



102ND GENERAL ASSEMBLY

State of Illinois

2021 and 2022

HB3609

Introduced 2/22/2021, by Rep. Mary E. Flowers

SYNOPSIS AS INTRODUCED:

410 ILCS 620/16.2 new

Amends the Illinois Food, Drug and Cosmetic Act. Provides that the amendatory provisions apply to any manufacturer of a prescription drug that is purchased or reimbursed by specified parties. Provides that a manufacturer of a prescription drug with a wholesale acquisition cost of more than \$40 for a course of therapy shall notify specified parties if the increase in the wholesale acquisition cost of the prescription drug is more than 10%, including the proposed increase and cumulative increase. Provides that the notice of price increase shall be provided in writing at least 60 days prior to the planned date of the increase. Provides that no later than 30 days after notification of a price increase or new prescription drug the manufacturer shall report specified additional information to specified parties. Provides that a manufacturer of a prescription drug shall provide written notice if the manufacturer is introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the a specified threshold. Provides that failure to provide notice under the amendatory provisions shall result in a civil penalty of \$10,000 per day for every day after the notification period that the manufacturer fails to report the information. Requires the Department of Public Health to conduct an annual public hearing on the aggregate trends in prescription drug pricing. Requires the Department to publish on its website a report detailing findings from the public hearing and a summary of details from reports provided under the amendatory provisions, except for information identified as a trade secret or exempted under the Freedom of Information Act. Provides that the amendatory provisions shall not restrict the legal ability of a pharmaceutical manufacturer to change prices as permitted under federal law.

LRB102 03816 CPF 13830 b

FISCAL NOTE ACT
MAY APPLY

A BILL FOR

1 AN ACT concerning health.

2 **Be it enacted by the People of the State of Illinois,**
3 **represented in the General Assembly:**

4 Section 5. The Illinois Food, Drug and Cosmetic Act is
5 amended by adding Section 16.2 as follows:

6 (410 ILCS 620/16.2 new)

7 Sec. 16.2. Prescription drug price increases.

8 (a) This Section shall apply to any manufacturer of a
9 prescription drug that is purchased or reimbursed by any of
10 the following:

11 (1) A State purchaser, including, but not limited to,
12 State retirement systems, the Department of Corrections,
13 the Department of Healthcare and Family Services, the
14 Department of Public Health, or any entity acting on
15 behalf of a State purchaser.

16 (2) A health insurer.

17 (3) A health care service plan provider.

18 (4) A pharmacy benefit manager.

19 (b) A manufacturer of a prescription drug with a wholesale
20 acquisition cost of more than \$40 for a course of therapy shall
21 notify each party described in subsection (a) if there is an
22 increase in the wholesale acquisition cost of the prescription
23 drug of more than 10%, including the proposed increase and

1 cumulative increase that has occurred within the previous 2
2 calendar years prior to the date of the proposed increase.

3 For purposes of this subsection, "course of therapy" means
4 either of the following:

5 (1) The recommended daily dosage units of a
6 prescription drug pursuant to its prescribing label as
7 approved by the federal Food and Drug Administration for a
8 normal course of treatment that is 30 days or more.

9 (2) The recommended daily dosage units of a
10 prescription drug pursuant to its prescribing label as
11 approved by the federal Food and Drug Administration for a
12 normal course of treatment that is less than 30 days.

13 (c) The notice required under subsection (b) shall be
14 provided in writing at least 60 days prior to the planned date
15 of the increase in the wholesale acquisition cost.

16 (d) No later than 30 days after providing notification of
17 a price increase under subsection (b), a manufacturer shall
18 report the following information to each party described in
19 subsection (a):

20 (1) The latest applicable wholesale acquisition cost.

21 (2) The date of the latest previous increase in
22 wholesale acquisition cost.

23 (3) The per-unit dollar amount of the scheduled
24 increase in wholesale acquisition cost.

25 (4) A schedule of wholesale acquisition cost increases
26 for the previous 5 years, where available, or for the

1 years since the drug has been approved by the federal Food
2 and Drug Administration if that length of time is less
3 than 5 years.

4 (5) The date and price of acquisition, if the drug was
5 not developed by the manufacturer.

6 (6) A description of each financial and non-financial
7 factor that contributes to the wholesale acquisition cost,
8 including the following:

9 (A) A percentage of the price attributable to each
10 factor.

11 (B) An explanation of the role of each factor in
12 the price of the drug.

13 (e) A manufacturer of a prescription drug shall provide
14 written notice to each party described in subsection (a) if
15 the manufacturer is introducing a new prescription drug to
16 market at a wholesale acquisition cost that exceeds the
17 threshold set for a specialty drug under the Medicare Part D
18 program. This notice shall be provided no later than 30 days
19 prior to the release of the drug on the commercial market.

20 (f) No later than 30 days after providing the notification
21 of a new prescription drug under subsection (e), a
22 manufacturer shall report the following information to each
23 party described in subsection (a):

24 (1) The latest applicable wholesale acquisition cost.

25 (2) The date of the latest previous increase in
26 wholesale acquisition cost.

1 (3) The per-unit dollar amount of the scheduled
2 increase in wholesale acquisition cost.

3 (4) A schedule of wholesale acquisition costs
4 increases for the previous 5 years, where available, or
5 for the years since the drug has been approved by the
6 federal Food and Drug Administration if that length of
7 time is less than 5 years.

8 (5) The date and price of acquisition, if the drug was
9 not developed by the manufacturer.

10 (6) A description of each financial and non-financial
11 factor that contributes to the wholesale acquisition cost,
12 including the following:

13 (A) A percentage of the price attributable to each
14 factor.

15 (B) An explanation of the role of each factor in
16 the price of the drug.

17 (g) Failure to provide the information required under
18 subsections (b), (d), (e), or (f) to each party described in
19 subsection (a) shall result in a civil penalty of \$10,000 per
20 day for every day after the notification period that the
21 manufacturer fails to provide the information.

22 (h) The Department of Public Health shall conduct an
23 annual public hearing on the aggregate trends in prescription
24 drug pricing. The hearing shall provide for public discussion
25 of overall price increases, emerging trends, decreases in drug
26 spending, and the impact of prescription drug spending on

1 health care affordability and premiums.

2 (i) The Department of Public Health shall publish on its
3 website a report detailing findings from the public hearing
4 held under subsection (h) and a summary of information
5 provided under subsections (b), (d), (e), and (f).

6 (j) The Department of Public Health may not post on its
7 website any information described in subsections (d) or (f) of
8 this Section that is identified as a trade secret under the
9 Illinois Trade Secrets Act.

10 (k) The Department of Public Health shall keep
11 confidential all information provided to the Department that
12 would qualify for an exemption under Section 7 of the Freedom
13 of Information Act.

14 (l) This Section shall not restrict the legal ability of a
15 pharmaceutical manufacturer to change prices as permitted
16 under federal law.