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## Physicians, Acupuncture, Physician Assistants, Cancer and Glaucoma Treatment, Respiratory Care, Clinical Perfusionists, and Orthotics and Prosthetics Practice HB 178

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## PROFESSIONS AND BUSINESSES

***Physicians, Acupuncture, Physician Assistants, Cancer and Glaucoma Treatment, Respiratory Care, Clinical Perfusionists, and Orthotics and Prosthetics Practice: Amend Chapter 34 of Title 43 of the Official Code of Georgia Annotated, Relating to Physicians, Acupuncture, Physician Assistants, Cancer and Glaucoma Treatment, Respiratory Care, Clinical Perfusionists, and Orthotics and Prosthetics Practice, so as to Provide for Additional Powers of the Georgia Composite Medical Board Relating to Pain Management; Enact the “Georgia Pain Management Clinic Act”; Provide for Legislative Intent; Require the Licensure of Pain Management Clinics; Provide for Definitions; Provide for Requirements for Licensure; Provide for Denial, Suspension, and Revocation of Licenses; Provide for Notice to the Board Upon Occurrence of Certain Events; Provide for Renewal of Licenses; Provide for a Penalty for Violation of the Act; Provide for Reporting by Hospitals; Provide for Reports to the Georgia Composite Medical Board; Provide for Related Matters ; Repeal Conflicting Laws; and for Other Purposes***

CODE SECTIONS:	O.C.G.A. §§ 43-34-5 (amended); -280, -281, -282, -283, -284, -285, -287, -288, -289, -290 (new)
BILL NUMBER:	HB 178
ACT NUMBER:	128
GEORGIA LAWS:	2013 Ga. Laws 515
SUMMARY:	The Act provides for licensing and oversight powers of the Georgia Composite Medical Board with respect to pain management clinics, provides requirements for licensing of a pain management clinic (including ownership and reporting requirements), provides requirements for license renewal, denial, suspension, and revocation, and provides for criminal

penalties for operation of a pain management clinic without a license.

EFFECTIVE DATE: July 1, 2013

### *History*

Prescription drug abuse can be loosely defined as the use of prescription drugs for nonmedical reasons.<sup>1</sup> In recent years, it has become increasingly prevalent and has spread throughout the United States.<sup>2</sup> According to a 2007 National Drug Assessment study, prescription narcotics are the second most abused drugs nationwide, trailing only marijuana.<sup>3</sup> Accidental deaths by prescription drug overdoses have skyrocketed in recent years, and prescription drug overdoses in 2007 represented the second leading cause of accidental death behind traffic crashes.<sup>4</sup> This problem has become so serious that it has demanded responses from both the federal government<sup>5</sup> and those of several states.<sup>6</sup>

The growth and spread of prescription drug abuse can largely be attributed to the proliferation of “pill mills,” which is a term used to describe a “doctor, clinic or pharmacy that is prescribing or dispensing powerful narcotics inappropriately or for non-medical

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1. Medline Plus, *Prescription Drug Abuse*, U.S. Nat’l Library of Med., Nat’l Insts. of Health, <http://www.nlm.nih.gov/medlineplus/prescriptiondrugabuse.html> (last updated Sept. 3, 2013); *see also Prescription Drugs*, Nat’l Inst. on Drug Abuse, <http://www.drugabuse.gov/drugs-abuse/prescription-drugs> (last updated Dec. 2012) (defining “abused” as “taken for reasons or in ways or amounts not intended by a doctor, or taken by someone other than the person for whom they are prescribed”).

2. Ken Lammers, Jr., *Rise of the Pills*, 15 UDC/DCSL L. REV. 91, 91–92 (2011) (detailing the spread of addiction to and abuse of prescription drugs such as oxycodone (a/k/a OxyContin), hydrocodone (a/k/a Lortab, Vicodin), alprazolam (a/k/a Xanax) and buprenorphine (a/k/a Suboxone, Subutex) throughout Maine, Ohio, West Virginia, Eastern Kentucky, Maryland, Western Pennsylvania, and Southwestern Virginia). Prescription drug abuse has become a serious problem in several major cities, including New Orleans, Cincinnati, Philadelphia, Phoenix, San Diego, Seattle, New York City, and Boston. *Id.*

3. Pia Malbran, *What’s a Pill Mill?*, CBS News, May 31, 2007, [http://www.cbsnews.com/8301-501263\\_162-2872835-501263.html](http://www.cbsnews.com/8301-501263_162-2872835-501263.html) (surpassing cocaine, heroin, meth and crack).

4. *Id.*

5. Office of Nat’l Drug Control Policy, Exec. Office of the President, *Epidemic: Responding to America’s Prescription Drug Abuse Crisis* (2011) (outlining a comprehensive prevention plan based on action in four major areas to curb prescription drug abuse in the United States: education, monitoring, proper disposal, and enforcement).

