

1 tronicallly, in such manner as the Secretary may re-
2 quire, by April 1 of each year, a list of each such
3 drug that is marketed in the United States and,
4 with respect to each such drug, all of the following
5 information with respect to the previous year:

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

8 (B) Brand name.

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

11 (D) Therapeutic class or classes, as appli-
12 cable.

13 (E) Current wholesale acquisition cost per
14 30-day supply or typical course of treatment.

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

22 (G) Average net price per 30-day supply or
23 typical course of treatment, during the previous
24 calendar year, or, in the case of a drug that has
25 been marketed for only a portion of such year,

1 during the portion of time in such year that the
2 drug was marketed, taking into account all dis-
3 counts, rebates, and other fees or payments to
4 health insurance plans or pharmacy benefit
5 managers with respect to sales of the drug to
6 individuals covered by such a plan.

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

16 (2) TIMELINE FOR INITIAL SUBMISSION.—

17 (A) DRUGS MARKETED BEFORE DECEM-
18 BER 31, 2020.—Each manufacturer of a pre-
19 scription drug that is marketed at any time
20 during calendar year 2020, shall submit to the
21 Secretary, not later than April 1, 2021—

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

24 (ii) in addition to the information re-
25 quired under subparagraphs (F), (G), and

1 (H) of paragraph (1), such average whole-
2 sale acquisition cost, average net price, and
3 total rebates and other payments, de-
4 scribed in each of such subparagraphs, re-
5 spectively, with respect to the calendar
6 year immediately preceding the calendar
7 year for which such information is required
8 to be reported under such subparagraphs
9 (F), (G), and (H).

10 (B) SUBSEQUENTLY MARKETED DRUGS.—

11 With respect to a prescription drug that is first
12 marketed after December 31, 2020, each manu-
13 facturer of such a drug shall submit the infor-
14 mation required under subparagraphs (A)
15 through (E) of paragraph (1) not later than 60
16 days after the date on which the drug is first
17 marketed, and shall submit annual reports of
18 all of the information required under paragraph
19 (1) beginning on the first annual reporting date
20 that is more than 30 days after the date on
21 which the drug is first marketed.

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

24 (1) IN GENERAL.—Each manufacturer of a pre-
25 scription drug shall report to the Secretary, elec-

1 tronicallly, in such manner as the Secretary may re-
2 quire, any increase or decrease in the wholesale ac-
3 quisition cost of a prescription drug not later than
4 30 days prior to the date on which the price change
5 takes effect.

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

8 (A) the information required under sub-
9 paragraphs (A), (B), (C), (D), and (F) of sub-
10 section (a)(1);

11 (B) the wholesale acquisition cost per 30-
12 day supply or typical course of treatment imme-
13 diately prior to the price change;

14 (C) the new wholesale acquisition cost per
15 30-day supply or typical course of treatment,
16 when the change takes effect; and

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

21 (c) PUBLIC DATABASE.—

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

1 (2) CONSUMER SUBSCRIPTION OPTIONS.—The
2 system established under paragraph (1) shall enable
3 consumers to subscribe to price change notifica-
4 tions—

5 (A) for—

6 (i) all drugs;

7 (ii) a particular drug; or

8 (iii) a particular therapeutic class of
9 drugs; and

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

12 (3) TIMING.—The prescription drug informa-
13 tion reported under subsection (a) shall be made
14 publicly available not later than 30 days after being
15 reported to the Secretary. In the case of a price
16 change report required under subsection (b), the
17 Secretary shall make publicly available a notice of
18 the price change contained in such report on the day
19 such change takes effect.

20 (d) PRIVACY PROTECTIONS.—The information sub-
21 mitted under subparagraphs (A) through (F) of subsection
22 (a)(1) and paragraph (2)(A)(ii) shall be publicly available
23 through the database established under subsection (c). No
24 other information submitted to the Secretary pursuant to
25 subsection (a) or (b) that is proprietary, confidential, or

1 trade secret information shall be included in such data-
2 base.

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

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

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

14 (3) the term “Secretary” means the Secretary
15 of Health and Human Services; and

16 (4) the term “wholesale acquisition cost” has
17 the meaning given such term in section
18 1847A(c)(6)(B) of the Social Security Act (42
19 U.S.C. 1395w–3a (c)(6)(B)).

20 (f) PREEMPTION.—Effective on the date that the
21 public database under subsection (b)(3) first becomes
22 operational, no State or political subdivision of a State
23 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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