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

805

2011-2012 Regular Sessions

I N A S S E M B L Y

(PREFILED)

January 5, 2011

Introduced by M. of A. GOTTFRIED, SILVER, PAULIN, MAYERSOHN, DINOWITZ, CAHILL, PEOPLES-STOKES, BING, GALEF, GUNTHER, CYMBROWITZ, J. RIVERA, ENGLEBRIGHT, ORTIZ, ROBINSON, DESTITO, HOOPER, HOYT, ROSENTHAL, JAFFEE, MAGNARELLI, MAISEL, LANCMAN, CLARK, TITONE, ZEBROWSKI, RAMOS, COLTON -- Multi-Sponsored by -- M. of A. BENEDETTO, BOYLAND, BRENNAN, BROOK-KRASNY, FARRELL, GLICK, HEASTIE, HIKIND, JACOBS, KELLNER, LATIMER, LAVINE, LIFTON, V. LOPEZ, LUPARDO, MAGEE, MARKEY, McENENY, McKEVITT, MILLMAN, MOLINARO, PERRY, PHEFFER, PRETLOW, REILLY, P. RIVERA, SCARBOROUGH, SPANO, SWEENEY, TITUS, WEISENBERG, WRIGHT -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to creating the prescription drug discount program and to repeal certain provisions of the public health law relating thereto

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

Section 1. Legislative findings and declaration. The legislature hereby finds and declares that the high and rising cost of prescription drugs limits access to those of limited means. It makes it more likely that they will become eligible for Medicaid, imposing increased costs on Medicaid.

The legislature therefore declares that it is an appropriate public purpose and in the public interest for New York to exercise the powers of the state to provide its residents with means and methods of reducing the high cost of prescription drugs and avoid increased costs to the Medicaid program, and that the prescription drug assistance program created by this act is consistent with these public purposes.

The legislature further declares that the purpose of this act is to help reduce the cost of and improve access to prescription drugs, by providing a means to organize and thus maximize the market purchasing

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

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power of consumers to earn revenue from supplier rebates and use that revenue to make prescription drugs more affordable.

The legislature further declares its intent that the program, as a state prescription drug assistance program and as a program to help avoid increased costs to the Medicaid program, shall be able to negotiate rebates that are exempt from the "best price" rule of title XIX of the federal social security act.

S 2. Sections 270 through 277 of article 2-A of the public health law are designated title I and a new title heading is added to read as follows:

PREFERRED DRUG AND CLINICAL DRUG REVIEW PROGRAMS

S 3. Article 2-A of the public health law is amended by adding a new title II to read as follows:

TITLE II

PRESCRIPTION DRUG DISCOUNT CARD

SECTION 280. DEFINITIONS.
280-A. PRESCRIPTION DRUG DISCOUNT PROGRAM.
280-B. CONTRACTS.
280-C. REBATES.
280-D. RETAIL DISCOUNT PRICES.
280-E. DISTRIBUTION OF REBATE FUNDS.
280-F. REGISTRATION OF PARTICIPANTS.
280-G. EDUCATION AND OUTREACH.

S 280. DEFINITIONS. FOR PURPOSES OF THIS TITLE, THE FOLLOWING TERMS SHALL HAVE THE FOLLOWING MEANINGS, UNLESS THE CONTEXT REQUIRES OTHERWISE:

1. "CONTRACTOR" IS ANY PUBLIC, PRIVATE, OR NOT-FOR-PROFIT ENTITY WITH WHICH THE COMMISSIONER CONTRACTS FOR THE PURPOSE OF ADMINISTERING ANY ELEMENT OF THE PROGRAM OR PROVIDING TECHNICAL OR CLINICAL SUPPORT FOR THE PROGRAM. THERE MAY BE ONE OR MORE CONTRACTORS.

2. "COVERED DRUG" MEANS A PRESCRIPTION DRUG THAT IS DESIGNATED BY THE COMMISSIONER TO BE SUBJECT TO PURCHASE BY A PARTICIPANT UNDER THE PROGRAM UNDER SECTION TWO HUNDRED EIGHTY-C OF THIS TITLE.