6. *See, e.g.*, Ashley Dutko, Note & Comment, *Florida’s Fight Against Prescription Drug Abuse: Prescription Drug Monitoring Program*, 34 Nova L. Rev. 739, 745 (2010) (detailing Florida’s legislative response to its prescription drug abuse problem).

reasons.”<sup>7</sup> Pill mills often display several common characteristics, which include: accepting only cash as payment, no performing of a patient physical exam, no thorough examination of medical records, only dispensing pills from the clinic’s own pharmacy, treating pain with pills only, and employing security guards.<sup>8</sup> “It is against federal law for a doctor to prescribe pain medication without a legitimate medical purpose or ‘outside the usual course of medical practice.’”<sup>9</sup> Still, pill mills have been able to evade law enforcement by disguising themselves as “pain management” centers or clinics, opening and shutting down quickly, and changing locations frequently.<sup>10</sup>

Unfortunately, Georgia communities have not been immune to the explosion of pill mills, and accidental deaths by prescription drug overdoses have persisted.<sup>11</sup> Before 2013, Georgia was one of many states that did not have legislation in place to provide for statewide regulation of pain management clinics.<sup>12</sup> Without such legislation, local and state governmental entities were extremely limited in their ability to keep pill mills out of their jurisdictions and deal with the problems they create in their respective communities.<sup>13</sup> Many states, such as Florida, Kentucky, and Texas, experienced similar problems in their abilities to regulate pain clinics.<sup>14</sup> In particular, Florida became known as a haven for illegal pill mills and experienced sharp

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7. Malbran, *supra* note 3.

8. *Id.*

9. *Id.* A doctor who writes an invalid prescription can face a federal drug trafficking charge, which is a felony that carries a potential life prison sentence. *Id.*

10. *Id.*

11. See, e.g., Andria Simmons, *Georgia Trying to Control Pill Mills*, ATLANTA J.-CONST., Nov. 20, 2011, <http://www.ajc.com/news/news/local/georgia-trying-to-control-pill-mills/nQNqJ/> (chronicling the death of Cameron McClure, a twenty-seven year-old Jonesboro man, due to oxycodone overdose prescribed from a Stockbridge, Georgia pill mill and describing both how pill mills have grown and how prescription drug overdose deaths have risen in Georgia).

12. Bill Barrow, *Georgia House Approves Regulations for Pain Management Clinics*, Marietta Daily J., Feb. 21, 2013, available at [http://mdjonline.com/view/full\\_story/21772668/article-Georgia-House-approves-regulations-for-pain-management-clinics](http://mdjonline.com/view/full_story/21772668/article-Georgia-House-approves-regulations-for-pain-management-clinics).

13. *Id.* Localities have attempted to alleviate the pill mill problem in their respective communities by enacting citywide ordinances creating moratoriums on new pain management clinics. Joy Lukachick & Tim Omarzu, *State and Local Governments in Georgia Trying to Rein in Pill Mills*, Times Free Press, Mar. 12, 2012, available at <http://www.timesfreepress.com/news/2012/mar/12/tennessee-state-local-governments-trying-rein-pill/>.

14. Video Recording of House Floor Debate, Feb. 20, 2013 at 1 hr., 24 min., 15 sec. (remarks by Rep. Tom Weldon (R-3rd)), <http://www.gpb.org/lawmakers/2013/day-20> [hereinafter House Floor Video].

increases in accidental deaths by prescription drug overdoses.<sup>15</sup> The number of pill mills in Georgia also “ballooned” as a function of “surrounding states tighten[ing] their regulations.”<sup>16</sup>

In response to the growth and spreading of pill mills in Georgia, Attorney General Sam Olens called on state lawmakers to provide a legislative response.<sup>17</sup> Representative Tom Weldon (R-3rd) introduced a nearly-identical bill (to 2013 House Bill (HB) 178) to the Georgia General Assembly during the 2012 legislative session—HB 972, similarly entitled the Georgia Pain Management Clinic Act.<sup>18</sup> At that time, an estimated 150 pill mills had been operating across the state of Georgia.<sup>19</sup> However, the Senate-revised version of HB 972 was not voted on by the House of Representatives before the end of the 2012 legislative session, and the bill died before reaching Governor Nathan Deal’s desk for signature.<sup>20</sup> Two weeks after the legislature adjourned the 2012 session, another tragic death due to a prescription drug overdose occurred in Ringgold, GA, Representative Weldon’s district.<sup>21</sup> On February 1, 2013, Representative Weldon introduced HB 178, also entitled the “Georgia Pain Management Clinic Act,” during the 2013 Georgia General Assembly Session.<sup>22</sup>

HB 178 is modeled after several other states’ laws that provide for statewide regulation of pain management clinics.<sup>23</sup> The bill’s primary purposes include the conferral of authority to the Georgia Composite

15. Dutko, *supra* note 6, at 745.

16. *Ga. Tightens Reins on Distribution of Pain Drugs*, Associated Press, May 2, 2013, <http://www.myfoxboston.com/story/22143542/ga-tightens-reins-on-distribution-of-pain-drugs>. A significant portion of these pill mills were opened and operated by the same individuals that had owned them in Florida before its laws regulating pain management clinics went into effect. See Telephone Interview with Rep. Tom Weldon (R-3rd) (July 26, 2013) [hereinafter Weldon Interview].

17. *Ga. Tightens Reins on Distribution of Pain Drugs*, *supra* note 16.

18. Lukachick & Omarzu, *supra* note 13.

19. *Id.* Before the recent explosion in the number of pill mills in the state of Georgia, Representative Weldon estimated that there were only around 10 pill mills in the state. Weldon Interview, *supra* note 16.

