

FIRST REGULAR SESSION

SENATE BILL NO. 310

100TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR ARTHUR.

Read 1st time January 28, 2019, and ordered printed.

ADRIANE D. CROUSE, Secretary.

0167S.04I

AN ACT

To amend chapter 376, RSMo, by adding thereto nine new sections relating to prescription drug costs.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Chapter 376, RSMo, is amended by adding thereto nine new sections, to be known as sections 376.2060, 376.2061, 376.2062, 376.2064, 376.2066, 376.2068, 376.2070, 376.2072, and 376.2073, to read as follows:

376.2060. As used in sections 376.2060 to 376.2070, unless otherwise clearly indicated by context, the following terms shall mean:

(1) "Closed meeting", the same meaning as ascribed to such term in section 610.010;

(2) "Commission", the drug cost review commission established in section 376.2061;

(3) "Department", the department of insurance, financial institutions and professional registration;

(4) "Director", the director of the department of insurance, financial institutions and professional registration;

(5) "Drug", the same meaning as ascribed to such term in section 376.1350;

(6) "Enrollee", the same meaning as ascribed to such term in section 376.1350;

(7) "Health benefit plan", the same meaning as ascribed to such term in section 376.1350; however, for purposes of sections 376.2060 to 376.2070, the term shall be limited to plans providing coverage for outpatient prescription drugs;

(8) "Health carrier", the same meaning as ascribed to such term in section 376.1350;

21 (9) "Person", an individual, corporation, partnership, limited
22 liability company, association, joint stock company, business trust,
23 unincorporated organization, or other legal entity;

24 (10) "Pharmacist", an individual licensed to practice pharmacy
25 under chapter 338;

26 (11) "Pharmacy", the same meaning as ascribed to such term in
27 section 338.210;

28 (12) "Pharmacy benefits manager", the same meaning as ascribed
29 to such term in section 376.388;

30 (13) "Practice of pharmacy", the same meaning as ascribed to
31 such term in section 338.010;

32 (14) "Public meeting", the same meaning as ascribed to such term
33 in section 610.010;

34 (15) "Public vote", the same meaning as ascribed to such term in
35 section 610.010;

36 (16) "Rebate", a discount or concession, which affects the price
37 of an outpatient prescription drug, that a pharmaceutical manufacturer
38 directly provides to a:

39 (a) Health carrier for an outpatient prescription drug
40 manufactured by the pharmaceutical manufacturer; or

41 (b) Pharmacy benefits manager after the manager processes a
42 claim from a pharmacy or pharmacist for an outpatient prescription
43 drug manufactured by the pharmaceutical manufacturer.

44 Such term shall not include a "bona fide service fee", as defined in 42
45 CFR 447.502, as amended;

46 (17) "Specialty drug", a prescription outpatient specialty drug
47 covered under the Medicare Part D program established under Public
48 Law 108-173, the Medicare Prescription Drug, Improvement, and
49 Modernization Act of 2003, as amended, that exceeds the specialty tier
50 cost threshold established by the Centers for Medicare and Medicaid
51 Services.

 376.2061. 1. There is hereby established within the department
2 of insurance, financial institutions, and professional registration the
3 "Drug Cost Review Commission" for the purpose of protecting state
4 residents, state and local governments, commercial health benefit
5 plans, health care providers, pharmacies licensed in the state, and
6 other stakeholders within the health care system from excessive costs

7 of prescription drugs.

8 2. (1) The commission shall consist of the following members:

9 (a) The governor or his or her designee;

10 (b) The director of the department of insurance, financial
11 institutions and professional registration, or his or her designee;

12 (c) The president pro tempore of the senate or his or her
13 designee;

14 (d) The speaker of the house of representatives or his or her
15 designee;

16 (e) The attorney general or his or her designee.

17 (2) The director of the department of insurance, financial
18 institutions, and professional registration shall appoint two additional
19 members to serve during his or her tenure as director as alternative
20 members who shall participate in deliberations of the commission when
21 a member is recused.

22 (3) Any potential conflict of interest, including whether the
23 individual has an association, including a financial or personal
24 association, that has the potential to bias or has the appearance of
25 biasing an individual's decisions in matters related to the commission
26 or the conduct of the commission's activities, shall be considered and
27 disclosed when appointing members to the commission.

