

Requested by JOINT COMMITTEE ON WAYS AND MEANS

**PROPOSED AMENDMENTS TO
A-ENGROSSED HOUSE BILL 4005**

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

2 In line 3, before the period insert “; and declaring an emergency”.

3 On page 2, line 25, after “patient” delete the rest of the line and insert
4 “or other person.”.

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

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

8 On page 5, after line 43, insert:

9 **“SECTION 6.** Section 2 of this 2018 Act is amended to read:

10 **“Sec. 2.** (1) As used in this section:

11 “(a) ‘Drug’ has the meaning given that term in ORS 689.005.

12 “(b) ‘Health care facility’ has the meaning given that term in ORS 442.015.

13 “(c) ‘Health care service contractor’ has the meaning given that term in
14 ORS 750.005.

15 “(d)(A) ‘Manufacture’ means:

16 “(i) The production, preparation, propagation, compounding, conversion
17 or processing of a drug, either directly or indirectly by extraction from sub-
18 stances of natural origin or independently by means of chemical synthesis,
19 or by a combination of extraction and chemical synthesis; and

20 “(ii) The packaging or repackaging of a drug or labeling or relabeling of
21 a drug container.

1 “(B) ‘Manufacture’ does not include the preparation or compounding of
2 a drug by an individual for the individual’s own use or the preparation,
3 compounding, packaging or labeling of a drug:

4 “(i) By a health care practitioner incidental to administering or dispens-
5 ing a drug in the course of professional practice;

6 “(ii) By a health care practitioner or at the practitioner’s authorization
7 and supervision for the purpose of or incidental to research, teaching or
8 chemical analysis activities and not for sale;

9 “(iii) By a health care service contractor for dispensing to a subscriber
10 or delivery to a health care facility or outpatient clinic owned or operated
11 by the health care service contractor or an affiliate of the health care service
12 contractor;

13 “(iv) By a centralized repackaging operation for distribution to subscrib-
14 ers of health care service contractors or to pharmacies, health care facilities
15 or outpatient clinics operated by or affiliated with a health care service
16 contractor; or

17 “(v) By a health care facility for dispensing to a patient or other person.

18 “(e) ‘Manufacturer’ means a person that manufactures a prescription drug
19 that is sold in this state.

20 “(f) ‘New prescription drug’ has the meaning prescribed by the Depart-
21 ment of Consumer and Business Services by rule.

22 “(g) ‘Patient assistance program’ means a program that a manufacturer
23 offers to the general public in which a consumer may reduce the consumer’s
24 out-of-pocket costs for prescription drugs by using coupons or discount cards,
25 receiving copayment assistance or by other means.

26 “(h) ‘Prescription drug’ means a drug that must:

27 “(A) Under federal law, be labeled ‘Caution: Federal law prohibits dis-
28 pensing without prescription’ prior to being dispensed or delivered; or

29 “(B) Under any applicable federal or state law or regulation, be dispensed
30 only by prescription or restricted to use only by health care practitioners.

1 “(i) ‘Price’ means the wholesale acquisition cost as defined in 42 U.S.C.
2 1395w-3a(c)(6)(B).

3 “(2) No later than July 1, 2019, a manufacturer shall report the informa-
4 tion described in subsection (3) of this section to the department regarding
5 each prescription drug for which:

6 “(a) The price was \$100 or more for a one-month supply or for a course
7 of treatment lasting less than one month; and

8 “(b) There was a net increase of 10 percent or more in the price of the
9 prescription drug described in paragraph (a) of this subsection over the
10 course of the previous calendar year.

