

As Introduced

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H. B. No. 582

Representatives Burke, Bulp

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A B I L L

To amend sections 4729.75, 4729.77, 4729.79, 4729.83, 1
4729.84, and 5111.172 and to enact sections 2
4729.791, 4729.821, 4729.831, 4731.055, 5111.179, 3
and 5111.1710 of the Revised Code regarding the 4
State Board of Pharmacy's drug database and a 5
program for certain Medicaid recipients found to 6
have over used items or services. 7

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

Section 1. That sections 4729.75, 4729.77, 4729.79, 4729.83, 8
4729.84, and 5111.172 be amended and sections 4729.791, 4729.821, 9
4729.831, 4731.055, 5111.179, and 5111.1710 of the Revised Code be 10
enacted to read as follows: 11

Sec. 4729.75. (A) The state board of pharmacy may establish 12
and maintain a drug database. The board shall use the drug 13
database to monitor the misuse and diversion of controlled 14
substances, as defined in section 3719.01 of the Revised Code, and 15
other dangerous drugs the board includes in the database pursuant 16
to rules adopted under section 4729.83 of the Revised Code. In 17
establishing and maintaining the database, the board shall 18
electronically collect information pursuant to sections 4729.77 19
and 4729.78 of the Revised Code and shall disseminate information 20

as authorized ~~or required~~ by ~~sections~~ section 4729.79 and as 21
required by sections 4729.791 and 4729.80 of the Revised Code. The 22
board's collection and dissemination of information shall be 23
conducted in accordance with rules adopted under section 4729.83 24
of the Revised Code. 25

(B) A drug database established under this section shall 26
include both of the following: 27

(1) A process that permits information to be immediately 28
submitted to the database by those required by section 4729.77 of 29
the Revised Code to submit information to the board; 30

(2) The capacity to provide those authorized to view 31
information in the database immediate access to that information. 32

Sec. 4729.77. (A) If the state board of pharmacy establishes 33
and maintains a drug database pursuant to section 4729.75 of the 34
Revised Code, each pharmacy licensed as a terminal distributor of 35
dangerous drugs that dispenses drugs to patients in this state and 36
is included in the types of pharmacies specified in rules adopted 37
under section 4729.83 of the Revised Code shall submit to the 38
board the following prescription information: 39

(1) Terminal distributor identification; 40

(2) Patient identification; 41

(3) Prescriber identification; 42

(4) Purchaser identification, including any unique identifier 43
established in rules adopted by the board under division (B) of 44
section 4729.83 of the Revised Code; 45

(5) Date prescription was issued by prescriber; 46

~~(5)~~(6) Date prescription was dispensed; 47

~~(6)~~(7) Indication of whether prescription dispensed is new or 48
a refill; 49

(7) (8) Name, strength, and national drug code of the drug	50
dispensed;	51
(8) (9) Quantity of drug dispensed;	52
(9) (10) Number of days' supply of drug dispensed;	53
(10) (11) Serial or prescription number assigned by the	54
terminal distributor;	55
(11) (12) Source of payment for the prescription.	56
(B) The information shall be transmitted as specified by the	57
board in rules adopted under section 4729.83 of the Revised Code.	58
(1) The information shall be submitted electronically in the	59
format specified by the board, except that the board may grant a	60
waiver allowing the distributor to submit the information in	61
another format.	62
(2) The information shall be submitted in accordance with any	63
time limits specified by the board, except that the board may	64
grant an extension if either of the following occurs:	65
(a) The distributor suffers a mechanical or electronic	66
failure, or cannot meet the deadline for other reasons beyond the	67
distributor's control.	68
(b) The board is unable to receive electronic submissions.	69
(C) This section does not apply to a prescriber personally	70
furnishing or administering dangerous drugs to the prescriber's	71
patient.	72
<u>(D) If, based on review of information in the database, a</u>	73
<u>pharmacist at a pharmacy elects not to dispense a drug to a</u>	74
<u>patient, the pharmacy shall submit to the board the information</u>	75
<u>required by divisions (A)(1), (2), (3), and (5) of this section;</u>	76
<u>the name, strength, national drug code, and quantity of the</u>	77
<u>prescribed drug; and an indication that the drug was not</u>	78
<u>dispensed.</u>	79

