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

10026

I N A S S E M B L Y

May 6, 2016

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

AN ACT to amend the public health law, in relation to prescription drug cost transparency

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

Section 1. Legislative intent. It is the intent of the legislature to make information available to the public about the cost and utilization of pharmaceutical drugs. To fulfill this goal, the legislature finds that there should be annual reporting of drug costs and use that would be of use by policymakers, government agencies and others to understand pharmacy cost trends.

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. EACH MANUFACTURER OF A BRAND AND GENERIC MEDICATION THAT IS MADE AVAILABLE IN NEW YORK STATE SHALL FILE A REPORT ON PHARMACEUTICAL COSTS AS OUTLINED IN THIS SECTION.

2. THE MANUFACTURER OF A PHARMACEUTICAL DRUG THAT HAS A WHOLESALE ACQUISITION COST OF ONE THOUSAND DOLLARS FOR A THIRTY DAY SUPPLY SHALL FILE A REPORT PURSUANT TO THIS SECTION ON THE COSTS FOR EACH QUALIFYING DRUG. WHOLESALE ACQUISITION COST SHALL HAVE THE SAME MEANING AS FOUND IN SUBSECTION (C) OF 42 U.S. CODE SECTION 1395W-3A.

3. THE MANUFACTURER OF A PHARMACEUTICAL DRUG WHICH DURING A THREE MONTH PERIOD HAS A CUMULATIVE PRICE INCREASE OF THREE TIMES THE CONSUMER PRICE INDEX SHALL FILE A REPORT PURSUANT TO THIS SECTION ON THE COSTS FOR EACH QUALIFYING DRUG.

4. THE REPORT SHALL INCLUDE THE FOLLOWING FOR EACH DRUG DESCRIBED IN SUBDIVISIONS TWO AND THREE OF THIS SUBDIVISION:

(A) THE TOTAL COSTS FOR THE PRODUCTION OF THE DRUG INCLUDING ALL OF THE FOLLOWING:

(1) THE TOTAL RESEARCH AND DEVELOPMENT COSTS INCLUDING BUT NOT LIMITED TO:

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

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(I) THE TOTAL COSTS OF ANY STUDY DRUG MANUFACTURED DURING THIS REPORTING PERIOD IN SUPPORT OF THE U.S. FOOD AND DRUG ADMINISTRATION APPROVED USE OF THE DRUG;

(II) THE TOTAL COSTS OF ANY PRECLINICAL STUDIES CONDUCTED DURING THIS REPORTING PERIOD;

(III) THE TOTAL COSTS OF ANY CLINICAL TRIALS CONDUCTED DURING THIS REPORTING PERIOD;

(IV) THE TOTAL COSTS ASSOCIATED WITH THE PREPARATION AND SUBMISSION OF ANY REGULATORY DOCUMENTS SUBMITTED TO THE U.S. FOOD AND DRUG ADMINISTRATION DURING THIS REPORTING PERIOD;

(V) THE TOTAL COSTS OF POST APPROVAL CLINICAL STUDIES MANDATED BY THE U.S. FOOD AND DRUG ADMINISTRATION DURING THIS REPORTING PERIOD; AND

(VI) THE TOTAL COSTS OF POST APPROVAL STUDIES EARMARKED FOR PUBLICATION USING EXTERNAL PROVIDERS OF DATA DURING THIS REPORTING PERIOD;

(2) THE TOTAL COSTS FOR MATERIALS, MANUFACTURING AND ADMINISTRATION ATTRIBUTABLE TO THE DRUG FOR THIS REPORTING PERIOD;

(3) THE TOTAL COSTS PAID BY ANY ENTITY OTHER THAN THE MANUFACTURER OR PREDECESSOR FOR RESEARCH AND DEVELOPMENT, INCLUDING AN ITEMIZED LIST OF ANY AMOUNT FROM FEDERAL, STATE, OR OTHER GOVERNMENTAL PROGRAMS OR ANY FORM OF SUBSIDIES, GRANTS, OR OTHER SUPPORT FOR THIS REPORTING PERIOD; AND

(4) 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.

