ARKANSAS REGISTER

Proposed Rule Cover Sheet

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Name of Department Arkansas Department of Commerce

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Other Subdivision or Department, If Applicable

Previous Agency Name, If Applicable

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DRAFT

RULE 123

340B DRUG PROGRAM NONDISCRIMINATION REQUIREMENTS

I. AUTHORITY

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

II. DEFINITIONS

As used in this Rule:

(1) "Arkansas-based community pharmacy" means a Pharmacy located and conducting business in this State;

(2) "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;

(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 program 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 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.

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 subject to Section VIII 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.

VIII. ENFORCEMENT POLICY

For complaints filed at the Arkansas Insurance Department ("Department") for alleged violations of Ark. Code Ann. Ark. Code Ann. § 23-92-604(c)(1) and Ark. Code Ann. § 23-92-604(c)(2), the complainant's 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.

ALAN MCCLAIN
INSURANCE COMMISSIONER

DATE