28 3. (1) No person shall receive compensation as a member of the
29 commission, but members shall receive reimbursement for the actual
30 and necessary expenses incurred in attending meetings of the
31 commission or any subcommittee thereof.

32 (2) The chairman of the commission shall be elected by the
33 members of the commission.

34 (3) The chairman shall hire an executive director, general
35 counsel, and staff for the commission, who shall receive compensation
36 as provided in the budget of the commission.

37 4. (1) (a) Except as provided in this subdivision, the commission
38 shall hold a public meeting at least every six weeks to review
39 prescription drug product information submissions.

40 (b) The chairman may cancel or postpone a meeting if there are
41 no prescription drug product submissions to review.

42 (c) The commission may additionally hold closed meetings as
43 specified under chapter 610, but decisions of the commission shall be

44 made by public vote.

45 (2) The commission shall give notice of meetings as specified in
46 section 610.020 not less than two weeks prior to each meeting.

47 (3) Materials for each commission meeting shall be made
48 available to the public on the department's website not less than one
49 week prior to the meeting.

50 (4) The commission shall provide opportunity for public
51 comment at each public meeting of the commission.

52 (5) The commission shall provide the public with the opportunity
53 to provide written comments on pending decisions of the commission.

54 (6) The commission may allow expert testimony at commission
55 meetings, including during closed meetings.

56 (7) The following actions shall be made only in a public meeting:

57 (a) Deliberations on whether to subject a prescription drug to a
58 full cost review;

59 (b) Any review of a prescription drug cost analysis; and

60 (c) Any vote on whether to impose a cost or payment limit on
61 health carriers for a prescription drug product.

62 (8) A majority of the members of the commission shall constitute
63 a quorum.

64 (9) A member of the commission shall recuse himself or herself
65 from discussions and decisions related to a prescription drug under
66 review if the member or a person within the second degree of
67 consanguinity or affinity has received or could receive any of the
68 following:

69 (a) A direct financial benefit of any amount deriving from the
70 result or findings of a study or determination by or for the commission;
71 or

72 (b) A financial benefit from individuals or companies that own,
73 manufacture, or provide prescription drugs, services, or items to be
74 studied by the commission that in the aggregate exceeds five thousand
75 dollars per year.

376.2062. 1. No later than March 1, 2022, and annually thereafter,
2 each pharmacy benefits manager shall file a report with the
3 commission for the immediately preceding calendar year. The report
4 shall contain the following information for health carriers that
5 delivered, issued for delivery, renewed, amended, or continued health

6 benefit plans that included a pharmacy benefit managed by the
7 pharmacy benefits manager during such calendar year:

8 (1) The aggregate dollar amount of all rebates concerning drug
9 formularies used by such health carriers which such manager collected
10 from pharmaceutical manufacturers that manufactured outpatient
11 prescription drugs that:

12 (a) Were covered by such health carriers during such calendar
13 year; and

14 (b) Are attributable to patient utilization of such drugs during
15 such calendar year; and

16 (2) The aggregate dollar amount of all rebates, excluding any
17 portion of the rebates received by such health carriers, concerning
18 drug formularies that such manager collected from pharmaceutical
19 manufacturers that manufactured outpatient prescription drugs that:

20 (a) Were covered by such health carriers during such calendar
21 year; and

22 (b) Are attributable to patient utilization of such drugs by
23 covered persons under such health care plans during such calendar
24 year.

25 2. In consultation with pharmacy benefit managers, the
26 commission shall establish a standardized form for reporting the
27 information required under subsection 1 of this section. The form shall
28 be designed to minimize the administrative burden and cost of
29 reporting on the commission and on pharmacy benefit managers.

30 3. All documents, materials, or other information submitted to
31 the commission pursuant to subsection 1 of this section shall not be
32 subject to disclosure under chapter 610, except to the extent it is
33 included on an aggregated basis in the report required under
34 subsection 4 of this section. The commission shall not disclose
35 information submitted pursuant to subsection 1 of this section in a
36 manner that:

37 (1) Is likely to compromise the financial, competitive, or
38 proprietary nature of such information; or

39 (2) Would enable a third party to identify a health benefit plan,
40 health carrier, pharmacy benefits manager, or the value of a rebate
41 provided for a particular outpatient prescription drug or therapeutic
42 class of outpatient prescription drugs.

