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# THE BEST OF BOTH WORLDS: APPLYING FEDERAL COMMERCE AND STATE POLICE POWERS TO REDUCE PRESCRIPTION DRUG ABUSE

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## I. INTRODUCTION

Prescription drug<sup>1</sup> abuse is the fastest growing drug problem in the United States.<sup>2</sup> Although public perception sees prescription medications as inherently

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1. Noteworthy prescription medications that are often abused include opioids (such as hydrocodone and oxycodone), stimulants (such as dextroamphetamine and methylphenidate), and benzodiazepines (such as alprazolam and diazepam). These medications are all classed as controlled substances under federal and most states' laws. Controlled substances are drugs, substances, or immediate precursors of drugs that the government has determined it must regulate because of their potentially dangerous effects. *See* 21 U.S.C. § 802(6) (2011) (defining "controlled substance"); 21 C.F.R. § 1308.11–15 (2011) (listing current controlled substances in Schedules I–V). This Article addresses a federal Controlled Substances Act amendment applicable to controlled substances in Schedules II–V. 21 U.S.C. § 801 (2011). This Article often focuses on opioid pain medications because these pain relievers are the most commonly abused controlled substances. Nevertheless, solutions to prescription drug abuse must also apply to stimulants and benzodiazepines. *See* Andria Simmons, *Ga. Drug Overdose Deaths Drop: Fatalities off 9% from Prescriptions, Illegal Narcotics, GBI Reports*, ATLANTA J. CONST., Aug. 15, 2012, at B2 (stating that "the anti-anxiety drug alprazolam, also known as Xanax, topped the list of drugs most commonly found in . . . toxicology tests" for individuals who died of prescription drug-related overdoses); SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., RESULTS FROM THE 2011 NATIONAL SURVEY ON DRUG USE AND HEALTH: SUMMARY OF NATIONAL FINDINGS (2012), *available at* <http://www.samhsa.gov/data/nsduh/2k11results/nsduhresults2011.htm> (stating that "the most prevalent category of misused prescription drugs is pain relievers"). As discussed in the National Prescription Drug Abuse Prevention Strategy, "successful responses to prescription opioid diversion, misuse, and abuse will likely also be applicable to other classes of medications." CTR. FOR LAWFUL ACCESS & ABUSE DETERRENCE, NATIONAL PRESCRIPTION DRUG ABUSE PREVENTION STRATEGY: 2011-2012 UPDATE 9 (2012), *available at* [http://www.claad.org/downloads/CLAAD\\_Strategy2011\\_v3.pdf](http://www.claad.org/downloads/CLAAD_Strategy2011_v3.pdf).

safer than illicit street drugs,<sup>3</sup> prescription opioids caused 14,800 deaths in 2008,<sup>4</sup> which is more than cocaine and heroin combined.<sup>5</sup> Prescription drug abuse is even more prevalent than most illicit drug use, and prescription drug-related deaths have increased over 300-fold from 1999 to 2008.<sup>6</sup> These staggering figures have prompted the U.S. Centers for Disease Control and Prevention to call prescription drug abuse a national epidemic,<sup>7</sup> have prompted the current Presidential Administration to respond to the problem with a prescription drug abuse prevention plan,<sup>8</sup> and have prompted state governors and attorneys general to develop state-specific task forces and plans.<sup>9</sup>

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2. Leonard Paulozzi et al., *CDC Grand Rounds: Prescription Drug Overdoses – a U.S. Epidemic*, 61 *Morbidity & Mortality Wkly. Rep.* (CTRS. FOR DISEASE CONTROL & PREVENTION, ATLANTA, GA.), JAN. 13, 2012, AT 10, 10. Consistent with the National Prescription Drug Abuse Prevention Strategy, this Article regards as imprecise the Substance Abuse and Mental Health Services Administration’s National Survey on Drug Use and Health (NSDUH) definition of *nonmedical use* of prescription medications, which is “use without a prescription of the individual’s own or simply for the experience or feeling the drugs caused.” SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 1. This definition of nonmedical use does not differentiate between misuse and abuse. *Id.* In Katz et al., *Challenges in the Development of Prescription Opioid Abuse-Deterrent Formulations*, 23 *CLINICAL J. PAIN* 648 (2007), the definition(s) of misuse and abuse are more precise. Katz et al. define *misuse* as “use of medication (for a medical purpose) other than as directed or as indicated, whether willful or unintentional, and whether harm results or not.” *Id.* at 650. The authors define abuse as “the intentional self-administration of a medication for a nonmedical purpose such as altering one’s state of consciousness, eg. getting high.” *Id.* Katz et al.’s well-delineated definitions should be used when describing misuse and abuse. For the general purposes of this article, however, we will often use the phrase “prescription drug abuse” to encompass these various related definitions.

3. *Prescription Drug Abuse*, OFFICE OF NAT’L DRUG CONTROL POL’Y, <http://www.whitehouse.gov/ondcp/prescription-drug-abuse> (last visited May 7, 2013) (“Some individuals who misuse prescription drugs, particularly teens, believe these substances are safer than illicit drugs because they are prescribed by a healthcare professional and dispensed by a pharmacist.”).

4. Margaret Warner et al., *Drug Poisoning Deaths in the United States, 1980–2008*, 81 *NCHS DATA BRIEF* (Nat’l Ctr. for Health Statistics, Hyattsville, Md.), Dec. 2011, at 1, 3.

5. *Id.*

6. *See id.* (reporting that “drug poisoning deaths involving opioid analgesics” more than tripled from about 4,000 in 1999 to 14,800 in 2008).

7. Paulozzi et al., *supra* note 2, at 10.

8. Press Release, Ctrs. for Disease Control & Prevention, Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), *available at* [http://www.cdc.gov/media/releases/2011/p1101\\_flu\\_pain\\_killer\\_overdose.html](http://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html).

9. *See, e.g.*, N.M. STAT. ANN. § 24-2D-5.2 (LexisNexis 2007 & Supp. 2012) (requiring quarterly prescription drug misuse and overdose prevention and pain management advisory council meetings to discuss education of professional prescribers in New Mexico, among other issues); Press Release, Office of the Att’y Gen. of Ky., Attorney General’s Statewide Prescription Drug Abuse Task Force Marks 2nd Anniversary (Aug. 31, 2011) (touting the many accomplishments a state task force has made combating Kentucky’s prescription drug problem), *available at* <http://migration.kentucky.gov/newsroom/ag/taskforce2ndanniversary.htm>; OHIO PRESCRIPTION DRUG ABUSE TASK FORCE, FINAL REPORT: TASK FORCE RECOMMENDATIONS 5 (2010) (developing twenty policy recommendation to curb Ohio prescription drug epidemic), *available at* <http://www.odh.ohio.gov/~media/ODH/ASSETS/Files/web%20team/features/drug%20overdose/opdatffinalreport.ashx>.

Yet one hundred million patients in the U.S. suffer from chronic pain;<sup>10</sup> many are worried about access to medications that have become a vital part of their palliative care.<sup>11</sup> State-licensed health care providers serve as the gatekeepers for federally regulated medications.<sup>12</sup> These practitioners<sup>13</sup> face the conflict of treating patients in pain—an invisible symptom—and fearing discipline for improperly prescribing pain medication.<sup>14</sup> Even more disturbing is the fact that many physicians have never received the proper education or training to understand the consequences of prescribing controlled substances or how to take steps to prevent serious harm to their patients who are taking such medications.<sup>15</sup> Through mandatory education, physicians can learn how to adequately treat their patients while preventing abuse.<sup>16</sup>

While some state legislatures have taken proactive steps to prevent prescription drug abuse by requiring mandatory prescriber education, many have not.<sup>17</sup> Prescriber education is needed on a national level.<sup>18</sup> Moreover, the solution to the prescription drug abuse problem must address patient health, safety, and welfare under the purview of the states' plenary police powers, and movement of controlled substances through federally governed interstate commerce.<sup>19</sup> This Article proposes action that harnesses the state and federal systems to provide a

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10. INST. OF MED., RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING PREVENTION, CARE, EDUCATION, AND RESEARCH 1 (2011).

11. See Donna Leinwand Leger, *FDA Might Tighten Reins on Vicodin*, USA TODAY (Jan. 10, 2013, 8:55 AM), <http://www.usatoday.com/story/news/nation/2013/01/09/fda-might-tighten-reins-on-vicodin/1822211/>.

12. See 21 U.S.C. § 822 (2011) (requiring anyone who distributes controlled substances to register with the U.S. Attorney General prior to distribution).

13. "Practitioners" and "prescribers" refer to prescribing health care practitioners, including physicians, physician assistants, nurse practitioners, and dentists. See DRUG ENFORCEMENT ADMIN., U.S. DEPT. OF JUSTICE, PRACTITIONER'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT 18 (2006) (defining practitioners to include "physicians, dentists, veterinarians and other registrants authorized to prescribe, dispense, and administer controlled substances").

14. H. Westley Clark & Karen Lea Sees, *Opioids, Chronic Pain, and the Law*, 8 J. PAIN & SYMPTOM MGMT. 297, 304 (1993).

15. See Laxmaiah Manchikanti, *National Drug Control Policy and Prescription Drug Abuse: Facts and Fallacies*, 10 PAIN PHYSICIAN 399, 417 (2007) (noting that there is a lack of education among physicians regarding prescribing controlled substances and that surveys show that this lack of knowledge leads to improper use of prescriptions).

16. See *id.* at 420–21 (suggesting mandatory education for medical schools and residency programs on controlled substances, followed by continuing education each year, as a solution to the current lack of knowledge on proper prescribing of opioids among physicians).

17. See *infra* Part V.A (explaining that California, Massachusetts, Michigan, Oregon, and Tennessee all require some pain management or prescribing training for practitioner licensure).

18. See OFFICE OF NAT'L DRUG CONTROL POL'Y, OFFICE OF THE PRESIDENT, EPIDEMIC: RESPONDING TO AMERICA'S PRESCRIPTION DRUG ABUSE CRISIS, EXECUTIVE OFFICE OF THE PRESIDENT OF THE UNITED STATES 2, 3 (2011) (suggesting amending federal laws to require certain training on opioid prescribing practices for all prescribers).

19. See *infra* Parts III, IV.A (discussing states' plenary police powers and federal authority under the Commerce Clause).

comprehensive, effective solution: the Controlled Substances Act (CSA)<sup>20</sup> must require prescribers to obtain education and training on safe prescribing and abuse prevention methods before they may register to prescribe controlled substances.<sup>21</sup> By establishing mandatory education for every controlled substance prescriber nationwide pursuant to the CSA, the federal government is not encroaching on states' plenary police power because such action is authorized under the Commerce Clause of the United States Constitution.<sup>22</sup>

Part II of this Article discusses changes in prescribing practices and the need to educate prescribers, the gatekeepers of the supply of controlled substances. Part III discusses states' authority to regulate the practice of medicine, providing an overview of states' plenary police power.<sup>23</sup> Part IV discusses federal authority to regulate controlled substances. This includes an overview of the Commerce Clause, an overview of the CSA, and relevant case law that establishes the federal government's authority to mandate prescriber education pursuant to the Commerce Clause. Part V looks at other attempts to impose a prescriber education requirement. Part VI proposes how such an education requirement should work and uses Massachusetts and Virginia as models to show how a prescriber education mandate would fit into current state systems. Part VII discusses how the prescriber requirement will empower health care providers to prescribe appropriately, improve patient treatment, and reduce liability. This national effort will be successful because it will reach all controlled substance prescribers, and because it provides a way for the federal government to enhance its regulation of commerce without encroaching on states' plenary police powers.

## II. INTERRUPTING SUPPLY BY EDUCATING PRESCRIBERS

Over the past two decades, prescribers have generally been more willing to treat patients using controlled substances.<sup>24</sup> Given the current prescription drug abuse epidemic, prescribers must be more cautious in treating people with pain and other conditions for which controlled substances may be prescribed.<sup>25</sup> This Part

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20. 21 U.S.C. §§ 801–971 (2011) (controlling the manufacture and distribution of controlled substances); *see infra* Part IV.A.1 (describing the current application of the CSA).

21. *See infra* Parts VI, VII.

22. *See infra* Part III.C (discussing the judicial decisions on the Commerce Clause and the states' plenary power).

23. *See infra* Part III; *see also* *United States v. Lopez*, 514 U.S. 549, 566 (1995) (referencing Art. I, § 8 of the U.S. Constitution, which lists the powers of Congress, and therefore withholds from Congress and reserves for the states “a plenary police power that would [if not withheld from Congress] authorize enactment of every type of legislation”).

24. *See* Barry Meier, *Tightening the Lid on Pain Prescriptions*, N.Y. TIMES, Apr. 9, 2012, at A1 (discussing the recent increase in prescription of controlled substances, such as opioids, despite limited evidence on their effectiveness).

25. *See* Laxmaiah Manchikanti, *Prescription Drug Abuse: What is Being Done to Address This New Drug Epidemic? Testimony Before the Subcommittee on Criminal Justice, Drug Policy and Human*

discusses those changes in controlled substance prescribing, highlights the problem of practitioners receiving inadequate training on how to safely prescribe, and establishes the need for an education requirement.

