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

7022

I N S E N A T E

March 16, 2016

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:

Section 1. The public health law is amended by adding a new section 278-a to read as follows:

S 278-A. LIMITATION ON EXCESSIVE PRICE INCREASES; PRESCRIPTION DRUGS: 1. IN THE EVENT A MANUFACTURER, AS DEFINED IN SUBDIVISION TWENTY-ONE OF SECTION SIXTY-EIGHT HUNDRED TWO OF THE EDUCATION LAW, OF A BRAND OR GENERIC DRUG, MADE AVAILABLE IN NEW YORK, INCREASES THE WHOLESALE ACQUISITION COST (WAC) OF A DRUG BY A PERCENT EQUAL TO OR GREATER THAN ONE HUNDRED PERCENT AT ANY ONE TIME OR IN THE AGGREGATE IN ANY TWELVE MONTH PERIOD:

(A) THE MANUFACTURER SHALL, NOT LESS THAN THIRTY DAYS PRIOR TO INSTITUTING SUCH INCREASE, NOTIFY THE COMMISSIONER AND THE DRUG UTILIZATION REVIEW BOARD ESTABLISHED UNDER SECTION THREE HUNDRED SIXTY-NINE-BB OF THE SOCIAL SERVICES LAW. NOTICE SHALL BE PROVIDED ON THE FORM ESTABLISHED PURSUANT TO SUBDIVISION TWO OF THIS SECTION; AND

(B) THE COMMISSIONER SHALL REQUIRE PRIOR AUTHORIZATION AND AUTHORIZE MEDICAID MANAGED CARE PLANS TO REQUIRE PRIOR AUTHORIZATION FOR THE DRUG EFFECTIVE AS OF THE DATE OF THE PRICE INCREASE AND CONTINUING UNTIL A DETERMINATION IS MADE BY THE DRUG UTILIZATION REVIEW BOARD.

2. THE COMMISSIONER, IN CONSULTATION WITH THE DRUG UTILIZATION REVIEW BOARD, SHALL PRODUCE AND MAKE AVAILABLE TO MANUFACTURERS A PRICE INCREASE NOTIFICATION FORM THAT SHALL ELICIT:

(A) THE MOST RECENT WHOLESALE ACQUISITION COST (WAC) OF THE DRUG PRIOR TO AN INCREASE EQUAL TO OR GREATER THAN ONE HUNDRED PERCENT AT ANY ONE TIME OR IN THE AGGREGATE IN ANY TWELVE MONTH PERIOD IN EITHER PRICING MEASURE. FOR THE PURPOSES OF THIS SECTION WHOLESALE ACQUISITION COST (WAC) SHALL INCLUDE THE PRICES FOR EACH DOSAGE, SIZE OR CONCENTRATION OF 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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(B) THE WHOLESALE ACQUISITION COST (WAC) OF THE DRUG WHEN EXCEEDING THE ONE HUNDRED PERCENT THRESHOLD;
(C) ANY MATERIAL CHANGE IN INGREDIENT, PRODUCTION, OR MANUFACTURING COSTS RESULTING IN THE PRICE INCREASE;
(D) IN THE CASE OF A BRAND DRUG, THE EXPIRATION DATE OF THE PATENT;
(E) IN THE CASE OF A GENERIC DRUG, WHETHER THE DRUG IS A SOLE SOURCE DRUG; AND
(F) ANY OTHER INFORMATION THE MANUFACTURER DEEMS RELEVANT TO THE BOARD'S REVIEW.
3. UPON RECEIPT OF A PRICE INCREASE NOTIFICATION FORM, THE DRUG UTILIZATION REVIEW BOARD SHALL REVIEW THE PRICE INCREASE AND MAKE A DETERMINATION AS TO WHETHER THE PRICE INCREASE IS EXCESSIVE. IN MAKING A DETERMINATION THE BOARD SHALL CONSIDER:
(A) THE WHOLESALE ACQUISITION COST (WAC) OF THE DRUG IN COMPARISON TO ANY GENERIC EQUIVALENT OR THERAPEUTICALLY EQUIVALENT DRUG;
(B) THE FDA APPROVED OR COMPENDIUM SUPPORTED USE OF THE DRUG AND CRITICAL NEED TO THE PATIENT;
(C) ANY KNOWN MARKET FACTORS JUSTIFYING THE PRICE INCREASE, INCLUDING BUT NOT LIMITED TO:
(I) WHETHER THE DRUG HAS BEEN ABSENT FROM THE MARKET FOR ANY PERIOD OF TIME; AND
(II) CHANGES IN MANUFACTURING OR REGULATORY REQUIREMENTS OR COSTS.
(D) ANY MATERIAL CHANGE IN THE PREVALENCE OR SEVERITY OF THE DISEASE OR MEDICAL CONDITION OR CONDITIONS THAT THE DRUG IS APPROVED TO TREAT;
(E) IN THE CASE OF A BRAND DRUG, THE EXPIRATION DATE OF THE PATENT; AND
(F) IN THE CASE OF A GENERIC DRUG, WHETHER THE DRUG IS A SOLE SOURCE DRUG.
4. UPON A FINDING BY THE DRUG UTILIZATION REVIEW BOARD THAT A MANUFACTURER HAS INSTITUTED AN EXCESSIVE PRICE INCREASE, (I) THE BOARD SHALL REQUIRE PRIOR AUTHORIZATION FOR THE DRUG AND AUTHORIZE MEDICAID MANAGED CARE PLANS TO REQUIRE PRIOR AUTHORIZATION UNTIL THE BOARD DETERMINES OTHERWISE; AND (II) THE BOARD MAY REFER THE MATTER TO THE ATTORNEY GENERAL WITH ANY INFORMATION NECESSARY FOR THE INVESTIGATION AND PROSECUTION OF PRICE GOUGING VIOLATIONS UNDER SECTION THREE HUNDRED NINETY-SIX-RRR OF THE GENERAL BUSINESS LAW. IN THE EVENT THE BOARD DOES NOT FIND THAT THE MANUFACTURER HAS ENGAGED IN AN EXCESSIVE PRICE INCREASE, THE BOARD SHALL REMOVE THE REQUIREMENT FOR PRIOR AUTHORIZATION AND SUCH AUTHORITY GRANTED TO MEDICAID MANAGED CARE PLANS TO INSTITUTE PRIOR AUTHORIZATION UNDER THIS SECTION SHALL CEASE.
S 2. The general business law is amended by adding a new section 396-rrr to read as follows:
S 396-RRR. PRICE GOUGING; PRESCRIPTION DRUGS. 1. LEGISLATIVE FINDINGS AND DECLARATION. THE LEGISLATURE HEREBY FINDS THAT EXCESSIVE PRICE INCREASES TO PRESCRIPTION DRUGS THAT LACK JUSTIFICATION BASED ON MARKET FORCES CREATE A PUBLIC HEALTH RISK TO CONSUMERS THAT RELY ON THESE PRESCRIPTION DRUGS. IN ORDER TO PREVENT A MANUFACTURER, AS DEFINED IN SUBDIVISION TWENTY-ONE OF SECTION SIXTY-EIGHT HUNDRED TWO OF THE EDUCATION LAW, FROM TAKING UNFAIR ADVANTAGE OF CONSUMERS WHO RELY UPON AND MAY LOSE ACCESS TO THE PRESCRIPTION DRUGS IF THE MEDICATION HAS A SUDDEN AND EXCESSIVE PRICE INCREASE, THE LEGISLATURE DECLARES THAT THE PUBLIC INTEREST REQUIRES THAT SUCH CONDUCT BE PROHIBITED AND MADE SUBJECT TO CIVIL PENALTIES.
2. IN ORDER TO PREVENT A DRUG MANUFACTURER, AS DEFINED IN SUBDIVISION TWENTY-ONE OF SECTION SIXTY-EIGHT HUNDRED TWO OF THE EDUCATION LAW, FROM IMPOSING UNCONSCIONABLY AND UNJUSTIFIABLY EXCESSIVE PRICE INCREASES, THE

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

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

(A) THE INCREASE IN PRICE IS UNCONSCIONABLY EXTREME;

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

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

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

S 3. This act shall take effect immediately.