43 4. No later than July 1, 2022, and annually thereafter, the
44 commission shall submit a report to the standing committees of the
45 general assembly having jurisdiction over health insurance
46 matters. The report shall contain an aggregation of the information
47 submitted to the commission pursuant to subdivision (1) of subsection
48 1 of this section for the immediately preceding calendar year, and such
49 other information as the commission in its discretion deems relevant
50 for the purposes of this section. The commission shall provide each
51 pharmacy benefits manager and any third party affected by submission
52 of a report required by this subsection with a written notice describing
53 the content of the report.

54 5. The commission may impose a penalty of not more than seven
55 thousand five hundred dollars on a pharmacy benefits manager for
56 each violation of this section.

57 6. The commission may promulgate rules as necessary to
58 implement the provisions of this section. Any rule or portion of a rule,
59 as that term is defined in section 536.010 that is created under the
60 authority delegated in this section shall become effective only if it
61 complies with and is subject to all of the provisions of chapter 536, and,
62 if applicable, section 536.028. This section and chapter 536 are
63 nonseverable and if any of the powers vested with the general assembly
64 pursuant to chapter 536, to review, to delay the effective date, or to
65 disapprove and annul a rule are subsequently held unconstitutional,
66 then the grant of rulemaking authority and any rule proposed or
67 adopted after August 28, 2019, shall be invalid and void.

 376.2064. 1. Any health carrier that delivers, issues for delivery,
2 renews, amends, or continues a health benefit plan on or after January
3 1, 2022, shall submit the following information and data to the
4 commission, for such health benefit plan for the immediately preceding
5 calendar year, at the time that the health carrier submits a rate filing
6 for such health benefit plan pursuant to section 376.465 or 379.321:

7 (1) For covered outpatient prescription drugs that were
8 prescribed to enrollees under such health benefit plan during such
9 calendar year, the names of:

10 (a) The twenty-five most frequently prescribed outpatient
11 prescription drugs;

12 (b) The twenty-five outpatient prescription drugs that the health

13 benefit plan covered at the greatest cost, calculated by using the total
14 annual plan spending by such health benefit plan for each outpatient
15 prescription drug; and

16 (c) The twenty-five outpatient prescription drugs that
17 experienced the greatest year-over-year increase in cost, calculated by
18 using the total annual plan spending by such health benefit plan for
19 each outpatient prescription drug;

20 (2) The portion of the premium for such health benefit plan
21 which is attributable to each of the following categories of covered
22 outpatient prescription drugs that were prescribed to enrollees under
23 such health benefit plan during such calendar year:

24 (a) Brand name drugs;

25 (b) Generic drugs; and

26 (c) Specialty drugs.

27 (3) The year-over-year increase, calculated on a per member, per
28 month basis and expressed as a percentage, in the total annual cost of
29 each category of covered outpatient prescription drugs set forth in
30 subdivision (2) of this subsection;

31 (4) A comparison, calculated on a per enrollee, per month basis,
32 of the year-over-year increase in the cost of covered outpatient
33 prescription drugs to the year-over-year increase in the costs of other
34 contributors to the premium cost of such health benefit plan;

35 (5) The name of each specialty drug covered under such calendar
36 year;

37 (6) The names of the twenty-five most frequently prescribed
38 outpatient drugs for which the health carrier received rebates from
39 pharmaceutical manufacturers during such calendar year.

40 2. The commission may promulgate rules as necessary to
41 implement the provisions of this section. Any rule or portion of a rule,
42 as that term is defined in section 536.010 that is created under the
43 authority delegated in this section shall become effective only if it
44 complies with and is subject to all of the provisions of chapter 536, and,
45 if applicable, section 536.028. This section and chapter 536 are
46 nonseverable and if any of the powers vested with the general assembly
47 pursuant to chapter 536, to review, to delay the effective date, or to
48 disapprove and annul a rule are subsequently held unconstitutional,
49 then the grant of rulemaking authority and any rule proposed or

50 adopted after August 28, 2019, shall be invalid and void.

376.2066. No later than March 1, 2023, and annually thereafter,
2 each health carrier shall submit to the director, in a form and manner
3 prescribed by the director, a written certification for the immediately
4 preceding calendar year, certifying that the health carrier accounted
5 for all rebates in calculating the premium for health benefit plans that
6 such health carrier delivered, issued for delivery, renewed, amended,
7 or continued during such calendar year.