11 “(3) For each prescription drug described in subsection (2) of this section,
12 a manufacturer shall report to the department, in the form and manner pre-
13 scribed by the department:

14 “(a) The name and price of the prescription drug and the net increase,
15 expressed as a percentage, in the price of the drug over the course of the
16 previous calendar year;

17 “(b) The length of time the prescription drug has been on the market;

18 “(c) The factors that contributed to the price increase;

19 “(d) The name of any generic version of the prescription drug available
20 on the market;

21 “(e) The research and development costs associated with the prescription
22 drug that were paid using public funds;

23 “(f) The direct costs incurred by the manufacturer:

24 “(A) To manufacture the prescription drug;

25 “(B) To market the prescription drug;

26 “(C) To distribute the prescription drug; and

27 “(D) For ongoing safety and effectiveness research associated with the
28 prescription drug;

29 “(g) The total sales revenue for the prescription drug during the previous
30 calendar year;

1 “(h) The manufacturer’s profit attributable to the prescription drug dur-
2 ing the previous calendar year;

3 “(i) The introductory price of the prescription drug when it was approved
4 for marketing by the United States Food and Drug Administration and the
5 net yearly increase, by calendar year, in the price of the prescription drug
6 during the previous five years;

7 “(j) The 10 highest prices paid for the prescription drug during the pre-
8 vious calendar year in any country other than the United States;

9 “(k) Any other information that the manufacturer deems relevant to the
10 price increase described in subsection (2)(b) of this section; and

11 “(L) The documentation necessary to support the information reported
12 under this subsection.

13 “(4) The department may use any prescription drug price information the
14 department deems appropriate to verify that manufacturers have properly
15 reported price increases as required by subsections (2) and (3) of this section.

16 “(5) A manufacturer shall accompany the report provided under sub-
17 section (2) of this section with the following information about each patient
18 assistance program offered by the manufacturer to consumers residing in this
19 state for the prescription drugs described in subsection (2) of this section:

20 “(a) The number of consumers who participated in the program;

21 “(b) The total value of the coupons, discounts, copayment assistance or
22 other reduction in costs provided to consumers in this state who participated
23 in the program;

24 “(c) For each drug, the number of refills that qualify for the program, if
25 applicable;

26 “(d) If the program expires after a specified period of time, the period of
27 time that the program is available to each consumer; and

28 “(e) The eligibility criteria for the program and how eligibility is verified
29 for accuracy.

30 “(6) [*Beginning March 15, 2019, 30 days or less*] **No later than 30 days**

1 after a manufacturer introduces a new prescription drug for sale in the
2 United States at a price that exceeds the threshold established by the Cen-
3 ters for Medicare and Medicaid Services for specialty drugs in the Medicare
4 Part D program, the manufacturer shall notify the department, in the form
5 and manner prescribed by the department, of all the following information:

6 “(a) A description of the marketing used in the introduction of the new
7 prescription drug;

8 “(b) The methodology used to establish the price of the new prescription
9 drug;

10 “(c) Whether the United States Food and Drug Administration granted
11 the new prescription drug a breakthrough therapy designation or a priority
12 review;

13 “(d) If the new prescription drug was not developed by the manufacturer,
14 the date of and the price paid for acquisition of the new prescription drug
15 by the manufacturer;

16 “(e) The manufacturer’s estimate of the average number of patients who
17 will be prescribed the new prescription drug each month; and

18 “(f) The research and development costs associated with the new pre-
19 scription drug that were paid using public funds.

20 “(7)(a) After receiving the report or information described in subsections
21 (2), (3), (5) or (6) of this section, the department may make a written request
22 to the manufacturer for supporting documentation or additional information
23 concerning the report. The department shall prescribe by rule the periods:

24 “(A) Following the receipt of the report or information during which the
25 department may request additional information; and

26 “(B) Following a request by the department for additional information
27 during which a manufacturer may respond to the request.

28 “(b) The department may extend the period prescribed under paragraph
29 (a)(B) of this subsection, as necessary, on a case-by-case basis.

30 “(8) A manufacturer may be subject to a civil penalty, as provided in

1 section 3 of this 2018 Act, for:

2 “(a) Failing to submit timely reports or notices as required by this sec-
3 tion;

4 “(b) Failing to provide information required under this section;

5 “(c) Failing to respond in a timely manner to a written request by the
6 department for additional information under subsection (7) of this section;

7 or

8 “(d) Providing inaccurate or incomplete information under this section.

9 “(9) Except as provided in subsection (10) of this section, the department
10 shall post to its website all of the following information:

11 “(a) A list of the prescription drugs reported under subsection (2) of this
12 section and the manufacturers of those prescription drugs;

13 “(b) Information reported to the department under subsections (3) and (5)
14 to (7) of this section; and

15 “(c) Written requests by the department for additional information under
16 subsection (7) of this section.

