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Damned If They Do, Damned If They Don't: The Need for a Comprehensive Public Policy to Address the Inadequate Management of Pain

Amy J. Dilcher*

“Doctors feel damned if they do and damned if they don't The enormous confusion about pain has led to the hysteria around opiates.”¹

I. INTRODUCTION

I am dying in sustaining such a devouring pain. —Sophocles

Throughout history and across cultures, human beings have experienced pain. As early as the fifth century B.C., Sophocles documented the experience of pain and suffering in *Philoctetes*. Centuries later, the undertreatment of pain in the United States is a public health epidemic despite the availability of treatment for relieving most physical pain.² The

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1. Statement of Dr. Scott Fishman, Chief of the Division of Pain Medicine at the University of California at Davis Medical Center, regarding *Bergman v. Eden Med. Ctr.*, No. H205732-1 (Alameda County Ct. filed June 13, 2000), the first case in which a physician was held liable for elder abuse for undertreating a patient's pain.

2. Michael J. Reynolds, Note, *Morphine or Malpractice: Should Courts Recognize a Legal Duty to Prescribe Opiates for Treating Chronic Pain*, 15 ST. JOHN'S L. COMMENT 79, 79 (2000). See also Darlene Fujimoto, *Regulatory Issues in Pain Management*, 17 CLINICS IN GERIATRIC MED. 537, 537 (2001) (identifying inadequate pain assessment and treatment as a “significant public health problem in elderly patients, even in those suffering from cancer pain”); D.E. JORANSON ET AL., PAIN & POLICY STUDIES GROUP, UNIV. OF WIS. COMPREHENSIVE CANCER CTR., ACHIEVING BALANCE IN FEDERAL AND STATE PAIN POLICY: A GUIDE TO EVALUATION i (July 2000) (“It is well understood that inadequate management of pain is a serious health problem in the United States.”), available at <http://>

prevalence of undertreated moderate to severe pain is a persistent problem that affects more than fifty million Americans, including individuals with chronic non-malignant conditions and terminal illnesses.³ The inadequate management of pain costs the United States as much as \$100 billion per year in health care expenditures, disability payments, and lost productivity.⁴

Narcotics in the morphine class, known as opioids, are safe and effective in the treatment and management of pain.⁵ However, for opioids to be truly useful, they must be legally and practically accessible to medical professionals and their patients as and when needed to provide satisfactory relief from pain.⁶ Liberalizing the use of opioids would benefit a significant number of patients suffering from acute and chronic pain; indeed, the Agency for Healthcare Policy and Research, part of the Department of Health and Human Services, found that a full eighty percent (or more) of cancer patients could have their pain successfully managed by a combination of opioids and other analgesic drugs and that only ten percent of such patients experienced pain so profound as to be impervious to any sort of analgesic treatment.⁷

This article synthesizes a number of perspectives regarding the

www.medsch.wisc.edu/painpolicy; Press Release, U.S. Drug Enforcement Administration (DEA), DEA to Join Pain Advocates in Issuing Statement on Prescription Pain Medications (Oct. 23, 2001), available at <http://www.usdoj.gov/pubs/pressrel/pr1102301.html>.

3. Reynolds, *supra* note 2, at 79.

4. Melanie Thernstrom, *Pain, The Disease*, N.Y. TIMES, Dec. 16, 2001, § 6 (Magazine), at 66 (estimating total costs of chronic pain add up to more than \$100 billion annually); Reynolds, *supra* note 2, at 79 (estimating that the costs of chronic pain total "over \$70 billion per year in health care spending and lost productivity"); Press Release, American Pain Society, American Pain Society Urges Congress to Preserve Patient Access to Pain Medications (Dec. 11, 2001), at www.ampainsoc.org/whatsnew/121101.html ("Pain is one of the most common reasons people consult a physician, yet it frequently is inadequately treated, leading to enormous social cost in the form of needless suffering, lost productivity, and excessive health care expenditures.").

5. JORANSON ET AL., *supra* note 2, at 3; Reynolds, *supra* note 2, at 80; Fujimoto, *supra* note 2, at 537. For the purposes of this article, the term "narcotic" is synonymous with the terms "opioid," "pain medication," "controlled substance," and "morphine."

6. Fujimoto, *supra* note 2, at 537 (arguing that widespread perception that regulatory policies prohibit use of opioids to treat pain is a significant factor causing prescribers to inadequately relieve cancer pain and to undertreat or refuse to prescribe opioids for chronic pain).

7. Vincent Perron & Ronald S. Schonwetter, *Assessment and Management of Pain in Palliative Care Patients*, 8 CANCER CONTROL 15, 18 (2001) (noting that around the clock dosing, using other forms of treatment in addition to pain medication, and using noninvasive routes of administration provide good pain control for eighty percent of patients). See also Michael H. Levy, *Pharmacologic Treatment of Cancer Pain*, 335 NEW ENG. J. MED. 1124, 1127 (1996) ("Analgesic drugs should be scheduled at intervals that prevent the recurrence of pain and minimize the number of daily doses."). Analgesia means the absence of pain without a loss of consciousness. See THE AMERICAN HERITAGE STEADMAN'S MEDICAL DICTIONARY (27th ed. 2000).

comprehensive regulation of pain management and demonstrates that the inadequate treatment of pain results from a multitude of barriers, which includes government pain policies, enforcement actions, attitudes, inadequate education, and reimbursement policies. Part II of this article examines each of the components that contribute to the inadequate management of pain and recent cases involving the undertreatment of pain.

To date, efforts to improve pain management have been piecemeal and hence incomplete. Part III argues that the only way to adequately address the pain epidemic in this country is through a comprehensive public policy that addresses *all* of the barriers to pain management. Part III further examines legislation proposed in the 108th Congressional session, the Conquering Pain Act of 2003 (“Act” or “CPA”). The CPA, while a noteworthy effort on the part of Congress to promote more effective pain management, fails to adequately address some of the most serious problems facing doctors and other front-line practitioners, notably the fear of regulatory scrutiny.

Part IV offers recommendations for a more comprehensive policy - one that would enhance the management of pain through the use of controlled substances. The CPA should be amended to address problems with federal and state investigations and enforcement actions of controlled substance laws, to require health care providers and facilities to assess pain, to change Medicare and Medicaid reimbursement policies that impact the management of pain, and to improve the education of health care providers about the use of controlled substances to manage pain.

II. INADEQUATE PAIN MANAGEMENT IN THE UNITED STATES

The undertreatment of pain in the United States is well-documented in scientific literature. Almost thirty years ago, Dr. Richard Marks and Dr. Edward Sachar researched the inadequate management of pain in the hospital setting.⁸ Based on structured interviews and chart reviews of thirty-seven inpatients hospitalized at Montefiore Hospital and Medical Center in New York, 32% of the patients exhibited ongoing severe distress from pain despite receiving narcotic treatment.⁹ The physicians also noted that 41% of the subjects remained in moderate stress from pain, and 27% of the subjects complained of minimal distress from pain, even though both groups received pain medication.¹⁰ From this data, the authors concluded that there “was clearly a general pattern of undertreatment of pain with

8. Richard M. Marks & Edward J. Sachar, *Undertreatment of Medical Inpatients with Narcotic Analgesics*, 78 ANNALS OF INTERNAL MED. 173, 173 (1973).

9. *Id.* at 175.

10. *Id.*

narcotic analgesics, leading to widespread and significant patient distress.”¹¹

Recent studies demonstrate that the inadequate management of pain remains a problem in the United States. These studies have demonstrated continued inadequacies in treatment (1) of those patient populations most likely to suffer from chronic and acute pain, including terminally ill patients,¹² cancer patients,¹³ nursing home residents,¹⁴ elderly individuals,¹⁵ and chronic pain patients,¹⁶ and (2) in those medical environments where acute pain is routine, such as the emergency room,¹⁷ the post-operative unit,¹⁸ and the intensive care unit.¹⁹

In a 1994 study of 1308 outpatients with metastatic cancer, more than two-thirds exhibited pain.²⁰ While most of the patients who complained of pain received some type of alleviative treatment, 36% reported that their pain was severe enough to impair their ability function, affecting their enjoyment of life, level of activity, ability to walk, sleep, and work, and

11. *Id.* at 176.

12. Ezekiel J. Emanuel et al., *The Practice of Euthanasia and Physician Assisted Suicide in the United States*, 280 JAMA 507, 510 (1998); SUPPORT Principal Investigators, *A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients*, 274 JAMA 1591, 1595 (1995).

13. Charles S. Cleeland et al., 330 NEW ENG. J. MED. 592, 592 (1994) (noting that forty-two percent of outpatients with recurrent or metastatic cancer with complaints of pain were not provided with adequate pain relief). *See also* Levy, *supra* note 7, at 1124.

14. Wendy M. Stein, *Pain in the Nursing Home*, 17 CLINICS IN GERIATRIC MED. 575, 576 (2001) (estimating the prevalence of pain in nursing home residents ranges from forty-five to eighty percent). *See also* Brian A. Ferrell et al., *Pain in the Nursing Home*, 38 J. AM. GERIATRIC SOC'Y 409, 411 (1990) (concluding that as many as eighty percent of nursing home residents experience pain).

15. Brian A. Ferrell, *Pain Management in Elderly People*, 29 J. AM. GERIATRIC SOC'Y 64, 64 (1991) (revealing that twenty-five to fifty percent of elders living in the community reported complaints of pain).

16. *See generally* Myra Glajchen, *Chronic Pain: Treatment Barriers and Strategies for Clinical Practice*, 14 J. AM. BD. OF FAM. PRAC. 211 (2001).

17. Paula Tanabe & MaryBeth Buschmann, *Emergency Nurses' Knowledge of Pain Management Principles*, 26 J. EMERGENCY NURSING 299, 299 (2000) (noting that seventy-eight percent of all patients that arrived at the emergency department presented with pain as an initial symptom).

18. Harry Owen et al., *Post-operative Pain Therapy: A Survey of Patients' Expectations and Their Experiences*, 41 PAIN 303, 305 (1990). *See also* Bernardo Ng et al., *Ethnic Differences in Analgesic Consumption for Postoperative Pain*, 58 PSYCHOSOMATIC MED. 125, 128 (1996).

19. Ben A. Rich, *An Ethical Analysis of the Barriers to Effective Pain Management*, 9 CAMBRIDGE Q. OF HEALTHCARE ETHICS 54, 54 (2000) (noting fifty percent of intensive care unit patients suffered from moderate to severe pain during the last days of life, *citing* SUPPORT Principal Investigators, *A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients*, 274 JAMA 1591, 1591-98 (1995)).

20. Cleeland et al., *supra* note 13, at 592.

relations with others.²¹ The study determined that 42% of the outpatients who exhibited pain were not provided with adequate pain relief.²² The inadequate treatment of pain described in the study has many causes, each creating a separate barrier to pain management.

A. Fear of Regulatory Scrutiny as a Barrier to Pain Management

One of the primary barriers to pain management is fear of regulatory scrutiny.²³ A 1991 survey of ninety Wisconsin physicians revealed that, due to fears of regulatory inquiry, the majority of physicians (54%) prescribed fewer doses and lesser quantities of pain medication, allowed fewer refills, or selected a different drug than they otherwise would have.²⁴ In that same year, 40% of physician members of the American Pain Society reported that concerns about regulatory scrutiny, rather than medical considerations, led physicians to “avoid prescribing opioids for chronic non-cancer pain patients.”²⁵

The problem is no better today. A 2001 California survey showed that 40% of primary care physicians reported that fear of investigation tempered their use of opioids for patients with chronic non-malignant pain out of fear of investigation.²⁶ As a consequence of self-protective medical restraint, patients may be suffering needlessly simply because the regulatory environment is unfriendly to aggressive pain management.

1. Federal Law

For centuries, the medical profession has utilized opium (from which morphine is derived) to treat pain.²⁷ Despite the historical use of narcotics, opioids did not become a target of federal regulation in the United States

21. *Id.*

22. *Id.*

23. David E. Joranson & Aaron M. Gilson, *State Intractable Pain Policy: Current Status*, AM. PAIN SOC'Y BULL., March/April 1997, at <http://www.ampainsoc.org/pub/bulletin/mar97/policy.htm>.

24. David E. Weissman et al., *Wisconsin Physicians' Knowledge and Attitudes About Opioid Analgesic Regulations*, 90 WIS. MED. J. 671, 671 (1991), at www.medsch.wisc.edu/painpolicy/publicat/91wmj.htm.

25. David E. Joranson et al., *Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change*, 23 J. PAIN & SYMPTOM MGMT. 138, 139 (2002) (describing a 1990 survey of oncologists in which eighteen percent of the respondents reported excessive regulation of opioids as one of the top four barriers to pain management).

26. Michael Potter et al., *Opioids for Chronic Nonmalignant Pain: Attitudes and Practices of Primary Care Physicians in the UCSF/Stanford Collaborative Research Network*, 50 J. FAM. PRAC. 145, 148 (2001).

