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Sub. S. B. No. 198

To amend sections 3902.50 and 3902.70; to amend, for the purpose of adopting a new section number as indicated in parentheses, section 3902.72 (3902.75); and to enact new section 3902.72 of the Revised Code to prohibit drug manufacturers from taking certain actions regarding purchases made by 340B covered entities.

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

Section 1. That sections 3902.50 and 3902.70 be amended; section 3902.72 (3902.75) be amended for the purpose of adopting a new section number as indicated in parentheses; and new section 3902.72 of the Revised Code be enacted to read as follows:

Sec. 3902.50. As used in sections 3902.50 to ~~3902.72~~ 3902.75 of the Revised Code:

(A) "Ambulance" has the same meaning as in section 4765.01 of the Revised Code.

(B) "Clinical laboratory services" has the same meaning as in section 4731.65 of the Revised Code.

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(C) "Cost sharing" means the cost to a covered person under a health benefit plan according to any copayment, coinsurance, deductible, or other out-of-pocket expense requirement.

(D) "Covered" or "coverage" means the provision of benefits related to health care services to a covered person in accordance with a health benefit plan.

(E) "Covered person," "health benefit plan," "health care services," and "health plan issuer" have the same meanings as in section 3922.01 of the Revised Code.

(F) "Drug" has the same meaning as in section 4729.01 of the Revised Code.

(G) "Emergency facility" has the same meaning as in section 3701.74 of the Revised Code.

(H) "Emergency services" means all of the following as described in 42 U.S.C. 1395dd:

(1) Medical screening examinations undertaken to determine whether an emergency medical condition exists;

(2) Treatment necessary to stabilize an emergency medical condition;

(3) Appropriate transfers undertaken prior to an emergency medical condition being stabilized.

(I) "Health care practitioner" has the same meaning as in section 3701.74 of the Revised Code.

(J) "Pharmacy benefit manager" has the same meaning as in section 3959.01 of the Revised Code.

(K) "Prior authorization requirement" means any practice

implemented by a health plan issuer in which coverage of a health care service, device, or drug is dependent upon a covered person or a provider obtaining approval from the health plan issuer prior to the service, device, or drug being performed, received, or prescribed, as applicable. "Prior authorization requirement" includes prospective or utilization review procedures conducted prior to providing a health care service, device, or drug.

(L) "Unanticipated out-of-network care" means health care services, including clinical laboratory services, that are covered under a health benefit plan and that are provided by an out-of-network provider when either of the following conditions applies:

(1) The covered person did not have the ability to request such services from an in-network provider.

(2) The services provided were emergency services.

Sec. 3902.70. As used in this section and ~~section~~ sections 3902.71 and 3902.72 of the Revised Code:

(A) "340B covered entity" means an entity described in section 340B(a)(4) of the "Public Health Service Act," 42 U.S.C. 256b(a)(4) and includes any pharmacy under contract with the entity to dispense drugs on behalf of the entity.

(B) "340B drug pricing program" means the program authorized by section 340B of the "Public Health Service Act," 42 U.S.C. 256b.

(C) "Package" has the same meaning as in 21 U.S.C. 360eee.

(D) "Terminal distributor of dangerous drugs," ~~has~~ "manufacturer of dangerous drugs," "repackager of dangerous

drugs," and "third-party logistics provider" have the same meaning ~~meaning~~ as in section 4729.01 of the Revised Code.

~~(C)~~ (E) "Third-party administrator" has the same meaning as in section 5167.01 of the Revised Code.

Sec. 3902.72. (A) As used in this section:

(1) "340B drug" means a drug that meets all of the following criteria:

(a) The drug is a covered outpatient drug under the 340B drug pricing program.

(b) The drug is subject to any offer for reduced prices by a manufacturer pursuant to the 340B drug pricing program.

(c) The drug is purchased by a 340B grantee or would have been purchased by a 340B grantee if not for an action prohibited under this section.

(2)(a) "340B grantee" means an entity described in section 340B(a)(4)(A)-(K) of the "Public Health Service Act," 42 U.S.C. 256b(a)(4)(A)-(K) that is designated as an active entity under the health resources and services administration covered entity daily report.

(b) "340B grantee" includes any pharmacy, whether located within or outside this state, that is under contract with an entity described in division (A)(2)(a) of this section to dispense 340B drugs on behalf of the entity.

(B) No manufacturer of dangerous drugs, repackager of dangerous drugs, or third-party logistics provider, or an agent or affiliate of any of those entities, shall do either of the following:

(1) Deny, prohibit, restrict, discriminate against, or otherwise limit the acquisition of a 340B drug by or delivery of a 340B drug to a 340B grantee, unless the purchase or delivery is prohibited by the United States department of health and human services;

(2) Require a 340B grantee to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by or delivery of a 340B drug to a 340B grantee, unless the claims or utilization data sharing is required by the United States department of health and human services.

