

ARKANSAS REGISTER

Proposed Rule Cover Sheet



Secretary of State
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Name of Department _____

Agency or Division Name _____

Other Subdivision or Department, If Applicable _____

Previous Agency Name, If Applicable _____

Contact Person _____

Contact E-mail _____

Contact Phone _____

Name of Rule _____

Newspaper Name _____

Date of Publishing _____

Final Date for Public Comment _____

Location and Time of Public Meeting _____

PROPOSED RULE 123

340B DRUG PROGRAM NONDISCRIMINATION REQUIREMENTS

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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.

II. DEFINITIONS

As used in this Rule:

- (1) “Arkansas-based community pharmacy” means a Pharmacy licensed and located in this State;
- (2) “Covered entity” means an entity that meets the 340B Drug Pricing Program’s eligibility requirements found at 42 U.S.C. § 256b(a)(4) to participate and is enrolled in the 340B Drug Pricing Program;
- (3) “Patient” means an individual who has an established relationship with a covered entity and is seeking medical diagnosis and treatment from the covered entity
- (4) “Pharmacy” means the same as defined in § 17-92-101;
- (5) “Provider” means a licensed pharmacist as defined in § 17-35 92-101;
- (6)(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, § 20-77-2701 et seq.; or
 - (iii) A self-insured governmental plan or a pharmacy benefits manager for a self-insured governmental plan; and
- (7) "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.

III. 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 pharmacy benefits managers, private insurers, and 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.

IV. 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.

The prohibitions in this subsection shall only apply to drug pricing contracts with or on behalf of a covered entity located and conducting business in Arkansas and is inapplicable to conduct occurring exclusively and entirely outside the boundaries of this State.

The prohibitions in this subsection shall also only apply to 340B drug pricing contract pharmacy arrangement transactions pertaining to a patient of a covered entity.

V. PHARMACY CLAIMS

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

VI. PENALTIES

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

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.

ALAN MCCLAIN
INSURANCE COMMISSIONER

DATE



Michael Preston
SECRETARY OF COMMERCE

Alan McClain
COMMISSIONER,
ARKANSAS INSURANCE
DEPARTMENT

May 26, 2022

Honorable John Thurston
Arkansas Secretary of State
State Capitol Building
Little Rock, AR 72201
Attn. Arkansas Register

sent via email: register@sos.arkansas.gov

Re: Proposed Amended Rule 123 "340B DRUG PROGRAM NONDISCRIMINATION REQUIREMENTS"

Dear Secretary:

The Arkansas Insurance Department has scheduled a public hearing as to Proposed Amended Rule 123 "340B DRUG PROGRAM NONDISCRIMINATION REQUIREMENTS." Enclosed are the DOI Notices of Public Hearing and a copy of the proposed rule.

Please arrange to publish the information in a format acceptable to the Secretary for at least 30 days in advance. Can you send us confirmation that we can use in the transcript as a public hearing exhibit?

An electronic filing will be made within the statutorily required 7 days. Thanks for your help.

Sincerely,

Clara Mezza

Legal Administrative Coordinator/Legal Division

clara.mezza@arkansas.gov

501-683-3497

Enclosures



Michael Preston
SECRETARY OF COMMERCE

Alan McClain
COMMISSIONER,
ARKANSAS INSURANCE
DEPARTMENT

DATE: MAY 26, 2022

TO: ALL HEALTH INSURERS & HMOs, AND OTHER INTERESTED PARTIES

FROM: ARKANSAS INSURANCE DEPARTMENT

SUBJECT: PROPOSED RULE 123: 340B DRUG PROGRAM NONDISCRIMINATION REQUIREMENTS

NOTICE OF PUBLIC HEARING

Please find attached or available by electronic publication by the Arkansas Insurance Department ("AID") Proposed Rule 123, "340B DRUG PROGRAM NONDISCRIMINATION REQUIREMENTS."

Pursuant to Arkansas Administrative Procedures Act, and other applicable laws or rules, NOTICE is hereby given that a PUBLIC HEARING will be held on August 8th, 2022 at 10:00 A.M., in the Second Floor Hearing Room ("Riverview Room"), at the Arkansas Department of Commerce, 1 Commerce Way, Little Rock, AR 72202.

The purpose of the Public Hearing will be to determine whether the Director should adopt the Proposed Rule 123, "340B DRUG PROGRAM NONDISCRIMINATION REQUIREMENTS." The Arkansas Insurance Commissioner is proposing a rule which implements Act 1103 of 2021 pertaining to discriminatory activities governed by the Act. The Commissioner is re-filing this proposed Rule with new language and is hereby giving the public and interested parties notice of the newly proposed changes.

All interested persons are encouraged to make comments, statements, or opinions to the address below or attend the Public Hearing and present, orally or in writing, statements, arguments or opinions on the proposed Rule. All licensees and other interested persons are responsible for notifying all their personnel, agents, and employees about this Public Hearing. **The record will remain open for public comment until the close of public hearing, August 8th, 2022.** Persons wishing to testify or make comments are requested to submit intended statements in writing in advance. Direct your inquiries to: Booth Rand, Managing Attorney, Arkansas Insurance Department, 501-371-2820, email: booth.rand@arkansas.gov. A copy of the proposed Rule may be obtained or viewed at <https://www.insurance.arkansas.gov/pages/industry-regulation/legal/proposed-rules/>.

Sincerely,

Booth Rand
Managing Attorney
Arkansas Insurance Department