Sec. 4729.79. (A) If the state board of pharmacy establishes 80
and maintains a drug database pursuant to section 4729.75 of the 81
Revised Code, the board may provide information from the database 82
in accordance with the following: 83

(1) On receipt of a request from a designated representative 84
of a government entity responsible for the licensure, regulation, 85
or discipline of licensed health care professionals authorized to 86
prescribe drugs, the board may provide to the representative 87
information from the database relating to the professional who is 88
the subject of an active investigation being conducted by the 89
government entity. 90

(2) On receipt of a request from a federal officer, or a 91
state or local officer of this or any other state, whose duties 92
include enforcing laws relating to drugs, the board may provide to 93
the officer information from the database relating to the person 94
who is the subject of an active investigation being conducted by 95
the officer's employing government entity. 96

(3) Pursuant to a subpoena issued by a grand jury, the board 97
may provide to the grand jury information from the database 98
relating to the person who is the subject of an investigation 99
being conducted by the grand jury. 100

~~(4) On receipt of a request from a pharmacist or prescriber,~~ 101
~~the board may provide to the requestor information from the~~ 102
~~database relating to a current patient of the requestor, if the~~ 103
~~requestor certifies in a form specified by the board that it is~~ 104
~~for the purpose of providing medical or pharmaceutical treatment~~ 105
~~to the patient who is the subject of the request.~~ 106

~~(5)~~ On receipt of a request from an individual seeking the 107
individual's own database information in accordance with the 108
procedure established in rules adopted under section 4729.83 of 109
the Revised Code, the board may provide to the individual the 110

individual's own database information. 111

(5) On receipt of a request from a managed care organization 112
that has entered into a data security agreement with the board 113
required by section 5111.1710 of the Revised Code, the board may 114
provide to the managed care organization information from the 115
database relating to a medicaid recipient enrolled in the managed 116
care organization. 117

(B) The state board of pharmacy shall maintain a record of 118
each individual or entity that requests information from the 119
database pursuant to this section. In accordance with rules 120
adopted under section 4729.83 of the Revised Code, the board may 121
use the records to document and report statistics and law 122
enforcement outcomes. 123

The board may provide records of an individual's requests for 124
database information to the following: 125

(1) A designated representative of a government entity that 126
is responsible for the licensure, regulation, or discipline of 127
licensed health care professionals authorized to prescribe drugs 128
who is involved in an active investigation being conducted by the 129
government entity of the individual who submitted the requests for 130
database information; 131

(2) A federal officer, or a state or local officer of this or 132
any other state, whose duties include enforcing laws relating to 133
drugs and who is involved in an active investigation being 134
conducted by the officer's employing government entity of the 135
individual who submitted the requests for database information. 136

(C) Information contained in the database and any information 137
obtained from it is not a public record. Information contained in 138
the records of requests for information from the database is not a 139
public record. Information that does not identify a person may be 140
released in summary, statistical, or aggregate form. 141

~~(D) Nothing in this section requires a pharmacist or prescriber to obtain information about a patient from the database. A pharmacist or prescriber shall not be held liable in damages to any person in any civil action for injury, death, or loss to person or property on the basis that the pharmacist or prescriber did or did not seek or obtain information from the database.~~

Sec. 4729.791. (A) If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, the board shall grant access to the information in the database to each licensed health professional authorized to prescribe drugs and to each pharmacist practicing in this state. The board shall grant access to the database in a manner that enables each prescriber and pharmacist to use the database in accordance with division (B) of this section or with rules adopted by the state medical board under section 4731.055 of the Revised Code.

(B) Before a prescriber issues a prescription to a patient for a drug included in the database and before a pharmacist dispenses such a drug, the prescriber and pharmacist may review information in the database that pertains to the patient. At any other time, a prescriber or pharmacist may review information in the database pertaining to a patient for the purpose of providing medical treatment or pharmacist services to the patient.

(C) A prescriber or pharmacist shall not be held liable in damages to any person in a civil action for injury, death, or loss to person or property on the basis that the prescriber or pharmacist did or did not review information in the database pertaining to a patient.

