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HB 249 - Controlled Substances and Prescription Drug Monitoring Database

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CRIMES AND OFFENSES

Controlled Substances: Amend Chapter 13 of Title 16, Code Section 116.2 of Article 6 of Chapter 4 of Title 26, Article 1 of Chapter 2A of Title 31, Article 1 of Chapter 1 of Title 31, and Article 2 of Chapter 16 of Title 45 of the Official Code of Georgia Annotated, Relating to Controlled Substances, the Authority of Licensed Health Practitioners to Prescribe Opioid Antagonists and Immunity from Liability, the Obligations of the Department of Public Health, General Provisions for Health, and Death Investigations, Respectively, so as to Change Provisions Relating to the Use of the Electronic Data Base; Transfer Responsibilities for the Electronic Data Base of Prescription Information of the Georgia Drugs and Narcotics Agency to the Department of Public Health; Provide for the Department's Authority to Continue the Maintenance and Development of the Electronic Data Base of Prescription Information; Provide for Definitions; Collect More Information Regarding the Dispensing and Use of Certain Controlled Substances; Change the Frequency of Reporting Certain Prescriptions in the Electronic Data Base of Prescription Information; Clarify Provisions Relating to Confidentiality; Change Provisions Relating to Liability and Duties; Change Provisions Relating to the Definitions of Dangerous Drugs; Require the Department of Public Health Have Responsibility for the Electronic Prescription Monitoring Data Base; Provide for Information to Patients by Prescribers when Prescribing Opioids; Provide for Immunity for the State Health Officer under Certain Circumstances; Change Provisions Relating to the State Health Officer; Provide for His or Her Authority in Connection to Certain Dangerous Drugs; Provide for a Coroner's Inquest when an Individual Dies of a Suspected Drug Overdose; Amend Section 2 of Chapter 12 of Title 31 of the Official Code of Georgia Annotated, Relating to Reporting Disease, Confidentiality, Reporting Required by Pharmacists, Immunity from Liability as to Information Supplied, and Notification of Potential Bioterrorism, so as to Add Neonatal Abstinence Syndrome Reporting; Amend Chapter 5 of Title 26 of the Official Code of Georgia Annotated, Relating to

Drug Abuse Treatment and Education Programs, so as to Provide for Annual Inspection; Provide for Annual Reporting of Certain Data; Amend Part 2 of Article 6 of Chapter 2 of Title 20 of the Official Code of Georgia Annotated, Relating to Competencies and Core Curriculum in Elementary and Secondary Education, so as to Give a Short Title to a Code Section Relating to Cardiopulmonary Resuscitation and Use of Automated External Defibrillators in Schools; Provide for a Short Title; Provide for Related Matters; Repeal Conflicting Laws; and for Other Purposes

CODE SECTIONS:	O.C.G.A. §§ 16-13-56.1 (new); -57, -58, -59, -60, -61, -62, -63, -64, -65 (amended); -71 (amended); 20-2-149.1 (amended); 26-4-116.2 (amended); 26-5-22 (new); -23 (new); 31-1-10 (amended); 31-2A-4 (amended); 31-12-2 (amended); 45-16-24 (amended); 45-16-27 (amended)
BILL NUMBER:	HB 249
ACT NUMBER:	141
GEORGIA LAWS:	2017 Ga. Laws 319
SUMMARY:	The Act amends Georgia's controlled-substances statutes to expand medical provider requirements to record prescription drug information in an electronic prescription drug monitoring program database (PDMP). Medical providers are now required to use the PDMP to enter information about their prescription of certain types and quantities of opioids. The purpose of the act is to fight Schedule II opioid abuse throughout the state of Georgia. A medical provider's failure to report required information is reported to his or her respective state regulatory board

for possible reprimand. In addition to mandatory reporting, the Act includes various other provisions related to regulating opioid misuse. The Act removes naloxone's codification as a dangerous drug when naloxone is used for overdose prevention. Additionally, the Act requires law enforcement officers to notify the coroner or county medical examiner of apparent drug overdoses. Finally, the Act adds a name to a separate Code section regarding cardiopulmonary resuscitation and use of automated defibrillators.

Effective Date: July 1, 2017

History

Drug abuse is a serious public health concern.[1] In fact, having supplanted car accident fatalities in 2008,[2] "drug overdose deaths are the leading cause of injury death in the United States."[3] Opioid misuse is of particular concern, as more than 60% of all overdose deaths are related to opioid abuse.[4] Although the epidemic has been a concern for decades,[5] the crisis has significantly worsened over the past five years.[6] In response to this concern, states are looking to curb the epidemic and find solutions to protect their citizens.[7]

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1. *Drug Overdose Death Data*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last updated Dec. 16, 2016) (finding a statistically significant increase in overdose death rates from 2014 to 2015 in 19 States).

2. *DEA: Drug Overdoses Are Leading Cause of US Injury Deaths*, VOA NEWS (Nov. 5, 2015, 11:32 AM), https://www.voanews.com/a/dea-drug-overdoses-are-leading-cause-of-us-injury-deaths/3038150.html.

3. *The U.S. Opioid Epidemic*, U.S. DEP'T OF HEALTH & HUMAN SERVS., https://www.hhs.gov/opioids/about-the-epidemic/#us-epidemic (last visited May 27, 2017).

4. *Understanding the Epidemic*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/epidemic/ (last updated Dec. 16, 2016).

5. *Drug overdose deaths increased by 33-percent in past 5 years*, FOX NEWS (Dec. 17, 2016), http://www.foxnews.com/health/2016/12/17/drug-overdose-deaths-increased-by-33-percent-in-past-5-years.html ("Drug overdose deaths have increased by 33 percent in the past five years across the country, with some states seeing jumps of nearly 200 percent.").

6. *See Understanding the Epidemic*, *supra* note 4 (stating that the number of overdose deaths in the

Georgia is one of the states experiencing an increase in opioid abuse.[8] The state experienced a tenfold increase in prescription opioid overdose deaths between 1999 and 2014, and Georgia remains among the top eleven states with the most prescription opioid overdose deaths.[9] In 2016, 549 people died from prescription drug overdose—a rate of more than one-and-a-half Georgians per day.[10] According to Representative Kevin Tanner (R-9th), everyone shares the concern over opioid abuse because most everyone has been personally affected by addiction or overdose.[11]

Because of these unfortunate statistics, Georgia has recently considered programs to help those affected by opioid abuse.[12] In 2011, Georgia implemented a Prescription Drug Monitoring Program (PDMP),[13] a tool employed by nearly every state.[14] A PDMP is an electronic database used by the state to collect and analyze prescription drug information for "misuse, abuse, and patterns of controlled substance prescribing" by doctors.[15] Collecting this data gives prescribers access to the prescription history of their patients so

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United States has quadrupled in the past seventeen years).

7. *See* Diane Yap, *As governments respond to Rx drug abuse, pharmacists and their patients face challenges*, AM. PHARMACISTS ASS'N (Oct. 1, 2015), https://www.pharmacist.com/governments-respond-rx-drug-abuse-pharmacists-and-their-patients-face-challenges (discussing how the federal government, state governments, and pharmacists are all struggling to find methods to curb opioid abuse).

8. SUBSTANCE ABUSE RESEARCH ALL., PRESCRIPTION OPIOIDS AND HEROIN EPIDEMIC IN GEORGIA 5 (2017), http://www.senate.ga.gov/sro/Documents/StudyCommRpts/OpioidsAppendix.pdf (discussing the tenfold increase of prescription opioid overdose deaths between 1999 and 2014).

9. *Id.*

10. *Id*. at 6 fig. 3.

11. Interview with Rep. Kevin Tanner (R-9th) at 7 min., 27 sec. (Mar. 22, 2017) (on file with Georgia State University Law Review) [hereinafter Tanner Interview].

12. Jared Bruff & Megan Daugherty, *Crimes and Offenses: Controlled Substances*, 28 GA. ST. U. L. REV. 269, 270–71 (2011) (discussing how Georgia lagged in establishing legislation to prevent pill mills, or providers who prescribe painkillers inappropriately).

