

SENATE, No. 919

STATE OF NEW JERSEY 219th LEGISLATURE

INTRODUCED JANUARY 27, 2020

Sponsored by:

Senator TROY SINGLETON

District 7 (Burlington)

SYNOPSIS

Prohibits excessive increases in prices charged for essential off-patent and generic prescription drugs and biological products.

CURRENT VERSION OF TEXT

As introduced.



1 **AN ACT** concerning pharmaceutical pricing and supplementing Title
2 24 of the Revised Statutes.

3
4 **BE IT ENACTED** *by the Senate and General Assembly of the State*
5 *of New Jersey:*

6
7 1. As used in P.L. , c. (C.) (pending before the
8 Legislature as this bill):

9 “Director” means the Director of the Division of Consumer
10 Affairs in the Department of Law and Public Safety.

11 “Division” means the Division of Consumer Affairs in the
12 Department of Law and Public Safety.

13 “Essential off-patent or generic drug or biological product”
14 means any prescription drug or biological product, including any
15 drug-device or biological product-device combination product for
16 the delivery of the prescription drug or biological product:

17 (1) that is made available for sale in the State;

18 (2) for which all exclusive marketing rights, if any, granted
19 under the 52 Stat. 1040, 21 U.S.C. s.301 et seq., section 351 of the
20 "Public Health Service Act," 58 Stat. 682, 42 U.S.C. s.262, and
21 federal patent law, have expired;

22 (3) that is actively manufactured and marketed by three or fewer
23 manufacturers; and

24 (4) that appears on the current Model List of Essential Medicines
25 adopted by the World Health Organization or has been designated
26 by the Commissioner of Health as an essential medicine due to its
27 efficacy in treating a life-threatening health condition or a chronic
28 health condition that substantially impairs a person’s ability to
29 engage in activities of daily living.

30 “FDA” means the federal Food and Drug Administration.

31 “Price gouging” means any unconscionable increase in the price
32 of a prescription drug or biological product.

33 “Unconscionable increase” means an increase in the price of a
34 prescription drug or biological product that:

35 (1) is excessive and not justified by the cost of producing the
36 drug or biological product or the cost of appropriate expansion of
37 access to the drug or biological product to promote the public
38 health; and

39 (2) results in consumers for whom the drug or biological
40 product has been prescribed having no alternative but to purchase
41 the drug or biological product at an excessive price because of the
42 importance of the drug to the health of the consumers and
43 insufficient competition in the market for the drug or biological
44 product.

45 “Wholesale acquisition cost” means, with respect to a drug or
46 biological product, the manufacturer's list price for the drug or
47 biological product to wholesalers or direct purchasers in the United
48 States, not including prompt pay or other discounts, rebates, or

1 reductions in price, for the most recent month for which the
2 information is available, as reported in wholesale price guides or other
3 publications of drug or biological product pricing data.

4

5 2. a. A prescription drug or biological product manufacturer or
6 wholesale distributor shall not engage in price gouging in the sale
7 of an essential off-patent or generic drug or biological product.

8 b. It shall not constitute a violation of subsection a. of this
9 section for a wholesale distributor to increase the price of an
10 essential off-patent or generic drug or biological product if the price
11 increase is directly attributable to additional costs for the drug or
12 biological product imposed on the wholesale distributor by the
13 manufacturer of the drug or biological product.

14

15 3. a. The director may notify the Attorney General of any
16 increase in the price of an essential off-patent or generic drug or
17 biological product whenever:

18 (1) the price increase, individually or in combination with other
19 price increases:

20 (a) would result in an increase of 50 percent or more in the
21 wholesale acquisition cost of the drug or biological product within
22 the preceding one-year period; or

23 (b) would result in an increase of 50 percent or more in the price
24 paid by the Medicaid program or NJ FamilyCare program for the
25 drug or biological product within the preceding one-year period, as
26 certified by the Director of the Division of Medical Assistance and
27 Health Services in the Department of Human Services; and

28 (2) (a) a 30-day supply of the maximum recommended dosage
29 of the drug or biological product for any indication, according to the
30 FDA-approved label for the drug or biological product, would cost
31 more than \$80 at the wholesale acquisition cost of the drug or
32 biological product;

33 (b) a full course of treatment with the drug or biological
34 product, according to the FDA-approved label for the drug or
35 biological product, would cost more than \$80 at the wholesale
36 acquisition cost of the drug or biological product; or

37 (c) if the drug or biological product is made available to
38 consumers only in quantities that do not correspond to a 30-day
39 supply, a full course of treatment, or a single dose, the drug or
40 biological product would cost more than \$80 at the wholesale
41 acquisition cost of the drug or biological product to obtain a 30-day
42 supply or a full course of treatment.

