

# 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:

1 Section 1. The public health law is amended by adding a new section  
2 277-a to read as follows:

3 § 277-a. Prohibitions and required disclosures; prescription drug  
4 advertising. 1. Definitions. As used in this section, unless the context  
5 otherwise indicates, the following terms shall have the following mean-  
6 ings:

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

13 (b) "Manufacturer of prescription drugs" or "manufacturer" means a  
14 manufacturer of prescription drugs or biological products or an affil-  
15 iate of the manufacturer or a labeler that receives prescription drugs  
16 or biological products from a manufacturer or wholesaler and repackages  
17 those drugs or biological products for later retail sale and that has a  
18 labeler code from the federal Food and Drug Administration under 21 Code  
19 of Federal Regulations, 2027.20 (1999).

20 (c) "Regulated advertisement" means the presentation to the general  
21 public of a commercial message regarding a prescription drug or biolog-  
22 ical product by a manufacturer of prescription drugs that is:

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

25 (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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1 (iii) Printed in magazines or newspapers that are printed, distributed  
2 or sold in the state.

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

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

19 (a) The name of the entity that conducted or is conducting the clin-  
20 ical trial;

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

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

23 (d) Information concerning the results of the clinical trial, includ-  
24 ing potential or actual adverse effects of the drug.

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

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

42 5. Public education initiative. The department shall undertake a  
43 public education initiative to inform residents of the state about clin-  
44 ical trials and drug safety information.

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

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

52 § 3. This act shall take effect on the one hundred eightieth day after  
53 it shall have become a law. Effective immediately, the addition, amend-  
54 ment and/or repeal of any rule or regulation necessary for the implemen-  
55 tation of this act on its effective date are authorized to be made and  
56 completed on or before such effective date.