B-Engrossed House Bill 4005

Ordered by the House February 26 Including House Amendments dated February 13 and February 26

Sponsored by Representatives NOSSE, NOBLE, Senators BEYER, LINTHICUM; Representatives ALONSO LEON, BARNHART, FAHEY, HOLVEY, KENY-GUYER, KOTEK, LIVELY, SALINAS, SMITH DB, Senators BOQUIST, MONNES ANDERSON (Presession filed.)

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the

Requires prescription drug manufacturer to report annually information to Department of Conrequires prescription drug manufacturer to report annually information to Department of Consumer and Business Services regarding prices of prescription drugs and costs associated with developing and marketing prescription drugs. Authorizes department to impose civil penalties on manufacturer for failing to comply with reporting requirements.

Requires health insurers that offer prescription drug benefit to report to department specified information about prescription drug prices and impact of prescription drug prices on premium rates.

Authorizes department to adopt by rule fees on manufacturers.

Requires department to conduct annual public hearing on prescription drug prices and related information reported by manufacturers.

Establishes Task Force on the Fair Pricing of Prescription Drugs. Specifies membership and duties. Requires task force to submit report to Legislative Assembly by November 1, 2018

Declares emergency, effective on passage.

A BILL FOR AN ACT

Relating to the price of prescription drugs; creating new provisions; amending ORS 743.018 and 750.055; and declaring an emergency.

Whereas the state has a substantial public interest in the price and cost of prescription drugs; and

Whereas the state is a major purchaser of prescription drugs through the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services and the Department of Corrections; and

Whereas the state also provides major tax expenditures for health care through the tax exclusion of employer-sponsored health insurance coverage and the deductibility of the excess medical costs of individuals and families; and

Whereas the Legislative Assembly intends by sections 2, 3 and 5 of this 2018 Act to provide notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability for prescription drug pricing; and

Whereas the Legislative Assembly intends by this 2018 Act to permit a manufacturer of a prescription drug to voluntarily make pricing decisions regarding a prescription drug, including decisions that result in price increases; and

Whereas the Legislative Assembly intends by this 2018 Act to permit purchasers, both public and private, as well as pharmacy benefit managers, to negotiate discounts and rebates for prescription drugs consistent with existing state and federal law; now, therefore,

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1 Be It Enacted by the People of the State of Oregon:

<u>SECTION 1.</u> Sections 2 and 3 of this 2018 Act shall be known and may be cited as the Prescription Drug Price Transparency Act.

- **SECTION 2.** (1) As used in this section:
- (a) "Drug" has the meaning given that term in ORS 689.005.
- (b) "Health care facility" has the meaning given that term in ORS 442.015.
- (c) "Health care service contractor" has the meaning given that term in ORS 750.005.
- (d)(A) "Manufacture" means:

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- (i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and
 - (ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.
- (B) "Manufacture" does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug:
- (i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;
- (ii) By a health care practitioner or at the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;
- (iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;
- (iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated with a health care service contractor; or
 - (v) By a health care facility for dispensing to a patient or other person.
- (e) "Manufacturer" means a person that manufactures a prescription drug that is sold in this state.
- (f) "New prescription drug" has the meaning prescribed by the Department of Consumer and Business Services by rule.
- (g) "Patient assistance program" means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.
 - (h) "Prescription drug" means a drug that must:
- (A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without prescription" prior to being dispensed or delivered; or
- (B) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.
 - (i) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).
- (2) No later than July 1, 2019, a manufacturer shall report the information described in subsection (3) of this section to the department regarding each prescription drug for which:
 - (a) The price was \$100 or more for a one-month supply or for a course of treatment

lasting less than one month; and

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- (b) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this subsection over the course of the previous calendar year.
- (3) For each prescription drug described in subsection (2) of this section, a manufacturer shall report to the department, in the form and manner prescribed by the department:
- (a) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;
 - (b) The length of time the prescription drug has been on the market;
 - (c) The factors that contributed to the price increase;
 - (d) The name of any generic version of the prescription drug available on the market;
- (e) The research and development costs associated with the prescription drug that were paid using public funds;
 - (f) The direct costs incurred by the manufacturer:
 - (A) To manufacture the prescription drug;
 - (B) To market the prescription drug;
 - (C) To distribute the prescription drug; and
 - (D) For ongoing safety and effectiveness research associated with the prescription drug;
 - (g) The total sales revenue for the prescription drug during the previous calendar year;
 - (h) The manufacturer's profit attributable to the prescription drug during the previous calendar year;
 - (i) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;
 - (j) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;
 - (k) Any other information that the manufacturer deems relevant to the price increase described in subsection (2)(b) of this section; and
 - (L) The documentation necessary to support the information reported under this subsection.
 - (4) The department may use any prescription drug price information the department deems appropriate to verify that manufacturers have properly reported price increases as required by subsections (2) and (3) of this section.
 - (5) A manufacturer shall accompany the report provided under subsection (2) of this section with the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs described in subsection (2) of this section:
 - (a) The number of consumers who participated in the program;
 - (b) The total value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program;
 - (c) For each drug, the number of refills that qualify for the program, if applicable;
 - (d) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and
 - (e) The eligibility criteria for the program and how eligibility is verified for accuracy.
 - (6) Beginning March 15, 2019, 30 days or less after a manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold estab-

