STATE OF NEW YORK

6103

2019-2020 Regular Sessions

IN SENATE

May 16, 2019

Introduced by Sen. CARLUCCI -- read twice and ordered printed, and when printed to be committed to the Committee on Health

AN ACT to amend the public health law, in relation to advertising by drug manufacturers and the disclosure of clinical trials

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. The public health law is amended by adding a new section 277-a to read as follows:

§ 277-a. Prohibitions and required disclosures; prescription drug advertising. 1. Definitions. As used in this section, unless the context otherwise indicates, the following terms shall have the following meanings:

(a) "Clinical trial" means a clinical investigation as defined by the federal Food and Drug Administration that involves any trial to test the safety or efficacy of a drug or biological product with one or more human subjects and that is intended to be submitted to, or held for inspection by, the federal Food and Drug Administration as part of an application for a research or marketing permit.

(b) "Manufacturer of prescription drugs" or "manufacturer" means a manufacturer of prescription drugs or biological products or an affiliate of the manufacturer or a labeler that receives prescription drugs or biological products from a manufacturer or wholesaler and repackages those drugs or biological products for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 2027.20 (1999).

(c) "Regulated advertisement" means the presentation to the general public of a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs that is:

(i) Broadcast on television or radio from a station that is physically located in the state;

(ii) Broadcast over the Internet from a location in the state; or

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

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(iii) Printed in magazines or newspapers that are printed, distributed or sold in the state.

2. Regulated advertisement requirement. Beginning October fifteenth, two thousand twenty, a manufacturer may not present or cause to be presented in the state a regulated advertisement, unless such advertisement meets the requirements concerning misbranded drugs and devices and prescription drug advertising of federal law and regulations under 21 United States Code, Sections 331 and 352(n) and 21 Code of Federal Regulations, Part 202 and state rules and regulations.

3. Disclosure of clinical trials of prescription drugs. Beginning October fifteenth, two thousand twenty, a manufacturer or labeler of prescription drugs that is required to report marketing costs for prescription drugs shall post, with regard to such prescription drugs, on the publicly accessible Internet website of the federal National Institutes of Health or its successor agency or another publicly accessible website the following information concerning any clinical trial that the manufacturer conducted or sponsored on or after October fifteenth, two thousand nineteen:

(a) The name of the entity that conducted or is conducting the clinical trial;

(b) A summary of the purpose of the clinical trial;

(c) The dates during which the trial is taking or has taken place; and

(d) Information concerning the results of the clinical trial, including potential or actual adverse effects of the drug.

In order to satisfy the requirements of this subdivision, the publicly accessible website and manner of posting shall be acceptable to the department.

4. Fees. Beginning April first, two thousand twenty-one, each manufacturer of prescription drugs that are provided to persons through a state public health plan as defined in subdivision eleven of section two hundred seventy of this article shall pay a fee of one thousand dollars per calendar year to the department. Fees collected under this subdivision shall be used to cover the cost of overseeing implementation of this section, including but not limited to maintaining links to publicly accessible websites to which manufacturers are posting clinical trial information under subdivision three of this section and other relevant sites, assessing whether and the extent to which New York residents have been harmed by the use of a particular drug and undertaking the public education initiative under subdivision five of this section. Revenues received under this subdivision must be deposited into a general fund to be used for the purposes of this section.

5. Public education initiative. The department shall undertake a public education initiative to inform residents of the state about clinical trials and drug safety information.

6. Penalties. Each day a manufacturer is in violation of this chapter is considered a separate violation. Such manufacturer shall be subject to the penalties prescribed in section twelve of this chapter.

§ 2. Report. By January 15, 2021, the department of health shall report to the Legislature matters on the completeness and ease of public access to information provided by the drug manufacturers and the need for further action or legislation.

§ 3. This act shall take effect on the one hundred eightieth day after it shall have become a law. Effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date are authorized to be made and completed on or before such effective date.