376.2068. No later than March 1, 2023, and annually thereafter,
2 the commission shall submit a report to the standing committees of the
3 general assembly having jurisdiction over health insurance
4 matters. The report shall contain:

5 (1) An aggregation of the information and data submitted to the
6 commission pursuant to section 376.2064 for the immediately preceding
7 calendar year;

8 (2) A description of the impact of the cost of outpatient
9 prescription drugs on health insurance premiums in this state; and

10 (3) Such other information as the commission, in its discretion,
11 deems relevant to the cost of outpatient prescription drugs in this
12 state.

376.2070. No later than March 1, 2022, and annually thereafter,
2 the commission shall prepare a report, for the immediately preceding
3 calendar year, describing the rebate practices of health carriers. The
4 report shall be published on the department's public web site and shall
5 contain:

6 (1) An explanation of the manner in which health carriers
7 accounted for rebates in calculating premiums for health benefit plans
8 delivered, issued for delivery, renewed, amended, or continued during
9 such year;

10 (2) A statement disclosing whether, and describing the manner
11 in which, health carriers made rebates available to enrollees at the
12 point of purchase during such year;

13 (3) Any other manner in which health carriers applied rebates
14 during such year; and

15 (4) Such other information as the commission, in its discretion,
16 deems relevant for the purposes of this section.

376.2072. 1. As used in this section and section 376.2073, the

2 following terms shall mean:

3 (1) "Accelerated approval", the same meaning as ascribed to such
4 term in 21 U.S.C. Section 356, as amended;

5 (2) "Biologics license application", an application filed pursuant
6 to 21 CFR 601.2, as amended;

7 (3) "Breakthrough therapy", the same meaning as ascribed to
8 such term under 21 U.S.C. Section 356, as amended;

9 (4) "Commission", the drug cost review commission established
10 under section 376.2076;

11 (5) "Drug", the same meaning as such term is defined in section
12 376.1350;

13 (6) "Excess costs", costs of appropriate utilization of a
14 prescription drug product that are not sustainable for public or private
15 health care systems over a ten year time frame;

16 (7) "Fast track product", the same meaning as ascribed to such
17 term in 21 U.S.C. Section 356, as amended;

18 (8) "New drug application", the same meaning as ascribed to such
19 term in 21 CFR 314.3, as amended;

20 (9) "New molecular entity", the same meaning as ascribed to such
21 term in 21 U.S.C. Section 355-1, as amended;

22 (10) "Orphan drug", the same meaning as ascribed to such term
23 in 21 CFR 316.3, as amended;

24 (11) "Pipeline drug", a drug containing a new molecular entity for
25 which a sponsor has filed a new drug application or biologics license
26 application with, and received an action date from, the federal Food
27 and Drug Administration;

28 (12) "Prescription drug", a drug prescribed by a health care
29 provider to an individual in this state;

30 (13) "Priority review", the same meaning as ascribed to such term
31 in 21 U.S.C. Section 356, as amended;

32 (14) "Rebate", the same meaning as ascribed to such term in
33 section 376.2060;

34 (15) "Research and development cost", a cost that a
35 pharmaceutical manufacturer incurs in researching and developing a
36 new product, process, or service, including but not limited to a cost
37 that a pharmaceutical manufacturer incurs in researching and
38 developing a product, process, or service that the pharmaceutical

39 manufacturer has acquired from another person by license;

40 (16) "Sponsor", the same meaning as ascribed to such term in 21
41 CFR 316.3, as amended;

42 (17) "Wholesale acquisition cost", the same meaning as ascribed
43 to such term in 42 U.S.C. Section 1395w-3a, as amended.

44 2. Beginning January 1, 2021, each sponsor shall submit to the
45 commission, in a form and manner prescribed by the commission,
46 written notice that such sponsor has filed with the federal Food and
47 Drug Administration:

48 (1) A new drug application or biologics license application for a
49 pipeline drug, not later than sixty days after such sponsor receives an
50 action date from the federal Food and Drug Administration regarding
51 such application; or

52 (2) A biologics license application for a biosimilar drug, not later
53 than sixty days after such sponsor's receipt of an action date from the
54 federal Food and Drug Administration regarding such application.

