information in price change reports

under subsection (d) shall be publicly available through the database under this subsection.

(B) TIMING.—The information reported under subsection (c)(2)(A)(ii) shall be made publicly available not later than 30 days after receipt by the Secretary. Price change reports required under subsection (d) shall be made publically available not later than 30 business days after receipt by the Secretary, but not earlier than the reported price change will take effect.

(f) PRIVACY PROTECTIONS.—No information that will be made publicly available under this section is required to be submitted if such information is not already in the public domain. The Secretary shall carry out this section in accordance with applicable Federal law concerning the protection of commercial information and trade secrets.

(g) PREEMPTION.—Effective on the date that the public database under subsection (e) 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.