20. Video Recording of House Health and Human Services Committee, Feb. 11, 2013 at 30 min., 54 sec. (remarks by Rep. Sharon Cooper (R-43rd)), [http://media.legis.ga.gov/hav/13\\_14/2013/committees/health/health021113EDITED.wmv](http://media.legis.ga.gov/hav/13_14/2013/committees/health/health021113EDITED.wmv) [hereinafter House Committee Video].

21. *Id.* at 31 min., 47 sec. (remarks by Rep. Tom Weldon (R-3rd)) (describing death of Jon Tinker due to overdose of alcohol and Xanax, which he had been prescribed from a local pill mill).

22. HB 178, as introduced, 2013 Ga. Gen. Assem.

23. House Committee Video, *supra* note 20, at 1 hr., 8 min., 4 sec. (remarks by Rep. Tom Weldon (R-3rd)) (describing the bill as having been modeled after other states’ similar laws and designed to build upon their successes, most notably those flowing from Florida’s comprehensive legislative response).

Medical Board to license and regulate pain management clinics and the provision of penalties for individuals who operate pain management clinics illegally.<sup>24</sup> The Composite Medical Board is “the agency that licenses physicians, physician assistants, respiratory care professionals, perfusionists, acupuncturists, orthotists, prosthetists, auricular (ear) detoxification specialists, and residency training permits . . . [and that] investigates complaints and disciplines those who violate *The Medical Practice Act* or other laws governing the professional behavior of its licensees.”<sup>25</sup> Another of the bill’s main mechanisms, to achieve its goal of eliminating pill mills in Georgia, involved a requirement that only physicians would be legally permitted to own pain management clinics—perhaps the bill’s most controversial provision.<sup>26</sup>

### *Bill Tracking of HB 178*

#### *Consideration and Passage by the House*

Representatives Tom Weldon (R-3rd), Sharon Cooper (R-43rd), Tom Taylor (R-79th), Mickey Channell (R-120th), Butch Parrish (R-158th), and Mary Margaret Oliver (D-82nd) sponsored HB 178.<sup>27</sup> The House read the bill for the first time on February 1, 2013.<sup>28</sup> The House read the bill for the second time on February 4, 2013.<sup>29</sup> Speaker of the House David Ralston (R-7th) assigned it to the House Committee on Health and Human Services.<sup>30</sup> In Committee,

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24. Amended O.C.G.A. § 43-34-5(c) provides that the Georgia Composite Medical Board “shall have the following powers and duties: . . . To license and regulate pain management clinics; [and] To establish minimum standards for prescribing controlled substances for pain management . . . .” O.C.G.A. § 43-34-5(c)(24)–(25) (Supp. 2013). Also, new O.C.G.A. § 43-34-288 makes a person in “operat[ion of] a pain management clinic in the State of Georgia without a license in violation of this article . . . guilty of a felony.” O.C.G.A. § 43-34-288 (Supp. 2013).

25. *Purpose and Mission Statement*, Ga. Composite Med. Bd., <http://medicalboard.georgia.gov/purpose-and-mission-statement> (last visited May 27, 2013).

26. O.C.G.A. § 43-34-283(b)(1) (Supp. 2013). Representative Weldon noted that without such a requirement, there were “no brakes on the system with respect to ownership,” referring to the explosion of pill mills throughout Georgia in recent years. Weldon Interview, *supra* note 16.

27. See Georgia General Assembly, HB 178, Bill Tracking, <http://www.legis.ga.gov/Legislation/en-US/InjectSession.aspx?BillType=HB&BillNum=178>.

28. State of Georgia Final Composite Status Sheet, HB 178, May 9, 2013.

29. *Id.*

30. *Id.*

Representative Weldon answered questions from several other members of the House of Representatives with the help of Dr. Jean Rawlings Sumner, appearing on behalf of the Georgia Composite Medical Board.<sup>31</sup> Testimony was also given by Lilburn Police Chief Bruce Hedley, Catoosa County Coroner Vanita Hullander, Dr. Bruce Hines, representing the Georgia Society of Interventional Pain Physicians, and Dr. Jack Toney, representing the Georgia Society of Anesthesiologists.<sup>32</sup> Representative Ed Rynders (R-152nd) made several friendly amendments, which provided for background checks for new pain management clinic license applicants and a requirement that the Composite Medical Board refuse to renew a license if it determines that its operation is not in the public's best interest.<sup>33</sup> The House Committee on Health and Human Services favorably reported a Committee substitute to the bill on February 12, 2013.<sup>34</sup> The House read the Committee substitute as amended on February 20, 2013.<sup>35</sup> During the floor debate, Representative Weldon made favorable remarks about the bill and answered questions from Representatives Jay Roberts (R-155th) and Chuck Martin (R-49th), both of which pertained to the physician-ownership requirement, and Representative Edward Lindsey (R-54th) also made impassioned favorable remarks about the bill.<sup>36</sup> The House adopted the Committee substitute on February 20, 2013 by a vote of 150 to 15.<sup>37</sup>

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31. House Committee Video, *supra* note 20, at 53 min., 44 sec. (remarks by Dr. Jean Rawlings Sumner, Georgia Composite Medical Board).