#### A. Changes in Prescribing Opioids

Opioid medications relieve pain by reducing the effects of a painful stimulus in the part of the brain that feels emotions.<sup>26</sup> Until about fifteen years ago, opioids were routinely prescribed only for end-of-life care, for cancer, and after surgery.<sup>27</sup> Since then, pain care experts and organizations at the state and national level began emphasizing the importance of pain management.<sup>28</sup> These experts and organizations have made a case for using opioids to also treat chronic pain because some patients experience a reduction in pain with long-term opioid use.<sup>29</sup> Although many health care professionals now prescribe opioids to treat chronic pain, studies suggest that physicians may prescribe opioids too quickly, that opioids may ultimately be ineffective for chronic pain, and that such medication may pose serious health risks.<sup>30</sup> For instance, researchers have linked opioid use to increased sensitivity to pain, negative immune effects, sleep apnea, suppression of sexual hormone production, increased elderly falls and hip fractures, and overdose deaths.<sup>31</sup> Additionally, opioids can be addictive and can lead to psychological dependence,<sup>32</sup> leading many pain-care physicians to question the legitimacy of opioid use for treatment of chronic pain.<sup>33</sup> In fact, medical journals report that

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*Resources*, 9 PAIN PHYSICIAN 287, 306 (2006) (illustrating the need for physicians to carefully consider risks in prescribing certain pain medication).

26. See NAT'L INST. ON DRUG ABUSE, NIH PUB. NO. 11-4881, PRESCRIPTION DRUGS: ABUSE AND ADDICTION 2 (2011), available at <http://www.drugabuse.gov/sites/default/files/rprescription.pdf> (describing the way opioids affect the brain as pain relievers).

27. See Meier, *supra* note 24; Diane E. Hoffmann & Anita J. Tarzian, *Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards*, 31 J.L. MED. & ETHICS 21, 21 (2003) (discussing the evolution of treating pain with opioids).

28. See Meier, *supra* note 24 (discussing state and federal efforts to make opioid use safer). In 2001, at the national level, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the "Joint Commission" promulgated mandatory "unproven" pain management guidelines. See Manchikanti, *supra* note 15, at 409 (suggesting that combined factors, including support for pain management requirements from national organizations and state medical boards, as well as advances in science have led to a push for more prescribing).

29. See Manchikanti, *supra* note 15, at 409 (noting the widespread push to use opioids for chronic pain).

30. See Paulozzi et al., *supra* note 2, at 11 (discussing a study finding that opioids did not provide meaningful health benefits among injured workers); Jon Coppelman, *Opioid Catastrophe: The Data Leads to Doctors*, WORKERS' COMP INSIDER (Mar. 4, 2013, 1:30 PM), <http://www.workerscompinsider.com/2013/03/opioid-catatrop.html> (calling data on prescribed opioid use and effects among injured workers "alarming").

31. See Meier, *supra* note 24; Manchikanti, *supra* note 15, at 409–10.

32. See Meier, *supra* note 24.

33. See PHYSICIANS FOR RESPONSIBLE OPIOID PRESCRIBING, CAUTIOUS, EVIDENCE-BASED OPIOID PRESCRIBING 1–3 (2012), available at [http://www.supportprop.org/educational/PROP\\_Opioid](http://www.supportprop.org/educational/PROP_Opioid)

between four percent and twenty-six percent of those who take opioids for long-term pain treatment become addicted.<sup>34</sup>

Prompted by recent investigative journalism revealing strong ties between pharmaceutical companies and both medical professionals and organizations that have promoted expanded uses of opioids for pain treatment,<sup>35</sup> in May 2012, the U.S. Senate Finance Committee began an investigation into ties between industry funding and the groups backing the increased prescribing of opioid pain relievers.<sup>36</sup> The investigative reporting, Senate inquiries, and other recent events suggest that prescribing standards may be in flux. As such, there is a need to properly educate and train physicians on how to properly prescribe controlled substances.

### *B. The Need to Educate Prescribers*

Practitioners are gatekeepers to the supply of prescription medications, including controlled substances.<sup>37</sup> Both legitimate and illicit users cannot gain access to these medications until practitioners write prescriptions.<sup>38</sup> Consequently, approximately ninety-five percent of the supply for non-medical users comes from prescribers.<sup>39</sup> Yet, studies show that physicians typically receive little to no education or training in medical school on how to create proper pain management treatment plans, and on how to recognize signs of prescription drug diversion, misuse, and abuse.<sup>40</sup> Although many general practitioners prescribe controlled

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Prescribing.pdf (describing the lack of evidence on long-term efficacy of opioid treatment and how it contributes to physicians' reluctance to prescribe opioid treatment).

34. *Id.*

35. See Charles Ornstein & Tracy Weber, *The Champion of Painkillers*, PROPUBLICA (Dec. 23, 2011, 2:15 PM), <http://www.propublica.org/article/the-champion-of-painkillers> (describing the ties between pharmaceutical companies and medical professionals and organizations).

36. Press Release, Comm. on Finance, U.S. Senate, Baucus, Grassley Seek Answers about Opioid Manufacturers' Ties to Medical Groups (May 8, 2012), available at <http://www.finance.senate.gov/newsroom/chairman/release/?id=021c94cd-b93e-4e4e-bcf4-7f4b9fae0047>.

37. See Manuel Vallée, *Bypassing the Gatekeepers: Selling Prescription Drugs Directly to Consumers* 5 (Ctr. For Culture, Org., and Politics, Working Paper No. 2008-03, 2008), available at <http://www.irl.berkeley.edu/culture/papers/Vallee08.pdf>.

38. 21 U.S.C. § 829 (2011).

39. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 1 (noting that 1.9% of nonmedical users got their drugs from "a drug dealer or other stranger" while 0.3% purchased the drugs on the Internet). Approximately fifty-four percent of prescription pain drug abusers obtained the drug from a friend or relative, and the friend or relative presumably obtained the drug through a valid prescription. *Id.* Another 18.1% of non-medical users obtained their prescriptions from one physician. *Id.*

40. A national survey of residency programs in 2000 found that fifty-six percent of medical residency programs required substance use disorder training, ranging from three to twelve hours. OFFICE OF NAT'L DRUG CONTROL POL'Y, *supra* note 18, at 3. See also Diane E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y 231, 285 (2008) (noting that a study found that physicians only correctly identified ten percent of patients who were pretending to be patients to obtain opioid prescriptions in the study setting).

substances, typically only practitioners who specialize in addiction treatment and other similar specialties receive training in opioid prescribing and substance abuse prevention and detection.<sup>41</sup>

Medical malpractice decisions are often conditioned on the practitioner's adherence or non-adherence to common law standards of care and treatment guidelines.<sup>42</sup> Prescribers may oppose mandatory training requirements or guidelines for fear of the threat of malpractice liability that may result from failing to adhere to such standards and guidelines.<sup>43</sup> Furthermore, they may perceive legal rules and guidelines as a threat to their ability to use professional discretion.<sup>44</sup> However, such fear shows an even greater need for in-depth education, not only on how to properly prescribe controlled substances, but on the realistic repercussions that practitioners may face for improperly prescribing.

Even though practitioners may find it unfavorable, mandatory education and training for all who prescribe controlled substances is vital. Practitioners set the standard of care in their field because the test for liability looks to, among other facts, whether a practitioner followed an objectively reasonable standard of care in the community at issue.<sup>45</sup> With millions of Americans reporting chronic pain and use of prescribed controlled substances,<sup>46</sup> and approximately 15,000 deaths

41. OFFICE OF NAT'L DRUG CONTROL POL'Y, *supra* note 18, at 2–3.

42. See Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 660, 667 (2001) (noting that many states use custom as the standard of care for medical malpractice cases and discussing the use of practice guidelines in medical malpractice litigation).

43. See Sandra H. Johnson, *Regulating Physician Behavior: Taking Doctors' "Bad Law" Claims Seriously*, 53 ST. LOUIS U. L.J. 973, 1001–03 (2009) (suggesting that alleged malpractice, even if a physician is later exonerated, can chill prescribing); Hoffmann & Tarzian, *supra* note 27, at 21. Courts usually use a four-pronged test, where following a reasonable standard of care is part of the duty and breach of duty elements. See, e.g., *Conrad-Hutsell v. Colturi*, No. L-01-1227, 2002 WL 1290844, at \*2, \*1 (Ohio Ct. App. May 24, 2003) (using a medical malpractice test comprised of 1) duty, 2) breach of duty, 3) proximate cause; and 4) damages); *McCarroll v. Reed*, 679 P.2d 851, 854 (Okla. Civ. App. 1983) (using a medical malpractice test of duty, including the physician's obligation to use reasonable professional care and skill, breach of duty, and injury caused by the breach).

44. See Johnson, *supra* note 43, at 974–75 (arguing that some laws intended to help patients may actually have the effect of harming patients by negatively impacting medical decision making).

45. Complying with the objective standard of care in the medical community in which the practitioner practices is important to assessing reasonableness, and therefore, non-negligence. See C. Jerry Willis, *Establishing Standards of Care: Locality Rules or National Standards*, AAOS NOW (Feb. 2009), [http://www6.aaos.org/news/PDFopen/PDFopen.cfm?page\\_url=http://www.aaos.org/news/aaosnow/feb09/managing9.asp](http://www6.aaos.org/news/PDFopen/PDFopen.cfm?page_url=http://www.aaos.org/news/aaosnow/feb09/managing9.asp) (explaining that twenty-nine states and Washington, D.C., use a national standard of care, while twenty-one states use a locality standard of care). Compare *State Bd. of Med. Examiners v. McCroskey*, 880 P.2d 1188, 1194–95 (Colo. 1994) (applying a generally accepted, objectively reasonable standard of care and rejecting the prior determinations of standard of care based on prevailing practices in the defendant physician's community), with *Schaefer v. Larsen*, 688 S.W.2d 430, 432 (Tenn. Ct. App. 1984) (explaining that the standard of care is defined relative to the standard accepted by physicians in the community in which the defendant physician practices or by those in a similar community).

46. See generally INST. OF MED., *supra* note 10 (explaining that pain is a public health crisis and exploring the patient care, education, and research challenges of pain treatment).

resulting from opioid abuse per year,<sup>47</sup> now, more than ever, physicians need education on standards of care in controlled substance prescribing. Mandatory education will equip good-intentioned prescribers with the knowledge to properly treat patients while recognizing and preventing diversion, misuse, and abuse.<sup>48</sup>

Practitioners can be held criminally or civilly liable if they fail to properly exercise a reasonable standard of care.<sup>49</sup> To meet the standard of care, practitioners must possess a “reasonable degree of learning and skill which is ordinarily possessed by others of the profession.”<sup>50</sup> Reasonable care includes maintaining a familiarity with appropriate treatment standards articulated by laws and guidelines,<sup>51</sup> properly assessing a patient’s medical history,<sup>52</sup> especially when prescribing controlled substances,<sup>53</sup> which are riskier by definition;<sup>54</sup> and prescribing medications appropriately.<sup>55</sup> Courts look to practice guidelines, expert

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47. See Warner et al., *supra* note 4, at 5.

48. See *infra* Part VI (proposing an education requirement and using Massachusetts and Virginia as models).

49. PETER P. BUDETTI & TERESA M. WATERS, KAISER FAM. FOUND., MEDICAL MALPRACTICE LAW IN THE UNITED STATES 1–4 (2005), available at <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/medical-malpractice-law-in-the-united-states-report.pdf> (explaining that state statutes and tort law govern medical malpractice cases); see also Maia Szalavitz, *Perspective: Why Did Conrad Murray Just Get Four Years in Jackson’s Death?*, TIME (Nov. 30, 2011), <http://healthland.time.com/2011/11/30/perspective-why-did-conrad-murray-get-just-four-years-in-jacksons-death/> (comparing Dr. Murray’s criminal sentence of four years for involuntary manslaughter due to his role in Michael Jackson’s death with the twenty-five to thirty-year criminal sentences two physicians faced for drug dealing charges related to prescribing medications to patients who lied about their pain).

50. *Artist v. Butterweck*, 426 P.2d 559, 561 (Colo. 1967).

51. See *Moss v. Taglieri*, 842 A.2d 280 (N.J. Super. Ct. App. Div. 2004) (holding that a physician violated the appropriate standard of care by knowingly prescribing medication doses well above the limits allowed under regulations promulgated under the New Jersey Controlled Dangerous Substances Act); Hoffmann & Tarzian, *supra* note 27, at 26 (reporting the results of a 2001 survey of state medical boards finding that the majority of boards would investigate a practitioner who failed to prescribe medications according to state guidelines).

52. See *Watkins v. United States*, 589 F.2d 214, 219 (5th Cir. 1979) (affirming a decision finding a physician negligent for failing to conduct a full medical history in prescribing Valium to treat insomnia and mild anxiety); *Conrad-Hutsell v. Colturi*, No. L-01-1227, 2002 WL 1290844, at \*1, \*6 (Ohio Ct. App. May 24, 2003) (discussing charges against a physician accused of negligence for prescribing narcotics to a patient suffering from Crohn’s disease without seeking a complete medical history).

53. See *Osborne v. United States*, 166 F. Supp. 2d 479, 498–99 (S.D.W. Va. 2001) (explaining that the physicians in that case should not have continued prescribing potentially addictive medications to a patient with a known history of substance abuse).

