

As Introduced

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H. B. No. 535

Representative Gavarone

**Cosponsors: Representatives Young, Brown, Patton, Stein, Arndt, Hambley, Kick,
Smith, R., Ryan, Sprague**

A BILL

To amend sections 4729.01, 4729.44, 4729.75, 1
4729.79, and 4729.85 and to enact sections 2
3727.25 and 4765.45 of the Revised Code to 3
require certain reports regarding overdoses and 4
naloxone, to include naltrexone within the Ohio 5
Automated Rx Reporting System, and to name this 6
act the "Opioid Data and Communication Expansion 7
Act." 8

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

Section 1. That sections 4729.01, 4729.44, 4729.75, 9
4729.79, and 4729.85 be amended and sections 3727.25 and 4765.45 10
of the Revised Code be enacted to read as follows: 11

Sec. 3727.25. (A) Each hospital shall report to the 12
department of health on a monthly basis and in a manner 13
prescribed by the department all of the following information 14
for the previous month: 15

(1) The total number of drug overdose cases brought to the 16
hospital for treatment; 17

(2) Of the number described in division (A) (1) of this 18
section, the number that resulted in death and the number that 19
did not result in death. 20

When submitting reports, the hospital shall not include 21
any information that identifies or tends to identify specific 22
patients. 23

(B) Each month, the department shall compile the 24
information it receives under division (A) of this section and 25
shall publish the information on its internet web site. 26

(C) The department may adopt rules as necessary to 27
implement this section. The rules shall be adopted in accordance 28
with Chapter 119. of the Revised Code. 29

Sec. 4729.01. As used in this chapter: 30

(A) "Pharmacy," except when used in a context that refers 31
to the practice of pharmacy, means any area, room, rooms, place 32
of business, department, or portion of any of the foregoing 33
where the practice of pharmacy is conducted. 34

(B) "Practice of pharmacy" means providing pharmacist care 35
requiring specialized knowledge, judgment, and skill derived 36
from the principles of biological, chemical, behavioral, social, 37
pharmaceutical, and clinical sciences. As used in this division, 38
"pharmacist care" includes the following: 39

(1) Interpreting prescriptions; 40

(2) Dispensing drugs and drug therapy related devices; 41

(3) Compounding drugs; 42

(4) Counseling individuals with regard to their drug 43
therapy, recommending drug therapy related devices, and 44

assisting in the selection of drugs and appliances for treatment 45
of common diseases and injuries and providing instruction in the 46
proper use of the drugs and appliances; 47

(5) Performing drug regimen reviews with individuals by 48
discussing all of the drugs that the individual is taking and 49
explaining the interactions of the drugs; 50

(6) Performing drug utilization reviews with licensed 51
health professionals authorized to prescribe drugs when the 52
pharmacist determines that an individual with a prescription has 53
a drug regimen that warrants additional discussion with the 54
prescriber; 55

(7) Advising an individual and the health care 56
professionals treating an individual with regard to the 57
individual's drug therapy; 58

(8) Acting pursuant to a consult agreement with one or 59
more physicians authorized under Chapter 4731. of the Revised 60
Code to practice medicine and surgery or osteopathic medicine 61
and surgery, if an agreement has been established; 62

(9) Engaging in the administration of immunizations to the 63
extent authorized by section 4729.41 of the Revised Code; 64

(10) Engaging in the administration of drugs to the extent 65
authorized by section 4729.45 of the Revised Code. 66

(C) "Compounding" means the preparation, mixing, 67
assembling, packaging, and labeling of one or more drugs in any 68
of the following circumstances: 69

(1) Pursuant to a prescription issued by a licensed health 70
professional authorized to prescribe drugs; 71