- lished by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare
 Part D program, the manufacturer shall notify the department, in the form and manner
 prescribed by the department, of all the following information:
 - (a) A description of the marketing used in the introduction of the new prescription drug;
 - (b) The methodology used to establish the price of the new prescription drug;

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- (c) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;
- (d) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;
- (e) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and
- (f) The research and development costs associated with the new prescription drug that were paid using public funds.
- (7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this section, the department may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the periods:
- (A) Following the receipt of the report or information during which the department may request additional information; and
- (B) Following a request by the department for additional information during which a manufacturer may respond to the request.
- (b) The department may extend the period prescribed under paragraph (a)(B) of this subsection, as necessary, on a case-by-case basis.
- (8) A manufacturer may be subject to a civil penalty, as provided in section 3 of this 2018 Act, for:
 - (a) Failing to submit timely reports or notices as required by this section;
 - (b) Failing to provide information required under this section;
- (c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of this section; or
 - (d) Providing inaccurate or incomplete information under this section.
- (9) Except as provided in subsection (10) of this section, the department shall post to its website all of the following information:
- (a) A list of the prescription drugs reported under subsection (2) of this section and the manufacturers of those prescription drugs;
- (b) Information reported to the department under subsections (3) and (5) to (7) of this section; and
- (c) Written requests by the department for additional information under subsection (7) of this section.
- 39 (10)(a) The department may not post to its website any information described in sub-40 section (9) of this section if:
 - (A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret; and
 - (B) The public interest does not require disclosure of the information.
 - (b) If the department withholds any information from public disclosure pursuant to this subsection, the department shall post to its website a report describing the nature of the

1 information and the department's basis for withholding the information from disclosure.

- (c) A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to withhold information pursuant to paragraph (a) of this subsection.
- (11) The department shall make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.
- (12) The department may adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the department in carrying out the provisions of this section.
- (13) No later than December 15 of each year, the department shall compile and report the information collected by the department under this section to the interim committees of the Legislative Assembly related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on consumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services, the Oregon Educators Benefit Board and health insurance premiums in the commercial market.
- SECTION 3. (1) A manufacturer that fails to report or provide information as required by section 2 of this 2018 Act may be subject to a civil penalty as provided in this section.
- (2) The Department of Consumer and Business Services shall adopt a schedule of penalties, not to exceed \$10,000 per day of violation, based on the severity of each violation.
- (3) The department shall impose civil penalties under this section as provided in ORS 183.745.
- (4) The department may remit or mitigate civil penalties under this section upon terms and conditions the department considers proper and consistent with the public health and safety.
- (5) Civil penalties collected under this section shall be paid over to the State Treasurer and deposited in the General Fund to be made available for general governmental expenses.
- SECTION 4. Section 5 of this 2018 Act is added to and made a part of the Insurance Code. SECTION 5. (1) An insurer shall include with any filing under ORS 743.018 the following information regarding drugs reimbursed by the insurer under policies or certificates issued in this state:
 - (a) The 25 most frequently prescribed drugs;
 - (b) The 25 most costly drugs as a portion of total annual spending;
- 36 (c) The 25 drugs that have caused the greatest increase in total plan spending from one year to the next; and
 - (d) The impact of the costs of prescription drugs on premium rates.
 - (2) The Department of Consumer and Business Services shall conduct a public hearing annually on prescription drug prices, information reported to the department under section 2 of this 2018 Act and information described in subsection (1) of this section.
 - (3) The department shall regularly update the interim committees of the Legislative Assembly related to health on the information described in subsection (1) of this section.
 - (4) Subsection (1) of this section applies to an insurer that issues policies or certificates of health insurance for sale in this state that include a prescription drug benefit.