(C)(1) Whoever violates this section engages in an unfair and deceptive insurance act or practice under sections 3901.19 to 3901.26 of the Revised Code, and is subject to proceedings pursuant to those sections. If the superintendent, by written order, finds that any person is about to engage, is engaging, or has engaged in a violation of this section, the superintendent, in addition to the administrative remedies set forth in section 3901.22 of the Revised Code, may impose a civil penalty of fifty thousand dollars for each such violation, not to exceed ten million dollars annually. Each package of 340B drugs determined by the superintendent to be subject to a prohibited act under division (C) of this section constitutes a separate violation.

(2) In addition to the civil penalty, the superintendent of insurance may refer any complaint of a violation of division (C) of this section to the state board of pharmacy for the board to consider one or more of the sanctions set forth in division (A)(1) of section 4729.56 of the Revised Code.

(D) The superintendent of insurance may adopt rules, or may delegate authority to the board of pharmacy to adopt rules, pursuant to Chapter 119. of the Revised Code to implement the

provisions of this section.

(E) Nothing in this section shall be construed to conflict with or be less restrictive than applicable federal law or regulations, including 21 U.S.C. 355-1, or applicable laws or regulations of this state.

Sec. ~~3902.72~~ 3902.75. (A) As used in this section, "health care provider" has the same meaning as in section 3701.74 of the Revised Code.

(B) A health plan issuer, including a pharmacy benefit manager, shall, upon request of a covered person, the covered person's health care provider, or the third-party representative, furnish the following data for any and all drugs covered under a related health benefit plan:

(1) The covered person's eligibility information for any and all covered drugs;

(2) Cost-sharing information for any and all covered drugs, including a description of any variance in cost-sharing based on pharmacy, whether retail or mail order, or health care provider dispensing or administering the drugs;

(3) Any applicable utilization management requirements for any and all covered drugs, including prior authorization requirements, step therapy, quantity limits, and site-of-service restrictions.

(C) A health plan issuer, including a pharmacy benefit manager, providing the data required under division (B) of this section shall ensure that the data meets all of the following:

(1) It is current not later than one business day after any change is made.

(2) It is provided in real time.

(3) It is provided in the same format that the request is made by the covered person, the covered person's health care provider, or the third-party representative.

(D) The format in which a health plan issuer, including a pharmacy benefit manager, replies to a request made under division (B) of this section shall use established industry content and transport standards published by either of the following:

(1) A standards developing organization accredited by the American national standards institute, including the national council for prescription drug programs, ASC X12, health level 7;

(2) A relevant federal or state governing body, including the centers for medicare and medicaid services or the office of the national coordinator for health information technology.

(E) A health plan issuer, including a pharmacy benefit manager, shall furnish the data required under division (B) of this section regardless of whether the request is made using the drug's unique billing code, such as a national drug code or health care common procedure coding system code, or a descriptive term, such as the brand or generic name of the drug.

(F) A health plan issuer, including a pharmacy benefit manager, shall not deny or delay a request as a method of blocking the data required under division (B) of this section from being shared based on how the drug was requested.

(G) A health plan issuer, including a pharmacy benefit manager, furnishing the data required under division (B) of this section shall not do any of the following:

(1) Restrict, prohibit, or otherwise hinder, in any way, a health care provider from communicating or sharing any of the following:

(a) Any of the data required under division (B) of this section;

(b) Additional information on any lower-cost or clinically appropriate alternatives, whether or not they are covered under the covered person's health benefit plan;

(c) Additional payment or cost-sharing information that may reduce the covered person's out-of-pocket costs, such as cash price or patient assistance and support programs whether sponsored by a manufacturer, foundation, or other entity.

(2) Except as may be required by law, interfere with, prevent, or materially discourage access, exchange, or use of the data required under division (B) of this section, including any of the following:

(a) Charging fees;

(b) Not responding to a request at the time the request is made, if such a response is reasonably possible;

(c) Implementing technology in nonstandard ways;

(d) Instituting covered person consent requirements, processes, policies, procedures, or renewals that are likely to substantially increase the complexity or burden of accessing, exchanging, or using such data.

(3) Penalize a health care provider for disclosing such data to a covered person or for prescribing, administering, or ordering a clinically appropriate or lower-cost alternative.

(H)(1) A health plan issuer, including a pharmacy benefit manager, shall treat a personal representative of a covered person as the covered person for purposes of this section.

(2) If under applicable law a person has authority to act on behalf of a covered person in making decisions related to health care, a health plan issuer, including a pharmacy benefit manager, or its affiliates or entities acting on its behalf, shall treat such person as a personal representative under this section.

(I) Divisions (A) to (H) of this section take effect January 1, 2022.

Section 2. That existing sections 3902.50, 3902.70, and 3902.72 of the Revised Code are hereby repealed.