

**As Reported by the Senate Health, Human Services and Aging
Committee**

**125th General Assembly
Regular Session
2003-2004**

Sub. H. B. No. 377

**Representatives Raga, Calvert, Carmichael, Cirelli, Clancy, Daniels, C. Evans,
D. Evans, Flowers, Hagan, Martin, T. Patton, Schaffer, Schlichter, Schneider,
Slaby, G. Smith, J. Stewart, Willamowski**

—

A B I L L

To amend sections 4729.25 and 4729.26, to enact 1
sections 4729.75 to 4729.84, and to repeal 2
sections 4729.63 and 4729.66 of the Revised Code 3
to permit the State Board of Pharmacy to establish 4
and maintain a drug database to monitor the misuse 5
and diversion of controlled substances and certain 6
dangerous drugs. 7

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

Section 1. That sections 4729.25 and 4729.26 be amended and 8
sections 4729.75, 4729.76, 4729.77, 4729.78, 4729.79, 4729.80, 9
4729.81, 4729.82, 4729.83, and 4729.84 of the Revised Code be 10
enacted to read as follows: 11

Sec. 4729.25. (A) The state board of pharmacy shall enforce, 12
or cause to be enforced, this chapter. If it has information that 13
any provision of this chapter has been violated, it shall 14
investigate the matter, and take such action as it considers 15
appropriate ~~in accordance with its rules adopted under section~~ 16
~~4729.26 of the Revised Code. With regard to violations of sections~~ 17

~~4729.51 to 4729.62 of the Revised Code, the board's actions also~~ 18
~~shall be taken in accordance with section 4729.63 of the Revised~~ 19
~~Code.~~ 20

(B) Nothing in this chapter shall be construed to require the 21
state board of pharmacy to enforce minor violations of this 22
chapter if the board determines that the public interest is 23
adequately served by a notice or warning to the alleged offender. 24

Sec. 4729.26. The state board of pharmacy may adopt rules in 25
accordance with Chapter 119. of the Revised Code, not inconsistent 26
with the law, as may be necessary to carry out the purposes of and 27
to enforce the provisions of this chapter ~~pertaining to the~~ 28
~~practice of pharmacy.~~ The rules shall be published and made 29
available by the board to each pharmacist licensed under this 30
chapter. 31

Sec. 4729.75. The state board of pharmacy may establish and 32
maintain a drug database. The board shall use the drug database to 33
monitor the misuse and diversion of controlled substances, as 34
defined in section 3719.01 of the Revised Code, and other 35
dangerous drugs the board includes in the database pursuant to 36
rules adopted under section 4729.83 of the Revised Code. In 37
establishing and maintaining the database, the board shall 38
electronically collect information pursuant to sections 4729.77 39
and 4729.78 of the Revised Code and shall disseminate information 40
as authorized or required by sections 4729.79 and 4729.80 of the 41
Revised Code. The board's collection and dissemination of 42
information shall be conducted in accordance with rules adopted 43
under section 4729.83 of the Revised Code. 44

Sec. 4729.76. If the state board of pharmacy establishes and 45
maintains a drug database pursuant to section 4729.75 of the 46
Revised Code, the executive director of the board shall do all of 47

the following: 48

(A) Employ an administrator to manage and direct the duties of staff employed to operate the drug database. The administrator shall be a person who has had training and experience in areas related to the duties of the database. 49
50
51
52

(B) Employ such professional, technical, and clerical employees as are necessary, and employ or hire on a consulting basis other technical services required for the operation of the database; 53
54
55
56

(C) Fix the compensation of the administrator and all other staff employed to operate the database. 57
58

Sec. 4729.77. (A) If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, each pharmacy licensed as a terminal distributor of dangerous drugs that dispenses drugs to patients in this state and is included in the types of pharmacies specified in rules adopted under section 4729.83 of the Revised Code shall submit to the board the following prescription information: 59
60
61
62
63
64
65

