

2018 Regular Session

HOUSE BILL NO. 384

BY REPRESENTATIVE TALBOT

DRUGS/PRESCRIPTION: Creates and provides for a state prescription drug importation program

1 AN ACT  
2 To enact Part IX of Chapter 12 of Title 40 of the Louisiana Revised Statutes of 1950, to be  
3 comprised of R.S. 40:2255.21 through 2255.30, relative to prescription drugs; to  
4 create and provide for a program of prescription drug importation; to authorize the  
5 state to apply for federal approval to import prescription drugs from Canada; to  
6 provide for duties of the Louisiana Department of Health in establishing and  
7 administering the program; to assign certain functions within the program to the  
8 Louisiana Board of Pharmacy and the Louisiana Department of Insurance; to provide  
9 for compliance with applicable state and federal laws; to provide for assurances,  
10 restrictions, and limitations within the program; to provide for development of a  
11 pharmaceutical importation list; to provide for audits of entities that participate in the  
12 program; to prohibit certain conduct by pharmaceutical manufacturers; to provide  
13 for assessment of certain fees to fund program costs; to require reporting relative to  
14 prescription drug prices; to provide for administrative rulemaking; and to provide for  
15 related matters.

16 Be it enacted by the Legislature of Louisiana:

17 Section 1. Part IX of Chapter 12 of Title 40 of the Louisiana Revised Statutes of  
18 1950, comprised of R.S. 40:2255.21 through 2255.30, is hereby enacted to read as follows:

1                    PART IX. PRESCRIPTION DRUG AFFORDABILITY LAW2                    §2255.21. Short title

3                    This Part shall be known and may be cited as the Prescription Drug  
4                    Affordability Law.

5                    §2255.22. Definitions

6                    As used in this Part, the following terms have the meaning ascribed in this  
7                    Section:

8                    (1) "Department" means the Louisiana Department of Health.

9                    (2) "Drug" has the meaning ascribed in R.S. 40:961.

10                  (3) "Health insurer" means any of the following:

11                  (a) A health insurance issuer as defined in R.S. 22:1831.

12                  (b) A managed care organization as defined in 42 CFR 438.2.

13                  (c) The Office of Group Benefits.

14                  (d) A workers' compensation insurer authorized to provide workers'  
15                  compensation insurance in the state.

16                  (e) A self-insured employer.

17                  (4) "Pharmaceutical manufacturer" means any of the following:

18                  (a) A person who is engaged in the manufacturing of drugs or  
19                  pharmaceutical devices that are available for purchase by residents of the state.

20                  (b) A person who is responsible for setting the price of a drug or device that  
21                  is available for purchase by residents of the state on behalf of a person described in  
22                  Subparagraph (a) of this Paragraph.

23                  (5) "Prescription drug importation program" means the Canadian  
24                  Prescription Drug Importation Program established by the provisions of R.S.  
25                  40:2255.23.

1        §2255.23. Prescription drug importation program; creation; application and  
2                    certification

3                    A. The legislature hereby creates the Canadian Prescription Drug  
4                    Importation Program to be administered by the department in accordance with the  
5                    provisions of this Part.

6                    B. The department shall prepare and submit to the secretary of the United  
7                    States Department of Health and Human Services all of the following:

8                    (1) A letter of intent to seek approval for a program to allow for the  
9                    importation of prescription drugs from Canada into the state under the provisions of  
10                   21 U.S.C. 384(l).

11                   (2)(a) An application for all of the following:

12                   (i) The approval of a program to allow for the importation of prescription  
13                   drugs from Canada into the state under the provisions of 21 U.S.C. 384(l).

14                   (ii) Certification by the secretary of the United States Department of Health  
15                   and Human Services to the United States Congress, in accordance with 21 U.S.C.  
16                   384(l), that importation of Canadian prescription drugs will pose no additional risk  
17                   to public health and safety and will result in a significant reduction in the cost of  
18                   covered products to the American consumer.