- SECTION 6. Section 2 of this 2018 Act is amended to read:
- 2 **Sec. 2.** (1) As used in this section:
- (a) "Drug" has the meaning given that term in ORS 689.005.
- (b) "Health care facility" has the meaning given that term in ORS 442.015.
 - (c) "Health care service contractor" has the meaning given that term in ORS 750.005.
 - (d)(A) "Manufacture" means:

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- (i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and
 - (ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.
- (B) "Manufacture" does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug:
- (i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;
- (ii) By a health care practitioner or at the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;
- (iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;
- (iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated with a health care service contractor; or
 - (v) By a health care facility for dispensing to a patient or other person.
- (e) "Manufacturer" means a person that manufactures a prescription drug that is sold in this state.
- (f) "New prescription drug" has the meaning prescribed by the Department of Consumer and Business Services by rule.
- (g) "Patient assistance program" means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.
 - (h) "Prescription drug" means a drug that must:
- (A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without prescription" prior to being dispensed or delivered; or
- (B) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.
 - (i) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).
- (2) No later than July 1, 2019, a manufacturer shall report the information described in subsection (3) of this section to the department regarding each prescription drug for which:
- (a) The price was \$100 or more for a one-month supply or for a course of treatment lasting less than one month; and
- (b) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this subsection over the course of the previous calendar year.
- (3) For each prescription drug described in subsection (2) of this section, a manufacturer shall report to the department, in the form and manner prescribed by the department:
 - (a) The name and price of the prescription drug and the net increase, expressed as a percentage,

- in the price of the drug over the course of the previous calendar year;
 - (b) The length of time the prescription drug has been on the market;
- 3 (c) The factors that contributed to the price increase;
 - (d) The name of any generic version of the prescription drug available on the market;
- 5 (e) The research and development costs associated with the prescription drug that were paid 6 using public funds;
 - (f) The direct costs incurred by the manufacturer:
 - (A) To manufacture the prescription drug;
 - (B) To market the prescription drug;

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- 10 (C) To distribute the prescription drug; and
 - (D) For ongoing safety and effectiveness research associated with the prescription drug;
 - (g) The total sales revenue for the prescription drug during the previous calendar year;
 - (h) The manufacturer's profit attributable to the prescription drug during the previous calendar year;
 - (i) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;
 - (j) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;
 - (k) Any other information that the manufacturer deems relevant to the price increase described in subsection (2)(b) of this section; and
 - (L) The documentation necessary to support the information reported under this subsection.
 - (4) The department may use any prescription drug price information the department deems appropriate to verify that manufacturers have properly reported price increases as required by subsections (2) and (3) of this section.
 - (5) A manufacturer shall accompany the report provided under subsection (2) of this section with the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs described in subsection (2) of this section:
 - (a) The number of consumers who participated in the program;
 - (b) The total value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program;
 - (c) For each drug, the number of refills that qualify for the program, if applicable;
 - (d) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and
 - (e) The eligibility criteria for the program and how eligibility is verified for accuracy.
 - (6) [Beginning March 15, 2019, 30 days or less] No later than 30 days after a manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify the department, in the form and manner prescribed by the department, of all the following information:
 - (a) A description of the marketing used in the introduction of the new prescription drug;
 - (b) The methodology used to establish the price of the new prescription drug;
 - (c) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;
 - (d) If the new prescription drug was not developed by the manufacturer, the date of and the

1 price paid for acquisition of the new prescription drug by the manufacturer;

- (e) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and
- (f) The research and development costs associated with the new prescription drug that were paid using public funds.
- (7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this section, the department may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the periods:
- (A) Following the receipt of the report or information during which the department may request additional information; and
- (B) Following a request by the department for additional information during which a manufacturer may respond to the request.
- (b) The department may extend the period prescribed under paragraph (a)(B) of this subsection, as necessary, on a case-by-case basis.
- (8) A manufacturer may be subject to a civil penalty, as provided in section 3 of this 2018 Act, for:
 - (a) Failing to submit timely reports or notices as required by this section;
 - (b) Failing to provide information required under this section;
 - (c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of this section; or
 - (d) Providing inaccurate or incomplete information under this section.
 - (9) Except as provided in subsection (10) of this section, the department shall post to its website all of the following information:
 - (a) A list of the prescription drugs reported under subsection (2) of this section and the manufacturers of those prescription drugs;
 - (b) Information reported to the department under subsections (3) and (5) to (7) of this section; and
 - (c) Written requests by the department for additional information under subsection (7) of this section.
 - (10)(a) The department may not post to its website any information described in subsection (9) of this section if:
- (A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret; and
 - (B) The public interest does not require disclosure of the information.
 - (b) If the department withholds any information from public disclosure pursuant to this subsection, the department shall post to its website a report describing the nature of the information and the department's basis for withholding the information from disclosure.
 - (c) A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to withhold information pursuant to paragraph (a) of this subsection.
 - (11) The department shall make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.
 - (12) The department may adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the department in carrying out the provisions of this section.

