

5338

2015-2016 Regular Sessions

I N S E N A T E

May 13, 2015

Introduced by Sen. DIAZ -- read twice and ordered printed, and when printed to be committed 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:

1 Section 1. This act shall be cited and may be known as the "pharmaceu-  
2 tical cost transparency act of 2015".

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:

22 (I) THE TOTAL RESEARCH AND DEVELOPMENT COSTS PAID BY THE MANUFACTURER,  
23 AND SEPARATELY, THE TOTAL RESEARCH AND DEVELOPMENT COSTS PAID BY ANY  
24 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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1 (II) THE TOTAL COSTS OF CLINICAL TRIALS AND OTHER REGULATORY COSTS  
2 PAID BY THE MANUFACTURER, AND SEPARATELY, THE TOTAL COSTS OF CLINICAL  
3 TRIALS AND OTHER REGULATORY COSTS PAID BY ANY PREDECESSOR IN THE DEVEL-  
4 OPMENT OF THE DRUG.

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

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

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

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

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

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

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

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

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

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

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

43 S 3. This act shall take effect immediately.