19                   (b) The application required by Subparagraph (a) of this Paragraph shall  
20                   feature all of the following:

21                   (i) A description of the prescription drug importation program designed by  
22                   the department in accordance with the provisions of this Part, including measures  
23                   that will be taken to comply with existing state and federal law and to minimize risk  
24                   to public health and safety.

25                   (ii) An estimate of the reduction in the cost of covered products and health  
26                   insurance premiums to Louisiana consumers.

27                   C. If the application for the prescription drug importation program is not  
28                   approved by the secretary of the United States Department of Health and Human  
29                   Services, the department shall submit a new application in accordance with

1 Paragraph (B)(2) of this Section on or before December 1 annually until the earlier  
2 of the following dates:

3 (1) The date of approval of the prescription drug importation program by the  
4 secretary of the United States Department of Health and Human Services.

5 (2) January 1, 2023.

6 D. On or before December 1 of each year that the department submits an  
7 application under Subsection B or C of this Section, the department shall submit a  
8 written report to the House and Senate committees on health and welfare regarding  
9 the results of the application and any updated findings and recommendations.

10 §2255.24. Program requirements and standards

11 The prescription drug importation program established by the provisions of  
12 R.S. 40:2255.23 shall feature all of the following assurances, functions,  
13 requirements, and limitations:

14 (1) Allow for the importation of prescription drugs, exclusively, that have  
15 been identified by the department in the pharmaceutical importation list provided for  
16 in R.S. 40:2255.25.

17 (2) Monitor consumer prices to ensure that market competition and routine  
18 health plan administration provide significant savings for Louisiana consumers.

19 (3) Specify the actions that the department and the Louisiana Department of  
20 Insurance will take if market competition and routine health plan administration does  
21 not result in significant savings for Louisiana consumers.

22 (4) Only use Canadian suppliers regulated under applicable federal or  
23 provincial laws of Canada.

24 (5) If required by the secretary of the United States Department of Health  
25 and Human Services, establish a process to ensure the purity, chemical composition,  
26 and potency of imported products.

27 (6) Ensure that imported prescription drugs will not be distributed,  
28 dispensed, or sold outside of the state.

1           (7) Ensure that the program does not import a generic prescription drug that  
2           would violate United States patent laws.

3           (8) Comply with the track and trace requirements provided in Title II of the  
4           Drug Security and Quality Act, 4 U.S.C. 360eee et seq., prior to allowing imported  
5           prescription drugs to come into possession of the wholesaler.

6           (9) Ensure that the prescription drug supply and distribution chain is in  
7           compliance with applicable Louisiana law and United States federal law after  
8           imported prescription drugs are in the possession of the wholesaler.

9           (10) Ensure that the prescription drug importation program is adequately  
10          financed through an efficient approach that does not jeopardize significant consumer  
11          savings.

12          (11) Require publication of a wholesaler's acquisition cost of each imported  
13          prescription drug.

14          (12) With respect to an imported prescription drug, require a participating  
15          pharmacy to disclose, upon request, the price of the drug that the participating  
16          pharmacy will charge to a patient who is not covered by a health plan or contract.

17          (13) Include an audit function that complies with the provisions of R.S.  
18          40:2255.26.

19          (14) Ensure that participation by any wholesaler, health insurer, healthcare  
20          provider, or consumer is voluntary.

21          §2255.25. Pharmaceutical importation list

22                 A.(1) The department shall collaborate with the Louisiana Board of  
23                 Pharmacy to develop and periodically revise a pharmaceutical importation list in  
24                 accordance with this Section.

25                 (2) The department may coordinate with a working group created under the  
26                 direction of the Louisiana Board of Pharmacy to satisfy the requirements of this  
27                 Subsection.

28                 B.(1) The pharmaceutical importation list provided for in Subsection A of  
29                 this Section shall include prescription drugs that may be imported from Canada

1 under applicable Louisiana law and United States federal law and that are expected  
2 to generate substantial savings for Louisiana consumers.

3 (2) The pharmaceutical importation list shall not include any prescription  
4 drug that may not be imported under applicable Louisiana law or United States  
5 federal law.

