

3270

2013-2014 Regular Sessions

I N   S E N A T E

January 31, 2013

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Introduced by Sen. KRUEGER -- 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 requiring the manufacturer or labeler of each prescription drug to annually report the marketing costs of such drug to the department of health and to amend the tax law, in relation to eliminating deductibility for certain expenses incurred in the advertising of prescription drugs

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

1     Section 1. Legislative intent. The legislature hereby finds and  
2 declares that the price of prescription drugs in this state and across  
3 the nation has been increasing at an alarming rate over the past decade.  
4 Prescription drug costs are increasing at a faster rate than any other  
5 component of health care and are driving the increase in overall health  
6 care cost. As is apparent by the ubiquitous nature of the marketing and  
7 public information campaigns relating to prescription drugs, pharmaceutical  
8 manufacturers put a great deal of resources into marketing their  
9 products. This has been especially true since the 1997 relaxation of  
10 federal laws relating to prescription drug advertising. It is in the  
11 interest of assisting this state in its role as a purchaser of  
12 prescription drugs and administrator of prescription drug programs, to  
13 enable the state to determine the scope of prescription drug marketing  
14 costs and their effect on the cost, utilization and delivery of health  
15 care services, and thus further the role of this state as guardian of  
16 the public interest.

17     S 2. Section 206 of the public health law is amended by adding a new  
18 subdivision 29 to read as follows:

19     29. THE COMMISSIONER IS AUTHORIZED AND DIRECTED TO REQUIRE MANUFACTUR-  
20 ERS OR LABELERS OF PRESCRIPTION DRUGS, WHICH DISPENSE SUCH DRUGS IN THIS  
21 STATE AND WHICH EMPLOY, DIRECT OR UTILIZE MARKETING REPRESENTATIVES IN

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

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1 THE STATE, TO REPORT THE MARKETING COSTS OF EACH OF ITS PRESCRIPTION  
2 DRUGS DISPENSED IN THIS STATE.

3 (A) DEFINITIONS. AS USED IN THIS SUBDIVISION, UNLESS THE CONTEXT  
4 CLEARLY INDICATES OTHERWISE, THE FOLLOWING TERMS SHALL HAVE THE FOLLOW-  
5 ING MEANINGS:

6 (I) "LABELER" MEANS ANY PERSON OR ENTITY, HAVING A LABELER CODE FROM  
7 THE FEDERAL FOOD AND DRUG ADMINISTRATION, THAT RECEIVES A PRESCRIPTION  
8 DRUG FROM THE MANUFACTURER OR A WHOLESALER OF SUCH DRUG, AND REPACKAGES  
9 SUCH DRUG TO BE DISPENSED IN THIS STATE.

10 (II) "MANUFACTURER" MEANS A MANUFACTURER OF PRESCRIPTION DRUGS  
11 DISPENSED IN THIS STATE, AND SHALL INCLUDE THE SUBSIDIARY OR AFFILIATE  
12 OF SUCH MANUFACTURER.

13 (III) "MARKETING" MEANS ADVERTISING AND PROMOTIONAL ACTIVITIES FOR  
14 PRESCRIPTION DRUGS DISPENSED IN THIS STATE INCLUDING, BUT NOT LIMITED  
15 TO, THOSE ACTIVITIES DESCRIBED IN PARAGRAPH (B) OF THIS SUBDIVISION.

16 (B) MANNER OF REPORTING. ON OR BEFORE JULY FIRST EACH YEAR EVERY  
17 MANUFACTURER AND LABELER SHALL FILE A REPORT WITH THE DEPARTMENT ON ITS  
18 MARKETING ACTIVITIES CONDUCTED IN THIS STATE. SUCH REPORT SHALL BE  
19 SUBMITTED IN SUCH FORM AND MANNER, AND INCLUDE THE PAYMENT OF SUCH A FEE  
20 AS SHALL BE DETERMINED BY THE COMMISSIONER. EACH SUCH REPORT SHALL  
21 INCLUDE THE VALUE, NATURE, PURPOSE AND RECIPIENT OF MARKETING EXPENSES  
22 INCLUDING, BUT NOT LIMITED TO:

