## **EXHIBIT D3**

1	INTERIM STUDY PROPOSAL 2025-016
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3	State of Arkansas As Engrossed: \$2/5/25 \$3/10/25
4	95th General Assembly A Bill
5	Regular Session, 2025 SENATE BILL 140
6	
7	By: Senator J. Boyd
8	By: Representative Achor
9	Filed with: Senate Committee on Insurance and Commerce
10	pursuant to A.C.A. §10-3-217.
11	For An Act To Be Entitled
12	AN ACT TO MANDATE THE USE OF BIOSIMILAR MEDICINES
13	UNDER HEALTH BENEFIT PLANS; TO REQUIRE A HEALTHCARE
14	PROVIDER TO PRESCRIBE BIOSIMILAR MEDICINES; TO
15	IMPROVE ACCESS TO BIOSIMILAR MEDICINES; AND FOR OTHER
16	PURPOSES.
17	
18	
19	Subtitle
20	TO MANDATE THE USE OF BIOSIMILAR
21	MEDICINES UNDER HEALTH BENEFIT PLANS; TO
22	REQUIRE A HEALTHCARE PROVIDER TO
23	PRESCRIBE BIOSIMILAR MEDICINES; AND TO
24	IMPROVE ACCESS TO BIOSIMILAR MEDICINES.
25	
26	BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:
27	
28	SECTION 1. Arkansas Code Title 23, Chapter 79, is amended to add an
29	additional subchapter to read as follows:
30	
31	<u>Subchapter 29 — Mandate for Use of Biosimilar Medicines</u>
32	00.70.0001
33	23-79-2901. Definitions.
34	As used in this subchapter:
35 36	(1) "Beneficiary" means an individual who is entitled to receive healthcare services under the terms of a health benefit plan:
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1	(2) "Biosimilar medicine" means a biological product that
2	<u>is:</u>
3	(A) Licensed under 42 U.S.C. § 262(k), as it existed on
4	January 1, 2025; and
5	(B) Not listed as discontinued in the United States Food
6	and Drug Administration's Database of Licensed Biological Products, commonly
7	known as the "Purple Book";
8	(3) "Brand drug" means a drug product for which an
9	application has been approved under 21 U.S.C. § 355(c), as it existed
10	on January 1, 2025, or a biological product, other than a biosimilar
11	medicine, that is licensed under 42 U.S.C. § 262(a), as it existed on
12	January 1, 2025;
13	(4) "Formulary" means:
14	(A) A list of prescription drug products and
15	biological products that is developed by a pharmacy and therapeutics
16	committee or other clinical and pharmacy experts; and
17	(B) Represents a health benefit plan's prescription
18	drug products and biological products approved for use;
19	(5) "Generic drug" means a drug product:
20	(A) For which an application has been approved under
21	21 U.S.C. § 355(j), as it existed on January 1, 2025; and
22	(B) That has been listed in the United States Food
23	and Drug Administration's Approved Drug Products with Therapeutic
24	Equivalence Evaluations, commonly known as the "Orange Book" as
25	therapeutically equivalent to a reference listed drug, even if the
26	manufacturer of the drug product applies a trade name to the drug;
27	(6)(A) "Health benefit plan" means an individual, blanket,
28	or group plan, policy, or contract for healthcare services offered,
29	issued, renewed, delivered, or extended in this state by a healthcare
30	insurer.
31	(B) "Health benefit plan" includes:
32	(i) Indemnity and managed care plans; and
33	(ii) Nonfederal governmental plans as defined
34	in 29 U.S.C. § 1002(32), as it existed on January 1, 2025, including
35	plans providing health benefits to state and public school employees
36	under § 21-5-401 et seg.

1	(C) "Health benefit plan" does not include:
2	(i) A plan that provides only dental benefits
3	or eye and vision care benefits;
4	(ii) A disability income plan;
5	(iii) A credit insurance plan;
6	(iv) Insurance coverage issued as a supplement
7	to liability insurance;
8	(v) A medical payment under an automobile or
9	homeowners insurance plan;
10	(vi) A health benefit plan provided under
11	Arkansas Constitution, Article 5, § 32, the Workers' Compensation Law,
12	§ 11-9-101 et seq., or the Public Employee Workers' Compensation Act,
13	§ 21-5-601 et seq.;
14	(vii) A plan that provides only indemnity for
15	hospital confinement;
16	(viii) An accident-only plan;
17	(ix) A specified disease plan;
18	(x) A long-term-care-only plan; or
19	(xi) The Arkansas Medicaid Program;
20	(7)(A) "Healthcare insurer" means an entity subject to the
21	insurance laws of this state or the jurisdiction of the Insurance
22	Commissioner that contracts or offers to contract to provide health
23	insurance coverage, including without limitation an insurance company,
24	a hospital and medical service corporation, a health maintenance
25	organization, or a self- insured governmental or church plan in this
26	state.
27	(B) "Healthcare insurer" does not include:
28	(i) An entity that provides only dental
29	benefits or eye and vision care benefits; or
30	(ii) The Arkansas Medicaid Program;
31	(8) "Healthcare provider" means a type of provider that
32	renders healthcare services to patients for compensation including a
33	doctor of medicine or another licensed healthcare professional acting
34	within the provider's licensed scope of practice;
35	(9) "Limited distribution drug" means a prescription
36	medication that is restricted by a pharmaceutical manufacturer to a