54. See Controlled Substance Act, 21 U.S.C. § 801(2) (2011) (suggesting that, if unregulated, the use of controlled substances could have a “substantial and detrimental effect on the health and general welfare of the American people”).

55. *Conrad-Hutsell*, 2002 WL 1290844, at \*6 (listing duties required of all physicians when prescribing narcotics, including an inquiry into whether the practitioner was aware of the characteristics of the drug; knew the patient’s medical history and current condition; warned the patient of risk and side effects of the drug; and prescribed drugs in the correct dose, for correct durations, and administered the drug properly; and monitored the patient); see also *Ballenger v. Crowell*, 247 S.E.2d 287, 293–95 (N.C. Ct. App. 1978) (discussing negligence claims against a physician whose patient became strongly



opinion,<sup>56</sup> state laws and regulations,<sup>57</sup> and medical drug reference books<sup>58</sup> to determine whether a practitioner's treatment is in accordance with the standard of care. Therefore, prescribers must obtain a proper education and training on prescribing guidelines, laws, and standards.

Without the proper education and training, practitioners are more likely to breach the standard of care because they are not fully aware of the duties imposed up on them. They are more likely to improperly prescribe medications, which can result in diversion, misuse, and abuse, and also result in actions against the practitioner for medical malpractice or criminal liability.<sup>59</sup>

With the proper training and education, practitioners can improve their controlled substance prescribing behaviors, protect patients and communities, and avoid liability. As such, mandatory prescriber education is necessary. Yet, advocates of prescriber education must also get over the hurdle of proving that such a requirement under the CSA does not encroach on states' plenary police power—a hurdle that this Article establishes can be overcome.

### III. STATE AUTHORITY TO REGULATE THE PRACTICE OF MEDICINE

Controlled substances are regulated, both at the federal level through the CSA<sup>60</sup> and at the state level through state controlled substances acts, which can lead to differences in regulation from state to state.<sup>61</sup> Regulating the use of controlled substances is arguably activity that falls under states' plenary police power because it pertains to states' rights to regulate the health, safety, and welfare of their

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addicted to prescription drugs after relying on the physician's advice that the patient would always have to take such medication to treat a neurological condition).

56. See LAUREN KROHN, CAUSE OF ACTION AGAINST PHYSICIAN FOR NEGLIGENCE IN PRESCRIBING DRUGS OR MEDICINES, 9 CAUSES OF ACTION § 25 (2013) (stating that it is generally necessary for litigants to provide expert testimony in assisting the trial court in its determination of whether care was appropriate in medical malpractice cases).

57. See *infra* note 40 and accompanying text (discussing state laws and regulations of controlled substances).

58. See *Roland v. Tedesco*, 616 So. 2d 780, 785 (La. Ct. App. 1993) (using the physician's reference to the *Manual of Medical Therapeutics* and other medical literature during the patient's two-hour visit to the emergency room as evidence of the appropriateness of care); *Taglieri v. Moss*, 842 A.2d 280, 283 n.8 (N.J. Super. Ct. App. Div. 2004) (citing the *Physicians' Desk Reference* for an explanation of the drugs Percocet and Tylox); *Osborne v. United States*, 166 F. Supp. 2d 479, 498–99 (S.D.W. Va. 2001) (referring to the *Physicians' Desk Reference* to conclude that the physician should not have continued to prescribe addictive controlled substances to his patient who had a known history of substance abuse).

59. See David B. Brushwood et al., *Balance and the adoption of Abuse-Deterrent Opioid Formulations in Pain Management Practice*, 1 U. INCARNATE WORD PHARMACY REV. (2012), available at <http://uiwpharmacyreview.com/index.php/uiwpr/article/view/11/33> (noting that if patients are harmed health care practitioners face the possibility of civil liability lawsuits or criminal charges).

60. 21 U.S.C. §§ 801–971 (2011).

61. See Hoffmann, *supra* note 40, at 274 n.322 (stating that almost every state has a controlled substance statute similar to the CSA).

citizens.<sup>62</sup> Therefore, it would appear that a conflict exists between states' rights and the purview of the federal government. To understand this conflict, it is important to understand states' rights first. This Part provides an overview of constitutional doctrine of states' plenary police power.

Under the Tenth Amendment of the U.S. Constitution, powers not specifically granted to the federal government or prohibited to the states are reserved to the states.<sup>63</sup> States have an inherent authority to impose regulations on the private rights of their citizens in order to protect their citizens' health, safety, and welfare.<sup>64</sup> This authority is referred to as "state plenary police power."<sup>65</sup>

The authority to regulate the practice of medicine, in particular, falls under the purview of states' plenary police power rather than under the authority of the federal government.<sup>66</sup> For example, in *State v. Gee*, William R. Gee was an aspiring chiropractor in Arizona who practiced chiropractic science without first complying with the requirements under state law.<sup>67</sup> In order to practice, Mr. Gee needed a certificate in basic sciences and a license from the State Board of Chiropractic Examiners.<sup>68</sup> Of note, Mr. Gee claimed that the technical requirements prescribed by the Arizona Basic Science Act were unconstitutional because they violated the due process clauses of the Fourteenth Amendment of the U.S. Constitution and the Constitution of Arizona.<sup>69</sup> He took issue with the vagueness of the term "practice of healing" in the Act, and the discretion given to the State Board of Examiners in determining who passed the exam.<sup>70</sup> The United States Supreme Court ruled in favor of the state, concluding that it is unquestioned that the state legislature "has the power and duty to control and regulate such professions and practices affecting the public health and welfare."<sup>71</sup> The Court established that states regulate the practice of health care professions under their plenary police powers.<sup>72</sup>

#### IV. FEDERAL AUTHORITY TO REGULATE CONTROLLED SUBSTANCES

Although states have the authority to regulate the practice of medicine, the federal government has concurrent authority to regulate some aspects of the

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62. See *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1954) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power. The state's discretion in that field extends naturally to the regulation of all professions concerned with health.").

63. U.S. CONST. amend. X.

64. See *United States v. E. C. Knight Co.*, 156 U.S. 1, 11 (1895) (noting state authority "to protect the lives, health, and property of its citizens, and to preserve good order and the public morals").

65. *United States v. Lopez*, 514 U.S. 549, 566 (1995).

66. *Barsky*, 347 U.S. at 449.

67. 236 P.2d 1029, 1030 (Ariz. 1951).

68. *Id.*

69. *Id.* at 1032–33.

70. *Id.*

71. *Id.* at 1033.

72. *Id.*

practice of medicine as well; the federal government derives this power from the Commerce Clause.<sup>73</sup> This Part provides an overview of the Commerce Clause and discusses how the federal government derives its authority to regulate controlled substances pursuant to the Controlled Substances Act and its relevant case law. It also discusses recent restrictions and their practical impact on the CSA.

*A. The Controlled Substances Act and Federal Authority Under the Commerce Clause*

Before discussing the Commerce Clause, it is important to have an understanding of what the CSA entails.

*1. The Controlled Substances Act*

In 1970, Congress enacted the Controlled Substances Act (CSA), a federal law controlling the manufacture and distribution of controlled substances.<sup>74</sup> It requires adherence to registration, storage, and record-keeping requirements for those who manufacture, distribute, dispense, import, or export controlled substances.<sup>75</sup> The CSA attempts to ensure that records are kept of the handling of controlled substances as they move down the supply chain from the manufacturer to the end user.<sup>76</sup>

In 1973, Congress created the Drug Enforcement Administration (DEA) under the CSA, and gave the agency the authority to schedule and regulate controlled substances.<sup>77</sup> Under the CSA, the DEA is responsible for preventing, detecting, and investigating diversion of controlled substances while ensuring the availability of these drugs for legitimate use.<sup>78</sup> The Act classifies controlled substances using five schedules based on each drug's medical uses and potential for abuse.<sup>79</sup> The most dangerous controlled substances, such as heroin and synthetic "bath salts," are classified in Schedule I.<sup>80</sup> Schedule I substances cannot be prescribed under the CSA because, by definition, they have no accepted medical use.<sup>81</sup> Schedules II through V regulate drugs with medical uses that also have the potential for abuse.<sup>82</sup>

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73. U.S. Const. art. I, § 8, cl. 3.

74. 21 U.S.C. §§ 801–852 (2011).

75. *Id.*

76. *See United States v. Rosenberg*, 515 F.2d 190, 193 (9th Cir. 1975) (explaining that the CSA's record system was intended to monitor the distribution of drugs).

77. Reorganization Plan No. 2 of 1973, 3 C.F.R. 785 (1971–1975), *reprinted in* 21 U.S.C. 801 (2011).

78. DEP'T OF JUSTICE, <http://www.justice.gov/jmd/mps/manual/dea.htm> (last visited May 8, 2013) (discussing the DEA's mission).

79. 21 U.S.C. § 812 (2011).

80. § 812(c).

81. § 812(b)(1).

82. § 812(b)(2)–(5).

Prescribers licensed to practice in a state must register with the DEA every three years in order to prescribe controlled substances in Schedules II through V.<sup>83</sup> When prescribing controlled substances, registered practitioners must follow the prescription-writing,<sup>84</sup> order form,<sup>85</sup> and record-keeping<sup>86</sup> provisions of the CSA or face penalties.<sup>87</sup> Regulations under the CSA require that a controlled substance prescription be dated and signed as of the date of issue.<sup>88</sup> The prescription must include the patient's and practitioner's names and addresses; the practitioner's DEA registration number; the drug's name, strength, and dosage form; the quantity prescribed; the directions for use; and the number of refills.<sup>89</sup>

In addition to civil and criminal liability at common law, under the CSA, practitioners face criminal charges, including fines, revocation of licenses to practice medicine, and imprisonment, for improperly prescribing controlled substances.<sup>90</sup> In order to avoid penalties, "a prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."<sup>91</sup> When a practitioner commits a violation, the DEA can prosecute the practitioner under the CSA, or the practitioner may be prosecuted under state laws.<sup>92</sup> Tension exists between medical practitioners and federal drug enforcement efforts because health care practitioners see DEA interventions as a threat to their autonomy to practice medicine in a way that best serves their patients.<sup>93</sup>

Since the creation of the federal prescriber registration requirement,<sup>94</sup> the government's commerce power has expanded.<sup>95</sup> During the expansion, petitioners

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83. § 823(g).

84. § 829.

85. § 828.

86. § 827.

87. See OFFICE OF DIVERSION CONTROL, U.S. DEP'T OF JUSTICE, PRACTITIONER'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT 18-22 (2006), available at [http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract\\_manual012508.pdf](http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf).

88. *Id.*

89. *Id.*

90. 21 U.S.C. §§ 824, 841, 960, 962 (2011) (describing the penalties practitioners face for improperly prescribing controlled substances).

91. 21 C.F.R. § 1306.04(a) (2005).

92. See *supra* note 49; Hoffmann, *supra* note 40, at 274 n.322.

93. See Hoffmann, *supra* note 40, at 256-57 (describing the rift between practitioners and the government due to differing views on opioids and narcotics).

94. The controlled substance prescriber registration requirement originated under the Harrison Act, which required manufacturers and distributors of narcotics to register with a local internal revenue officer in order to control taxation of these substances. Harrison Narcotics Act, ch. 1, 38 Stat. 785 (1914), amended by the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970).

95. See ERWIN CHERMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES 269 (4th ed. 2011) (stating that between 1936 and 1995, the Supreme Court did not invalidate a single federal law under the Commerce Clause and that, additionally, the Court has rejected recent Commerce Clause challenges to federal statutes).

seized the opportunity to challenge the CSA's provisions that allow the federal government to regulate medications in commerce.<sup>96</sup> However, the Supreme Court has solidified the DEA's authority under the CSA to regulate controlled substances in the stream of commerce.<sup>97</sup> Even those who believe that the expansion of Commerce Clause has gone too far can find that the federal government has the authority to mandate a prescriber education requirement under the CSA.

## 2. *The Commerce Clause*

The U.S. Constitution authorized Congress “[t]o regulate commerce with foreign nations, and among the several states, and with the Indian tribes.”<sup>98</sup> Courts have interpreted this to mean that Congress may regulate 1) the channels of interstate commerce; 2) the instrumentalities of interstate commerce, including persons and things in interstate commerce; and 3) economic activities that have a substantial effect on interstate commerce.<sup>99</sup> Other iterations of the Commerce Clause test have been used since the first Supreme Court Commerce Clause case, *Gibbons v. Ogden*, in 1824.<sup>100</sup> Beginning with the third prong of the test and moving in descending order, this section analyzes how the prescriber education requirement is compatible with Congress's Commerce Clause power under all prongs of the test used since 1971.

In the seminal case *Gonzales v. Raich*, the Supreme Court specifically upheld section 801 of the CSA.<sup>101</sup> This section states that intrastate distribution of controlled substances impacts interstate flow of controlled substances, and therefore, the federal government has the authority to regulate intrastate flow of controlled substances.<sup>102</sup> *Raich* dealt with California's Compassionate Use Act, which allowed individuals with serious medical conditions to use marijuana to treat that condition upon a physician's determination that such treatment is

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96. See, e.g., *United States v. Rosenberg*, 515 F.2d 190, 196–200 (9th Cir. 1975) (stating that petitioner had several arguments, including that the CSA violated the Tenth Amendment); *United States v. Collier*, 478 F.2d 268, 272 (5th Cir. 1973) (stating that petitioner argued that the CSA improperly encroached upon the states' police powers under the Tenth Amendment).

