

Title 23. Public Utilities and Regulated Industries
Chapter I. State Insurance Department, Department of Commerce
Subchapter B. Life, Health, and Accident
Part 152. 340B Drug Program Nondiscrimination Requirements

Codification Notes. This part as promulgated prior to codification into the Code of Arkansas Rules provided as follows:

"I. AUTHORITY

This rule is issued pursuant to Ark. Code Ann. § 23-92-606 which mandates that the Insurance Commissioner ("Commissioner") shall promulgate a rule to implement the subchapter pertaining to the 340B Drug Pricing Nondiscrimination Act."

"VII. EFFECTIVE DATE

This Rule is effective after review and approval by the Arkansas Legislative Council, ten (10) days after filing of the approved Rule with the Arkansas Secretary of State."

Subpart 1. Generally

23 CAR § 152-101. Definitions.

As used in this part:

(1) "340B drug pricing" means the acquisition and delivery of 340B-priced drugs as established under Section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585;

(2) "Arkansas-based community pharmacy" means a pharmacy licensed and located in this state;

(3) "Covered entity" means an entity that meets the 340B Drug Pricing Program's eligibility requirements found at 42 U.S.C. § 256b(a)(4) and is enrolled in the 340B Drug Pricing Program;

(4) "Patient" means an individual who has an established relationship with a covered entity and is seeking medical diagnosis and treatment from the covered entity;

(5) "Pharmacy" means the same as defined in Arkansas Code § 17-92-101;

(6) "Provider" means a licensed pharmacist as defined in Arkansas Code § 17-92-101; and

(7)(A) "Third party" means:

(i) A payor or the payor's intermediary; or

(ii) A pharmacy benefits manager.

(B) "Third party" does not include:

(i) The Arkansas Medicaid Program;

(ii) A risk-based provider organization as established under the Medicaid Provider-Led Organized Care Act, Arkansas Code § 20-77-2701 et seq.; or

(iii) A self-insured governmental plan or a pharmacy benefits manager for a self-insured governmental plan.

Authority. Arkansas Code §§ 23-61-108, 23-92-606.

23 CAR § 152-102. Third party requirements.

A third party shall:

(1) Inform a patient that the patient is not required to use a mail-order pharmacy;

(2) Obtain a signed waiver from a patient before allowing the use of a mail-order pharmacy;

(3) Make drug formulary and coverage decisions based on the third party's normal course of business;

(4) Allow a patient the freedom to use any pharmacy or any provider the patient chooses, whether or not the pharmacy participates in 340B drug pricing; and

(5) Eliminate discriminatory contracting as it relates to:

(A) Transferring the benefit of 340B drug-pricing savings from one (1) entity, including critical access hospitals, federally qualified health centers, other

hospitals, or 340B drug-pricing participants and their underserved patients, to another entity, including without limitation:

- (i) Pharmacy benefits managers;
- (ii) Private insurers; and
- (iii) Managed care organizations;

(B) Pricing that occurs when offering a lower reimbursement for a drug purchased under 340B drug pricing than for the same drug not purchased under 340B drug pricing;

(C) Refusal to cover drugs purchased under 340B drug pricing;

(D) Refusal to allow 340B drug-pricing pharmacies to participate in networks; and

(E) Charging more than fair market value or seeking profit sharing in exchange for services involving 340B drug pricing.

Authority. Arkansas Code §§ 23-61-108, 23-92-606.

23 CAR § 152-103. Third party and pharmaceutical manufacturer prohibitions.

(a) A third party shall not:

(1) Coerce a patient into using a mail-order pharmacy;

(2) Require a patient to use a mail-order pharmacy;

(3) Discriminate, lower the reimbursement, or impose any separate terms upon a pharmacy in any other third-party contract on the basis that a pharmacy participates in 340B drug pricing;

(4) Require a pharmacy to reverse, resubmit, or clarify a 340B drug-pricing claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing;

(5) Require a billing modifier to indicate that the drug or claim is a 340B drug-pricing claim unless the drug or claim is being billed to the fee-for-service Arkansas Medicaid Program;

(6) Modify a patient's copayment on the basis of a pharmacy's participation in 340B drug pricing;

(7) Exclude a pharmacy from a network on the basis of the pharmacy's participation in 340B drug pricing;

(8) Establish or set network adequacy requirements based on 340B drug-pricing participation by a provider or a pharmacy; or

(9) Prohibit an entity authorized to participate in 340B drug pricing or a pharmacy under contract with an entity authorized to participate in 340B drug pricing from participating in the third party's provider network on the basis of participation in 340B drug pricing.

(b) A third party that is a pharmacy benefits manager shall not base the drug formulary or drug coverage decisions upon the 340B drug-pricing status of a drug, including price or availability, or whether a dispensing pharmacy participates in 340B drug pricing.

(c) A pharmaceutical manufacturer shall not:

(1) Prohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer; or

(2) Deny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing.

Authority. Arkansas Code §§ 23-61-108, 23-92-606.

23 CAR § 152-104. Pharmacy claims.

All pharmacy claims processed by a pharmacy that participates in 340B drug pricing are final at the point of adjudication.

Authority. Arkansas Code §§ 23-61-108, 23-92-606.

23 CAR § 152-105. Penalties.

The penalties, actions, or orders, as authorized under Arkansas Code §§ 23-66-209 and 23-66-210, shall apply to violations of this part.

Authority. Arkansas Code §§ 23-61-108, 23-92-606.