(2) Pursuant to the modification of a prescription made in 72

accordance with a consult agreement;	73
(3) As an incident to research, teaching activities, or chemical analysis;	74 75
(4) In anticipation of orders for drugs pursuant to prescriptions, based on routine, regularly observed dispensing patterns;	76 77 78
(5) Pursuant to a request made by a licensed health professional authorized to prescribe drugs for a drug that is to be used by the professional for the purpose of direct administration to patients in the course of the professional's practice, if all of the following apply:	79 80 81 82 83
(a) At the time the request is made, the drug is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer.	84 85 86 87 88
(b) A limited quantity of the drug is compounded and provided to the professional.	89 90
(c) The drug is compounded and provided to the professional as an occasional exception to the normal practice of dispensing drugs pursuant to patient-specific prescriptions.	91 92 93
(D) "Consult agreement" means an agreement that has been entered into under section 4729.39 of the Revised Code.	94 95
(E) "Drug" means:	96
(1) Any article recognized in the United States pharmacopoeia and national formulary, or any supplement to them, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;	97 98 99 100

(2) Any other article intended for use in the diagnosis, 101
cure, mitigation, treatment, or prevention of disease in humans 102
or animals; 103

(3) Any article, other than food, intended to affect the 104
structure or any function of the body of humans or animals; 105

(4) Any article intended for use as a component of any 106
article specified in division (E) (1), (2), or (3) of this 107
section; but does not include devices or their components, 108
parts, or accessories. 109

(F) "Dangerous drug" means any of the following: 110

(1) Any drug to which either of the following applies: 111

(a) Under the "Federal Food, Drug, and Cosmetic Act," 52 112
Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is 113
required to bear a label containing the legend "Caution: Federal 114
law prohibits dispensing without prescription" or "Caution: 115
Federal law restricts this drug to use by or on the order of a 116
licensed veterinarian" or any similar restrictive statement, or 117
the drug may be dispensed only upon a prescription; 118

(b) Under Chapter 3715. or 3719. of the Revised Code, the 119
drug may be dispensed only upon a prescription. 120

(2) Any drug that contains a schedule V controlled 121
substance and that is exempt from Chapter 3719. of the Revised 122
Code or to which that chapter does not apply; 123

(3) Any drug intended for administration by injection into 124
the human body other than through a natural orifice of the human 125
body; 126

(4) Any drug that is a biological product, as defined in 127
section 3715.01 of the Revised Code. 128

(G) "Federal drug abuse control laws" has the same meaning	129
as in section 3719.01 of the Revised Code.	130
(H) "Prescription" means all of the following:	131
(1) A written, electronic, or oral order for drugs or	132
combinations or mixtures of drugs to be used by a particular	133
individual or for treating a particular animal, issued by a	134
licensed health professional authorized to prescribe drugs;	135
(2) For purposes of sections 2925.61, 4723.488, 4729.44,	136
4730.431, and 4731.94 of the Revised Code, a written,	137
electronic, or oral order for naloxone issued to and in the name	138
of a family member, friend, or other individual in a position to	139
assist an individual who there is reason to believe is at risk	140
of experiencing an opioid-related overdose.	141
(3) <u>For purposes of section 4729.44 of the Revised Code, a</u>	142
<u>written, electronic, or oral order for naloxone issued to and in</u>	143
<u>the name of either of the following:</u>	144
(a) <u>An individual who there is reason to believe is at</u>	145
<u>risk of experiencing an opioid-related overdose;</u>	146
(b) <u>A family member, friend, or other individual in a</u>	147
<u>position to assist an individual who there is reason to believe</u>	148
<u>is at risk of experiencing an opioid-related overdose.</u>	149
(4) For purposes of sections 4723.4810, 4729.282,	150
4730.432, and 4731.93 of the Revised Code, a written,	151
electronic, or oral order for a drug to treat chlamydia,	152
gonorrhoea, or trichomoniasis issued to and in the name of a	153
patient who is not the intended user of the drug but is the	154
sexual partner of the intended user;	155
(4) (5) For purposes of sections 3313.7110, 3313.7111,	156

3314.143, 3326.28, 3328.29, 4723.483, 4729.88, 4730.433, 157
4731.96, and 5101.76 of the Revised Code, a written, electronic, 158
or oral order for an epinephrine autoinjector issued to and in 159
the name of a school, school district, or camp; 160