32. *Id.* at 1 hr., 23 min., 47 sec. (remarks by Chief Bruce Hedley, City of Lilburn Chief of Police); *Id.* at 1 hr., 30 min., 27 sec. (remarks by Vanita Hullander, Catoosa County Coroner); *Id.* at 1 hr., 41 min., 33 sec. (remarks by Dr. Bruce Hines, Georgia Society of Interventional Pain Physicians); *Id.* at 1 hr., 45 min., 22 sec. (remarks by Dr. Jack Toney, Georgia Society of Anesthesiologists). Representative Weldon credited the Georgia Society of Interventional Pain Physicians, in addition to the Attorney General's Office, with providing substantive input on the bill. Weldon Interview, *supra* note 16.

33. House Committee Video, *supra* note 20, at 1 hr., 52 min., 7 sec. (remarks by Rep. Ed Rynders (R-152nd)).

34. State of Georgia Final Composite Status Sheet, HB 178, May 9, 2013.

35. *Id.*

36. House Floor Video, *supra* note 14, at 1 hr., 35 min., 14 sec. (remarks by Rep. Tom Weldon (R-3rd)); *Id.* at 1 hr., 38 min., 18 sec. (remarks by Rep. Tom Weldon (R-3rd)); *Id.* at 1 hr., 45 min., 46 sec. (remarks by Rep. Edward Lindsey (R-54th)).

37. State of Georgia Final Composite Status Sheet, HB 178, May 9, 2013; Georgia House of Representatives Voting Record, HB 178 (Feb. 20, 2013).

*Consideration and Passage by the Senate*

Senator Renee Unterman (R-45th) sponsored HB 178 in the Senate, and the bill was first read there on February 21, 2013.<sup>38</sup> Lieutenant Governor Casey Cagle (R) assigned it to the Senate Health and Human Services Committee.<sup>39</sup> While before the Health and Human Services Committee, representatives from both the Georgia Society of Anesthesiologists and Georgia Society of Interventional Pain Physicians favorably advocated for the passage of the bill.<sup>40</sup> However, representatives from the Georgia Association of Nurse Anesthetists (GANA) argued that the provision of the bill requiring advanced practice nurses working in pain management clinics to work pursuant to physician protocols<sup>41</sup> would effectively eliminate certified registered nurse anesthetists (CRNAs) from working in these clinics.<sup>42</sup> Under existing law, CRNAs do not work pursuant to physician protocols that are signed between two parties and then filed with the board of medicine, but rather under direct orders from physicians.<sup>43</sup> Under questioning from the Committee chair, Representative Weldon and Dr. Hines both advocated for keeping the bill as written because it empowered the Medical Composite Board to assess this issue and set forth applicable standards.<sup>44</sup> Specifically, Representative Weldon noted that the term “protocol” had room for interpretation, while Dr. Hines noted that

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38. See Georgia General Assembly, HB 178, Bill Tracking, <http://www.legis.ga.gov/Legislation/en-US/InjectSession.aspx?BillType=HB&BillNum=178>; State of Georgia Final Composite Status Sheet, HB 178, May 9, 2013. Representative Weldon credited Senator Unterman for her efforts getting the bill through the Senate. Weldon Interview, *supra* note 16.

39. State of Georgia Final Composite Status Sheet, HB 178, May 9, 2013.

40. Audio Recording of Senate Health and Human Services Committee, Mar. 13, 2013 at 1 hr., 8 min., 13 sec. (remarks by Dr. Jack Toney, Georgia Society of Anesthesiologists) (on file with Georgia State University Law Review) [hereinafter Senate Committee Recording]; *Id.* at 1 hr., 10 min., 16 sec. (remarks by Dr. Bruce Hines, Georgia Society of Interventional Pain Physicians).

41. HB 178 (HCS), p. 6, ln. 168–69, 2013 Ga. Gen. Assem.; Senate Committee Recording, *supra* note 40, at 1 hr., 12 min., 34 sec. (remarks by Christy Dunkelberger, GANA). GANA proposed changing the bill by adding words clarifying eligible employees as including “an advanced practice nurse who is working according to the laws governing APRNs.” *Id.* at 1 hr., 14 min. (remarks by Christy Dunkelberger, GANA).

42. Senate Committee Recording, *supra* note 40, at 1 hr., 14 min. (remarks by Christy Dunkelberger, GANA).

43. *Id.* at 1 hr., 15 min., 31 sec. (remarks by Christy Dunkelberger, GANA).