43 b. At the request of the Attorney General, the manufacturer of
44 an essential off-patent or generic drug or biological product
45 identified in a notice provided pursuant to subsection a. of this
46 section shall, no later than 45 days after receipt of the request,
47 submit a statement to the Attorney General:

- 1 (1) itemizing the components of the cost of producing the drug
2 or biological product;
- 3 (2) identifying the circumstances and timing of any increase in
4 materials or manufacturing costs that caused any increase in the
5 price of the drug or biological product within the one-year period
6 preceding the date of the price increase;
- 7 (3) identifying the circumstances and timing of any expenditures
8 made by the manufacturer to expand access to the drug or biological
9 product and explaining any improvement in public health associated
10 with those expenditures; and
- 11 (4) providing any other information that the manufacturer
12 believes to be relevant to a determination as to whether a violation
13 of P.L. , c. (C.) (pending before the Legislature as this bill)
14 has occurred.
- 15 c. The Attorney General may require a manufacturer or a
16 wholesale distributor to produce any records or documents that may
17 be relevant to a determination as to whether a violation of
18 P.L. , c. (C.) (pending before the Legislature as this bill)
19 has occurred.
- 20 d. Upon petition of the Attorney General, a court may issue an
21 order:
- 22 (1) compelling a manufacturer to submit the statement required
23 pursuant to subsection b. of this section or a manufacturer or
24 wholesale distributor to produce specific records or documents as
25 requested by the Attorney General pursuant to subsection c. of this
26 section;
- 27 (2) restraining or enjoining a violation of P.L. , c. (C.)
28 (pending before the Legislature as this bill);
- 29 (3) restoring to any consumer, including any third party payor,
30 any money acquired by a manufacturer or wholesale distributor as a
31 result of a price increase that violates P.L. , c. (C.)
32 (pending before the Legislature as this bill);
- 33 (4) requiring a manufacturer that has engaged in price gouging
34 in the sale of an essential off-patent or generic drug or biological
35 product to make the drug or biological product available to
36 wholesale distributors, pharmacies, and consumers in the State, for
37 a period of up to one year, at a price that does not exceed the price
38 at which the drug or biological product was made available to such
39 wholesale distributors, pharmacies, and consumers immediately
40 prior to the violation of P.L. , c. (C.) (pending before the
41 Legislature as this bill); and
- 42 (5) assessing a civil penalty of up to \$10,000 against a
43 manufacturer or wholesale distributor for each violation of
44 P.L. , c. (C.) (pending before the Legislature as this bill).
45 For the purposes of this paragraph, each sale of an essential off-
46 patent or generic drug or biological product at a price that
47 constitutes price gouging shall be deemed to be a separate violation.

1 e. The Attorney General shall not commence an action seeking
2 relief pursuant to paragraphs (2) through (5) of subsection d. of this
3 section unless the Attorney General has provided the manufacturer
4 or wholesale distributor an opportunity to meet with the Attorney
5 General to provide a justification for the increase in the price of the
6 essential off-patent or generic drug or biological product.

7 f. Any information provided by a manufacturer pursuant to
8 subsection b. of this section, or by a manufacturer or wholesale
9 distributor pursuant to subsection c. of this section, shall be deemed
10 confidential and shall not be disclosed to the public or otherwise
11 subject to public access, inspection, or copying, unless such
12 confidentiality is waived by the manufacturer or wholesale
13 distributor.

14 g. It shall not be a defense to an action brought by the Attorney
15 General pursuant to subsection d. of this section that a manufacturer
16 alleged to have violated P.L. , c. (C.) (pending before the
17 Legislature as this bill) did not sell the essential off-patent or
18 generic drug or biological product directly to a consumer in this
19 State.

20
21 4. The Director of the Division of Consumer Affairs in the
22 Department of Law and Public Safety shall, pursuant to the
23 “Administrative Procedure Act,” P.L.1968, c.410 (C.52:14B-
24 1 et seq.) adopt such rules and regulations as shall be necessary to
25 implement the provisions of this act.

26
27 5. This act shall take effect the first day of the seventh month
28 next following the date of enactment, except that the Director of the
29 Division of Consumer Affairs in the Department of Law and Public
30 Safety may take any advance administrative action as may be
31 necessary to implement the provisions of this act.