55 3. (1) Beginning January 1, 2021, and not more than annually
56 thereafter, the commission may, in consultation with the commissioner
57 of administration, conduct a study of each pharmaceutical
58 manufacturer of a pipeline drug that, in the opinion of the commission
59 in consultation with the commissioner of administration and the
60 director of the department of social services, may have significant
61 impact on state expenditures for outpatient prescription drugs. The
62 commission may work with the commissioner of administration to
63 utilize existing state resources and contracts, or contract with a third
64 party, including but not limited to an accounting firm, to conduct such
65 study.

66 (2) Each pharmaceutical manufacturer that is the subject of a
67 study conducted as specified under subdivision (1) of this subsection
68 shall submit to the commission, or to any contractor engaged by the
69 commission or the commissioner of administration to perform such
70 study, the following information for the pipeline drug that is the
71 subject of such study:

72 (a) The primary disease, condition, or therapeutic area studied
73 in connection with such drug, and whether such drug is therapeutically
74 indicated for such disease, condition, or therapeutic area;

75 (b) Each route of administration studied for such drug;

- 76 (c) Clinical trial comparators, if applicable, for such drug;
- 77 (d) The estimated year of market entry for such drug;
- 78 (e) Whether the federal Food and Drug Administration has
- 79 designated the drug as an orphan drug, a fast track product, or a
- 80 breakthrough therapy; and
- 81 (f) Whether the federal Food and Drug Administration has
- 82 designated the drug for accelerated approval and, if the drug contains
- 83 a new molecular entity, for priority review.
- 84 4. (1) No later than March 1, 2021, and annually thereafter, the
- 85 commission, in consultation with the commissioner of administration,
- 86 the director of the department of social services, and the director of the
- 87 department of health and senior services, shall prepare a list of not
- 88 more than ten outpatient prescription drugs that the commission, in its
- 89 discretion, determines are provided at substantial cost to the state,
- 90 considering the net cost of such drugs, or are critical to public
- 91 health. The list shall include outpatient prescription drugs from
- 92 different therapeutic classes of outpatient prescription drugs and at
- 93 least one generic outpatient prescription drug.
- 94 (2) The commission shall not list any outpatient prescription
- 95 drug under subdivision (1) of this subsection unless the wholesale
- 96 acquisition cost of the drug, less all rebates paid to the state for such
- 97 drug during the immediately preceding calendar year:
- 98 (a) Increased by at least twenty per cent during the immediately
- 99 preceding calendar year, or by at least fifty per cent during the
- 100 immediately preceding three calendar years; and
- 101 (b) Was not less than sixty dollars for a thirty-day supply of the
- 102 drug or for a course of treatment of the drug lasting less than thirty
- 103 days.
- 104 (3) (a) The pharmaceutical manufacturer of an outpatient
- 105 prescription drug included on a list prepared by the commission
- 106 pursuant to subdivision (1) of this subsection shall provide to the
- 107 commission, in a form specified by the commission:
- 108 a. A written, narrative description, suitable for public release,
- 109 of all factors that caused the increase in the wholesale acquisition cost
- 110 of the listed outpatient prescription drug; and
- 111 b. Aggregate, company-level research and development costs and
- 112 such other capital expenditures that the commission, in its discretion,

113 deems relevant for the most recent year for which the final audited
114 data are available.

115 (b) The quality and types of information and data that a
116 pharmaceutical manufacturer submits to the commission under this
117 subdivision shall be consistent with the quality and types of
118 information and data that the pharmaceutical manufacturer includes
119 in its annual consolidated report on federal Securities and Exchange
120 Commission Form 10-K or any other public disclosure.

121 (4) The commission shall establish a standardized form for
122 reporting information and data pursuant to this subsection after
123 consulting with pharmaceutical manufacturers. The form shall be
124 designed to minimize the administrative burden and cost of reporting
125 on the commission and pharmaceutical manufacturers.

126 5. The commission may impose a penalty not to exceed seven
127 thousand five hundred dollars on a pharmaceutical manufacturer or
128 sponsor for each violation of this section by the pharmaceutical
129 manufacturer or sponsor.

