SB0069S02

SB0069S04 compared with SB0069S02

{Omitted text} shows text that was in SB0069S02 but was omitted in SB0069S04 inserted text shows text that was not in SB0069S02 but was inserted into SB0069S04

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1 Medication Amendments

2025 GENERAL SESSION STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor:

3 LONG TITLE

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4 General Description:

This bill addresses participation in a federal drug discount program.

6 **Highlighted Provisions:**

- 7 This bill:
 - defines terms:
- 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}
 - {requires the commissioner of insurance to designate a third party entity to:}
- {receive} permits a manufacturer to request certain {deidentified} claim information{;} from 340B entities; and
 - {confirm whether a 340B entity participates in the drug discount program; and}

| 18 | • {report the claim } requires 340B entities to submit information to {a pharmaceutical |
|----|---|
| | manufacturer} the Insurance Department. |
| 17 | Money Appropriated in this Bill: |
| 18 | None |
| 19 | Other Special Clauses: |
| 20 | None |
| 22 | ENACTS: |
| 23 | 31A-46-311, Utah Code Annotated 1953, Utah Code Annotated 1953 |
| 24 | 31A-46-312, Utah Code Annotated 1953, Utah Code Annotated 1953 |
| 25 | |
| 26 | Be it enacted by the Legislature of the state of Utah: |
| 27 | Section 1. Section 1 is enacted to read: |
| 28 | 31A-46-311. Prohibited actions with respect to the 340B drug discount program. |
| 31 | (1) As used in this {section, "manufacturer} section, "manufacturer" means a pharmaceutical |
| | manufacturer, including an agent or affiliate of a pharmaceutical manufacturer. |
| 33 | (2) A manufacturer may not: |
| 34 | (a) directly or indirectly restrict or prohibit: |
| 35 | (i) a pharmacy from contracting with a 340B entity, including by denying the pharmacy access to a drug |
| | that is manufactured by the manufacturer; |
| 37 | (ii) a 340B entity from contracting with a pharmacy, including by denying the 340B entity access to a |
| | drug that is manufactured by the manufacturer; |
| 39 | (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 |
| 41 | (iv) a 340B entity from receiving 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; or |
| 44 | {(b) {directly or indirectly:}-} |
| 45 | {(i) {require a 340B entity to purchase a 340B drug from a supplier if the manufacturer would |
| | otherwise permit the 340B entity to purchase a drug that is not a 340B drug from the supplier; or}} |
| 48 | {(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, |

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third party entity: }

or delivery of a 340B drug to, a 340B entity, unless the data or information sharing is required by federal law; or } } {(c)} (b) interfere with: (i) a contract between a pharmacy and a 340B entity; or (ii) the ability of a pharmacy and a 340B entity to enter into a contract. (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. (4) Nothing in this section {is to } shall be construed to conflict with federal law. Section 2. Section 2 is enacted to read: 31A-46-312. {Designated entity ---} Claim information sharing and use -- 340B entity public reporting. (1) As used in this section: {(a) {"Board of pharmacy" means the Utah State Board of Pharmacy created in Section 58-17B-201.} } (a) "Bad debt" means the amount of money charged by a 340B entity for providing health care services to a patient for which the 340B entity does not receive payment. (b) "Claim information" means information that is: (i) described in Subsection (2); and {(b)} (ii) {"Claim information" means information} related to a claim for a 340B drug that is: {(i)} (A) dispensed by a contract pharmacy; and {(ii)} (B) manufactured by a single pharmaceutical manufacturer. (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. {(d) {"Designated entity" means a third party entity that is designated as described in Subsection (2).}} {(e)} (d) {"Participating 340B entity} "Financial assistance" means the cost incurred by a 340B entity {that is} for providing health care services to a {hospital described in 42 U.S.C. Sec. 256b(a)(4) (L)} patient at a reduced cost or no cost. {(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).}-

(b) {In making the designation described in Subsection (2)(a), the commissioner shall ensure that the

