

# Departments Withdraw HHS' Cost-Sharing Regulations for Now

By: Alex Mattingly on August 29, 2019 on [graydon.law](https://graydon.law)

In April 2019, the Department of Health and Human Services (HHS) issued final regulations that were set to become effective January 1, 2020. HHS had expressed concern that the availability of a coupon may cause physicians and patients to choose an expensive brand name drug when a less expensive and equally effective generic or other alternative is available, and the finalized cost-sharing regulations were established to counter this concern. The new regulations stated that financial assistance provided to plan participants by drug manufacturers to reduce or eliminate out-of-pocket costs is not required to be counted toward the annual out-of-pocket maximum where the prescription was for a brand drug that has an available and medically appropriate generic equivalent. HHS, the Department of Labor, and the Treasury Department (the "Departments") acknowledged that it was reasonable to interpret this rule to mean that plans must count all forms of assistance not specifically excluded by the regulations towards the annual out-of-pocket maximum.

**[The Departments have now issued a joint FAQ](#)** regarding the implementation of these regulations, effectively retracting the cost-sharing regulations due to the potential conflict with current IRS guidance on HSA eligibility. To be eligible to participate in an HSA, a participant must be enrolled in a high deductible health plan, which requires the participant to pay for 100% of health costs (with some exclusions) until the participant's deductible has been met. IRS guidance has stated that manufacturer coupons will not count towards a participant's deductible. The conflict between the cost-sharing regulations and IRS rules would arise when a participant with prescription drug costs that are heavily subsidized by a manufacturer causes the participant to hit the out-of-pocket maximum before hitting his deductible. Although the deductible is often set well below the out-of-pocket maximum, the cost of the drugs paid by the manufacturer coupons is only counted towards the out-of-pocket maximum, not the deductible. Once the out-of-pocket maximum has been hit, the Plan is responsible for covering any future medical costs, meaning that medical costs are not being paid by the Participant before reaching his deductible. The cost-sharing regulations therefore could make a participant ineligible that is otherwise eligible to participate in an HSA.

Due to this conflict between the cost-sharing regulations and IRS guidance, the Departments stated in the FAQ that, until joint guidance is issued and effective, the

Departments will not penalize a group health plan that does not comply with the new HHS regulations. This FAQ guidance means that group health plans may exclude the value of drug manufacturers' coupons from the annual limitation on cost sharing in all circumstances until further notice. When further guidance has been issued, we will provide an update on the Benefits Insight Blog.