27. ROSELYNE REY, *THE HISTORY OF PAIN* 42-43 (Louise Elliot Wallace et al., trans., Harvard University Press ed. 1995).

until the early 1900s. The first attempt to regulate the distribution and marketing of narcotics was the Pure Food and Drug Act of 1906.²⁸ In 1914, Congress twice attempted to regulate narcotics with the Harrison Act²⁹ and the Narcotic Drugs Import and Export Act.³⁰ In 1970, Congress repealed both of these laws and enacted the Comprehensive Drug Abuse Prevention and Control Act, of which Title II is known as the Controlled Substances Act (“CSA”).³¹

In addition to the CSA, the Federal Food, Drug, and Cosmetic Act (“FDCA”)³² regulates the overall distribution or delivery of drugs.³³ The FDCA requires that the Food and Drug Administration (“FDA”) approve every new drug introduced into interstate commerce.³⁴ The FDA has approved the use of many controlled substances as safe and effective under the FDCA.³⁵

The FDA requires that all approved controlled substances be dispensed to patients only by prescription.³⁶ Upon FDA approval of controlled substances for use, health care providers may prescribe, and pharmacists may dispense, these substances to patients in compliance with the CSA and state laws and guidelines. While the FDCA and the CSA are the primary federal laws governing the manufacture, distribution, and dispensing of controlled substances, they do not regulate the practice of medicine. Medical, dental, nursing, and pharmacy licenses are issued at the state level through licensure boards.³⁷

28. Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (prohibiting the interstate commerce of adulterated drugs) (repealed by Food, Drug, and Cosmetic Act, ch. 627, 52 Stat. 1040-1059 (1938)).

29. Harrison Narcotics Act of 1914, Pub. L. No. 63-223, 38 Stat. 785 (repealed 1970); *United States v. Brandenburg*, 155 F.2d 110, 111 (3d Cir. 1946):

Under . . . the statute, it is unlawful for any person to sell, barter, or exchange or give away certain drugs (including [morphine]), except in pursuance of a written order on a form issued for that purpose by the Secretary of the Treasury. An exception is made to “the dispensing or distribution of any of the drugs . . . to a patient by a physician . . . in the course of his professional practice only.

30. Narcotic Drugs Import and Export Act of 1914, Pub. L. No. 63-230, 38 Stat. 275 (repealed 1970).

31. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1242 (codified as amended in scattered sections of 21 U.S.C.).

32. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-99 (2000). *See also* 21 U.S.C.A. §§ 301-99 (West 2003).

33. 21 U.S.C. §§ 351-60. *See also* 21 U.S.C.A. §§ 351-60.

34. 21 U.S.C. § 355 (2000). *See also* 21 U.S.C.A. § 355.

35. *See, e.g.*, Laurence Hammack, *OxyContin*, ROANOKE TIMES, 2001, at <http://www.roanoke.com/archives> (noting that the FDA approved the use of 10 mg, 20 mg, and 40 mg extended-release tablets of OxyContin).

36. 21 C.F.R. § 290.1 (2003).

37. *See, e.g.*, N.Y. PUB. HEALTH LAW § 3310.1 (McKinney 2002) (requiring licensure

a. Categories of Controlled Substances

The CSA classifies narcotics and other controlled substances in five categories, or schedules. The scheduling of controlled substances, overseen by the Drug Enforcement Administration (“DEA”), FDA, and the National Institute on Drug Abuse, is determined by several factors, including the potential for abuse, the risk to public health, and the risk of psychological or physiological dependence.³⁸

Schedule I substances have a high potential for abuse and are not approved for medical use.³⁹ Schedule I substances include heroin, marijuana, and lysergic acid.⁴⁰ Neither retail pharmacies nor providers are authorized to dispense Schedule I substances. These substances are available to health care providers solely for investigational research, and a research protocol must be approved by the FDA prior to registration with the DEA for handling Schedule I substances.⁴¹

A drug is included in Schedule II if it meets three requirements: (1) a high potential for abuse; (2) a currently accepted medical use in treatment in the United States; and (3) the abuse of the drug may lead to severe psychological or physical dependence.⁴² Among Schedule II substances are fentanyl, morphine, hydromorphone, oxycodone, and amphetamines.⁴³ In contrast to Schedule I substances, health care providers are authorized to prescribe Schedule II substances with certain limitations.⁴⁴ For example, unlike other prescription drugs, which a pharmacist may dispense upon receiving a telephone or fax prescription, a pharmacist generally may not dispense a Schedule II drug before having received and reviewed an original, signed prescription.⁴⁵ Also unlike other prescription drugs, a prescription for a Schedule II drug may not include an authorization for refills.⁴⁶

prior to dispensing controlled substances).

38. 21 U.S.C. § 811(c) (2000) (directing the Attorney General to consider: (1) the drug’s actual or relative potential for abuse; (2) scientific evidence of its pharmacologic effect; (3) the state of current scientific knowledge regarding the drug; (4) the drug’s history and current pattern of abuse; (5) the scope, duration, and significance of abuse; (6) any risk to the public health; (7) the psychic or physiological dependence liability; and (8) whether the substance is an immediate precursor of a substance that is already controlled).

39. 21 U.S.C. § 812(b)(1) (2000). *See generally* 21 U.S.C. § 812(b)(1)-(6), (c).

40. 21 C.F.R. § 1308.11(c)(11), (d)(18)-(19) (2003).

41. *See* 21 C.F.R. § 1301.18(a) (2003).

42. 21 U.S.C. § 812(b)(2).

43. 21 U.S.C. § 812(c) Schedule II (b)(6); 21 C.F.R. § 1308.12(b)(1)(12), (14)-(15), (d)(1) (2003).

44. 21 U.S.C. § 829(a) (2000). *See generally* 21 U.S.C. § 829(a)-(b).

45. 21 C.F.R. § 1306.11(a) (2003).

46. 21 C.F.R. § 1306.12 (2003) (forbidding refills on Schedule II drugs); 21 C.F.R. §

Schedule III substances have a lower potential for abuse than substances in Schedules I and II, are accepted for medical use, and may lead to low to moderate physical dependence or a high psychological dependence.⁴⁷ Examples include secobarbital, pentobarbital, and anabolic steroids.⁴⁸ Schedule IV drugs have a low potential for abuse in comparison to Schedule III drugs, are currently accepted medical for medical use, and may lead to limited physical or psychological dependence in comparison to Schedule III substances.⁴⁹ Among Schedule IV drugs are alprazolam, phenobarbital, triazolam, and fenfuramine.⁵⁰ Schedule V substances have a low potential for abuse relative to Schedule IV substances, are currently accepted for medical use, and may lead to limited physical and psychological dependence relative to the drugs in Schedule IV.⁵¹ Examples include low doses of codeine and opium.⁵²

The CSA authorizes pharmacists to dispense Schedule III, IV, and V substances pursuant to a written, fax, or telephone prescription from a health care provider.⁵³ Schedule III and IV drugs are limited to five refills; there is no refill limit for Schedule V drugs.⁵⁴

b. Prescription Requirements

The CSA and its implementing regulations establish mandatory prescription requirements with which health care providers who intend to distribute or dispense narcotics must comply.⁵⁵ The CSA imposes a general prohibition on the distribution and dispensing of controlled substances in the United States, with a few well-delineated exceptions.⁵⁶ Among the exceptions is a provision that authorizes dispensing controlled substances pursuant to registration with the Attorney General (“DEA registration”).⁵⁷

1306.22(a) (2003) (permitting up to five refills on Schedule III and IV drugs).

47. 21 U.S.C. § 812(b)(3).

48. 21 C.F.R. § 1308.13(c)(1)(ii)-(iii), (f)(1) (2003).

49. 21 U.S.C. § 812(b)(4).

50. 21 C.F.R. § 1308.14(c)(1), (42), (48), (d)(1) (2003).

51. 21 U.S.C. § 812(b)(5).

52. 21 C.F.R. § 1308.15(c)(1), (5) (2003).

53. 21 U.S.C. § 829(b); 21 C.F.R. § 1306.21(a) (2003).

54. 21 C.F.R. § 1306.22(a)(1) (2003).

55. 21 U.S.C. § 842(a)(1) (2000). *See also* 21 U.S.C.A. § 842(a)(1) (West 2003). *See generally* 21 U.S.C. § 842(a)-(c).

56. 21 U.S.C. § 841(a)(1) (2000) (prohibiting any person from knowingly or intentionally creating, distributing, or dispensing, or possessing with the intent to distribute or dispense, a controlled substance).

57. 21 U.S.C. § 822(b). *See also* 21 U.S.C.A. § 841(a)(1) (West 2003). *See generally* 21 U.S.C. § 822(a)-(d).

Under this exception, in order to dispense⁵⁸ a controlled substance, a medical practitioner or pharmacist must first be state-licensed, both to practice and to prescribe controlled substances, and then must also successfully complete DEA registration.⁵⁹ Health care providers need a DEA registration in order to prescribe controlled substances, even if their state licenses allow them to prescribe other prescription medication. A practitioner will generally be approved for registration, unless the DEA determines that the issuance of the registration is inconsistent with the public interest.⁶⁰ The DEA considers five factors to determine whether registration is consistent with the public interest:

- (1) the recommendation of the appropriate State licensing board or professional disciplinary authority;
- (2) the applicant's experience in dispensing, or conducting research with respect to controlled substances;
- (3) the applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances;
- (4) compliance with applicable State, Federal, or local laws relating to controlled substances; and
- (5) such other conduct which may threaten the public health and safety.⁶¹

If these five factors are satisfied, the DEA will grant registration and the licensed health care provider will be authorized to prescribe or dispense narcotics so long as it is for a legitimate medical purpose in the course of professional practice. While the phrase "legitimate medical purpose" is not defined under the CSA, the DEA may assess whether a controlled substance provides a therapeutic benefit to the medical condition of the patient (i.e., the substances improve pain relief).⁶² A prescription for a controlled substance that is not intended to treat a medical condition (as when diverted to street or recreational use) will be determined to have no legitimate medical purpose.⁶³

58. The term "dispense" means "to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance." 21 USC § 802 (2000).

59. 21 U.S.C. § 822(a)(2); 21 C.F.R. §§ 1301.11, .13 (2003). *See also* 21 U.S.C. § 822(d), 21 C.F.R. §§ 1301.22-.24 (2003) (permitting and specifying conditions for a waiver of registration).

60. 21 U.S.C. § 823(f) (2000). *See also* 21 U.S.C.A. § 823(f) (West 2003).

61. 21 U.S.C. § 823(f).

62. *See, e.g.*, Murray J. Walker, Jr., M.D., 55 Fed. Reg. 5306 (Dep't Justice, Feb. 14, 1990) (hearing on registration revocation) (finding physician prescribed opioids to patients and undercover DEA agents for "no legitimate medical purpose").

63. *Id.* An important ongoing debate is whether the use of controlled substances for

c. Penalties Under the CSA

In addition to registration requirements, the CSA establishes a range of administrative, civil, and criminal penalties. The Attorney General, through the DEA, is charged with implementing and enforcing the CSA.⁶⁴ The Attorney General may suspend or revoke a provider's registration to distribute or dispense a controlled substance if the provider has acted in a manner inconsistent with the public interest.⁶⁵

In determining whether revocation or suspension of a registration is in the public interest, the DEA may assess whether registrants' practices threaten the "public health and safety" independently of whether the State suspended or revoked their licenses to practice the healing arts or prescribe controlled substances.⁶⁶ Thus, while the DEA must ensure that practitioners are in good standing as state licensees before registering them,⁶⁷ it is not

physician-assisted suicide ("PAS") is a legitimate medical purpose under the CSA. In 2001, the U.S. Attorney General issued an interpretive rule that prohibited the prescribing, administering, or dispensing controlled substances for the purposes of assisting suicide. *See* Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,608 (Nov. 9, 2001). The rule was aimed at overruling Oregon's PAS law and specifically allowed for the revocation of DEA registration of any health care provider who participated in assisted suicide using controlled substances. *Id.* In response, the State of Oregon filed suit in federal court seeking a preliminary injunction to prevent the federal government from invalidating the state's PAS law. *See Oregon v. Ashcroft*, 192 F. Supp. 2d 1077, 1079 (D. Or. 2001). The court granted Oregon's motion for summary judgment and issued a permanent injunction preventing enforcement of the rule. *Id.* at 1093. The Department of Justice appealed, and the case is presently pending before the Ninth Circuit Court of Appeals. *See* Compassion News: Ashcroft v. Oregon Archive, at http://www.compassionindying.org/ashcroft_archive.php. An affirmance of the injunction would insure that states retain their traditional authority to define what constitutes a legitimate medical purpose of controlled substances, *see* U.S. v. Evers, 643 F.2d 1043, 1048 (5th Cir. 1981), and would insulate Oregon health care providers from the onerous fear of federal prosecution for prescribing controlled substances for assisted suicides.

64. 21 U.S.C. § 871(b) (2000).

