HOUSE AMENDMENTS TO A-ENGROSSED HOUSE BILL 4005

By JOINT COMMITTEE ON WAYS AND MEANS

February 26

On page 1 of the printed A-engrossed bill, line 2, delete the first "and".

In line 3, before the period insert "; and declaring an emergency".

On page 2, line 25, after "patient" delete the rest of the line and insert "or other person.".

In line 40, delete "March 15 of each year" and insert "July 1, 2019".

On page 3, line 42, delete "No later than 30 days" and insert "Beginning March 15, 2019, 30 days or less".

On page 5, after line 43, insert:

"**SECTION 6.** Section 2 of this 2018 Act is amended 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, 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;

"(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*] **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 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 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 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;

"(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) 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 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.".

In line 44, delete "6" and insert "8".

On page 6, line 43, delete "7" and insert "9".

On page 8, line 12, delete "8" and insert "10".

On page 9, after line 29, insert:

"**SECTION 11. (1) The Task Force on the Fair Pricing of Prescription Drugs is established.**

"(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:

"(A) One member from the House of Representatives who is a member of the majority party.

"(B) One member from the House of Representatives who is a member of the minority party.

"(c) The Governor shall appoint the following members:

"(A) One representative from the Department of Consumer and Business Services;

"(B) One representative from the Oregon Health Authority;

"(C) One representative from the Oregon Health Policy Board; and

"(D) Individuals representing:

"(i) Pharmaceutical manufacturers;

"(ii) Insurance companies offering health insurance in this state;

"(iii) Pharmacy benefit managers;

"(iv) Prescription drug wholesalers;

"(v) Consumers;

"(vi) Independent pharmacies;

"(vii) Large retail pharmacy chains;

"(viii) Hospitals;

"(ix) Biopharmaceutical companies based in Oregon;

"(x) Coordinated care organizations; and

"(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.**

"**SECTION 15. 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.**".