~~(5)~~ (6) For purposes of Chapter 3728. and sections 161
4723.483, 4729.88, 4730.433, and 4731.96 of the Revised Code, a 162
written, electronic, or oral order for an epinephrine 163
autoinjector issued to and in the name of a qualified entity, as 164
defined in section 3728.01 of the Revised Code. 165

(I) "Licensed health professional authorized to prescribe 166
drugs" or "prescriber" means an individual who is authorized by 167
law to prescribe drugs or dangerous drugs or drug therapy 168
related devices in the course of the individual's professional 169
practice, including only the following: 170

(1) A dentist licensed under Chapter 4715. of the Revised 171
Code; 172

(2) A clinical nurse specialist, certified nurse-midwife, 173
or certified nurse practitioner who holds a current, valid 174
license to practice nursing as an advanced practice registered 175
nurse issued under Chapter 4723. of the Revised Code; 176

(3) An optometrist licensed under Chapter 4725. of the 177
Revised Code to practice optometry under a therapeutic 178
pharmaceutical agents certificate; 179

(4) A physician authorized under Chapter 4731. of the 180
Revised Code to practice medicine and surgery, osteopathic 181
medicine and surgery, or podiatric medicine and surgery; 182

(5) A physician assistant who holds a license to practice 183
as a physician assistant issued under Chapter 4730. of the 184
Revised Code, holds a valid prescriber number issued by the 185

state medical board, and has been granted physician-delegated	186
prescriptive authority;	187
(6) A veterinarian licensed under Chapter 4741. of the	188
Revised Code.	189
(J) "Sale" or "sell" includes any transaction made by any	190
person, whether as principal proprietor, agent, or employee, to	191
do or offer to do any of the following: deliver, distribute,	192
broker, exchange, gift or otherwise give away, or transfer,	193
whether the transfer is by passage of title, physical movement,	194
or both.	195
(K) "Wholesale sale" and "sale at wholesale" mean any sale	196
in which the purpose of the purchaser is to resell the article	197
purchased or received by the purchaser.	198
(L) "Retail sale" and "sale at retail" mean any sale other	199
than a wholesale sale or sale at wholesale.	200
(M) "Retail seller" means any person that sells any	201
dangerous drug to consumers without assuming control over and	202
responsibility for its administration. Mere advice or	203
instructions regarding administration do not constitute control	204
or establish responsibility.	205
(N) "Price information" means the price charged for a	206
prescription for a particular drug product and, in an easily	207
understandable manner, all of the following:	208
(1) The proprietary name of the drug product;	209
(2) The established (generic) name of the drug product;	210
(3) The strength of the drug product if the product	211
contains a single active ingredient or if the drug product	212
contains more than one active ingredient and a relevant strength	213

can be associated with the product without indicating each 214
active ingredient. The established name and quantity of each 215
active ingredient are required if such a relevant strength 216
cannot be so associated with a drug product containing more than 217
one ingredient. 218

(4) The dosage form; 219

(5) The price charged for a specific quantity of the drug 220
product. The stated price shall include all charges to the 221
consumer, including, but not limited to, the cost of the drug 222
product, professional fees, handling fees, if any, and a 223
statement identifying professional services routinely furnished 224
by the pharmacy. Any mailing fees and delivery fees may be 225
stated separately without repetition. The information shall not 226
be false or misleading. 227

(O) "Wholesale distributor of dangerous drugs" or 228
"wholesale distributor" means a person engaged in the sale of 229
dangerous drugs at wholesale and includes any agent or employee 230
of such a person authorized by the person to engage in the sale 231
of dangerous drugs at wholesale. 232

(P) "Manufacturer of dangerous drugs" or "manufacturer" 233
means a person, other than a pharmacist or prescriber, who 234
manufactures dangerous drugs and who is engaged in the sale of 235
those dangerous drugs. 236

