

As Introduced

136th General Assembly

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H. B. No. 276

Representatives John, Holmes

To amend sections 3902.50 and 3902.70; to amend, 1
for the purpose of adopting a new section number 2
as indicated in parentheses, section 3902.72 3
(3902.75); and to enact new section 3902.72 of 4
the Revised Code to prohibit drug manufacturers 5
from taking certain actions regarding 6
reimbursements made to 340B covered entities. 7

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

Section 1. That sections 3902.50 and 3902.70 be amended; 8
section 3902.72 (3902.75) be amended for the purpose of adopting 9
a new section number as indicated in parentheses; and new 10
section 3902.72 of the Revised Code be enacted to read as 11
follows: 12

Sec. 3902.50. As used in sections 3902.50 to ~~3902.72~~ 13
3902.75 of the Revised Code: 14

(A) "Ambulance" has the same meaning as in section 4765.01 15
of the Revised Code. 16

(B) "Clinical laboratory services" has the same meaning as 17
in section 4731.65 of the Revised Code. 18

(C) "Cost sharing" means the cost to a covered person 19
under a health benefit plan according to any copayment, 20

coinsurance, deductible, or other out-of-pocket expense 21
requirement. 22

(D) "Covered" or "coverage" means the provision of 23
benefits related to health care services to a covered person in 24
accordance with a health benefit plan. 25

(E) "Covered person," "health benefit plan," "health care 26
services," and "health plan issuer" have the same meanings as in 27
section 3922.01 of the Revised Code. 28

(F) "Drug" has the same meaning as in section 4729.01 of 29
the Revised Code. 30

(G) "Emergency facility" has the same meaning as in 31
section 3701.74 of the Revised Code. 32

(H) "Emergency services" means all of the following as 33
described in 42 U.S.C. 1395dd: 34

(1) Medical screening examinations undertaken to determine 35
whether an emergency medical condition exists; 36

(2) Treatment necessary to stabilize an emergency medical 37
condition; 38

(3) Appropriate transfers undertaken prior to an emergency 39
medical condition being stabilized. 40

(I) "Health care practitioner" has the same meaning as in 41
section 3701.74 of the Revised Code. 42

(J) "Pharmacy benefit manager" has the same meaning as in 43
section 3959.01 of the Revised Code. 44

(K) "Prior authorization requirement" means any practice 45
implemented by a health plan issuer in which coverage of a 46
health care service, device, or drug is dependent upon a covered 47

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" and "third-party administrator"
have the same meanings as in section 5167.01 of the Revised
Code.

(B)

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

(C) "Terminal distributor of dangerous drugs," ~~has~~
"manufacturer of dangerous drugs," "repackager of dangerous
drugs," and "third-party logistics provider," have the same
~~meaning-meanings~~ as in section 4729.01 of the Revised Code.

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

<u>Sec. 3902.72. (A) As used in this section:</u>	76
<u>(1) "340B drug" means a drug that meets all of the</u>	77
<u>following criteria:</u>	78
<u>(a) The drug is a covered outpatient drug under the 340B</u>	79
<u>drug pricing program.</u>	80
<u>(b) The drug is subject to any offer for reduced prices by</u>	81
<u>a manufacturer pursuant to the 340B drug pricing program.</u>	82
<u>(c) The drug is purchased by a 340B grantee or would have</u>	83
<u>been purchased by a 340B grantee if not for an action prohibited</u>	84
<u>under this section.</u>	85
<u>(2) "340B grantee" means an entity described in section</u>	86
<u>340B(a) (4) (A)-(K) of the "Public Health Service Act," 42 U.S.C.</u>	87
<u>256b(a) (4) (A)-(K) that is designated as an active entity under</u>	88
<u>the health resources and services administration covered entity</u>	89
<u>daily report.</u>	90
<u>(B) No manufacturer of dangerous drugs, repackager of</u>	91
<u>dangerous drugs, or third-party logistics provider, or an agent</u>	92
<u>or affiliate of any of those entities, shall do either of the</u>	93
<u>following:</u>	94
<u>(1) Deny, prohibit, restrict, discriminate against, or</u>	95
<u>otherwise limit the acquisition of a 340B drug by or delivery of</u>	96
<u>a 340B drug to a 340B grantee, unless the purchase or delivery</u>	97
<u>is prohibited by the United States department of health and</u>	98
<u>human services;</u>	99
<u>(2) Require a 340B grantee to submit any claims or</u>	100
<u>utilization data as a condition for allowing the acquisition of</u>	101
<u>a 340B drug by or delivery of a 340B drug to a 340B grantee,</u>	102
<u>unless the claims or utilization data sharing is required by the</u>	103