(1) Terminal distributor identification; 66

(2) Patient identification; 67

(3) Prescriber identification; 68

(4) Date prescription was issued by prescriber; 69

(5) Date prescription was dispensed; 70

(6) Indication of whether prescription dispensed is new or a refill; 71
72

(7) Name, strength, and national drug code of the drug dispensed; 73
74

(8) Quantity of drug dispensed; 75

<u>(9) Number of days' supply of drug dispensed;</u>	76
<u>(10) Serial or prescription number assigned by the terminal distributor;</u>	77 78
<u>(11) Source of payment for the prescription.</u>	79
<u>(B) The information shall be transmitted as specified by the board in rules adopted under section 4729.83 of the Revised Code.</u>	80 81
<u>(1) The information shall be submitted electronically in the format specified by the board, except that the board may grant a waiver allowing the distributor to submit the information in another format.</u>	82 83 84 85
<u>(2) The information shall be submitted in accordance with any time limits specified by the board, except that the board may grant an extension if either of the following occurs:</u>	86 87 88
<u>(a) The distributor suffers a mechanical or electronic failure, or cannot meet the deadline for other reasons beyond the distributor's control.</u>	89 90 91
<u>(b) The board is unable to receive electronic submissions.</u>	92
<u>(C) This section does not apply to a prescriber personally furnishing or administering dangerous drugs to the prescriber's patient.</u>	93 94 95
<u>Sec. 4729.78.</u> <u>(A) If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, each wholesale distributor of dangerous drugs that delivers drugs to prescribers in this state shall submit to the board the following purchase information:</u>	96 97 98 99 100
<u>(1) Purchaser identification;</u>	101
<u>(2) Identification of the drug sold;</u>	102
<u>(3) Quantity of the drug sold;</u>	103

<u>(4) Date of sale;</u>	104
<u>(5) The wholesale distributor's license number issued by the board.</u>	105 106
<u>(B) The information shall be transmitted as specified by the board in rules adopted under section 4729.83 of the Revised Code.</u>	107 108
<u>(1) The information shall be submitted electronically in the format specified by the board, except that the board may grant a waiver allowing the distributor to submit the information in another format.</u>	109 110 111 112
<u>(2) The information shall be submitted in accordance with any time limits specified by the board, except that the board may grant an extension if either of the following occurs:</u>	113 114 115
<u>(a) The distributor suffers a mechanical or electronic failure, or cannot meet the deadline for other reasons beyond the distributor's control.</u>	116 117 118
<u>(b) The board is unable to receive electronic submissions.</u>	119
<u>Sec. 4729.79.</u> <u>(A) If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, the board may provide information from the database in accordance with the following:</u>	120 121 122 123
<u>(1) On receipt of a request from a designated representative of a government entity responsible for the licensure, regulation, or discipline of licensed health care professionals authorized to prescribe drugs, the board may provide to the representative information from the database relating to the professional who is the subject of an active investigation being conducted by the government entity.</u>	124 125 126 127 128 129 130
<u>(2) On receipt of a request from a federal officer, or a state or local officer of this or any other state, whose duties</u>	131 132

include enforcing laws relating to drugs, the board may provide to 133
the officer information from the database relating to the person 134
who is the subject of an active investigation being conducted by 135
the officer's employing government entity. 136

(3) Pursuant to a subpoena issued by a grand jury, the board 137
may provide to the grand jury information from the database 138
relating to the person who is the subject of an investigation 139
being conducted by the grand jury. 140

(4) On receipt of a request from a pharmacist or prescriber, 141
the board may provide to the requestor information from the 142
database relating to a current patient of the requestor, if the 143
requestor certifies in a form specified by the board that it is 144
for the purpose of providing medical or pharmaceutical treatment 145
to the patient who is the subject of the request. 146

(5) On receipt of a request from an individual seeking the 147
individual's own database information in accordance with the 148
procedure established in rules adopted under section 4729.83 of 149
the Revised Code, the board may provide to the individual the 150
individual's own database information. 151

(B) The state board of pharmacy shall maintain a record of 152
each individual or entity that requests information from the 153
database pursuant to this section. In accordance with rules 154
adopted under section 4729.83 of the Revised Code, the board may 155
use the records to document and report statistics and law 156
enforcement outcomes. 157

The board may provide records of an individual's requests for 158
database information to the following: 159

(1) A designated representative of a government entity that 160
is responsible for the licensure, regulation, or discipline of 161
licensed health care professionals authorized to prescribe drugs 162
who is involved in an active investigation being conducted by the 163

government entity of the individual who submitted the requests for 164
database information; 165

(2) A federal officer, or a state or local officer of this or 166
any other state, whose duties include enforcing laws relating to 167
drugs and who is involved in an active investigation being 168
conducted by the officer's employing government entity of the 169
individual who submitted the requests for database information. 170

(C) Information contained in the database and any information 171
obtained from it is not a public record. Information contained in 172
the records of requests for information from the database is not a 173
public record. Information that does not identify a person may be 174
released in summary, statistical, or aggregate form. 175

(D) Nothing in this section requires a pharmacist or 176
prescriber to obtain information about a patient from the 177
database. A pharmacist or prescriber shall not be held liable in 178
damages to any person in any civil action for injury, death, or 179
loss to person or property on the basis that the pharmacist or 180
prescriber did or did not seek or obtain information from the 181
database. 182