65. 21 U.S.C. § 824(a) (2000). *See also* § 824(c) (requiring an order to show cause and a hearing before the Attorney General before a registration may be denied, revoked or suspended); 21 U.S.C.A. § 824 (West 2003).

66. H.R. REP. NO. 106-378, at 4 (1999), *available at* 1999 WL 816955. *See, e.g.*, Hugh I. Schade, M.D., 60 Fed. Reg. 56,354 (denial of application) (Dep't Justice Nov. 8, 1995) (denying registration to a physician whose conduct objectively threatened "public health and safety" when he prescribed potentially lethal amounts of Darvocet to a depressed patient who used them to commit suicide); Samuel Fertig, M.D., 49 Fed. Reg. 6577 (denial of application) (Dep't Justice Feb. 22, 1984) (denying registration to a physician who prescribed massive quantities of controlled substances to several young individuals who used them in lethal overdoses, ruling that the physician "was responsible, directly or indirectly, for the deaths of several young people" and that the application must be denied to protect "public health and safety").

67. Jose R. Castro, M.D., 62 Fed. Reg. 16,189 (denial of application) (Dep't Justice Apr. 4, 1997) ("The DEA does not have statutory authority under the Controlled Substances Act to issue or maintain a registration if the applicant or registrant is without state authority to

required to wait until the practitioners' state licenses have been suspended or revoked before withdrawing their DEA registrations. The DEA will, however, consider practitioners' state licensing status as a factor in determining whether to suspend or revoke registration.⁶⁸ The suspension or revocation of DEA registration is a formidable penalty, first because it likely disrupts providers' practices by precluding them in some cases from prescribing medically-appropriate medication, and perhaps more onerously, because it may constitute grounds for state disciplinary action.

Failure to comply with the CSA also subjects providers to potentially severe civil and criminal penalties, including a civil fine of up to \$25,000⁶⁹ and, for willful violators, up to one year in prison and a fine of up to \$25,000.⁷⁰ However, while the substantial penalties provided for by the CSA do serve as a reminder that the federal government views DEA registration as a grave responsibility, actual prosecution for abusive prescription of controlled substances is often left to the states.⁷¹

2. DEA Policies and Position Statements

Federal policy on the medical use of controlled substances is embodied not only in the CSA and associated regulations, but also in DEA manuals and statements. For example, the DEA recognized in its 1990 Physician's Manual that the use of controlled substances to manage pain is a legitimate medical use and encouraged physicians to prescribe, dispense or administer narcotics when used for a legitimate medical purpose.⁷²

More recently, in 2001, the DEA joined with twenty-one pain and health organizations to issue a joint statement on the use and abuse of pain medication and physician reluctance to manage pain with controlled

handle controlled substances in the state in which he conducts business.”).

68. 21 U.S.C. § 824(a)(3). The CSA was enacted to establish a uniform national standard for the control and availability of narcotics, and a system of enforcement and penalties that is independent of State law. H.R. REP. NO. 106-378, pt. 1, at 2 (1999) (House Comm. on the Judiciary, considering the Pain Relief Promotion Act of 1999, HR 2260 (1999)). See also Hugh I. Schade, M.D., 60 Fed. Reg. at 56,356 (denying application for registration even though the physician had a valid license to practice medicine in the state of California).

69. 21 U.S.C. § 842(c)(1)(A) (2000). See also 21 U.S.C.A. § 842(c)(1)(A) (West 2003).

70. 21 U.S.C. § 842(c)(2)(A). Penalties are even more severe for practitioners found to have abused their prescribing authority. Illicit distribution, use of a false registration number, and falsifying DEA registration records are each punishable by imprisonment of up to four years and fines of up to \$30,000. 21 U.S.C.A. § 843(d)(1).

71. See, e.g., Anne Alpers, *Criminal Act or Palliative Care? Prosecutions Involving Care of the Dying*, 26 J.L. MED. & ETHICS 308, 312-15 (1998) (cataloging state medical board disciplinary actions taken against physicians in assisted dying cases).

72. DEA, U.S. DEPT. OF JUSTICE (DOJ), PHYSICIAN'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT OF 1970 (1990).

substances.⁷³ The statement was noteworthy, not only because it affirmed government support for the legitimate use of prescription drugs for patients in pain, but also because it was the first ever public collaboration between the DEA and organizations supporting pain management.⁷⁴

Importantly, the statement recognized that the undertreatment of pain is a serious problem in the United States that affects both chronic pain sufferers and the terminally ill. The statement also recognized that there exists shared responsibility between health care professionals, law enforcement, and regulatory personnel, both for ensuring that controlled substances are available to chronic and terminal patients and for assuring that pain control drugs are not abused. Finally, the statement emphasized that while the prevention of drug abuse is an important societal goal, it should not thwart pain management efforts.⁷⁵ However, while the joint statement voices support for the use of narcotics to manage pain, it fails to adequately address the reluctance of health care providers to prescribe controlled substances for fear of federal investigations and enforcement actions.

3. Enforcement

As noted above, the federal government takes seriously the mandate of the CSA and has the authority to pursue significant penalties for its violation; however, for all of the regulatory and prosecutorial power afforded by the CSA, it is rare for the DEA to actually revoke a registration or pursue criminal prosecution under the Act. While there are more than 950,000 practitioners registered with the DEA to prescribe controlled substances,⁷⁶ the DEA revoked only thirty practitioner registrations in 2002.⁷⁷ Nevertheless, the number of DEA actions against health care providers is increasing. The thirty practitioner revocations in 2002 represent a significant increase from the ten revocations in 2000 and the thirteen revocations in 2001.⁷⁸

73. DEA Press Release, *supra* note 2.

74. *Id.*

75. *Id.* In fact, DEA Administrator Asa Hutchinson urged a policy that:

[P]rotects the appropriate use of opioid pain relievers for patients who need them while also preventing abuse and diversion of drugs We don't want to cause patients who have legitimate needs for these medications, to be discouraged or afraid to use them. And we don't want to restrict doctors and pharmacists from providing these medications when appropriate

Id.

76. DEA, DOJ, REGISTRANT POPULATION: SUMMARY, at <http://www.deadiversion.usdoj.gov/drugreg/pop/summary.htm>.

77. DEA, DOJ, REGISTRANT ACTIONS: 2002, at http://www.deadiversion.usdoj.gov/fed_regs/actions/2002/index.html.

78. DEA, DOJ, REGISTRANT ACTIONS: 2000, at <http://www.deadiversion.usdoj.gov/>

When the DEA investigates a health care provider for violations of the CSA it begins by investigating the provider's prescribing practices. The DEA may initiate an investigation if it finds that a practitioner is prescribing controlled substances in aberrantly high quantities, or if it receives a complaint from a patient, pharmacist, or health care provider.⁷⁹ Under the CSA and implementing regulations, the DEA has the power to conduct administrative inspections for the purpose of completing a physical inventory of the controlled substances on the premises and reviewing records and information concerning the distribution of controlled substances by a health care provider. The DEA may also inquire into any significant increases in the prescribing of controlled substances.⁸⁰ As part of its investigation, the DEA may send undercover agents to a provider's office to attempt to obtain prescriptions for controlled substances.⁸¹

DEA investigations can last several months, after which the DEA may take formal action to suspend or revoke a health care provider's DEA registration or may pursue criminal prosecution under the CSA. The DEA's investigatory and prosecutorial powers are broad, far-reaching, and fearsome; the mere fact of being investigated by the DEA, even without a subsequent finding of culpability, can taint a practitioner's reputation and affect his practice. For example, in 1987 the DEA investigated Dr. Albert Brady, an oncologist from Portland, Oregon, for prescribing high doses of the painkiller Dilaudid to a cancer patient in a nursing home.⁸² The DEA suspected that Dr. Brady was supplying Dilaudid to the black market rather than to his patient.⁸³ Although the DEA ultimately concluded that Dr. Brady was not illicitly prescribing Dilaudid, it nevertheless notified the State Board of Medical Examiners, which fined Dr. Brady \$5000 and suspended his license for a month for overprescribing controlled substances.⁸⁴ Dr. Brady told the *Journal of NIH Research* that, as a result of this experience, his two partners "changed their practice overnight and became reluctant to prescribe sufficient doses of painkillers."⁸⁵

fed_regs/actions/2000/index.html; DEA, DOJ, REGISTRANT ACTIONS: 2001, at http://www.deadiversion.usdoj.gov/fed_regs/actions/2001/index.html.

79. See, e.g., Hugh I. Schade, M.D., 60 Fed. Reg. at 56,355 (reporting that the DEA began an investigation of Dr. Schade after receiving information that Dr. Schade had purchased quantities of controlled substances in "in excess of average U.S. and California practitioners").

80. 21 C.F.R. § 1316.03(c), (e) (2003).

81. *U.S. v. Rosen*, 582 F.2d 1032, 1032 n.2 (5th Cir. 1978).

82. Jacob Sullum, *No Relief in Sight*, REASON, Jan. 1998, at <http://www.reason.com/9701/fe.jacob.html>.

83. *Id.*

84. *Id.*

85. *Id.* See also Hugh McIntosh, 83 J. NAT'L CANCER INST. 1282, 1283 (1991)

While Dr. Brady's case may not be typical, it illustrates the impact that the DEA can have when it takes action, and the potentially chilling effect a mere investigation can have, not only on a practitioner's future conduct, but on the conduct of the entire medical profession. Indeed, recent federal investigations targeting the abusive distribution and use of the painkiller OxyContin have created a climate of fear surrounding the legitimate use of the drug, and perhaps other controlled substances, for pain management. OxyContin, a highly effective time-release pain medication, was introduced in 1995 and quickly acquired a reputation as a miracle drug for those with severe and chronic pain.⁸⁶ However, at the same time that OxyContin was helping patients win the war on pain, it was being sold on the black market and used as an illicit street drug. Consequently, over the past two years the DEA and the FDA have closely examined the misuse and abuse of OxyContin and scrutinized providers that prescribe the drug. Thus far, the DEA has relegated to the states the task of prosecuting the inappropriate prescription of OxyContin.⁸⁷ Even so, the fear of possible DEA prosecution, state prosecution, or state de-licensing has stoked physicians' fears about using OxyContin, even where its use would be medically appropriate.⁸⁸ Thus, doctors seem to be taking a more conservative approach to prescribing effective painkillers, setting back hard-won progress in the war against pain.⁸⁹ Any policy that purports to improve pain management must address the issue of over-regulation of effective pain medication at the expense of patient welfare.

It should be noted, though, that while the DEA has arguably over-regulated OxyContin and other painkillers, illicit and improper prescription and use of these drugs is a genuine problem. Doctors who abuse their authority to prescribe controlled substances are probably few in number, but represent a legitimate target for criminal prosecution. For instance, in *United States v. Larson*, a physician was convicted of distributing a controlled substance and conspiracy to distribute a controlled substance.⁹⁰ In affirming the conviction, the court rejected the physician's argument that

(describing the case of Dr. Ronald H. Blum, associate director of the Kaplan Cancer Center at New York University, in which, after Dr. Blum endured an eighteen month investigation and incurred \$10,000 in legal fees, the DEA dismissed all charges).

86. Tanya Alberts & Damon Adams, *OxyContin Crackdown Raises Physician, Patient Concerns*, AMEDNEWS.COM, June 25, 2001, at <http://www.amednews.com/2001/pr110625.html> (noting physician fears of DEA and licensure actions are growing in light of OxyContin controversy).

87. See *infra* text accompanying notes 199-209.

88. Alberts & Adams, *supra* note 86.

89. *Id.*

90. *United States v. Larson*, 507 F.2d 385, 390 (9th Cir. 1974).

the Government was required to present expert testimony to establish that the physician did not prescribe controlled substances in the usual course of medical practice and that he or she was acting other than for a legitimate medical purpose.⁹¹ The court found that the jury could make inferences from ordinary testimonial evidence and the facts and circumstances surrounding the prescriptions.⁹²

The court determined that the evidence was sufficient to sustain Dr. Larson's conviction. First, Dr. Larson prescribed excessive quantities of controlled substances, he camouflaged the excess by spreading the quantities over multiple prescriptions, and he charged a fee for each prescription.⁹³ Additionally, Dr. Larson cautioned a "patient" about having his prescription filled repeatedly at the same pharmacy.⁹⁴ Lastly, Dr. Larson used the street name for the drugs he prescribed, including "reds" (seconal) and "speed" (methamphetamine).⁹⁵ The court found that these facts and circumstances, without more, supported the jury's determination that Dr. Larson was not acting for a legitimate medical purpose or in the usual course of his professional practice.

Cases like Dr. Larson's, while rare, illustrate the type of conduct that the CSA was intended to protect against. Despite the limited number of formal actions against physicians for over-prescribing controlled substances for pain relief, federal enforcement actions and the resulting penalties imposed against physicians for prescribing drugs create a barrier to the adequate treatment of pain. Stories like Dr. Brady's have had a chilling effect on physicians who prescribe controlled substances to manage pain. Even though the chance of a federal investigation involving prescriptions for controlled substances is quite low, it should come as no surprise that physicians remain reluctant to prescribe pain medication for fear of the potential penalties and the consequent loss of professional standing and ability to earn a livelihood.⁹⁶ With so much at stake, providers choose to undertreat pain instead of treating their patients as they would like to. Any policy that is intended to improve pain management must address the fear of regulatory scrutiny. This might include revising the guidelines for DEA investigations and enforcement actions to include a safe harbor provision

91. *Id.* at 387.