17 “(10)(a) The department may not post to its website any information de-
18 scribed in subsection (9) of this section if:

19 “(A) The information is conditionally exempt from disclosure under ORS
20 192.345 as a trade secret; and

21 “(B) The public interest does not require disclosure of the information.

22 “(b) If the department withholds any information from public disclosure
23 pursuant to this subsection, the department shall post to its website a report
24 describing the nature of the information and the department’s basis for
25 withholding the information from disclosure.

26 “(c) A person may petition the Attorney General, as provided in ORS
27 192.411, to review a decision by the department to withhold information
28 pursuant to paragraph (a) of this subsection.

29 “(11) The department shall make available to consumers, online and by
30 telephone, a process for consumers to notify the department about an in-

1 crease in the price of a prescription drug.

2 “(12) The department may adopt rules as necessary for carrying out the
3 provisions of this section, including but not limited to rules establishing fees
4 to be paid by manufacturers to be used solely to pay the costs of the de-
5 partment in carrying out the provisions of this section.

6 “(13) No later than December 15 of each year, the department shall com-
7 pile and report the information collected by the department under this sec-
8 tion to the interim committees of the Legislative Assembly related to health.
9 The report shall include recommendations for legislative changes, if any, to
10 contain the cost of prescription drugs and reduce the impact of price in-
11 creases on consumers, the Department of Corrections, the Public Employees’
12 Benefit Board, the Oregon Health Authority, the Department of Human
13 Services, the Oregon Educators Benefit Board and health insurance premi-
14 ums in the commercial market.

15 **“SECTION 7.** Section 2 of this 2018 Act, as amended by section 6 of this
16 2018 Act, is amended to read:

17 **“Sec. 2.** (1) As used in this section:

18 “(a) ‘Drug’ has the meaning given that term in ORS 689.005.

19 “(b) ‘Health care facility’ has the meaning given that term in ORS 442.015.

20 “(c) ‘Health care service contractor’ has the meaning given that term in
21 ORS 750.005.

22 “(d)(A) ‘Manufacture’ means:

23 “(i) The production, preparation, propagation, compounding, conversion
24 or processing of a drug, either directly or indirectly by extraction from sub-
25 stances of natural origin or independently by means of chemical synthesis,
26 or by a combination of extraction and chemical synthesis; and

27 “(ii) The packaging or repackaging of a drug or labeling or relabeling of
28 a drug container.

29 “(B) ‘Manufacture’ does not include the preparation or compounding of
30 a drug by an individual for the individual’s own use or the preparation,

1 compounding, packaging or labeling of a drug:

2 “(i) By a health care practitioner incidental to administering or dispensing
3 a drug in the course of professional practice;

4 “(ii) By a health care practitioner or at the practitioner’s authorization
5 and supervision for the purpose of or incidental to research, teaching or
6 chemical analysis activities and not for sale;

7 “(iii) By a health care service contractor for dispensing to a subscriber
8 or delivery to a health care facility or outpatient clinic owned or operated
9 by the health care service contractor or an affiliate of the health care service
10 contractor;

11 “(iv) By a centralized repackaging operation for distribution to subscrib-
12 ers of health care service contractors or to pharmacies, health care facilities
13 or outpatient clinics operated by or affiliated with a health care service
14 contractor; or

15 “(v) By a health care facility for dispensing to a patient or other person.

16 “(e) ‘Manufacturer’ means a person that manufactures a prescription drug
17 that is sold in this state.

18 “(f) ‘New prescription drug’ has the meaning prescribed by the Depart-
19 ment of Consumer and Business Services by rule.

20 “(g) ‘Patient assistance program’ means a program that a manufacturer
21 offers to the general public in which a consumer may reduce the consumer’s
22 out-of-pocket costs for prescription drugs by using coupons or discount cards,
23 receiving copayment assistance or by other means.

