

HHS Proposes Banning Rx Rebates Paid in Medicare and Other Government Programs

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On January 31, 2019, the U.S. Department of Health and Human Services (HHS) released proposed regulations that would prohibit pharmaceutical companies from paying rebates to pharmacy benefit managers (PBMs) in government health care programs such as Medicare. If finalized in their current form, the proposed regulations would take effect on January 1, 2020.

HHS Proposal Would Ban Rx Rebates Paid in Federal Health Programs

The proposed regulations, which are subject to a 60-day comment period, would eliminate the current safe harbor protection for these rebates under federal anti-kickback statutes. In practice, the safe harbor exempts pharmaceutical rebates from being considered an illegal kickback. The proposed regulations would eliminate that protection and potentially subject the rebates to review under federal anti-kickback laws.

The HHS proposal would exclude from the safe harbor's definition of a "discount" reductions in the price of drugs offered by drug manufacturers to PBMs, Medicare Part D plans, and Medicaid managed care plans. Instead, the proposed regulations would create a new safe harbor designed for price reductions on pharmaceutical products at the point of sale, and for fixed-fee services arrangements between manufacturers and PBMs.

Impact on Employer Group Health Plans

Since the proposed regulations only apply to rebates in federal health programs, the proposed regulations do not apply to rebates paid in the private insurance market. However, federal programs under Medicare and Medicaid often influence plan designs in the private market. In addition, Congress has the power to regulate or prohibit rebates in private insurance.

Impact on Individuals in Medicare Part D

Under the proposal, administration officials estimate that total beneficiary cost sharing in Medicare Part D would decrease and premiums would increase, and that the decrease in total beneficiary cost sharing would offset the total increase in premiums across all beneficiaries. Premiums for Medicare drug plans under the proposal could increase anywhere from 8% to 22%, while average costs patients pay out of pocket would fall 9% to 14%, according to estimates released by HHS.

Resources

The new release is available [here](#).

A fact sheet is available [here](#).

The proposed regulations are temporarily available [here](#).

(The proposed regulations will be published in the February 6, 2019, *Federal Register*.)

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