13. *See Prescription Drug Monitoring Frequently Asked Questions (FAQ)*, PRESCRIPTION DRUG MONITORING PROGRAM & TECHNICAL ASSISTANCE CTR., http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq (last visited May 27, 2017) (stating forty-nine states and the District of Columbia currently have an operational prescription drug monitoring database).

14. Bruff & Daugherty, *supra* note 12, at 281–82 (discussing the creation of the PDMP by Act 229 in 2011).

15. *Georgia Prescription Drug Monitoring Program*, GA. DRUGS & NARCOTICS AGENCY, https://gdna.georgia.gov/georgia-prescription-drug-monitoring-program (last visited May 27, 2017).

they can identify trends or provide early intervention to their patients, if necessary.[16]

Despite the seemingly beneficial attributes of the database, Georgia's original law included a flaw that reduced its impact: no physician was required to register or participate in the PDMP under the 2011 legislation.[17] As of the end of Georgia's 2017 legislative session, only 25% of practicing physician prescribers had registered for the database, and only 12% of practicing physician prescribers actively used the database.[18] Georgia's PDMP was fully operational in 2013 when the program received funding,[19] yet 2014 was Georgia's deadliest year on record, with 588 prescription opioid overdose deaths—a 33% increase over 2013.[20] Therefore, faced with a continuously-growing opioid epidemic, Georgia state legislators began looking for new options to address overdose deaths only five years after implementing the PDMP.[21]

On December 14, 2016, Georgia Governor Nathan Deal (R) issued an executive order aimed at curbing the epidemic by allowing pharmacies to dispense naloxone over-the-counter.[22] Naloxone is a

16. *Prescription Drug Monitoring Programs (PDMP)*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/pdmp/ (last updated Mar. 21, 2017).

17. *See* 2011 Ga. L. 659, § 2, at 665 (formerly found at O.C.G.A. § 16-13-57 (2016)). This section of the 2011 legislation created the PDMP. *Id.* Nothing in the statute required physician participation. *See id.; see also 2016 Public Policy Agenda for Georgia Pharmacists*, FRANCES CULLEN, P.C. (July 19, 2016), http://www.francullen.com/Blog/2016-Public-Policy-Agenda-for-Georgia-Pharmacists.shtml ("Currently, only pharmacists are required to enter Schedule II prescriptions into PDMP; accessing the system is voluntary for physicians. This means that patients are still falling through the cracks.").

18. Tanner Interview, *supra* note 11, at 2 min., 30 sec. ("They aren't required to use [the database]. So only 25% or so of the doctors have registered to use the database. And out of that only about half of those are using it. So about 12%.").

19. *2016 Public Policy Agenda for Georgia Pharmacists*, *supra* note 17 ("The PDMP was initially funded in 2013 through a $400,000 grant from the Bureau of Justice Assistance, so there was no cost to the state of Georgia."). There was concern from the beginning about whether the PDMP would be functional. Bruff & Daugherty, *supra* note 12, at 292. The funding came two years after the inception of the database. *Id.* ("If the Agency is successful in obtaining funding, the program may be operational by 2013. If not, the program may just be a great idea that never comes to life.").

20. SUBSTANCE ABUSE RESEARCH ALL., *supra* note 8 at 6 fig. 3 (2017), http://www.senate.ga.gov/sro/Documents/StudyCommRpts/OpioidsAppendix.pdf (discussing the number of prescription opioid overdose deaths in Georgia).

21. Tanner Interview, *supra* note 11, at 5 min., 12 sec. ("I started working on this issue about a year ago actively.").

22. Press Release, Office of the Governor, Deal Expands Access to Emergency Tool to Parents to Help Fight Opioid Epidemic (Dec. 14, 2016), https://gov.georgia.gov/press-releases/2016-12-14/deal-expands-access-emergency-tool-parents-help-fight-opioid-epidemic (discussing Governor Deal's standing order to allow naloxone to be dispensed over-the-counter).

drug administered to individuals experiencing a drug overdose.[23] If timely administered, the drug can reverse the effects of an opioid overdose and thus save the life of the overdosing individual.[24] The Governor's proactive step to lessen overdoses and make the "drug accessible to anyone in a position to assist persons at risk of overdose will save countless lives."[25]

By the time the 2017 legislative session arrived, legislators were also considering options to further address the opioid epidemic.[26] Two legislators in particular spearheaded the effort: Representative Kevin Tanner and Senator Renee Unterman (R-45th).[27] Because the opioid epidemic involves more than doctors inappropriately prescribing prescription painkillers, the General Assembly addressed various issues in one bill.[28] These issues included the following: (1) the voluntary nature of the PDMP,[29] (2) the existing naloxone executive order,[30] and (3) the difficulty of tracking the overdose deaths across the state.[31] To address each of these concerns, the Georgia General Assembly passed House Bill (HB) 249 and created a more expansive program to fight Georgia's opioid epidemic.[32]

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23. *See* Press Release, Ctrs. for Disease Control & Prevention, Expanding Naloxone Use Could Reduce Overdose Deaths and Save Lives (Apr. 24, 2015), https://www.cdc.gov/media/releases/2015/p0424-naloxone.html (discussing how Emergency Medical Services staff administer naloxone to individuals suffering opioid overdose).

24. *Id.*

25. Joshua Silavent, *Georgia Pharmacists Given OK to Dispense Anti-Overdose Drug*, GAINESVILLE TIMES (Dec. 16, 2016, 12:30 AM), http://www.gainesvilletimes.com/archives/120885/ (discussing the order by the Governor).

26. Tanner Interview, *supra* note 11, at 12 min., 13 sec. ("[M]y work on this legislation didn't start, and I know Senator Unterman's did not start, the day session started. This has been a year-plus process.").

27. *Id.*

28. *Id.* at 19 min., 15 sec. ("You know there's other factors in this thing that makes it a more expansive bill than just about doctors having to check a database. And again, it's kind of looking at this from a global perspective of, how can we turn the tide on opioid abuse?").

29. *Id.* at 5 min., 43 sec. ("[O]ne of the things we saw that had worked in other states is when doctors are required to check the PDMP.").

30. Video Recording of House Proceedings at 49 min., 33 sec. (Mar. 3, 2017) (remarks by Rep. Kevin Tanner (R-9th)), https://www.youtube.com/watch?v=TbSIN21fBss [hereinafter House Proceedings Video] ("One of the other things that [HB 249] does is codify that naloxone, which the Governor [] allowed through an executive order to be sold over-the counter.").

31. Tanner Interview, *supra* note 11, at 6 min., 19 sec. ("[I]t's important to know where those are occurring because we can respond with resources into those areas. But in Georgia, the coroners and the medical examiners are not required to report those to the Chief Medical Examiner office.").

32. Press Release, Office of the Governor, Deal Signs Opioid Legislation (May 4, 2017), https://gov.georgia.gov/press-releases/2017-05-04/deal-signs-opioid-legislation (discussing Governor Deal signing HB 249 into law).

Bill Tracking of HB 249

Consideration and Passage by the House

Representatives Kevin Tanner (R-9th), Mark Newton (R-123rd), Jon Burns (R-159th), Jan Jones (R-47th), Andrew Welch (R-110th), and Bubber Epps (R-144th) sponsored HB 249 in the House.[33] The House read the bill for the first time on February 7, 2017, and committed the bill to the House Judiciary Non-Civil Committee.[34] The House read the bill for the second time on February 8, 2017.[35] On February 27, 2017, the House Judiciary Non-Civil Committee favorably reported the bill by substitute.[36]

The House Committee substitute reflected the authors' desire to prevent "doctor-shopping" without unduly restricting doctors' ability to prescribe needed medications.[37] In response to conversations with Governor Nathan Deal and the Georgia Drugs and Narcotics Agency, which currently administers the prescription drug monitoring database, the Committee substitute shifted responsibility for the electronic database from that agency to the Department of Public Health.[38]

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33. Georgia General Assembly, HB 249, Bill Tracking, http://www.legis.ga.gov/legislation/en-US/Display/20172018/HB/249.