(D) Except as provided in rules adopted under section 4731.055 of the Revised Code, nothing in this section requires a

pharmacist or prescriber to obtain information about a patient 173
from the database. 174

Sec. 4729.821. If the state board of pharmacy establishes and 175
maintains a drug database pursuant to section 4729.75 of the 176
Revised Code, the department of health, the department of 177
insurance, and the state board of pharmacy shall, to the extent 178
existing eligible funds are available, cooperate to contribute 179
sufficient funds to permit the board to develop and operate in the 180
drug database the capacity to immediately update database 181
information and allow immediate access by authorized users, as 182
provided by section 4729.75 of the Revised Code. The departments 183
and board shall seek funding sources to permit the board to 184
develop and operate the drug database in that manner. In doing so, 185
the departments and board may collaborate to apply for grants or 186
seek federal funds that may be available for developing and 187
operating the drug database. 188

The director of budget and management may transfer cash 189
between funds of the department of health, the department of 190
insurance, and the state board of pharmacy as necessary to achieve 191
the objectives of this section. 192

Sec. 4729.83. For purposes of establishing and maintaining a 193
drug database pursuant to section 4729.75 of the Revised Code, the 194
state board of pharmacy shall adopt rules in accordance with 195
Chapter 119. of the Revised Code to carry out and enforce sections 196
4729.75 to 4729.82 of the Revised Code. The rules shall specify 197
all of the following: 198

(A) A means of identifying each patient, terminal distributor 199
of dangerous drugs, and each purchase at wholesale of dangerous 200
drugs about which information is entered into the drug database; 201

(B) A means of identifying each purchaser of dangerous drugs, 202

<u>which may include assignment of a unique identifier for each</u>	203
<u>purchaser;</u>	204
<u>(C) A means for a pharmacy to indicate that a pharmacist has</u>	205
<u>elected not to dispense a drug to a patient;</u>	206
(D) Requirements for the transmission of information from	207
terminal distributors and wholesale distributors of dangerous	208
drugs for purposes of the database;	209
(C) (E) An electronic format for the submission of information	210
from terminal distributors and wholesale distributors of dangerous	211
drugs;	212
(D) (F) A procedure whereby a terminal distributor or a	213
wholesale distributor of dangerous drugs unable to submit	214
information electronically may obtain a waiver to submit	215
information in another format;	216
(E) (G) A procedure whereby the board may grant a request from	217
a law enforcement agency or a government entity responsible for	218
the licensure, regulation, or discipline of licensed health care	219
professionals authorized to prescribe drugs that information that	220
has been stored for two years be retained when the information	221
pertains to an open investigation being conducted by the agency or	222
entity;	223
(F) (H) A procedure whereby a terminal or wholesale	224
distributor may apply for an extension to the time by which	225
information must be transmitted to the board;	226
(G) (I) A procedure whereby a person or government entity to	227
which the board is authorized to provide information may submit a	228
request to the board for the information and the board may verify	229
the identity of the requestor;	230
(H) (J) A procedure whereby the board can use the database	231
request records required by division (B) of section 4729.79 of the	232

Revised Code to document and report statistics and law enforcement outcomes;	233 234
(I) (K) A procedure whereby an individual may request the individual's own database information and the board may verify the identity of the requestor;	235 236 237
(J) (L) A reasonable fee that the board may charge under section 4729.82 of the Revised Code for providing an individual with the individual's own database information pursuant to section 4729.79 of the Revised Code;	238 239 240 241
(K) (M) The specific dangerous drugs other than controlled substances that must be included in the database;	242 243
(L) (N) The types of pharmacies licensed as terminal distributors of dangerous drugs that are required to submit prescription information to the board pursuant to section 4729.77 of the Revised Code;	244 245 246 247
<u>(O) The manner in which prescribers and pharmacists are to be granted access to the database for purposes of section 4729.791 of the Revised Code.</u>	248 249 250
<u>Sec. 4729.831. The state board of pharmacy shall adopt rules in accordance with Chapter 119. of the Revised Code specifying the terms of a data security agreement described in section 5111.1710 of the Revised Code. The rules shall comply with privacy and security regulations promulgated under the "Health Insurance Portability and Accountability Act of 1996," Pub. L. No. 104-191, as amended, as specified in 45 C.F.R. Parts 160 and 164, as amended.</u>	251 252 253 254 255 256 257 258
Sec. 4729.84. (A) If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, the board shall present a biennial report to the standing committees of the house of representatives and the senate	259 260 261 262

that are primarily responsible for considering health and human 263
services issues. The initial report shall be presented not later 264
than two years after the database is established. 265

