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

8265

2015-2016 Regular Sessions

I N A S S E M B L Y

June 16, 2015

Introduced by M. of A. BLAKE -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to establishing the pharmaceutical cost transparency act of 2015

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

Section 1. This act shall be cited and may be known as the "pharmaceutical cost transparency act of 2015".

S 2. The public health law is amended by adding a new section 278-a to read as follows:

S 278-A. PRESCRIPTION DRUG COST TRANSPARENCY. 1. LEGISLATIVE INTENT. A. IT IS THE INTENT OF THE LEGISLATURE TO MAKE INFORMATION AVAILABLE TO THE PUBLIC ABOUT THE COST OF ULTRA-HIGH-PRICED PHARMACEUTICALS, IN ORDER TO MAKE PHARMACEUTICAL PRICING AS TRANSPARENT AS THE PRICING IN OTHER SECTORS OF THE HEALTH CARE INDUSTRY.

B. THE LEGISLATURE FINDS THAT THERE SHOULD BE ANNUAL COST REPORTING ON THE MOST EXPENSIVE DRUGS THAT WOULD BE OF USE TO POLICYMAKERS, GOVERNMENT AGENCIES, AND OTHERS TO UNDERSTAND COSTS FOR THESE IMPORTANT PRODUCTS.

2. EACH MANUFACTURER OF A PRESCRIPTION DRUG, MADE AVAILABLE IN NEW YORK, THAT HAS A WHOLESALE ACQUISITION COST OF TEN THOUSAND DOLLARS ($10,000) OR MORE ANNUALLY OR PER COURSE OF TREATMENT, SHALL FILE A REPORT PURSUANT TO THIS SECTION ON THE COSTS FOR EACH QUALIFYING DRUG.

3. THE REPORT REQUIRED PURSUANT TO SUBDIVISION TWO OF THIS SECTION SHALL INCLUDE ALL OF THE FOLLOWING FOR EACH DRUG:

A. THE TOTAL COSTS FOR THE PRODUCTION OF THE DRUG, INCLUDING ALL OF THE FOLLOWING:

(I) THE TOTAL RESEARCH AND DEVELOPMENT COSTS PAID BY THE MANUFACTURER, AND SEPARATELY, THE TOTAL RESEARCH AND DEVELOPMENT COSTS PAID BY ANY PREDECESSOR IN THE DEVELOPMENT OF THE DRUG.

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

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(II) THE TOTAL COSTS OF CLINICAL TRIALS AND OTHER REGULATORY COSTS PAID BY THE MANUFACTURER, AND SEPARATELY, THE TOTAL COSTS OF CLINICAL TRIALS AND OTHER REGULATORY COSTS PAID BY ANY PREDECESSOR IN THE DEVELOPMENT OF THE DRUG.

(III) THE TOTAL COSTS FOR MATERIALS, MANUFACTURING, AND ADMINISTRATION ATTRIBUTABLE TO THE DRUG.

(IV) THE TOTAL COSTS PAID BY ANY ENTITY OTHER THAN THE MANUFACTURER OR PREDECESSOR FOR RESEARCH AND DEVELOPMENT, INCLUDING ANY AMOUNT FROM FEDERAL, STATE, OR OTHER GOVERNMENTAL PROGRAMS OR ANY FORM OF SUBSIDIES, GRANTS, OR OTHER SUPPORT.

(V) ANY OTHER COSTS TO ACQUIRE THE DRUG, INCLUDING COSTS FOR THE PURCHASE OF PATENTS, LICENSING OR ACQUISITION OF ANY CORPORATE ENTITY OWNING ANY RIGHTS TO THE DRUG WHILE IN DEVELOPMENT, OR ALL OF THESE.

(VI) THE TOTAL MARKETING AND ADVERTISING COSTS FOR THE PROMOTION OF THE DRUG DIRECTLY TO CONSUMERS, INCLUDING, BUT NOT LIMITED TO, COSTS ASSOCIATED WITH DIRECT TO CONSUMER COUPONS AND AMOUNT REDEEMED, TOTAL MARKETING AND ADVERTISING COSTS FOR PROMOTION OF THE DRUG DIRECTLY OR INDIRECTLY TO PRESCRIBERS, AND ANY OTHER ADVERTISING FOR THE DRUG.

B. A CUMULATIVE ANNUAL HISTORY OF AVERAGE WHOLESALE PRICE AND WHOLESALE ACQUISITION COST INCREASES FOR THE DRUG (EXPRESSED AS PRECENTAGES), INCLUDING THE MONTHS EACH INCREASE IN EACH CATEGORY, AVERAGE WHOLSALE PRICE AND WHOLESALE ACQUISITION COST, TOOK EFFECT.

C. THE TOTAL PROFIT ATTRIBUTABLE TO THE DRUG AS REPRESENTED IN TOTAL DOLLARS AND REPRESENTED AS A PERCENTAGE OF THE TOTAL COMPANY PROFITS THAT WERE DERIVED FROM THE SALE OF THE DRUG.

D. THE TOTAL AMOUNT OF FINANCIAL ASSISTANCE THE MANUFACTURER HAS PROVIDED THROUGH PATIENT PRESCRIPTION ASSISTANCE PROGRAMS, IF AVAILABLE.

4. ALL OF THE INFORMATION IN SUBDIVISION THREE OF THIS SECTION SHALL BE ITEMIZED AND DOCUMENTED BY THE MANUFACTURER, AND AUDITED BY A FULLY INDEPENDENT THIRD-PARTY AUDITOR PRIOR TO FILING.

5. THE INFORMATION REQUIRED BY THIS SECTION SHALL BE FILED ANNUALLY WITH THE DEPARTMENT ON A FORM PRESCRIBED BY THE DEPARTMENT AND SHALL BE SUBMITTED NO LATER THAN MAY FIRST OF EACH YEAR.

6. NOTWITHSTANDING ANY OTHER SECTION OF LAW TO THE CONTRARY, THE DEPARTMENT SHALL ISSUE A REPORT ANNUALLY TO THE LEGISLATURE OUTLINING THE INFORMATION SUBMITTED PURSUANT TO THIS SECTION, AND THE DEPARTMENT SHALL POST THE REPORT PUBLICLY ON ITS WEBSITE.

7. THE DEPARTMENT SHALL CONVENE AN ADVISORY PANEL TO DEVELOP THE FORM REQUIRED BY THIS SECTION. THE PANEL SHALL INCLUDE, BUT NEED NOT BE LIMITED TO, REPRESENTATIVES FROM THE PHARMACEUTICAL INDUSTRY, HEALTH CARE SERVICE PLANS AND INSURERS, PHARMACY BENEFIT MANAGERS, GOVERNMENTAL AGENCIES, CONSUMER ADVOCATES, AND PHYSICIANS.

S 2. This act shall take effect immediately.