34. State of Georgia Final Composite Status Sheet, HB 249, May 11, 2017.

35. *Id.*

36. *Id.*

37. Video Recording of House Judiciary Committee Non-Civil Division Meeting at 57 min, 48 sec. (Feb. 27, 2017) (remarks by Rep. Kevin Tanner (R-9th)), https://livestream.com/accounts/19771755/events/6810993/videos/150571239 [hereinafter House Judiciary Non-Civil Committee Video]. Representative Cooper shared concerns raised by constituents that the legislation may cause doctors to become overly cautious when prescribing opioids, reducing access to pain medications by those who need them, such as cancer patients. *Id.* at 54 min., 48 sec. (remarks by Rep. Sharon Cooper (R-43rd)). "Doctor-shopping" occurs when patients visit multiple prescribers to obtain prescriptions for drugs, like opioids, for illicit use. CTRS. FOR DISEASE CONTROL & PREVENTION, DOCTOR SHOPPING LAWS 1 (n.d.), https://www.cdc.gov/phlp/docs/menu-shoppinglaws.pdf.

38. House Judiciary Non-Civil Committee Video*, supra* note 37, at 58 min., 42 sec. (remarks by Rep. Kevin Tanner (R-9th)). The change responds to a lack of resources within the Drugs and Narcotics Agency to support the database. *Id.* To reflect this change, the Committee substitute replaces the word "agency" with "department" throughout the bill. HB 249 (HCS) § 1-2, p. 2, ll. 31, 43, 57, 2017 Ga. Gen. Assemb.; *id.* p. 3, ll. 60, 63, 66, 68, 75, 95; *id.* p. 4, ll. 102, 104, 106, 109, 110, 114, 116, 122, 125, 127; *id.* p. 5, ll. 137, 144, 148; *id.* p. 7, ll. 224, 234, 240; *id.* p. 8, ll. 248, 253; HB 249 (HCS) p. 9, ll. 286–87, 2017 Ga. Gen. Assemb.; *id.* p. 10, l. 320; *id.* p. 11, l. 353. "Department" is defined as the Department of Public Health. *See id.* § 1-2, p. 2, l. 27–29.

Because current law does not require database enrollment, the House Committee substitute specified deadlines for prescriber enrollment in the prescription drug monitoring database.[39] The Committee substitute also set testing standards for the database, because the new enrollment and usage requirements would drastically increase the number of users and overload the current system.[40]

In addition, the House Committee substitute increases the frequency with which dispensers, such as pharmacists, must update required prescription information in the database to every twenty-four hours.[41] The Committee made this change because prescribers will now be required to check the database before prescribing certain drugs and will need the most up-to-date information to make informed decisions.[42] The Committee substitute also inserted language that encourages, but does not require, dispensers to reference the prescription monitoring database to help detect the overprescribing of controlled substances, including opioids.[43]

To ensure that the prescription information cannot be shared or misused, the House Committee substitute included language about protecting personal identification information in compliance with the Health Insurance Portability and Accessibility Act (HIPAA).[44] This language is repeated later in the bill, relating to the inclusion of

39. *Id.* § 1-2, p. 2, ll. 44–49. According to the authors, only about 25% of prescribers are currently registered to use the database, and only half of those who are registered actually use the database. House Judiciary Non-Civil Committee Video, *supra* note 37, at 59 min., 50 sec. (remarks by Rep. Kevin Tanner (R-9th)).

40. HB 249 (HCS) § 1-2, p. 2, ll. 50–55, 2017 Ga. Gen. Assemb.; House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 0 min., 22 sec. (remarks by Rep. Kevin Tanner (R-9th)). The House Committee substitute clarifies that the database monitoring requirements will only become effective if the database is certified as operable. HB 249 (HCS) § 1-2, p. 10, ll. 320–21, 2017 Ga. Gen. Assemb.

41. HB 249 (HCS) § 1-2, p. 4, ll. 97–100.

42. House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 1 min., 5 sec. (remarks by Rep. Kevin Tanner (R-9th)).

43. HB 249 (HCS) § 1-2, p. 9, ll. 295–98. ("[D]ispensers are encouraged to obtain [information about a patient from the prescription monitoring data base] while keeping in mind that the purpose of such data base includes reducing duplicative prescribing and overprescribing of controlled substances.").

44. *Id.* § 1-2, p. 4, ll. 114–21; House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 1 min., 40 sec. (remarks by Rep. Kevin Tanner (R-9th)).

prescription information in a patient's electronic health or medical record.[45]

The House Committee substitute also reflected concerns from hospitals about prescribers' ability to balance the new monitoring requirements with their demanding workloads.[46] To alleviate this concern, the Committee substitute granted prescribers the authority to designate up to two employees or contractors per shift who may access the database and provide the required prescription information on the prescriber's behalf.[47] The House Committee substitute mandates, rather than permits, steps the Department of Public Health must take when a prescriber reports a patient's "usage, misuse, abuse, or underutilization of a controlled substance."[48]

The authors of the House Committee substitute wanted to narrowly tailor the legislation to include only those drugs that raise concerns about abuse, overdose, or addiction.[49] Therefore, the House Committee substitute required that prescribers log specific benzodiazepines in the database: diazepam (e.g., Valium), alprazolam (e.g., Xanax), and lorazepam (e.g., Ativan).[50] Further, the Committee substitute clarified that prescribers do not have to check the database before prescribing Schedule II drugs unless the legislation specifies otherwise.[51] Finally, the House Committee specified those instances when a prescriber does not need to check the database.[52] The changes aimed to incentivize doctors to refrain

45. HB 249 (HCS) § 1-2, p. 7, ll. 223–24, 2017 Ga. Gen. Assemb.; *compare id.* § 1-2, p. 7, ll. 225–28, *with id.* § 1-2, p. 4, ll. 114–21.

46. House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 2 min., 21 sec. (remarks by Rep. Kevin Tanner (R-9th)).

47. HB. 249 (HCS), § 1-2, pp. 6–7, ll. 202–07. These designees may include a registered nurse, officer manager, or other employee or contractor who has been appropriately screened. *See* House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 2 min. 53 sec. (remarks by Rep. Kevin Tanner (R-9th)).

48. HB. 249 (HCS), § 1-2, p. 7, l. 214, 2017 Ga. Gen. Assemb. (changing "may" to "shall").

49. *See* House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 10 min., 3 sec. (remarks by Rep. Kevin Tanner (R-9th)).

50. HB. 249 (HCS), § 1-2, p. 9, ll. 306–07.

51. *Id.* § 1-2, p. 10, ll. 334–37 (requiring prescribers to check the database for prescriptions of "those controlled substances listed in paragraph (1) or (2) of Code section 16-13-26 and benzodiazepines, including only diazepam, alprazolam, or lorazepam.").

52. *Id.* § 1-2, pp. 9–10, ll. 309–117. The exceptions include prescriptions for a three-day supply (no more than twenty-six pills), prescriptions given to patients while being treated in a hospital or health care facility, such as a nursing home, or a ten-day supply (no more than forty pills) for patients who have had outpatient surgery. *Id.*

from overprescribing these medicines, focusing on instances where doctor-shopping is a concern.[53] The House Committee substitute also required prescribers to provide information to patients about the risk of opioid abuse and options for safe disposal of unused opioids.[54]

The House read the bill for the third time on March 3, 2017.[55] Representative Tanner and Representative Rich Golick (R-40th) offered a floor amendment that made minor changes to certain terms used throughout the House Committee substitute bill to add clarity, ensure consistency, and correct a typographical error.[56] The amendment was adopted.[57] The House passed the Committee substitute, as amended, on March 3, 2017, by a vote of 167 to 1.[58]

Consideration and Passage by the Senate

Senator Renee Unterman (R-45th) sponsored HB 249 in the Senate.[59] The Senate first read HB 249 on March 3, 2017.[60] The Senate assigned it to the Senate Committee on Health and Human Services.[61] The Committee on Health and Human Services favorably reported the bill by substitute on March 20, 2017.[62]

The Senate Committee substitute reflects the collaboration of Senator Unterman and Representative Tanner.[63] Most significantly,

53. House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 7 min., 5 sec. (remarks by Rep. Kevin Tanner (R-9th)).

54. HB. 249 (HCS), § 2-1, p. 13, ll. 422–25, 2017 Ga. Gen. Assemb. The Committee substitute also defines "opioids" as used in the legislation. *Id.* § 2-1, p. 13, ll. 420–21.