6 C.(1) A participating health insurer shall provide the department and the  
7 Louisiana Board of Pharmacy or the board's designee with any information that the  
8 department requests concerning the net per-unit cost of the health insurer's twenty  
9 highest-cost drugs and the quantity of those drugs dispensed by the health insurer to  
10 covered individuals.

11 (2) No information provided pursuant to this Subsection shall contain any  
12 personally identifiable health information protected by the Health Insurance  
13 Portability and Accountability Act, 42 U.S.C. 1320d et seq.

14 (3) All information provided to the department, the Louisiana Board of  
15 Pharmacy, and designees of the board pursuant to this Subsection is hereby declared  
16 to be proprietary information and not subject to disclosure under the Public Records  
17 Law, R.S. 44:1 et seq.

18 D. The department may request and utilize the information described in  
19 Subsection C of this Section exclusively for the purposes of developing the  
20 pharmaceutical importation list and implementing and enforcing provisions of this  
21 Part.

22 E.(1) The department shall review the pharmaceutical importation list every  
23 three months to ensure that the list continues to meet the requirements of Subsection  
24 B of this Section.

25 (2) The department shall establish policies and procedures for updating the  
26 pharmaceutical importation list, and shall promulgate such policies and procedures  
27 by rule in accordance with the Administrative Procedure Act.

1        §2255.26. Audits

2                A. The functions of the prescription drug importation program established  
3        by the provisions of R.S. 40:2255.23 shall include audits of suppliers, importers,  
4        wholesalers, retail pharmacies, health insurers, and other persons who participate in  
5        the program as appropriate and necessary. The audit function shall, at minimum,  
6        incorporate a review of all of the following:

7                (1) The methodology used to determine the prescription drugs with the  
8        greatest potential for savings.

9                (2) The process used to ensure that Canadian suppliers are of high quality,  
10        high performance, and in full compliance with Canadian laws.

11                (3) Methods used to ensure that imported prescription drugs under the  
12        prescription drug importation program are not shipped, sold, or dispensed outside the  
13        state once in the possession of the wholesaler or the wholesaler's contractors.

14                (4) Processes used to ensure that imported prescription drugs are pure,  
15        unadulterated, potent, and safe.

16                B. The audit function provided for in this Section shall ensure that Louisiana  
17        consumers benefit from significant savings by verifying all of the following:

18                (1) That participating pharmacies and administering providers are not  
19        charging rates that jeopardize significant consumer savings to any consumer or  
20        participating health plan.

21                (2) That the prescription drug importation program is adequately financed  
22        to support all administrative functions while generating significant consumer  
23        savings.

24                (3) That the prescription drug importation program does not put consumers  
25        at a higher health and safety risk than if the program did not exist.

26                (4) That the prescription drug importation program continues to provide  
27        Louisiana consumers with substantial savings on imported prescription drugs.

28                (5) That the ability of any participating pharmacy to negotiate professional  
29        fees is not impeded.

1           C. The department shall collaborate with the Louisiana Department of  
2           Insurance to conduct audits in accordance with this Section and to enforce the  
3           provisions of this Part.

4           §2255.27. Conditions for implementation; fees

5           A.(1) The department shall commence to implement the prescription drug  
6           importation program only after all of the following actions have occurred:

7           (a) The secretary of the United States Department of Health and Human  
8           Services certifies to the United States Congress, in accordance with 21 U.S.C. 384(l),  
9           that importation of Canadian prescription drugs will pose no additional risk to public  
10           health and safety, and will result in a significant reduction in the cost of covered  
11           products to the American consumer.

12           (b) The secretary of the United States Department of Health and Human  
13           Services approves the prescription drug importation program.

14           (c) All other requirements of state and federal law for the importation of  
15           prescription drugs from Canada have been satisfied.

16           (d) The department has collected fees pursuant to Subsection C of this  
17           Section in an amount sufficient to cover the startup costs of the prescription drug  
18           program.

