

STATE OF NEW YORK

3829

2019-2020 Regular Sessions

IN ASSEMBLY

January 31, 2019

Introduced by M. of A. McDONALD -- Multi-Sponsored by -- M. of A. THIELE
-- read once and referred to the Committee on Health

AN ACT to amend the public health law and the general business law, in
relation to price gouging on prescription drugs

The People of the State of New York, represented in Senate and Assem-
bly, do enact as follows:

1 Section 1. The public health law is amended by adding a new section
2 278-a to read as follows:

3 § 278-a. Limitation on excessive price increases; prescription drugs:
4 1. In the event a manufacturer, as defined in subdivision twenty-one of
5 section sixty-eight hundred two of the education law, of a brand or
6 generic drug, made available in New York, increases the wholesale acqui-
7 sition cost (WAC) of a drug by a percent equal to or greater than one
8 hundred percent at any one time or in the aggregate in any twelve month
9 period:

10 (a) The manufacturer shall, not less than thirty days prior to insti-
11 tuting such increase, notify the commissioner and the drug utilization
12 review board established under section three hundred sixty-nine-bb of
13 the social services law. Notice shall be provided on the form estab-
14 lished pursuant to subdivision two of this section; and

15 (b) The commissioner shall require prior authorization and authorize
16 Medicaid managed care plans to require prior authorization for the drug
17 effective as of the date of the price increase and continuing until a
18 determination is made by the drug utilization review board.

19 2. The commissioner, in consultation with the drug utilization review
20 board, shall produce and make available to manufacturers a price
21 increase notification form that shall elicit:

22 (a) The most recent wholesale acquisition cost (WAC) of the drug prior
23 to an increase equal to or greater than one hundred percent at any one
24 time or in the aggregate in any twelve month period in either pricing
25 measure. For the purposes of this section wholesale acquisition cost

EXPLANATION--Matter in italics (underscored) is new; matter in brackets
[-] is old law to be omitted.

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1 (WAC) shall include the prices for each dosage, size or concentration of
2 the drug offered or sold by the manufacturer;

3 (b) The wholesale acquisition cost (WAC) of the drug when exceeding
4 the one hundred percent threshold;

5 (c) Any material change in ingredient, production, or manufacturing
6 costs resulting in the price increase;

7 (d) In the case of a brand drug, the expiration date of the patent;

8 (e) In the case of a generic drug, whether the drug is a sole source
9 drug; and

10 (f) Any other information the manufacturer deems relevant to the
11 board's review.

12 3. Upon receipt of a price increase notification form, the drug utili-
13 zation review board shall review the price increase and make a determi-
14 nation as to whether the price increase is excessive. In making a deter-
15 mination the board shall consider:

16 (a) The wholesale acquisition cost (WAC) of the drug in comparison to
17 any generic equivalent or therapeutically equivalent drug;

18 (b) The FDA approved or compendium supported use of the drug and crit-
19 ical need to the patient;

20 (c) Any known market factors justifying the price increase, including
21 but not limited to:

22 (i) whether the drug has been absent from the market for any period of
23 time; and

24 (ii) changes in manufacturing or regulatory requirements or costs.

25 (d) Any material change in the prevalence or severity of the disease
26 or medical condition or conditions that the drug is approved to treat;

27 (e) In the case of a brand drug, the expiration date of the patent;
28 and

29 (f) In the case of a generic drug, whether the drug is a sole source
30 drug.

31 4. Upon a finding by the drug utilization review board that a manufac-
32 turer has instituted an excessive price increase, (a) the board shall
33 require prior authorization for the drug and authorize Medicaid managed
34 care plans to require prior authorization until the board determines
35 otherwise; and (b) the board may refer the matter to the attorney gener-
36 al with any information necessary for the investigation and prosecution
37 of price gouging violations under section three hundred ninety-six-rrr
38 of the general business law. In the event the board does not find that
39 the manufacturer has engaged in an excessive price increase, the board
40 shall remove the requirement for prior authorization and such authority
41 granted to Medicaid managed care plans to institute prior authorization
42 under this section shall cease.

43 § 2. The general business law is amended by adding a new section 396-
44 rrr to read as follows:

45 § 396-rrr. Price gouging; prescription drugs. 1. Legislative findings
46 and declaration. The legislature hereby finds that excessive price
47 increases to prescription drugs that lack justification based on market
48 forces create a public health risk to consumers that rely on these
49 prescription drugs. In order to prevent a manufacturer, as defined in
50 subdivision twenty-one of section sixty-eight hundred two of the educa-
51 tion law, from taking unfair advantage of consumers who rely upon and
52 may lose access to the prescription drugs if the medication has a sudden
53 and excessive price increase, the legislature declares that the public
54 interest requires that such conduct be prohibited and made subject to
55 civil penalties.

1 2. In order to prevent a drug manufacturer, as defined in subdivision
2 twenty-one of section sixty-eight hundred two of the education law, from
3 imposing unconscionably and unjustifiably excessive price increases, the
4 attorney general may, upon referral from the drug utilization review
5 board as codified in section two hundred seventy-eight-a of the public
6 health law, apply in the name of the people of the state of New York to
7 the supreme court within the judicial district in which such violations
8 are alleged to have occurred, on notice of five days, for an order
9 enjoining or restraining commission or continuance of the alleged unlaw-
10 ful acts. In any such proceeding, the court may impose a civil penalty
11 in an amount not to exceed twenty-five thousand dollars and, where
12 appropriate, order restitution to aggrieved consumers.

13 3. Whether a price is unconscionably and unjustifiably excessive is a
14 question of law for the court. The court's determination that a
15 violation of this section has occurred shall be based upon the following
16 factors:

17 (a) the increase in price is unconscionably extreme;

18 (b) the drug is vital and medically necessary to the health of the
19 consumer;

20 (c) the drug is a sole source drug without a therapeutic equivalent;
21 and

22 (d) the price increase was within the control of the manufacturer and
23 not caused by costs imposed on or factors beyond the control of the
24 manufacturer.

25 § 3. This act shall take effect immediately.