55. State of Georgia Final Composite Status Sheet, HB 249, May 11, 2017.

56. House Proceedings Video, *supra* note 30, at 51 min., 3 sec. (Mar. 3, 2017) (remarks by Rep. Tanner (R-9th)); *id.* at 52 min. (clerk's reading of amendment by Rep. Tanner and Rep. Golick (R-40th)). The Committee substitute contained a typographical error throughout the bill, replacing references to "data base," "program," and "program established pursuant to Code section 16-13-59" with the incorrect acronym. House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 12 min., 36 sec.; House Floor Amendment to HB 249 (AM 29 2594), introduced by Reps. Rich Golick (R-45th) and Kevin Tanner (R-9th), Mar. 3, 2017.

57. House Proceedings Video, *supra* note 30, at 53 min., 26 sec. (Mar. 3, 2017) (remarks by Rep. David Ralston (R-7th)).

58. Georgia House of Representatives Voting Record, HB 249, #186 (Mar. 3, 2017).

59. Georgia General Assembly, HB 249, Bill Tracking, http://www.legis.ga.gov/legislation/en-US/Display/20172018/HB/249.

60. State of Georgia Final Composite Status Sheet, HB 249, May 11, 2017.

61. *Id.*

62. *Id.*

63. Audio Recording of Senate Health and Human Services Committee at 14 min., 5 sec. (Mar. 16, 2017) (remarks by Sen. Unterman) (on file with the Georgia State University Law Review).

the Senate Committee substitute deleted the language limiting the types of benzodiazepines covered by the legislation, thus expanding the number of prescription drugs triggering the requirement to check the database.[64] In addition, the Senate Committee substitute adds prescriptions for terminally-ill patients to the list of instances where prescribers do not have to review the PDMP before writing a prescription.[65]

The Senate Committee substitute allowed a state health officer to permit and set standards for the prescription of opioid antagonists, such as naloxone (e.g., Narcan).[66] The Committee substitute required the state health officer be a licensed medical practitioner in Georgia.[67] The Committee intended this change to incorporate the Governor's executive order relating to naloxone.[68]

Mirroring a provision in Senator Unterman's failed bill,[69] the Committee substitute defined "neonatal abstinence syndrome" and established notice and reporting requirements when patients exhibit symptoms of the syndrome.[70]

The Senate Committee substitute also created two new requirements related to licensed narcotic treatment programs.[71] First, it required annual inspection of all licensed narcotic treatment programs.[72] Second, it called for an annual report of the number of patients enrolled in and discharged from drug abuse treatment programs.[73]

The Senate read the bill for the second time on March 20, 2017, and for the third time on March 22, 2017.[74] No Senate floor amendments were introduced, and, on March 22, 2017, the Senate

64. *Compare* HB 249 (HCSFA), § 1-2, p. 9, ll. 306–07, 2017 Ga. Gen. Assemb., *with* HB 249 (SCS), § 1-2, p. 10, ll. 323–24, 2017 Ga. Gen. Assemb. The same changes were made to identical language found later in the bill. *Compare* HB 249 (HCSFA), § 1-2, p. 10, ll. 336–37, 2017 Ga. Gen. Assemb., *with* HB 249 (SCS), § 1-2, p. 11, ll. 353–55, 2017 Ga. Gen. Assemb.

65. HB 249 (SCS), § 1-2, p. 10, l. 336, 2017 Ga. Gen. Assemb.

66. *Id.* § 3-2, p. 15, ll. 487–89.

67. *Id.* § 3-2, p. 15, ll. 482–83.

68. *See* Audio Recording of Senate Health and Human Services Committee, *supra* note 63, at 21 min., 51 sec (remarks by Senator Unterman).

69. *Id.* at 23 min., 6 sec.; *see* SB 81, § 3-1, pp. 10–11, ll. 311–27.

70. HB 249 (SCS), § 4-1, p. 15, ll. 496–508, 2017 Ga. Gen. Assemb.

71. *Id.* § 5-1, p. 16, ll. 511–26.

72. *Id.* § 5-1, p. 16, ll. 514–19.

73. *Id.* § 5-1, p. 16, ll. 520–26.

74. State of Georgia Final Composite Status Sheet, HB 249, May 11, 2017.

passed the Committee substitute of HB 249 without objection by a vote of 50 to 0.[75]

Reconsideration and Passage by the House

The Senate transmitted the bill to the House on March 22, 2016.[76] Representative Tanner offered a floor amendment to the Senate substitute, replacing "up to" with "a minimum of" on lines 422 and 425, relating to naloxone dosages.[77] On March 28, 2017, the House agreed to the Senate substitute with Representative Tanner's amendment by a vote of 164 to 9.[78] The same day, the House transmitted the bill to the Senate, and the Senate agreed to the House amendment to the Senate Committee substitute, passing the bill by a vote of 50 to 0.[79]

The House sent the bill to Governor Nathan Deal (R) on April 7, 2017.[80] The Governor signed the bill into law on May 4, 2017, and the bill became effective on July 1, 2017.[81]

The Act

The Act amends the following portions of the Official Code of Georgia Annotated: Chapter 13 of Title 16, relating to controlled substances; Section 116.2 of Article 6 of Chapter 4 of Title 26, relating to the authority to prescribe opioids; Section 4 of Article 1 of Chapter 2A of Title 31, relating to the Department of Public Health; Article 1 of Chapter 1 of Title 31, relating to the general health provisions; Article 2 of Chapter 16 of Title 45, relating to death investigations; Section 2 of Chapter 12 of Title 31, relating to reporting disease; Chapter 5 of Title 26, relating to drug abuse

75. Georgia Senate Voting Record #217, HB 249 (Mar. 22, 2017).

76. State of Georgia Final Composite Status Sheet, HB 249, May 11, 2017.

77. House Floor Amendment to HB 249 (AM 29 2626), introduced by Rep. Kevin Tanner (R-45th), Mar. 3, 2017.

78. Georgia House of Representatives Voting Record #348, HB 249 (Mar. 28, 2017).

79. Georgia Senate Voting Record #320, HB 249 (Mar. 28, 2017).

80. State of Georgia Final Composite Status Sheet, HB 249, May 11, 2017.

81. O.C.G.A. § 1-3-4(a)(1) (2017) ("Any Act which is approved by the Governor or which becomes law without his approval on or after the first day of January and prior to the first day of July of a calendar year shall become effective on the first day of July"); State of Georgia Final Composite Status Sheet, HB 249, May 11, 2017.

treatment and education programs; and Part 2 of Article 6 of Chapter 2 of Title 20, relating to use of automated external defibrillators in schools.[82]

Part 1

Section 1-1 of the Act, styles the Act as the "Jeffrey Dallas Gay, Jr., Act,"[83] and most of the remaining sections of Part 1 amend Chapter 13 of Title 16, relating to the electronic prescription drug monitoring program database.[84]

First, this part of the Act adds two definitions to Code section 16-13-57: "Department," referring to the Department of Public Health, and "PDMP," referring to the prescription drug monitoring database.[85] The Act updates these terms throughout the Code for consistency.[86]

The Act adds subsections (c) and (d) to Code section 16-13-57.[87] Subsection (c) requires prescribers with a current DEA registration number to enroll in the PDMP no later than January 1, 2018.[88] Prescribers who receive a DEA registration number after January 1,

82. 2017 Ga. Laws 319, at 319–20. Section 7 of the Act adds a short title to O.C.G.A. § 20-2-149.1: the "Cory Joseph Wilson Act." *Id.* at 335. This section of the Act was originally introduced as SB 245 by Senators Butch Miller (R-49th), Renee Unterman (R-45th), Dean Burke (R-11th), Ben Watson (R-1st), Chuck Hufstetler (R-52nd), and Steve Henson (D-41st). Georgia General Assembly, SB 245, Bill Tracking, http://www.senate.ga.gov/senators/en-US/Member.aspx?Member=21&Session=25. The bill did not progress beyond second readers, and died on cross-over day. State of Georgia Final Composite Sheet, SB 245, May 11, 2017. Instead, the Senate Health and Human Services Committee, where SB 245 originated, added the exact language of SB 245 to the Senate Committee Substitute of HB 249. Audio Recording of Senate Health and Human Services Committee, *supra* note 63, at 23 min., 42 sec. (remarks by Senator Unterman).

