

MARKUP 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**

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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

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DATE

1 State of Arkansas  
2 93rd General Assembly  
3 Regular Session, 2021  
4

As Engrossed: H4/15/21

# A Bill

HOUSE BILL 1881

5 By: Representatives M. Gray, Wardlaw, Murdock, V. Flowers  
6 By: Senator Rapert  
7

## For An Act To Be Entitled

9 AN ACT TO ESTABLISH THE 340B DRUG PRICING  
10 NONDISCRIMINATION ACT; AND FOR OTHER PURPOSES.  
11

## Subtitle

14 TO ESTABLISH THE 340B DRUG PRICING  
15 NONDISCRIMINATION ACT.  
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18 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:  
19

20 SECTION 1. Arkansas Code Title 23, Chapter 92, is amended to add an  
21 additional subchapter to read as follows:  
22

### Subchapter 6 – 340B Drug Pricing Nondiscrimination Act

#### 23-92-601. Title.

26 This subchapter shall be known and may be cited as the "340B Drug  
27 Pricing Nondiscrimination Act".  
28

#### 23-92-602. Definitions.

##### As used in this subchapter:

31 (1) "Patient" means an individual seeking medical diagnosis and  
32 treatment;

33 (2) "Pharmacy" means the same as defined in § 17-92-101;

34 (3) "Provider" means a licensed pharmacist as defined in § 17-  
35 92-101;

36 (4)(A) "Third party" means:



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

2 (ii) A pharmacy benefits manager.

3 (B) "Third party" does not include:

4 (i) The Arkansas Medicaid Program;

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

8 (iii) A self-insured governmental plan or a pharmacy  
9 benefits manager for a self-insured governmental plan; and

10 (5) "340B drug pricing" means the program established under  
11 section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585.

12  
13 23-92-603. Third-party requirements.

14 A third party shall:

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

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

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

21 (4) Allow a patient the freedom to use any pharmacy or any  
22 provider the patient chooses, whether or not the pharmacy participates in  
23 340B drug pricing; and

24 (5) Eliminate discriminatory contracting as it relates to:

25 (A) Transferring the benefit of 340B drug-pricing savings  
26 from one (1) entity, including critical access hospitals, federally qualified  
27 health centers, other hospitals, or 340B drug-pricing participants and their  
28 underserved patients, to another entity, including without limitation  
29 pharmacy benefits managers, private insurers, and managed care organizations;

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

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

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

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

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4 23-92-604. Third party and pharmaceutical manufacturer – Prohibitions.

5 (a) A third party shall not:

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

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

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

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

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

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

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

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

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

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

31 (c) A pharmaceutical manufacturer shall not:

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

35 (2) Deny or prohibit 340B drug pricing for an Arkansas-based  
36 community pharmacy that receives drugs purchased under a 340B drug pricing

1 contract pharmacy arrangement with an entity authorized to participate in  
2 340B drug pricing.

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4 23-92-605. Pharmacy claims.

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

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8 23-92-606. Rules.

9 The Insurance Commissioner shall promulgate rules to implement this  
10 subchapter.

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12 */s/M. Gray*

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15 **APPROVED: 5/3/21**

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