97. See *infra* Part IV.A.2.

98. U.S. CONST. art. I, § 8, cl. 3.

99. See *Gonzales v. Raich*, 545 U.S. 1, 16–17 (2005) (articulating the three categories of activity that Congress may regulate pursuant to its Commerce Clause powers). The Commerce Clause test used in *Raich* was first articulated in *Perez v. United States*, 402 U.S. 146, 150 (1971).

100. 22 U.S. (9 Wheat.) 1 (1824). In *Gibbons*, the Court decided that the federal right to operate a ferry under federal law trumped a New York state ferry boat law. *Id.* at 239–40. The Court interpreted “among the several states” to mean that Congress can regulate intrastate waterways that have interstate effects, and that *commerce* includes intercourse between parts of nations, not just exchange of commodities. *Id.* at 194–95, 229–30.

101. 545 U.S. at 22.

102. See 21 U.S.C. § 801 (2011); see also 545 U.S. 21 n.32, 22 (discussing Congress's findings regarding the interstate effects of intrastate commerce).

appropriate.<sup>103</sup> Yet, the CSA classifies marijuana as a Schedule I controlled substance, meaning that it has no legally recognized medical function and that physicians are not allowed to prescribe it.<sup>104</sup> Per her physician's instructions, Angel Raich grew marijuana at home to treat the effects of an inoperable brain tumor, such as severe seizures and multiple chemical sensitivities, among other things.<sup>105</sup> The DEA took the opportunity to challenge the Compassionate Use Act by seizing the doctor-prescribed marijuana from Raich's home.<sup>106</sup>

The government argued that consuming locally grown marijuana for medical purposes affects the interstate market of marijuana, and therefore, the federal government may regulate it.<sup>107</sup> The Supreme Court articulated the Commerce Clause test, which empowers Congress to regulate the channels, instrumentalities, and activities with substantial effects on interstate commerce.<sup>108</sup> Although the home-grown marijuana was grown and used intrastate, it was a fungible product indistinguishable from marijuana that illicitly passed through commerce, and it could have moved into the national market.<sup>109</sup> Therefore, it fell under the third prong of the test, which allows the federal government to regulate activities with a substantial effect on interstate commerce, and as such, the Court ruled the federal government could regulate growing medical marijuana because this activity has substantial effects on interstate commerce.<sup>110</sup>

The federal government can also regulate prescription controlled substances under the second prong of the Commerce Clause test because these drugs are "things" in interstate commerce.<sup>111</sup> In a 1969 case, *Daniel v. Paul*, the Supreme Court determined that the federal government could regulate a recreational facility in Arkansas pursuant to the Commerce Clause because three out of four items sold at the facility's snack bar traveled in interstate commerce.<sup>112</sup> The Court established that food is a "thing" in commerce by showing that the "principal ingredients going into the bread [as well as certain ingredients in the soft drinks] were produced and

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103. Compassionate Use Act of 1996, CAL. HEALTH & SAFETY CODE § 11362.5(b)(1)(A) (West 2012).

104. 21 U.S.C. § 812(b)(1) (2011).

105. *Raich*, 545 U.S. at 6–7; Brief for Respondents at \*4, *Raich*, 545 U.S. 1 (No. 03-1454) (citing statement of Frank Henry Lucido, M.D.).

106. *Raich*, 545 U.S. at 7.

107. *See id.* at 20.

108. *Id.* at 16–17.

109. *See id.* at 22 (finding that Congress was "well within its authority" to regulate intrastate marijuana as a "fungible commodity"); *id.* at 40 (Scalia, J., concurring) (explaining how drugs like marijuana are fungible commodities).

110. *See id.* at 20–22 (majority opinion).

111. *See id.* at 16–17, 26 (describing the second prong of the Commerce Clause and explaining how the CSA is within Congress's powers). Controlled substances contain components shipped in interstate commerce or are themselves shipped in interstate commerce. *See id.* at 50 (O'Connor, J., dissenting) (asserting that most substances regulated under the CSA, unlike marijuana, require elements traveling in interstate commerce).

112. 395 U.S. 298, 300, 305 (1969).

processed in other States.”<sup>113</sup> The facility’s snack bar sold hot dogs with buns, hamburgers with buns, soft drinks, and milk, and so a “substantial portion of the food served in the snack bar [had] moved in interstate commerce.”<sup>114</sup> Therefore, the snack bar food items were items in interstate commerce, and the lake facility that sold them could be regulated under Congress’s commerce power in conjunction with the Civil Rights Act of 1964.<sup>115</sup>

Again, in *United States v. Sullivan*, Congress found that “things” that had traveled within commerce could be regulated by the commerce power.<sup>116</sup> In this case, which was tried under the Federal Food, Drug and Cosmetic Act, Jordan James Sullivan, a retail druggist, appealed misbranding charges that resulted when he moved sulfathiazole tablets from a properly labeled container to containers without proper instructions for use.<sup>117</sup> At issue was whether the federal government could regulate the drugs under the Commerce Clause if the drugs’ manufacturers had previously shipped the drugs in interstate commerce, even though Dr. Sullivan only held them for intrastate sale.<sup>118</sup> The Court found that, because the drugs had previously traveled across state lines, they were considered “things” in interstate commerce under the commerce power,<sup>119</sup> and therefore, the Court found Dr. Sullivan guilty of misbranding under federal law, even though the drugs were held only for local, intrastate sale.<sup>120</sup>

The proposed CSA Amendment requiring prescriber education is valid under all three prongs of the Commerce Clause test. First, the federal government can mandate a prescriber education requirement under the third prong of the Commerce Clause, as in *Raich*.<sup>121</sup> Practitioners, as gatekeepers along the supply chain of prescription controlled substances, are engaging in an activity that could have a significant impact on commerce. Like the marijuana in *Raich* that could travel interstate after it was grown, controlled medications can move interstate after being prescribed within a state.<sup>122</sup> With the proper education, physicians may change their

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113. *Id.* (quoting the decision of the District Court below).

114. *Id.* (internal quotation marks omitted).

115. *Id.*

116. *United States v. Sullivan*, 332 U.S. 689, 697 (1948).

117. *Id.* at 690–92.

118. *Id.* at 692.

119. *Id.* at 697.

120. *Id.* at 697–98. The Court noted Congress’s power “under the commerce clause to regulate the branding of articles that have completed an interstate shipment and are being held for future sales in purely local or intrastate commerce.” *Id.* at 698.

121. *Gonzales v. Raich*, 545 U.S. 1, 25 (2005) (quoting *United States v. Morrison*, 529 U.S. 598, 610 (2000) (“Where economic activity substantially affects interstate commerce, legislation regulating that activity will be sustained.”)).

122. *See* 21 U.S.C. § 801(4) (2011) (finding that local disbursement or possession of controlled substances contributes to growth in the interstate traffic for such substances).

prescribing habits, either prescribing more or fewer controlled substances.<sup>123</sup> Therefore, given the prescribers' substantial effects on commerce, Congress may require that practitioners engage in mandatory training under the third prong of the Commerce Clause test.<sup>124</sup>

Second, the federal government derives authority to issue a prescriber education requirement through the second prong of the Commerce Clause test.<sup>125</sup> Almost every controlled substance contains ingredients that move in interstate commerce, similar to the snack bar ingredients in *Paul*.<sup>126</sup> And, almost every controlled substance is shipped through interstate commerce at some point before use, similar to the medication in *Sullivan*.<sup>127</sup> Therefore, like the food products sold in *Paul* and the medications held for local sale in *Sullivan*, controlled substances are things of interstate commerce that may be regulated under the second prong of the Commerce Clause test.<sup>128</sup> As Justice Scalia stated in *Raich*, it is "self-evident" that items falling under the channels or instrumentalities of interstate commerce prongs fall under the commerce test because they are the "ingredients of interstate commerce itself."<sup>129</sup>

Third, the federal government can obtain authority to mandate a prescriber education requirement to regulate the gatekeepers of the supply of controlled substances through the first prong of the Commerce Clause test that provides the power to regulate the channels of interstate commerce.<sup>130</sup> In *Heart of Atlanta Motel*

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123. See, e.g., Michael E. Pichichero, *Physician Education Intervention Influenced Prescribing for Otitis Media*, 8 J. MANAGED CARE PHARMACY 141, 144 (2005) (finding that after attending a continuing medical education program, physicians significantly decreased inappropriate antibiotic prescribing for a certain type of ear infection).

124. See, e.g., *Wickard v. Filburn*, 317 U.S. 111, 125 (1942) (stating that although the wheat at issue was intended for private consumption, Congress may still exert power on activities not naturally regarded as regulating commerce if the activities have a substantial effect on interstate commerce); see also 21 U.S.C. § 871(a)(1) (2011) (authorizing the Attorney General to carry out educational and training programs concerning drug abuse); *Raich*, 545 U.S. at 17 (highlighting the third prong of the Commerce Clause test).

125. See, e.g., *Daniel v. Paul*, 395 U.S. 298, 305 (1969) (determining in that case that the Commerce Clause is applicable because most of the snack bar food items contains elements that travelled interstate); see also § 871(a)(1); *Raich*, 545 U.S. at 16–17 (noting that under the second prong, Congress has authority to regulate and protect the instrumentalities of interstate commerce).

126. See 21 U.S.C. § 801(3) (2011) (acknowledging that controlled substances have a significant effect on interstate commerce because many of the substances are transported in interstate commerce after manufacture even if they are only intended for local distribution); *Paul*, 395 U.S. at 305 (finding that three out of the four sold snack food items contained ingredients that originated outside the state).

127. See § 801(3)(B) (noting that even locally dispensed controlled substances are typically transported in interstate commerce immediately prior to the disbursement); *United States v. Sullivan*, 332 U.S. 689, 698 (1948) (determining that Congress may regulate the branding of medication that has completed an interstate shipment where it is being held for local distribution or intrastate commerce).

128. See *supra* notes 125–27 and accompanying text.

129. *Raich*, 545 U.S. at 34 (Scalia, J., concurring).

130. See 21 U.S.C. § 871(a)(1) (2011); *id.* at 12–13 (noting that Congress intended to prevent drugs from entering illicit channels of commerce by enacting the CSA); see also *Caminetti v. United States*,



*v. United States*, the Supreme Court upheld the constitutionality of the Title II of the Civil Rights Act of 1964.<sup>131</sup> It held that the law was a valid exercise of congressional power to prohibit from discriminating by race when boarding travelers. Congress has this authority “to keep the channels of interstate commerce free from immoral and injurious uses.”<sup>132</sup> These individuals responsible for transporting others to the motel via channels of interstate commerce, such as interstate roadways, could be regulated under the first prong of the commerce test.<sup>133</sup>

Like the flow of travelers through the interstate channels of travel in *Heart of Atlanta Motel*, controlled substances pass through an interstate supply chain from manufacturer to distributor, to pharmacy, to patient.<sup>134</sup> The CSA was enacted to regulate the national supply chain of controlled substances.<sup>135</sup> As stated in *United States v. Collier*, a case upholding the constitutionality of the CSA, discussed further below, the Fifth Circuit said:

. . . Congress fashioned the Comprehensive Drug Control Act to provide “a ‘closed’ system of drug distribution for legitimate handlers of such drugs. Such a closed system should significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.”<sup>136</sup>

In keeping with this rationale for regulation under the CSA, practitioners need mandatory education to fulfill their role as gatekeepers of potentially dangerous medications in the channel of commerce.<sup>137</sup> If practitioners are not allowed or are too afraid to prescribe, the channel is blocked. If practitioners overprescribe, the channel is flooded. This analysis of regulating the gatekeepers of the supply of controlled substances is consistent with the stance of those who believe that the Commerce Clause has been interpreted too broadly.<sup>138</sup> Unlike the substantial

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242 U.S. 470, 491 (1917) (noting Congress’s authority to regulate the channels of interstate commerce to keep them free from injurious uses).

131. 379 U.S. 241, 261 (1964).

132. *Id.* at 256 (quoting *Caminetti*, 242 U.S. at 491).

133. *Id.* at 255–56.

134. *See id.* at 256 (explaining that commerce among the states includes exchanges between citizens and the transport of people and property).

135. *See* 21 U.S.C. 801 (2011).

136. 478 F.2d 268, 273 (1973) (citing H.R. REP. NO. 91-1444, 4566, 4571–72 (1970)).

137. *See Public Policy Statement on Measure to Counteract Prescription Drug Diversion, Misuse and Addiction*, AM. SOC’Y ADDICTION MED. (Jan. 25, 2012), <http://www.asam.org/docs/public-policy-statements/1-counteract-drug-diversion-1-12.pdf?sfvrsn=0> (arguing that increased education of health practitioners would improve patient outcomes and curb misuse of controlled substances).