83. 2017 Ga. Laws 319, § 1-1, at 320; *See* Derreck Booth, *Sen. Miller Reflects on Legislation to Save Lives*, ACCESSWDUN (Mar. 26, 2017), http://accesswdun.com/article/2017/3/517344/sen-miller-reflects-on-legislation-to-save-lives. Senator Miller's legislation, SB 121, relating to over-the-counter access to naloxone, is also titled the Jeffrey Dallas Gay, Jr. Act. 2017 Ga. Laws 22, § 1, at 22. Section 1-3 and 1-4 of HB 249 applies to the same Chapter and Title of the Code as SB 121, and therefore falls within the Act. *Compare* 2017 Ga. Laws 21, §§ 1–3, at 22–23, *with* 2017 Ga. Laws 319, §§ 1-3 to 1-5, at 329–30. The Act is named in honor of a young Gainesville, Georgia man who died in 2012 as a result of prescription drug addiction and overdose. Booth, *supra*. Gay's family has been active in advocating for opioid abuse awareness and prevention since his death. *Id.*

84. *See* 2017 Ga. Laws 319, §§1-2 to 1-4, at 320–29.

85. O.C.G.A. § 16-13-57 (Supp. 2017).

86. O.C.G.A §§ 16-13-57 to -64 (Supp. 2017).

87. 2017 Ga. Laws 319, §1-2, at 321.

88. O.C.G.A. § 16-13-57(c) (Supp. 2017).

2018, must register for the PDMP within 30 days.[89] The subsection includes an administrative penalty for failure to comply with the registration deadline.[90] Subsection (d) requires the Department of Public Health to randomly test the PDMP during a three-month period to ensure it is accessible and operational.[91]

The Act, addressing privacy concerns related to the sharing and misuse of PDMP information, amends Code section 16-13-59(e) to require that the Department of Public Health remove personally identifying information from any prescription records retained by the Department.[92]

The Act deletes the existing language about delegates of authorized prescribers and dispensers in Code section 16-13-60.[93] The Act replaces this language with a subsection permitting the prescriber to authorize up to two individuals meeting specified criteria to provide prescription information in accordance with Code section 16-13-59.[94]

The Act adds a pharmacist from the State Board of Pharmacy and a representative from the Department of Public Health to the list of Electronic Database Review Advisory Committee members.[95]

In Code section 16-13-63, subsection (a)(1) clarifies that dispensers are not required to reference the PDMP before dispensing a prescription to a patient.[96] However, the amended Code section also emphasizes that the "purpose of such data base includes reducing duplicative prescribing and overprescribing of controlled substances"

89. *Id.*

90. *Id.* ("A prescriber who violates this subsection shall be held administratively accountable to the state regulatory board governing such prescriber for such violation."). For example, a physician will be penalized by the medical board. House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 9 min., 18 sec. (remarks by Rep. Kevin Tanner (R-9th)).

91. O.C.G.A. § 16-13-57(d) (Supp. 2017); *see also* House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 0 min., 30 sec. (remarks by Rep. Kevin Tanner (R-9th)), (discussing concerns that increased traffic will overload the current database and determining it is necessary monitor the technology).

92. O.C.G.A. § 16-13-59(e) (Supp. 2017); House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 1 min., 42 sec. (remarks by Rep. Kevin Tanner (R-9th)) ("One of the things we want to make very sure of is that the department cannot share this information, this private information.").

93. 2017 Ga. Laws 319, §1-2, at 323.

94. 2017 Ga. Laws 319, § 1-2, at 323–26; O.C.G.A. § 16-13-60 (Supp. 2017); *see* discussion *supra* notes 46–48 (addressing hospitals' concerns that prescribers be able to balance the new database requirement with their demanding workload).

95. O.C.G.A. § 16-13-61(b)(11) to -(12) (Supp. 2017).

96. O.C.G.A. § 16-13-63(a)(1) (Supp. 2017).

and encourages dispensers to check the database.[97] Thus, although dispensers are not required to check the database before dispensing a controlled substance, this Code section encourages dispensers to do so to help detect and combat overprescribing of controlled substances like opioids.

Subsection (a)(2) of Code section 16-13-63 requires a prescriber check the PDMP the first time he or she prescribes a controlled substance to a patient and at least once every ninety days thereafter, with several exceptions.[98] Violators of this subsection are subject to administrative action by the regulatory board governing the prescriber.[99] Subsection (b) provides a cause of action for any injury sustained because of a violation of subsection (a) and allows for attorneys' fees.[100] The previous version of this Code section did not provide a private cause of action based on violation of the Code section.[101]

The Act codifies Governor Deal's executive order authorizing over-the-counter access to naloxone in Code section 16-13-71.[102] Naloxone, commonly marketed under the brand names Narcan and Evzio, is an opioid antagonist, meaning it can rapidly reverse opioid overdoses.[103] The new subsection exempts naloxone from the definition of a dangerous drug when used for drug overdose prevention or when dispensed in certain quantities, thus allowing greater access.[104]

Finally, Section 1-5 of the Act adds subsection (15) to Code section 31-2A-4, relating to obligations of the Department of Public Health.[105] This subsection transfers responsibility for the

97. *Id.*

98. O.C.G.A. § 16-13-63(a)(2). The exceptions are discussed *supra* note 52.

99. O.C.G.A. § 16-13-63(a)(2)(C). The penalty is at the discretion of the administrative board governing the prescriber (i.e., the state medical board determines the penalty for a physician who violates this provision). *See* House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 9 min., 18 sec. (remarks by Rep. Kevin Tanner (R-9th)).

100. O.C.G.A. § 16-13-63(b). Similar language was deleted from Code section 16-13-4(d). 2017 Ga. Laws 319–20.

101. 2017 Ga. Laws 319.

102. O.C.G.A. § 16-13-71(b)(635), -(c)(14.25); House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 10 min., 33 sec. (Remarks by Rep. Kevin Tanner (R-9th)).

103. *Opioid Overdose Reversal with Naloxone (Narcan, Evzio)*, NAT'L INST. HEALTH (Sept. 2016), https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio.

104. O.C.G.A. § 16-13-71(c)(14.25).

105. 2017 Ga. Laws 319, § 1-5, at 330.

maintenance and administration of the PDMP to the Department.[106] Previously, the Georgia Drugs and Narcotics Agency maintained and administered the database.[107]

Part 2

Section 2-1 of the Act amends Chapter 13 of Title 16, relating to controlled substances, adding a definition of "opioids."[108] Additionally, the new Code section requires prescribers to provide information to patients about the risks of addiction and safe disposal when prescribing opioids.[109] This information may be communicated orally or in writing, such as through a pamphlet.[110]

Part 3

Part 3 amends Code section 31-1-10, creating additional requirements for and giving additional duties to the state health officer.[111] Most significantly, the Act gives the health officer authority to set standards for the prescription of opioid antagonists, like naloxone.[112] Finally, state health officers are immunized from liability for actions performed under this section.[113]

106. O.C.G.A. § 31-2A-4(15) (Supp. 2017).

107. House Judiciary Non-Civil Committee Video, *supra* note 37, at 58 min., 45 sec. (Remarks by Rep. Kevin Tanner (R-9th)).

