

FIRST REGULAR SESSION

HOUSE BILL NO. 1186

100TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE CLEMENS.

2306H.011

DANA RADEMAN MILLER, Chief Clerk

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;

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

16 (8) "Health carrier", the same meaning as ascribed to such term in section
17 376.1350;

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

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

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

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

25 (13) "Practice of pharmacy", the same meaning as ascribed to such term in section
26 338.010;

27 (14) "Public meeting", the same meaning as ascribed to such term in section
28 610.010;

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

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

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

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

37

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

40 (17) "Specialty drug", a prescription outpatient specialty drug covered under the
41 Medicare Part D program established under Pub. L. 108-173, the Medicare Prescription
42 Drug, Improvement, and Modernization Act of 2003, as amended, that exceeds the
43 specialty tier cost threshold established by the Centers for Medicare and Medicaid
44 Services.

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

6 2. (1) The commission shall consist of the following members:

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

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

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

11 (d) The speaker of the house of representatives or his or her designee; and

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

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

17 (3) Any potential conflict of interest, including whether the individual has an
18 association, including a financial or personal association, that has the potential to bias or
19 has the appearance of biasing an individual's decisions in matters related to the
20 commission or the conduct of the commission's activities, shall be considered and disclosed
21 when appointing members to the commission.

22 3. (1) No person shall receive compensation as a member of the commission, but
23 members shall receive reimbursement for the actual and necessary expenses incurred in
24 attending meetings of the commission or any subcommittee thereof.

25 (2) The chair of the commission shall be elected by the members of the commission.

26 (3) The chair shall hire an executive director, general counsel, and staff for the
27 commission, who shall receive compensation as provided in the budget of the commission.

28 4. (1) (a) Except as provided in this subdivision, the commission shall hold a public
29 meeting at least every six weeks to review prescription drug product information
30 submissions.

31 (b) The chair may cancel or postpone a meeting if there are no prescription drug
32 product submissions to review.

33 (c) The commission may additionally hold closed meetings as specified under
34 chapter 610, but decisions of the commission shall be made by public vote.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 (b) Are attributable to patient utilization of such drugs during such calendar year;

12 and

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

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

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

19 **2. In consultation with pharmacy benefit managers, the commission shall establish**
20 **a standardized form for reporting the information required under subsection 1 of this**
21 **section. The form shall be designed to minimize the administrative burden and cost of**
22 **reporting on the commission and on pharmacy benefit managers.**

23 **3. All documents, materials, or other information submitted to the commission**
24 **under subsection 1 of this section shall not be subject to disclosure under chapter 610,**
25 **except to the extent it is included on an aggregated basis in the report required under**
26 **subsection 4 of this section. The commission shall not disclose information submitted**
27 **under subsection 1 of this section in a manner that:**

28 **(1) Is likely to compromise the financial, competitive, or proprietary nature of such**
29 **information; or**

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

33 **4. No later than July 1, 2022, and annually thereafter, the commission shall submit**
34 **a report to the standing committees of the general assembly having jurisdiction over health**
35 **insurance matters. The report shall contain an aggregation of the information submitted**
36 **to the commission under subdivision (1) of subsection 1 of this section for the immediately**
37 **preceding calendar year, and such other information as the commission in its discretion**
38 **deems relevant for the purposes of this section. The commission shall provide each**
39 **pharmacy benefits manager and any third party affected by submission of a report**
40 **required by this subsection with a written notice describing the content of the report.**

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

43 **6. The commission may promulgate rules as necessary to implement the provisions**
44 **of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that**
45 **is created under the authority delegated in this section shall become effective only if it**
46 **complies with and is subject to all of the provisions of chapter 536 and, if applicable,**
47 **section 536.028. This section and chapter 536 are nonseverable, and if any of the powers**
48 **vested with the general assembly pursuant to chapter 536 to review, to delay the effective**
49 **date, or to disapprove and annul a rule are subsequently held unconstitutional, then the**
50 **grant of rulemaking authority and any rule proposed or adopted after August 28, 2019,**
51 **shall be invalid and void.**