(Q) "Terminal distributor of dangerous drugs" or "terminal 237
distributor" means a person who is engaged in the sale of 238
dangerous drugs at retail, or any person, other than a 239
manufacturer, repackager, outsourcing facility, third-party 240
logistics provider, wholesale distributor, or pharmacist, who 241
has possession, custody, or control of dangerous drugs for any 242

purpose other than for that person's own use and consumption.	243
"Terminal distributor" includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist or licensed health professional authorized to prescribe drugs.	244 245 246 247 248
(R) "Promote to the public" means disseminating a representation to the public in any manner or by any means, other than by labeling, for the purpose of inducing, or that is likely to induce, directly or indirectly, the purchase of a dangerous drug at retail.	249 250 251 252 253
(S) "Person" includes any individual, partnership, association, limited liability company, or corporation, the state, any political subdivision of the state, and any district, department, or agency of the state or its political subdivisions.	254 255 256 257 258
(T) "Animal shelter" means a facility operated by a humane society or any society organized under Chapter 1717. of the Revised Code or a dog pound operated pursuant to Chapter 955. of the Revised Code.	259 260 261 262
(U) "Food" has the same meaning as in section 3715.01 of the Revised Code.	263 264
(V) "Pain management clinic" has the same meaning as in section 4731.054 of the Revised Code.	265 266
(W) "Investigational drug or product" means a drug or product that has successfully completed phase one of the United States food and drug administration clinical trials and remains under clinical trial, but has not been approved for general use by the United States food and drug administration.	267 268 269 270 271

"Investigational drug or product" does not include controlled substances in schedule I, as established pursuant to section 3719.41 of the Revised Code, and as amended.

(X) "Product," when used in reference to an investigational drug or product, means a biological product, other than a drug, that is made from a natural human, animal, or microorganism source and is intended to treat a disease or medical condition.

(Y) "Third-party logistics provider" means a person that provides or coordinates warehousing or other logistics services pertaining to dangerous drugs including distribution, on behalf of a manufacturer, wholesale distributor, or terminal distributor of dangerous drugs, but does not take ownership of the drugs or have responsibility to direct the sale or disposition of the drugs.

(Z) "Repackager of dangerous drugs" or "repackager" means a person that repacks and relabels dangerous drugs for sale or distribution.

(AA) "Outsourcing facility" means a facility that is engaged in the compounding and sale of sterile drugs and is registered as an outsourcing facility with the United States food and drug administration.

Sec. 4729.44. (A) As used in this section:

(1) "Board of health" means a board of health of a city or general health district or an authority having the duties of a board of health under section 3709.05 of the Revised Code.

(2) "Physician" means an individual authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine

and surgery. 301

(B) If use of the protocol developed pursuant to rules 302
adopted under division (G) of this section has been authorized 303
under section 3707.56 or 4731.942 of the Revised Code, a 304
pharmacist or pharmacy intern may dispense naloxone without a 305
prescription to either of the following in accordance with that 306
protocol: 307

(1) An individual who there is reason to believe is 308
experiencing or at risk of experiencing an opioid-related 309
overdose; 310

(2) A family member, friend, or other ~~person~~ individual in 311
a position to assist an individual who there is reason to 312
believe is at risk of experiencing an opioid-related overdose. 313

(C) A pharmacist or pharmacy intern who dispenses naloxone 314
under this section shall instruct the individual to whom 315
naloxone is dispensed to summon emergency services as soon as 316
practicable either before or after administering naloxone. 317

(D) A pharmacist may document on a prescription form the 318
dispensing of naloxone by the pharmacist or a pharmacy intern 319
supervised by the pharmacist ~~on a prescription form~~. The form 320
may be assigned a number for record-keeping purposes. 321

(E) This section does not affect the authority of a 322
pharmacist or pharmacy intern to fill or refill a prescription 323
for naloxone. 324

(F) A board of health that in good faith authorizes a 325
pharmacist or pharmacy intern to dispense naloxone without a 326
prescription in accordance with a protocol developed pursuant to 327
rules adopted under division (G) of this section is not liable 328
for or subject to any of the following for any action or 329

omission of the individual to whom the naloxone is dispensed: 330
damages in any civil action, prosecution in any criminal 331
proceeding, or professional disciplinary action. 332

A physician who in good faith authorizes a pharmacist or 333
pharmacy intern to dispense naloxone without a prescription in 334
accordance with a protocol developed pursuant to rules adopted 335
under division (G) of this section is not liable for or subject 336
to any of the following for any action or omission of the 337
individual to whom the naloxone is dispensed: damages in any 338
civil action, prosecution in any criminal proceeding, or 339
professional disciplinary action. 340