92. *Id.*

93. *Id.*

94. *Id.* at 387-88.

95. *Id.* at 388.

96. Ann M. Martino, *In Search of a New Ethic for Treating Patients with Chronic Pain: What Can Medical Boards Do?*, 26 J.L. MED. & ETHICS 332, 337 (1998) (arguing that physicians have perversely strong incentives to undertreat chronic pain, leading to the syndrome of "opiophobia," the fear of prescribing narcotics).

that would immunize health care providers who, in good faith, prescribe controlled substances for pain.⁹⁷

4. Federal Policies Strike a Balance Between the Control and Availability of Narcotics

Although federal enforcement actions against physicians impede pain management, David Joranson of the Pain & Policy Studies Group of the University of Wisconsin Comprehensive Cancer Center, has suggested that the CSA, as a whole, represents a “balanced” approach in which the availability of drugs to patients for pain relief is balanced with the control of narcotics to prevent drug diversion and abuse.⁹⁸ Few would challenge the notion that a balanced approach is both desirable and necessary as a way to address and minimize the fears of health care providers who limit prescriptions of opioids out of fear of regulatory scrutiny.

a. Aspects of Federal Policy That Enhance Pain Management

While the CSA penalizes those providers who abuse their authority to prescribe, the CSA contains provisions which it can be implied that the use of narcotics is promoted in order to better manage pain. For example, federal policy specifically reflects the appropriateness of using narcotics to treat pain. This should be viewed by health care providers as encouragement to prescribe pain medication without fear of undue reprisals. It is also clear from the plain language of the statute that Congress intended that the CSA not unduly restrict practitioners from prescribing narcotics.⁹⁹ Section 801 of the CSA recognizes that controlled substances “have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.”¹⁰⁰

The CSA further provides that psychotropic substances¹⁰¹ should be controlled in accordance with the drug schedules established under the CSA to ensure that these substances are available for legitimate medical and scientific purposes.¹⁰² This is significant because psychotropic drugs, which are powerful mind- and mood-altering substances, are frequently

97. See *infra* Part IV.A.

98. JORANSON ET AL., *supra* note 2, at 3.

99. 21 U.S.C. § 801 (2000). See also 21 U.S.C.A. § 801 (West 2003).

100. 21 U.S.C. § 801 (listing Congress’ findings and declarations).

101. Psychotropics are “[d]rugs that affect psychic function, behavior, or experience.” TABER’S CYCLOPEDIA MEDICAL DICTIONARY 1632 (Clayton L. Thomas ed., 1993). Psychotropics include antidepressants, anti-anxiety medications, anticonvulsants, antipsychotics, lithium, and sleeping pills.

102. 21 U.S.C. § 801(1).

used in combination with opioids to treat pain caused by nervous system damage.¹⁰³ Congressional support for legitimate medical use of psychotropics, including for medical pain management, suggests concomitant support for the legitimate medical use of opioids to treat pain. Thus, Joranson's view that the CSA effectively balances the need for effective pain treatment with the need to prevent drug abuse finds unambiguous support in both the text and tenor of the statute; simply put, the law is not intended to diminish the medical usefulness of opioids. It is in this context that it becomes more important for federal regulators to be aware that pain management is a fundamental part of medical practice.

There are other aspects of the CSA that are noteworthy because they support a policy of effective pain management by allowing patients to have access to drugs without overburdening the provider with administrative requirements:

- The CSA does not limit the quantity of drug prescribed or dispensed and avoids using quantity or duration to determine the legitimacy of the physician's treatment of the patient.
- There are no maximum doses identified under the CSA for controlled substances.
- The CSA does not limit the period of validity for a controlled substances prescription.¹⁰⁴
- The CSA does not limit the number of refills of a controlled substance prescription for Schedules III, IV and V.
- The CSA permits pharmacists to dispense a controlled substance upon receiving oral authorization of a prescribing health care provider in emergency situations.
- Prescriptions for a Schedule II controlled substance may be transmitted via facsimile provided that the original prescription is presented to the pharmacist for review prior to dispensing the controlled substance.¹⁰⁵

These provisions promote the availability of controlled substances to patients and thus enhance pain management.

b. Aspects of Federal Regulation That Impede Pain Management

While the CSA, taken as a whole, strikes a balance between preventing the diversion of narcotics and making narcotics available to patients, there

103. Joyce M. Black & Esther Matasarran-Jacobs, LUCKMANN AND SORENSEN'S MEDICAL-SURGICAL NURSING: A PSYCHOPHYSIOLOGIC APPROACH 321 (1993).

104. JORANSON ET AL., *supra* note 2, at 29.

105. 21 C.F.R. § 1306.11(a) (2003).

are some provisions in federal policy that may impede pain management.¹⁰⁶ For example, section 1306.7 of the regulations implementing the CSA provides:

This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure . . . has been found after reasonable efforts.¹⁰⁷

While the purpose of this section appears to have been to encourage pain management by addressing provider concerns about regulatory scrutiny, the regulation implies that opioids should be used only in narrowly defined circumstances and only where other treatments have failed.¹⁰⁸ While there is little debate that both non-pharmacologic alternatives and non-opioid medications are valuable, the decision to use a particular treatment for pain should be based on medical judgment, not governmental scrutiny.¹⁰⁹ The regulation fails to reflect that the use of opioid analgesics is an important part of medical practice and that opioids may be used effectively and safely to relieve pain. Thus, the regulation impedes pain management.¹¹⁰

Consider 42 U.S.C. § 14,402 which provides that no provision of the Act should be construed to discourage the use of drugs to alleviate pain, even if such use may increase the risk of death, so long as the purpose in using the drugs is not to cause death or to assist in the causing of death.¹¹¹ This section, with its prohibitory reference to physician-assisted suicide, impedes the management of pain with controlled substances because it perpetuates the erroneous belief that opioids hasten death, even when used simply for pain management. The concern reflected in this provision is that use of the medication will sedate the patient into unconsciousness. While depressed respirations, sedation, and confusion are potential side effects of opioid therapy, research reflects that opioids do not hasten death when titrated appropriately.¹¹² Titration involves the gradual increase of the amount of an opioid until a balance is reached between pain relief and the adverse side

106. 21 C.F.R. § 1306.7 (2003).

107. 21 C.F.R. § 1306.7.

108. See JORANSON ET AL., *supra* note 2, at 26.

109. *Id.*

110. *Id.*

111. 42 U.S.C. § 14402 (2000).

112. See *infra* text accompanying notes 228-238. See generally Susan Anderson Fohr, *The Double Effect of Pain Medication: Separating Myth from Reality*, 1 J. PALLIATIVE MED. 315 (1998) (discussing fear from the potential side effects of opioid therapy).

effects of the medication, i.e., sedation or respiratory depression.¹¹³ As is currently written, the provision creates a barrier to pain management. It should be amended to reflect that opioids are not likely to hasten death when titrated appropriately.

B. State Regulation of Controlled Substances Is a Barrier to Pain Management

In addition to the federal government, individual states regulate the prescription, dispensing, and administration of drugs and the regulation of the medical, pharmacy, and nursing professions. Unlike federal policy, which is relatively balanced, state regulation of controlled substances causes a number of critical problems,¹¹⁴ which have “the potential to interfere with decisions about the care of individual patients that require medical expertise rather than government dictum.”¹¹⁵ The draconian enforcement provisions in many state regulations, coupled with a very real fear of the litigious environment for health care providers, generally has curtailed the ability of providers to prescribe drugs to manage pain. Indeed, many state policies have failed to balance the control of pain medication prescriptions with the ability of patients to obtain narcotics to control pain.

1. State Pain Policy Background

State pain policies may be prescribed not only by legislated statutes and regulations but also through guidelines and regulations of medical, pharmaceutical, or nursing boards. All fifty states have statutes and regulations that govern controlled substances. Many of the states classify controlled substances according to the schedules provided in the Federal CSA.¹¹⁶ Every state has adopted a form of the model Uniform Controlled Substances Act.¹¹⁷ All of the state laws permit prescriptions for controlled

113. Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Clinicians' Perspective*, 24 J.L. MED. & ETHICS 296, 298 (1996). See also Glajchen, *supra* note 16, at 215 (noting patients usually develop tolerance to these side effects within one week to ten days of drug therapy); Levy, *supra* note 7, at 1128.

114. JORANSON ET AL., *supra* note 2, at 4.

115. *Id.*

116. Cf. MASS. GEN. LAWS ch. 94(c), § 2 (2001) (establishing the five controlled substances schedules under the CSA and adding a sixth schedule for all prescription drugs not included in the fifth schedule).

117. See UNIF. CONTROLLED SUBSTANCES ACT 1994 (setting forth, in the References & Annotations, a table of jurisdictions where either the 1970, 1990 or 1994 version of the Act has been adopted). The original Uniform Controlled Substances Act was drafted by the National Conference of Commissioners on Uniform State Laws in 1970. The Commissioners subsequently revised the Act in 1990 and again amended it in 1994 to reflect research regarding the use of narcotics to manage pain. See generally

substances, although, unlike federal law, most do not specifically recognize the legitimate medical use of controlled substances.¹¹⁸ Moreover, some states restrict the physician's discretion by limiting the quantity of drug that can be prescribed at one time,¹¹⁹ limiting the validity of a controlled substance prescription,¹²⁰ and prohibiting prescriptions issued to substance abusers or requiring that such prescriptions be reported to a state agency.¹²¹

Furthermore, several state policies contain antiquated provisions that confuse the terms "physical dependence," "tolerance," and "addiction."¹²² Addiction is defined as a "psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm." Physical dependence, on the other hand, is a "physiological state of neuroadaptation which is characterized by the emergence of a withdrawal syndrome if the drug is stopped or decreased abruptly or if an antagonist is administered."¹²³ Physical dependence is a foreseeable result of opioid use and is not, itself, synonymous with addiction.¹²⁴ Physical tolerance is the "progressive decline of the potency of an opioid with continued use."¹²⁵ It is due to physical tolerance that patients require increasing doses of controlled substances to achieve a consistent analgesic effect.

The regulation of professional practice in medicine, nursing, and pharmacy occurs at the state level,¹²⁶ although federal agencies substantially affect professional practices by denying or ending a provider's participation in programs such as Medicare or revoking their registrations to prescribe controlled substances. State agencies issue regulations that govern the specific requirements for prescribing and dispensing controlled substances.¹²⁷ In comparison to DEA regulations, state regulations

<http://www.nccusl.org>.

118. JORANSON ET AL., *supra* note 2, at 490.

119. DEL. REG. § 40-700-021 (2001) (prohibiting more than 100 dosage units to be dispensed at one time), *reprinted in* JORANSON ET AL., *supra* note 2, at 110.

120. DEL. REG. § 40-700-021 (requiring prescriptions for Schedule II and III drugs to be filled within seven days of the original date of the prescription).

121. CAL. HEALTH & SAFETY CODE § 11156 (West 2001) (prohibiting prescriptions for controlled substances to be issued to an "addict or habitual user").

122. *See* MD. CODE ANN., CRIMES & PUNISHMENTS art. 27, § 277 (2001) (repealed by Acts 2002, ch. 26, § 2, eff. Oct. 1, 2002).

123. Fujimoto, *supra* note 2, at 545.

124. *Id.* (quoting FED'N OF STATE MED. BDS. OF U.S., INC., MODEL GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES OF THE TREATMENT OF PAIN (May 1998)).

125. Perron & Schonwetter, *supra* note 7, at 20.

126. *Cf.* United States v. Evers, 643 F.2d 1043, 1048 (5th Cir. 1981) (commenting that the Federal Food, Drug, and Cosmetic Act was not intended to regulate the practice of medicine).

127. *See, e.g.*, WASH. ADMIN. CODE § 246-840-421 (2002) (setting forth requirements

governing the prescribing and dispensing of controlled substances are often more stringent.¹²⁸

State laws authorize professional boards to license and discipline members of the profession, to investigate complaints against licensees, to conduct investigations and hold administrative proceedings, and to adopt regulations to implement their statutory authority.¹²⁹ Board investigations of a licensee are typically initiated by a complaint or by a referral from another agency.¹³⁰ Boards differ greatly as to the procedures used for inquiry and investigation into complaints. Some professional boards are statutorily required to investigate each complaint received; other boards may initiate proceedings at their discretion.¹³¹ The board investigations, often a form of administrative review,¹³² may result in disciplinary actions, which can range from a warning or reprimand to a suspension or revocation of prescribing privileges or a revocation of the provider's license.¹³³ After administrative requirements have been exhausted, the provider may appeal the decision to the state courts.¹³⁴ The criminal provisions of state controlled substance laws are enforced by state and local law enforcement and, in some instances, the state's attorney general.¹³⁵

2. State Policies Are a Barrier to Pain Management

By contrast to federal law, state policies fail to strike a balance between curtailing drug abuse and making pain management drugs available to those who need them. State policies impede pain management in three critical

for advanced nurse practitioners to qualify for prescriptive authority of Schedule II through Schedule V substances); WASH. ADMIN. CODE § 246-887-020 (2002) (providing documentation requirements for pharmacists); WASH. ADMIN. CODE § 246-919-600 (dispensing requirements for physician prescriptions of controlled substances); WASH. ADMIN. CODE § 246-919-800 (setting forth guidelines for using opioids to treat pain).