138. *See generally* Randy Barnett, *The Original Meaning of the Commerce Clause*, 68 U. CHI. L. REV. 101 (2001) (providing one law scholar’s argument that Congress’s power under the Commerce Clause should be narrowly construed).

effects argument under the third prong, controlling the supply of potentially injurious substances in commerce is fully within Congress's traditional commerce power used since 1824, as held in *Gibbons v. Ogden*.<sup>139</sup>

The prescriber education mandate argument can also be made under the Necessary and Proper Clause of the Constitution.<sup>140</sup> Under the Necessary and Proper Clause, as forged by Justice Scalia in his concurrence to *Raich*, the federal government can obtain authority to regulate the gatekeepers of the supply of controlled substances.<sup>141</sup> Justice Scalia agreed that Congress has the power to regulate intrastate goods that could flow through interstate commerce.<sup>142</sup> But he disagreed with the validity of the third prong of the Commerce Clause test because he thought that activities that only have a substantial effect on interstate commerce could not be justified as true things of interstate commerce.<sup>143</sup> Instead, he argued that Congress's power over things not of interstate commerce derives from the Necessary and Proper Clause of the Constitution.<sup>144</sup> Justice Scalia found that the CSA's provisions were necessary and proper in order to allow the federal government to stop diversion and oversee proper supply of controlled substances.<sup>145</sup> The application of the Necessary and Proper Clause hinged on whether the CSA was an appropriate means to allow the federal government to achieve these goals.<sup>146</sup> Justice Scalia suggested that preventing diversion was not a violation of sovereignty of the sort that would be inappropriate,<sup>147</sup> and that it was sufficient to authorize the application of the CSA to Angel Raich.<sup>148</sup> This reasoning can be extended to require prescriber education to help ensure that controlled substances stay within the appropriate chain of supply. Thus, a federal prescriber education requirement is constitutional under both the Commerce Clause and the Necessary and Proper Clause.

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139. 22 U.S. (9 Wheat.) 1, 70–71 (1824).

140. See U.S. Const. art. I, § 8, cl. 18.

141. *Gonzales v. Raich*, 545 U.S. 1, 33–42 (2005) (Scalia, J., concurring) (noting that even if intrastate activities do not substantially affect interstate commerce Congress can still regulate such activities through the Necessary and Proper Clause).

142. *Id.* at 35.

143. *Id.* at 34.

144. *Id.* at 35 (“[W]here necessary to make a regulation of interstate commerce effective, Congress may regulate even those intrastate activities that do not themselves substantially affect interstate commerce.”); U.S. CONST. art. I, § 8, cl. 18 (authorizing Congress to “make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof”).

145. *Raich*, 545 U.S. at 38.

146. *Id.* at 40.

147. *Id.* at 41.

148. *Id.* at 41–42.

*B. Recent Restrictions on Commerce Power Do Not Affect the CSA's  
Constitutionality*

Commerce Clause jurisprudence includes a seventy-year period of restriction beginning after the civil war in 1867 and continuing to 1937 when the Supreme Court largely invalidated challenged federal laws.<sup>149</sup> From 1937<sup>150</sup> until the mid-1990s, the commerce power was unshaken and continued to expand through Supreme Court findings.<sup>151</sup> Then, a recent line of cases restricted the Commerce Clause power.<sup>152</sup> *United States v. Lopez* and *United States v. Morrison* addressed whether noneconomic conduct can be construed as asserting substantial effects on commerce through the third prong of the Commerce Clause test.<sup>153</sup> *National Federation of Independent Business v. Sebelius* addressed whether Congress may compel commerce.<sup>154</sup> The prescriber education mandate can be distinguished from the regulations that were overturned in each of these cases.

In *Lopez*, Alfonso Lopez challenged the constitutionality of the federal Gun-Free School Zones Act of 1990 (the “Act”), which prohibited possessing a firearm in a school zone.<sup>155</sup> Alfonso Lopez, Jr., a twelfth-grade student, brought a concealed gun to school to deliver it to another person in exchange for money.<sup>156</sup> After school authorities discovered he was carrying the weapon, he was charged with violating the Act.<sup>157</sup> Lopez argued that the federal statute was unconstitutional “as it is beyond the power of Congress to legislate control over our public schools.”<sup>158</sup> The government argued that the possession of a firearm in an educational setting would substantially impact interstate commerce because it

149. See ERWIN CHERMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES 145–59 (3d ed. 2009) (discussing Commerce Clause jurisprudence during this time period).

150. The first case to begin changing the Commerce Clause doctrine was *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1 (1937). See also James Gray Pope, *The Thirteenth Amendment Versus the Commerce Clause: Labor and the Shaping of American Constitutional Law, 1921–1957*, 102 COLUM. L. REV. 1, 88 (2002) (discussing the expansion of Congress’s Commerce Clause powers between 1921 and 1957 in the context of labor law).

151. See CHERMERINSKY, *supra* note 149, at 159–83.

152. See *United States v. Lopez*, 514 U.S. 549, 567 (1995) (finding that possession of a gun in a school zone is not economic activity that affects interstate commerce); *United States v. Morrison*, 529 U.S. 598, 613 (2000) (finding that Congress cannot regulate a noneconomic activity by saying that it cumulatively has a substantial effect on interstate commerce); *Solid Waste Agency v. United States Army Corps of Eng’rs*, 531 U.S. 159, 174 (2001) (finding that Congress could not exercise Commerce Clause powers to regulate intrastate land inhabited by migratory birds); *Jones v. United States*, 529 U.S. 848, 859 (2000) (finding that residences used for everyday living are not commercial activity regulated under the Commerce Clause).

153. *Lopez*, 514 U.S. at 559–61; *Morrison*, 529 U.S. at 611, 617.

154. *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2586 (2012) (noting that Congress’s power to regulate commerce reflects the understanding that Congress may not mandate economic activity).

155. 514 U.S. at 551.

156. *Id.*

157. *Id.*

158. *Id.*

would likely lead to a violent crime, which would then affect the general economic condition by raising insurance costs and limiting the willingness to travel to an area perceived to be unsafe.<sup>159</sup> Unlike the case of prescribed controlled substances, there was no evidence that Lopez's gun had traveled interstate or that the law at issue would substantially affect commerce in guns because the law was specific to guns near schools.<sup>160</sup> Therefore, the Supreme Court rejected these arguments, finding instead that the presence of a gun near a school was not economic activity.<sup>161</sup> It held that, under the government's reasoning, Congress's power could extend over almost anything, including "criminal law enforcement or education where States historically have been sovereign."<sup>162</sup> Our case for the prescriber education regulation can be distinguished because, as described above in Part IV.A., the activity of releasing a supply of controlled substances to consumers does have substantial effects on commerce, unlike the noneconomic possession of a gun near a school in *Lopez*.

In *Morrison*, the Supreme Court found the Violence Against Women Act (VAWA) unconstitutional based on *Lopez*.<sup>163</sup> Christy Brzonkala alleged that she was raped by Virginia Polytechnic Institute football players and sued for civil damages under the VAWA, which provides a federal civil remedy for victims of gender-motivated violence.<sup>164</sup> After the defendants challenged the constitutionality of VAWA, Brzonkala and the government argued that the VAWA should be upheld under the third prong of the Commerce Clause.<sup>165</sup> They argued that gender-motivated violence affects interstate commerce by

detering potential victims from traveling interstate, from engaging in employment in interstate business, and from transacting with business, and in places involved in interstate commerce; . . . by diminishing national productivity, increasing medical and other costs, and decreasing the supply of and the demand for interstate products.<sup>166</sup>

The Supreme Court rejected Brzonkala's and the government's argument, and found that the VAWA was unconstitutional because the acts of violence had only an "attenuated" effect on interstate commerce rather than a substantial one.<sup>167</sup> Moreover, the acts of violence only resulted in indirect economic consequences,

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159. *Id.* at 563–64.

160. *Id.* at 567 ("Respondent was a local student at a local school; there is no indication that he had recently moved in interstate commerce, and [under the law at issue] there is no requirement that his possession of the firearm have any concrete tie to interstate commerce.").

161. *Id.*

162. *Id.* at 564.

163. *United States v. Morrison*, 529 U.S. 598, 602 (2000).

164. *Id.* at 604; 42 U.S.C. § 13981 (2011).

165. *Morrison*, 529 U.S. at 607.

166. *Id.* at 615 (internal citations omitted).

167. *Id.* at 612, 615, 617.

and intrastate actions must be economic in nature to be viewed in aggregate by courts.<sup>168</sup> If cumulative effects of noneconomic activity could justify such as economic activity, it would allow Congress to regulate any violent crime in the country.<sup>169</sup> Unlike those who commit violence against women, prescribers of controlled substances do substantially affect interstate commerce by their actions.<sup>170</sup>

The majority opinion in the recent Supreme Court case, *Sebelius*, found that the federal government could not mandate health insurance under the Commerce Clause.<sup>171</sup> The case follows the line of cases that recognize limits of Congress's Commerce Clause power.<sup>172</sup> However, like *Lopez* and *Morrison*, which overturned legislation that can be distinguished from the proposed legislation at hand on the grounds that the regulations on guns near schools and violence against women, respectively, were *noneconomic* regulations,<sup>173</sup> the regulation in *Sebelius* can be distinguished from that in the proposed CSA Amendment.<sup>174</sup> In *Sebelius*, the Supreme Court held that the Affordable Care Act was not a valid embodiment of the legislature's commerce power, and instead upheld the Act under Congress's taxing power.<sup>175</sup> The Act compels individuals to purchase health insurance or to pay a fine for not purchasing insurance.<sup>176</sup> The rationale behind the law is that many seemingly healthy people unexpectedly have health events requiring costly medical care, and that these uninsured individuals raise costs for hospitals and paying health insurance customers.<sup>177</sup>

Justice Roberts' majority opinion found that the Constitution "gave Congress the power to *regulate* commerce, not to *compel* it."<sup>178</sup> Because this law would require those persons not currently acting in the health insurance market to engage there, this law would be compelling specific commercial activity by individuals.<sup>179</sup>

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168. *Id.* at 613.

169. *Id.* at 615.

170. *See supra* Part IV.A (showing that health care providers are gatekeepers of the supply of controlled substances, and both controlled substances and prescribers of controlled substances may be regulated under Congress's Commerce Clause power).

171. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2593 (2012).

172. *See supra* Part IV.B (discussing Commerce Clause jurisprudence).

173. *See supra* notes 153–70 and accompanying text.

174. *See Nat'l Fed'n of Indep. Bus.*, 132 S. Ct. at 2609–11 (Ginsburg, J., concurring) (discussing the economic issues that the Patient Protection and Affordable Care Act was designed to regulate).

175. *Id.* at 2593, 2600 (majority opinion) ("The Affordable Care Act's requirement that certain individuals pay a financial penalty for not obtaining health insurance may reasonably be characterized as a tax.").

176. *See id.* at 2580.

177. *Id.* at 2585.

178. *Id.* at 2589 (emphasis in original).

179. *See id.* at 2590.

The proposed prescriber education requirement does not compel commerce, and therefore, is viable after the *Sebelius* ruling.<sup>180</sup> Commerce related to controlled substances has and will occur whether or not the proposed prescriber education requirement is enacted. The mandate would require prescribers of controlled substances to act and be educated in prescribing, but the regulation would only be applied to practitioners who actively choose to act themselves, by registering to prescribe controlled substances. Unlike the uninsured actors who will be compelled to buy health insurance or pay a tax under the Affordable Care Act “because they are doing nothing,”<sup>181</sup> the prescribers that would be regulated under the education mandate actively make the choice to prescribe controlled substances in commerce. And, the commerce exists outside of the proposed regulation on prescribers. Like other areas that have safety risks that cannot adequately be controlled without federal oversight of activity, this sort of regulation of existing commerce is constitutional.<sup>182</sup>

### C. States’ Plenary Police Power vs. the Commerce Clause

The proposed federal prescriber education requirement mandates professional training for state-licensed practitioners who prescribe controlled substances. This requirement is permitted under the Commerce Clause, but also does not undermine the regulation of medical practice reserved to the states because, as shown in the following cases, core provisions of the CSA have survived challenges based on states’ plenary police power. For instance, in *United States v. Collier* and *United States v. Rosenberg*, the Fifth and Ninth circuits, respectively, established the constitutionality of regulations under the CSA and asserted that such regulations do not invalidate the states’ police powers to regulate medicine.<sup>183</sup>

In *Collier*, Dr. Henry M. Collier appealed his conviction under the CSA for distributing methadone outside of the usual course of his professional practice based on his improper prescribing of methadone, which is a synthetic opioid.<sup>184</sup> He specifically attacked § 841(a)(1) of the CSA, which applies criminal sanctions to

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180. See *supra* note 154 and accompanying text.

181. See *Nat’l Fed’n of Indep. Bus.*, 132 S. Ct. at 2587.

182. For example, state police powers traditionally include regulation of motor vehicles, but in 1986, the federal government passed the Commercial Motor Vehicle Safety Act to ensure that drivers of large vehicles are qualified to do so, and to remove unsafe large-vehicle drivers from highways. *Commercial Driver’s License Program (CDL/CDLIS)*, FED. MOTOR CARRIER SAFETY ADMIN., U.S. DEP’T OF TRANSP., <http://www.fmcsa.dot.gov/registration-licensing/cdl/cdl.htm> (last visited May 9, 2013). Because states had varying rules regarding drivers of large trucks and buses and could not adequately regulate large vehicles moving between states, it was necessary for the federal government to involve itself. *Id.* Like the CSA Amendment proposed in this Article, the federal commercial drivers’ license retained the states’ authority to issue drivers licenses, but required that states meet minimum requirements. *Id.*

183. *United States v. Collier*, 478 F.2d 268, 272–74 (5th Cir. 1973); *United States v. Rosenberg*, 515 F.2d 190, 197–98 (9th Cir. 1975).