19           (2)(a) The department may, to the extent allowed under Louisiana law and  
20           United States federal law, do all of the following prior to commencing to implement  
21           the prescription drug importation program:

22           (i) Design the prescription drug importation program.

23           (ii) Negotiate with wholesalers in Canada and the United States regarding  
24           the potential implementation of the prescription drug importation program.

25           (b) The department shall not do any of the following prior to commencing  
26           to implement the prescription drug importation program:

27           (i) Authorize the importation of any prescription drugs under this Part.

28           (ii) Implement any provisions of the prescription drug importation program  
29           that would violate Louisiana law or United States federal law.

1           B. The department shall implement the prescription drug importation  
2           program by contracting with any wholesale pharmacy that meets all of the following  
3           conditions:

4           (1) Is licensed as a wholesale drug distributor in this state.

5           (2) Is compliant with all applicable program requirements provided in this  
6           Part.

7           (3) Agrees to any additional conditions of participation that the department  
8           may establish in accordance with the requirements of United States federal law and  
9           this Part.

10           C.(1)(a) The department shall establish fees to be assessed to entities that  
11           participate in the prescription drug importation program to cover all startup and  
12           implementation costs of the program.

13           (b) The department shall utilize fee amounts collected in accordance with  
14           this Paragraph exclusively for implementation of the provisions of this Part.

15           (c) The fees assessed in accordance with this Paragraph shall not exceed the  
16           amount necessary to cover the costs that the department incurs in implementing the  
17           provisions of this Part.

18           (2)(a) The Louisiana Department of Insurance may establish fees to be  
19           assessed to insurers that participate in the prescription drug importation program in  
20           connection with any function specified in R.S. 40:2255.24(3) or 2255.26(C).

21           (b) The Louisiana Department of Insurance shall utilize fee amounts  
22           collected in accordance with this Paragraph exclusively for the functions specified  
23           in Subparagraph (a) of this Paragraph.

24           (c) The fees assessed in accordance with this Paragraph shall not exceed the  
25           amount necessary to cover the costs that the Louisiana Department of Insurance  
26           incurs in connection with the functions specified in Subparagraph (a) of this  
27           Paragraph.

1        §2255.28. Pharmaceutical manufacturers; prohibited conduct; penalties

2            A. No pharmaceutical manufacturer shall do any of the following:

3            (1) Take any action, by agreement, unilaterally, or otherwise, that has the  
4            effect of fixing or otherwise controlling the price that a pharmaceutical supplier,  
5            distributor, or dispenser charges or advertises for pharmaceuticals in the prescription  
6            drug importation program.

7            (2) Discriminate against a pharmaceutical supplier, distributor, or dispenser  
8            based on whether the supplier, distributor, or dispenser participates in the  
9            prescription drug importation program.

10           B. The attorney general may bring a civil action or seek an injunction against  
11           any person who violates any provision of this Section, and may seek any remedy  
12           available to the attorney general for violations of state antitrust law.

13        §2255.29. Pharmaceutical manufacturers; report required

14           A. For each drug that has an annual wholesale acquisition cost of ten  
15           thousand dollars or more, a pharmaceutical manufacturer shall submit a report to the  
16           department if a price increase for that drug will result in an increase in the wholesale  
17           acquisition cost that is equal to either of the following:

18           (1) At least seven and one-half percent over a period of twelve months.

19           (2) At least eighteen percent over a period of thirty-six months.

20           B. A pharmaceutical manufacturer subject to the reporting requirement  
21           provided in Subsection A of this Section shall submit its report to the department no  
22           later than thirty days before the day on which the price increase takes effect. Each  
23           such report shall include all of the following information:

24           (1) The increase in the cost of the drug, expressed as a percentage increase  
25           based on the price of the drug before the cost increase.

26           (2) A justification for each price increase.

27           (3) The date on which each price increase takes effect.

1           (4) The total profit derived from sales of the drug, expressed in total dollars  
2           and as a percentage of the pharmaceutical manufacturer's total profits for that  
3           calendar year.