3. "FIDUCIARY RELATIONSHIP" MEANS A RELATIONSHIP IN WHICH ONE PERSON OR ENTITY IS UNDER A DUTY TO ACT FOR THE BENEFIT OF THE OTHER PERSON OR ENTITY IN THE RELATIONSHIP ON MATTERS WITHIN THE SCOPE OF THE RELATIONSHIP, AND OWES A DUTY OF GOOD FAITH, TRUST, CONFIDENCE, AND CANDOR TO THE OTHER PERSON OR ENTITY.

4. "MANUFACTURER" HAS THE SAME MEANING ASCRIBED TO SUCH TERM IN SECTION NINETEEN HUNDRED TWENTY-SEVEN OF THE FEDERAL SOCIAL SECURITY ACT.

5. "PARTICIPANT" MEANS A NATURAL PERSON WHO MEETS THE ELIGIBILITY GUIDELINES ESTABLISHED IN SECTION TWO HUNDRED EIGHTY-F OF THIS TITLE AND REGISTERS TO PARTICIPATE IN THE PROGRAM.

6. "PARTICIPATING RETAILER" MEANS ANY PERSON OR ENTITY SELLING PRESCRIPTION DRUGS AT RETAIL PRICES THAT IS REGISTERED AS A PARTICIPATING RETAILER IN THE PROGRAM.

7. "PROGRAM" MEANS THE PRESCRIPTION DRUG DISCOUNT PROGRAM ESTABLISHED BY THIS TITLE.

8. "REBATE AGREEMENT" MEANS AN AGREEMENT EXECUTED WITH A MANUFACTURER OR OTHER ENTITY TO PROVIDE REBATES TO THE PROGRAM PURSUANT TO THIS TITLE.

S 280-A. PRESCRIPTION DRUG DISCOUNT PROGRAM. 1. THE PRESCRIPTION DRUG DISCOUNT PROGRAM IS HEREBY ESTABLISHED IN THE DEPARTMENT. ITS PURPOSE SHALL BE TO PROVIDE ACCESS TO PRESCRIPTION DRUGS TO PARTICIPANTS AT DISCOUNTED COST, AND TO OBTAIN APPROPRIATE REBATES FROM MANUFACTURERS,

AS AUTHORIZED IN THIS TITLE. FOR THE PURPOSES OF MARKETING AND OTHER PURPOSES, THE COMMISSIONER MAY CHOOSE ANOTHER NAME FOR THE PROGRAM; PROVIDED, HOWEVER, THAT ANY SUCH CHANGE OF NAME SHALL NOT AFFECT THE LEGAL DESCRIPTION OR INTENT OF THE PROGRAM, OR ITS EXEMPTION, IF ANY, FROM THE "BEST PRICE" RULE OF TITLE XIX OF THE FEDERAL SOCIAL SECURITY ACT. THE PROGRAM SHALL BE ADMINISTERED IN A MANNER THAT MAXIMIZES SAVINGS FOR THE PARTICIPANTS CONSISTENT WITH THIS TITLE WHILE MINIMIZING ANY COST TO THE STATE, INCLUDING COORDINATING OR COMBINING ADMINISTRATION OF ANY ASPECT OF THE PROGRAM WITH MEDICAID OR EPIC TO THE EXTENT CONSISTENT WITH THE INTERESTS OF THOSE PROGRAMS AND THEIR PARTICIPANTS.