Sec. 4729.80. If the state board of pharmacy establishes and 183
maintains a drug database pursuant to section 4729.75 of the 184
Revised Code, the board shall review the information in the drug 185
database. If the board determines from the review that a violation 186
of law may have occurred, it shall notify the appropriate law 187
enforcement agency or a government entity responsible for the 188
licensure, regulation, or discipline of licensed health care 189
professionals authorized to prescribe drugs and supply information 190
required by the agency or entity for an investigation of the 191
violation of law that may have occurred. 192

Sec. 4729.81. If the state board of pharmacy establishes a 193

drug database pursuant to section 4729.75 of the Revised Code, the 194
information collected for the database shall be retained in the 195
database for two years. The information shall then be destroyed 196
unless a law enforcement agency or a government entity responsible 197
for the licensure, regulation, or discipline of licensed health 198
care professionals authorized to prescribe drugs has submitted a 199
written request to the board for retention of specific information 200
in accordance with rules adopted by the board under section 201
4729.83 of the Revised Code. 202

Sec. 4729.82. If the state board of pharmacy establishes and 203
maintains a drug database pursuant to section 4729.75 of the 204
Revised Code, the board shall not impose any charge on a terminal 205
distributor of dangerous drugs, pharmacist, or prescriber for the 206
establishment or maintenance of the database. The board shall not 207
charge any fees for the transmission of data to the database or 208
for the receipt of information from the database, except that the 209
board may charge a fee in accordance with rules adopted under 210
section 4729.83 of the Revised Code to an individual who requests 211
the individual's own database information under section 4729.79 of 212
the Revised Code. 213

Sec. 4729.83. For purposes of establishing and maintaining a 214
drug database pursuant to section 4729.75 of the Revised Code, the 215
state board of pharmacy shall adopt rules in accordance with 216
Chapter 119. of the Revised Code to carry out and enforce sections 217
4729.75 to 4729.82 of the Revised Code. The rules shall specify 218
all of the following: 219

(A) A means of identifying each patient, terminal distributor 220
of dangerous drugs, and each purchase at wholesale of dangerous 221
drugs about which information is entered into the drug database; 222

(B) Requirements for the transmission of information from 223

<u>terminal distributors and wholesale distributors of dangerous</u>	224
<u>drugs for purposes of the database;</u>	225
<u>(C) An electronic format for the submission of information</u>	226
<u>from terminal distributors and wholesale distributors of dangerous</u>	227
<u>drugs;</u>	228
<u>(D) A procedure whereby a terminal distributor or a wholesale</u>	229
<u>distributor of dangerous drugs unable to submit information</u>	230
<u>electronically may obtain a waiver to submit information in</u>	231
<u>another format;</u>	232
<u>(E) A procedure whereby the board may grant a request from a</u>	233
<u>law enforcement agency or a government entity responsible for the</u>	234
<u>licensure, regulation, or discipline of licensed health care</u>	235
<u>professionals authorized to prescribe drugs that information that</u>	236
<u>has been stored for two years be retained when the information</u>	237
<u>pertains to an open investigation being conducted by the agency or</u>	238
<u>entity;</u>	239
<u>(F) A procedure whereby a terminal or wholesale distributor</u>	240
<u>may apply for an extension to the time by which information must</u>	241
<u>be transmitted to the board;</u>	242
<u>(G) A procedure whereby a person or government entity to</u>	243
<u>which the board is authorized to provide information may submit a</u>	244
<u>request to the board for the information and the board may verify</u>	245
<u>the identity of the requestor;</u>	246
<u>(H) A procedure whereby the board can use the database</u>	247
<u>request records required by division (B) of section 4729.79 of the</u>	248
<u>Revised Code to document and report statistics and law enforcement</u>	249
<u>outcomes;</u>	250
<u>(I) A procedure whereby an individual may request the</u>	251
<u>individual's own database information and the board may verify the</u>	252
<u>identity of the requestor;</u>	253

(J) 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; 254
255
256
257

(K) The specific dangerous drugs other than controlled substances that must be included in the database; 258
259

(L) 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. 260
261
262
263

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 that are primarily responsible for considering health and human services issues. The initial report shall be presented not later than two years after the database is established. 264
265
266
267
268
269
270

(B) Each report presented under this section shall include all of the following: 271
272

(1) The cost to the state of establishing and maintaining the database; 273
274

(2) Information from terminal distributors of dangerous drugs, prescribers, and the board regarding the board's effectiveness in providing information from the database; 275
276
277

(3) The board's timeliness in transmitting information from the database. 278
279

Section 2. That existing sections 4729.25 and 4729.26 and sections 4729.63 and 4729.66 of the Revised Code are hereby repealed. 280
281
282