AMENDMENT NO._____ Calendar No._____

Purpose: To require negotiation of lower covered part D drug prices on behalf of Medicare beneficiaries and to provide for broader prescription drug importation.

IN THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.

H. R. 34

To authorize and strengthen the tsunami detection, forecast, warning, research, and mitigation program of the National Oceanic and Atmospheric Administration, and for other purposes.

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 Mr. SANDERS

Viz:

At the appropriate place in division A, insert the following:

SEC. _____. NEGOTIATION OF LOWER COVERED PART D DRUG PRICES ON BEHALF OF MEDICARE BENEFICIARIES.

(a) NEGOTIATION BY SECRETARY.—Section 1860D–11 of the Social Security Act (42 U.S.C. 1395w–111) is amended by striking subsection (i) (relating to noninterference) and inserting the following:

''(i) NEGOTIATION OF LOWER DRUG PRICES.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, the Secretary shall negotiate with pharmaceutical manufacturers the prices (including discounts, rebates, and other price concessions) that may be charged to PDP sponsors and MA organizations for covered part D drugs for part D eligible individuals who are enrolled under a prescription drug plan or under an MA–PD plan.

''(2) NO CHANGE IN RULES FOR FORMULARIES.—

''(A) IN GENERAL.—Nothing in paragraph (1) shall be construed to authorize the Secretary to establish or require a particular formulary.

''(B) CONSTRUCTION.—Subparagraph (A) shall not be construed as affecting the Secretary's authority to ensure appropriate and adequate access to covered part D drugs under prescription drug plans and under MA–PD plans, including compliance of such plans with formulary requirements under section 1860D–4(b)(3).

''(3) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing the sponsor of a prescription drug plan, or an organization offer-

ing an MA–PD plan, from obtaining a discount or reduction of the price for a covered part D drug below the price negotiated under paragraph (1).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act and shall first apply to negotiations and prices for plan years beginning on January 1, 2017.

SEC. ___. PRESCRIPTION DRUG IMPORTATION.

(a) IMPORTATION BY PHARMACISTS AND WHOLESALERS.—Section 804(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(b)) is amended by striking ''The Secretary,'' and inserting ''The Secretary, not later than January 1, 2017,''.

(b) IMPORTATION BY INDIVIDUALS.—

(1) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384) is amended—

(A) in subsection (f), by striking ''within Canada'';

(B) in subsection (j)—

(i) in paragraph (1), in the matter preceding subparagraph (A), by inserting ''from countries other than Canada'' after ''devices''; and

(ii) in paragraph (3)—

(I) in the heading, by striking ''FROM CANADA'' and inserting ''FROM COUNTRIES OTHER THAN CANADA''; and

(II) in subparagraph (C), by striking ''from Canada,''; and

(C) by striking subsection (l) and inserting the following:

''(l) IMPORTATION OF PRESCRIPTION DRUGS FROM CANADA.—Individuals may import from Canada any prescription drug that meets the requirements of subparagraphs (A) through (F) of subsection (j)(3).''.

(2) REGULATIONS.—Not later than January 1, 2017, the Secretary of Health and Human Services shall promulgate regulations with respect to subsection (l) of section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384) (as amended by paragraph (1)(B)).

(3) EFFECTIVE DATE.—The amendments made by paragraph (1) shall take effect on the effective date of the final regulations promulgated in accordance with paragraph (2).

(c) FDASIA AMENDMENT.—Subsection (c) of section 708 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 126 Stat. 1068) is

amended by striking ''The amendment made by'' and all that follows through the period at the end and inserting ''The amendment made by subsection (a) and the regulations promulgated under subsection (b) shall apply beginning on the effective date of the regulations promulgated under section 804(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(b)) and the amendments made by section 201(b) of the 21st Century Cures Act.''.