24 “(h) ‘Prescription drug’ means a drug that must:

25 “(A) Under federal law, be labeled ‘Caution: Federal law prohibits dis-
26 pensing without prescription’ prior to being dispensed or delivered; or

27 “(B) Under any applicable federal or state law or regulation, be dispensed
28 only by prescription or restricted to use only by health care practitioners.

29 “(i) ‘Price’ means the wholesale acquisition cost as defined in 42 U.S.C.
30 1395w-3a(c)(6)(B).

1 “(2) No later than [*July 1, 2019*] **March 15 of each year**, a manufacturer
2 shall report the information described in subsection (3) of this section to the
3 department regarding each prescription drug for which:

4 “(a) The price was \$100 or more for a one-month supply or for a course
5 of treatment lasting less than one month; and

6 “(b) There was a net increase of 10 percent or more in the price of the
7 prescription drug described in paragraph (a) of this subsection over the
8 course of the previous calendar year.

9 “(3) For each prescription drug described in subsection (2) of this section,
10 a manufacturer shall report to the department, in the form and manner pre-
11 scribed by the department:

12 “(a) The name and price of the prescription drug and the net increase,
13 expressed as a percentage, in the price of the drug over the course of the
14 previous calendar year;

15 “(b) The length of time the prescription drug has been on the market;

16 “(c) The factors that contributed to the price increase;

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18 on the market;

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20 drug that were paid using public funds;

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22 “(A) To manufacture the prescription drug;

23 “(B) To market the prescription drug;

24 “(C) To distribute the prescription drug; and

25 “(D) For ongoing safety and effectiveness research associated with the
26 prescription drug;

27 “(g) The total sales revenue for the prescription drug during the previous
28 calendar year;

29 “(h) The manufacturer’s profit attributable to the prescription drug dur-
30 ing the previous calendar year;

1 “(i) The introductory price of the prescription drug when it was approved
2 for marketing by the United States Food and Drug Administration and the
3 net yearly increase, by calendar year, in the price of the prescription drug
4 during the previous five years;

5 “(j) The 10 highest prices paid for the prescription drug during the pre-
6 vious calendar year in any country other than the United States;

7 “(k) Any other information that the manufacturer deems relevant to the
8 price increase described in subsection (2)(b) of this section; and

9 “(L) The documentation necessary to support the information reported
10 under this subsection.

11 “(4) The department may use any prescription drug price information the
12 department deems appropriate to verify that manufacturers have properly
13 reported price increases as required by subsections (2) and (3) of this section.

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15 section (2) of this section with the following information about each patient
16 assistance program offered by the manufacturer to consumers residing in this
17 state for the prescription drugs described in subsection (2) of this section:

18 “(a) The number of consumers who participated in the program;

19 “(b) The total value of the coupons, discounts, copayment assistance or
20 other reduction in costs provided to consumers in this state who participated
21 in the program;

22 “(c) For each drug, the number of refills that qualify for the program, if
23 applicable;

24 “(d) If the program expires after a specified period of time, the period of
25 time that the program is available to each consumer; and

26 “(e) The eligibility criteria for the program and how eligibility is verified
27 for accuracy.

28 “(6) No later than 30 days after a manufacturer introduces a new pre-
29 scription drug for sale in the United States at a price that exceeds the
30 threshold established by the Centers for Medicare and Medicaid Services for

1 specialty drugs in the Medicare Part D program, the manufacturer shall no-
2 tify the department, in the form and manner prescribed by the department,
3 of all the following information:

4 “(a) A description of the marketing used in the introduction of the new
5 prescription drug;

6 “(b) The methodology used to establish the price of the new prescription
7 drug;

8 “(c) Whether the United States Food and Drug Administration granted
9 the new prescription drug a breakthrough therapy designation or a priority
10 review;

11 “(d) If the new prescription drug was not developed by the manufacturer,
12 the date of and the price paid for acquisition of the new prescription drug
13 by the manufacturer;

14 “(e) The manufacturer’s estimate of the average number of patients who
15 will be prescribed the new prescription drug each month; and

16 “(f) The research and development costs associated with the new pre-
17 scription drug that were paid using public funds.

