As Passed by the Senate

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 Senators Wachtmann, Schuring, Blessing, Spada

A BILL

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
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 sections 4729.75, 4729.76, 4729.77, 4729.78, 4729.79, 4729.80,
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 4729.81, 4729.82, 4729.83, and 4729.84 of the Revised Code be
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 enacted to read as follows:
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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 (B) Nothing in this chapter shall be construed to require the
state board of pharmacy to enforce minor violations of this
chapter if the board determines that the public interest is
adequately served by a notice or warning to the alleged offender.

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 and45maintains a drug database pursuant to section 4729.75 of the46Revised Code, the executive director of the board shall do all of47

the following: (A) Employ an administrator to manage and direct the duties 49 of staff employed to operate the drug database. The administrator 50 shall be a person who has had training and experience in areas 51 related to the duties of the database. 52 (B) Employ such professional, technical, and clerical 53 employees as are necessary, and employ or hire on a consulting 54 basis other technical services required for the operation of the 55 database; 56 (C) Fix the compensation of the administrator and all other 57 staff employed to operate the database. 58 **sec. 4729.77.** (A) If the state board of pharmacy establishes 59 and maintains a drug database pursuant to section 4729.75 of the 60 Revised Code, each pharmacy licensed as a terminal distributor of 61 dangerous drugs that dispenses drugs to patients in this state and 62 is included in the types of pharmacies specified in rules adopted 63 under section 4729.83 of the Revised Code shall submit to the 64 board the following prescription information: 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 71 refill; 72 (7) Name, strength, and national drug code of the drug 73 dispensed; 74

(8) Quantity of drug dispensed;

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

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

184 the section 4/29./5 OL 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
<u>unless a law enforcement agency or a government entity responsible</u>	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 a214drug database pursuant to section 4729.75 of the Revised Code, the215state board of pharmacy shall adopt rules in accordance with216Chapter 119. of the Revised Code to carry out and enforce sections2174729.75 to 4729.82 of the Revised Code. The rules shall specify218all of the following:219

(A) A means of identifying each patient, terminal distributor220of dangerous drugs, and each purchase at wholesale of dangerous221drugs about which information is entered into the drug database;222

(B) Requirements for the transmission of information from 223

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

(J) A reasonable fee that the board may charge under section	254
4729.82 of the Revised Code for providing an individual with the	255
individual's own database information pursuant to section 4729.79	256
of the Revised Code;	257
(K) The specific dangerous drugs other than controlled	258
substances that must be included in the database;	259
(L) The types of pharmacies licensed as terminal distributors	260
of dangerous drugs that are required to submit prescription	261
information to the board pursuant to section 4729.77 of the	262
Revised Code.	263
Sec. 4729.84. (A) If the state board of pharmacy establishes	264
and maintains a drug database pursuant to section 4729.75 of the	265
Revised Code, the board shall present a biennial report to the	266
standing committees of the house of representatives and the senate	267
that are primarily responsible for considering health and human	268
services issues. The initial report shall be presented not later	269
than two years after the database is established.	270
(B) Each report presented under this section shall include	271
all of the following:	272
(1) The cost to the state of establishing and maintaining the	273
<u>database;</u>	274
(2) Information from terminal distributors of dangerous	275
drugs, prescribers, and the board regarding the board's	276
effectiveness in providing information from the database;	277
(3) The board's timeliness in transmitting information from	278
<u>the database.</u>	279
Section 2. That existing sections 4729.25 and 4729.26 and	280
sections 4729.63 and 4729.66 of the Revised Code are hereby	281
repealed.	282