

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:

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

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

9 S 278-A. PRESCRIPTION DRUG COST TRANSPARENCY. 1. EACH MANUFACTURER OF
10 A BRAND AND GENERIC MEDICATION THAT IS MADE AVAILABLE IN NEW YORK STATE
11 SHALL FILE A REPORT ON PHARMACEUTICAL COSTS AS OUTLINED IN THIS SECTION.

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

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

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

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

25 (1) THE TOTAL RESEARCH AND DEVELOPMENT COSTS INCLUDING BUT NOT LIMITED
26 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 REPORT-
ING 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 ADMINIS-
TRATION 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 PUBLICA-
TION 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 THOU-
SAND 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 THOU-
SAND SEVENTEEN AND ISSUE ADDENDUMS ON A QUARTERLY BASIS REFLECTING THE
REQUIREMENTS OF PARAGRAPH (D) OF SUBDIVISION FOUR OF THIS SECTION TO THE

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

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

8 8. THE DEPARTMENT SHALL MAINTAIN THE CONFIDENTIALITY OF ANY INFORMA-
9 TION SUBMITTED PURSUANT TO THIS SECTION THAT THE COMMISSIONER DEEMS TO
10 BE CONFIDENTIAL, PROPRIETARY INFORMATION OF THE PRESCRIPTION DRUG
11 MANUFACTURER AND THE DISCLOSURE OF WHICH WOULD CAUSE THE MANUFACTURER
12 COMPETITIVE HARM. THIS CONFIDENTIAL PROPRIETARY INFORMATION SHALL NOT BE
13 MADE PUBLIC BY THE DEPARTMENT AND IS EXEMPT FROM DISCLOSURE UNDER THE
14 STATE FREEDOM OF INFORMATION LAW.

15 S 3. This act shall take effect immediately.