SB0069S02 compared with SB0069

{Omitted text} shows text that was in SB0069 but was omitted in SB0069S02 inserted text shows text that was not in SB0069 but was inserted into SB0069S02

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1 Medication Amendments

2025 GENERAL SESSION STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor:

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3 LONG TITLE

- 4 General Description:
- 5 This bill addresses {the acquisition of certain drugs by pharmaceutical entities} participation in a federal drug discount program.
- **6 Highlighted Provisions:**
- 7 This bill:
- 8 defines terms {, including "340B drug" and "pharmaceutical entity"; and };
- 9 prohibits a pharmaceutical manufacturer from restricting, prohibiting, or otherwise interfering with a 340B entity's ability to:
- acquire a 340B drug; or
- participate in the 340B drug discount program;
- permits the Public Employees' Benefit and Insurance Program to adjust its business practices to mitigate any resulting financial impacts; and
- 15 requires the commissioner of insurance to designate a third party entity to:
- <u>receive certain deidentified claim information;</u>
- confirm whether a 340B entity participates in the drug discount program; and

9	• {bans interfering with } report the claim information to a pharmaceutical {entity's acquisition of		
	a 340B drug} manufacturer.		
19	Money Appropriated in this Bill:		
20	None		
21	Other Special Clauses:		
22	None		
24	ENACTS:		
25	31A-46-311, Utah Code Annotated 1953, Utah Code Annotated 1953		
26	31A-46-312, Utah Code Annotated 1953, Utah Code Annotated 1953		
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28	Be it enacted by the Legislature of the state of Utah:		
29	Section 1. Section 1 is enacted to read:		
30	31A-46-311. Prohibited actions with respect to {a pharmaceutical entity} the 340B drug		
	discount program.		
21	(1) As used in this {section, "manufacturer" means a pharmaceutical manufacturer, including an		
	agent or affiliate of a pharmaceutical manufacturer.		
22	{(a) {"340B entity" means an entity authorized to participate in the federal 340B drug discount		
	program, as described in 42 U.S.C. Sec. 256b(a)(4).}		
24	{(b) {"Manufacturer" means the same as that term is defined in Section 1927(k) of the Social Security		
	Act.}}		
26	{(c) {"Pharmaceutical entity" means a:}}		
27	{(i)} (2) {pharmaceutical } A manufacturer{;} may not:		
28	{(ii) {a person involved in the distribution of a pharmaceutical manufacturer's products, including a		
	distributor or a third-party logistics provider; or } }		
30	{(iii) {an agent or affiliate of a person described in Subsection (1)(a) or (1)(b).} }		
31	{(2)} (a) {A pharmaceutical entity may not } directly or indirectly restrict or prohibit:		
32	{(a)} (i) a pharmacy from contracting with a 340B entity, including by denying the pharmacy access to		
	a drug that is manufactured by the {pharmaceutical entity} manufacturer;		
34	(b) (ii) a 340B entity from contracting with a pharmacy, including by denying the 340B entity access		
	to a drug that is manufactured by the {pharmaceutical entity} manufacturer;		
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- (iii) the acquisition, dispensing, or delivery of a 340B drug to any location authorized by a 340B entity to receive the drug, unless prohibited by federal law; or
- 38 {(d)} (iv) a 340B entity from receiving {a} 340B drug discount program pricing for a 340B drug, including by imposing a time limitation on a 340B entity to replenish or submit a claim for a 340B drug{-};
- 41 {(3)} (b) {A pharmaceutical entity may not } directly or indirectly:
- 42 {(a)} (i) require a 340B entity to purchase a 340B drug from a {certain} supplier if the {pharmaceutical entity} manufacturer would otherwise permit the 340B entity to purchase a drug that is not a 340B drug from the supplier; or
- 45 {(b)} (ii) require a 340B entity to submit any claim data, utilization data, or information about a 340B entity's contracts with a third-party as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity, unless the data or information sharing is required by federal law; or
- 49 (c) {otherwise} interfere with:
- 50 (i) a contract between a pharmacy and a 340B entity; or
- 51 (ii) the ability of a pharmacy and a 340B entity to enter into a contract.
- 55 (3) The Public Employees' Benefit and Insurance Program created in Section 49-20-103 may adjust the program's business practices to mitigate any financial impacts resulting from this section.
- 52 (4) Nothing in this section is to be construed to conflict with federal law.
- Section 2. Section 2 is enacted to read:
- 60 <u>31A-46-312.</u> Designated entity -- Claim information sharing and use -- 340B entity public reporting.
- 62 (1) As used in this section:
- (a) "Board of pharmacy" means the Utah State Board of Pharmacy created in Section 58-17B-201.
- 65 (b) "Claim information" means information related to a claim for a 340B drug that is:
- 66 (i) dispensed by a contract pharmacy; and
- 67 (ii) manufactured by a single manufacturer.
- 68 (c) "Contract pharmacy" means a pharmacy contracting with an entity participating in the 340B drug discount program to dispense drugs purchased through the 340B drug discount program.
- 71 (d) "Designated entity" means a third party entity that is designated as described in Subsection (2).