- (13) No later than December 15 of each year, the department shall compile and report the information collected by the department under this section to the interim committees of the Legislative Assembly related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on consumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services, the Oregon Educators Benefit Board and health insurance premiums in the commercial market.
- **SECTION 7.** Section 2 of this 2018 Act, as amended by section 6 of this 2018 Act, is amended 9 to read:
 - **Sec. 2.** (1) As used in this section:
 - (a) "Drug" has the meaning given that term in ORS 689.005.
 - (b) "Health care facility" has the meaning given that term in ORS 442.015.
 - (c) "Health care service contractor" has the meaning given that term in ORS 750.005.
 - (d)(A) "Manufacture" means:

- (i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and
 - (ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.
- (B) "Manufacture" does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug:
- (i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;
- (ii) By a health care practitioner or at the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;
- (iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;
- (iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated with a health care service contractor; or
 - (v) By a health care facility for dispensing to a patient or other person.
- (e) "Manufacturer" means a person that manufactures a prescription drug that is sold in this state.
- (f) "New prescription drug" has the meaning prescribed by the Department of Consumer and Business Services by rule.
- (g) "Patient assistance program" means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.
 - (h) "Prescription drug" means a drug that must:
- (A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without prescription" prior to being dispensed or delivered; or
- (B) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.
 - (i) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).
- (2) No later than [July 1, 2019] March 15 of each year, a manufacturer shall report the infor-

- mation described in subsection (3) of this section to the department regarding each prescription drug for which:
 - (a) The price was \$100 or more for a one-month supply or for a course of treatment lasting less than one month; and
 - (b) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this subsection over the course of the previous calendar year.
 - (3) For each prescription drug described in subsection (2) of this section, a manufacturer shall report to the department, in the form and manner prescribed by the department:
 - (a) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;
 - (b) The length of time the prescription drug has been on the market;
 - (c) The factors that contributed to the price increase;
 - (d) The name of any generic version of the prescription drug available on the market;
 - (e) The research and development costs associated with the prescription drug that were paid using public funds;
 - (f) The direct costs incurred by the manufacturer:
 - (A) To manufacture the prescription drug;
 - (B) To market the prescription drug;

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- 19 (C) To distribute the prescription drug; and
- 20 (D) For ongoing safety and effectiveness research associated with the prescription drug;
- 21 (g) The total sales revenue for the prescription drug during the previous calendar year;
- 22 (h) The manufacturer's profit attributable to the prescription drug during the previous calendar 23 year;
 - (i) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;
 - (j) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;
 - (k) Any other information that the manufacturer deems relevant to the price increase described in subsection (2)(b) of this section; and
 - (L) The documentation necessary to support the information reported under this subsection.
 - (4) The department may use any prescription drug price information the department deems appropriate to verify that manufacturers have properly reported price increases as required by subsections (2) and (3) of this section.
 - (5) A manufacturer shall accompany the report provided under subsection (2) of this section with the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs described in subsection (2) of this section:
 - (a) The number of consumers who participated in the program;
 - (b) The total value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program;
 - (c) For each drug, the number of refills that qualify for the program, if applicable;
 - (d) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and
 - (e) The eligibility criteria for the program and how eligibility is verified for accuracy.
 - (6) No later than 30 days after a manufacturer introduces a new prescription drug for sale in

- the United States at a price that exceeds the threshold established by the Centers for Medicare and 1
- Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify 2
- the department, in the form and manner prescribed by the department, of all the following informa-
 - (a) A description of the marketing used in the introduction of the new prescription drug;
 - (b) The methodology used to establish the price of the new prescription drug;

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- (c) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;
- (d) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;
- (e) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and
- (f) The research and development costs associated with the new prescription drug that were paid using public funds.
- (7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this section, the department may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the periods:
- (A) Following the receipt of the report or information during which the department may request additional information; and
- (B) Following a request by the department for additional information during which a manufacturer may respond to the request.
- (b) The department may extend the period prescribed under paragraph (a)(B) of this subsection, as necessary, on a case-by-case basis.
- (8) A manufacturer may be subject to a civil penalty, as provided in section 3 of this 2018 Act, 25 for: 26
 - (a) Failing to submit timely reports or notices as required by this section;
 - (b) Failing to provide information required under this section;
 - (c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of this section; or
 - (d) Providing inaccurate or incomplete information under this section.
 - (9) Except as provided in subsection (10) of this section, the department shall post to its website all of the following information:
 - (a) A list of the prescription drugs reported under subsection (2) of this section and the manufacturers of those prescription drugs;
- (b) Information reported to the department under subsections (3) and (5) to (7) of this section; 36 and
 - (c) Written requests by the department for additional information under subsection (7) of this section.
 - (10)(a) The department may not post to its website any information described in subsection (9) of this section if:
- (A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret; 42 and 43
 - (B) The public interest does not require disclosure of the information.
- (b) If the department withholds any information from public disclosure pursuant to this sub-45

- section, the department shall post to its website a report describing the nature of the information and the department's basis for withholding the information from disclosure.
- (c) A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to withhold information pursuant to paragraph (a) of this subsection.
- (11) The department shall make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.
- (12) The department may adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the department in carrying out the provisions of this section.
- (13) No later than December 15 of each year, the department shall compile and report the information collected by the department under this section to the interim committees of the Legislative Assembly related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on consumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services, the Oregon Educators Benefit Board and health insurance premiums in the commercial market.