130 6. The commission may promulgate rules as necessary to
131 implement the provisions of this section. Any rule or portion of a rule,
132 as that term is defined in section 536.010 that is created under the
133 authority delegated in this section shall become effective only if it
134 complies with and is subject to all of the provisions of chapter 536, and,
135 if applicable, section 536.028. This section and chapter 536 are
136 nonseverable and if any of the powers vested with the general assembly
137 pursuant to chapter 536, to review, to delay the effective date, or to
138 disapprove and annul a rule are subsequently held unconstitutional,
139 then the grant of rulemaking authority and any rule proposed or
140 adopted after August 28, 2019, shall be invalid and void.

376.2073. 1. (1) A manufacturer of a patent-protected brand-
2 name drug or biologic shall notify the commission:

3 (a) If the wholesale acquisition cost of the drug is increasing by
4 more than ten percent or by more than ten thousand dollars during any
5 twelve-month period; or

6 (b) If the manufacturer intends to introduce to market a brand-
7 name drug that has a wholesale acquisition cost of thirty thousand
8 dollars per calendar year or per course of treatment.

9 (2) The notice provided by manufacturers pursuant to

10 subdivision (1) of this subsection shall:

11 (a) Be provided in writing at least thirty days before the planned
12 effective date of the increase or the introduction of the drug to market;
13 and

14 (b) Include a justification for the proposed pricing which
15 includes any documents and research related to the manufacturer's
16 selection of the introductory price or price increase, including life
17 cycle management, net average price to the state, market competition
18 and context, projected revenue, and the estimated value or cost
19 effectiveness of the product, if available.

20 2. The commission, in consultation with stakeholders and
21 experts, shall establish a threshold for manufacturer reporting of brand
22 prescription drugs, including biologics and biosimilars. The reporting
23 threshold shall apply to brand name prescription drugs that are not
24 reported under subsection 1 of this section but that impose costs on the
25 state health care system that create significant challenges to
26 affordability.

27 3. (1) A manufacturer of a generic or off-patent sole source
28 branded product drug shall notify the commission if the manufacturer
29 is increasing the wholesale acquisition cost of the drug by more than
30 twenty-five percent or by more than three hundred dollars during any
31 twelve-month period.

32 (2) The notice provided pursuant to subdivision (1) of this
33 subsection shall:

34 (a) Be provided in writing at least thirty days before the planned
35 effective date of the increase or the introduction of the drug to market;
36 and

37 (b) Include a justification for the proposed pricing which
38 includes any documents and research related to the manufacturer's
39 selection of the price increase, including life cycle management, net
40 average price to the state, market competition and context, projected
41 revenue, and the estimated value or cost effectiveness of the product,
42 if available.

43 4. The commission, in consultation with stakeholders and
44 experts, shall establish a threshold for manufacturer reporting of
45 generic and off-patent sole source branded prescription drugs. The
46 reporting threshold established by the commission pursuant to this

47 subsection shall apply to generic and off-patent sole source branded
48 prescription drugs that are not reported under subsection 1 of this
49 section but that impose costs on the state health care system that
50 create significant challenges to affordability.

51 5. Where possible, the commission shall access manufacturer
52 justification information made public by other states. If manufacturer
53 justification information is not available from other state sources, the
54 commission shall require manufacturers to submit to the commission
55 any documents and research related to the manufacturer's selection of
56 the introductory price or price increase, including life cycle
57 management, net average price in the state, market competition and
58 context, projected revenue, and the estimated value or cost
59 effectiveness of the product, if available.

60 6. (1) The commission shall inform the public about the reports
61 provided under this section and section 376.2072.

62 (2) The commission shall allow the public to request commission
63 review of the cost of any prescription drug reported under this section
64 or section 376.2072.

65 (3) (a) The chairman of the commission shall review any request
66 made under subdivision (2) of this subsection to determine whether to
67 review the cost of the prescription drug.

68 (b) The chairman of the commission may initiate a review of the
69 cost of a prescription drug reported under this section in the absence
70 of a request made under subdivision (2) of this subsection.

71 (c) Notwithstanding the other provisions of this subdivision, any
72 member of the commission may request a vote on whether or not to
73 review a prescription drug.

74 7. (1) If the commission conducts a review of the cost of a
75 prescription drug, the review shall determine if a utilization of the
76 drug which is fully consistent with the federal Food and Drug
77 Administration label has led or will lead to excess costs for health care
78 systems in the state.

