

5338--A

2015-2016 Regular Sessions

I N S E N A T E

May 13, 2015

Introduced by Sens. DIAZ, PERKINS -- read twice and ordered printed, and when printed to be committed to the Committee on Health -- recommitted to the Committee on Health in accordance with Senate Rule 6, sec. 8 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the public health law, in relation to establishing the pharmaceutical cost transparency act of 2016

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

1 Section 1. This act shall be cited and may be known as the "pharmaceutical cost transparency act of 2016".

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

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

10 B. THE LEGISLATURE FINDS THAT THERE SHOULD BE ANNUAL COST REPORTING ON
11 THE MOST EXPENSIVE DRUGS THAT WOULD BE OF USE TO POLICYMAKERS, GOVERN-
12 MENT AGENCIES, AND OTHERS TO UNDERSTAND COSTS FOR THESE IMPORTANT
13 PRODUCTS.

14 2. EACH MANUFACTURER OF A PRESCRIPTION DRUG, MADE AVAILABLE IN NEW
15 YORK, THAT HAS A WHOLESALE ACQUISITION COST OF TEN THOUSAND DOLLARS
16 (\$10,000) OR MORE ANNUALLY OR PER COURSE OF TREATMENT, SHALL FILE A
17 REPORT PURSUANT TO THIS SECTION ON THE COSTS FOR EACH QUALIFYING DRUG.

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

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

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

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

4 (II) THE TOTAL COSTS OF CLINICAL TRIALS AND OTHER REGULATORY COSTS
5 PAID BY THE MANUFACTURER, AND SEPARATELY, THE TOTAL COSTS OF CLINICAL
6 TRIALS AND OTHER REGULATORY COSTS PAID BY ANY PREDECESSOR IN THE DEVEL-
7 OPMENT OF THE DRUG.

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

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

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

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

22 B. A CUMULATIVE ANNUAL HISTORY OF AVERAGE WHOLESALE PRICE AND WHOLE-
23 SALE ACQUISITION COST INCREASES FOR THE DRUG (EXPRESSED AS PERCENTAGES),
24 INCLUDING THE MONTHS EACH INCREASE IN EACH CATEGORY, AVERAGE WHOLESALE
25 PRICE AND WHOLESALE ACQUISITION COST, TOOK EFFECT.

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

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

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

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

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

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

46 S 3. This act shall take effect immediately.