184. 478 F.2d at 270.

physicians for unlawfully prescribing and dispensing controlled substances.<sup>185</sup> He argued that the provision “violate[d] the Tenth Amendment by invading the state’s residual police power to control medical practice” because the provision does not require a showing that the conduct of individual acts affected interstate commerce.<sup>186</sup> The court held that § 801 constituted a permissible exercise of Congress’s powers under the Commerce Clause because Congress itself had already specifically determined that local distribution and possession of controlled substances have a substantial and direct effect upon interstate commerce.<sup>187</sup> Therefore, the only issue on appeal was whether the CSA allowed the federal government to regulate activity without encroaching on states’ authority.<sup>188</sup> The court found that the CSA was directly targeted at physicians, such as Dr. Collier, who legally had the privilege under state law to prescribe drugs.<sup>189</sup> The purpose of the CSA was partially to stop individuals from diverting controlled substances from legitimate channels to the illicit market.<sup>190</sup> The CSA did this by creating a closed system that regulated those with access to controlled substances, including state-licensed professionals.<sup>191</sup> The court noted that “Congress could reasonably decide that in order to effectively regulate interstate commerce in drugs, it is necessary to insure that persons within legitimate distribution channels, including dispensing physicians . . . , [do] not divert drugs into the illicit market.”<sup>192</sup> The court found that the provision did not encroach on states’ plenary police power.<sup>193</sup>

In *Rosenberg*, undercover agents executed a successful sting operation in Dr. Maurice W. Rosenberg’s office for prescribing controlled substances upon patients’ requests for such medication, without performing an examination or determining whether his patients had a legitimate medical need for such medications.<sup>194</sup> A jury convicted Dr. Rosenberg of twenty-seven counts of illegally distributing Schedule II, III, and IV substances under the CSA.<sup>195</sup> He appealed with a number of constitutional claims, including an assertion that, under the Tenth Amendment, only the state of California could determine whether his acts were appropriate, based on the state’s purview over medical practice.<sup>196</sup> He argued that the language in the CSA provision indicated Congress’s intent that the federal government rely

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185. *Id.*; see also 21 U.S.C. § 841(b) (2011) (listing penalties for violating the CSA).

186. *Collier*, 478 F.2d at 272.

187. *Id.* at 273.

188. *Id.*

189. *Id.*

190. *Id.*

191. *Id.*

192. *Id.*

193. *Id.* at 272–73.

194. *United States v. Rosenberg*, 515 F.2d 190, 191 (9th Cir. 1975).

195. *Id.* at 191–92.

196. *Id.* at 198. Dr. Rosenberg claimed that the federal government must rely on the state of California’s concept of acts within the course of professional practice because medical practice is under the purview of the states. *Id.*

on a state determination.<sup>197</sup> The court noted that the Tenth Amendment was a truism, and that, although the state clearly has the power to regulate controlled substances, the federal government also has concurrent, regulatory power under both its taxing authority and the Commerce Clause.<sup>198</sup>

More recently, objections were made on Tenth Amendment grounds to a proposed CSA Amendment, under the Pain Relief Promotion Act of 1999.<sup>199</sup> That legislation sought to amend the CSA to prohibit the use of controlled substances for physician-assisted suicide, after the State of Oregon passed the Death with Dignity Act.<sup>200</sup> Dissenters argued that the Act, H.R. 2260, would federalize the practice of medicine, which had always been the purview of the states.<sup>201</sup> States would not be free to act as laboratories of democracy.<sup>202</sup> Further, opponents argued that another potential side effect of this legislation was the “politicization of medical standards.”<sup>203</sup> Ultimately, this bill failed.<sup>204</sup>

Applying the *Collier* and *Rosenberg* precedents, a constitutional challenge against the prescriber education requirement based upon a plenary police power argument does not hold up.<sup>205</sup> Whereas the CSA provisions upheld in these cases allow the federal government to regulate local activity, the prescriber education requirement would be less invasive of states’ plenary police power to control the practice of medicine.<sup>206</sup> In the face of the prescription drug epidemic, instead of reserving all discretion to the federal government, the prescriber education requirement would empower states to come up with their own professional training standards targeted to better combat the diversion of prescription drugs within the boundaries of each state.

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197. *Id.*

198. *Id.* at 198.

199. H.R. REP. NO. 106–378 (1999).

200. *Id.*

201. *Id.*

202. *Id.*

203. *Id.*

204. See *Senate Adjourns Without Acting on the Pain Relief Promotion Act Bill*, THE BODY.COM (Spring 2001), <http://www.thebody.com/content/art16728.html> (noting that the Pain Relief Promotion Act did not pass due to public opposition and controversy).

205. See *United States v. Collier*, 478 F.2d 268, 272–73 (5th Cir. 1973) (holding that a CSA provision making it illegal for physicians to dispense certain controlled substances directly to users other than “in the course to his professional practice” did not invade states’ residual police powers under the Tenth Amendment); *United States v. Rosenberg*, 515 F.2d 190, 198 (9th Cir. 1975) (finding that Congress has the power to regulate drug dispensation and that such regulation does not violate the Tenth Amendment).

206. Compare *Rosenberg*, 515 F.2d at 198 (providing that Congress may regulate drug dispensation under the Interstate Commerce Clause), with *California v. United States*, 104 F.3d 1086, 1093 (9th Cir. 1997) (holding that an independent constitutional obligation to provide alien children with an education did not implicate the Tenth Amendment’s preservation of the states’ plenary police power), with *Burroughs v. Dep’t of the Army*, 445 F. App’x 347, 349–50 (Fed. Cir. 2011) (holding that Congress has the ability to draft into statutes minimum education requirements for positions requiring scientific or technical knowledge).



The dissenters' words regarding the Pain Relief Promotion Act of 1999 can be used to promote the prescriber education requirement.<sup>207</sup> The 1999 congressional report stated that “[b]ecause the optimal approach is often not clear, our Federal system encourages States to try different approaches. With local variations, the country can discover the best course of action.”<sup>208</sup> The prescriber education mandate would require states’ active lead to create medical standards, which would *promote* states’ police power over health and safety. Therefore, the requirement would respond to a national crisis, but respect each state’s jurisdiction to create and implement standards for prescriber education, fit to local concerns and preferences.

#### V. ATTEMPTS AND RECOMMENDATIONS FOR A PRESCRIBER EDUCATION REQUIREMENT

Practitioner education is not only a means of reducing practitioner liability; it is also a necessary step in addressing the prescription drug abuse epidemic. This section reviews the few states that currently have legislation on prescriber education, and a recent federal attempt to require education for prescribers of controlled substances.

##### A. *State Legislation Requiring Specific Controlled Substance Education for Licensure*

State licensing boards determine requirements for initial professional licensing and for license renewal in each state. Most states require continuing practitioner education for periodic relicensure.<sup>209</sup> A handful of states have created laws aimed at educating practitioners in controlled substance prescribing as part of licensure or re-licensure. California and Oregon require that prescribers complete a one-time pain management course.<sup>210</sup> Michigan requires pain and symptom management training for re-licensure.<sup>211</sup> Massachusetts requires effective pain management training to obtain or renew a license.<sup>212</sup> Tennessee requires one of forty relicensure education hours to be in safe prescribing practices.<sup>213</sup> Other states, including Ohio, Rhode Island, and Texas, recommend pain management training or

207. See H.R. REP. NO. 106–378 (arguing that health professionals should have the “knowledge and discretion” to avoid unintentional distribution of drugs).

208. *Id.* (quoting *Pain Relief Promotion Act of 1999: Hearing on H.R. 2260 Before the Subcomm. on Const.*, 106th Cong. (1999) (statement of David Orentlicher, Dir., Ctr. of Law & Health, Ind. Univ. Sch. of Law, at 5)).

209. See AM. MED. ASS’N, STATE MEDICAL LICENSURE REQUIREMENTS AND STATISTICS 65, 67 (2013).

210. CAL. BUS. & PROF. CODE § 2190.5 (West 2013); OR. REV. STAT. § 413.590(1) (2011).

211. MICH. COMP. LAWS ANN. § 333.16204(1) (2008).

212. MASS. GEN. LAWS ANN. ch. 94C, § 18(e) (West Supp. 2012).

213. TENN. COMP. R. & REGS. 0880-02-.19(1)(b) (2010).

include it as one of the options for mandatory relicensure training.<sup>214</sup> New Mexico requires all physicians with federal controlled-substance registrations to take five hours of continuing education on pain management each year, including lessons on the pharmacology and risks of controlled substances, and information about the problems of abuse, addiction, and diversion of medicine.<sup>215</sup>

Yet, these few states with their varying requirements are not enough.<sup>216</sup> Even if more states respond to the problem by enacting legislation, only a comprehensive solution in which every state requires every practitioner to receive mandatory training on prescribing controlled substances can succeed. Short of a federal mandate, illicit abusers can obtain prescription drugs from neighboring states with fewer or less specific prescriber controls.<sup>217</sup>

### B. The FDA Opioid REMS

Congress granted the U.S. Food and Drug Administration (FDA) authority to enact Risk Evaluation and Mitigation Strategies (REMS) as part of the Food and Drug Administration Amendments Act of 2007 (FDAAA).<sup>218</sup> The FDAAA authorized the FDA to require pharmaceutical manufacturers to propose strategies to mitigate certain risks of drugs that have a high or suspected high risk of abuse and overdose.<sup>219</sup> The FDA may impose REMS to ensure that the benefits of a drug continue to outweigh the risks.<sup>220</sup>

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214. OHIO ADMIN. CODE 4731-21-03 (2012) (encouraging practitioners who regularly treat patients with intractable pain to complete pain management coursework); 41-31 R.I. CODE R. § 6.2.1 (LexisNexis 2013) (establishing that a list of continuing education topics on “current public health needs” shall be published); *Physician Licensing: Frequently Asked Questions*, R. I. DEPT. OF HEALTH, <http://www.health.ri.gov/publications/frequentlyaskedquestions/PhysicianLicensing.pdf> (last visited May 10, 2013) (including pain management as a continuing education topic); TEX. OCC. CODE ANN. § 156.055 (West 2012) (encouraging practitioners who treat pain patients to include continuing medical education in pain treatment).

215. N.M. CODE R. § 24-2D-5.1 (LexisNexis 2012); see also Kate Nash, *Medical Board OKs New Rules to Combat Prescription Drug Abuse*, NEW MEXICAN (Aug. 10, 2012), <http://www.sfnewmexican.com/Local%20News/081112medboard#.UWV87rVax2B>.

216. See *supra* notes 209–15; see also MedScape News Today, *A Guide to State Opioid Prescribing Policies*, <http://www.medscape.com/resource/pain/opioid-policies> (last visited May 20, 2013) (illustrating variations in opioid prescription regulation among states).

217. See Amy L. Cadwell, *In the War of Prescription Drug Abuse, E-Pharmacies Making Doctor Shopping Irrelevant*, 7 HOUS. J. HEALTH L. & POL’Y 85, 120–22 (2007) (explaining current gaps in federal and state laws designed to prevent prescription drug abuse and emphasizing the need for a controlling federal mandate).

218. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007). The FDA’s Risk Evaluation and Mitigation Strategy for Extended-Release and Long-Acting Opioids is an effort to reduce risks of these drugs by introducing new safety measures. See *Approved Risk Evaluation and Mitigation Strategies (REMS)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm> (last updated May 29, 2013).

219. 21 U.S.C. § 355-1 (2011).

220. *Id.*

As originally contemplated when proposed, the REMS for long-acting and extended release opioids had a stringent education requirement for prescribers.<sup>221</sup> But, the resulting opioid REMS, finalized in 2012, has a much less stringent education requirement.<sup>222</sup> Prior to the opioid REMS finalization, two FDA advisory committees overwhelmingly agreed that the opioid REMS cannot meet its purpose to decrease abuse, misuse, addiction, and overdose deaths from improper use of opioid medication unless it requires mandatory prescriber education regarding safe prescribing and abuse detection.<sup>223</sup> However, the final REMS compels manufacturers of long-acting and extended-release opioids to provide product warnings to patients and offer only *voluntary* education programs for opioid prescribers.<sup>224</sup> The voluntary training program will most likely be carried out through manufacturer grants to recognized continuing medical education groups that will be required to obtain FDA approval of their educational materials.<sup>225</sup> This

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221. *Id.* In April 2009, the FDA published a notice for public meeting dates to discuss a REMS for certain opioid drugs, such as fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. Risk Evaluation and Mitigation Strategies for Certain Opioid Drugs, 74 Fed. Reg. 17969 (Apr. 20, 2009). The Federal Register announcement requested comments on the type of education that should be provided and how the certification should be administered. *Id.* The FDA conducted a lengthy process for comment—spanning three years—to elicit feedback from the public, physicians, and manufacturers on its planned opioid REMS. See *Questions and Answers: FDA approves a Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting (ER/LA) Opioid Analgesics*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm309742.htm> (last updated Apr. 26, 2013) (explaining the various public meetings that FDA held between 2009 and 2011 to receive REMS feedback).