2. THE COMMISSIONER MAY REQUIRE EVERY MANUFACTURER PARTICIPATING IN A REBATE AGREEMENT, EVERY PARTICIPANT AND EVERY PARTICIPATING RETAILER TO PROVIDE ANY INFORMATION, AND MAY CONDUCT SUCH AUDITS AND INVESTIGATIONS, AS REASONABLY NECESSARY FOR EFFECTIVE ADMINISTRATION OF THE PROGRAM. ALL INDIVIDUAL IDENTIFYING INFORMATION RELATING TO ANY PATIENT OR CONSUMER ACQUIRED BY THE PROGRAM SHALL BE KEPT CONFIDENTIAL BY THE COMMISSIONER AND SHALL BE USED SOLELY FOR THE PURPOSE OF ADMINISTERING THE PROGRAM. ANY MATTER RELATING TO TRADE OR COMPETITIVE SECRETS OF MANUFACTURERS AND PARTICIPATING RETAILERS, AND ANY MATTER CONCERNING PRICING AND PROFIT, WHICH IS OBTAINED PURSUANT TO THIS SUBDIVISION, OR PURSUANT TO ANY INVESTIGATION OR AUDIT AUTHORIZED PURSUANT TO THIS TITLE, OR OBTAINED INDIRECTLY BY ANY OTHER AUDITS OR INVESTIGATIONS, SHALL BE KEPT CONFIDENTIAL.

3. IF THE IMPLEMENTATION OF THE PROGRAM REQUIRES ANY FEDERAL APPROVAL OR WAIVER, THE COMMISSIONER SHALL EXPEDITIOUSLY APPLY FOR AND USE HIS OR HER BEST EFFORTS TO OBTAIN SUCH APPROVAL OR WAIVER, CONSISTENT WITH THIS TITLE AND ANY STATE LAW APPLICABLE TO MEDICAID OR EPIC.

4. THE COMMISSIONER MAY MAKE REGULATIONS AND ESTABLISH TERMS AND CONDITIONS CONSISTENT WITH THIS TITLE AND OTHER APPLICABLE LAW, FOR IMPLEMENTATION OF THE PROGRAM.

S 280-B. CONTRACTS. 1. THE COMMISSIONER MAY CONTRACT WITH, OR AMEND AN EXISTING CONTRACT WITH, ONE OR MORE PUBLIC, PRIVATE, OR NOT-FOR-PROFIT ENTITIES TO ADMINISTER ANY AND ALL COMPONENTS OF THE PROGRAM OR TO PROVIDE TECHNICAL OR CLINICAL SUPPORT FOR THE PROGRAM.

2. (A) EVERY CONTRACTOR SHALL HAVE A FIDUCIARY RELATIONSHIP WITH AND OBLIGATION TO THE COMMISSIONER AND THE PROGRAM.

(B) ALL FUNDS RECEIVED BY ANY CONTRACTOR IN RELATION TO THE PROGRAM SHALL BE RECEIVED BY THE CONTRACTOR SOLELY ON BEHALF OF THE PROGRAM FOR USE OR DISTRIBUTION ONLY PURSUANT TO THIS TITLE, INCLUDING THE CONTRACTOR'S CONTRACT WITH THE COMMISSIONER; EXCEPT FOR ANY PAYMENT EXPRESSLY PROVIDED FOR IN THE CONTRACT TO COMPENSATE THE CONTRACTOR FOR ITS SERVICES. THE CONTRACTOR SHALL ACCOUNT TO THE COMMISSIONER FOR ALL FUNDS RECEIVED AND PROCESSED BY THE CONTRACTOR IN RELATION TO THE PROGRAM. THE COMMISSIONER AND THE COMPTROLLER SHALL HAVE ACCESS TO ALL BOOKS AND RECORDS OF THE CONTRACTOR IN RELATION TO THE PROGRAM.

(C) THE CONTRACTOR SHALL DISCLOSE TO THE COMMISSIONER AND THE COMPTROLLER THE TERMS AND CONDITIONS OF ANY CONTRACT OR ARRANGEMENT BETWEEN THE CONTRACTOR AND ANY PARTY RELATING TO THE PROGRAM.

S 280-C. REBATES. 1. THE COMMISSIONER SHALL ENTER INTO AGREEMENTS WITH MANUFACTURERS TO ACHIEVE REBATES FROM MANUFACTURERS FOR THEIR DRUG PRODUCTS PURCHASED BY PARTICIPANTS THROUGH THE PROGRAM.