44. *Id.* at 1 hr., 17 min., 26 sec. (remarks by Rep. Tom Weldon (R-3rd); *Id.* at 1 hr., 18 min., 7 sec. (remarks by Dr. Bruce Hines, Georgia Society of Interventional Pain Physicians); *Id.* at 1 hr., 18 min., 27 sec.



part of the problem the bill combated was the amount of people writing medications for the subset of chronic pain patients.<sup>45</sup> The Committee passed the bill without making the changes requested by GANA.<sup>46</sup>

The Senate Committee on Health and Human Services favorably reported the House Committee substitute on March 14, 2013.<sup>47</sup> The bill was read a second time in the Senate on March 20, 2013, and a third time on March 21, 2013.<sup>48</sup> Also on March 21, 2013, Senator Lester Jackson (D-2nd) offered an amendment to insert “or a certified registered nurse anesthetist practicing pursuant to laws governing the scope of practice of certified registered nurse anesthetists” after “pursuant to a physician protocol,” which was withdrawn.<sup>49</sup> Senators Cecil Staton (R-18th) and Buddy Carter (R-1st) offered an amendment to (1) specify only requiring a majority ownership by physicians licensed in Georgia for all pain management clinics and (2) authorize the board to revoke, suspend, or restrict the clinic’s license where a physician who owns (jointly or otherwise) a pain management clinic leaves that practice or has his license to practice suspended by the board.<sup>50</sup> This amendment was defeated by a vote of 18 to 29.<sup>51</sup> On that same day, the Senate passed the House Committee substitute to the bill by a vote of 44 to 5 and transmitted it back to the House of Representatives.<sup>52</sup> The House of Representatives then sent the bill to Governor Nathan Deal for signature on April 1, 2013.<sup>53</sup> Governor Deal signed the bill into law on May 2, 2013.<sup>54</sup>

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45. *Id.* at 1 hr., 16 min., 46 sec. (remarks by Rep. Tom Weldon (R-3rd); *Id.* at 1 hr., 18 min., 07 sec., 1 hr., 18 min., 27 sec. (remarks by Dr. Bruce Hines, Georgia Society of Interventional Pain Physicians).

46. *Id.* at 1 hr., 19 min., 33 sec. (remarks by Sen. Renee Unterman (R-45th)).

47. State of Georgia Final Composite Status Sheet, HB 178, May 9, 2013.

48. *Id.*

49. Failed Senate Floor Amendment to HB 178, introduced by Sen. Lester Jackson (D-2nd), Mar. 21, 2013.

50. Failed Senate Floor Amendment to HB 178, introduced by Sen. Cecil Staton (R-18th) and Sen. Buddy Carter (R-1st), Mar. 21, 2013.

51. Georgia Senate Voting Record, HB 178 (Mar. 21, 2013).

52. State of Georgia Final Composite Status Sheet, HB 178, May 9, 2013; Georgia Senate Voting Record, HB 178 (Mar. 21, 2013).

53. State of Georgia Final Composite Status Sheet, HB 178, May 9, 2013.

54. *Id.*

*The Act*

The Act amends Chapter 34 of Title 43 of the Official Code of Georgia Annotated with the purpose of endowing the Composite Medical Board of Georgia with the ability to license pain management clinics as well as establish minimum standards for prescribing pain management controlled substances.<sup>55</sup> Section 1 amends the existing code structure by expressly granting the Composite Medical Board these powers.<sup>56</sup>

Section 2 creates several additions to the Code in sections 43-34-280 through 43-34-290. Code section 43-34-281 presents the General Assembly's intent behind the Act as balancing the need "to obtain appropriate and safe medical care to treat conditions in which the control of pain is an element" against the growing problem of "illegal and improper distribution of controlled substances."<sup>57</sup> Code section 43-34-282 provides the statute's definitions and notably limits the applicability of the Act to pain management clinics defined as (1) "a medical practice advertising 'treatment of pain' or utilizing 'pain' in the name of the clinic" or (2) "a medical practice or clinic with greater than 50 percent of its annual patient population being treated for [non-terminal] chronic pain" with the use of Schedule II or III controlled substances.<sup>58</sup>

Code section 43-34-283 creates a biennial licensing requirement as well as mandates that all pain management clinics are owned by physicians licensed in Georgia.<sup>59</sup> Pain management clinics in existence prior to July 1, 2013 may continue to operate without meeting the physician-ownership requirement provided that the non-physician owner or entity operates only one clinic and meets the Act's other requirements for pain management clinics, including its

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55. O.C.G.A. § 43-34-5(c)(24)–(25) (Supp. 2013).

56. *Id.*

57. O.C.G.A. § 43-34-281(a) (Supp. 2013).

58. O.C.G.A. § 43-34-282(7) (Supp. 2013). The definitions further clarify that the term pain management clinic shall not refer to "any clinic or practice owned, in whole or in part, or operated by a hospital licensed pursuant to Chapter 7 of Title 31 or by a health system or any ambulatory surgical center, skilled nursing facility, hospice, or home health agency licensed pursuant to Chapter 7 of Title 31." *Id.* However, hospitals with outpatient clinics that have a patient population that would meet the definition of pain management clinic as defined by the Act must notify the Composite Medical Board of its existence. O.C.G.A. § 43-34-289 (Supp. 2013).