A pharmacist or pharmacy intern authorized under this 341
section to dispense naloxone without a prescription who does so 342
in good faith is not liable for or subject to any of the 343
following for any action or omission of the individual to whom 344
the naloxone is dispensed: damages in any civil action, 345
prosecution in any criminal proceeding, or professional 346
disciplinary action. 347

(G) The state board of pharmacy shall, after consulting 348
with the department of health and state medical board, adopt 349
rules to implement this section. The rules shall specify a 350
protocol under which pharmacists or pharmacy interns may 351
dispense naloxone without a prescription. 352

All rules adopted under this section shall be adopted in 353
accordance with Chapter 119. of the Revised Code. 354

Sec. 4729.75. The state board of pharmacy may establish 355
and maintain a drug database. The board shall use the drug 356
database to monitor the misuse and diversion of the following: 357
controlled substances, as defined in section 3719.01 of the 358

Revised Code; medical marijuana, as authorized under Chapter 359
3796. of the Revised Code; and other dangerous drugs the board 360
includes in the database pursuant to rules adopted under section 361
4729.84 of the Revised Code. ~~In~~ 362

The board also shall use the drug database to monitor 363
naltrexone. 364

In establishing and maintaining the database, the board 365
shall electronically collect information pursuant to sections 366
4729.77, 4729.771, 4729.772, 4729.78, and 4729.79 of the Revised 367
Code and shall disseminate information as authorized or required 368
by sections 4729.80 and 4729.81 of the Revised Code. The board's 369
collection and dissemination of information shall be conducted 370
in accordance with rules adopted under section 4729.84 of the 371
Revised Code. 372

Sec. 4729.79. (A) If the state board of pharmacy 373
establishes and maintains a drug database pursuant to section 374
4729.75 of the Revised Code, each licensed health professional 375
authorized to prescribe drugs, except as provided in division 376
(C) of this section, who personally furnishes to a patient a 377
controlled substance, naltrexone, or other dangerous drug the 378
board includes in the database pursuant to rules adopted under 379
section 4729.84 of the Revised Code shall submit to the board 380
the following information: 381

(1) Prescriber identification; 382

(2) Patient identification; 383

(3) Date drug was furnished by the prescriber; 384

(4) Indication of whether the drug furnished is new or a 385
refill; 386

(5) Name, strength, and national drug code of drug furnished;	387 388
(6) Quantity of drug furnished;	389
(7) Number of days' supply of drug furnished;	390
(8) Source of payment for the drug furnished;	391
(9) Identification of the owner of the drug furnished.	392
(B) (1) The information shall be transmitted as specified by the board in rules adopted under section 4729.84 of the Revised Code.	393 394 395
(2) The information shall be submitted electronically in the format specified by the board, except that the board may grant a waiver allowing the prescriber to submit the information in another format.	396 397 398 399
(3) 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:	400 401 402
(a) The prescriber's transmission system suffers a mechanical or electronic failure, or the prescriber cannot meet the deadline for other reasons beyond the prescriber's control.	403 404 405
(b) The board is unable to receive electronic submissions.	406
(C) (1) The information required to be submitted under division (A) of this section may be submitted on behalf of the prescriber by the owner of the drug being personally furnished or by a delegate approved by that owner.	407 408 409 410
(2) The requirements of this section to submit information to the board do not apply to a prescriber who is a veterinarian.	411 412
(D) If the board becomes aware of a prescriber's failure	413

to comply with this section, the board shall notify the 414
government entity responsible for licensing the prescriber. 415

Sec. 4729.85. If the state board of pharmacy establishes 416
and maintains a drug database pursuant to section 4729.75 of the 417
Revised Code, the board shall prepare reports regarding the 418
database and present or submit them in accordance with both of 419
the following: 420

(A) The board shall present a biennial report to the 421
standing committees of the house of representatives and the 422
senate that are primarily responsible for considering health and 423
human services issues. Each report shall include all of the 424
following: 425