United States department of health and human services. 104

(C) (1) Whoever violates this section engages in an unfair 105
and deceptive insurance act or practice under sections 3901.19 106
to 3901.26 of the Revised Code, and is subject to proceedings 107
pursuant to those sections. If the superintendent, by written 108
order, finds that any person is about to engage, is engaging, or 109
has engaged in a violation of this section, the superintendent, 110
in addition to the administrative remedies set forth in section 111
3901.22 of the Revised Code, may impose a civil penalty of fifty 112
thousand dollars for each such violation, not to exceed ten 113
million dollars annually. Each package of 340B drugs determined 114
by the superintendent to be subject to a prohibited act under 115
division (C) of this section constitutes a separate violation. 116

(2) In addition to the civil penalty, the superintendent 117
of insurance may refer any complaint of a violation of division 118
(C) of this section to the state board of pharmacy for the board 119
to consider one or more of the sanctions set forth in division 120
(A) (1) of section 4729.56 of the Revised Code. 121

(D) The superintendent of insurance may adopt rules, or 122
may delegate authority to the board of pharmacy to adopt rules, 123
pursuant to Chapter 119. of the Revised Code to implement the 124
provisions of this section. 125

(E) Nothing in this section shall be construed to conflict 126
with or be less restrictive than applicable federal law or 127
regulations, including 21 U.S.C. 355-1, or applicable laws or 128
regulations of this state. 129

Sec. 3902.72 3902.75. (A) As used in this section, "health 130
care provider" has the same meaning as in section 3701.74 of the 131
Revised Code. 132

(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: 161

(1) A standards developing organization accredited by the 162
American national standards institute, including the national 163
council for prescription drug programs, ASC X12, health level 7; 164

(2) A relevant federal or state governing body, including 165
the centers for medicare and medicaid services or the office of 166
the national coordinator for health information technology. 167

(E) A health plan issuer, including a pharmacy benefit 168
manager, shall furnish the data required under division (B) of 169
this section regardless of whether the request is made using the 170
drug's unique billing code, such as a national drug code or 171
health care common procedure coding system code, or a 172
descriptive term, such as the brand or generic name of the drug. 173

(F) A health plan issuer, including a pharmacy benefit 174
manager, shall not deny or delay a request as a method of 175
blocking the data required under division (B) of this section 176
from being shared based on how the drug was requested. 177

(G) A health plan issuer, including a pharmacy benefit 178
manager, furnishing the data required under division (B) of this 179
section shall not do any of the following: 180

(1) Restrict, prohibit, or otherwise hinder, in any way, a 181
health care provider from communicating or sharing any of the 182
following: 183

(a) Any of the data required under division (B) of this 184
section; 185

(b) Additional information on any lower-cost or clinically 186
appropriate alternatives, whether or not they are covered under 187
the covered person's health benefit plan; 188

(c) Additional payment or cost-sharing information that 189
may reduce the covered person's out-of-pocket costs, such as 190
cash price or patient assistance and support programs whether 191
sponsored by a manufacturer, foundation, or other entity. 192

(2) Except as may be required by law, interfere with, 193
prevent, or materially discourage access, exchange, or use of 194
the data required under division (B) of this section, including 195
any of the following: 196

(a) Charging fees; 197

(b) Not responding to a request at the time the request is 198
made, if such a response is reasonably possible; 199

(c) Implementing technology in nonstandard ways; 200

(d) Instituting covered person consent requirements, 201
processes, policies, procedures, or renewals that are likely to 202
substantially increase the complexity or burden of accessing, 203
exchanging, or using such data. 204

(3) Penalize a health care provider for disclosing such 205
data to a covered person or for prescribing, administering, or 206
ordering a clinically appropriate or lower-cost alternative. 207

(H) (1) A health plan issuer, including a pharmacy benefit 208
manager, shall treat a personal representative of a covered 209
person as the covered person for purposes of this section. 210

(2) If under applicable law a person has authority to act 211
on behalf of a covered person in making decisions related to 212
health care, a health plan issuer, including a pharmacy benefit 213
manager, or its affiliates or entities acting on its behalf, 214
shall treat such person as a personal representative under this 215
section. 216

(I) Divisions (A) to (H) of this section take effect	217
January 1, 2022.	218
Section 2. That existing sections 3902.50, 3902.70, and	219
3902.72 of the Revised Code are hereby repealed.	220