

The Right Rebate Act of 2019

Sec. 1. Short Title: The Right Rebate Act of 2019

Sec. 2. Preventing the Misclassification of Drugs under the Medicaid drug rebate program (MDRP)

This section amends the Social Security Act to provide for the application of a civil monetary penalty (CMP) when a drug manufacturer participating in the MDRP knowingly misclassifies or submits incorrect drug category information for a covered drug.

The amount of the CMP is not to exceed 2 times the amount of the difference between the total rebates the manufacturer paid in all States for all rebate periods during which the drug was misclassified *and* the total amount of rebates the manufacturer would have been required to pay with respect to the drug in all States for all rebate periods during which the drug was misclassified.

CMPs applied for knowingly misclassifying a drug are in addition to any other penalties as prescribed by law.

The Secretary shall retain, in addition to any amount retained by the Secretary to recoup investigation and litigation costs related to enforcement to this provision, an amount equal to 25 percent of the total amount of CMP collected under this provision. This sum shall be available to the Secretary, without further appropriation, for activities related to oversight and enforcement of this Act. This fund will be used to improve drug data reporting systems, evaluating and ensuring manufacturer compliance with rebate obligations, and improved oversight and enforcement related to ensuring manufactures accurately and fully report drug information related to drug classification.

The legislation provides States the ability to recover incorrect rebate payments. If the Secretary determines a manufacturer paid a lower per-unit rebate to a State due to misclassification of a drug, the manufacturer shall pay the State an amount equal to the product of (1) the difference between the per-unit rebate amount paid for the period and the per-unit rebate amount that should have been paid for the period and (2) the total units of the drug paid for under the State plan during the period.

The Secretary has the authority to correct misclassifications. If the Secretary determines a manufacturer has misclassified a covered drug, the Secretary shall notify the manufacturer and require a correction within a timely manner. Should the manufacturer fail to correct the misclassification in a timely manner, the Secretary may correct the misclassification on behalf of the manufacturer, suspend the misclassified drug as a covered drug in the MDRP, or impose a CMP for each rebate period during which the drug is misclassified.

The legislation requires a report to Congress on at least an annual basis, which describes any drugs that have been identified as misclassified, along with the actions taken to correct the misclassifications and to ensure payment of any unpaid rebate amounts. This report will be available to the public on a timely basis.

Actions taken under this Act shall be in addition to other remedies available to the Secretary, including terminating the manufacturer's rebate agreement for non-compliance with the terms of such agreement and pursuing CMPs.

The amendments made by this Act shall take effect on the date on enactment.