

#### 116TH CONGRESS 1ST SESSION

# S. 1664

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

May 23 (legislative day, May 22), 2019

Mr. Scott of Florida (for himself, Ms. Collins, and Mr. Gardner) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

# A BILL

To require reporting on prescription drug expenditures under group health plans and on prescription drug price changes, 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 "Prescription Drug
- 5 Price Reporting Act".
- 6 SEC. 2. PRESCRIPTION DRUG PRICE REPORTING REQUIRE-
- 7 MENTS.
- 8 (a) Submission of Data.—

1	(1) In general.—Each manufacturer of a pre-
2	scription drug shall submit to the Secretary, elec-
3	tronically, in such manner as the Secretary may re-
4	quire, by April 1 of each year, a list of each such
5	drug that is marketed in the United States and,
6	with respect to each such drug, all of the following
7	information with respect to the previous year:
8	(A) Each applicable National Drug Code
9	(or J-Code).
10	(B) Brand name.
11	(C) Generic name and chemical name, as
12	applicable.
13	(D) Therapeutic class or classes, as appli-
14	cable.
15	(E) Current wholesale acquisition cost per
16	30-day supply or typical course of treatment.
17	(F) Average wholesale acquisition cost for
18	the drug per 30-day supply or typical course of
19	treatment during the previous calendar year, or,
20	in the case of a drug that has been marketed
21	for only a portion of such year, during the por-
22	tion of time in such year that the drug was
23	marketed.
24	(G) Average net price per 30-day supply or
25	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, 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 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 pre-

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2	scription drug shall report to the Secretary, elec-
3	tronically, in such manner as the Secretary may re-
4	quire, any increase or decrease in the wholesale ac-
5	quisition cost of a prescription drug not later than
6	30 days prior to the date on which the price change
7	takes effect.
8	(2) Content.—A price change report under
9	paragraph (1) shall include—
10	(A) the information required under sub-
11	paragraphs (A), (B), (C), (D), and (F) of sub-
12	section (a)(1);
13	(B) the wholesale acquisition cost per 30-
14	day supply or typical course of treatment imme-
15	diately prior to the price change;
16	(C) the new wholesale acquisition cost per
17	30-day supply or typical course of treatment
18	when the change takes effect; and
19	(D) financial and non-financial factors the
20	manufacturer took into consideration when
21	making the price change, including any changes
22	or improvements to the drug.
23	(c) Public Database.—
24	(1) In general.—The Secretary shall establish
25	an internet-based system to post prescription drug

1 information reported under subsection (a) and price 2 change reports required under subsection (b). 3 (2) Consumer subscription options.—The system established under paragraph (1) shall enable 5 consumers to subscribe to price change notifica-6 tions— 7 (A) for— 8 (i) all drugs; 9 (ii) a particular drug; or 10 (iii) a particular therapeutic class of 11 drugs; and 12 (B) that are limited to price changes that 13 are at or over a specified amount. 14 (3) Timing.—The prescription drug informa-15 tion reported under subsection (a) shall be made 16 publicly available not later than 30 days after being 17 reported to the Secretary. Price change reports re-18 quired under subsection (b) shall be made publically 19 available no later than 5 business days after submis-20 sion to the Secretary. 21 (d) Privacy Protections.—The information sub-22 mitted under subparagraphs (A) through (F) of subsection 23 (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

- 1 subsection (a) or (b) that is proprietary, confidential, or
- 2 trade secret information shall be included in such data-
- 3 base.
- 4 (e) Definitions.—For purposes of this section—
- 5 (1) the term "manufacturer" has the meaning
- 6 given such term in section 581 of the Federal Food,
- 7 Drug, and Cosmetic Act (21 U.S.C. 360eee);
- 8 (2) the term "prescription drug" means a drug
- 9 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
- 14 Cosmetic Act (21 U.S.C. 353(b)(1));
- 15 (3) the term "Secretary" means the Secretary
- of Health and Human Services; and
- 17 (4) the term "wholesale acquisition cost" has
- the meaning given such term in section
- 19 1847A(c)(6)(B) of the Social Security Act (42)
- 20 U.S.C. 1395w-3a (c)(6)(B)).
- 21 (f) Preemption.—Effective on the date that the
- 22 public database under subsection (b)(3) first becomes
- 23 operational, no State or political subdivision of a State
- 24 may establish or continue in effect any law requiring the

- 1 manufacturer to report or make public prescription drug
- 2 pricing information.

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