Rep. Muscatel, Graf. 12
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2019-0908h
01/04

Amendment to HB 703-FN

Amend RSA 318:67 and RSA 318:68 as inserted by section 1 of the bill by replacing them with the following:

New High-Cost Prescription Drugs

318:67 Definitions. In this subdivision:

I. "Department" means the insurance department.

II. “Manufacturer” means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, whether directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs. The term shall not include a wholesale distributor of prescription drugs, a retailer, or a pharmacist licensed under the board.

III. “Prescription drug” means a drug defined in 21 U.S.C. section 321.

318:68 Notice Required.

I. A prescription drug manufacturer shall notify the department in writing if it is introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program. The manufacturer shall provide the written notice within 3 calendar days following the release of the drug in the commercial market. A manufacturer may make the notification pending approval by the United States Food and Drug Administration (FDA) if commercial availability is expected within 3 calendar days following the approval.

II. No later than 30 calendar days following notification required under paragraph I, the manufacturer shall provide the following information to the department in a format that the department prescribes:

(a) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally.

(b) The estimated volume of patients who may be prescribed the drug.

(c) Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval.

(d) The date and price of acquisition if the drug was not developed by the manufacturer.

III. The manufacturer may limit the information required under paragraph II to that which

is otherwise in the public domain or publicly available.

IV. The department shall publish on its Internet website, at least quarterly, the information reported to it under this section. The information shall be published in a manner that identifies the information that is disclosed on a per-drug basis and shall not be aggregated in a manner that would not allow identification of the drug.

V. The attorney general may bring a civil action for injunctive relief, costs, and attorney's fees and impose on a manufacturer that fails to provide the information required under paragraph II, a civil penalty of not more than $1,000 per day for every day after the notification period described in paragraph II that the required information is not reported. In any action brought under this section, the attorney general shall have the same authority to investigate and obtain remedies as if the action were brought under the RSA 358-A.

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AMENDED ANALYSIS

This bill requires prescription drug manufacturers to provide certain notice to the insurance department if they are introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program.