(B) Each report presented under this section shall include 266
all of the following: 267

(1) The cost to the state of establishing and maintaining the 268
database; 269

(2) Information from terminal distributors of dangerous 270
drugs, prescribers, and the board regarding the board's 271
effectiveness in providing information from the database; 272

(3) The board's timeliness in transmitting information from 273
the database; 274

(4) The total number of prescriptions for which drugs were 275
not dispensed due to the election of a pharmacist as indicated by 276
information provided to the board under division (D) of section 277
4729.77 of the Revised Code. 278

Sec. 4731.055. (A) As used in this section: 279

(1) "Dangerous drug" has the same meaning as in section 280
4729.01 of the Revised Code. 281

(2) "Drug database" means a database established by the state 282
board of pharmacy pursuant to section 4729.75 of the Revised Code. 283

(3) "Physician" means an individual authorized under this 284
chapter to practice medicine and surgery or osteopathic medicine 285
and surgery. 286

(B) The state medical board shall adopt rules in accordance 287
with Chapter 119. of the Revised Code that establish standards and 288
procedures to be followed by physicians regarding review of 289
patient information available through the drug database. The rules 290
shall include at least one of the following: 291

(1) A provision under which a physician who prescribes to patients, in total, a quantity of dangerous drugs exceeding an amount specified by the board is required to submit patient information to the drug database and review patient information in it; 292
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(2) A provision under which a physician who prescribes to an individual patient a supply of dangerous drugs exceeding an amount specified by the board is required to submit patient information in the drug database and review patient information in it. 297
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(C) The rules adopted under this section shall not apply if the state board of pharmacy does not establish a drug database or discontinues operation of a drug database. 301
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Sec. 5111.172. (A) When contracting under section 5111.17 of the Revised Code with a managed care organization that is a health insuring corporation, the department of job and family services may require the health insuring corporation to provide coverage of prescription drugs for medicaid recipients enrolled in the health insuring corporation. In providing the required coverage, the health insuring corporation may, subject to the department's approval, use strategies for the management of drug utilization. 304
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(B) As used in this division, "controlled substance" has the same meaning as in section 3719.01 of the Revised Code. 312
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If a health insuring corporation is required under this section to provide coverage of prescription drugs, the department shall permit the health insuring corporation to develop and implement a pharmacy utilization management program under which prior authorization through the program is established as a condition of obtaining a controlled substance pursuant to a prescription. ~~The Any such program may include processes for requiring medicaid recipients at high risk for fraud or abuse involving controlled substances to have their prescriptions for~~ 314
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~~controlled substances filled by a pharmacy, medical provider, or 323
health care facility designated by shall be consistent with the 324
program the health insuring corporation is required to implement 325
under section 5111.179 of the Revised Code. 326~~

Sec. 5111.179. Not later than one year after the effective 327
date of this section, each contract the department of job and 328
family services enters into with a managed care organization under 329
section 5111.17 of the Revised Code shall require the managed care 330
organization to implement a program consistent with 42 U.S.C. 331
1396n(a)(2) and 42 C.F.R. 431.54(e) for medicaid recipients 332
enrolled in the organization who are found to have utilized items 333
or services under the medicaid program at a frequency or amount 334
that is not medically necessary. The program shall include a 335
component that educates medicaid recipients about proper 336
utilization of items and services provided under the medicaid 337
program. 338

Sec. 5111.1710. Not later than one year after the effective 339
date of this section and if the state board of pharmacy 340
establishes and maintains a drug database pursuant to section 341
4729.75 of the Revised Code, each contract the department of job 342
and family services enters into with a managed care organization 343
under section 5111.17 of the Revised Code shall require the 344
managed care organization to enter into a data security agreement 345
with the board governing the managed care organization's use of 346
the database. The data security agreement shall contain terms 347
specified by the board in rules adopted pursuant to section 348
4729.831 of the Revised Code. 349

Section 2. That existing sections 4729.75, 4729.77, 4729.79, 350
4729.83, 4729.84, and 5111.172 of the Revised Code are hereby 351
repealed. 352