INTERIM STUDY PROPOSAL 2025-016

State of Arkansas *As Engrossed: S2/5/25 S3/10/25*
95th General Assembly **A Bill**
Regular Session, 2025 SENATE BILL 140

By: Senator J. Boyd
By: Representative Achor

Filed with: Senate Committee on Insurance and Commerce pursuant to A.C.A. §10-3-217.

For An Act To Be Entitled

AN ACT TO MANDATE THE USE OF BIOSIMILAR MEDICINES UNDER HEALTH BENEFIT PLANS; TO REQUIRE A HEALTHCARE PROVIDER TO PRESCRIBE BIOSIMILAR MEDICINES; TO IMPROVE ACCESS TO BIOSIMILAR MEDICINES; AND FOR OTHER PURPOSES.

Subtitle

TO MANDATE THE USE OF BIOSIMILAR MEDICINES UNDER HEALTH BENEFIT PLANS; TO REQUIRE A HEALTHCARE PROVIDER TO PRESCRIBE BIOSIMILAR MEDICINES; AND TO IMPROVE ACCESS TO BIOSIMILAR MEDICINES.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code Title 23, Chapter 79, is amended to add an additional subchapter to read as follows:

Subchapter 29 — Mandate for Use of Biosimilar Medicines

23-79-2901. Definitions.

As used in this subchapter:

(1) "Beneficiary" means an individual who is entitled to receive healthcare services under the terms of a health benefit plan;

(2) "Biosimilar medicine" means a biological product that is:

(A) Licensed under 42 U.S.C.§ 262(k), as it existed on January 1, 2025; and

(B) Not listed as discontinued in the United States Food and Drug Administration's Database of Licensed Biological Products, commonly known as the "Purple Book";

(3) "Brand drug" means a drug product for which an application has been approved under 21 U.S.C. § 355(c), as it existed on January 1, 2025, or a biological product, other than a biosimilar medicine, that is licensed under 42 U.S.C. § 262(a), as it existed on January 1, 2025;

(4) "Formulary" means:

(A) A list of prescription drug products and biological products that is developed by a pharmacy and therapeutics committee or other clinical and pharmacy experts; and

(B) Represents a health benefit plan's prescription drug products and biological products approved for use;

(5) "Generic drug" means a drug product:

(A) For which an application has been approved under 21 U.S.C. § 355(j), as it existed on January 1, 2025; and

(B) That has been listed in the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book" as therapeutically equivalent to a reference listed drug, even if the manufacturer of the drug product applies a trade name to the drug;

(6)(A) "Health benefit plan" means an individual, blanket, or group plan, policy, or contract for healthcare services offered, issued, renewed, delivered, or extended in this state by a healthcare insurer.

(B) "Health benefit plan" includes:

(i) Indemnity and managed care plans; and

(ii) Nonfederal governmental plans as defined in 29 U.S.C. § 1002(32), as it existed on January 1, 2025, including plans providing health benefits to state and public school employees under § 21-5-401 et seq.

(C) "Health benefit plan" does not include:

(i) A plan that provides only dental benefits or eye and vision care benefits;

(ii) A disability income plan;

(iii) A credit insurance plan;

(iv) Insurance coverage issued as a supplement to liability insurance;

(v) A medical payment under an automobile or homeowners insurance plan;

(vi) A health benefit plan provided under Arkansas Constitution, Article 5, § 32, the Workers' Compensation Law, § 11-9-101 et seq., or the Public Employee Workers' Compensation Act, § 21-5-601 et seq.;

(vii) A plan that provides only indemnity for hospital confinement;

(viii) An accident-only plan;

(ix) A specified disease plan;

(x) A long-term-care-only plan; or

(xi) The Arkansas Medicaid Program;

(7)(A) "Healthcare insurer" means an entity subject to the insurance laws of this state or the jurisdiction of the Insurance Commissioner that contracts or offers to contract to provide health insurance coverage, including without limitation an insurance company, a hospital and medical service corporation, a health maintenance organization, or a self- insured governmental or church plan in this state.

(B) "Healthcare insurer" does not include:

(i) An entity that provides only dental benefits or eye and vision care benefits; or

(ii) The Arkansas Medicaid Program;

(8) "Healthcare provider" means a type of provider that renders healthcare services to patients for compensation including a doctor of medicine or another licensed healthcare professional acting within the *provider's licensed scope of practice;*

(9) "Limited distribution drug" means a prescription medication that is restricted by a pharmaceutical manufacturer to a

limited number of specialty pharmacies due to the prescription medication's:

(A) Complex use, including special handling, monitoring, or administration;

(B) High cost; or

(C) Safety concerns;

(10) "Reference listed drug" means the listed drug product identified by the United States Food and Drug Administration as a drug product upon which an applicant relies in seeking approval of the applicant's application submitted under 21 U.S.C. § 355(j), as it existed on January 1, 2025;

(*11*) "Reference product" means a single biological product that is licensed by the United States Food and Drug Administration under 42 U.S.C. § 262(a), as it existed on January 1, 2025, against which a proposed biosimilar medicine or interchangeable biological product is compared and listed as a reference product in the United States Food and Drug Administration's Database of Licensed Biological Products, commonly known as the "Purple Book"; and

(*12*) "Wholesale acquisition cost" means the same as defined in section 1847A(c)(6)(B) of the Social Security Act, 42 U.S.C. § 1395w-3a, as it existed on January 1, 2025.