59. O.C.G.A. § 43-34-283(a)–(b)(1) (Supp. 2013).

reporting requirements.<sup>60</sup> Where a physician practices at more than one clinic, each clinic must receive a license and the license will be nontransferable.<sup>61</sup> Further, Code section 43-34-283 also empowers the Medical Composite Board with the ability to set minimum standards of continuing medical education; establishes background check requirements for new license applicants; places ultimate responsibility to comply with the laws on the owner and physicians working in the clinic; and requires a physician, a physician's assistant with an approved job description, or advanced practice registered nurse working pursuant to specific protocols to be onsite for the clinic to provide medical treatment.<sup>62</sup>

The new Code sections also detail licensing revocation and reporting procedures. The Composite Medical Board may revoke licenses where an applicant has “[f]urnished false or fraudulent material information in [his] application,” “[b]een convicted of a crime under any state or federal law relating to any controlled substance,” or had his federal registrations to practice suspended or revoked.<sup>63</sup> Code section 43-34-285 details mandatory reporting requirements clinic owners must make to the Board, including the closing of a clinic, change of ownership, change in practicing physicians, loss or theft of drugs, and criminal convictions of employees.<sup>64</sup> The remaining Code sections mandate registration with the Georgia State Board of Pharmacy for clinics also dispensing controlled substances; set forth the license renewal procedure, which establishes continuing education requirements for clinic owners and practitioners; criminalizes the illegal operation of a clinic; and allows law enforcement to forward investigation records to the Composite Medical Board where the death under investigation may have been caused as the result of medication administered by a clinic under the Act.<sup>65</sup>

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60. O.C.G.A. § 43-34-283(b)(2)–(3) (Supp. 2013).

61. O.C.G.A. § 43-34-283(a) (Supp. 2013).

62. O.C.G.A. § 43-34-283(c)–(g) (Supp. 2013).

63. O.C.G.A. § 43-34-284 (Supp. 2013).

64. O.C.G.A. § 43-34-285(1)–(6) (Supp. 2013). Representative Weldon believes that the establishment of reporting requirements for pain management clinics is one of the two most important parts of the bill (the other being the physician-ownership requirement). Weldon Interview, *supra* note 16.

65. O.C.G.A. §§ 43-34-286–290 (Supp. 2013).

*Analysis**Georgia Looks to Florida to Battle Pill Mills*

In passing the Georgia Pain Management Clinic Act, the General Assembly looked at the laws of several states as a blueprint for its own legislation.<sup>66</sup> However, the state that Georgia primarily turned to was Florida.<sup>67</sup> Florida offered substantial guidance as, prior to 2010, Florida had suffered a great deal of similar problems regarding pill mills.<sup>68</sup> Prior to enacting its legislation, Florida was the “center of the illegal sale of prescription drugs.”<sup>69</sup> In the first six months of 2010, “[d]octors in the state purchased 89 percent of the oxycodone sold to practitioners nationwide.”<sup>70</sup> At its peak, over 1,000 pain clinics operated in the state and Florida earned the nickname “Oxy Express.”<sup>71</sup>

With the passage of Florida’s tough laws coupled with an aggressive campaign to shut down the pill mills, authorities closed more than 400 clinics in a one-year period.<sup>72</sup> From 2011 to 2012, the total number of pain clinics in Florida fell to just above 400.<sup>73</sup> Moreover, the Florida Department of Law Enforcement reported a drop in deaths from two of the most popular opioids, hydrocodone and oxycodone.<sup>74</sup> Further signs that the Florida Act was a success: law enforcement saw the price of illegally sold oxycodone *double* and treatment centers saw more addicts seeking help because they could no longer afford prescription drugs.<sup>75</sup> At the end of 2012, the Centers for Disease Control and Prevention classified Florida as

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66. House Committee Video, *supra* note 20, at 1 hr., 8 min., 4 sec. (remarks by Rep. Tom Weldon (R-3rd)). Georgia looked at laws in Kentucky, Texas, Louisiana, Ohio, and Mississippi. *Id.*

67. *Id.*

68. Lizette Alvarez, *Florida Shutting ‘Pill Mill’ Clinics*, N.Y. Times, Aug. 31, 2011, available at [http://www.nytimes.com/2011/09/01/us/01drugs.html?pagewanted=all&\\_r=0](http://www.nytimes.com/2011/09/01/us/01drugs.html?pagewanted=all&_r=0).

69. *Id.*

70. *Id.*

71. *Id.*

72. *Id.*

73. Timothy W. Martin, *Florida ‘Pill Mill’ Crackdown Sets Off a Rush Into Georgia*, WALL ST. J., Dec. 25, 2012, available at <http://online.wsj.com/article/SB10001424127887324478304578173341194754984.html#project%3DGEORGIA1226%26articleTabs%3Darticle> (click on graphics tab to see data chart).

74. *Id.*

75. Alvarez, *supra* note 68.

having more prescription drug laws than any other state in the nation.<sup>76</sup>

Following the crackdown in Florida, the pain management business “sprinted” across the Georgia border.<sup>77</sup> Between 2010 and 2012, the number of pain clinics skyrocketed from only 10 to over 125 and “[p]er capita prescription sales of oxycodone tripled between 2000 and 2010.”<sup>78</sup> With minimal laws policing the ownership and regulation of these pain clinics, their numbers flourished. One newsworthy case involved a former used-car dealer with no medical training who was able to establish and open his own pain management clinic within only a few months.<sup>79</sup> In his own words, he described “[t]he [Georgia] laws are minimal at best” and having “a green light from every agency that we spoke to.”<sup>80</sup>

Certainly, Georgia caught the pill mill epidemic, but the question remains: can Georgia replicate Florida’s success with its new laws? In comparing the two legal frameworks, several differences exist that could lead to a different outcome in effectiveness. First, Florida coupled its legislative efforts with law enforcement crackdowns using “strike forces to close illicit pain clinics and tracking controlled-substance sales.”<sup>81</sup> Representative Weldon reinforced that, going forward, the Georgia Drug and Narcotics Agency (DNA) must be sufficiently funded so that it has the resources it needs to stay on top of the problem and be proactive in the same way, thereby reducing untimely deaths from abuse of prescription drugs dispensed by pill mills.<sup>82</sup> Moreover, one of the things government officials have named most crucial to shutting down the drug pipeline early, a prescription drug monitoring system,<sup>83</sup> is practiced in both Georgia and Florida.<sup>84</sup> The scheme, which aims to prevent pharmacy-hopping

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76. Martin, *supra* note 73.