128. JORANSON ET AL., *supra* note 2, at 19, 20.

129. *E.g.*, W. VA. CODE § 30-3-7 (2002).

130. *See, e.g.*, W. VA. CODE § 30-3-14 (2002) (recognizing that the medical board may initiate disciplinary proceedings against physicians upon receipt of information from peer review committees or complaints from citizens, physicians, or pharmacists).

131. *See, e.g.*, W. VA. CODE § 30-3-14 (2002) (granting discretion to the medical board to initiate disciplinary proceedings against physicians based on information from peer review committees or complaints from citizens, physicians, or pharmacists).

132. *See generally* MED. BD. OF CA. REG. tit. 16, § 1361 (2002) (board disciplinary actions resolved pursuant to Administrative Procedure Act).

133. *See, e.g.*, LA. REV. STAT. ANN. § 37:1285A(6) (West 2002) (explaining that the medical board may suspend or revoke any license or impose probation when controlled substances are prescribed for an illegitimate medical purpose).

134. *See, e.g.*, WASH. REV. CODE § 34.05.510 (2003); WASH. ADMIN. CODE § 246-10-706 (2002); W. VA. CODE § 30-3-14 (2002).

135. *See, e.g.*, DEL. CODE ANN. tit. 16, § 4796 (2002).

ways: (1) by failing to recognize the medical value and use of opioids; (2) by using terminology that confuses physical dependence with addiction; and (3) by restricting medical decisions.¹³⁶ While these critical areas are handled differently by each state, certain commonalties are shared.

a. State Policies Fail to Recognize the Medical Value and Use of Opioids

Some state policies fail to recognize the medical value of opioids by implying that controlled substances should be used as a last resort. For example, an Arizona Medical Board guideline provides that the patient's symptoms must clearly support a diagnosis that requires opioid therapy and that "all reasonable alternative therapies have been explored."¹³⁷ A patient may be excluded from opioid therapy if he has a history of chemical dependency, a major psychiatric disorder, or a "chaotic social situation."¹³⁸ This guideline impedes pain management because it requires that opioids be used only after *other* alternative therapies have been explored. Furthermore, it implies that opioids should not be used in certain patient populations, for example, those patients with a history of chemical dependency or a major psychiatric disorder.¹³⁹ The guideline fails to recognize that the use of opioid analgesics is an important part of medical practice and that the use of controlled substances can be a safe and effective way to manage pain for all patients.¹⁴⁰ Consequently, the guideline fails to strike a balance between control and availability by placing the prevention of drug abuse ahead of access to narcotics for pain relief, and thereby interferes with pain management.

b. State Policies Confuse Physical Dependence with Addiction

State policies also fail to use terminology that distinguishes physical dependence from addiction. For example, prior to being repealed, Maryland's Controlled Substance Act defined a drug dependent person as one who was "in a state of psychic or physical dependence, or both, arising from administration of that controlled dangerous substance on a continuous basis."¹⁴¹ In defining a "drug dependent person," Maryland's Act

136. JORANSON ET AL., *supra* note 2, at 4.

137. 31 AZ. STATE BD. OF MED. EXAMINERS, GUIDELINES FOR PRESCRIBING CONTROLLED SUBSTANCES (revised June 2003), available at http://www.bomex.org/Regulatory/policy/7_policy.asp.

138. *Id.*

139. JORANSON ET AL., *supra* note 2, at 26.

140. *Id.*

141. MD. CODE ANN., CRIMES & PUNISHMENTS § 277 (2001) (repealed by Acts 2002, ch.

inappropriately confused psychological addiction with physical dependence. The World Health Organization and others have made clear that physical dependence on opioids - the sudden cessation of opioid drug therapy would result in withdrawal syndrome - is not "drug dependence" but rather is "a behavioral pattern characterized by craving for the drug and an overwhelming preoccupation with obtaining it."¹⁴²

Although physical dependence and tolerance occur in patients who take opioids over a long period, studies have shown that psychological dependence is extremely rare.¹⁴³ State pain policies should define abuse-related terms (i.e. drug dependence) so as to avoid any confusion between psychological addiction and physical dependence or tolerance. Undue anxiety about psychological dependence on opioids has caused health care providers and patients to use inadequate doses of opioids to treat pain.¹⁴⁴ In this way, Maryland impedes pain management because it implies that the prevention of drug abuse is more important than the availability of narcotics for pain relief.

c. State Policies Restrict Medical Decisions

State policies restrict medical decisions in at least three ways. First, a number of state policies restrict providers from prescribing pain medication based on patient characteristics such as age, diagnosis, prognosis, and a history of drug abuse. For example, California's Controlled Substances Act prohibits providers from prescribing or administering a controlled substance to an "addict or habitual user."¹⁴⁵ This restriction preempts a health care provider's medical discretion to treat pain in patients who are in the restricted category. Medical research reflects that controlled substances can be prescribed legitimately to individuals who are psychologically addicted to opioids, provided that controlled substances are warranted by the individual's medical condition.¹⁴⁶ California's Controlled Substances Act prohibition substitutes government judgment for medical decision-making. As written, California's provision fails to strike a balance by which the control of narcotics is an equivalent priority to the availability of opioids for pain relief and is thus a barrier to pain management.

Second, some state policies mandate that providers consult with at least

26, § 2, eff. Oct. 1, 2002) (emphasis added).

142. JORANSON ET AL., *supra* note 2, at 24.

143. *Id.*

144. *Id.*

145. CAL. HEALTH & SAFETY CODE § 11156 (West 2001).

146. Yael Swica & William Breitbart, *Treating Pain in Patients with AIDS and a History of Substance Abuse*, 176 W. J. MED. 33, 33-39 (2002).

one other provider prior to issuing a prescription for the use of controlled substance to treat intractable pain. For example, Colorado's Medical Board Guidelines define intractable pain as "pain in which the cause cannot be removed or otherwise treated and no relief or cure has been found after reasonable efforts, including *evaluation by one or more physicians specializing in the treatment of the area of the body perceived as the source of the pain.*"¹⁴⁷ While physician consultation is an important part of medical practice, Colorado's mandate that one or more pain specialists evaluate the patient appears to regulate medical decisions about pain management. The requirement does not take into account the expertise of the prescribing physician or the patient's needs, which could call for immediate attention. Federal policy is appropriately silent on this issue, leaving the decision about whether consultation is needed to the discretion of the physician. Colorado's guideline fails to strike a balance between control of narcotics and the availability of opioids for pain relief, and is thus a barrier to pain management.

Third, while federal law does not limit the quantity of drugs prescribed or dispensed and avoids identifying a specific quantity or duration that it deems to be legitimate, some state policies limit the amount of controlled substances that can be prescribed or dispensed at one time in an attempt to control the availability of narcotics and to prevent patients from becoming addicted to controlled substances. For example, Delaware's Uniform Controlled Substance Regulation limits the validity of a prescription for a Schedule II substance to seven days from the original date of the prescription, except for Schedule II prescriptions for the terminally ill or residents of long-term care facilities, which are valid for up to sixty days from the issue date.¹⁴⁸ Delaware also limits the quantity prescribed to one hundred dosage units, with an exception being made for individuals with a medically documented terminal illness or residents of long-term care facilities.¹⁴⁹

While these restrictions reflect an important goal of preventing abuse of controlled substances, they may not be sufficient to meet the individual needs of patients under all circumstances. State policymakers must realize the real-life implications that a limitation on the quantity or the duration of

147. COLO. MED. BD., POLICY 10-14, GUIDELINES FOR PRESCRIBING CONTROLLED SUBSTANCES FOR INTRACTABLE PAIN (1996) (emphasis added).

148. DEL. REG. § 40-700-021 (2001). *See also* CONN. GEN. STAT. § 21a-251(b) (2003) (explaining that Connecticut's Controlled Substances Act restricts the quantity of Schedule II controlled substances that can be prescribed within seven-days of the order entry; however, the seven-day period may be extended for another seven days with the prescribing practitioner's signature).

149. DEL. REG. § 40-700-021.

a prescription drug may have. For instance, patients may not have access or transportation to a pharmacy to fill a prescription for pain medication, the availability of which may not coincide with the duration of the prescriptions. Also, the medical condition of a patient may limit the individual's ability to go to doctor appointments or to a pharmacy to fill prescriptions for pain medication. Further, some patients may live in rural areas requiring them to travel long distances to health care providers and to pharmacies. Delaware's restrictions are barriers to the management of pain because such policies impede the availability of controlled substances to patients suffering in pain.

3. Recent Developments in State Pain Policy

a. Intractable Pain Treatment Acts

Over the past ten years, several states have attempted to improve patient access to pain management and address physician reluctance to prescribe opioids for fear of disciplinary action by enacting Intractable Pain Treatment Acts ("IPTAs").¹⁵⁰ These Acts immunize physicians from disciplinary action by state medical boards provided that the physicians comply with certain requirements. For example, Texas's IPTA prohibits a medical board from subjecting a physician to disciplinary actions where, in the course of the physician's treatment of a person for intractable pain, the physician prescribed or administered dangerous drugs or controlled substances.¹⁵¹ The Texas IPTA defines "intractable pain" as a "pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or *none has been found after reasonable efforts*."¹⁵² While the goal of IPTAs was to address physician reluctance to prescribe opioids for the treatment of chronic pain due concern about regulatory scrutiny,¹⁵³ "physicians in many states remain reluctant to write such prescriptions."¹⁵⁴

150. TEX. REV. CIV. STAT. ANN. art. 4495c (Vernon 2001) (adopted by Acts 1989, 71st leg., 1st C.S., ch. 5, § 1, eff. Nov. 1, 1989).

151. TEX. REV. CIV. STAT. ANN. art. 4495c, §§ 3, 5.

152. TEX. REV. CIV. STAT. ANN. art. 4495c, § 2(3) (emphasis added).

153. JORANSON ET AL., *supra* note 2, at 495 (asserting that the primary goal of IPTAs was to address physician reluctance to prescribe opioids for the treatment of chronic pain by providing immunity from discipline by state medical boards). Joranson suggests that the IPTAs also may have alerted state regulators and law enforcement officials to the use of opioids for intractable pain. *Id.*

154. *California Initiative Attempts to Reassure Physicians Who Prescribe Opioids*, ALCOHOLISM & DRUG WKLY., Feb. 15, 1999, available at 1999 WL 9620110.

Although IPTAs attempted to improve patient access to pain management and mitigate physician reticence to prescribe opioids, IPTAs impede pain management. First, the language in the IPTAs suggests that opioids are a last resort and that the use of opioids is not considered part of ordinary medical practice.¹⁵⁵ Second, IPTAs apply only to prescriptions of intractable pain, not other types of pain where the source of pain is known and for which relief can be achieved.¹⁵⁶ Third, the use of the term “intractable” implies that pain that is not treatable, even though chronic pain can be treated.¹⁵⁷ Fourth, IPTAs exclude pain patients who use drugs “nontherapeutically” (i.e., substance abusers).¹⁵⁸ Fifth, IPTAs often impose additional requirements, such as consultation with another physician and informed consent.¹⁵⁹ Given these issues, IPTAs are not the “most direct or effective way to address the desirable goal of relieving physician concern about regulatory scrutiny.”¹⁶⁰

b. State Special Prescription Programs

Some states have adopted laws requiring that physicians complete special prescription forms by using triplicate, duplicate, or single-copy state-issued documents.¹⁶¹ For example, New York requires that all prescriptions for Schedule II substances be prepared by the physician in triplicate on an official form prepared and issued by New York’s Department of Health (“DPH”).¹⁶² A completed form identifies the patient, the prescribing physician, and details regarding the use of the controlled

155. Joranson & Gilson, *supra* note 23 (identifying risks of IPTAs). See, e.g., CAL. BUS. & PROF. CODE § 2241.5(b) (West 2002); COLO. REV. STAT. § 12-36-117(1.5)(b) (2002); MINN. STAT. § 152.125 (2002) (subdivision 1); MO. REV. STAT. § 334.105.2(2) (2002); N.D. CENT. CODE § 19-03.3-01(2) (2002); OHIO REV. CODE ANN. § 4731.052(C) (West 2002); OR. REV. STAT. § 677.470(2) (2002); R.I. GEN. LAWS § 5-37.4-2(B) (2002); TEX. REV. CIV. STAT. ANN. art. 4495(c), § 2(3); W. VA. CODE § 30-3A-1(3) (2002).