2. THE COMMISSIONER SHALL USE BEST EFFORTS TO MAXIMIZE THE LEVEL OF REBATES OBTAINED FROM MANUFACTURERS TO THE EXTENT ALLOWABLE BY LAW OR REGULATION. THE COMMISSIONER MAY SEEK ANY FEDERAL APPROVAL NEEDED TO ENSURE REBATES RECEIVED UNDER THIS PROGRAM ARE EXCLUDED FROM THE DEFI-

NITION OF "BEST PRICE" UNDER SECTION NINETEEN HUNDRED TWENTY-SEVEN OF THE FEDERAL SOCIAL SECURITY ACT.

3. TO ADVANCE THE PURPOSES OF THE PROGRAM, THE COMMISSIONER MAY COORDINATE NEGOTIATIONS UNDER THE PROGRAM WITH GOVERNMENTAL AND NON-GOVERNMENTAL ENTITIES, IN THIS STATE OR ELSEWHERE.

4. THE COMMISSIONER SHALL DESIGNATE DRUGS TO BE SUBJECT TO PURCHASE BY PARTICIPANTS UNDER THE PROGRAM. THE COMMISSIONER MAY LIMIT DESIGNATION UNDER THE PROGRAM TO DRUGS COVERED BY A REBATE AGREEMENT.

5. THE COMMISSIONER MAY SEEK SUPPLEMENTAL REBATES FROM MANUFACTURERS CONSISTENT WITH THOSE REBATES PROVIDED TO THE MEDICAID PROGRAM FOR DRUGS ON THE PREFERRED DRUG LIST PURSUANT TO TITLE ONE OF THIS ARTICLE. IN EXCHANGE FOR THE PROVISION OF SUCH REBATES, THE COMMISSIONER MAY DESIGNATE SUCH DRUGS AS PREFERRED DRUGS IN PROGRAM MARKETING AND EDUCATIONAL ACTIVITIES AND MATERIALS. THE COMMISSIONER IS AUTHORIZED TO LIMIT PROGRAM COVERAGE OF DRUGS IN THERAPEUTIC CLASSES INCLUDED IN THE PREFERRED DRUG PROGRAM TO THOSE ON THE PREFERRED DRUG LIST.

S 280-D. RETAIL DISCOUNT PRICES. 1. A PERSON OR ENTITY MAY BECOME A PARTICIPATING RETAILER BY AGREEING TO THE TERMS AND CONDITIONS OF PROGRAM PARTICIPATION, AND MEETING QUALIFICATIONS, AS ESTABLISHED BY THE COMMISSIONER. THE COMMISSIONER MAY REQUIRE PERIODIC RE-REGISTRATION.

2. A PARTICIPATING RETAILER MAY NOT CHARGE A PARTICIPANT A PRICE FOR A COVERED DRUG WHICH IS HIGHER THAN THE AMOUNT PAID BY THE MEDICAID PROGRAM PURSUANT TO SECTION THREE HUNDRED SIXTY-SEVEN-A OF THE SOCIAL SERVICES LAW, LESS THE APPLICABLE REBATE AMOUNT ADVANCED BY THE PROGRAM IN ACCORDANCE WITH SECTION TWO HUNDRED EIGHTY-E OF THIS TITLE.

S 280-E. DISTRIBUTION OF REBATE FUNDS. 1. THE APPROPRIATE CONTRACTOR SHALL EXPEDITIOUSLY MAKE PAYMENTS TO PARTICIPATING RETAILERS FOR THE ESTIMATED REBATE AMOUNTS, RELATING TO COVERED DRUGS DISPENSED BY PARTICIPATING RETAILERS TO PROGRAM PARTICIPANTS, SUBJECT TO SUBSEQUENT RECONCILIATION AGAINST ACTUAL REBATES COLLECTED FROM MANUFACTURERS. RECONCILIATION SHALL NOT REQUIRE RECOUPMENT FROM OR PAYMENTS TO PARTICIPANTS OR PARTICIPATING RETAILERS FOR PREVIOUS PURCHASES UNDER THE PROGRAM, BUT MAY INCLUDE, AS APPROPRIATE, PROVISION FOR ADJUSTMENT AGAINST ESTIMATED REBATE AMOUNTS FACTORED INTO FUTURE PRICES TO BE PAID BY PARTICIPANTS.

