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I N   S E N A T E

March 16, 2016

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Introduced by Sen. HANNON -- read twice and ordered printed, and when printed to be committed to the Committee on Health

AN ACT to amend the public health law and the general business law, in relation to price gouging on prescription drugs

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

1     Section 1. The public health law is amended by adding a new section  
2     278-a to read as follows:  
3     S 278-A. LIMITATION ON EXCESSIVE PRICE INCREASES; PRESCRIPTION DRUGS:  
4     1. IN THE EVENT A MANUFACTURER, AS DEFINED IN SUBDIVISION TWENTY-ONE OF  
5     SECTION SIXTY-EIGHT HUNDRED TWO OF THE EDUCATION LAW, OF A BRAND OR  
6     GENERIC DRUG, MADE AVAILABLE IN NEW YORK, INCREASES THE WHOLESALE ACQUI-  
7     SITION COST (WAC) OF A DRUG BY A PERCENT EQUAL TO OR GREATER THAN ONE  
8     HUNDRED PERCENT AT ANY ONE TIME OR IN THE AGGREGATE IN ANY TWELVE MONTH  
9     PERIOD:  
10     (A) THE MANUFACTURER SHALL, NOT LESS THAN THIRTY DAYS PRIOR TO INSTI-  
11     TUTING SUCH INCREASE, NOTIFY THE COMMISSIONER AND THE DRUG UTILIZATION  
12     REVIEW BOARD ESTABLISHED UNDER SECTION THREE HUNDRED SIXTY-NINE-BB OF  
13     THE SOCIAL SERVICES LAW. NOTICE SHALL BE PROVIDED ON THE FORM ESTAB-  
14     LISHED PURSUANT TO SUBDIVISION TWO OF THIS SECTION; AND  
15     (B) THE COMMISSIONER SHALL REQUIRE PRIOR AUTHORIZATION AND AUTHORIZE  
16     MEDICAID MANAGED CARE PLANS TO REQUIRE PRIOR AUTHORIZATION FOR THE DRUG  
17     EFFECTIVE AS OF THE DATE OF THE PRICE INCREASE AND CONTINUING UNTIL A  
18     DETERMINATION IS MADE BY THE DRUG UTILIZATION REVIEW BOARD.  
19     2. THE COMMISSIONER, IN CONSULTATION WITH THE DRUG UTILIZATION REVIEW  
20     BOARD, SHALL PRODUCE AND MAKE AVAILABLE TO MANUFACTURERS A PRICE  
21     INCREASE NOTIFICATION FORM THAT SHALL ELICIT:  
22     (A) THE MOST RECENT WHOLESALE ACQUISITION COST (WAC) OF THE DRUG PRIOR  
23     TO AN INCREASE EQUAL TO OR GREATER THAN ONE HUNDRED PERCENT AT ANY ONE  
24     TIME OR IN THE AGGREGATE IN ANY TWELVE MONTH PERIOD IN EITHER PRICING  
25     MEASURE. FOR THE PURPOSES OF THIS SECTION WHOLESALE ACQUISITION COST  
26     (WAC) SHALL INCLUDE THE PRICES FOR EACH DOSAGE, SIZE OR CONCENTRATION OF  
27     THE DRUG OFFERED OR SOLD BY THE MANUFACTURER;

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

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1 (B) THE WHOLESALE ACQUISITION COST (WAC) OF THE DRUG WHEN EXCEEDING  
2 THE ONE HUNDRED PERCENT THRESHOLD;

3 (C) ANY MATERIAL CHANGE IN INGREDIENT, PRODUCTION, OR MANUFACTURING  
4 COSTS RESULTING IN THE PRICE INCREASE;

5 (D) IN THE CASE OF A BRAND DRUG, THE EXPIRATION DATE OF THE PATENT;

6 (E) IN THE CASE OF A GENERIC DRUG, WHETHER THE DRUG IS A SOLE SOURCE  
7 DRUG; AND

8 (F) ANY OTHER INFORMATION THE MANUFACTURER DEEMS RELEVANT TO THE  
9 BOARD'S REVIEW.

10 3. UPON RECEIPT OF A PRICE INCREASE NOTIFICATION FORM, THE DRUG UTILI-  
11 ZATION REVIEW BOARD SHALL REVIEW THE PRICE INCREASE AND MAKE A DETERMI-  
12 NATION AS TO WHETHER THE PRICE INCREASE IS EXCESSIVE. IN MAKING A DETER-  
13 MINATION THE BOARD SHALL CONSIDER:

14 (A) THE WHOLESALE ACQUISITION COST (WAC) OF THE DRUG IN COMPARISON TO  
15 ANY GENERIC EQUIVALENT OR THERAPEUTICALLY EQUIVALENT DRUG;

16 (B) THE FDA APPROVED OR COMPENDIUM SUPPORTED USE OF THE DRUG AND CRIT-  
17 ICAL NEED TO THE PATIENT;

18 (C) ANY KNOWN MARKET FACTORS JUSTIFYING THE PRICE INCREASE, INCLUDING  
19 BUT NOT LIMITED TO:

20 (I) WHETHER THE DRUG HAS BEEN ABSENT FROM THE MARKET FOR ANY PERIOD OF  
21 TIME; AND

22 (II) CHANGES IN MANUFACTURING OR REGULATORY REQUIREMENTS OR COSTS.

23 (D) ANY MATERIAL CHANGE IN THE PREVALENCE OR SEVERITY OF THE DISEASE  
24 OR MEDICAL CONDITION OR CONDITIONS THAT THE DRUG IS APPROVED TO TREAT;

25 (E) IN THE CASE OF A BRAND DRUG, THE EXPIRATION DATE OF THE PATENT;  
26 AND

27 (F) IN THE CASE OF A GENERIC DRUG, WHETHER THE DRUG IS A SOLE SOURCE  
28 DRUG.