156. Joranson & Gilson, *supra* note 23. See also TEX. REV. CIV. STAT. ANN. art. 4495(c), § 2(3) (providing the type of pain to which Texas’s IPTA applies).

157. JORANSON ET AL., *supra* note 2, at 495; Joranson & Gilson, *supra* note 23. See, e.g., TEX. REV. CIV. STAT. ANN. art. 4495(c), § 2(3) (defining intractable pain).

158. JORANSON ET AL., *supra* note 2, at 495; Joranson & Gilson, *supra* note 23. See, e.g., CAL. BUS. & PROF. CODE § 2241.5(e); MO. REV. STAT. § 334.106(3); N.D. CENT. CODE § 19-03-3-05 (2002).

159. JORANSON ET AL., *supra* note 2, at 495; Joranson & Gilson, *supra* note 23. See, e.g., CAL. BUS. & PROF. CODE § 2241.5(b); COLO. REV. STAT. § 12-36-117(1.5)(b); OHIO REV. CODE ANN. § 4731.052; OR. REV. STAT. § 677.474(3) (2002).

160. JORANSON ET AL., *supra* note 2, at 495; Joranson & Gilson, *supra* note 23.

161. See N.Y. PUB. HEALTH § 3338(2) (Consol. 2001); N.Y. COMP. CODES R. & REGS. tit. 10, §§ 80.67, 80.71 (2003).

162. N.Y. PUB. HEALTH § 3338(2); N.Y. COMP. CODES R. & REGS. tit. 10, §§ 80.67, 80.71.

substance.¹⁶³ One copy of the form is retained by the physician,¹⁶⁴ a second copy by the pharmacist,¹⁶⁵ and a third copy of the prescription is filed with DPH.¹⁶⁶ The DPH is required to retain its copy of the prescription for a period of five years, after which the prescriptions must be destroyed.¹⁶⁷ Public disclosure of a patient's identity, which is listed on a prescription for a Schedule II substance, is expressly prohibited.¹⁶⁸

In *Whalen v. Roe*, a group of patients who regularly received prescriptions for Schedule II drugs, doctors who prescribed the medication, and two associations of physicians challenged New York's prescription requirements.¹⁶⁹ These groups argued that the prescription requirements violated the right to privacy protected by the Fourteenth Amendment because patients who required Schedule II drugs declined treatment for fear that information contained on the prescriptions would be misused and that physicians were reluctant to prescribe these drugs for fear of regulatory scrutiny.¹⁷⁰ While the United States Supreme Court recognized that there was a constitutionally protected zone of privacy that included interests in avoiding disclosure of personal matters and in making important personal decisions, it held that the law adequately protected privacy (1) by limiting access to the information to authorized state employees responsible for protecting the health of the community, and (2) by providing for built-in protections from disclosure, such as the express prohibition on disclosing the identity of a patient for whom a prescription for a Schedule II controlled substance is written.¹⁷¹ The Court further held that, in contrast to a total prohibition on the use of Schedule II substances, the law did not deprive the public of access to the drugs.¹⁷² The Court upheld the constitutionality of New York's prescription requirements, finding that the law was the product of a rational legislative decision to minimize the abuse of dangerous drugs and did not invade any right or liberty protected by the Fourteenth

163. N.Y. PUB. HEALTH § 3332(2)(a)-(d) (Consol. 2001); N.Y. COMP. CODES R. & REGS. tit. 10, § 80.71.

164. N.Y. PUB. HEALTH § 3331(6) (Consol. 2001).

165. N.Y. PUB. HEALTH § 3333(4) (Consol. 2001); N.Y. COMP. CODES R. & REGS. tit. 10, § 80.73(c)(2) (2003).

166. N.Y. PUB. HEALTH § 3331(6); N.Y. COMP. CODES R. & REGS. tit. 10, § 80.73(c)(3).

167. N.Y. PUB. HEALTH § 3379(3) (Consol. 2001).

168. N.Y. PUB. HEALTH § 3371 (Consol. 2001); N.Y. COMP. CODES R. & REGS. tit. 10, § 80.107 (2003).

169. *Whalen v. Roe*, 429 U.S. 589, 595 (1977).

170. *Id.* at 599.

171. *Id.* at 598-602.

172. *Id.* at 602-03 (recognizing, however, that the concern about disclosures of identity information discouraged the use of Schedule II substances).

Amendment.¹⁷³

Similar prescription requirements are often used by state health departments, law enforcement agencies, and licensing boards, to monitor prescriptions of Schedule II drugs for the purpose of detecting fraud and abuse. For instance, Kentucky's prescription monitoring system assisted law enforcement in staging "Operation Oxyfest," the state's largest drug-abuse raid to date, resulting in the arrest of 252 people.¹⁷⁴ The extent to which prescription information is tracked and monitored by state health departments or law enforcement agencies varies greatly.¹⁷⁵ As of December 21, 2001, seventeen states monitor patients who get prescriptions and the providers who prescribe the medication.¹⁷⁶

Research collected in the wake of *Whalen v. Roe* reflects that special prescription monitoring programs continue to have a negative impact on prescribing controlled substances for legitimate purposes.¹⁷⁷ In jurisdictions with such monitoring programs, health care providers are reluctant to prescribe pain medication because they fear that the completion of the special state-issued forms will trigger an investigation into their prescribing habits by the state health department or law enforcement agency.¹⁷⁸ Critics who oppose prescription monitoring systems argue that they violate patients' privacy, are costly, and harm those in need of medication by causing doctors to prescribe fewer and less potent drugs.¹⁷⁹ For example, recent media reports reflect that physicians attempt to evade electronic monitoring systems by prescribing tranquilizers, which have greater potential side effects than Schedule II medication and are generally not tracked by state electronic monitoring systems.¹⁸⁰ Despite evidence that physicians avoid prescribing controlled substances due to recently-enacted state prescription monitoring programs, it is unlikely that courts will invalidate these programs. Relying on *Whalen v. Roe*, courts will likely find that the special prescription monitoring programs are a product of an orderly and rational legislative decision to minimize the abuse of dangerous drugs and protect the health of the community.¹⁸¹ While state prescription

173. *Id.* at 606.

174. Melody Peterson & Barry Meier, *Few States Track Prescriptions as a Method to Bar Overdoses*, N.Y. TIMES, Dec. 21, 2001, available at www.nytimes.com.

175. JORANSON ET AL., *supra* note 2, at 491.

176. David Brushwood, *Maximizing the Value of Electronic Monitoring Programs*, 31 J.L. MED. & ETHICS 41 & n.13 (2003).

177. JORANSON ET AL., *supra* note 2, at 491 (citations omitted).

178. *Id.* at 30.

179. Peterson & Meier, *supra* note 174.

180. *Id.*

181. *Cf.* Brushwood, *supra* note 176, at 43 (noting the uncertainty of whether the

monitoring programs provide an important societal benefit of preventing drug diversion and drug abuse, a more balanced approach is needed to address the accompanying reluctance of health care providers to prescribe controlled substances to patients for legitimate medical purposes.

4. State Medical Board Actions

State medical boards negatively influence physician prescribing practices by monitoring prescriptions and disciplining providers who, in the opinion of state medical boards, “over-prescribe” controlled substances for pain management.¹⁸² The case of Dr. Katherine Hoover illustrates the extent to which states scrutinize providers who prescribe controlled substances and the potential penalties that may result from such scrutiny.

In March 1994, Florida’s state licensing agency filed an administrative complaint alleging that Dr. Hoover, a board-certified physician in internal medicine, had: (1) inappropriately and excessively prescribed Schedule II controlled substances to seven of her patients, all of whom had been treated by Dr. Hoover for chronic pain arising from non-cancerous conditions; and (2) provided care that fell below the level of skill and treatment, which is recognized by a reasonably prudent physician as being acceptable under similar conditions and circumstances.¹⁸³ Dr. Hoover requested a formal hearing to challenge the allegations.¹⁸⁴

At the hearing, two expert witnesses for the State opined that Dr. Hoover’s conduct fell below the standard of care because she prescribed excessive and perhaps lethal amounts of narcotics.¹⁸⁵ The experts’ opinions were based solely on computer printouts from pharmacies where the physician’s patients had filled their prescriptions.¹⁸⁶ The printouts indicated only the quantity of drug filled for each patient and only occasionally referred to the patient’s diagnosis.¹⁸⁷ Neither of the expert physicians specialized in the treatment of chronic pain and both experts referred their

widespread dissemination of information under electronic prescription monitoring programs would alter the Supreme Court’s view of the impact of such programs on the privacy interests of patients).

182. Reynolds, *supra* note 2, at 2 (advocating that chronic pain patients should utilize tort law medical malpractice actions against physicians who under prescribe opioid medications).

183. Hoover v. Agency for Healthcare Admin., 676 So. 2d 1380, 1381 (Fla. Dist. Ct. App. 1996).

184. *Id.*

185. *Id.* at 1382.

186. *Id.* at 1381.

187. *Id.*

patients to pain management clinics.¹⁸⁸ Dr. Hoover provided detailed testimony as to her treatment of each patient, the patients' progress under the prescribed medication, and the appropriateness of the medication and amounts prescribed.¹⁸⁹

The hearing officer found that the agency failed to meet its burden of proof on all charges.¹⁹⁰ The agency subsequently requested that the board of medicine review the findings of fact and conclusions of law.¹⁹¹ The board of medicine accepted all of the agency's exceptions, amended the findings of fact in accordance with the agency's suggestions, and found Dr. Hoover in violation of Florida law.¹⁹² The board's penalty included a reprimand, a \$4000 fine, and two years probation, in addition to required continuing medical education on prescribing abusable drugs.¹⁹³ Dr. Hoover appealed the decision to the District Court of Appeals of Florida.¹⁹⁴

The District Court reversed the medical board's decision. First, the court found that the evidence was insufficient to support a breach of the standard of care.¹⁹⁵ Second, the court determined that the hearing officer was entitled to give greater weight to the testimony of Dr. Hoover and her expert witnesses where the agency's physician experts did not examine the patients or regularly engage in the treatment of chronic pain.¹⁹⁶ Third, the court concluded that the hearing officer's finding that Dr. Hoover's prescriptions did not exceed the federal guidelines for treatment of intractable pain in cancer patients (even though none of the patients had cancer) was relevant and reasonable.¹⁹⁷

While at least one scholar has suggested that the *Hoover* case and others like it support the argument that physicians who follow established medical practices for treating pain with opioids should have nothing to fear from state regulatory actions,¹⁹⁸ it is important to point out that Dr. Hoover was not vindicated until appellate review was complete. It is therefore understandable that cases like Dr. Hoover's, in which the state medical board's decision is ultimately found to be erroneous, may provide little consolation to physicians who prescribe controlled substances for pain

188. *Id.* at 1382.

189. *Hoover*, 676 So. 2d at 1382-84.

190. *Id.* at 1382.

191. *Id.*

192. *Id.*

193. *Id.*

194. *Id.*

195. *Hoover*, 676 So. 2d at 1385.

196. *Id.* at 1384.

197. *Id.* at 1383.

198. Reynolds, *supra* note 2, at 85-86.

management. Health care providers who are wrongly accused of prescribing controlled substances in violation of state law will likely endure negative publicity, loss of reputation in the medical community, revocation of hospital privileges, and will likely lose patients, time, and wages. Stories like Dr. Hoover's have had a chilling effect on physicians who prescribe narcotics to manage pain.¹⁹⁹ Physicians are reluctant to prescribe pain medication for fear of investigations and disciplinary actions by the state professional licensing boards, which are often triggered solely by the quantity of medication that a provider prescribes. With the potential for sanctions, many providers choose to refer their patients to other providers or pain management clinics for the treatment of pain to avoid prosecutions by state medical boards.²⁰⁰ This situation clearly impedes the management of pain.

5. Law Enforcement

The enforcement of controlled substance laws by state medical boards, coupled with criminal actions against health care providers, exacerbate health care providers' reluctance to prescribe narcotics for pain management. While there are only a few reported cases, anecdotal evidence suggests that doctors, nurses, and other health care providers are distressed by potential criminal prosecution for prescribing and/or administering pain medications to patients with terminal illnesses.²⁰¹ Criminal actions against providers for prescribing pain medication to patients, although rare, increase the reluctance to prescribe opioids and thus impede pain management.²⁰²

Between 1990 and 1998, few health care providers were convicted of criminal charges associated with the management of pain. For example, Ann Alpers identified six physicians who had been formally charged or indicted for homicide between 1990 and 1998.²⁰³ Of these, two physicians were acquitted, one pled guilty and received community service, one was convicted of involuntary manslaughter, a "lesser offense" in relation to homicide, one physician was convicted of attempted first-degree murder, and one physician was convicted of second-degree murder. Both murder

199. *Id.* at 86.

200. *Hoover*, 676 So. 2d at 1382.