4           (5) The total expenditures of the pharmaceutical manufacturer on materials  
5           and manufacturing for the drug.

6           (6) The total research and development costs paid by the pharmaceutical  
7           manufacturer for the development and production of the drug.

8           (7) The total administrative, marketing, and advertising costs for the drug.

9           (8) Any costs associated with direct-to-consumer coupons and patient  
10          assistance programs for the drug.

11          C.(1) The department shall publish information submitted pursuant to the  
12          provisions of this Section at least once in every three month period and in a manner  
13          that allows the information to be identified separately for each drug.

14          (2) Notwithstanding Paragraph (1) of this Subsection, the department shall  
15          not disclose any information deemed to be a trade secret under the laws of this state.  
16          §2255.30. Rulemaking

17          The secretary of the department shall promulgate all such rules in accordance  
18          with the Administrative Procedure Act as are necessary to implement the provisions  
19          of this Part.

20          Section 2.(A) The secretary of the Louisiana Department of Health shall take such  
21          actions as are necessary to cause the letter of intent required by R.S. 40:2255.23(B)(1), as  
22          enacted by Section 1 of this Act, to be submitted to the secretary of the United States  
23          Department of Health and Human Services on or before July 31, 2018.

24          (B) The secretary of the Louisiana Department of Health shall take such actions as  
25          are necessary to cause the application required by R.S. 40:2255.23(B)(2), as enacted by  
26          Section 1 of this Act, to be submitted to the secretary of the United States Department of  
27          Health and Human Services on or before December 31, 2018.

---

**DIGEST**

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

---

HB 384 Original

2018 Regular Session

Talbot

**Abstract:** Requires the La. Department of Health to develop and submit for federal approval a program for importing prescription drugs from Canada.

Proposed law creates the Canadian Prescription Drug Importation Program to be administered by the La. Department of Health (LDH).

Proposed law requires LDH to prepare and submit to the secretary of the U.S. Department of Health and Human Services all of the following:

- (1) A letter of intent to seek approval for a program to allow for the importation of prescription drugs from Canada into the state under the applicable provisions of federal law.
- (2) An application for all of the following:
  - (a) The approval of a program to allow for the importation of prescription drugs from Canada into the state under the applicable provisions of federal law.
  - (b) Certification by the secretary of the U.S. Department of Health and Human Services to the U.S. Congress, in accordance with federal law, that importation of Canadian prescription drugs will do all of the following:
    - (i) Pose no additional risk to public health and safety.
    - (ii) Result in a significant reduction in the cost of covered products to the American consumer.

Proposed law requires that the letter of intent described in (1) above be submitted on or before July 31, 2018; and that the application described in (2) above be submitted on or before Dec. 31, 2018.

Proposed law requires that the application for the prescription drug importation program feature all of the following:

- (1) A description of the program including measures that will be taken to comply with existing state and federal law and to minimize risk to public health and safety.
- (2) An estimate of the reduction in the cost of covered products and health insurance premiums to La. consumers.

Proposed law stipulates that if the application for the program is not approved by the federal health agency, then LDH shall submit a new application on or before Dec. 1 annually until the earlier of the following dates:

- (1) The date of approval of the program.
- (2) Jan. 1, 2023.

Proposed law requires that or before Dec. 1 of each year that LDH submits an application for approval of the prescription drug importation program, the department shall submit a written report to the House and Senate committees on health and welfare regarding the results of the application and any updated findings and recommendations.

