§ 280. Medicaid drug cap. 1. The legislature hereby finds and declares that there is a significant public interest for the Medicaid program to manage drug costs in a manner that ensures patient access while providing financial stability for the state and participating providers. Since two thousand eleven, the state has taken significant steps to contain costs in the Medicaid program by imposing a statutory limit on annual growth. Drug expenditures, however, continually outpace other cost components causing significant pressure on the state, providers, and patient access operating under the Medicaid global cap. It is therefore intended that the department establish a supplemental rebate program as part of a focused and sustained effort to balance the growth of drug expenditures with the growth of total Medicaid expenditures.

2. The commissioner shall review at least annually the department of health state funds Medicaid drug expenditures to identify drugs in the eightieth percentile or higher of total spend, net of rebate or in the eightieth percentile or higher based on cost per claim, net of rebate.

3. (a) The commissioner may identify and refer drugs in the eightieth percentile or higher of total spend, net of rebate or in the eightieth percentile or higher based on cost per claim, net of rebate, to the drug utilization review board established by section three hundred sixty-nine-bb of the social services law for a recommendation as to whether a target supplemental Medicaid rebate should be paid by the manufacturer of the drug to the department and the target amount of the rebate.

(b) If the department intends to refer a drug to the drug utilization review board pursuant to paragraph (a) of this subdivision, the department shall notify the manufacturer of such drug and shall attempt to reach agreement with the manufacturer on a rebate for the drug prior to referring the drug to the drug utilization review board for review. Such rebate may be based on evidence-based research, including, but not limited to, such research operated or conducted by or for other state governments, the federal government, the governments of other nations, and third party payers or multi-state coalitions, provided however that the department shall account for the effectiveness of the drug in treating the conditions for which it is prescribed or in improving a

patient's health, quality of life, or overall health outcomes, and the likelihood that use of the drug will reduce the need for other medical care, including hospitalization.

(c) In the event that the commissioner and the manufacturer have previously agreed to a supplemental rebate for a drug pursuant to paragraph (b) of this subdivision or paragraph (e) of subdivision seven of section three hundred sixty-seven-a of the social services law, the drug shall not be referred to the drug utilization review board for any further supplemental rebate for the duration of the previous rebate agreement, provided however, the commissioner may refer a drug to the drug utilization review board if the commissioner determines there are significant and substantiated utilization or market changes, new evidence-based research, or statutory or federal regulatory changes that warrant additional rebates. In such cases, the department shall notify the manufacturer and provide evidence of the changes or research that would warrant additional rebates, and shall attempt to reach agreement with the manufacturer on a rebate for the drug prior to referring the drug to the drug utilization review board for review.

(d) The department shall consider a drug's actual cost to the state, including current rebate amounts, prior to seeking an additional rebate pursuant to paragraph (b) or (c) of this subdivision.

(e) If the commissioner is unsuccessful in entering into a rebate arrangement with the manufacturer of the drug satisfactory to the department, the drug manufacturer shall, in that event be required to provide to the department, on a standard reporting form developed by the department, the following information:

(i) the actual cost of developing, manufacturing, producing (including the cost per dose of production), and distributing the drug;

(ii) research and development costs of the drug, including payments to predecessor entities conducting research and development, such as biotechnology companies, universities and medical schools, and private research institutions;

(iii) administrative, marketing, and advertising costs for the drug, apportioned by marketing activities that are directed to consumers, marketing activities that are directed to prescribers, and the total cost of all marketing and advertising that is directed primarily to consumers and prescribers in New York, including but not limited to

prescriber detailing, copayment discount programs, and direct-to-consumer marketing;

(iv) the extent of utilization of the drug;

(v) prices for the drug that are charged to purchasers outside the United States;

(vi) prices charged to typical purchasers in the state, including but not limited to pharmacies, pharmacy chains, pharmacy wholesalers, or other direct purchasers;

(vii) the average rebates and discounts provided per payer type in the state; and

(viii) the average profit margin of each drug over the prior five-year period and the projected profit margin anticipated for such drug.

(f) All information disclosed pursuant to paragraph (e) of this subdivision shall be considered confidential and shall not be disclosed by the department in a form that identifies a specific manufacturer or prices charged for drugs by such manufacturer.

4. In determining whether to recommend a target supplemental rebate for a drug, the drug utilization review board shall consider the actual cost of the drug to the Medicaid program, including federal and state rebates, and may consider, among other things:

(a) the drug's impact on Medicaid drug spending, and the adequacy of capitation rates of participating Medicaid managed care plans, and the drug's affordability and value to the Medicaid program; or

(b) significant and unjustified increases in the price of the drug; or

(c) whether the drug may be priced disproportionately to its therapeutic benefits.