201. Marilyn Frank-Stromborg & Anjeanette Christensen, *A Serious Look at the Undertreatment of Pain: Part I*, 5 CLINICAL J. OF ONCOLOGY NURSING NO. 5, 235, 235 (2001).

202. Alpers, *supra* note 71, at 311.

203. *Id.* (estimating that at least thirteen physicians have been investigated by law enforcement for their management of pain in patients with end-stage disease, none of whom were formally indicted or prosecuted).

convictions, however, were reversed on appeal.²⁰⁴ With respect to nurses, Alpers identified four nurses who underwent criminal investigation for the management of pain, two of whom were indicted.²⁰⁵

Since Alpers' article, the abuse of OxyContin and media attention regarding this issue have escalated. Law enforcement officers in several states have brought criminal actions against providers for over prescribing OxyContin to patients who subsequently died. In February 2002, in the first case of its kind, a jury found Dr. James F. Graves guilty of four counts of manslaughter, five counts of unlawful delivery of a controlled substance, and one count of racketeering for prescribing OxyContin to patients.²⁰⁶ Prosecutors argued that Dr. Graves recklessly wrote prescriptions to anyone willing to pay for an office visit without asking the proper pre-prescribing questions, which they argued, led to several patient deaths.²⁰⁷ Dr. Graves argued that he followed medical protocols and legitimately prescribed OxyContin and other pain medication to patients he saw in his office, further asserting that patients would not have died had they taken the medication properly.²⁰⁸ While Dr. Graves plans to appeal the verdict, he faces up to thirty years in prison.²⁰⁹ In another case, state prosecutors in Florida charged Dr. Denis Deonarine with first-degree murder, a more serious crime than manslaughter, after his patient died from an OxyContin overdose.²¹⁰

Because of increased focus on OxyContin, the reluctance of providers to prescribe OxyContin and other pain medications will continue, if not intensify. The reluctance of providers to prescribe narcotics for fear of criminal sanctions fails to achieve a balance in state pain policy. Instead, the prevention of abuse through enforcement actions overshadows efforts to improve the availability of controlled substances to patients in pain. Commentators have argued that the collective impact is to dissuade doctors

204. *Id.* Cf. Frank-Stromborg & Christensen, *supra* note 201, at 235 (stating that hospital administrators are alarmed by the possibility that physicians may be criminally prosecuted for administering pain medications to dying patients).

205. Alpers, *supra* note 71, at 311.

206. Tanya Albert, *Florida Physician Guilty of Manslaughter in OxyContin Case*, AM. MED. NEWS, Mar. 11, 2002, available at http://www.ama-assn.org/sci-pubs/amnews/pick_02/pr120311.html. The fact that a physician was convicted on a criminal charge of manslaughter is likely to have an effect on how physicians treat patients with chronic pain. *Id.* According to B. Eliot Cole, M.D., Continuing Medical Education Director at the American Academy of Pain Management, "[e]very one of these headlines probably makes 10,000 doctors wish they had gone to law school." *Id.*

207. *Id.*

208. *Id.*

209. *Id.*

210. *Id.*

from aggressively treating pain.²¹¹ These arguments are plausible notwithstanding the dearth of decisional law on this issue, principally because of the increased media focus on criminal investigations for OxyContin abuse coupled with the specter of criminal investigations. Because these enforcement efforts have the potential to impact provider livelihood and liberty, it should come as no surprise that providers would choose to undertreat pain.

C. Attitudinal Barriers to Pain Management

The undertreatment of pain in the medical setting has sources that run far deeper than reluctance [of health care providers] to provide adequate pain medication.²¹²

Although the reluctance of health care providers to prescribe narcotics for fear of criminal sanctions has exacerbated the problem of undertreatment of pain,²¹³ underprescribing narcotics for pain is caused by a multitude of factors. The attitudes of health care providers, patients and their families, and the public at large, are among the factors that both create and perpetuate barriers to pain management. For example, two major misconceptions about narcotics and pain present barriers to the management of pain: (1) a fear that opioids cause addiction, and (2) that the use of opioids can lead to terminal sedation. These misconceptions perpetuate the underprescribing of narcotics to treat pain and create barriers to proper and adequate treatment of pain.²¹⁴

1. Opiophobia

Torture, despair, agony, and death are the symptoms of “opiophobia,” a well-documented medical syndrome fed by fear, superstition, and the war on drugs. Doctors suffer the syndrome. Patients suffer the

211. E.g., Alpers, *supra* note 71, at 324-25.

212. Martino, *supra* note 96, at 334 (citing David B. Morris, *Pain's Dominion: What We Make of Pain*, WILSON Q., Sept. 22, 1994, at 3).

213. *Id.* at 332.

214. Patricia M. Clark, *Pharmacologic Pain Management in the Elderly Cancer Patient*, Medscape Conference Coverage of the 26th Congress of the Oncology Nursing Society, May 17-20, 2001, available at www.medscape.com/viewarticle/418569 (noting patient beliefs about pain can be barriers to the management of pain). See also David E. Joranson & Aaron M. Gilson, *Pharmacists' Knowledge of and Attitudes Toward Opioids: Pain Medication in Relation to Federal and State Policies*, 41 J. AM. PHARMACEUTICAL ASSOC. 213, 217 (2001). In a 2001 survey of pharmacists, Joranson and Gilson concluded that the incorrect knowledge and inappropriate attitudes of some pharmacists could contribute to a failure to dispense valid prescriptions for opioid analgesics to patients in pain. *Id.*

consequences.²¹⁵

Both health care providers and patients alike have been affected by what is described as “opiophobia.”²¹⁶ Opiophobia is the fear that the use of narcotics causes drug addiction and drug abuse, and consequently is a factor that creates a barrier to pain management.²¹⁷ The fear of addiction to narcotics appears to be based on the widespread misperception that physical dependence is equivalent to addiction. Recent studies confirm that health care providers are reluctant to prescribe, dispense, or administer opioids because they fear causing addiction or contributing to the drug abuse problem.²¹⁸ For example, in a survey of 386 physicians in Texas, 25% of the respondents believed that any patient who is given opioids for pain relief is at significant risk for addiction.²¹⁹ More than 90% of physicians “believed that they must exercise caution when prescribing potentially addictive medications to patients with chronic pain.”²²⁰

Fear of drug addiction and drug abuse is far greater for patients in chronic pain in comparison to terminally ill individuals.²²¹ For example, in a survey of 161 primary care physicians, 35% of the respondents were never willing to prescribe Schedule II opioids on a twenty-four hour basis for patients with chronic non-malignant pain, even after exhaustive evaluation and attempts at treatment.²²² Two percent of the physicians were never willing to prescribe Schedule III opioids (e.g., Tylenol with codeine)

215. Sullum, *supra* note 82.

216. John P. Morgan, *American Opiophobia: Customary Underutilization of Opioid Analgesics*, 5 ADVANCES IN ALCOHOL & SUBSTANCE ABUSE 163, 163-73 (1986).

217. See Sullum, *supra* note 82. Sullum states that opiophobia is a result of deeply rooted prejudices and that Americans have always had mixed feelings about drugs. *Id.* To deal with our ambivalence, we tend to divide drugs into neat categories: good and bad, legal and illegal, therapeutic and recreational. We are not comfortable with drugs that straddle categories, as the opioids do. The discomfort is strengthened by historical experience, ranging from Civil War veterans hooked on morphine to middle-class housewives hooked on over-the-counter remedies in the years before the Harrison Narcotics Act of 1914. *Id.*

218. David E. Joranson et al., *Trends in Medical Use and Abuse of Opioid Analgesics*, 283 JAMA 1710, 1710 (2000).

219. Sharon M. Weinstein et al., *Physicians' Attitudes Toward Pain and the Use of Opioid Analgesics: Results of a Survey from the Texas Cancer Pain Initiative*, 93 S. MED. J. 479, 482 (2000).

220. *Id.*

221. See generally Jamie H. Von Roenn et al., *Physician Attitudes and Practice in Cancer Pain Management: A Survey from the Eastern Cooperative Oncology Group*, 119 ANNALS OF INTERNAL MED. 121 (1993) (surveying health care practitioners to determine the amount of knowledge about cancer pain and to determine the methods of pain control being used by physicians), available at <http://www.annals.org/cgi/content/full/119/2/121>.

222. Michael Potter et al., *Opioids for Chronic Nonmalignant Pain: Attitudes and Practices of Primary Care Physicians in the UCSF/Stanford Collaborative Research Network*, 50 J. FAM. PRAC. 145, 147-48 (2001).

as needed for patients with chronic and persistent non-malignant pain.²²³ The surveyors concluded that the reluctance of primary care physicians to prescribe opioids for chronic non-malignant pain is connected to concerns about dependence, tolerance, and addiction, and that primary care physicians were generally more concerned about physical dependence, tolerance, and addiction than they were about diversion for illegal use, regulatory scrutiny, or side effects.²²⁴

Health care providers often confuse the terms physical dependence, tolerance, and psychological dependence and “mistakenly interpret a satisfactory analgesic drug effect as euphoria.”²²⁵ Despite provider fears, there is evidence that patients treated with narcotics rarely become psychologically addicted to pain medication.²²⁶ For example, in 1980, researchers at Boston University Medical Center reported that they had reviewed records of 11,882 hospital patients treated with narcotics and found “only four cases of reasonably well documented addiction in patients who had no history of addiction.”²²⁷ Similarly, a 1982 study of 10,000 burn victims who had received narcotic injections, most of them for weeks or months, found no cases of drug abuse that could be attributed to pain treatment.²²⁸ These studies demonstrate that the legitimate use of controlled substances is unlikely to cause psychological addiction to narcotics.

Scientific literature also supports the notion that the use of controlled substances does not contribute to an increase in opioid abuse. In a recent evaluation, researchers found that the medical use of opioids had increased between 1990 and 1996, but there was no evidence of a corresponding increase in abuse.²²⁹ Misconceptions about opioids cause reluctance on the part of health care providers to prescribe, dispense, or administer narcotics for pain relief, particularly in chronic pain patients and are thus a barrier to the adequate management of pain with controlled substances.

223. *Id.* at 147.

224. *Id.* (assessing pharmacists' attitudes toward the legality of prescribing opioids and finding that only seventy-five percent of pharmacists considered prolonged prescribing for cancer pain to be lawful and acceptable medical practice).

225. Weinstein et al., *supra* note 219, at 479.

226. Fujimoto, *supra* note 2, at 545-46 (citing Samuel Perry & George Heidrich, *Management of Pain During Debridement: A Survey of US Burn Units*, 13 PAIN 267 (1982)).

227. Sullum, *supra* note 82 (citing Jane Porter & Herschel Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 NEW ENG. J. MED. 123 (1980)).

228. Sullum, *supra* note 82.

229. Joranson et al., *supra* note 218, at 1712 (noting that the the incidence of drug addiction for patients taking opioids is less than one percent). *See also* Tanabe & Buschmann, *supra* note 17, at 299.

2. Fear That High Doses of Pain Medications Will Lead to Death

In contrast to chronic pain, the public at large and health care providers generally support the use of controlled substances to comfort terminally ill patients suffering in pain.²³⁰ However, both health care providers and patients have concerns that opioids may result in terminal sedation. As physical tolerance develops, there is fear that higher doses of narcotics will slow the patient's breathing to a point that the breathing ceases and the patient dies. While this misconception is prevalent,²³¹ there is little empirical evidence that a faster death ensues when opioids are used to manage severe pain in dying patients.²³² In fact, when properly titrated, opioids are entirely safe. Nevertheless, some providers are reluctant to prescribe opioids to terminally ill patients for fear of terminal sedation.

Although appropriate titration generally does not result in terminal sedation, it is difficult to determine the correct amount of drugs to administer. Clinicians suggest that there is no maximal or optimal quantity of an opioid analgesic drug for either chronic or cancer pain.²³³ The appropriate dose is one that relieves the patient's pain without causing adverse side effects.²³⁴ In some instances, patients with severe cancer pain may require 1200 to 1800 milligrams of oral morphine per day, while other cancer patients may require a greater dosage of intravenous morphine at 1000 to 4500 milligrams per hour.²³⁵ Clinicians such as Dr. Michael Levy recommend that the "initial dose of a drug should be based on the patient's

230. Von Roenn et al., *supra* note 219.

231. JORANSON ET AL., *supra* note 2, at 27. Courts, likely relying on the opinions of health care providers, have reinforced the erroneous belief that opioids cause respiratory depression and hasten death. For example, in *Vacco v. Quill*, the United States Supreme Court held that New York's ban on assisted suicide did not violate the Equal Protection Clause of the Fourteenth Amendment. See 521 U.S. 793, 796 (1997). See also *concurring op.* Washington v. Glucksberg, 521 U.S. 702 (1997) (O'Connor, J., concurring). In a concurring opinion, Justice O'Connor, joined by Justices Ginsberg and Breyer, stated that the provision of pain-relieving medications to a patient that hastened death would not violate the state laws prohibiting assisted suicide. *Id.* at 737. Justice O'Connor wrote that "a patient who is suffering from a terminal illness and who is experiencing great pain has no legal barriers to obtaining medication, from qualified physicians, to alleviate that suffering, even to the point of causing unconsciousness, and hastening death." *Id.* at 736-37. She further stated, "[t]here is no dispute that dying patients . . . can obtain palliative care, even when doing so would hasten their deaths." *Id.* at 737-38. While these statements support the use of opioids for pain management, they do not reflect the empirical evidence on this subject, which demonstrates that opioids, if appropriately titrated, do not generally result in terminal sedation.