222. Compare *supra* note 221 and accompanying text (discussing the lengthy process which the FDA underwent to receive feedback on the best approach to educating prescribers), with *Extended-Release (ER) and Long-Acting (LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS)* U.S. FOOD & DRUG ADMIN., 22 (2013), <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM311290.pdf> (describing the current setup for the REMS education program).

223. See John F. Peppin et al., *Issues and Critiques of the Forthcoming Risk Evaluation and Mitigation Strategy (REMS) for Opioids in Pain Management*, 27 ISSUES L. & MED. 91, 102–06 (2012) (enumerating the various reasons the FDA committee cited in approving or disapproving the Opioid REMS). Even advisory committee members who voted for the proposed REMS commented that it would not be able to address the problem, saying, “I voted yes not because I think it will work but because I think it will fail and that will force a new look at this serious problem.”; “REMS is severely flawed and I agree with all the people who voted ‘No,’ but I think we need to start somewhere.” Comments from the “No” group included, “. . . we are proposing action on people not involved in the problem.”; “This group needs to send a message to Congress that what they’re getting from FDA is insufficient; the DATA 2000 is a good model of what needs to be done here.” *Id.*; see also CTR. FOR LAWFUL ACCESS & ABUSE DETERRENCE, *supra* note 1, at 19 (stating that committee members advised the FDA that mandatory education for prescribers should be a primary component of any REMS program).

224. See Thomas Sullivan, *FDA Releases Final Risk Evaluation and Mitigation Strategies (REMS) for Extended Release/Long Acting Opioids Including a Prescriber Education Program*, POL’Y & MED. (July 9, 2012), <http://www.policymed.com/2012/07/fda-releases-final-risk-evaluation-and-mitigation-strategies-rems-for-extended-releaselong-acting-opioids-including-a-pres.html> (describing the FDA’s voluntary education program for prescribers, including the lack of mandatory training).

225. See *id.* (discussing the expectation that companies will provide educational grants).

program is consistent with the fact that FDA is not authorized to regulate prescriber behavior or professional practice.<sup>226</sup> But, because of this limitation, the opioid REMS does not properly target those who must change their behaviors to stop the epidemic.<sup>227</sup> Responsible prescribers, who would be most likely to participate in such voluntary training, usually already have the resources and the know-how to avoid contributing to the problem.

The REMS is still useful because, under the “learned intermediary doctrine,” when a manufacturer warns a practitioner of the risks of a drug, the practitioner then has the duty to convey the warning to patients.<sup>228</sup> Although the REMS does not go far enough, the opioid REMS will place a heightened duty on practitioners, suggesting one further reason for practitioners to undergo training.<sup>229</sup>

### *C. Buprenorphine as a Model for Education Requirements*

The Drug Addiction Treatment Act of 2000 (DATA 2000) specifically requires that practitioners take eight hours of state courses to prescribe certain controlled substances in the office setting.<sup>230</sup> Similarly to this Article’s prescriber education proposal, except relating only to opioid addiction treatment medications rather than to all controlled substances, this currently enacted law is a viable regulation on practitioners.<sup>231</sup> DATA 2000 requires education for prescribers of Schedule III, IV, and V opioid addiction treatment medications, including buprenorphine.<sup>232</sup> Prescribers can waive the requirement by proving prior education through relevant certifications or other training in prescription medication abuse detection and deterrence.<sup>233</sup>

Much of the justification for federal registration to prescribe buprenorphine is applicable to a general controlled substance prescriber education requirement. The DATA 2000 House report justified its authority as an exercise of the Commerce

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226. Cf. U.S. FOOD & DRUG ADMIN., *FDA Authority*, in REGULATORY PROCEDURES MANUAL 2-1, 2-2–2-40 (2012), available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074340.pdf> (providing an overview on FDA’s statutory authority, none of which provides authority to regulate prescriber behavior or professional practice).

227. Cf. *First Opioid Voluntary REMS Training Goes Live*, ANESTHESIOLOGY NEWS (Mar. 22, 2013), [http://www.anesthesiologynews.com/ViewArticle.aspx?d=Web%2BExclusives&d\\_id=175&i=March+2013&i\\_id=937&a\\_id=22833](http://www.anesthesiologynews.com/ViewArticle.aspx?d=Web%2BExclusives&d_id=175&i=March+2013&i_id=937&a_id=22833) (discussing how the FDA urges prescribers to take advantage of the opioid prescribing, implying that REMS does compel such prescribers to take the training).

228. *Kennedy v. Medtronic, Inc.*, 851 N.E.2d 778, 784 (Ill. App. Ct. 2006) (quoting *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 117 Ill. 2d 507, 517 (1987)).

229. See *First Opioid Voluntary REMS Training Goes Live*, *supra* note 227 (stating that the FDA envisions prescribers “taking advantage of training opportunities on opioid therapy” to be a key role for prescribers in helping to curtail opioid abuse).

230. 21 U.S.C. § 823(g) (2011).

231. See Peppin et al., *supra* note 223, at 103 tbl.3 (including comments from joint FDA advisory committee members that opioid education be modeled after the buprenorphine framework).

232. § 823(g).

233. *Id.*

Clause.<sup>234</sup> The DATA 2000 House report cited the 600,000 heroin users in need of addiction treatment and the costs of heroin addiction to families and communities.<sup>235</sup> It suggested that the framework in place under the CSA should be used to further regulate certain controlled substances with risks of abuse.<sup>236</sup>

Similar to the justification for DATA 2000, the current CSA prescriber registration system can be used as the framework for a mandatory prescriber education program at a relatively low cost.<sup>237</sup> Under the public interest theory of economic regulation, in the midst of a market failure due to information asymmetry, Congress should act.<sup>238</sup> In the case of pharmaceuticals, information asymmetry occurs when manufacturers and government have more information about the appropriateness or the effectiveness of medications than prescribers and patients.<sup>239</sup> The costs of this asymmetry in the prescription drug epidemic are enormous. Abuse of opioid pain relievers costs health insurers \$72.5 billion annually in direct health care costs.<sup>240</sup> Thus, if Congress were to complete a cost benefit analysis, the need for legislation similar to DATA 2000 that covers all controlled substance prescribing would be clear.

#### *D. The Rockefeller Bill*

Realizing the need for such legislation, United States Senator Jay Rockefeller of West Virginia introduced the Prescription Drug Abuse Prevention and Treatment Act to the Senate in March 2011 and, after the 2011 bill failed to pass, reintroduced the bill in 2013.<sup>241</sup> The bill includes a workable, mandatory prescriber education component.<sup>242</sup> Under the prescriber education provision, the CSA would be amended to require physicians to complete sixteen hours of training every three years in order to prescribe methadone or other controlled substances.<sup>243</sup> The

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234. H.R. REP. NO. 106-441 (1999).

235. *Id.*

236. *Id.*

237. § 823(g) (requiring qualified practitioners dispensing drugs for narcotic treatment to register annually).

238. See SUSAN E. DUDLEY & JERRY BRITO, REGULATION: A PRIMER 12-14 (2d ed. 2012), (stating that the public interest theory suggests that markets are usually efficient in allocating scarce resources, but, under certain circumstances, may fail, thus requiring politicians to intervene and regulate to serve the public interest).

239. See SARA BENNETT ET AL., WORLD HEALTH ORG., PUBLIC-PRIVATE ROLES IN THE PHARMACEUTICAL SECTOR: IMPLICATIONS FOR EQUITABLE ACCESS AND RATIONAL DRUG USE 22-23 (1997), available at <http://apps.who.int/medicinedocs/pdf/whozip27e/whozip27e.pdf> (arguing for government intervention in the pharmaceutical market on the ground that it is subject to informational imbalance because prescribers and patients are less informed about drug efficacy than manufacturers).

240. COAL. AGAINST INS. FRAUD, PRESCRIPTION FOR PERIL 38 (2007), available at <http://www.insurancefraud.org/downloads/drugDiversion.pdf>.

241. Prescription Drug Abuse Prevention and Treatment Act of 2011, S. 507, 112th Cong. (2011); Prescription Drug Abuse Prevention and Treatment Act of 2013, S. 348, 113th Cong. (2013).

242. S. 348.

243. *Id.*

training would be provided by an expert medical pain society<sup>244</sup> and would specifically cover: “(i) the treatment and management of opioid-dependent patients; (ii) pain management treatment guidelines; and (iii) early detection of opioid addiction, including through such methods as Screening, Brief Intervention, and Referral to Treatment (SBIRT).”<sup>245</sup> Enforcement would be funded through use of a portion of the DEA registration fee for prescribers.<sup>246</sup>

The current Rockefeller bill could be amended by focusing solely on the prescriber education component and by including specific training requirements on the risks of *all* controlled substances, not just opioids.<sup>247</sup> Moreover, the current bill does not mention implementation by the states, so it would probably be administered directly through the federal government.<sup>248</sup> Instead, the bill should suggest that the prescriber education be carried out through the existing state education framework for practitioners.<sup>249</sup> Additionally, the mandatory controlled substances education should be required to occur before a practitioner can register to prescribe these substances in addition to later training.<sup>250</sup>

In sum, this Part of the Article gives examples of attempts at educating prescribers in controlled substance prescribing that can be used to inform how the proposed CSA Amendment should be formulated.

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244. *Id.* Under the proposed bill, the training would be provided by:

the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, the American Academy of Pain Management, the American Pain Society, the American Academy of Pain Medicine, the American Board of Pain Medicine, the American Society of Interventional Pain Physicians, or any other organization that the Secretary determines is appropriate for purposes of this subparagraph.

*Id.*

245. *Id.* SBIRT is aimed at stopping substance abuse before it becomes serious. Rebecca A. Clay, *Screening, Brief Intervention, and Referral to Treatment: New Populations, New Effectiveness Data*, SAMSHA News (SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., ROCKVILLE, MD.), Nov.-Dec. 2009, at 1, 1. Patients in health care venues are quickly screened to assess their alcohol and drug use. *Id.* at 2. If they are deemed at risk, they receive an intervention to “rais[e] their awareness of substance abuse and motivate[e] them to change their behavior.” *Id.*

246. S. 348.

247. Larry K. Houck, *Legislative Fixes Focus on Controlled Substance Issues*, FDA Law Blog (Mar. 22, 2011), [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2011/03/legislative-fixes-focus-on-controlled-substance-issues.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/03/legislative-fixes-focus-on-controlled-substance-issues.html). Described as “ambitious,” the bill takes on seven opioid prescribing topics. *Id.* Beyond the prescriber education piece, the bill includes: consumer education, a moratorium on large dose methadone hydrochloride tablets, access requirements for opioid treatment programs, clinical standards for controlled substances, state drug monitoring program requirements for answering drug enforcement information requests, and mortality reporting. See S. 348, *supra* note 241, §§ 3–8. Detractors of the further reach of drug enforcement would especially dislike the component requiring that state prescription monitoring programs receiving federal money in exchange for compliance with drug enforcement information requests. See *id.* §8.

248. See generally S. 348, *supra* note 241 (making no mention of state implementation of S. 507).

249. See discussion *infra* Part VI.A.

250. See *infra* Part VI.A.

VI. THE NECESSARY SOLUTION: PRACTICAL COMPONENTS OF THE FEDERAL  
STATUTE

Under current state health systems, requirements for initial medical licensing vary by state.<sup>251</sup> For medical license renewal, most states require practitioners to complete continuing medical education.<sup>252</sup> The average number of state-mandated, continuing medical education credits per year range from fifteen to fifty credits.<sup>253</sup> Many states have further requirements for the content of these credits.<sup>254</sup>

This Part first makes recommendations for the proposed Amendment. Then it uses Massachusetts, a state that already requires controlled substance education for prescribers, as a model to show how the new federal requirement would be seamless.<sup>255</sup> It uses Virginia, a state that currently requires continuing medical education, but does not require education for controlled substance prescribers, as a model for how the new mandate would fit into a system that currently does not require such training.<sup>256</sup> It also looks at states that have no continuing medical education requirements to see how such a mandate would work in those states.<sup>257</sup>

*A. Specific Recommendations for the Prescriber Education Requirement*

The prescriber education requirement could be inserted as Section 3 of 21 U.S.C. § 823(g).<sup>258</sup> It could be modeled particularly after the current education component in the Rockefeller bill<sup>259</sup> and the buprenorphine prescriber education requirements.<sup>260</sup> Like the buprenorphine waiver, prescribers with demonstrated knowledge or training should be exempted from further requirements.<sup>261</sup> Competence in an area may be demonstrated through awarded recognition or by

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251. See *State-Specific Requirements for Initial Medical Licensure*, Fed'n of State Med. Bds., [http://www.fsmb.org/usmle\\_elinitial.html](http://www.fsmb.org/usmle_elinitial.html) (last updated Aug. 2012) (outlining the differences in medical licensure requirements among states).

252. See AM. MED. ASS'N, *supra* note 209, at 67–69 tbl.21 (listing state-specific continuing medical education requirements).

253. See *id.*

254. See *id.* (finding, for example, that Iowa requires training for “identifying and reporting child and abuse,” and Kentucky requires two credits on HIV/AIDS every ten years).