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19 (2), (3), (5) or (6) of this section, the department may make a written request
20 to the manufacturer for supporting documentation or additional information
21 concerning the report. The department shall prescribe by rule the periods:

22 “(A) Following the receipt of the report or information during which the
23 department may request additional information; and

24 “(B) Following a request by the department for additional information
25 during which a manufacturer may respond to the request.

26 “(b) The department may extend the period prescribed under paragraph
27 (a)(B) of this subsection, as necessary, on a case-by-case basis.

28 “(8) A manufacturer may be subject to a civil penalty, as provided in
29 section 3 of this 2018 Act, for:

30 “(a) Failing to submit timely reports or notices as required by this sec-

1 tion;

2 “(b) Failing to provide information required under this section;

3 “(c) Failing to respond in a timely manner to a written request by the
4 department for additional information under subsection (7) of this section;

5 or

6 “(d) Providing inaccurate or incomplete information under this section.

7 “(9) Except as provided in subsection (10) of this section, the department
8 shall post to its website all of the following information:

9 “(a) A list of the prescription drugs reported under subsection (2) of this
10 section and the manufacturers of those prescription drugs;

11 “(b) Information reported to the department under subsections (3) and (5)
12 to (7) of this section; and

13 “(c) Written requests by the department for additional information under
14 subsection (7) of this section.

15 “(10)(a) The department may not post to its website any information de-
16 scribed in subsection (9) of this section if:

17 “(A) The information is conditionally exempt from disclosure under ORS
18 192.345 as a trade secret; and

19 “(B) The public interest does not require disclosure of the information.

20 “(b) If the department withholds any information from public disclosure
21 pursuant to this subsection, the department shall post to its website a report
22 describing the nature of the information and the department’s basis for
23 withholding the information from disclosure.

24 “(c) A person may petition the Attorney General, as provided in ORS
25 192.411, to review a decision by the department to withhold information
26 pursuant to paragraph (a) of this subsection.

27 “(11) The department shall make available to consumers, online and by
28 telephone, a process for consumers to notify the department about an in-
29 crease in the price of a prescription drug.

30 “(12) The department may adopt rules as necessary for carrying out the

1 provisions of this section, including but not limited to rules establishing fees
2 to be paid by manufacturers to be used solely to pay the costs of the de-
3 partment in carrying out the provisions of this section.

4 “(13) No later than December 15 of each year, the department shall com-
5 pile and report the information collected by the department under this sec-
6 tion to the interim committees of the Legislative Assembly related to health.
7 The report shall include recommendations for legislative changes, if any, to
8 contain the cost of prescription drugs and reduce the impact of price in-
9 creases on consumers, the Department of Corrections, the Public Employees’
10 Benefit Board, the Oregon Health Authority, the Department of Human
11 Services, the Oregon Educators Benefit Board and health insurance premi-
12 ums in the commercial market.”.

13 In line 44, delete “6” and insert “8”.

14 On page 6, line 43, delete “7” and insert “9”.

15 On page 8, line 12, delete “8” and insert “10”.

16 On page 9, after line 29, insert:

17 **“SECTION 11. (1) The Task Force on the Fair Pricing of Pre-**
18 **scription Drugs is established.**

19 **“(2) The task force consists of 18 members appointed as follows:**

20 **“(a) The President of the Senate shall appoint:**

21 **“(A) One member from the Senate who is a member of the majority**
22 **party.**

23 **“(B) One member from the Senate who is a member of the minority**
24 **party.**

25 **“(b) The Speaker of the House of Representatives shall appoint:**

26 **“(A) One member from the House of Representatives who is a**
27 **member of the majority party.**

28 **“(B) One member from the House of Representatives who is a**
29 **member of the minority party.**

30 **“(c) The Governor shall appoint the following members:**

1 **“(A) One representative from the Department of Consumer and**
2 **Business Services;**