376.2064. 1. Any health carrier that delivers, issues for delivery, renews, amends,
2 **or continues a health benefit plan on or after January 1, 2022, shall submit the following**
3 **information and data to the commission, for such health benefit plan for the immediately**

preceding calendar year, at the time that the health carrier submits a rate filing for such health benefit plan under section 376.465 or 379.321:

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

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

(b) The twenty-five outpatient prescription drugs that the health benefit plan covered at the greatest cost, calculated by using the total annual plan spending by such health benefit plan for each outpatient prescription drug; and

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

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

(a) Brand name drugs;

(b) Generic drugs; and

(c) Specialty drugs;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

376.2072. 1. As used in this section and section 376.2073, the following terms shall mean:

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

(2) "Biologics license application", an application filed under 21 CFR 601.2, as amended;

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

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

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

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

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

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

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

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

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

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

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

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

31 (15) "Research and development cost", a cost that a pharmaceutical manufacturer
32 incurs in researching and developing a new product, process, or service including, but not
33 limited to, a cost that a pharmaceutical manufacturer incurs in researching and developing
34 a product, process, or service that the pharmaceutical manufacturer has acquired from
35 another person by license;

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

38 (17) "Wholesale acquisition cost", the same meaning as ascribed to such term in
39 42 U.S.C. Section 1395w-3a, as amended.

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

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

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

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

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

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

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

(c) Clinical trial comparators, if applicable, for such drug;

(d) The estimated year of market entry for such drug;

(e) Whether the federal Food and Drug Administration has designated the drug as an orphan drug, a fast track product, or a breakthrough therapy; and

(f) Whether the federal Food and Drug Administration has designated the drug for accelerated approval and, if the drug contains a new molecular entity, for priority review.

4. (1) No later than March 1, 2021, and annually thereafter, the commission, in consultation with the commissioner of administration, the director of the department of social services, and the director of the department of health and senior services, shall prepare a list of not more than ten outpatient prescription drugs that the commission, in its discretion, determines are provided at substantial cost to the state, considering the net cost of such drugs, or are critical to public health. The list shall include outpatient

78 prescription drugs from different therapeutic classes of outpatient prescription drugs and
79 at least one generic outpatient prescription drug.

80 (2) The commission shall not list any outpatient prescription drug under
81 subdivision (1) of this subsection unless the wholesale acquisition cost of the drug, less all
82 rebates paid to the state for such drug during the immediately preceding calendar year:

83 (a) Increased by at least twenty percent during the immediately preceding calendar
84 year, or by at least fifty percent during the immediately preceding three calendar years;
85 and

86 (b) Was not less than sixty dollars for a thirty-day supply of the drug or for a
87 course of treatment of the drug lasting less than thirty days.

88 (3) (a) The pharmaceutical manufacturer of an outpatient prescription drug
89 included on a list prepared by the commission pursuant to subdivision (1) of this subsection
90 shall provide to the commission, in a form specified by the commission:

91 a. A written, narrative description, suitable for public release, of all factors that
92 caused the increase in the wholesale acquisition cost of the listed outpatient prescription
93 drug; and

94 b. Aggregate, company-level research and development costs and such other capital
95 expenditures that the commission, in its discretion, deems relevant for the most recent year
96 for which the final audited data is available.

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

102 (4) The commission shall establish a standardized form for reporting information
103 and data pursuant to this subsection after consulting with pharmaceutical manufacturers.
104 The form shall be designed to minimize the administrative burden and cost of reporting
105 on the commission and pharmaceutical manufacturers.

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

109 6. The commission may promulgate rules as necessary to implement the provisions
110 of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that
111 is created under the authority delegated in this section shall become effective only if it
112 complies with and is subject to all of the provisions of chapter 536 and, if applicable,
113 section 536.028. This section and chapter 536 are nonseverable, and if any of the powers

114 vested with the general assembly pursuant to chapter 536 to review, to delay the effective
115 date, or to disapprove and annul a rule are subsequently held unconstitutional, then the
116 grant of rulemaking authority and any rule proposed or adopted after August 28, 2019,
117 shall be invalid and void.