(1) The cost to the state of establishing and maintaining 426
the database; 427

(2) Information from the board, terminal distributors of 428
dangerous drugs, prescribers, and retail dispensaries licensed 429
under Chapter 3796. of the Revised Code regarding the board's 430
effectiveness in providing information from the database; 431

(3) The board's timeliness in transmitting information 432
from the database. 433

(B) The board shall submit a semiannual report to the 434
governor, the president of the senate, the speaker of the house 435
of representatives, the attorney general, the chairpersons of 436
the standing committees of the house of representatives and the 437
senate that are primarily responsible for considering health and 438
human services issues, the department of public safety, the 439
state dental board, the board of nursing, the state vision 440
professionals board, the state medical board, and the state 441
veterinary medical licensing board. The state board of pharmacy 442

shall make the report available to the public on its internet 443
web site. Each report submitted shall include all of the 444
following for the period covered by the report: 445

(1) An aggregate of the information submitted to the board 446
under section 4729.77 of the Revised Code regarding 447
prescriptions for controlled substances containing opioids, 448
including all of the following: 449

(a) The number of prescribers who issued the 450
prescriptions; 451

(b) The number of patients to whom the controlled 452
substances were dispensed; 453

(c) The average quantity of the controlled substances 454
dispensed per prescription; 455

(d) The average daily morphine equivalent dose of the 456
controlled substances dispensed per prescription. 457

(2) An aggregate of the information submitted to the board 458
under section 4729.79 of the Revised Code regarding controlled 459
substances containing opioids that have been personally 460
furnished to a patient by a prescriber, other than a prescriber 461
who is a veterinarian, including all of the following: 462

(a) The number of prescribers who personally furnished the 463
controlled substances; 464

(b) The number of patients to whom the controlled 465
substances were personally furnished; 466

(c) The average quantity of the controlled substances that 467
were furnished at one time; 468

(d) The average daily morphine equivalent dose of the 469

controlled substances that were furnished at one time. 470

(3) An aggregate of the information submitted to the board 471
under section 4729.771 of the Revised Code regarding medical 472
marijuana; 473

(4) An aggregate of the information submitted to the board 474
under sections 4729.77 and 4729.79 of the Revised Code regarding 475
naltrexone, including all of the following: 476

(a) The number of prescribers who issued the prescriptions 477
for or personally furnished the drug; 478

(b) The number of patients to whom the drug was dispensed 479
or personally furnished; 480

(c) The average quantity of the drug dispensed per 481
prescription or furnished at one time. 482

Sec. 4765.45. (A) If the department of public safety 483
collects any of the following information regarding the 484
administration of naloxone by emergency medical service 485
personnel or any firefighter or volunteer firefighter, the 486
department of public safety shall report the information to the 487
department of health on a monthly basis and in a manner 488
prescribed by the department of health: 489

(1) The five-digit postal zip code plus four-digit add-on 490
where the naloxone was administered; 491

(2) The date on which the naloxone was administered; 492

(3) The number of doses administered; 493

(4) The name of the emergency medical service organization 494
or fire department that administered the naloxone; 495

(5) Whether or not an overdose was reversed; 496

<u>(6) Whether the individual was taken to a hospital.</u>	497
<u>When reporting to the department of health, the department</u>	498
<u>of public safety shall not include any information that</u>	499
<u>identifies or tends to identify specific individuals to whom</u>	500
<u>naloxone was administered.</u>	501
<u>(B) Each month, the department of health shall compile the</u>	502
<u>information received under division (A) of this section,</u>	503
<u>organize it by county, and forward it to each board of alcohol,</u>	504
<u>drug addiction, and mental health services in this state.</u>	505
<u>(C) The department of health may adopt rules as necessary</u>	506
<u>to implement this section. The rules shall be adopted in</u>	507
<u>accordance with Chapter 119. of the Revised Code.</u>	508
Section 2. That existing sections 4729.01, 4729.44,	509
4729.75, 4729.79, and 4729.85 of the Revised Code are hereby	510
repealed.	511
Section 3. This act shall be known as the "Opioid Data and	512
Communication Expansion Act."	513