108. 2017 Ga. Laws 319, § 2-1, at 330.

109. O.C.G.A. § 16-13-56.1 (Supp. 2017).

110. House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 11 min., 25 sec. (Remarks by Rep. Kevin Tanner (R-9th)). This requirement is drafted broadly and does not specify how much information must be provided or from what sources prescribers should derive this information. *See* O.C.G.A. § 16-13-56.1.

111. 2017 Ga. Laws 319, § 3-1, at 330. This Section also updates Code section 26-4-116.2 by adding references to Code section 31-1-10. 2017 Ga. Laws 319, § 3-1, at 330–31.

112. O.C.G.A. § 31-1-10 (Supp. 2017).

113. O.C.G.A. § 26-4-116.2(e)(3). Relating to immunity, the Act also changes the Code section's language from "[t]he following individuals *are* immune" to "[t]he following individuals *shall be* immune," and changes immunity from "criminal liability" to immunity from "criminal responsibility." *See* 2017 Ga. Laws 319, § 3-1, at 330–31.

Part 4

Section 4-1 of the Act amends Code section 31-12-2, creating reporting requirements for neonatal abstinence syndrome.[114] The new subsections define the disease, require reporting cases of the disease to the Department of Public Health, and require the Department provide an annual report on the disease to state legislators.[115]

Part 5

Section 5-1 of the Act amends Chapter 5 of Title 26, adding two new Code sections.[116] Code section 26-5-22 requires annual onsite inspections of all licensed narcotic treatment programs.[117] Code section 26-5-23 requires annual reporting of the number of patients enrolled in and discharged from such treatment programs.[118] These provisions will help with the legislation's broad goal of collecting data about opioid addiction and overdose so that the State can better understand and react to the opioid epidemic.[119]

Part 6

Section 6-1 of the Act amends Article 2 of Chapter 16 of Title 45, requiring any death resulting from an apparent drug overdose be immediately reported to the coroner or medical examiner of the county where the death occurred.[120] This change will allow the Georgia Bureau of Investigation to identify patterns of opioid overdose and allocate resources accordingly.[121]

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114. 2017 Ga. Laws 319, § 4-1, 331–32. Neonatal abstinence syndrome refers to medical complications that arise when a newborn, exposed to addictive substances in utero, experiences opioid withdrawal. Karen McQueen & Jodie Murphy-Oikonen, *Neonatal Abstinence Syndrome*, 375 NEW ENGL. J. MED. 2468, 2469 (2016).

115. O.C.G.A. § 31-12-2(a.1) (Supp. 2017).

116. 2017 Ga. Laws 319, § 5-1, at 332.

117. O.C.G.A. § 26-5-22 (Supp. 2017).

118. O.C.G.A. § 26-5-23 (Supp. 2017).

119. *See* House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 12 min, 6 sec. (Remarks by Rep. Kevin Tanner (R-9th)).

120. O.C.G.A. § 45-16-24(a)(10) (Supp. 2017). Section 6 of the Act also amends Code section 45-16-27 by replacing permissive language with mandatory language and the word "person" with "individual." 2017 Ga. Laws 319.

121. House Judiciary Non-Civil Committee Video, *supra* note 37, at 1 hr., 12 min., 6 sec.

Analysis

A PDMP with mandatory reporting introduces two important concerns for legislators: due process rights for physicians and privacy rights for physicians and their patients.[122] Regarding due process, the General Assembly provided state regulatory boards the discretion to hold physicians accountable for violating the mandatory guidelines of the PDMP.[123] This could create a situation where the prescribers believe they "have been denied due process [because] the board overstepped their authority [or] made the incorrect decision" and thus appeal the board's decision. As for privacy rights, previous concerns about the privacy of patient information on the database are exasperated by the fact that more patients will now be entered into the system due to its mandatory nature.[124]

Due Process Implications

The new PDMP law creates a potentially worrisome situation where a physician could lose his or her license for failing to update the PDMP.[125] Currently, state medical boards may revoke a license when the board determines a physician "overprescribes" painkillers.[126] The new law, however, allows the board to revoke a physician's license, not just for the affirmative act of overprescribing, but also for the passive act of failing to use the PDMP.[127]

By giving the state medical board a new reason to revoke a physician's livelihood, the PDMP may very well pose both substantive and procedural due process concerns.[128] The Fifth

122. Tanner Interview, *supra* note 11, at 2 min., 3 sec. (discussing the possibility of physicians losing their license due to a decision made by the medical board); *id.* at 13 min., 47 sec. (discussing the public's concern about privacy and the legislation's strong penalties for misusing the information).

123. O.C.G.A. § 16-13-63(a)(2)(C).

124. Tanner Interview, *supra* note 11, at 13 min., 17 sec. (discussing the public's concern over privacy when the original legislation passed in 2011).

125. O.C.G.A. § 16-13-63(a)(2)(C) (Supp. 2017).

126. United States v. Ilayayev, 800 F. Supp. 2d 417, 434 (E.D.N.Y. 2011) (discussing how states regularly revoke licenses for overprescribing painkillers).

127. This bill does not address the over-prescription of opioids. In fact, Representative Kevin Tanner (R-9th) discussed a previous embodiment of the bill that limited the number of painkillers a physician could prescribe. Tanner Interview, *supra* note 11, at 16 min., 27 sec. Representative Tanner stated the bill should not "tell a doctor how to practice medicine." *Id.*

128. *See* Rebecca L. Haffajee, *Preventing Opioid Misuse with Prescription Drug Monitoring*

Amendment of the United States Constitution protects an individual's liberty and property interests from improper intrusion by the federal government.[129] Additionally, the Fourteenth Amendment provides individuals this same protection from state governments.[130] The due process required by the Fifth and Fourteenth Amendments provides both substantive and procedural due process rights.[131] Substantive due process is the particular property or liberty interest that the constitution protects from unwarranted governmental intrusions, such as a physician's right to make a living.[132] Procedural due process protects the individual by providing appropriate procedures—such as notice and a fair hearing—if the government does deprive the individual of that interest.[133]

If the PDMP raises substantive due process issues, the question is whether the state has adequate justification to enter the individual's realm of interests.[134] The state of Georgia gives the Georgia Composite Medical Board broad authority "[t]o revoke, suspend, issue terms and conditions, place on probation, limit practice, fine, require additional medical training, require medical community service, or otherwise sanction licensees . . . ."[135] The Supreme Court of the United States agrees that the "[s]tates have a compelling interest in the practice of professions within their boundaries, and . . . as part of their power to protect the public health, safety, and other valid interests they have broad power to establish standards for licensing practitioners and regulating the practice of professions."[136] Additionally, the United States Supreme Court has long held that states have broad powers to create regulations that promote public

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Programs: A Framework for Evaluating the Success of State Public Health Laws, 67 HASTINGS L.J. 1621, 1652–53 (2016).

129. U.S. CONST. amend. V ("No person shall...be deprived of life, liberty, or property, without due process of law.").

130. U.S. CONST. amend. XIV, § 1 ("[N]or shall any state deprive any person of life, liberty, or property, without due process of law . . . .").

131. *See* Haffajee, *supra* note 128, at 1653.

132. Carolyn R. Cody, *Professional Licenses and Substantive Due Process: Can States Compel Physicians to Provide Their Services?*, 22 WM. & MARY BILL RTS. J. 941, 942–43 (2014) (discussing how a license to practice is a protectable property interest).

133. *See* Haffajee, *supra* note 128, at 1653.