3 **“(B) One representative from the Oregon Health Authority;**

4 **“(C) One representative from the Oregon Health Policy Board; and**

5 **“(D) Individuals representing:**

6 **“(i) Pharmaceutical manufacturers;**

7 **“(ii) Insurance companies offering health insurance in this state;**

8 **“(iii) Pharmacy benefit managers;**

9 **“(iv) Prescription drug wholesalers;**

10 **“(v) Consumers;**

11 **“(vi) Independent pharmacies;**

12 **“(vii) Large retail pharmacy chains;**

13 **“(viii) Hospitals;**

14 **“(ix) Biopharmaceutical companies based in Oregon;**

15 **“(x) Coordinated care organizations; and**

16 **“(xi) Medical providers.**

17 **“(3) The task force shall develop a strategy to create transparency**
18 **for drug prices across the entire supply chain of pharmaceutical pro-**
19 **ducts, including but not limited to manufacturers, insurers, pharmacy**
20 **benefit managers, distributors, wholesalers and retail pharmacies.**

21 **“(4) A majority of the voting members of the task force constitutes**
22 **a quorum for the transaction of business.**

23 **“(5) Official action by the task force requires the approval of a**
24 **majority of the voting members of the task force.**

25 **“(6) The task force shall elect one of its members to serve as**
26 **chairperson.**

27 **“(7) If there is a vacancy for any cause, the appointing authority**
28 **shall make an appointment to become immediately effective.**

29 **“(8) The task force shall meet at times and places specified by the**
30 **call of the chairperson or of a majority of the voting members of the**

1 **task force.**

2 **“(9) The task force may adopt rules necessary for the operation of**
3 **the task force.**

4 **“(10) The task force shall submit a report in the manner provided**
5 **by ORS 192.245, and may include recommendations for legislation, to**
6 **the interim committees of the Legislative Assembly related to health**
7 **no later than November 1, 2018. The report must contain a cost-**
8 **effective and enforceable solution that exposes the cost factors that**
9 **negatively impact prices paid by Oregonians for pharmaceutical pro-**
10 **ducts.**

11 **“(11) The Legislative Policy and Research Director shall provide**
12 **staff support to the task force.**

13 **“(12) Members of the Legislative Assembly appointed to the task**
14 **force are nonvoting members of the task force and may act in an ad-**
15 **visory capacity only.**

16 **“(13) Members of the task force who are not members of the Leg-**
17 **islative Assembly are not entitled to compensation or reimbursement**
18 **for expenses and serve as volunteers on the task force.**

19 **“(14) All agencies of state government, as defined in ORS 174.111,**
20 **are directed to assist the task force in the performance of the task**
21 **force’s duties and, to the extent permitted by laws relating to**
22 **confidentiality, to furnish information and advice the members of the**
23 **task force consider necessary to perform their duties.**

24 **“SECTION 12. Section 11 of this 2018 Act is repealed on December**
25 **31, 2020.**

26 **“SECTION 13. (1) Sections 1 to 5 of this 2018 Act and the amend-**
27 **ments to ORS 743.018 and 750.055 by sections 8 to 10 of this 2018 Act**
28 **become operative on January 1, 2019.**

29 **“(2) The Department of Consumer and Business Services shall take**
30 **all steps necessary before January 1, 2019, to carry out the provisions**

1 of sections 1 to 5 of this 2018 Act and the amendments to ORS 743.018
2 and 750.055 by sections 8 to 10 of this 2018 Act on and after January
3 1, 2019.

4 “(3) The amendments to section 2 of this 2018 Act by section 6 of
5 this 2018 Act become operative on March 15, 2019.

6 “(4) The amendments to section 2 of this 2018 Act by section 7 of
7 this 2018 Act become operative on July 2, 2019.

8 “SECTION 14. Notwithstanding any other law limiting expenditures,
9 the limitation on expenditures established by section 1 (5), chapter 372,
10 Oregon Laws 2017, for the biennium ending June 30, 2019, as the max-
11 imum limit for payment of expenses from fees, moneys or other reve-
12 nues, including Miscellaneous Receipts, but excluding lottery funds
13 and federal funds, collected or received by the Department of Con-
14 sumer and Business Services, for the Division of Financial Regulation,
15 is increased by \$425,022 for carrying out sections 2, 3 and 5 of this 2018
16 Act.

17 “SECTION 15. This 2018 Act being necessary for the immediate
18 preservation of the public peace, health and safety, an emergency is
19 declared to exist, and this 2018 Act takes effect on its passage.”.

20