32 33 34 STATEMENT

35
36 This bill prohibits manufacturers and wholesale distributors of
37 prescription drugs biological products from excessively increasing
38 the price of certain prescription drugs and biological products
39 without justification.

40 Specifically, manufacturers and wholesale distributors may not
41 engage in price gouging in the sale of an essential off-patent or
42 generic drug or biological product. Price gouging is defined to
43 mean an increase in the price of a drug or biological product that:
44 (1) is excessive and not justified by the cost of producing the drug
45 or biological product or expanding access to the drug or biological
46 product to promote the public health; and (2) results in consumers
47 having no alternative but to purchase the drug or biological product
48 at an excessive price because of the importance of the drug or

1 biological product to their health and insufficient marketplace
2 competition. Under the bill, wholesale distributors will not be
3 found to have violated this prohibition if the distributor increases
4 the price of a drug or biological product in direct response to
5 additional costs for the drug or biological product imposed on the
6 distributor by the manufacturer.

7 The bill defines “essential off-patent or generic drug or
8 biological product” to mean any prescription drug or biological
9 product, including any drug-device or biological product-device
10 combination product for the delivery of the prescription drug or
11 biological product: (1) that is made available for sale in the State;
12 (2) for which all exclusive marketing rights granted under federal
13 law have expired; (3) that is actively manufactured and marketed by
14 three or fewer manufacturers; and (4) that appears on the current
15 Model List of Essential Medicines adopted by the World Health
16 Organization or has been otherwise designated as an essential
17 medicine by the Commissioner of Health.

18 The Director of the Division of Consumer Affairs in the
19 Department of Law and Public Safety may notify the Attorney
20 General of any increase in the price of an essential off-patent or
21 generic drug or biological product whenever: (1) the price increase,
22 individually or in combination with other price increases, would
23 result in an increase of 50 percent or more in the wholesale
24 acquisition cost for the drug or biological product or in the price
25 paid for the drug or biological product by the State Medicaid or NJ
26 FamilyCare programs within a one-year period; and (2) the
27 wholesale acquisition cost of the drug or biological product is more
28 than \$80 for a 30-day supply or a full course of treatment.

29 At the request of the Attorney General, the manufacturer of an
30 essential off-patent or generic drug or biological product identified
31 in a notice provided under the bill will be required to submit, within
32 45 days of receiving the request, a statement to the Attorney
33 General: (1) detailing the cost of producing the drug or biological
34 product; (2) identifying the circumstances and timing of any cost
35 increases in the preceding year; (3) identifying the circumstances
36 and timing of any expenditures made by the manufacturer to expand
37 access to the drug or biological product, and explaining any
38 resulting improvements in public health; and (4) any other
39 information the manufacturer determines to be relevant to a
40 determination as to whether a violation of the provisions of the bill
41 has occurred.

42 The Attorney General may require a manufacturer or a wholesale
43 distributor to produce any records or documents that may be
44 relevant to a determination as to whether a violation of the bill has
45 occurred. The Attorney General may additionally petition for a
46 court order compelling submission of any required statement or
47 records; restraining or enjoining a violation of the bill; restoring to
48 any consumer, including any third party payor, any money acquired

1 by the manufacturer or wholesale distributor as a result of a price
2 increase that violates the bill; requiring a manufacturer that has
3 engaged in price gouging to make the drug or biological product
4 available in the State, for a period of up to one year, at a price that
5 does not exceed the price immediately prior to the violation; and
6 assessing a civil penalty of up to \$10,000 against a manufacturer or
7 wholesale distributor who has violated the provisions of the bill.
8 For the purposes of assessing the civil penalty, each sale of a drug
9 or biological product at a price that constitutes price gouging will
10 be deemed a separate violation. It will not be a defense to an action
11 brought by the Attorney General that a manufacturer did not sell the
12 essential off-patent or generic drug or biological product directly to
13 a consumer in New Jersey.

14 The Attorney General may not commence an action seeking a
15 court order for any relief, other than an order compelling
16 submission of required statements or records, unless the Attorney
17 General has provided the manufacturer or wholesale distributor the
18 opportunity to meet with the Attorney General to provide a
19 justification for the price increase.

20 Any information provided by a manufacturer or wholesale
21 distributor under the bill will be confidential and may not be
22 disclosed to the public or otherwise subjected to public access,
23 inspection, or copying, unless the manufacturer or wholesale
24 distributor waives confidentiality.