23 (I) ALL EXPENSES ASSOCIATED WITH ADVERTISING, MARKETING AND DIRECT  
24 PROMOTION OF PRESCRIPTION DRUGS THROUGH RADIO, TELEVISION, MAGAZINES,  
25 NEWSPAPERS, DIRECT MAIL AND TELEPHONE COMMUNICATIONS AS THEY PERTAIN TO  
26 RESIDENTS OF THIS STATE;

27 (II) WITH REGARD TO ALL PROVIDERS OF HEALTHCARE SERVICES REGULATED BY  
28 THE DEPARTMENT UNDER THE PROVISIONS OF ARTICLE TWENTY-EIGHT, THIRTY-SIX  
29 OR FORTY-FOUR OF THIS CHAPTER, INCLUDING HEALTH MAINTENANCE ORGANIZA-  
30 TIONS ESTABLISHED PURSUANT TO ARTICLE FORTY-THREE OF THE INSURANCE LAW,  
31 THE FOLLOWING INFORMATION:

32 (A) ALL EXPENSES ASSOCIATED WITH EDUCATIONAL OR INFORMATIONAL  
33 PROGRAMS, MATERIALS AND SEMINARS, AND REMUNERATION FOR PROMOTING OR  
34 PARTICIPATING IN EDUCATIONAL OR INFORMATIONAL SESSIONS, REGARDLESS OF  
35 WHETHER THE MANUFACTURER OR LABELER PROVIDES THE EDUCATIONAL OR INFORMA-  
36 TIONAL SESSIONS OR MATERIALS,

37 (B) ALL EXPENSES ASSOCIATED WITH FOOD, ENTERTAINMENT AND GIFTS VALUED  
38 AT MORE THAN SEVENTY-FIVE DOLLARS, AND ANYTHING PROVIDED TO A HEALTH  
39 CARE PROFESSIONAL FOR LESS THAN MARKET VALUE,

40 (C) ALL EXPENSES ASSOCIATED WITH TRIPS AND TRAVEL, AND

41 (D) ALL EXPENSES ASSOCIATED WITH PRODUCT SAMPLES, EXCEPT FOR SAMPLES  
42 THAT WILL BE DISTRIBUTED FREE OF CHARGE TO PATIENTS; AND

43 (III) THE AGGREGATE COST OF ALL EMPLOYEES AND CONTRACTORS OF THE  
44 MANUFACTURER OR LABELER WHO DIRECTLY OR INDIRECTLY ENGAGE IN THE ADVER-  
45 TISING OR PROMOTIONAL ACTIVITIES LISTED IN SUBPARAGRAPHS (I) AND (II) OF  
46 THIS PARAGRAPH, INCLUDING ALL FORMS OF PAYMENT TO SUCH EMPLOYEES AND  
47 CONTRACTORS. THE COST REPORTED PURSUANT TO THIS SUBPARAGRAPH SHALL  
48 REFLECT ONLY THAT PORTION OF PAYMENT TO EMPLOYEES AND CONTRACTORS THAT  
49 PERTAINS TO ACTIVITIES WITHIN THIS STATE OR TO RECIPIENTS OF THE ADVER-  
50 TISING OR PROMOTIONAL ACTIVITIES WHO ARE RESIDENTS OF OR ARE EMPLOYED IN  
51 THIS STATE.

52 (C) EXCEPTIONS. THE FOLLOWING MARKETING EXPENSES SHALL NOT BE SUBJECT  
53 TO THE REPORTING REQUIREMENTS OF THIS SUBDIVISION:

54 (I) EXPENSES OF SEVENTY-FIVE DOLLARS OR LESS;

(II) REASONABLE COMPENSATION AND REIMBURSEMENT FOR EXPENSES IN CONNECTION WITH A BONA FIDE CLINICAL TRIAL OF A NEW VACCINE, THERAPY OR TREATMENT; AND

(III) SCHOLARSHIPS AND REIMBURSEMENT OF EXPENSES FOR ATTENDING A SIGNIFICANT EDUCATIONAL, SCIENTIFIC OR POLICY-MAKING CONFERENCE OR SEMINAR OF A NATIONAL, REGIONAL OR SPECIALTY MEDICAL OR OTHER PROFESSIONAL ASSOCIATION IF THE RECIPIENT OF THE SCHOLARSHIP IS CHOSEN BY THE ASSOCIATION SPONSORING THE CONFERENCE OR SEMINAR.

