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42 U.S. Code § 1395w-114b

Manufacturer rebate for certain drugs with prices increasing faster than inflation

(a) Requirements

(1) Secretarial provision of information

Not later than 9 months after the end of each applicable period (as defined in subsection (g)(7)), subject to paragraph (3), the Secretary shall, for each part D rebatable drug, report to each manufacturer of such part D rebatable drug the following for such period:

(A) The amount (if any) of the excess annual manufacturer price increase described in subsection (b)(1)(A)(ii) for each dosage form and strength with respect to such drug and period.

(B) The rebate amount specified under subsection (b) for each dosage form and strength with respect to such drug and period.

(2) Manufacturer requirements

For each applicable period, the manufacturer of a part D rebatable drug, for each dosage form and strength with respect to such drug, not later than 30 days after the date of receipt from the Secretary of the information described in paragraph (1) for such period, shall provide to the Secretary a rebate that is equal to the amount specified in subsection (b) for such dosage form and strength with respect to such drug for such period.

(3) Transition rule for reporting

The Secretary may, for each rebatable covered part D drug, delay the timeframe for reporting the information and rebate amount described in subparagraphs (A) and (B) of such paragraph for the applicable periods beginning October 1, 2022, and October 1, 2023, until not later than December 31, 2025.

(b) Rebate amount

(1) In general

(A) Calculation

For purposes of this section, the amount specified in this subsection for a dosage form and strength with respect to a part D rebatable drug and applicable period is, subject to subparagraph (C), paragraph (5)(B), and paragraph (6), the estimated amount equal to the product of—

(i) subject to subparagraph (B) of this paragraph, the total number of units of such dosage form and strength for each rebatable covered part D drug dispensed under this part during the applicable period; and

(ii) the amount (if any) by which—

(I) the annual manufacturer price (as determined in paragraph (2)) paid for such dosage form and strength with respect to such part D rebatable drug for the period; exceeds

(II) the inflation-adjusted payment amount determined under paragraph (3) for such dosage form and

strength with respect to such part D rebatable drug for the period.

(B) Excluded units

For purposes of subparagraph (A)(i), beginning with plan year 2026, the Secretary shall exclude from the total number of units for a dosage form and strength with respect to a part D rebatable drug, with respect to an applicable period, units of each dosage form and strength of such part D rebatable drug for which the manufacturer provides a discount under the program under section 256b of this title.

(C) Reduction or waiver for shortages and severe supply chain disruptions

The Secretary shall reduce or waive the amount under subparagraph (A) with respect to a part D rebatable drug and an applicable period—

(i) in the case of a part D rebatable drug that is described as currently in shortage on the shortage list in effect under section 356e of title 21 at any point during the applicable period;

(ii) in the case of a generic part D rebatable drug (described in subsection (g)(1)(C)(ii)) or a biosimilar (defined as a biological product licensed under section 262(k) of this title), when the Secretary determines there is a severe supply chain disruption during the applicable period, such as that caused by a natural disaster or other unique or unexpected event; and

(iii) in the case of a generic Part [1] D rebatable drug (as so described), if the Secretary determines that without such reduction or waiver, the drug is likely to be described as in shortage on such shortage list during a subsequent applicable period.