

Background

- Under the Medicaid Rebate statute, manufacturers are required to pay rebates to state Medicaid programs in exchange for guaranteed coverage of most FDA-approved medicines. For innovator medicines, these rebates are calculated in part based on the manufacturer's best price. Previously, manufacturer cost-sharing assistance was exempt from calculations of best price because the assistance is provided to patients, not to health plans or other third parties.
- On December 31, 2020, the Centers for Medicare & Medicaid Services (CMS) published a final rule, known as the Accumulator Rule, that requires manufacturers to "ensure" that patient assistance is provided entirely to patients as a condition of excluding the patient assistance from best price.
- Unfortunately, through accumulator adjustment programs, health insurers can siphon the cost-sharing assistance that the manufacturer provided to the patient away from counting toward deductibles or out-of-pocket maximums.
- The Accumulator Rule provides that when an accumulator adjustment program takes assistance a manufacturer has given to a patient, even without the patient's or the manufacturer's authorization or even knowledge, that assistance must be treated as a price discount offered to the health insurer.
- CMS further contends that, because the health insurer is eligible for best price, the financial assistance taken away from the patient by an accumulator adjustment program lowers the manufacturer's best price for the medicine, meaning the manufacturer must give the same discount for that drug to state Medicaid programs.
- In effect, by using patient assistance to increase manufacturers' Medicaid rebate liability, the Accumulator Rule penalizes pharmaceutical manufacturers for the assistance they provide to patients.

The Accumulator Rule Is Against the Law and Should Be Declared Invalid

By treating assistance given to patients as part of the "price" manufacturers provide to health insurers, the Accumulator Rule contradicts the Medicaid rebate statute. It violates the letter of the law by stretching the meaning of the word "price" beyond all commonsense recognition. And it violates the spirit of the law by essentially taxing manufacturers for providing assistance to patients.

- The Medicaid Rebate Act defines best price as "the lowest price available from the manufacturer" to specified buyers, such as health insurers. Sales to patients are best price exempt.
- In the Accumulator Rule, CMS treats assistance offered by manufacturers to patients as if it were a price discount to health insurers, just because the insurers have figured out a way to take that assistance away from the patients for whom it was intended.
- That is simply not what the word "price" means. A "price" is the amount that a seller intentionally offers and voluntarily agrees to accept from a buyer. But here, the manufacturer does not intend to offer the financial assistance at issue to the health insurers, but rather wants it to fully benefit patients. The health insurers are acting against the manufacturers' will. That is not what the law means when it says "lowest price available."
- The rule also is contrary to the intent of Congress, which did not want to discourage manufacturers from offering discounts or assistance to patients. As CMS admits, "patients are not one of the entities described in the statutory definition of Best Price," and thus by statute, assistance provided to patients must not affect best price for purposes of a manufacturer's Medicaid rebates.