134. *Id.*

135. O.C.G.A § 43-34-5(c)(10) (2017).

136. Goldfarb v. Va. State Bar, 421 U.S. 773, 792 (1975).

health.[137] Therefore, even though the new PDMP regulation may not be the same as a typical "overprescribing" issue faced by medical boards,[138] most courts would likely agree that the PDMP is substantially related to promoting public health.[139] For instance, the Supreme Court of California recently held that the government's "interests in protecting the public from unlawful use and diversion of a particularly dangerous class of prescription drugs and protecting the patients from negligent or incompetent physicians" outweighs a physician's interest in protecting her own right to privacy.[140]

Procedural due process is also required if a physician is accused of violating the new PDMP laws. Georgia courts provide a broad standard for the medical board, and the Georgia Court of Appeals described the standard of review as follows:

> In order to comply with the requirements of due process, the hearing granted by an administrative body must be a full and fair one, before an impartial officer, board, or body free of bias, hostility, and prejudgment. The fact that the administrative agency is both the accuser and judge does not deprive [the] accused of due process of law, especially where an appeal from the determination of the agency may be had to the courts.[141]

Therefore, the state medical board has broad discretion as long as the proceeding is "full and fair."[142] The opportunity to appeal further protects the accused.[143]

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137. Haffajee, *supra* note 128, at 1645 (noting that the ability of state governments to protect and preserve public health dates back to the *Federalist Papers*, and has been consistently upheld by the United States Supreme Court).

138. Failer v. Dep't of Health, 139 So. 3d 359, 363 (Fla. Dist. Ct. App. 2014) (discussing how revoking the license of an over-prescriber relates to a concrete public-health concern).

139. *See Georgia Prescription Drug Monitoring Program*, *supra* note 15 (discussing the benefits of the PDMP); *see also* Haffajee, *supra* note 128, at 1655 ("PDMPs bear a real and substantial relation to the protection of public health and safety: they aim to inform optimal prescribing as well as to address patients and prescribers with outlier fill and prescribing patterns, respectively.").

140. Lewis v. Superior Court, 397 P.3d 1011, 1022 (Cal. 2017). Although the substantive due process right in this case was the right to privacy provided by the California Constitution, the case is illustrative of how courts find state PDMP laws as important tools for the state in regulating public health. *Id.*

141. Ga. Bd. of Dentistry v. Pence, 223 Ga. App. 603, 604, 478 S.E.2d 437, 440 (1996) (citations omitted) (discussing due process in the context of dental licensing).

142. *Id.*

Privacy

The concern surrounding database information privacy is not new; legislators voiced their concern when the General Assembly enacted the original PDMP laws in 2011.[144] Because the new laws are mandatory rather than optional, even more patient information will be entered into the database, raising additional privacy concerns.[145]

The new laws maintain three original safeguards for protecting the information.[146] First, the law permits disclosure only to certain individuals.[147] However, the new law allows authorized disclosure to more individuals in additional roles.[148] Second, the Electronic Database Review Advisory Committee still oversees the database's security.[149] Third, the law provides substantial penalties to individuals who use the information in the database for anything other than its intended purpose.[150]

Despite these safeguards, individuals continue to have concerns over intrusions by three groups: the state government, the federal government, and third parties.[151] First, patients whose information is in the PDMP may be concerned about the state government compiling and accessing their prescription history.[152] However, in 1977, the Supreme Court in *Whalen v. Roe* held that maintaining

143. *Id.*

144. Bruff & Daugherty, *supra* note 12, at 289–90 (discussing the privacy concerns for individuals in the database).

145. *See* Tanner Interview, *supra* note 11, at 13 min., 47 sec. (discussing how, under the Act, more individuals are allowed access to the database, but noting that the act also ensures the penalties of a felony remain as a deterrent for misuse of the database).

146. O.C.G.A. § 16-13-60(c); *see also* Bruff & Daugherty, *supra* note 12, at 289–90.

147. O.C.G.A. § 16-13-60(c). The statute permits disclosure "only to authorized prescribers or dispensers for providing care to a specific patient, upon request by a patient, prescriber, or dispenser about whom the information concerns, to law enforcement with a search warrant, or to the Agency or Medical Board with an administrative subpoena." Bruff & Daugherty, *supra* note 12, at 289.

148. O.C.G.A. § 16-13-60(c). The new law increases the PDMP's efficiency by expanding authorized disclosure to include two individuals working with the prescriber or dispenser, two individuals working in a healthcare facility where the prescriber is practicing, or two individuals per shift or rotation in an emergency department. *Id.*

149. O.C.G.A. § 16-13-61.

150. O.C.G.A. § 16-13-64(b), to -(c) (Supp. 2017); Bruff & Daugherty, *supra* note 12, at 289.

151. *See* Haffajee, *supra* note 128, at 1647–49 (discussing the state and federal government authority to administer PDMPs); Bruff & Daugherty, *supra* note 12, at 289–90.

152. *See* Whalen v. Roe, 429 U.S. 589, 591 (1977) (discussing a challenge to New York's Controlled Substances Act of 1972 requiring the recording of prescription drug history).

prescription databases did not violate the Fourteenth Amendment.[153] In *Whalen*, a group of concerned patients and physicians challenged New York's use of a prescription database, arguing that collection of such data violated the Fourteenth Amendment and may stigmatize the patients as "drug addicts" and cause them to avoid medical treatment.[154] The Court held that these databases are legitimate uses of state power and are not an immediate threat of "invasion of any right or liberty protected by the Fourteenth Amendment."[155] But even though the Supreme Court found compilation of data into databases constitutional, another concern may be whether the procedures in place for obtaining the information are legal or constitutional—a concern not addressed in *Whalen*.[156]

The Georgia General Assembly provided the procedure for state law enforcement agencies to access the information in the 2011 version of the PDMP.[157] Code section 16-13-60 provides that state officials must obtain a search warrant to access the database.[158] According to the Georgia Department of Public Health guidelines, all law enforcement and regulatory agency warrants are subject to review pursuant to HIPAA and other state and federal privacy laws.[159]

Second, individuals may have concerns about the federal government accessing personal information found in the database.[160]

153. *Id.* at 603–04.

154. *See, e.g.*, *id.* at 595.

155. *Id.* at 603–04.

156. Tucker v. City of Florence, 765 F. Supp. 2d 1320, 1323 (N.D. Ala. 2011) (discussing a challenge to the constitutionality of obtaining information from a PDMP by asserting to the agency that the officer had "probable cause"). In *Tucker*, the Northern District of Alabama found an officer's mere averment that he "had probable cause" was sufficient under Alabama law that required only an "affidavit stating probable cause for the use of the requested information." *See id.* at 1336–72; *see also* ALA. CODE § 20-2-214(5) (2011). Alabama subsequently changed the statute to require an "application to the department accompanied by a declaration that probable cause exists for the use of the requested information." ALA. CODE § 20-2-214(7) (West, Westlaw through 2017 Reg. Sess.).

157. *See* O.C.G.A. § 16-13-60(c)(3) (Supp. 2017) (stating that a search warrant is required for state officials to access information in the database).

158. *Id.* (stating that the Department of Public Health is authorized to provide information "[t]o local or state law enforcement or prosecutorial officials pursuant to the issuance of a search warrant . . . or to federal law enforcement or prosecutorial officials pursuant to the issuance of a search warrant pursuant to 21 U.S.C. or a grand jury subpoena pursuant to 18 U.S.C.").

159. *Georgia Prescription Drug Monitoring Program (GA PDMP)*, GA. DRUGS AND NARCOTICS AGENCY https://gdna.georgia.gov/georgia-prescription-drug-monitoring-program-ga-pdmp (last visited Sept. 17, 2017).

160. *See* United States v. Zadeh, No. 4:14-CV-106-O, 2014 U.S. Dist. LEXIS 181500, at *2 (N.D.