SECTION 8. ORS 743.018 is amended to read:

- 743.018. (1) Except for group life and health insurance, and except as provided in ORS 743.015, every insurer shall file with the Director of the Department of Consumer and Business Services all schedules and tables of premium rates for life and health insurance to be used on risks in this state, and shall file any amendments to or corrections of such schedules and tables. Premium rates are subject to approval, disapproval or withdrawal of approval by the director as provided in ORS 742.003, 742.005, 742.007 and 743.019.
- (2) Except as provided in ORS 743B.013 and subsection (3) of this section, a rate filing by a carrier for any of the following health benefit plans subject to ORS 743.004, 743.022, 743.535 and 743B.003 to 743B.127 shall be available for public inspection immediately upon submission of the filing to the director:
 - (a) Health benefit plans for small employers.
 - (b) Individual health benefit plans.
 - (3) The director may by rule:
 - (a) Specify all information a carrier must submit as part of a rate filing under this section; and
- (b) Identify the information submitted that will be exempt from disclosure under this section because the information constitutes a trade secret and would, if disclosed, harm competition.
- (4) The director, after conducting an actuarial review of the rate filing, may approve a proposed premium rate for a health benefit plan for small employers or for an individual health benefit plan if, in the director's discretion, the proposed rates are:
 - (a) Actuarially sound;
 - (b) Reasonable and not excessive, inadequate or unfairly discriminatory; and
 - (c) Based upon reasonable administrative expenses.
- (5) In order to determine whether the proposed premium rates for a health benefit plan for small employers or for an individual health benefit plan are reasonable and not excessive, inadequate or unfairly discriminatory, the director may consider:
- (a) The insurer's financial position, including but not limited to profitability, surplus, reserves and investment savings.
 - (b) Historical and projected administrative costs and medical and hospital expenses, including

expenses for drugs reported under section 5 of this 2018 Act.

- (c) Historical and projected loss ratio between the amounts spent on medical services and earned premiums.
 - (d) Any anticipated change in the number of enrollees if the proposed premium rate is approved.
 - (e) Changes to covered benefits or health benefit plan design.
- (f) Changes in the insurer's health care cost containment and quality improvement efforts since the insurer's last rate filing for the same category of health benefit plan.
- (g) Whether the proposed change in the premium rate is necessary to maintain the insurer's solvency or to maintain rate stability and prevent excessive rate increases in the future.
- (h) Any public comments received under ORS 743.019 pertaining to the standards set forth in subsection (4) of this section and this subsection.
- (6) The requirements of this section do not supersede other provisions of law that require insurers, health care service contractors or multiple employer welfare arrangements providing health insurance to file schedules or tables of premium rates or proposed premium rates with the director or to seek the director's approval of rates or changes to rates.

SECTION 9. ORS 750.055 is amended to read:

750.055. (1) The following provisions apply to health care service contractors to the extent not inconsistent with the express provisions of ORS 750.005 to 750.095:

- (a) ORS 705.137, 705.138 and 705.139.
- 20 (b) ORS 731.004 to 731.150, 731.162, 731.216 to 731.362, 731.382, 731.385, 731.386, 731.390, 731.398 21 to 731.430, 731.428, 731.450, 731.454, 731.485, as provided in subsection (2) of this section, ORS 22 731.488, 731.504, 731.508, 731.509, 731.510, 731.511, 731.512, 731.574 to 731.620, 731.640 to 731.652, 23 731.730, 731.731, 731.735, 731.737, 731.750, 731.752, 731.804, 731.808 and 731.844 to 731.992.
- 24 (c) ORS 732.215, 732.220, 732.230, 732.245, 732.250, 732.320, 732.325 and 732.517 to 732.596, not including ORS 732.582.
- 26 (d) ORS 733.010 to 733.050, 733.080, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695 to 733.780.
 - (e) ORS 734.014 to 734.440.
 - (f) ORS 735.600 to 735.650.