23-79-2902. Formulary.

(a) A health benefit plan shall publish in a manner that is easily accessible to a beneficiary, a prospective beneficiary, the state, and the public an up-to-date, accurate, and complete list of all covered drug products and biological products on the health benefit plan's formulary, including without limitation:

(1) A tiering structure that has been adopted for the health benefit plan; and

(2) Any restrictions on the manner in which a drug product or biological product can be obtained.

(b) A formulary is easily accessible under subsection (a) of this section if:

(1) The formulary can be viewed on the health benefit plan's public website through a clearly identifiable link or tab

without requiring an individual to create or access an account or enter a policy number; and

(2) An individual can easily discern which formulary list applies to which health benefit plan if a healthcare insurer offers more than one (1) health benefit plan.

(c) If a change is made to the formulary of a health benefit plan during the plan year, the easily accessible formulary shall:

(1) Be updated within thirty (30) calendar days; and

(2) Contain, in bold type, the date of the update, with the updates clearly identifiable.

23-79-2903. Generic drugs.

(a) If a generic drug is marketed pursuant to such approval, and has a wholesale acquisition cost that is less than the wholesale acquisition cost of the reference listed drug on the generic drug's initial date of marketing, then a health benefit plan that provides coverage for the generic drug's reference listed drug at the time of the generic drug's marketing date shall:

(1) *Within a reasonable amount of time* make the generic drug available on the formulary with more favorable cost sharing, including without limitation actual out-of-pocket costs, relative to the reference listed drug; and

(2) Not impose:

(A) A prior authorization, a step therapy requirement, or other limitation on coverage of a generic drug for which formulary placement is required under *this section with the exception of limited distribution drugs*; or

(B) A restriction on a pharmacy through which a beneficiary may obtain the generic drug that makes it more difficult for the beneficiary to obtain coverage of or access to the generic drug than to obtain coverage of or access to the reference listed drug.

(b) This section shall remain in force as long as the wholesale acquisition cost of a generic drug is lower than the wholesale acquisition cost of the generic drug's reference listed drug.

23-79-2904. Biosimilar medicines.

(a) If a biosimilar medicine is marketed pursuant to such licensure, and has a wholesale acquisition cost that is less than the wholesale acquisition cost of the reference product of the biosimilar medicine on the initial date of marketing, then a health benefit plan that provide coverage for the biosimilar medicine's reference product at the time of the biosimilar medicine's marketing date shall:

(1) *Within a reasonable amount of time* make at least one (1) biosimilar medicine available on the formulary on a tier with more favorable cost sharing, including actual out-of-pocket costs, relative to the reference product; and

(2) Not impose:

(A) A prior authorization, a step therapy requirement, or other limitation on coverage of a biosimilar medicine for which formulary placement is required under *this section with the exception of limited distribution drugs*; or

(B) A restriction on *an accredited pharmacy* through which a beneficiary may obtain the biosimilar medicine that makes it more difficult for a beneficiary to obtain coverage of or access to the biosimilar medicine than to obtain coverage of or access to the reference product.

(b) This section shall remain in force as long as the wholesale acquisition cost of a biosimilar medicine is lower than the wholesale acquisition cost of the biosimilar medicine's reference product.

23-79-2905. Purpose and construction of subchapter.

(a) A health benefit plan is not required under this subchapter to:

(1) Continue providing coverage for a brand drug after a generic drug or biosimilar medicine is approved or licensed, as applicable, and marketed; or

(2) Provide coverage for a brand drug, generic drug, biological product, or biosimilar medicine if the pharmacy and therapeutics committee or the clinical and pharmacy experts that develop the health benefit plan's formulary determines that the brand drug, generic drug, biological product, or biosimilar medicine is no

longer medically appropriate or cost-effective.

(b) The application of this subchapter shall not interfere with or prevent a pharmacy from the practice of pharmacy as defined in § 17-92-101.

23-79-2906. Rules.

(a) The Insurance Commissioner may promulgate rules necessary to implement this subchapter.

(b) The State Board of Finance may promulgate rules necessary to implement this subchapter that may apply to the State and Public School Life and Health Insurance Program.

SECTION 2. DO NOT CODIFY. Effective date. This act is effective on and after January 1, 2026.

/s/J. Boyd

Referred requested by the Arkansas Senate
Prepared by: ANS/AMS