S T A T E O F N E W Y O R K

1636

2011-2012 Regular Sessions

I N A S S E M B L Y

January 11, 2011

Introduced by M. of A. COLTON -- read once and referred 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

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

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

S 2. Section 206 of the public health law is amended by adding a new subdivision 28 to read as follows:

28. THE COMMISSIONER IS AUTHORIZED AND DIRECTED TO REQUIRE MANUFACTURERS OR LABELERS OF PRESCRIPTION DRUGS, WHICH DISPENSE SUCH DRUGS IN THIS STATE AND WHICH EMPLOY, DIRECT OR UTILIZE MARKETING REPRESENTATIVES IN THE STATE, TO REPORT THE MARKETING COSTS OF EACH OF ITS PRESCRIPTION DRUGS DISPENSED IN THIS STATE.

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

LBD02419-01-1

(A) DEFINITIONS. AS USED IN THIS SUBDIVISION, UNLESS THE CONTEXT CLEARLY INDICATES OTHERWISE, THE FOLLOWING TERMS SHALL HAVE THE FOLLOWING MEANINGS:

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

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

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

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

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

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

(A) ALL EXPENSES ASSOCIATED WITH EDUCATIONAL OR INFORMATIONAL PROGRAMS, MATERIALS AND SEMINARS, AND REMUNERATION FOR PROMOTING OR PARTICIPATING IN EDUCATIONAL OR INFORMATIONAL SESSIONS, REGARDLESS OF WHETHER THE MANUFACTURER OR LABELER PROVIDES THE EDUCATIONAL OR INFORMATIONAL SESSIONS OR MATERIALS,

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

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

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

(III) THE AGGREGATE COST OF ALL EMPLOYEES AND CONTRACTORS OF THE MANUFACTURER OR LABELER WHO DIRECTLY OR INDIRECTLY ENGAGE IN THE ADVERTISING OR PROMOTIONAL ACTIVITIES LISTED IN SUBPARAGRAPHS (I) AND (II) OF THIS PARAGRAPH, INCLUDING ALL FORMS OF PAYMENT TO SUCH EMPLOYEES AND CONTRACTORS. THE COST REPORTED PURSUANT TO THIS SUBPARAGRAPH SHALL REFLECT ONLY THAT PORTION OF PAYMENT TO EMPLOYEES AND CONTRACTORS THAT PERTAINS TO ACTIVITIES WITHIN THIS STATE OR TO RECIPIENTS OF THE ADVERTISING OR PROMOTIONAL ACTIVITIES WHO ARE RESIDENTS OF OR ARE EMPLOYED IN THIS STATE.

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

(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 TWELVE 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. This act shall take effect on the one hundred eightieth day after it shall have become a law. 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.