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- 30 (g) ORS 742.001 to 742.009, 742.013, 742.016, 742.061, 742.065, 742.150 to 742.162 and 742.518 to 31 742.542.
- 32 (h) ORS 743.004, 743.005, 743.007, 743.008, 743.010, 743.018, 743.019, 743.020, 743.022, 743.023, 743.028, 743.029, 743.038, 743.040, 743.044, 743.050, 743.100 to 743.109, 743.402, 743.405, 743.406, 34 743.417, 743.472, 743.492, 743.495, 743.498, 743.522, 743.523, 743.524, 743.526, 743.535, 743.550, 743.650 to 743.656, 743.680 to 743.689, 743.788 and 743.790.
- 36 (i) ORS 743A.010, 743A.012, 743A.014, 743A.020, 743A.034, 743A.036, 743A.040, 743A.044, 743A.048, 743A.051, 743A.052, 743A.058, 743A.060, 743A.062, 743A.063, 743A.064, 743A.065, 743A.066, 743A.068, 743A.070, 743A.080, 743A.082, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.105, 743A.108, 743A.110, 743A.124, 743A.140, 743A.141, 743A.148, 743A.150, 743A.160, 743A.168, 743A.170, 743A.175, 743A.185, 743A.188, 743A.190, 743A.192, 743A.250, 743A.252 and 743A.260 and section 2, chapter 771, Oregon Laws 2013.
- 42 (j) ORS 743B.001, 743B.003 to 743B.127, 743B.128, 743B.130, 743B.195 to 743B.204, 743B.220, 743B.222, 743B.225, 743B.227, 743B.250, 743B.252, 743B.253, 743B.254, 743B.255, 743B.256, 743B.257, 743B.258, 743B.280 to 743B.285, 743B.287, 743B.300, 743B.310, 743B.320, 743B.323, 743B.330, 743B.340, 743B.341, 743B.342, 743B.343 to 743B.347, 743B.400, 743B.403, 743B.407, 743B.420, 743B.423, 743B.450,

- 1 743B.451, 743B.452, 743B.453, 743B.470, 743B.475, 743B.505, 743B.555, 743B.555, 743B.601, 743B.602 2 and 743B.800 and section 5 of this 2018 Act.
 - (k) The following provisions of ORS chapter 744:

- 4 (A) ORS 744.001 to 744.009, 744.011, 744.013, 744.014, 744.018, 744.022 to 744.033, 744.037, 744.052 to 744.089, 744.091 and 744.093, relating to the regulation of insurance producers;
 - (B) ORS 744.605, 744.609, 744.619, 744.621, 744.626, 744.631, 744.635, 744.650, 744.655 and 744.665, relating to the regulation of insurance consultants; and
 - (C) ORS 744.700 to 744.740, relating to the regulation of third party administrators.
 - (L) ORS 746.005 to 746.140, 746.160, 746.220 to 746.370, 746.600, 746.605, 746.607, 746.608, 746.610, 746.615, 746.625, 746.635, 746.650, 746.655, 746.660, 746.668, 746.670, 746.675, 746.680 and 746.690.
 - (2) The following provisions of the Insurance Code apply to health care service contractors except in the case of group practice health maintenance organizations that are federally qualified pursuant to Title XIII of the Public Health Service Act:
 - (a) ORS 731.485, if the group practice health maintenance organization wholly owns and operates an in-house drug outlet.
 - (b) ORS 743A.024, unless the patient is referred by a physician, physician assistant or nurse practitioner associated with a group practice health maintenance organization.
 - (3) For the purposes of this section, health care service contractors are insurers.
 - (4) Any for-profit health care service contractor organized under the laws of any other state that is not governed by the insurance laws of the other state is subject to all requirements of ORS chapter 732.
 - (5)(a) A health care service contractor is a domestic insurance company for the purpose of determining whether the health care service contractor is a debtor, as defined in 11 U.S.C. 109.
 - (b) A health care service contractor's classification as a domestic insurance company under paragraph (a) of this subsection does not subject the health care service contractor to ORS 734.510 to 734.710.
 - (6) The Director of the Department of Consumer and Business Services may, after notice and hearing, adopt reasonable rules not inconsistent with this section and ORS 750.003, 750.005, 750.025 and 750.045 that are necessary for the proper administration of these provisions.
 - SECTION 10. ORS 750.055, as amended by section 21, chapter 771, Oregon Laws 2013, section 7, chapter 25, Oregon Laws 2014, section 82, chapter 45, Oregon Laws 2014, section 9, chapter 59, Oregon Laws 2015, section 7, chapter 100, Oregon Laws 2015, section 7, chapter 224, Oregon Laws 2015, section 11, chapter 362, Oregon Laws 2015, section 10, chapter 470, Oregon Laws 2015, section 30, chapter 515, Oregon laws 2015, section 10, chapter 206, Oregon Laws 2017, section 6, chapter 417, Oregon Laws 2017, and section 22, chapter 479, Oregon Laws 2017, is amended to read:
 - 750.055. (1) The following provisions apply to health care service contractors to the extent not inconsistent with the express provisions of ORS 750.005 to 750.095:
 - (a) ORS 705.137, 705.138 and 705.139.
 - (b) ORS 731.004 to 731.150, 731.162, 731.216 to 731.362, 731.382, 731.385, 731.386, 731.390, 731.398 to 731.430, 731.428, 731.450, 731.454, 731.485, as provided in subsection (2) of this section, ORS 731.488, 731.504, 731.508, 731.509, 731.510, 731.511, 731.512, 731.574 to 731.620, 731.640 to 731.652, 731.730, 731.731, 731.735, 731.737, 731.750, 731.752, 731.804, 731.808 and 731.844 to 731.992.
- 43 (c) ORS 732.215, 732.220, 732.230, 732.245, 732.250, 732.320, 732.325 and 732.517 to 732.596, not 44 including ORS 732.582.
 - (d) ORS 733.010 to 733.050, 733.080, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695