77. *Id.*

78. *Id.*

79. *Id.*

80. *Id.*

81. Martin, *supra* note 73. The crackdown married state and federal resources. *Id.*

82. Weldon Interview, *supra* note 16.

83. Alvarez, *supra* note 68.

84. *Georgia Approves Prescription Drug Monitoring Program*, Drugfree.Org, May 17, 2011, <https://www.drugfree.org/join-together/addiction/georgia-approves-prescription-drug-monitoring-program>; Arian Campo-Flores, *Florida Targeting ‘Pill Mills,’* Wall St. J., May 9, 2011, available at [http://online.wsj.com/article\\_email/SB10001424052748704681904576311102593116480-1MyQjAxMTAxMDAwODEwNDgyWj.html](http://online.wsj.com/article_email/SB10001424052748704681904576311102593116480-1MyQjAxMTAxMDAwODEwNDgyWj.html).

or doctor-shopping, requires pharmacies to record the sale of controlled substances in a database.<sup>85</sup> In theory, this system allows pharmacists to see how often a patient is prescribed and purchases pain drugs and the abuse can be tracked accordingly.<sup>86</sup>

Another distinguishing factor, Florida's statutory regime was an omnibus overhaul of existing law,<sup>87</sup> while some have criticized the Georgia framework as lacking focus and being overly broad.<sup>88</sup> Specifically, GANA noted the bill overreached by covering pain medication injections, which were "not the intended target nor a stated problem."<sup>89</sup> In its assessment of HB 178, GANA also highlighted the absence of legislation aimed at controlling and dispensing narcotic pills.<sup>90</sup> Comparatively, under Florida law, Schedule II through V drugs may not be dispensed in excess of a 72-hour supply for any patient purchasing drugs from a regulated clinic,<sup>91</sup> effectively barring the sale of prescription drugs from within the pain management clinics.<sup>92</sup> Georgia's new legislation has no such bar, but does require clinics that dispense drugs to be registered with Georgia State Board of Pharmacy.<sup>93</sup> According to Representative Lee Hawkins (R-27th), this provision will be effective because the Georgia State Board of Pharmacy as subpoena powers, and, while working in tandem with the Georgia Drugs and Narcotics Agency (DNA), it can act as "a secondary mechanism for safety."<sup>94</sup> As noted above, legislators have expressed the desire to ensure that the Georgia DNA receives sufficient funding to review pain management

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85. O.C.G.A. §§ 16-13-57 to -64 (Supp. 2013); *see also Georgia Approves Prescription Drug Monitoring Program*, *supra* note 84.

86. *Georgia Approves Prescription Drug Monitoring Program*, *supra* note 84. Of note, the monitoring program was not enacted as part of the Georgia Pain Management Clinic Act, but as part of other legislation. *See* O.C.G.A. §§ 16-13-57 to -65 (Supp. 2013).

87. *Compare* 2010 Fla. Sess. Law Serv. 2629 (West), *with* O.C.G.A. §§ 43-34-5(c)(24)-(25), -280 to -290 (Supp. 2013).

88. Electronic Mail Interview with Christy A. Dunkelberger, Legal Counsel/Executive Director, GANA (July 25, 2013) [hereinafter Dunkelberger Interview].

89. *Id.*

90. *Id.*

91. Fla. Stat. § 458.3265 (West, Westlaw through 2013).

92. Campo-Flores, *supra* note 85.

93. O.C.G.A. § 43-34-286 (Supp. 2013).

94. House Committee Video, *supra* note 20, at 1 hr., 6 min., 51 sec. (remarks by Rep. Lee Hawkins (R-27th)).

clinics' dispensing of prescription drugs and respond appropriately where the records suggest improper clinic practices.<sup>95</sup>

More controversial, both states also share the requirement that only a medical professional may own a pain management clinic.<sup>96</sup> As described by Representative Weldon, the physician-ownership mandate is essential to curtailing pill mills.<sup>97</sup> It requires ownership by an individual who has spent years investing in a medical career and is someone with "something to lose" and has "skin in the game, so to speak."<sup>98</sup> By having this requirement, lawmakers hope physicians will focus more on their practice, center it around providing good healthcare, thereby preventing the profit incentive from altering the doctor's care of patients.<sup>99</sup> In other words, this provision is designed to prevent pain management clinics from "run[ning] [patients] through [pain management clinics] like cattle, . . . so they can get their prescriptions and [clinics] can get their money."<sup>100</sup>

Still, Georgia's legislation has a significant carve-out on the physician-ownership mandate for already existing pain management clinics.<sup>101</sup> Arguably, the limited retroactive effect of Georgia's laws could limit its ability to close clinics operated by bad actors.<sup>102</sup> However, those clinics must still meet the reporting and license requirements outlined in the Act.<sup>103</sup> Opponents of the mandate also point out that many other health-care enterprises, such as hospitals and clinics, have a variety of ownership structures.<sup>104</sup> They argue that

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95. Weldon Interview, *supra* note 16.