Proposed law provides that prescription drug importation program shall feature all of the following assurances, functions, requirements, and limitations:

- (1) Allow for the importation of prescription drugs, exclusively, that have been identified by LDH in the pharmaceutical importation list provided for in proposed law.
- (2) Monitor consumer prices to ensure that market competition and routine health plan administration provide significant savings for La. consumers.
- (3) Specify the actions that LDH and the La. Department of Insurance will take if market competition and routine health plan administration does not result in significant consumer savings.
- (4) Only use Canadian suppliers regulated under applicable federal or provincial laws of Canada.
- (5) If required by the secretary of the U.S. Department of Health and Human Services, establish a process to ensure the purity, chemical composition, and potency of imported products.
- (6) Ensure that imported prescription drugs will not be distributed, dispensed, or sold outside of the state.
- (7) Ensure that the program does not import a generic prescription drug that would violate U.S. patent laws.
- (8) Comply with the track and trace requirements provided in the federal Drug Security and Quality Act prior to allowing imported prescription drugs to come into possession of the wholesaler.
- (9) Ensure that the prescription drug supply and distribution chain is in compliance with present law and U.S. federal law after imported prescription drugs are in the possession of the wholesaler.
- (10) Ensure that the program is adequately financed through an efficient approach that does not jeopardize significant consumer savings.
- (11) Require publication of a wholesaler's acquisition cost of each imported prescription drug.
- (12) With respect to an imported prescription drug, require a participating pharmacy to disclose, upon request, the price of the drug that the participating pharmacy will charge to a patient who is not covered by a health plan or contract.
- (13) Include an audit function that complies with the provisions of proposed law.
- (14) Ensure that participation by any wholesaler, health insurer, healthcare provider, or consumer is voluntary.

Proposed law requires LDH to coordinate with the La. Board of Pharmacy to develop and periodically revise a pharmaceutical importation list. Provides that such list shall include prescription drugs that may be imported from Canada under present law and U.S. federal law

and that are expected to generate substantial savings for La. consumers. Stipulates that the list shall not include any prescription drug that may not be imported under present law or U.S. federal law.

Proposed law requires any health insurer participating in the program to provide LDH and the La. Board of Pharmacy or the board's designee with any information that LDH requests concerning the net per-unit cost of the health insurer's 20 highest-cost drugs and the quantity of those drugs dispensed by the health insurer to covered individuals. Stipulates that no such information shall contain any personally identifiable health information protected by federal law. Declares all such information to be proprietary information and not subject to disclosure under present law relative to public records, R.S. 44:1 et seq.

Proposed law requires LDH to review the pharmaceutical importation list every three months to ensure that the list continues to meet the requirements of proposed law.

Proposed law provides that the prescription drug importation program shall include audits of suppliers, importers, wholesalers, retail pharmacies, health insurers, and other persons who participate in the program as appropriate and necessary. Requires that such audit function incorporate a review of all of the following:

- (1) The methodology used to determine the prescription drugs with the greatest potential for savings.
- (2) The process used to ensure that Canadian suppliers are of high quality, high performance, and in full compliance with Canadian laws.
- (3) Methods used to ensure that prescription drugs imported under the program are not shipped, sold, or dispensed outside of La. once in the possession of the wholesaler or the wholesaler's contractors.
- (4) Processes used to ensure that imported prescription drugs are pure, unadulterated, potent, and safe.

Proposed law requires that the audit function verify all of the following:

- (1) That participating pharmacies and administering providers are not charging rates that jeopardize significant consumer savings to any consumer or participating health plan.
- (2) That the program is adequately financed to support all administrative functions while generating significant consumer savings.
- (3) That the program does not put consumers at a higher health and safety risk than if the program did not exist.
- (4) That the program continues to provide La. consumers with substantial savings on imported prescription drugs.
- (5) That the ability of any participating pharmacy to negotiate professional fees is not impeded.

Proposed law requires LDH to collaborate with the La. Department of Insurance to conduct audits in accordance with proposed law and to enforce the provisions of proposed law.

Proposed law provides that LDH shall commence to implement the prescription drug importation program only after all of the following have occurred:

- (1) The secretary of the U.S. Department of Health and Human Services certifies to the U.S. Congress that importation of Canadian prescription drugs will pose no

additional risk to public health and safety, and will result in a significant reduction in the cost of covered products to the American consumer.

- (2) The secretary of the U.S. Department of Health and Human Services approves the program.
- (3) All other requirements of present law and federal law for the importation of prescription drugs from Canada have been satisfied.
- (4) LDH has collected fees authorized by proposed law in an amount sufficient to cover the startup costs of the program.