255. See *infra* Part VI.B.

256. See *infra* Part VI.C.

257. See *infra* Part VI.D.

258. See 21 U.S.C. § 823(g) (2011) (stating practitioner requirements for dispensing narcotic drugs for treatments).

259. Prescription Drug Abuse Prevention and Treatment Act of 2013, S. 348, 113th Cong. § 4 (2013).

260. § 823(g).

261. See *id.* (stating that qualifying physicians can receive a waiver to practice opioid addiction therapy if the physician has completed at least eight hours of specific training).

those who have a specific medical certification, such as pain medicine or addiction medicine, or recognized specialty such as anesthesiology.<sup>262</sup>

The prescriber education mandate should require controlled substance education before a prescriber can register with the DEA to prescribe controlled substances, as well as for registration renewal.<sup>263</sup> Practitioners taking courses in safe controlled substance prescribing and abuse prevention while attending an accredited medical school should be deemed to meet the initial education requirement for prescribing controlled substances.<sup>264</sup> When crafting the legislation, experts should determine a minimum number of course hours necessary per registration term for prescribers of controlled substances. The safe prescribing and abuse prevention courses should be integrated into education courses practitioners already must take to meet state licensing requirements, without taking more courses than they already take for licensure. State licensing boards should approve the specific content of the controlled substances education program for each class of prescribers (i.e., physicians, physician assistants, and nurse practitioners) in their state and could require further hours than federally mandated, if preferred to meet state licensure or controlled substance prescribing standards.<sup>265</sup>

The prescriber education legislation should also add a section under 21 U.S.C. § 843 of the CSA on prohibited acts, which would prohibit misstatement of facts to the DEA regarding prescriber controlled substance education.<sup>266</sup> The penalties currently in force in that section would then apply.<sup>267</sup> As with most actions under the CSA against prescribers, the DEA would investigate controlled substance prescribers' compliance based on tips or complaints that usually emanate from the state.<sup>268</sup> In investigating complaints, the DEA should work with the relevant state medical board to determine whether the federal documentation requirements for controlled substance education were met. For instance, in Virginia, pursuant to an investigation request, the process for obtaining the physician's documentation of training could be similar to what is now utilized for the random auditing process for continuing medical education.<sup>269</sup> As included in the Rockefeller bill, funding for

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262. *See id.* (stating that a physician is considered qualified if the physician holds a board certification in addiction psychiatry from certain medical organizations).

263. *See supra* Part II.A.

264. *See supra* Part II.A.

265. *See supra* Part III (discussing the states' authority to regulate the practice of medicine pursuant varying state controlled substances acts).

266. *See* 21 U.S.C. § 843 (2011) (discussing the unlawful acts that a prescriber may commit, but failing to make a misstatement of the facts by the prescriber unlawful).

267. § 834(d)(i).

268. *See* H.R. REP. NO. 106-378 (1999) (stating that civil actions revoking a practitioner's license are hardly ever initiated by the DEA because usually, state action precipitates DEA initiation of a civil action).

269. 18 VA. ADMIN. CODE § 85-20-235(D) (2012) (detailing the continued competency requirements for renewing an active medical license).



enforcement could be drawn from a portion of the prescriber registration fees or it could be drawn through funding currently available for DEA enforcement.<sup>270</sup>

### *B. Massachusetts as a Model*

In Massachusetts, prescribers must take one hundred credits of continuing professional development every two years with at least forty hours in Category 1, which are courses accredited by certain medical organizations listed in the Massachusetts statute.<sup>271</sup> Massachusetts also has various stipulations on the content of the continuing education. At least fifty-one of the credits must be in the practitioner's primary areas of practice, with additional requirements of ten hours in risk management, two hours focusing on the board's regulations, and two hours in end-of-life-care issues.<sup>272</sup>

Moreover, Massachusetts is one of the few states that already requires pain management and opioid education before practitioners initially receive or renew their professional license. Three education hours must encompass "(i) effective pain management; (ii) identification of patients at high risk for substance abuse; and (iii) counseling patients about the side effects, addictive nature, and proper storage and disposal of prescription medications."<sup>273</sup> The law directs each related licensing board to develop appropriate standards for such training.<sup>274</sup> Massachusetts offers a free online course that meets the statutory education requirement.<sup>275</sup>

Enactment of a new federal education requirement would likely fit seamlessly into Massachusetts' current education scheme because Massachusetts has robust prescriber education requirements.<sup>276</sup> If the federal requirements were more stringent or required further hours of controlled substance education on average per year, Massachusetts practitioners would need to meet the further federal requirements that go beyond the current state scheme.

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270. Prescription Drug Abuse Prevention and Treatment Act of 2013, S. 348, 113th Cong. § 4(d) (2013).

271. 243 MASS. CODE REGS. 2.06(6)(a)(1) (2012).

272. 2.06(6)(a), (b), (h).

273. MASS. GEN. LAWS ANN. ch. 94C, § 18(e)(i)–(iii) (West Supp. 2012).

274. §18(e)(iii).

275. *Safe and Effective Opioid Prescribing for Chronic Pain*, OPIOIDPRESCRIBING.COM, <http://www.opioidprescribing.com> (last visited June. 3, 2013) (offering a series of online presentations through the Boston University School of Medicine regarding how clinicians can work with patients living with chronic pain).

276. 243 MASS. CODE REGS. 2.06(6)(d) (2012) (describing Massachusetts' educational requirements for renewing a controlled substance prescriber license, which includes requiring licensees to take training courses in identifying patients at high risk for abuse and counseling patients on the side effects and addictive nature of prescription medicines).

### C. Virginia as a Model

The Virginia Board of Medicine requires sixty hours of “continued competency requirements” every two years.<sup>277</sup> Practitioners are free to determine the contents of the curriculum, with the following few restrictions.<sup>278</sup> The Board requires at least thirty “Type 1” hours in “activities or courses offered by an accredited sponsor or organization sanctioned by the profession.”<sup>279</sup> The rest of the Virginia credits may be “Type 2,” which are “chosen by the licensee to address such areas as ethics, standards of care, patient safety, new medical technology, and patient communication.”<sup>280</sup> These may be earned through self study, medical publications, attending professional meetings, learning new procedures, sitting on medical ethics panels, and so forth.<sup>281</sup> Newly licensed physicians are exempted from the sixty-hour requirement.<sup>282</sup>

In Virginia, physicians who are not trained in prescribing controlled substances while in medical school can still obtain their medical licenses.<sup>283</sup> No further medical education is required for licensure until completing the requirements for re-licensure by the fourth year of practice.<sup>284</sup> Under the prescriber education requirement, Virginia practitioners desiring to prescribe controlled substances would need to complete an education course designed or recognized by Virginia. The Virginia Board of Medicine would need to ensure that Virginia’s available courses meet the educational standard for registration under the CSA. The training would need to occur before initial controlled substance registration and as part of a practitioner’s required sixty hours of training every two years.<sup>285</sup> Prescribers who have taken a qualifying class in medical school before initial licensure or who are otherwise specifically recognized, certified, or of a qualifying specialty, would be deemed to satisfy the requirement.

### D. States Without Continuing Medical Education Requirements

Some states do not currently require continuing medical education at all. Colorado, Indiana, Montana, New York, South Dakota, and Vermont have no requirement, although Vermont has new legislation that will go into effect in

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277. 18 VA. ADMIN. CODE § 85-20-235(A) (2012).

278. *Id.*

279. *Id.*

280. *Id.*

281. See *Frequently Asked Questions for the Virginia Board of Medicine*, VA. BD. OF MED., [http://www.dhp.virginia.gov/medicine/medicine\\_faq.htm#continuing](http://www.dhp.virginia.gov/medicine/medicine_faq.htm#continuing) (last visited May 10, 2013).

282. § 85-20-235(B).

283. See *supra* notes 277–82 and accompanying text (discussing educational requirements for practitioners in Virginia).

284. § 85-20-235(B) (indicating that a newly-licensed practitioner is exempt from training requirements associated with a license renewal for the first two-year period; therefore, the next required re-licensure would occur four years after the initial medical license was received).

285. See *id.*

2014.<sup>286</sup> Although state-specific education efforts targeting the local environment are preferable, the prescriber education requirement could include stipulations allowing prescribers in states without education requirements to substitute a program from a nationally accredited program recognized under the federal law. Like the Rockefeller bill, the CSA amendment could defer to the judgment of credible medical organizations, such as the American Medical Association, the American Society of Anesthesiologists, and the American Society of Addiction Medicine, in defining the programs in addition to those that are state approved.<sup>287</sup>

VII. BENEFITS OF THE PROPOSED PRESCRIBER EDUCATION REQUIREMENT:  
EDUCATION TO EMPOWER PHYSICIANS TO PRESCRIBE APPROPRIATELY,  
IMPROVE PATIENT TREATMENT, AND REDUCE LIABILITY

An education requirement, through the longstanding, stable, state-regulated health systems, recognizes the importance of protecting states' rights to govern the practice of medicine and other professions.<sup>288</sup> The epidemic status of the prescription drug abuse problem suggests that swift, coordinated action among government authorities is necessary.<sup>289</sup>

Opponents of an education mandate suggest that such a requirement would make prescribers fearful of criminal liability, and that it would cause many practitioners to eliminate controlled substance prescribing from their practices.<sup>290</sup> The resulting reduction in numbers of prescribers, in turn, is purported to limit access to medications for patients suffering with pain or other conditions for which controlled substances are prescribed.<sup>291</sup> On the contrary, educated physicians can make healthier prescribing decisions for patients and will counsel patients on proper use of controlled substances.<sup>292</sup> Rather than reducing access to controlled substances, practitioners will be empowered through training to prescribe drugs

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286. See AM. MED. ASS'N, *supra* note 209, at 67–69 tbl.21.

287. See *supra* note 244 and accompanying text.

288. See *supra* Part IV.C.

289. See *supra* notes 2–9 and accompanying text.

290. See, e.g., Hoffmann, *supra* note 40, at 234–35 (stating that the law enforcement climate for opioid prescribing is causing the prescriber pool to dwindle); Johnson, *supra* note 43, at 1029–30 (stating the impact of changes in treatment practices resulting from opioid investigations); see also *Opioid REMS Industry Working Group Meeting with Stakeholders*, U.S. FOOD & DRUG ADMIN. 16, 34, 68 (Nov. 18, 2009), <http://www.fda.gov/downloads/drugs/drugsafety/informationbydrugclass/ucm193696.pdf> (featuring slides from the FDA stakeholder meeting and the Industry Working Group meeting in late 2009 that suggests that attendees believed that a mandatory education requirement would result in limiting patient access to opioids, especially in rural areas and for already vulnerable populations including the poor, people of color, and women).

291. See sources cited *supra* note 290.

292. See *supra* Part II.B.

without fear.<sup>293</sup> Those unwilling to obtain education in safe prescribing pose a threat to patients and should not be prescribing controlled substances.<sup>294</sup>

Controlled substance prescribers who follow their state-based training can take comfort in learning medical board investigation practices and negligence case law, which protect practitioners who implement reasonable precautions to prevent diversion, misuse, and abuse.<sup>295</sup> Accordingly, practitioners who complete training programs and follow state guidance should have a strong defense if they ever face an investigation or a prescribing liability case.<sup>296</sup>

Opponents of practitioner education suggest agreement on controlled substance prescribing standards is impossible because of the varying opinions in the medical community.<sup>297</sup> Physicians do face uncertainty when even experts cannot agree. But inaction will not solve the problem for patients, practitioners, or the public. The reasonable care standard for physicians is defined as the standard recognized by other professionals in the community.<sup>298</sup> State-based education programs present an opportunity to develop appropriate standards for different locales and situations.<sup>299</sup> It is important that prescribers take steps to educate themselves so that they can stay abreast of evolving standards and shield themselves from liability.<sup>300</sup>

Without a workable solution to the prescription drug abuse epidemic, patients, prescribers, and manufacturers may face even tighter controls that could further threaten the availability and marketability of medications that have potential for diversion, misuse, and abuse.<sup>301</sup> With proper training, physicians will be able to prescribe (or not prescribe) with confidence.<sup>302</sup> Greater education and certainty will increase access to medications for legitimate patients, equip physicians to better educate those patients, and reduce physicians' chances of liability for inappropriate prescribing.<sup>303</sup>

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293. *See supra* Part II.B.

294. *See supra* Part II.B.

295. *See supra* Part II.B.

296. *See supra* Part II.B.

297. *See Hoffmann, supra* note 40, at 291 (discussing the high variability and vagaries of current prescriptive practices that have led to confusion among practitioners).

298. *See supra* note 45 and accompanying text.

299. *See supra* Part V.A.

300. *See supra* Part II.A–B.

301. *See Meier, supra* note 24 (discussing the tightening of controls for prescribing opioids in Washington as a result of misuse and abuse).

302. *See supra* Part II.B.

303. *See supra* Part II.B.

#### VIII. CONCLUSION

The federal government must take action aimed directly at the reducing the diversion of prescription medications. Enacting a mandatory prescriber education requirement under the CSA that respects states' plenary police powers and that is consistent with the federal government's authority under the Commerce Clause and Necessary and Proper Clause can properly address this epidemic at the first point of failure: where a physician improperly writes a prescription for a controlled substance because he or she does not know any better.