

ARKANSAS REGISTER

Proposed Rule Cover Sheet



Secretary of State
John Thurston
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Little Rock, Arkansas 72201-1094
(501) 682-5070
www.sos.arkansas.gov



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 _____



Michael Preston
SECRETARY OF COMMERCE

Alan McClain
COMMISSIONER,
ARKANSAS INSURANCE
DEPARTMENT

DATE: FEBRUARY 22, 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 April 14th, 2022 at 9 A.M., in the Second Floor Hearing Room ("Diamond Mine 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.

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, April 14th, 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

NOTICE OF RULE MAKING AND PUBLIC HEARING

The Arkansas Insurance Department will host a Public Hearing on April 14th, 2022, at 9:00 AM., in the Second Floor Diamond Mine Hearing Room, in the Arkansas Department of Commerce Building, One Commerce Way, Little Rock, Arkansas 72202. The Arkansas Insurance Commissioner is considering adopting proposed Rule 123 "340B DRUG PROGRAM NONDISCRIMINATION REQUIREMENTS" to consider adoption of a proposed rule which implements Act 1103 of 2021, pertaining to discriminatory activities related to the 340B program, including but not limited to reviewing or adopting standards related to the following: (1) clarifying that "Arkansas-based community pharmacy" means a Pharmacy located and conducting business in this State and that a "Covered entity" means an entity that meets the requirements found at 42 U.S.C. §256b(a)(4) to participate and is enrolled in the 340B Drug Pricing Program; (2) clarifying that the prohibitions in the proposed rule apply to direct drug pricing contract pharmacy arrangements between a pharmaceutical manufacturer and a covered entity located and conducting business in Arkansas and is inapplicable to conduct occurring exclusively outside the boundaries of this State and that 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; (3) clarifying an enforcement policy that covered entity must first exhaust all available federal arbitration and federal administrative rights for cancellation or limitation on contracting with outside pharmacies through United States Department of Health and Human Services ("HRSA") rules, and if HRSA determines, under the administrative dispute resolution process described in 42 U.S.C. § 256b(d)(3) and 42 C.F.R. §§10.20–24, that a drug manufacturer has improperly denied a pharmacy 340B drug pricing, or that a drug manufacturer has improperly prohibited 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; then, upon such violations, such actions may be reviewed to constitute an unfair and deceptive act or practice under Ark. Code Ann. §§ 23-66-209 and 23-66-210. Copies of the proposed Rule may be obtained by writing or calling the Arkansas Insurance Department at 501-371-2820, or by visiting its Internet site at <https://www.insurance.arkansas.gov/pages/industry-regulation/legal/proposed-rules/>.



Michael Preston
SECRETARY OF COMMERCE

Alan McClain
COMMISSIONER,
ARKANSAS INSURANCE
DEPARTMENT

February 23, 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,

A handwritten signature in blue ink that reads "Clara D. Mezza".

Clara Mezza
Legal Administrative Coordinator/Legal Division
clara.mezza@arkansas.gov
501-683-3497

Enclosures