

Better Data Could Help Medicaid Programs Cut Drug Spending

Manufacturer information can help states increase rebates, limit overpayment

This model legislation for the policy described in “Better Data Could Help Medicaid Programs Reduce Drug Spending” serves as a guide for how states could implement a modified average manufacturer price so that their Medicaid programs do not overpay relative to commercial insurers. In many cases this could also be implemented through changes in regulations, depending 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, modified average manufacturer price, best price, modified best price, and the supplemental rebate amount.
 - 4) The preferred drug list may contain only 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 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 drug sold by a manufacturer or labeler with an active supplemental rebate agreement, the manufacturer or labeler shall calculate and submit to the department, on a quarterly basis, the modified average manufacturer price for the drug.
 - a) The modified average manufacturer price shall equal:

i) The manufacturer's sales to all purchasers (excluding sales exempted in subparagraph (b)) in the United States for such covered outpatient drug in the calendar quarter; net of

(1) Any price concessions (including discounts, rebates, payments, free goods contingent on any purchase requirement, chargebacks, and other financial transactions as defined by the department), including but not limited to price concessions provided to wholesalers, retail community pharmacies, specialty pharmacies, mail order pharmacies, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, long-term care providers, manufacturers, and any other entities specified by the department; and

(2) Any bundled price concessions or discounts, as defined by 42 U.S.C. Section 1396r-8 and its subsequent amendments and implementing regulations;

ii) Divided by the total number of such units of such covered outpatient drug sold by the manufacturer in such quarter.

b) The following sales and associated price concessions shall be exempted from the calculation of modified average manufacturer price:

i) Customary prompt-pay discounts extended to wholesalers;

ii) Bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, as defined in regulations by the department, which may include (but are not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);

iii) Reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction;

iv) Discounts provided by manufacturers under 42 U.S.C. Section 1395w-114a;

v) Any prices charged on or after Oct. 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a state home receiving funds under Section 1741 of Title 38, the Department of Defense, the Public Health Service, or a covered entity described in Subsection (a)(5)(B) (including inpatient prices charged to hospitals described in 42 U.S.C. Section 256b(a)(4)(L));

vi) Any prices charged under the Federal Supply Schedule of the General Services Administration;

vii) Any prices used under a State pharmaceutical assistance program;

viii) Any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

ix) Any prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under 42 U.S.C. Section 1395w-141;

x) Any prices charged which are negotiated by a Medicare prescription drug plan or an MA-PD plan with respect to covered Part D drugs or by a qualified retiree prescription drug plan (as defined in 42 U.S.C. Section 1395w-132(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits

under Part A or enrolled under Part B of such subchapter, or any discounts provided by manufacturers under the Medicare coverage gap discount program under 42 U.S.C. Section 1395w-114a;

- xi) Rebates provided under 42 U.S.C. Section 1396r-8;
- xii) Rebates provided under this section;
- xiii) Sales to prisons, jails, or correctional facilities;
- xiv) Other transactions identified by the department through regulations.

7) For each drug sold by a manufacturer or labeler with an active supplemental rebate agreement, the manufacturer or labeler shall calculate and submit to the department, on a quarterly basis, the modified best price for the drug. The modified best price shall equal the lowest price available from the manufacturer during the rebate period to any purchaser net of any price concessions or discounts included in subparagraph 6(a), excluding prices and price concessions exempted from the calculation of modified average manufacturer price under subparagraph 6(b) of this section.

8) In this section, reimbursement amount means the amount the department will reimburse a pharmacy or other provider for a drug under the Medicaid fee-for-service program during the rebate period. If no such amount is established, the reimbursement amount shall be the greater of the average sales price of the drug, as defined by 42 U.S.C. Section 1395w-3a, or the national average drug acquisition cost supplied by the Centers for Medicare and Medicaid Services.

9) For each drug sold by a manufacturer or labeler with an active supplemental rebate agreement, the department shall calculate, on a quarterly basis, a state rebate amount for the drug. The state rebate amount shall equal the greater of:

- a) The difference between the reimbursement amount and the modified best price for the dosage form and strength of the drug, or
- b) The difference between the reimbursement amount and 100 percent minus 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) multiplied by the modified average manufacturer price for the dosage form and strength of the drug.

10) The supplemental rebate shall equal the greater of:

- a) The state rebate amount, or
- b) The reimbursement amount net of any additional rebate amount negotiated by the state with the manufacturer, either individually or as part of a multistate negotiation.

11) 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 10(a) and (b) of this section.

12) 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 multistate negotiation.

13) There shall be no cap on the amount of the supplemental rebate.

14) 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.

15) The department shall have authority to issue regulations implementing the provisions of this section.