(B) THE TOTAL ADMINISTRATIVE COSTS FOR THE PROMOTION OF THE DRUG, INCLUDING BUT NOT LIMITED TO:

(I) MARKETING AND ADVERTISING COSTS;

(II) DIRECT TO CONSUMER ADVERTISING COSTS;

(III) PRESCRIBER EDUCATION COSTS;

(IV) PROFESSIONAL EDUCATION COSTS;

(V) LOBBYING COSTS; AND

(VI) FINANCIAL ASSISTANCE TO PATIENT GROUPS, DISEASE ASSOCIATIONS, OR OTHER CONSUMER ORGANIZATIONS.

(C) THE TOTAL PROFIT AS REPRESENTED IN TOTAL DOLLARS AND A PERCENTAGE OF TOTAL COMPANY PROFIT DERIVED FROM THE SALE OF THE DRUG.

(D) THE TOTAL AMOUNT OF FINANCIAL ASSISTANCE THE MANUFACTURER HAS PROVIDED THROUGH PATIENT PRESCRIPTION ASSISTANCE PROGRAMS IF SUCH PROGRAMS ARE AVAILABLE, INCLUDING BUT NOT LIMITED TO:

(I) COSTS ASSOCIATED WITH DIRECT TO CONSUMER COUPONS AND AMOUNT REDEEMED;

(II) COSTS ASSOCIATED WITH COPAYMENT ASSISTANCE PROGRAMS; AND

(III) COSTS ASSOCIATED WITH SAMPLE DOSES, TRIAL DOSES, OR WHERE THE DRUG PRODUCT IS PROVIDED BUT NOT SOLD.

(E) THE WHOLESALE ACQUISITION COST OF THE DRUG AS PUBLICLY REPORTED FOR EACH DRUG, INCLUDING A FIVE-YEAR HISTORY OF WHOLESALE ACQUISITION COST PRICE INCREASES, EXPRESSED AS A PERCENTAGE, AND THE MONTH OR MONTHS EACH INCREASE TOOK EFFECT AND ANY EXPLANATION FOR THE PRICE INCREASE.

5. INFORMATION SHALL BE FILED WITH THE DEPARTMENT ANNUALLY, CONSISTENT WITH SUBDIVISIONS TWO AND THREE OF THIS SECTION, ON A FORM PRESCRIBED BY THE DEPARTMENT AND SHALL BE SUBMITTED NO LATER THAN MAY FIRST, TWO THOUSAND SEVENTEEN. SUCH INFORMATION SHALL BE UPDATED QUARTERLY.

6. THE DEPARTMENT SHALL ISSUE A REPORT OUTLINING THE INFORMATION SUBMITTED PURSUANT TO THIS SECTION BY DECEMBER THIRTY-FIRST, TWO THOUSAND SEVENTEEN AND ISSUE ADDENDUMS ON A QUARTERLY BASIS REFLECTING THE REQUIREMENTS OF PARAGRAPH (D) OF SUBDIVISION FOUR OF THIS SECTION TO THE

LEGISLATURE. SUCH INFORMATION SHALL BE MADE PUBLICLY AVAILABLE ON THE DEPARTMENT'S WEBSITE.

7. THE DEPARTMENT SHALL CONVENE AN ADVISORY WORKGROUP TO DEVELOP THE FORMS REQUIRED BY THIS SECTION. THE WORKGROUP SHALL INCLUDE, BUT IS NOT LIMITED TO, REPRESENTATIVES FROM THE PHARMACEUTICAL INDUSTRY, HEALTH INSURANCE PLANS, PHARMACY BENEFIT MANAGERS, GOVERNMENTAL AGENCIES, CONSUMER ADVOCATES, AND PHYSICIANS.

8. THE DEPARTMENT SHALL MAINTAIN THE CONFIDENTIALITY OF ANY INFORMATION SUBMITTED PURSUANT TO THIS SECTION THAT THE COMMISSIONER DEEMS TO BE CONFIDENTIAL, PROPRIETARY INFORMATION OF THE PRESCRIPTION DRUG MANUFACTURER AND THE DISCLOSURE OF WHICH WOULD CAUSE THE MANUFACTURER COMPETITIVE HARM. THIS CONFIDENTIAL PROPRIETARY INFORMATION SHALL NOT BE MADE PUBLIC BY THE DEPARTMENT AND IS EXEMPT FORM DISCLOSURE UNDER THE STATE FREEDOM OF INFORMATION LAW.

S 3. This act shall take effect immediately.