29 4. UPON A FINDING BY THE DRUG UTILIZATION REVIEW BOARD THAT A MANUFAC-  
30 Turer HAS INSTITUTED AN EXCESSIVE PRICE INCREASE, (I) THE BOARD SHALL  
31 REQUIRE PRIOR AUTHORIZATION FOR THE DRUG AND AUTHORIZE MEDICAID MANAGED  
32 CARE PLANS TO REQUIRE PRIOR AUTHORIZATION UNTIL THE BOARD DETERMINES  
33 OTHERWISE; AND (II) THE BOARD MAY REFER THE MATTER TO THE ATTORNEY  
34 GENERAL WITH ANY INFORMATION NECESSARY FOR THE INVESTIGATION AND PROSE-  
35 CUTION OF PRICE GOUGING VIOLATIONS UNDER SECTION THREE HUNDRED  
36 NINETY-SIX-RRR OF THE GENERAL BUSINESS LAW. IN THE EVENT THE BOARD DOES  
37 NOT FIND THAT THE MANUFACTURER HAS ENGAGED IN AN EXCESSIVE PRICE  
38 INCREASE, THE BOARD SHALL REMOVE THE REQUIREMENT FOR PRIOR AUTHORIZATION  
39 AND SUCH AUTHORITY GRANTED TO MEDICAID MANAGED CARE PLANS TO INSTITUTE  
40 PRIOR AUTHORIZATION UNDER THIS SECTION SHALL CEASE.

41 S 2. The general business law is amended by adding a new section 396-  
42 rrr to read as follows:

43 S 396-RRR. PRICE GOUGING; PRESCRIPTION DRUGS. 1. LEGISLATIVE FINDINGS  
44 AND DECLARATION. THE LEGISLATURE HEREBY FINDS THAT EXCESSIVE PRICE  
45 INCREASES TO PRESCRIPTION DRUGS THAT LACK JUSTIFICATION BASED ON MARKET  
46 FORCES CREATE A PUBLIC HEALTH RISK TO CONSUMERS THAT RELY ON THESE  
47 PRESCRIPTION DRUGS. IN ORDER TO PREVENT A MANUFACTURER, AS DEFINED IN  
48 SUBDIVISION TWENTY-ONE OF SECTION SIXTY-EIGHT HUNDRED TWO OF THE EDUCA-  
49 TION LAW, FROM TAKING UNFAIR ADVANTAGE OF CONSUMERS WHO RELY UPON AND  
50 MAY LOSE ACCESS TO THE PRESCRIPTION DRUGS IF THE MEDICATION HAS A SUDDEN  
51 AND EXCESSIVE PRICE INCREASE, THE LEGISLATURE DECLARES THAT THE PUBLIC  
52 INTEREST REQUIRES THAT SUCH CONDUCT BE PROHIBITED AND MADE SUBJECT TO  
53 CIVIL PENALTIES.

54 2. IN ORDER TO PREVENT A DRUG MANUFACTURER, AS DEFINED IN SUBDIVISION  
55 TWENTY-ONE OF SECTION SIXTY-EIGHT HUNDRED TWO OF THE EDUCATION LAW, FROM  
56 IMPOSING UNCONSCIONABLY AND UNJUSTIFIABLY EXCESSIVE PRICE INCREASES, THE

1 ATTORNEY GENERAL MAY, UPON REFERRAL FROM THE DRUG UTILIZATION REVIEW  
2 BOARD AS CODIFIED IN SECTION TWO HUNDRED SEVENTY-EIGHT-A OF THE PUBLIC  
3 HEALTH LAW, APPLY IN THE NAME OF THE PEOPLE OF THE STATE OF NEW YORK TO  
4 THE SUPREME COURT OF THE STATE OF NEW YORK WITHIN THE JUDICIAL DISTRICT  
5 IN WHICH SUCH VIOLATIONS ARE ALLEGED TO HAVE OCCURRED, ON NOTICE OF FIVE  
6 DAYS, FOR AN ORDER ENJOINING OR RESTRAINING COMMISSION OR CONTINUANCE OF  
7 THE ALLEGED UNLAWFUL ACTS. IN ANY SUCH PROCEEDING, THE COURT MAY IMPOSE  
8 A CIVIL PENALTY IN AN AMOUNT NOT TO EXCEED TWENTY-FIVE THOUSAND DOLLARS  
9 AND, WHERE APPROPRIATE, ORDER RESTITUTION TO AGGRIEVED CONSUMERS.

10 3. WHETHER A PRICE IS UNCONSCIONABLY AND UNJUSTIFIABLY EXCESSIVE IS A  
11 QUESTION OF LAW FOR THE COURT. THE COURT'S DETERMINATION THAT A  
12 VIOLATION OF THIS SECTION HAS OCCURRED SHALL BE BASED UPON THE FOLLOWING  
13 FACTORS:

14 (A) THE INCREASE IN PRICE IS UNCONSCIONABLY EXTREME;

15 (B) THE DRUG IS VITAL AND MEDICALLY NECESSARY TO THE HEALTH OF THE  
16 CONSUMER;

17 (C) THE DRUG IS A SOLE SOURCE DRUG WITHOUT A THERAPEUTIC EQUIVALENT;  
18 AND

19 (D) THE PRICE INCREASE WAS WITHIN THE CONTROL OF THE MANUFACTURER AND  
20 NOT CAUSED BY COSTS IMPOSED ON OR FACTORS BEYOND THE CONTROL OF THE  
21 MANUFACTURER.

22 S 3. This act shall take effect immediately.