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- (e) "Participating 340B entity" means a 340B entity that is a hospital described in 42 U.S.C. Sec. 256b(a)(4)(L).
- 75 (2)
 - (a) The commissioner, in collaboration with the board of pharmacy, shall designate one third party entity to receive claim information as described in Subsection (3).
- 77 (b) In making the designation described in Subsection (2)(a), the commissioner shall ensure that the third party entity:
- 79 (i) is capable of carrying out the requirements of this section;
- 80 (ii)
 - (A) is not owned or controlled by a pharmaceutical manufacturer; and
- 81 (B) does not otherwise have a contractual or other relationship with a pharmaceutical manufacturer that would create a conflict of interest; and
- 83 (iii) in carrying out the provisions of this section, will use:
- 84 (A) technology that complies with privacy and security requirements under state and federal law; and
- 86 (B) reasonable and necessary terms.
- 87 (c) If the commissioner is unable to designate a third party entity that meets the requirements of Subsection (2)(b), a participating 340B entity is not required to post as described in Subsection (6).
- 90 (3) A participating 340B entity shall:
- 91 (a) provide to the designated entity the following claim information:
- 92 (i) prescription number;
- 93 (ii) prescribed date;
- 94 (iii) fill date;
- 95 (iv) national drug code;
- 96 (v) quantity;
- 97 (vi) pharmacy identification; and
- 98 (vii) 340B covered entity identification;
- 99 (b) ensure the claim information provided is deidentified in accordance with federal law; and
- (c) provide the claim information in accordance with the rules described in Subsection (7).
- 103 (4) Upon request, the designated entity:
- (a) shall inform a pharmaceutical manufacturer whether a 340B entity is a participating 340B entity that provides claim information for any 340B drug; and

- (b) may provide to a pharmaceutical manufacturer claim information for a 340B drug manufactured by the pharmaceutical manufacturer that the designated entity received under Subsection (3).
- 109 (5)
 - (a) The designated entity or a pharmaceutical manufacturer may only use claim information received under this section to identify a rebate for an insurer or a third party administrator that is ineligible for payment under the pharmaceutical manufacturers policy.
- 113 (b) The designated entity or a pharmaceutical manufacturer may not use claim information received under this section to:
- (i) establish restrictions or limitations on a participating 340B entity's ability to purchase a 340B drug, including by establishing:
- (A) allocations on purchasing based on the number of claims for which the participating 340B entity provides claim information; or
- (B) time limits for a participating 340B entity to replenish or replace inventory of a 340B drug;
- (ii) recoup from a participating 340B entity a discount for a 340B drug;
- 122 (iii) discriminate against, lower the reimbursement for, or impose any separate condition on a participating 340B entity; or
- (iv) take any other action that is not expressly authorized under this part.
- 125 (6) A participating 340B entity shall post on the participating 340B entity's publicly available website:
- 127 (a) the name of the participating 340B entity;
- (b) a copy of the participating 340B entity's annual 340B program recertification;
- (c) if the participating 340B entity is required to conduct a community health needs assessment under Section 501(r)(3)(A), Internal Revenue Code, a copy of the participating 340B entity's community health needs assessment;
- (d) a statement that the participating 340B entity is in compliance with the 340B drug discount program; and
- (e) <u>a description of the impact of the 340B drug discount program on the patients and community served by the participating 340B entity.</u>
- 136 (7) In accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, the commissioner, in collaboration with the board of pharmacy, shall make rules that establish the frequency in which a participating 340B entity shall provide claim information to the designated entity.
- Section 3. **Effective date.**

This bill takes effect on May 7, 2025. 2-25-25 10:09 AM