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- (e) ORS 734.014 to 734.440.
- 3 (f) ORS 735.600 to 735.650.
- 4 (g) ORS 742.001 to 742.009, 742.013, 742.016, 742.061, 742.065, 742.150 to 742.162 and 742.518 to 742.542.
 - (h) ORS 743.004, 743.005, 743.007, 743.008, 743.010, 743.018, 743.019, 743.020, 743.022, 743.023, 743.028, 743.029, 743.038, 743.040, 743.044, 743.050, 743.100 to 743.109, 743.402, 743.405, 743.406, 743.417, 743.472, 743.492, 743.495, 743.498, 743.522, 743.523, 743.524, 743.526, 743.535, 743.550, 743.650 to 743.656, 743.680 to 743.689, 743.788 and 743.790.
- 10 (i) ORS 743A.010, 743A.012, 743A.014, 743A.020, 743A.034, 743A.036, 743A.040, 743A.044, 743A.048, 743A.051, 743A.052, 743A.058, 743A.060, 743A.062, 743A.063, 743A.064, 743A.065, 743A.066, 743A.068, 743A.070, 743A.080, 743A.082, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.105, 743A.108, 743A.110, 743A.124, 743A.141, 743A.148, 743A.150, 743A.160, 743A.168, 743A.170, 743A.175, 743A.185, 743A.188, 743A.190, 743A.192, 743A.250, 743A.252 and 743A.260.
- 15 (j) ORS 743B.001, 743B.003 to 743B.127, 743B.128, 743B.130, 743B.195 to 743B.204, 743B.220, 743B.222, 743B.225, 743B.227, 743B.250, 743B.252, 743B.253, 743B.254, 743B.255, 743B.256, 743B.257, 743B.258, 743B.280 to 743B.285, 743B.287, 743B.300, 743B.310, 743B.320, 743B.323, 743B.330, 743B.340, 743B.341, 743B.342, 743B.343 to 743B.347, 743B.400, 743B.403, 743B.407, 743B.420, 743B.423, 743B.450, 743B.451, 743B.452, 743B.453, 743B.470, 743B.475, 743B.505, 743B.555, 743B.555, 743B.601, 743B.602 and 743B.800 and section 5 of this 2018 Act.
 - (k) The following provisions of ORS chapter 744:
 - (A) ORS 744.001 to 744.009, 744.011, 744.013, 744.014, 744.018, 744.022 to 744.033, 744.037, 744.052 to 744.089, 744.091 and 744.093, relating to the regulation of insurance producers;
 - (B) ORS 744.605, 744.609, 744.619, 744.621, 744.626, 744.631, 744.635, 744.650, 744.655 and 744.665, relating to the regulation of insurance consultants; and
 - (C) ORS 744.700 to 744.740, relating to the regulation of third party administrators.
 - (L) ORS 746.005 to 746.140, 746.160, 746.220 to 746.370, 746.600, 746.605, 746.607, 746.608, 746.610, 746.615, 746.625, 746.635, 746.650, 746.655, 746.660, 746.668, 746.670, 746.675, 746.680 and 746.690.
 - (2) The following provisions of the Insurance Code apply to health care service contractors except in the case of group practice health maintenance organizations that are federally qualified pursuant to Title XIII of the Public Health Service Act:
 - (a) ORS 731.485, if the group practice health maintenance organization wholly owns and operates an in-house drug outlet.
 - (b) ORS 743A.024, unless the patient is referred by a physician, physician assistant or nurse practitioner associated with a group practice health maintenance organization.
 - (3) For the purposes of this section, health care service contractors are insurers.
 - (4) Any for-profit health care service contractor organized under the laws of any other state that is not governed by the insurance laws of the other state is subject to all requirements of ORS chapter 732.
 - (5)(a) A health care service contractor is a domestic insurance company for the purpose of determining whether the health care service contractor is a debtor, as defined in 11 U.S.C. 109.
 - (b) A health care service contractor's classification as a domestic insurance company under paragraph (a) of this subsection does not subject the health care service contractor to ORS 734.510 to 734.710.
 - (6) The Director of the Department of Consumer and Business Services may, after notice and