(D) DEPARTMENT REPORTS. ANNUALLY ON OR BEFORE NOVEMBER THIRTIETH, THE DEPARTMENT SHALL SUBMIT A REPORT, PROVIDING INFORMATION IN AGGREGATE FORM, ON PRESCRIPTION DRUG MARKETING EXPENSES TO THE GOVERNOR, TEMPORARY PRESIDENT OF THE SENATE AND SPEAKER OF THE ASSEMBLY. ON OR BEFORE JANUARY FIRST, TWO THOUSAND FOURTEEN AND EVERY TWO YEARS THEREAFTER, THE DEPARTMENT SHALL PROVIDE A REPORT TO THE GOVERNOR, TEMPORARY PRESIDENT OF THE SENATE AND SPEAKER OF THE ASSEMBLY, PROVIDING INFORMATION IN AGGREGATE FORM, CONTAINING AN ANALYSIS OF THE DATA SUBMITTED TO THE DEPARTMENT, INCLUDING THE SCOPE OF PRESCRIPTION DRUG MARKETING ACTIVITIES AND EXPENSES AND THEIR EFFECT ON THE COST, UTILIZATION AND DELIVERY OF HEALTH CARE SERVICES AND ANY RECOMMENDATIONS WITH REGARD TO MARKETING ACTIVITIES OF PRESCRIPTION DRUG MANUFACTURERS AND LABELERS.

(E) CONFIDENTIALITY; PUBLIC INFORMATION. NOTWITHSTANDING ANY PROVISION OF LAW TO THE CONTRARY, ALL INFORMATION SUBMITTED TO THE DEPARTMENT PURSUANT TO THIS SUBDIVISION SHALL BE CONFIDENTIAL AND NOT A PUBLIC RECORD AS DEFINED IN SECTION EIGHTY-SIX OF THE PUBLIC OFFICERS LAW. DATA COMPILED IN AGGREGATE FORM BY THE DEPARTMENT FOR THE PURPOSES OF REPORTING REQUIRED BY THIS SUBDIVISION SHALL BE A PUBLIC RECORD AS DEFINED IN SECTION EIGHTY-SIX OF THE PUBLIC OFFICERS LAW, AS LONG AS IT DOES NOT REVEAL TRADE INFORMATION THAT IS PROTECTED BY STATE OR FEDERAL LAW.

(F) VIOLATIONS. ANY PERSON WHO VIOLATES ANY PROVISION OF THIS SUBDIVISION SHALL BE LIABLE TO THE PEOPLE OF THE STATE FOR A CIVIL PENALTY OF TEN THOUSAND DOLLARS, PLUS COURT COSTS AND ATTORNEYS' FEES, WHICH SHALL BE ENFORCED PURSUANT TO TITLE TWO OF THIS ARTICLE.

(G) RULES. ANY AND ALL RULES AND REGULATIONS NECESSARY TO IMPLEMENT THE PROVISIONS OF THIS SUBDIVISION SHALL BE PROMULGATED BY THE COMMISSIONER.

S 3. Paragraph (b) of subdivision 9 of section 208 of the tax law is amended by adding a new subparagraph 21 to read as follows:

(21) EXPENSES INCURRED BY A MANUFACTURER OR DISTRIBUTOR OF A DRUG, THE DISPENSING OF WHICH TO A CONSUMER WITHOUT A PRESCRIPTION IS PROHIBITED BY EITHER FEDERAL OR STATE LAW, FOR THE ADVERTISING OF SUCH DRUG TO CONSUMERS.

S 4. Subsection (b) of section 612 of the tax law is amended by adding a new paragraph 40 to read as follows:

(40) EXPENSES INCURRED BY A MANUFACTURER OR DISTRIBUTOR OF A DRUG, THE DISPENSING OF WHICH TO A CONSUMER WITHOUT A PRESCRIPTION IS PROHIBITED BY EITHER FEDERAL OR STATE LAW, FOR THE ADVERTISING OF SUCH DRUG TO CONSUMERS.

S 5. This act shall take effect on the one hundred eightieth day after it shall have become a law; provided that effective immediately, any rules and regulations necessary to implement the provisions of this act on its effective date are authorized to be made on or before such effective date and provided further that the provisions of sections three and four of this act shall take effect immediately and shall apply to taxable years beginning on or after January first of the year in which it shall have become a law.