96. O.C.G.A. § 43-34-283(b)(1) (Supp. 2013); Fla. Stat. § 458.3265(1)(d) (West, Westlaw through 2013).

97. House Floor Video, *supra* note 14, at 1 hr., 38 min., 18 sec. (remarks by Rep. Tom Weldon (R-3rd)).

98. *Id.*

99. *Id.* Representative Cooper and Senator Unterman both emphasized the necessity of including the physician-ownership requirement as a part of the bill. Weldon Interview, *supra* note 16.

100. House Committee Video, *supra* note 20, at 58 min., 23 sec. (remarks by Rep. Tom Weldon (R-3rd)).

101. O.C.G.A. § 43-34-283(b)(2)–(3) (Supp. 2013). Florida's laws also have several exemptions from registration for varying types of clinics. *See* Fla. Stat. § 458.3265(2)(a)–(f) (West, Westlaw through 2013).

102. Representative Weldon expressed that maybe more could have been done "as far as punishment for violators." Weldon Interview, *supra* note 16. However, stepping back and looking back at the bill as a whole, he was "happy with [it]." *Id.*

103. House Floor Video, *supra* note 14, at 1 hr., 36 min., 54 sec. (remarks by Rep. Tom Weldon (R-3rd)).

104. Dunkelberger Interview, *supra* note 88.

limiting ownership to only physicians is thus a problematic restraint on trade and an unnecessary intrusion into the marketplace.<sup>105</sup> Lastly, critics argue that the mandate will limit access to pain management services, choice of providers, and ultimately raise the cost of these services, particularly in rural areas.<sup>106</sup>

Therefore, despite sharing similar tools to combat pill mills with Florida's legislation, the ultimate effectiveness of Georgia's Act will not be known until it has been in place for some time. While Georgia's pill mill crisis is still on a smaller scale than Florida's, the omnibus efforts may have been the key to Florida's success. Adopting a model employing a targeted law enforcement plan and more legislation aimed at controlling the dispensation of narcotic pills may be tools that the Georgia Assembly could consider incorporating in the future. However, while not written into the text of the Act, the Georgia DNA will still play a vital role in shutting down illicit pain management clinics.

*Limiting Practitioners and the Role of the Composite Medical Board*

Two additional concerns broached by critics of HB 178 were new statutory limitations on CRNAs' scope of practice and the role of the Medical Composite Board. Under the Act, an advanced practice registered nurse working in a pain management facility must be "authorized to prescribe controlled substances pursuant to a physician protocol."<sup>107</sup> Per GANA, this provision completely excludes CRNAs "from providing pain management services in [pain management clinic] facilities."<sup>108</sup> Moreover, because CRNAs are the primary

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105. *Id.*; Barrow, *supra* note 12.

106. Dunkelberger Interview, *supra* note 88.

107. O.C.G.A. § 43-34-283(g) (Supp. 2013).

108. Dunkelberger Interview, *supra* note 88.

CRNAs are primarily the only advanced practice registered nurses who administer injectable pain management services. Pain management services are within the scope of practice of CRNAs under Georgia law. CRNAs provide pain management services under the direction of a duly licensed physician according to O.C.G.A. [§ ]43-26-11.1. CRNAs do not work under 'prescriptive authority protocols' that other APRN[s] in this state do. Because HB 178 requires any advanced practice registered nurse who works in a pain management clinic to work under a 'prescriptive authority protocol[,] []CRNAs are excluded from providing pain management services under this Bill.

*Id.*



advanced practice nurses administering injectable pain management services, such services will now be limited in the clinics.<sup>109</sup> Though HB 178 was initially meant to protect CRNAs, a shift in position by legislators kept the provision in.<sup>110</sup> Alternatively, argues GANA, HB 178 should have been limited to controlling the dispensation of oral narcotic medications.<sup>111</sup>

The secondary concern of critics of HB 178, is the expanded role of the Medical Composite Board. As demonstrated in committee debates, architects of the bill intended for the Medical Composite Board to have a great deal of discretionary power.<sup>112</sup> However, GANA notes, “the purpose of the Medical [Composite] Board is to govern the practice of physicians . . . not ‘facilities.’”<sup>113</sup> As an alternative, GANA unsuccessfully proposed pain management clinics be regulated by “Healthcare Facility Regulation (HFR), a division of the Department of Community Health (DCH).”<sup>114</sup>

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109. *See id.*

110. *Id.*

111. *Id.*

112. *See* Senate Committee Recording, *supra* note 40, at 1 hr., 17 min., 26 sec. (remarks by Rep. Tom Weldon (R-3rd)).

113. Dunkelberger Interview, *supra* note 88; *see also Purpose and Mission Statement*, Ga. Composite Med. Bd., <http://medicalboard.georgia.gov/purpose-and-mission-statement> (last visited May 27, 2013).

114. Dunkelberger Interview, *supra* note 88.