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         {(i) {is capable of carrying out the requirements of this section;}}
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         {<del>(ii)</del> }
         {(A) {is not owned or controlled by a pharmaceutical manufacturer; and} }
         {(B) {does not otherwise have a contractual or other relationship with a pharmaceutical manufacturer
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             that would create a conflict of interest; and}}
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         {(iii) {in carrying out the provisions of this section, will use:}}
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         {(A) {technology that complies with privacy and security requirements under state and federal law;
             and}}
         {(B) {reasonable and necessary terms.}-}
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         {(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).
             }
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         {(3) {A participating 340B entity shall:}-}
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         (e) "Uncompensated care" means the sum of a 340B entity's bad debt and financial assistance.
         {(a)} (2) {provide to the designated} A pharmaceutical manufacturer may request from a 340B entity
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             the following claim information:
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         {(i)} (a) prescription number;
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         {(ii)} (b) prescribed date;
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         {(iii)} (c) fill date;
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         {(iv)} (d) national drug code;
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         {(v)} (e) quantity;
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         {(vi)} (f) pharmacy identification; {and}
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         (g) prescriber identification number; and
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         \{(vii)\}\ (h) 340B covered entity identification\{\frac{1}{7}\}.
         {(b) {ensure the claim information provided is deidentified in accordance with federal law; and} }
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         {(c) {provide the claim information in accordance with the rules described in Subsection (7).}}
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         {(4) {Upon request, the designated entity:}-}
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         {(a) {shall inform a pharmaceutical manufacturer whether a 340B entity is a participating 340B entity
             that provides claim information for any 340B drug; and}
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         {(b)} (3) {may provide to} A 340B entity that receives a request from a pharmaceutical manufacturer
             {claim information for a 340B drug manufactured by } as described in Subsection (2) shall provide
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| | to the pharmaceutical manufacturer {that } the {designated entity received under Subsection (3)} |
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| | requested claim information. |
| 109 | { (5) } |
| | {(a)} (4) {The designated entity or a } 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} manufacturer's policy. |
| 113 | {(b) {The designated entity or a pharmaceutical manufacturer may not use claim information received |
| | under this section to:}-} |
| 115 | {(i) {establish restrictions or limitations on a participating 340B entity's ability to purchase a 340B |
| | drug, including by establishing:}} |
| 117 | {(A) {allocations on purchasing based on the number of claims for which the participating 340B entity |
| | <pre>provides claim information; or} }</pre> |
| 119 | {(B) {time limits for a participating 340B entity to replenish or replace inventory of a 340B drug;}-} |
| 121 | {(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} } |
| 124 | {(iv) {take any other action that is not expressly authorized under this part.}-} |
| 82 | <u>(5)</u> |
| 125 | {(6)} (a) {A participating} Beginning on July 1, 2026, a 340B entity shall {post on } annually provide, |
| | on or before the {participating-} first day of the month after the 340B entity files the 340B entity's |
| | {publicly available website} Medicare cost report, the following to the department in a form and |
| | manner determined by the department: |
| 127 | {(a)} (i) the name of the {participating} 340B entity; |
| 128 | {(b)} (ii) a copy of the {participating} 340B entity's annual 340B program recertification; |
| 129 | {(e)} (iii) 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 most recent community health needs assessment; |
| 132 | {(d)} (iv) a statement that the {participating} 340B entity is in compliance with the 340B drug discount |
| | program; {and} |
| 93 | (v) the total number of contract pharmacies with which the 340B entity contracts; |

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| | (vi) the total number of contract pharmacies located out-of-state and the states in which out-of-state |
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| | contract pharmacies are located; and |
| 96 | (vii) for the prior year: |
| 134 | {(e)} (A) a description of the impact of the 340B drug discount program on the patients and community |
| | served by the {participating} 340B entity{-}; |
| 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.}-} |
| 99 | (B) the total operating costs of the 340B entity; |
| 100 | (C) the total uncompensated care provided by the 340B entity; and |
| 101 | (D) the total number of prescriptions and the percentage of the 340B entity's prescriptions filled at |
| | contract pharmacies. |
| 103 | (b) An officer of the 340B entity shall certify the completeness and accuracy of the information |
| | submitted in accordance with Subsection (5)(a). |
| 105 | <u>(c)</u> |
| | (i) The department shall use the information described in Subsection (5)(a) to prepare a report detailing |
| | aggregate information received from a 340B entity. |
| 107 | (ii) The department shall submit the report described in Subsection (5)(c)(i) to the Health and Human |
| | Services Interim Committee on or before July 1, 2027. |
| 109 | (iii) The department shall post the report described in Subsection (5)(c)(ii) on a publicly accessible |
| | website. |
| 111 | Nothing in this section shall be construed to conflict with federal law. |
| 112 | Section 3. Effective date. |
| | This bill takes effect on May 7, 2025. |

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