1	limited number of specialty pharmacies due to the prescription
2	medication's:
3	(A) Complex use, including special handling,
4	monitoring, or administration;
5	(B) High cost; or
6	(C) Safety concerns;
7	(10) "Reference listed drug" means the listed drug product
8	identified by the United States Food and Drug Administration as a drug
9	product upon which an applicant relies in seeking approval of the
10	applicant's application submitted under 21 U.S.C. § 355(j), as it
11	existed on January 1, 2025;
12	(11) "Reference product" means a single biological product
13	that is licensed by the United States Food and Drug Administration
14	under 42 U.S.C. § 262(a), as it existed on January 1, 2025, against
15	which a proposed biosimilar medicine or interchangeable biological
16	product is compared and listed as a reference product in the United
17	States Food and Drug Administration's Database of Licensed Biological
18	Products, commonly known as the "Purple Book"; and
19	(12) "Wholesale acquisition cost" means the same as
20	defined in section 1847A(c)(6)(B) of the Social Security Act, 42
21	<u>U.S.C.</u> § 1395w-3a, as it existed on January 1, 2025.
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23	<u>23-79-2902. Formulary.</u>
24	(a) A health benefit plan shall publish in a manner that is
25	easily accessible to a beneficiary, a prospective beneficiary, the
26	state, and the public an up-to-date, accurate, and complete list of
27	all covered drug products and biological products on the health
28	benefit plan's formulary, including without limitation:
29	(1) A tiering structure that has been adopted for the
30	health benefit plan; and
31	(2) Any restrictions on the manner in which a drug product
32	or biological product can be obtained.
33	(b) A formulary is easily accessible under subsection (a) of
34	this section if:
35	(1) The formulary can be viewed on the health benefit
36	plan's public website through a clearly identifiable link or tab

1	without requiring an individual to create or access an account or
2	enter a policy number; and
3	(2) An individual can easily discern which formulary list
4	applies to which health benefit plan if a healthcare insurer offers
5	more than one (1) health benefit plan.
6	(c) If a change is made to the formulary of a health benefit
7	plan during the plan year, the easily accessible formulary shall:
8	(1) Be updated within thirty (30) calendar days; and
9	(2) Contain, in bold type, the date of the update, with
10	the updates clearly identifiable.
11	
12	23-79-2903. Generic drugs.
13	(a) If a generic drug is marketed pursuant to such approval, and
14	has a wholesale acquisition cost that is less than the wholesale
15	acquisition cost of the reference listed drug on the generic drug's
16	initial date of marketing, then a health benefit plan that provides
17	coverage for the generic drug's reference listed drug at the time of
18	the generic drug's marketing date shall:
19	(1) Within a reasonable amount of time make the generic
20	drug available on the formulary with more favorable cost sharing,
21	including without limitation actual out-of-pocket costs, relative to
22	the reference listed drug; and
23	(2) Not impose:
24	(A) A prior authorization, a step therapy
25	requirement, or other limitation on coverage of a generic drug for
26	which formulary placement is required under this section with the
27	exception of limited distribution drugs; or
28	(B) A restriction on a pharmacy through which a
29	beneficiary may obtain the generic drug that makes it more difficult
30	for the beneficiary to obtain coverage of or access to the generic
31	drug than to obtain coverage of or access to the reference listed
32	drug.
33	(b) This section shall remain in force as long as the wholesale
34	acquisition cost of a generic drug is lower than the wholesale
35	acquisition cost of the generic drug's reference listed drug.

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1	<u>23-79-2904. Biosimilar medicines.</u>
2	(a) If a biosimilar medicine is marketed pursuant to such
3	licensure, and has a wholesale acquisition cost that is less than the
4	wholesale acquisition cost of the reference product of the biosimilar
5	medicine on the initial date of marketing, then a health benefit plan
6	that provide coverage for the biosimilar medicine's reference product
7	at the time of the biosimilar medicine's marketing date shall:
8	(1) Within a reasonable amount of time make at least one
9	(1) biosimilar medicine available on the formulary on a tier with more
10	favorable cost sharing, including actual out-of-pocket costs, relative
11	to the reference product; and
12	(2) Not impose:
13	(A) A prior authorization, a step therapy
14	requirement, or other limitation on coverage of a biosimilar medicine
15	for which formulary placement is required under this section with the
16	exception of limited distribution drugs; or
17	(B) A restriction on an accredited pharmacy through
18	which a beneficiary may obtain the biosimilar medicine that makes it
19	more difficult for a beneficiary to obtain coverage of or access to
20	the biosimilar medicine than to obtain coverage of or access to the
21	reference product.
22	(b) This section shall remain in force as long as the wholesale
23	acquisition cost of a biosimilar medicine is lower than the wholesale
24	acquisition cost of the biosimilar medicine's reference product.
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26	23-79-2905. Purpose and construction of subchapter.
27	(a) A health benefit plan is not required under this subchapter
28	to:
29	(1) Continue providing coverage for a brand drug after a
30	generic drug or biosimilar medicine is approved or licensed, as
31	applicable, and marketed; or
32	(2) Provide coverage for a brand drug, generic drug,
33	biological product, or biosimilar medicine if the pharmacy and
34	therapeutics committee or the clinical and pharmacy experts that
35	develop the health benefit plan's formulary determines that the brand
36	drug, generic drug, biological product, or biosimilar medicine is no

1	longer medically appropriate or cost-effective.
2	(b) The application of this subchapter shall not interfere with
3	or prevent a pharmacy from the practice of pharmacy as defined in §
4	<u>17-92-101.</u>
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6	23-79-2906. Rules.
7	(a) The Insurance Commissioner may promulgate rules necessary to
8	implement this subchapter.
9	(b) The State Board of Finance may promulgate rules necessary to
10	implement this subchapter that may apply to the State and Public
11	School Life and Health Insurance Program.
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13	SECTION 2. DO NOT CODIFY. Effective date. This act is
14	effective on and after January 1, 2026.
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16	/s/J. Boyd
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19	Referred requested by the Arkansas Senate
20	Prepared by: ANS/AMS
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