

Use of Medicaid Inflation Rebates Could Discourage Drug Price Increases

New inflation penalties could reduce drug costs for all payers

This model legislation for the policy described in “Use of State Medicaid Inflation Rebates Could Discourage Drug Price Increases” serves as a guide for how states could implement a new inflation penalty to reduce drug costs for all payers. In many cases this also could be implemented through changes in regulations, though it is dependent on each state’s regulatory framework.

- 1) Definitions-
 - a) In this section, Average Manufacturer Price, Best Price, and Covered Outpatient Drug have the meanings defined by 42 U.S.C. Section 1396r-8 and its subsequent amendments.
- 2) The Department of Health shall establish a preferred drug list for the Medicaid program, including both fee-for-service and managed care programs. The Department may establish preferred drug lists for any other program administered by the Department.
- 3) For every covered outpatient drug sold by a manufacturer or labeler with an active supplemental rebate agreement, the pharmaceutical manufacturer or labeler shall report to the Department of Health, on a quarterly basis, the average manufacturer price, the best price, the inflation rebate amount, and the supplemental rebate amount.
- 4) The preferred drug list may contain only covered outpatient drugs provided by a manufacturer or labeler that has an active supplemental rebate agreement with the Department, except that the Department shall establish a process by which low-cost generic and other drugs without supplemental rebate agreements may be considered for inclusion on the preferred drug list.
- 5) The Department shall establish a standard supplemental rebate agreement that includes the following provisions:
 - a) A manufacturer or labeler will pay supplemental rebates to the Department using the calculation methodology in this section.
 - b) Supplemental rebates will be paid for all covered outpatient drugs purchased, reimbursed, or otherwise made available to beneficiaries of any program for which the Department has established a preferred drug list under this section.
 - c) Other provisions as necessary to implement the supplemental rebate program.
- 6) For each covered outpatient drug included on a preferred drug list, the manufacturer or labeler shall calculate and submit to the Department, on a quarterly basis, the “inflation rebate amount” for the covered outpatient drug.
 - a) The inflation rebate amount shall equal-
 - i) The amount (if any) by which—

- (1) The average manufacturer price for the dosage form and strength of the covered outpatient drug for the period exceeds
 - (2) The average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the covered outpatient drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990,
- ii) Multiplied by-
- (1) Two, if the average manufacturer price for the dosage form and strength of the covered outpatient drug for the period exceeds 1.1 multiplied by the amount calculated under clause (a)(i)(2) of this paragraph or
 - (2) Three, if the average manufacturer price for the dosage form and strength of the covered outpatient drug for the period exceeds 1.25 multiplied by the amount calculated under clause (a)(i)(2) of this paragraph.
- b) In the case of a covered outpatient drug approved by the Food and Drug Administration after Oct. 1, 1990, clause (i)(2) of subparagraph (a) shall be applied by substituting “the first full calendar quarter after the day on which the drug was first marketed” for “the calendar quarter beginning July 1, 1990” and “the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed” for “September 1990”.
- c) In the case of a covered outpatient drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation with respect to such drug under this section shall be the amount computed under this section for such new drug or, if greater, the product of—
- i) The average manufacturer price of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form;
 - ii) The highest inflation rebate amount (calculated as a percentage of average manufacturer price) under this section for any strength of the original single source drug or innovator multiple source drug; and
 - iii) The total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).
- d) In this subparagraph, the term “line extension” means, with respect to a drug, a new formulation of the drug, such as, but not limited to, an extended release formulation.
- 7) The supplemental rebate shall equal the greater of-
- a) The inflation rebate amount minus the federal Medicaid unit rebate amount calculated under 42 U.S.C. Section 1396r-8 plus the greater of-

- i) The average manufacturer price multiplied by the minimum rebate percentage or applicable percentage (as such rebate percentages are specified in 42 U.S.C. Section 1396r-8(c) for the drug) for the dosage form and strength of the covered outpatient drug, or
 - ii) The average manufacturer price minus the best price, or
 - b) The average manufacturer price net of any additional rebate amount negotiated by the state with the manufacturer, either individually or as part of a multi-state negotiation.
- 8) Nothing in this section shall be construed to prevent or discourage the state from negotiating supplemental rebate agreements, either individually or as part of a multi-state negotiation.
 - 9) There shall be no cap on the amount of the supplemental rebate.
 - 10) The state shall submit an invoice to the manufacturer, following the standard Medicaid rebate procedures under 42 U.S.C. Section 1396r-8, for the supplemental rebate for the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed for which payment was made by the State, either directly or through a program of the state, during the rebate period. The manufacturer shall promptly pay the supplemental rebate, except that the manufacturer may reduce the supplemental rebate through payment of the federal Medicaid unit rebate amount calculated under 42 U.S.C. Section 1396r-8 so long as the total rebate received by the state, inclusive of both the federal unit rebate amount and the supplemental rebate amount, equals the greater of subparagraphs 7(a) and 7(b) of this section.
 - 11) All reports and calculations made under this section shall remain confidential. The Department shall establish procedures to ensure the confidentiality of all submissions under this section.
 - 12) The Department shall have authority to issue regulations implementing the provisions of this section.