2. THE COMMISSIONER MAY MAKE ARRANGEMENTS WITH MANUFACTURERS CONCERNING THE TIMING OR STRUCTURE OF THE REBATE PAYMENTS AS IN HIS OR HER DETERMINATION SHALL BEST FACILITATE LOWER PRICES FOR PARTICIPANTS, EXPEDITIOUS PAYMENT OF REBATES AND EFFICIENT ADMINISTRATION OF THE PROGRAM.

S 280-F. REGISTRATION OF PARTICIPANTS. 1. TO BE ELIGIBLE TO BE A PARTICIPANT, A PERSON SHALL BE A RESIDENT OF NEW YORK, REGARDLESS OF AGE, WHO HAS A HOUSEHOLD INCOME EQUAL TO OR LESS THAN THE GREATER OF (A) THREE HUNDRED FIFTY PERCENT OF THE FEDERAL POVERTY LEVEL FOR A HOUSEHOLD OF THAT SIZE (AS DEFINED AND UPDATED BY THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES); OR (B) THE INCOME ELIGIBILITY LEVELS ESTABLISHED UNDER SUBDIVISION ONE OR TWO OF SECTION TWO HUNDRED FORTY-TWO OF THE ELDER LAW, IS NOT IN RECEIPT OF MEDICAID, AND MEETS SUCH OTHER REQUIREMENTS AS THE COMMISSIONER MAY ESTABLISH CONSISTENT WITH THIS TITLE. ANY PERSON ENROLLED IN THE PRESCRIPTION DRUG DISCOUNT PROGRAM UNDER SECTION TWO HUNDRED EIGHTY-H OF THIS TITLE SHALL BE ELIGIBLE TO BE A PARTICIPANT UNDER THIS PROGRAM.

2. ANY PERSON ELIGIBLE TO BE A PARTICIPANT MAY BECOME A PARTICIPANT IN THE PROGRAM BY REGISTERING WITH THE PROGRAM. ANY PERSON ENROLLED IN THE PRESCRIPTION DRUG DISCOUNT PROGRAM UNDER SECTION TWO HUNDRED EIGHTY-H OF THIS TITLE SHALL AUTOMATICALLY BE REGISTERED BY THE COMMISSIONER IN THIS PROGRAM.

3. THE COMMISSIONER SHALL ADVISE EACH APPLICANT THAT THE PROGRAM DOES NOT APPLY TO ANY PRESCRIPTION DRUG PURCHASE FOR WHICH REIMBURSEMENT (IN WHOLE OR IN PART) IS PROVIDED BY ANY THIRD-PARTY PAYER. THE COMMISSIONER MAY REQUIRE PERIODIC RE-REGISTRATION AND MAY REQUIRE THE PARTICIPANT TO INFORM THE PROGRAM OF ANY CHANGE IN THE INFORMATION PROVIDED. THE COMMISSIONER SHALL MAKE THE APPLICATION PROCESS AS SIMPLE AS REASONABLY POSSIBLE TO MAXIMIZE PARTICIPATION IN THE PROGRAM CONSISTENT WITH PROPER ADMINISTRATION OF THIS TITLE.