5. (a) If the drug utilization review board recommends a target rebate amount on a drug referred by the commissioner, the department shall negotiate with the drug's manufacturer for a supplemental rebate to be paid by the manufacturer in an amount not to exceed such target rebate amount.

(b) The supplemental rebate required by paragraph (a) of this subdivision shall apply to drugs dispensed to enrollees of managed care providers pursuant to section three hundred sixty-four-j of the social services law and to drugs dispensed to Medicaid recipients who are not

enrollees of such providers.

(c) Where the department and a manufacturer enter into a rebate agreement pursuant to this section, which may be in addition to existing rebate agreements entered into by the manufacturer with respect to the same drug, no additional rebates shall be required to be paid by the manufacturer to a managed care provider or any of a managed care provider's agents, including but not limited to any pharmacy benefit manager, while the department is collecting the rebate pursuant to this section.

(d) In formulating a recommendation concerning a target rebate amount for a drug, the drug utilization review board may consider:

(i) publicly available information relevant to the pricing of the drug;

(ii) information supplied by the department relevant to the pricing of the drug;

(iii) information relating to value-based pricing provided, however, if the department directly invites any third party to provide cost-effectiveness analysis or research related to value-based pricing, and the department receives and considers such analysis or research for use by the board, such third party shall disclose any funding sources. The department shall, if reasonably possible, make publicly available the following documents in its possession that it relies upon to provide cost effectiveness analyses or research related to value-based pricing: (A) descriptions of underlying methodologies; (B) assumptions and limitations of research findings; and (C) if available, data that presents results in a way that reflects different outcomes for affected subpopulations;

(iv) the seriousness and prevalence of the disease or condition that is treated by the drug;

(v) the extent of utilization of the drug;

(vi) the effectiveness of the drug in treating the conditions for which it is prescribed, or in improving a patient's health, quality of life, or overall health outcomes;

(vii) the likelihood that use of the drug will reduce the need for other medical care, including hospitalization;

(viii) the average wholesale price, wholesale acquisition cost, retail price of the drug, and the cost of the drug to the Medicaid program

minus rebates received by the state;

(ix) in the case of generic drugs, the number of pharmaceutical manufacturers that produce the drug;

(x) whether there are pharmaceutical equivalents to the drug; and

(xi) information supplied by the manufacturer, if any, explaining the relationship between the pricing of the drug and the cost of development of the drug and/or the therapeutic benefit of the drug, or that is otherwise pertinent to the manufacturer's pricing decision; any such information, including the information on the standard reporting form requirement in paragraph (e) of subdivision three of this section, provided shall be considered confidential and shall not be disclosed by the drug utilization review board in a form that identifies a specific manufacturer or prices charged for drugs by such manufacturer.

6. (a) After taking into account all rebates and supplemental rebates received by the department, including rebates received to date pursuant to this section, the commissioner may: subject any drug of a manufacturer referred to the drug utilization review board under this section to prior approval in accordance with existing processes and procedures when such manufacturer has not entered into a supplemental rebate arrangement as required by this section; direct a managed care plan to limit or reduce reimbursement for a drug provided by a medical practitioner if the drug utilization review board recommends a target rebate amount for such drug and the manufacturer has failed to enter into a rebate arrangement required by this section; direct managed care plans to remove from their Medicaid formularies any drugs of a manufacturer who has a drug that the drug utilization review board recommends a target rebate amount for and the manufacturer has failed to enter into a rebate arrangement required by this section; promote the use of cost effective and clinically appropriate drugs other than those of a manufacturer who has a drug that the drug utilization review board recommends a target rebate amount and the manufacturer has failed to enter into a rebate arrangement required by this section; allow manufacturers to accelerate rebate payments under existing rebate contracts; and such other actions as authorized by law. The commissioner shall provide written notice to the legislature at least thirty days prior to taking action pursuant to this paragraph.

(b) The commissioner shall be authorized to take the actions described in paragraph (a) of this subdivision. In addition, no such actions shall be deemed to supersede the provisions of paragraph (b) of subdivision three of section two hundred seventy-three of this article or the provisions of subdivisions twenty-five and twenty-five-a of section three hundred sixty-four-j of the social services law; provided further that nothing in this section shall prevent access by a Medicaid recipient to a drug which is the only treatment for a particular disease or condition.

7. The commissioner shall provide a report by July first annually to the drug utilization review board, the governor, the speaker of the assembly, and the temporary president of the senate on savings achieved through the supplemental rebate programs in the last fiscal year. Such report shall provide data on what savings were achieved through actions pursuant to subdivisions three, five and six of this section, respectively, and what savings were achieved through other means and how such savings were calculated and implemented.