SUMMARY

ARKANSAS INSURANCE DEPARTMENT PROPOSED RULE 123

340B DRUG PROGRAM NONDISCRIMINATION REQUIREMENTS

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To: Arkansas Legislative Council & Arkansas Bureau of Legislative Research

From: Booth Rand, Managing Attorney, Arkansas Insurance Department

CC: Alan McClain, Arkansas Insurance Commissioner; Jim Brader, General Counsel;

Date: May 25, 2022

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LEGISLATIVE AUTHORITY FOR RULE

This rule is issued pursuant to Ark. Code Ann. § 23-92-606 ("Act 1103 of 2021") which mandates that the Insurance Commissioner ("Commissioner") shall a promulgate rule to implement the subchapter pertaining to the 340B Drug Pricing Nondiscrimation Act ("Act 1103").

BACKGROUND AND PURPOSE OF RULE

The purpose of this Rule is to help reduce or remove federal commerce clause and preemption claims against Act 1103 of 2021 which have been raised in Federal District Court, by supplying new definitions not in the Act, and to add penalties for violations of the Act, not supplied in the Act.

EXPLANATION OF THE PROPOSED RULE

AID is re-noticing this earlier proposed Rule governing Act 1103 and the 340b drug program. A brief background or explanation about why we are re-noticing this Rule is important.

On or about February 22, 2022, following approval by ADOC and the Governor's office allowing promulgation of the rule, the Department filed a proposed draft Rule, Rule 123 "340b Drug Program Nondiscrimination Requirements." Following filing of the proposed Rule at BLR/ALC, the Department held a hearing on the proposed draft rule on April 14, 2022. The Department received significant opposition to the proposed rule from the Arkansas Hospital Association and area hospitals, primarily on the proposed rule's requirements which (1) required arbitration of complaints with the Federal agency, HRSA, before applying state law enforcement, and (2) the Department limited jurisdiction of the Rule to 340b hospital covered entities which had a direct contract with the pharmaceutical manufacturers. The reason for the proposed limitations were due to concerns over federal pre-emption and federal commerce clause infringement claims derived from Act 1103 itself. The Department and the AG's Office are currently in litigation in federal court against PHARMA which has raised these concerns.

Following the hearing, AID met with the AG's office and intervenors and the hospital association related to the Department's proposed language. AID agreed to remove the arbitration and direct contracting limitations. AID also agreed to supply different definition language to help reduce the federal preemption and commerce clause claims raised against Act 1103.

We are re-notifying the public and re-filing this proposed Rule because we believe we may be making a material change to the earlier filed Rule. So out of an abundance of caution we are filing this with BLR/ALC and going through rulemaking again.

The proposed re-notified Rule in this re-filing provides the following changes:

- We removed any arbitration requirement with HRSA before we begin state enforcement to help reduce hospital objections or concerns
- We removed the direct contracting language between pharmaceutical manufacturers and covered entity hospitals as to the application of Act 1103 to help reduce hospital objections or concerns
- We supplied a definition of "Arkansas-based community pharmacy" to mean a pharmacy licensed and located in this State to help reduce commerce clause infringement claims
- We supplied a definition of "340B drug pricing" to mean "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, to help reduce federal pre-emption claims by explaining we were not regulating "pricing" of the drugs
- We supplied a penalties and fines provision not supplied in Act 1103.