Both versions of Georgia's PDMP laws require law enforcement agencies obtain "search warrant[s] pursuant to 21 U.S.C." or "grand jury subpoena[s] pursuant to 18 U.S.C." in order to access information in the database.[161] However, federal courts have recently held that mere administrative subpoenas (such as those used by the DEA) are sufficient to access the information.[162] Therefore, although state agencies may be required to show probable cause, federal agencies may be able to obtain the information under a lesser standard, such as information "reasonably relevant" to an inquiry under the agency's authority.[163]

Two cases recently addressed whether administrative subpoenas are sufficient for a federal agency to access information in a state PDMP.[164] On April 21, 2016, the Fifth Circuit upheld the use of the "reasonably relevant" standard when deciding whether to enforce an administrative subpoena.[165] In *United States v. Zadeh*, a physician refused to comply with a subpoena from the DEA asking for medical records of the physician's patients.[166] The court sided with five other circuit courts by reasoning that:

> [A]n administrative subpoena is enforceable so long as 1) it satisfies the terms of its authorizing statute, 2) the documents requested were relevant to the [agency's] investigation, 3) the information sought is not already in the

Tex. Dec. 3, 2014) (discussing a challenge to the constitutionality and legality of the federal government using administrative subpoenas to access the data in the database).

161. O.C.G.A. § 16-13-60(C)(3) (Supp. 2017).

162. *See Zadeh*, 2014 U.S. Dist. LEXIS 181500, at *25 (holding that individuals have a reduced expectation of privacy in the "pervasively regulated industry" of prescription drugs, and the federal Controlled Substances Act provides that the federal government may reasonably rely upon administrative subpoenas to access information in PDMP databases).

163. *United States v. Zadeh*, 820 F.3d 746, 755 (5th Cir. 2016). "Under the 'reasonable relevance' standard, courts will enforce an administrative subpoena issued in aid of an investigation if: '(1) the subpoena is within the statutory authority of the agency; (2) the information sought is reasonably relevant to the inquiry; and (3) the demand is not unreasonably broad or burdensome.'" *Id.*

164. *See id.* at 749; Or. Prescription Drug Monitoring Program v. United States DEA, 998 F. Supp. 2d 957, 967 (D. Or. 2014), rev'd, No. 14-35402, 2017 U.S. App. LEXIS 11292, at *18 (9th Cir. June 26, 2017).

165. *Zadeh*, 820 F.3d at 755–56.

166. *Id.* at 749.

> [agency's] possession, and 4) enforcing the subpoena will not constitute an abuse of the court's process.[167]

The court held that the DEA met the lowered threshold.[168]

On June 26, 2017, the Ninth Circuit similarly reversed a decision by the District Court for the District of Oregon that held individuals have a heightened expectation of privacy regarding their information in PDMPs.[169] In *Oregon Prescription Drug Monitoring Program v. United States DEA*, the Oregon PDMP refused to comply with a subpoena from the DEA because it violated Oregon law requiring "a valid court order based on probable cause."[170] The district court sided with the PDMP, finding individuals with information in the PDMP have a heightened expectation of privacy, and the administrative subpoena violated the Fourth Amendment's probable cause requirement.[171] The Ninth Circuit reversed, holding the Controlled Substances Act (CSA), which allows the DEA to obtain records pursuant to an administrative subpoena, preempted the Oregon PDMP law requiring a valid court order prior to disclosure of prescription records.[172] The CSA provides that the Attorney General may "require the production of any records . . . which the Attorney General finds relevant or material to the investigation."[173] The Ninth Circuit concluded that a warrant based on probable cause was not required.[174] The court reasoned that the Oregon law "interferes with the methods by which the federal statute was designed to reach [its] goal," thus making it "an obstacle to the full implementation of the CSA."[175] Therefore, although the Georgia PDMP laws require federal agencies to show probable cause to access the database, federal agencies may be able to rely instead on more easily obtained

167. *Id.* at 757. The court sided with reasoning provided by the Sixth Circuit, but the court further stated that "[t]he Third, Fourth, Seventh and Tenth Circuits have also applied versions of the reasonable relevance test in upholding administrative subpoenas for medical records." *Id.*

168. *Id.* at 758.

169. Or. Prescription Drug Monitoring Program v. United States DEA, No. 14-35402, 2017 U.S. App. LEXIS 11292, at *16 (9th Cir. June 26, 2017).

170. Or. Prescription Drug Monitoring Program v. United States DEA, 998 F. Supp. 2d 957, 960 (D. Or. 2014), rev'd, No. 14-35402, 2017 U.S. App. LEXIS 11292, at *18 (9th Cir. June 26, 2017).

171. *Id.* at 967.

172. *Or. Prescription Drug Monitoring Program*, 2017 U.S. App. LEXIS 11292, at *18.

173. 21 U.S.C. § 876 (2012).

174. *Or. Prescription Drug Monitoring Program*, 2017 U.S. App. LEXIS 11292, at *18.

175. *Id.* (quoting Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 103 (1992)).

administrative subpoenas that are "reasonably relevant" to their investigation.[176] The Eleventh Circuit, however, has not yet ruled on this issue.[177]

Finally, individuals may have concerns about third party access to personal information stored in the database.[178] The 2011 law that created the PDMP also established the Electronic Database Review Advisory Committee.[179] The Act adds a pharmacist from the State Board of Pharmacy and a representative from the Department of Public Health to the Advisory Committee.[180] Additionally, the new law maintains substantial penalties to deter unauthorized use of the database.[181] Misuse of the database information is a felony carrying possible penalties of imprisonment of not less than two years, a fine up to $250,000, or both.[182] Therefore, the new PDMP laws should create a more effective program while maintaining the security of patient information across the state.[183]

This legislative session, the Georgia Assembly took a step towards curbing opioid abuse by shifting the PDMP from a voluntary to a mandatory reporting system. The General Assembly knew the 2011 PDMP did not adequately address the existing opioid problem, and this new legislation was an attempt to swing "the pendulum over to a substantial step forward" from the previous laws.[184] The new laws also generate urgency by providing the state medical board the authority to hold physicians accountable for failure to check the database.[185] Although Georgia does not go as far as some states where criminal penalties exist for failure to consult the registry,[186]

176. *See* O.C.G.A. § 16-13-60(a)(3) (Supp. 2017).

177. A Lexis Advance and Westlaw search for "PDMP and 'administrative subpoenas'" returns no results for an 11th Circuit opinion on the issue.

178. Bruff & Daugherty, *supra* note 12, at 289 (discussing the concerns over security breaches to unauthorized third parties).

179. 2011 Ga. Laws 659 (codified at O.C.G.A. § 16-13-61 (Supp. 2017)).

180. O.C.G.A. § 16-13-61(b).

181. Tanner Interview, *supra* note 11, at 14 min., 0 sec. ("[W]e still maintain the integrity of protecting that information. And that is a felony.").

182. O.C.G.A. § 16-13-64 (Supp. 2017).

183. Tanner Interview, *supra* note 11, at 14 min.

184. *Id.*, at 3 min., 45 sec.

185. O.C.G.A. § 16-13-63(a)(2)(C).

186. *See, e.g.*, Marilyn Schatz, *Complying with I-STOP: The New York State Prescription Monitoring Program*, DATELINE (Med. Liab. Mut. Ins. Co., New York, N.Y.) Fall 2013, at 7, https://secure.mlmic.com/pdf/DatelineSpecialEd_FINAL.pdf (discussing New York's PDMP laws and how failure to comply is considered willful misconduct); *see also* N.Y. Pub. Health § 12-b (2017)

this new form of accountability represents a measured step in the right direction towards curbing the opioid crisis.[187] If the new laws do not shift the pendulum far enough to create a positive effect, then some legislators are willing to revisit the PDMP laws in the future.[188] Only time will tell if the cumulative effects of the Act's measured approach are enough to mitigate one of our nation's largest health care crises.

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(discussing a possible $2,000 fine and up to one year imprisonment for willful misconduct).

187. Tanner Interview, *supra* note 11, at 3 min., 30 sec.

188. *Id.*, at 3 min., 50 sec. ("Let's monitor that and see if it's enough; and if it's not enough, then we'll take additional steps in the future.").