79 (2) In determining costs and excess costs, the commission shall
80 consider:

81 (a) The price at which the prescription drug has been or will be
82 sold in the state;

83 (b) The average monetary price concession, discount, or rebate

84 the manufacturer provides to health carriers in the state or is expected
85 to provide to health carriers in the state as reported by manufacturers
86 and health carriers, expressed as a percent of the wholesale acquisition
87 cost;

88 (c) The total amount of the concession, discount, or rebate the
89 manufacturer provides to each pharmacy benefit manager operating in
90 the state for the prescription drug under review, expressed as a
91 percent of the wholesale acquisition cost;

92 (d) The price at which therapeutic alternatives have been or will
93 be sold in the state;

94 (e) The average monetary price concession, discount, or rebate
95 the manufacturer provides to health carriers in the state or is expected
96 to provide to health carriers in the state for therapeutic alternatives;

97 (f) The cost to health carriers based on patient access consistent
98 with federal Food and Drug Administration labeled indications;

99 (g) The impact on patient access resulting from the cost of the
100 product relative to insurance benefit design;

101 (h) The current or expected dollar value of drug-specific patient
102 access programs that are supported by manufacturers;

103 (i) The relative financial impacts to health, medical, or other
104 social services costs as can be quantified and compared to baseline
105 effects of existing therapeutic alternatives; and

106 (j) Any other factor deemed relevant by the commission and
107 established by rule.

108 (3) If the commission is unable to determine whether a
109 prescription drug product will produce or has produced excess costs
110 using the factors listed in subdivision (2) of this subsection, the
111 commission shall consider the following factors:

112 (a) Manufacturer research and development costs, as indicated
113 on the manufacturer's federal tax filing for the most recent tax year in
114 proportion to the manufacturer's sales in the state;

115 (b) The portion of direct-to-consumer marketing costs eligible for
116 favorable federal tax treatment in the most recent tax year which are
117 specific to the prescription drug product under review and that are
118 multiplied by the ratio of total manufacturer in-state sales to total
119 manufacturer sales in the United States for the product under review;

120 (c) Gross and net manufacturer revenues for the most recent tax

121 year;

122 (d) Any additional factors proposed by the manufacturer which
123 the commission deems relevant; and

124 (e) Any additional factors deemed relevant by the commission
125 and established by rule.

126 8. (1) If the commission finds that the spending on a
127 prescription drug product reviewed under this section creates excess
128 costs for health carriers or consumers, the commission shall establish
129 the level of reimbursement that shall be billed and paid among:

130 (a) Health carriers and pharmacies or administering providers;

131 (b) Wholesalers and distributors and pharmacies or
132 administering providers; and

133 (c) Pharmacies or administering providers and uninsured
134 consumers or enrollees in a deductible period.

135 (2) The commission shall determine how each participant in the
136 supply chain of the prescription drug shall be remunerated.

137 9. (1) Subject to subdivision (2) of this subsection, any
138 submission made to the commission related to a drug cost review shall
139 be made available to the public, with the exception of information
140 determined by the commission to be proprietary.

141 (2) The commission, after public notice and comment, shall
142 establish standards for the information to be considered proprietary
143 under subdivision (1) of this subsection, including standards for
144 heightened consideration of proprietary information for submissions
145 for a cost review of a drug that is not yet approved by the federal Food
146 and Drug Administration.

147 10. (1) Subject to subdivision (3) of this subsection, the
148 commission shall be funded by an assessment on each manufacturer
149 required to provide notice to the commission under subsections 1 or 3
150 of this section.

151 (2) The commission shall determine by rule the amount of the
152 assessment required under subdivision (1) of this subsection.

153 (3) The commission shall be established using funds
154 appropriated from general revenue, which shall be repaid to the state
155 with the assessments required under subdivision (2) of this subsection.

156 11. No later than August 28, 2020, and annually thereafter, the
157 commission shall publish on the department's public web site a report

158 **on:**

159 **(1) Prescription drug price trends;**

160 **(2) The number of manufacturers required to notify the**
161 **commission about drug pricing under subsections 1 or 3 of this section;**

162 **and**

163 **(3) The number of products that were subject to commission**
164 **review, including the results of the review and the number and**
165 **disposition of appeals and administrative or judicial reviews of**
166 **commission decisions.**

Unofficial ✓

Bill

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