4. THE COMMISSIONER SHALL REVIEW ALL APPLICATIONS TO DETERMINE IF THE APPLICANT APPEARS TO MEET THE ELIGIBILITY REQUIREMENTS FOR THE FAMILY HEALTH PLUS PROGRAM UNDER SECTION THREE HUNDRED SIXTY-NINE-EE OF THE SOCIAL SERVICES LAW, THE CHILD HEALTH INSURANCE PROGRAM UNDER SECTION TWENTY-FIVE HUNDRED TEN AND TWENTY-FIVE HUNDRED ELEVEN OF THIS CHAPTER, OR MEDICAL ASSISTANCE UNDER ARTICLE FIVE OF THE SOCIAL SERVICES LAW. IF THE APPLICANT DOES APPEAR TO MEET ELIGIBILITY REQUIREMENTS FOR ANY OF THOSE PROGRAMS, THE COMMISSIONER SHALL, IN ADDITION TO ANY OTHER ACTIONS TAKEN UNDER THIS TITLE, PROVIDE THE APPLICANT WITH INFORMATION AND ENROLLMENT MATERIAL ABOUT SUCH OTHER PROGRAM. HOWEVER, THE COMMISSIONER SHALL REGISTER THE APPLICANT UNDER THIS SECTION IF THE APPLICANT IS OTHERWISE ELIGIBLE.

S 280-G. EDUCATION AND OUTREACH. THE COMMISSIONER SHALL CONDUCT EDUCATION AND OUTREACH TO PROMOTE THE PROGRAM AND TO ENCOURAGE ELIGIBLE PERSONS AND ENTITIES TO BECOME PARTICIPANTS AND PARTICIPATING RETAILERS.

S 4. Section 280 of the public health law, as added by section 75 of part C of chapter 58 of the laws of 2008, is renumbered section 280-h, and amended to read as follows:

S 280-h. Prescription drug discount program. 1. The prescription drug discount program is hereby established in the department. The drug discount card shall be available to any resident between the ages of fifty and sixty-four, and any resident of any age who has been determined to meet the disability criteria in 20 C.F.R. S 404.1505, who: meets the income eligibility levels established under subdivision one or two of section two hundred forty-two of the elder law; is not in receipt of medical assistance under title eleven of article five of the social services law. The drug discount card shall offer discounts on drug purchases which are not covered by other public or private third party payment sources. Provided, however, that participation by a provider pharmacy and drug manufacturers shall be voluntary and reimbursement to the provider pharmacy under the drug discount card program shall be adjudicated and paid within two business days for any rebates, dispensing fees and drug costs not paid by the resident eligible for such program at the point of sale.

2. THE COMMISSIONER SHALL, AS EXPEDITIOUSLY AS POSSIBLE, INTEGRATE THE OPERATION OF THE PRESCRIPTION DRUG DISCOUNT PROGRAM UNDER THIS SECTION WITH THE PRESCRIPTION DRUG DISCOUNT PROGRAM UNDER SECTION TWO HUNDRED EIGHTY-A OF THIS TITLE. WHEN THE COMMISSIONER BEGINS REGISTERING PARTICIPANTS UNDER SECTION TWO HUNDRED EIGHTY-A OF THIS TITLE, HE OR SHE SHALL CEASE ENROLLING PARTICIPANTS UNDER THIS SECTION. ANY PERSON ENROLLED IN THE PROGRAM UNDER THIS SECTION SHALL BE AUTOMATICALLY REGISTERED BY THE COMMISSIONER IN THE PROGRAM UNDER SECTION TWO HUNDRED EIGHTY-A OF THIS TITLE.

S 5. Section 280-h of the public health law, as amended by section four of this act, is REPEALED.

S 6. Severability. If any provision of this act, or any application of any provision of this act, is held to be invalid, or ruled by any federal agency to violate or be inconsistent with any applicable federal

law or regulation, that shall not affect the validity or effectiveness of any other provision of this act, or of any other application of any provision of this act.

S 7. This act shall take effect immediately; provided, however that:

(a) the amendments to article 2-A of the public health law made by sections two and four of this act shall not affect the repeal of such article and shall be deemed repealed therewith;

(b) section five of this act shall take effect on the one hundred eightieth day after this act shall have become a law;

(c) any rebate payment due from any drug manufacturer and any reimbursement due under section 280-h of the public health law shall be paid notwithstanding the repeal of section 280-h made by section five of this act; and

(d) the amendments to article 2-A of the public health law made by section three of this act shall survive the expiration and repeal of such article as provided in section 79 of part C of chapter 58 of the laws of 2005, as amended.