- hearing, adopt reasonable rules not inconsistent with this section and ORS 750.003, 750.005, 750.025 and 750.045 that are necessary for the proper administration of these provisions.
- 3 SECTION 11. (1) The Task Force on the Fair Pricing of Prescription Drugs is established.
- 4 (2) The task force consists of 18 members appointed as follows:
 - (a) The President of the Senate shall appoint:
 - (A) One member from the Senate who is a member of the majority party.
- (B) One member from the Senate who is a member of the minority party.
 - (b) The Speaker of the House of Representatives shall appoint:
- 9 (A) One member from the House of Representatives who is a member of the majority party.
- 11 (B) One member from the House of Representatives who is a member of the minority party.
 - (c) The Governor shall appoint the following members:
- 14 (A) One representative from the Department of Consumer and Business Services;
- 15 (B) One representative from the Oregon Health Authority;
- 16 (C) One representative from the Oregon Health Policy Board; and
- 17 **(D) Individuals representing:**
- 18 (i) Pharmaceutical manufacturers;
- 19 (ii) Insurance companies offering health insurance in this state;
- 20 (iii) Pharmacy benefit managers;
- 21 (iv) Prescription drug wholesalers;
- 22 (v) Consumers;

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- 23 (vi) Independent pharmacies;
- 24 (vii) Large retail pharmacy chains;
- 25 (viii) Hospitals:
- 26 (ix) Biopharmaceutical companies based in Oregon;
- 27 (x) Coordinated care organizations; and
- 28 (xi) Medical providers.
 - (3) The task force shall develop a strategy to create transparency for drug prices across the entire supply chain of pharmaceutical products, including but not limited to manufacturers, insurers, pharmacy benefit managers, distributors, wholesalers and retail pharmacies.
 - (4) A majority of the voting members of the task force constitutes a quorum for the transaction of business.
 - (5) Official action by the task force requires the approval of a majority of the voting members of the task force.
 - (6) The task force shall elect one of its members to serve as chairperson.
 - (7) If there is a vacancy for any cause, the appointing authority shall make an appointment to become immediately effective.
 - (8) The task force shall meet at times and places specified by the call of the chairperson or of a majority of the voting members of the task force.
 - (9) The task force may adopt rules necessary for the operation of the task force.
 - (10) The task force shall submit a report in the manner provided by ORS 192.245, and may include recommendations for legislation, to the interim committees of the Legislative Assembly related to health no later than November 1, 2018. The report must contain a cost-

- effective and enforceable solution that exposes the cost factors that negatively impact prices paid by Oregonians for pharmaceutical products.
- (11) The Legislative Policy and Research Director shall provide staff support to the task force.
- (12) Members of the Legislative Assembly appointed to the task force are nonvoting members of the task force and may act in an advisory capacity only.
- (13) Members of the task force who are not members of the Legislative Assembly are not entitled to compensation or reimbursement for expenses and serve as volunteers on the task force.
- (14) All agencies of state government, as defined in ORS 174.111, are directed to assist the task force in the performance of the task force's duties and, to the extent permitted by laws relating to confidentiality, to furnish information and advice the members of the task force consider necessary to perform their duties.
 - SECTION 12. Section 11 of this 2018 Act is repealed on December 31, 2020.
- SECTION 13. (1) Sections 1 to 5 of this 2018 Act and the amendments to ORS 743.018 and 750.055 by sections 8 to 10 of this 2018 Act become operative on January 1, 2019.
- (2) The Department of Consumer and Business Services shall take all steps necessary before January 1, 2019, to carry out the provisions of sections 1 to 5 of this 2018 Act and the amendments to ORS 743.018 and 750.055 by sections 8 to 10 of this 2018 Act on and after January 1, 2019.
- (3) The amendments to section 2 of this 2018 Act by section 6 of this 2018 Act become operative on March 15, 2019.
- (4) The amendments to section 2 of this 2018 Act by section 7 of this 2018 Act become operative on July 2, 2019.
- SECTION 14. Notwithstanding any other law limiting expenditures, the limitation on expenditures established by section 1 (5), chapter 372, Oregon Laws 2017, for the biennium ending June 30, 2019, as the maximum limit for payment of expenses from fees, moneys or other revenues, including Miscellaneous Receipts, but excluding lottery funds and federal funds, collected or received by the Department of Consumer and Business Services, for the Division of Financial Regulation, is increased by \$425,022 for carrying out sections 2, 3 and 5 of this 2018 Act.
- <u>SECTION 15.</u> This 2018 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2018 Act takes effect on its passage.