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

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

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

8 (2) The notice provided by manufacturers pursuant to subdivision (1) of this
9 subsection shall:

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

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

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

22 3. (1) A manufacturer of a generic or off-patent sole source branded product drug
23 shall notify the commission if the manufacturer is increasing the wholesale acquisition cost
24 of the drug by more than twenty-five percent or by more than three hundred dollars
25 during any twelve-month period.

26 (2) The notice provided under subdivision (1) of this subsection shall:

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

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

33 4. The commission, in consultation with stakeholders and experts, shall establish
34 a threshold for manufacturer reporting of generic and off-patent sole source branded
35 prescription drugs. The reporting threshold established by the commission pursuant to
36 this subsection shall apply to generic and off-patent sole source branded prescription drugs
37 that are not reported under subsection 1 of this section but that impose costs on the state
38 health care system that create significant challenges to affordability.

39 5. If possible, the commission shall access manufacturer justification information
40 made public by other states. If manufacturer justification information is not available
41 from other state sources, the commission shall require manufacturers to submit to the
42 commission any documents and research related to the manufacturer's selection of the
43 introductory price or price increase, including life cycle management, net average price in
44 the state, market competition and context, projected revenue, and the estimated value or
45 cost effectiveness of the product, if available.

46 6. (1) The commission shall inform the public about the reports provided under
47 this section and section 376.2072.

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

50 (3) (a) The chair of the commission shall review any request made under
51 subdivision (2) of this subsection to determine whether to review the cost of the
52 prescription drug.

53 (b) The chair of the commission may initiate a review of the cost of a prescription
54 drug reported under this section in the absence of a request made under subdivision (2) of
55 this subsection.

56 (c) Notwithstanding the other provisions of this subdivision, any member of the
57 commission may request a vote on whether to review a prescription drug.

58 7. (1) If the commission conducts a review of the cost of a prescription drug, the
59 review shall determine if a utilization of the drug which is fully consistent with the federal
60 Food and Drug Administration label has led or will lead to excess costs for health care
61 systems in the state.

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

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

64 (b) The average monetary price concession, discount, or rebate the manufacturer
65 provides to health carriers in the state or is expected to provide to health carriers in the
66 state as reported by manufacturers and health carriers, expressed as a percent of the
67 wholesale acquisition cost;

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

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

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

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

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

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

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

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

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

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

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

96 (c) Gross and net manufacturer revenues for the most recent tax year;

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

99 (e) Any additional factors deemed relevant by the commission and established by
100 rule.

101 8. (1) If the commission finds that the spending on a prescription drug product
102 reviewed under this section creates excess costs for health carriers or consumers, the
103 commission shall establish the level of reimbursement that shall be billed and paid among:

104 (a) Health carriers and pharmacies or administering providers;
105 (b) Wholesalers, distributors, and pharmacies or administering providers; and
106 (c) Pharmacies or administering providers and uninsured consumers or enrollees
107 in a deductible period.

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

110 9. (1) Subject to subdivision (2) of this subsection, any submission made to the
111 commission related to a drug cost review shall be made available to the public, with the
112 exception of information determined by the commission to be proprietary.

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

118 10. (1) Subject to subdivision (3) of this subsection, the commission shall be funded
119 by an assessment on each manufacturer required to provide notice to the commission
120 under subsection 1 or 3 of this section.

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

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

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

128 (1) Prescription drug price trends;

129 (2) The number of manufacturers required to notify the commission about drug
130 pricing under subsection 1 or 3 of this section; and

131 (3) The number of products that were subject to commission review, including the
132 results of the review and the number and disposition of appeals and administrative or
133 judicial reviews of commission decisions.

✓