
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)