

117TH CONGRESS
1ST SESSION

S. 1323

To require the Secretary of Health and Human Services to establish reference prices for prescription drugs for purposes of Federal health programs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 22, 2021

Mr. MERKLEY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To require the Secretary of Health and Human Services to establish reference prices for prescription drugs for purposes of Federal health programs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “End Price Gouging
5 for Medications Act”.

6 **SEC. 2. REFERENCE PRICES FOR PRESCRIPTION DRUGS.**

7 (a) REFERENCE PRICES.—The Secretary of Health
8 and Human Services (referred to in this section as the

1 “Secretary”), in accordance with subsection (b), shall es-
 2 tablish annual reference prices for each prescription drug.
 3 Notwithstanding any other provision of law, with respect
 4 to enrollees or beneficiaries in any of the Federal health
 5 programs described in subsection (c), the retail list price
 6 for a drug shall not exceed the reference price for such
 7 drug.

8 (b) CRITERIA.—

9 (1) IN GENERAL.—Each year, the Secretary
 10 shall establish the reference price for each prescrip-
 11 tion drug under subsection (a)—

12 (A) by determining the median retail list
 13 price for the drug among the reference coun-
 14 tries in which the drug is available, if drug pric-
 15 ing information is available for at least 3 of
 16 such countries; or

17 (B) in the case of a drug for which drug
 18 pricing information or dosage equivalents are
 19 not available for at least 3 of the reference
 20 countries, by determining an appropriate price
 21 based on the Secretary’s determination of—

22 (i) the added therapeutic effect of the
 23 drug;

24 (ii) the value of the drug;

25 (iii) patient access to the drug;

1 (iv) the costs associated with re-
2 searching and developing the drug; and

3 (v) other factors, as the Secretary de-
4 termines appropriate.

5 (2) REFERENCE COUNTRIES.—For purposes of
6 paragraph (1), the reference countries are Japan,
7 Germany, the United Kingdom, France, Italy, Can-
8 ada, Australia, Spain, the Netherlands, Switzerland,
9 and Sweden.

10 (c) FEDERAL HEALTH PROGRAMS.—The reference
11 prices established under subsection (a) shall apply with re-
12 spect to covered inpatient and outpatient drugs under—

13 (1) the Medicare program under title XVIII of
14 the Social Security Act (42 U.S.C. 1395 et seq.);

15 (2) a State Medicaid plan under title XIX of
16 the Social Security Act (42 U.S.C. 1396 et seq.);

17 (3) the State Children’s Health Insurance Pro-
18 gram under title XXI of the Social Security Act (42
19 U.S.C. 1397aa et seq.);

20 (4) the TRICARE program under chapter 55 of
21 title 10, United States Code;

22 (5) hospital care and medical services furnished
23 by the Department of Veterans Affairs under chap-
24 ters 17 and 18 of title 38, United States Code;

1 (6) the Federal Employees Health Benefits
 2 Program established under chapter 89 of title 5,
 3 United States Code; and

4 (7) any health program, service, function, activ-
 5 ity, or facility funded, in whole or part, under the
 6 Indian Health Care Improvement Act (25 U.S.C.
 7 1601 et seq.), including through direct or contract
 8 care provided under such Act or through a contract
 9 or compact under the Indian Self-Determination and
 10 Education Assistance Act (25 U.S.C. 5304 et seq.).

11 (d) APPLICABILITY TO OTHER PURCHASERS OF
 12 DRUGS.—Notwithstanding any other provision of law, a
 13 drug manufacturer shall offer prescription drugs at the
 14 reference price to all individuals, including individuals who
 15 are not insured and individuals who are covered under a
 16 group health plan or group or individual health insurance
 17 coverage. In the case of individuals covered by a group
 18 health plan or group or individual health insurance cov-
 19 erage, such requirement is met if the amount covered
 20 under such plan or coverage plus the cost-sharing amount
 21 does not exceed the reference price.

22 (e) ENFORCEMENT.—

23 (1) CIVIL PENALTY.—A drug manufacturer who
 24 does not comply with the requirements of subsection

25 (a) shall be subject to a civil penalty, for each year

1 in which the violation occurs and with respect to
2 each drug for which the violation occurs, in an
3 amount equal to 5 times the difference between—

4 (A) the total amount received by the man-
5 ufacturer for sales of the drug under the Fed-
6 eral health programs under subsection (c) for
7 the year; less

8 (B) the total amount the manufacturer
9 would have received for sales of the drug under
10 such programs for the year if the manufacturer
11 had complied with subsection (a).

12 (2) AMOUNTS COLLECTED.—Each year, the
13 Secretary of the Treasury shall transfer to the Di-
14 rector of the National Institutes of Health an
15 amount equal to the amount collected in civil pen-
16 alties under subsection (e) for the previous year. The
17 Director of the National Institutes of Health shall
18 use amounts so transferred for purposes of con-
19 ducting drug research and development.

20 (f) APPLICABILITY TO BRAND AND GENERIC
21 DRUGS.—The reference price established under subsection
22 (a) shall apply to drugs approved under subsection (c) or
23 (j) of section 505 of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 355) or under subsection (a) or (k)

1 of section 351 of the Public Health Service Act (42 U.S.C.
2 262).