Proposed law provides that LDH may do all of the following prior to commencing to implement the prescription drug importation program:

- (1) Design the program.
- (2) Negotiate with wholesalers in Canada and the U.S. regarding the potential implementation of the program.

Proposed law prohibits LDH from doing any of the following prior to commencing to implement the prescription drug importation program:

- (1) Authorizing the importation of any prescription drugs under proposed law.
- (2) Implementing any provisions of the program that would violate present law or U.S. federal law.

Proposed law requires LDH to implement the prescription drug importation program by contracting with any wholesale pharmacy that meets all of the following conditions:

- (1) Is licensed as a wholesale drug distributor in La.
- (2) Is compliant with all applicable program requirements provided in proposed law.
- (3) Agrees to any additional conditions of participation that the department may establish in accordance with the requirements of United States federal law and this Part.

Proposed law requires LDH to assess fees to entities that participate in the prescription drug importation program to cover all startup and implementation costs of the program. Stipulates that LDH shall utilize such fee amounts exclusively for implementation of the provisions of proposed law. Provides that such fees shall not exceed the amount necessary to cover the costs of implementing proposed law.

Proposed law authorizes the La. Department of Insurance to assess fees to insurers that participate in the prescription drug importation program in connection with proposed law relative to the following:

- (1) Actions in cases when health plan administration does not result in significant savings.
- (2) Conducting audits in collaboration with LDH.

Proposed law stipulates that the La. Department of Insurance shall utilize fee amounts collected in accordance with proposed law exclusively for the functions specified in proposed law. Provides that such fees shall not exceed the amount necessary to cover the costs to the department of administering its duties pursuant to proposed law.

Proposed law prohibits pharmaceutical manufacturers from doing any of the following:

- (1) Taking any action, by agreement, unilaterally, or otherwise, that has the effect of fixing or otherwise controlling the price that a pharmaceutical supplier, distributor, or dispenser charges or advertises for pharmaceuticals in the prescription drug importation program.
- (2) Discriminating against a pharmaceutical supplier, distributor, or dispenser based on whether the supplier, distributor, or dispenser participates in the prescription drug importation program.

Proposed law authorizes the La. attorney general to bring a civil action or seek an injunction against any person who violates proposed law relative to prohibited conduct by pharmaceutical manufacturers, and to seek any remedy available for violations of state antitrust law.

Proposed law provides that for each drug with an annual wholesale acquisition cost of \$10,000 or more, a pharmaceutical manufacturer shall submit a report to LDH if a price increase for that drug will result in an increase in the wholesale acquisition cost that is equal to either of the following:

- (1) At least 7.5% over a period of 12 months.
- (2) At least 18% over a period of 36 months.

Proposed law requires pharmaceutical manufacturers subject to the reporting requirement provided in proposed law to submit their reports to LDH no later than 30 days before the day on which the price increase takes effect. Requires that each report include all of the following information:

- (1) The increase in the cost of the drug, expressed as a percentage increase based on the price of the drug before the cost increase.
- (2) A justification for each price increase.
- (3) The date on which each price increase takes effect.
- (4) The total profit derived from sales of the drug, expressed in total dollars and as a percentage of the pharmaceutical manufacturer's total profits for that calendar year.
- (5) The total expenditures of the pharmaceutical manufacturer on materials and manufacturing for the drug.
- (6) The total research and development costs paid by the pharmaceutical manufacturer for the development and production of the drug.
- (7) The total administrative, marketing, and advertising costs for the drug.
- (8) Any costs associated with direct-to-consumer coupons and patient assistance programs for the drug.

Proposed law requires LDH to publish information on drug price increases submitted by pharmaceutical manufacturers pursuant to proposed law at least once in every three month period and in a manner that allows the information to be identified separately for each drug. Stipulates that in doing so, LDH shall not disclose any information deemed to be a trade secret under present law.

(Adds R.S. 40:2255.21-2255.30)