

ARKANSAS INSURANCE DEPARTMENT

IN RE ACT 1103 OF 2021

AID ORDER # 2021-37

**PHARMACEUTICAL RESEARCH &
MANUFACTURERS OF AMERICA**

ORDER GRANTING PETITION FOR DECLARATORY RULING

Comes now the Arkansas Insurance Department (“Department”), by and through its attorney, Booth Rand, and, for its Order, states the following findings:

1. On July 29, 2021, the Department received a request for a Declaratory Ruling from the Pharmaceutical Research and Manufacturers of America (“PhRMA,” hereafter, “Petitioner”) pertaining to the State’s ability to enforce two provisions in Act 1103 of 2021, the “340B Drug Pricing Nondiscrimination Act” (hereafter, “Act 1103”) enacted by the Arkansas Legislature: Ark. Code Ann. § 23-92-604(c)(1) and Ark. Code Ann. § 23-92-604(c)(2).

2. From Act 1103, Ark. Code Ann. § 23-92-604(c)(1) states that “a pharmaceutical manufacturer shall not 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.”

3. From Act 1103, Ark. Code Ann. § 23-92-604(c)(2) provides that “a pharmaceutical manufacturer shall not 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.”

4. The Petitioner states that its members are “pharmaceutical manufacturers” under Ark. Code Ann. § 23-92-604 of Act 1103.

5. The Petitioners assert that the above referenced two provisions in Act 1103 are preempted by the Supremacy Clause of the US Constitution because they conflict with the requirements, purposes and objectives of the federal 340B statute and program. The Petitioners also allege that Act 1103 appears to violate the Commerce Clause of the US Constitution. The Petitioners describe that there exists pending federal litigation and explains that key issues of federal law are being decided in federal litigation over transfers of drugs at 340B prices to contract pharmacies at the request of covered entities.

6. Act 1103 vests jurisdiction and enforcement of its provisions, including rule-making powers, with the Arkansas Insurance Commissioner. The provisions of Act 1103 are to go into effect on July 28, 2021.

7. Department Rule 121, “Declaratory Orders,” permits affected persons to petition the Commissioner concerning the applicability of statutory provisions, rules or orders over which the agency has authority. The Commissioner finds under Section 4 of Rule 121 that provisions in a statute may substantially affect the Petitioner and the Petitioner’s particular set of circumstances and the question or issue on which the Petitioner seeks a Declaratory Order.

8. The Commissioner finds that this issue needs resolution and is therefore ripe for administrative review.

9. The Commissioner additionally finds that, although not requested by the Petitioner, due to the number of potentially affected parties, and due to the magnitude of the issue, there is a need for a public hearing on this matter.

WHEREFORE, the Commissioner grants the Petitioners' request for a Declaratory Petition and shall set this matter for an administrative hearing under Arkansas Insurance Department Rule 121 and shall issue an Order or Ruling pertaining to the Petition, following an administrative hearing on this matter, and makes the following additional Orders:

(1) The Commissioner will appoint an outside hearing officer to preside over this matter under Rule 121;

(2) The Commissioner suspends enforcement of Ark. Code Ann. § 23-92-604(c)(1) and Ark. Code Ann. § 23-92-604(c)(2) pending completion of Declaratory review whether such provisions are preempted or inconsistent with federal law. This suspension shall be for ninety (90) days from the date of the Petition unless further extended by Order of the Commissioner.

(3) The Department shall publish this Order with a Bulletin advising other interested parties of their opportunity to intervene in this matter.

7-29-21

DATE

Alan McClain

Alan McClain

Insurance Commissioner

State of Arkansas