232. Fohr, *supra* note 112, at 315-28.

233. Glajchen, *supra* note 16, at 214; Levy, *supra* note 7, at 1126.

234. Levy, *supra* note 7, at 1126.

235. *Id.* (citations omitted) (stating generally that dosage levels in cancer patients exceed those of patients with chronic pain).

level of pain and the efficacy of prior analgesic therapy.”²³⁶ Subsequent drug therapy should be based on “a continuing assessment of the efficacy of the therapy, with the dosage titrated upward as needed.”²³⁷ Because opioids have no ceiling effect, the dose of pain medication can be increased until pain relief is achieved or until the side effects of the medication become intolerable.²³⁸ Clinicians note that sedation and cognitive impairment typically can be managed by allowing time for tolerance to develop after drug therapy is initiated or after the dose is escalated, and also by combining the use of non-opioid, non-sedating drugs with the use of opioids.²³⁹ Clinicians also recommend that opioids be administered at regular intervals to prevent the recurrence of pain rather than administered as needed by the patient. This practice reduces overall drug consumption and minimizes the number of daily doses of medication.²⁴⁰ The erroneous belief that opioids cause terminal sedation makes health care providers reluctant to prescribe, dispense, or administer narcotics for pain relief and thus presents a barrier to the adequate management of pain with controlled substances.

3. Philosophy of Medicine

In addition to the misconceptions surrounding opioid use, the philosophical perspective of Western medicine unnecessarily perpetuates the inadequate management of pain and the negative attitudes of health care providers toward the use of opioids to treat pain.²⁴¹ First, health care providers place great weight in the objective approach to diagnosis.²⁴² This approach ultimately fails because pain is subjective, not objective.²⁴³ In order to assess pain, health care providers must rely on first-person reports

236. *Id.*

237. *Id.*

238. Glajchen, *supra* note 16, at 214-15 (noting that side effects of narcotics in patients with cancer or chronic pain include sedation, confusion, nausea, vomiting, and constipation, the most common side effect among such patients).

239. *Id.* at 215 (noting that patients usually develop tolerance to these side effects within one week to ten days of drug therapy); Levy, *supra* note 7, at 1128.

240. Glajchen, *supra* note 16, at 214 (stating that regular intervals reduce overall drug consumption); Levy, *supra* note 7 (explaining that scheduled intervals minimize the number of daily doses).

241. David B. Resnik et al., *The Undertreatment of Pain: Scientific, Clinical, Cultural, and Philosophical Factors*, 4 MED. HEALTH CARE PHIL. 277, 282 (2001) (stating that the philosophy behind modern medicine—the scientific approach to health and disease—plays a key role in explaining why health care providers undertreat pain).

242. *Id.*

243. *Id.* at 278.

from patients.²⁴⁴ The subjectivity of pain interferes with its incorporation into modern medicine. Although health care providers are taught to talk to patients about pain and include pain assessment in the initial exam and health history, they tend to put greater weight on objective tests.²⁴⁵ Chronic non-malignant pain challenges this approach given that objective tests cannot identify the source of this type of pain.

Second, the causal basis of pain is often poorly understood.²⁴⁶ Only within the past thirty years has the health care community begun to understand how the body perceives pain.²⁴⁷ When health care providers do not know or understand the causal basis for a medical condition, they frequently view the condition as not real.²⁴⁸ Doctors may treat patients' reports of pain as imaginary, exaggerated, fraudulent, or merely psychological.²⁴⁹

Third, health care providers view pain as a "mere" symptom of disease rather than a separate phenomenon with a pathology of its own. As a result, pain treatment may be given less emphasis in a patient's plan of care.²⁵⁰ Other treatment concerns, such as prolonging life and restoring health, may be viewed as more important than pain management. With this mindset, pain has traditionally not been studied in isolation. However, recently there has been a focus on the comfort of patients, as evidenced by the increasing number of pain specialists, pain centers, and palliative care.²⁵¹

Fourth, there often are no "magic bullets" to alleviate pain.²⁵² Because pain has psychological, social, cultural, and spiritual components, no magic cure exists to eliminate pain. Pain control is a complex problem that requires a multi-disciplinary approach.²⁵³ Despite clinicians' best intentions, pain and symptom control is often inadequate because the entire healthcare system has been designed around the cure of disease rather than palliation.²⁵⁴ Fifth, pain does not fit the expert knowledge model. While

244. *Id.* at 283.

245. *Id.*

246. *Id.* at 284.

247. Resnick et al., *supra* note 241, at 279.

248. *Id.* at 284.

249. *Id.* at 278.

250. *Id.*

251. MITCHELL MAX ET AL., AM. PAIN SOC'Y, TREATMENT OF PAIN AT THE END OF LIFE: A POSITION STATEMENT FROM THE AMERICAN PAIN SOCIETY, at <http://www.ampainsoc.org/advocacy/treatment.htm>.

252. Resnick et al., *supra* note 241, at 285.

253. *Id.*

254. MAX ET AL., *supra* note 251 (citing U.S. PUB. HEALTH SERV., AGENCY FOR HEALTH CARE POLICY & RESEARCH, PUB. NO. 94-0592, MANAGEMENT OF CANCER PAIN: CLINICAL PRACTICE GUIDELINE NO. 9 (1990)).

health care providers are generally educated and trained to be experts on medical issues, pain reverses the usual model of the doctor-patient relationship by placing the knowledge and authority in the hands of patients, not health care providers.²⁵⁵

For these reasons, the medical model results in negative attitudes on the part of health care providers toward the use of opioids to treat pain, which consequently results in the inadequate management of pain. Public policies to improve the management of pain should allocate funds to medical, pharmacy, and nursing schools for training and continuing education to address these issues.²⁵⁶

4. Inadequate Education in the Areas of Pain Management

Inadequate education about pain management resulting in negative attitudes about opioids is yet another factor that creates a barrier to pain management. In a survey of 386 physicians in Texas, more than fifty percent erroneously believed that drug addiction is a common result of the legitimate prescription of controlled substances.²⁵⁷ Further, approximately one-third of the respondents incorrectly believed that increasing requests for analgesics indicated tolerance to pain medication. They disagreed that almost all cancer patients suffer pain and that almost all cancer patients should receive opioids to relieve chronic pain.²⁵⁸

Inadequate knowledge about pain management is not limited to physicians alone.²⁵⁹ A study of 305 emergency room nurses reported that forty-four percent of the time, inadequate knowledge of pain management principles affected their practice in the emergency department.²⁶⁰ Because emergency room nurses screen and classify individuals in the emergency room to determine the priority of treatment, and are often the first health care providers to examine and/or interview a patient experiencing pain, the knowledge base of emergency room nurses has a profound impact on an emergency department's treatment of pain. The researchers found that the emergency nurses did not understand the difference between physical dependence, addiction, and tolerance.²⁶¹ The researchers concluded that a

255. Resnick et al., *supra* note 241, at 285.

256. *Id.* See also *infra* Part IV.D.

257. Weinstein et al., *supra* note 219, at 485.

258. *Id.*

259. Tanabe & Buschmann, *supra* note 17, at 299-305 (stating that emergency room nurses may not have a good understanding of the management of pain with drugs, or of issues such as risk of addiction).

260. *Id.* at 303-04.

261. *Id.* at 304 (noting that only sixty-one percent of questions in this areas were answered correctly).

“[m]isunderstanding of these terms may lead emergency room nurses to be overly concerned about addiction, which may lead to the undertreatment of pain.”²⁶²

Health care providers who have an inadequate knowledge about the use of controlled substances to manage pain are more reluctant to prescribe, dispense, or administer opioids to manage pain. Accordingly, public policies to improve the management of pain should include remedies to address the inadequate knowledge of pain management. For example, the receipt of federal money by professional schools and universities could be contingent upon compliance with a requirement that they incorporate pain management and the use of controlled substances to treat pain into their curricula.²⁶³ Moreover, funds could be allocated to academic institutions and professional schools for education about pain management.²⁶⁴ This would ensure that future health care providers receive at least some exposure to pain management early in their careers. Finally, DEA registration to prescribe controlled substances could be made contingent on continuing medical education in the use of controlled substances to manage pain.²⁶⁵

D. Reimbursement For Pain Management Is a Barrier to Adequate Pain Management

In addition to education, the Medicare and Medicaid programs play a critical role in pain relief in the United States. Since 1965, the federal government has provided funding for health care through the Medicare and Medicaid Programs. However, Medicare and Medicaid reimbursement policies often impede pain management.²⁶⁶ Limited prescription drug coverage, government investigations of physician diagnoses, and hospice eligibility requirements prevent Medicare and Medicaid beneficiaries from accessing pain management services.

262. *Id.*

263. *See infra* Part IV.D.

264. *See infra* Part IV.D.

265. *See infra* Part IV.D.

266. This article touches upon the most significant reimbursement issues impacting pain management in the Medicare and Medicaid programs. For a comprehensive discussion of reimbursement issues related to pain management in the Medicare and Medicaid programs, see Timothy Jost, *Public Financing of Pain Management: Leaky Umbrellas and Ragged Safety Nets*, 26 J.L. MED. & ETHICS 290, 291 (1998). For a discussion of managed care reimbursement of pain management, see Dianne E. Hoffman, *Pain Management and Palliative Care in the Era of Managed Care: Issues for Health Insurers*, 26 J.L. MED. & ETHICS 267, 267 (1998).

1. Medicare Reimbursement

The Medicare program provides payment for services and medications for almost all persons over the age of sixty-five, disabled persons under sixty-five years of age, and persons with end-stage renal disease.²⁶⁷ Medicare Part A provides coverage for inpatient hospital care,²⁶⁸ skilled nursing facilities,²⁶⁹ and hospice care²⁷⁰ whereas Medicare Part B generally provides coverage for physician services.²⁷¹ Medicare also reimburses providers for services such as pain medication injections,²⁷² infusion pumps,²⁷³ and electrical stimulation.²⁷⁴

267. 42 U.S.C. § 1395c (2000).

268. 42 U.S.C. § 1395d(a)(1) (2000) (providing coverage for inpatient hospital care “up to 150 days during any spell of illness minus 1 day for each day of such services in excess of 90 received during any preceding spell of illness.”). Inpatient hospital coverage includes drugs, 42 U.S.C. § 1395x(b)(2) (2000), 42 U.S.C.A. § 1395x(2) (West 2003), 42 C.F.R. § 409.10(a)(5) (2003), but a hospital admission solely for the purpose of administering a drug which has not been determined “reasonably necessary” is not covered. CTRS. FOR MEDICARE & MEDICAID SERVS. (CMS), DEP’T OF HEALTH & HUMAN SERVS. (DHHS), MEDICARE INTERMEDIARY MANUAL § 3101.3, available at <http://www.cms.hhs.gov/manuals> (last modified Nov. 26, 2003). However, Medicare provides payment for four weeks of inpatient hospitalization for pain rehabilitation. CMS, DHHS, COVERAGE ISSUES MANUAL § 35-21 [hereinafter CMS COVERAGE ISSUES MANUAL], available at <http://www.cms.hhs.gov/manuals> (last modified Nov. 26, 2003). Additionally, Medicare will provide payment for an outpatient hospital pain rehabilitation program provided that the patient’s pain is attributable to a physical cause, the usual methods of treatment have not been successful in alleviating the pain, and a significant loss of ability by the patient to function independently has resulted from the pain. *Id.* at § 35-21.1.

269. 42 U.S.C. § 1395d(a)(2) (providing coverage for up to 100 days of during any spell of illness post-hospital extended care services). See § 1395x(i) (defining post-hospital extended care and services).

270. 42 U.S.C. § 1395d(d) (explaining hospice care election and waiver of rights).

271. 42 U.S.C. § 1395k(a)(2)(B) (2000); 42 C.F.R. § 410.10 (2003). See also 42 U.S.C.A. § 1395k(a)(2)(B) (West 2003).

272. Medicare Part B covers drugs that are administered incidental to a physician’s professional services that cannot be self-administered and that are commonly furnished in a physician’s office or clinic without charge or included in a physician’s bill. 42 C.F.R. § 410.26 (2003). Generally, injections satisfy this requirement. Injections are not covered, however, if standard medical practice indicates that the administration of the medication by mouth is effective and is an accepted or preferred method of administration. CMS COVERAGE ISSUES MANUAL, *supra* note 268, at § 2049.2.

273. Jost, *supra* note 266, at 292. Infusion pumps are covered under the durable medical equipment benefit. 42 C.F.R. § 410.38 (2003).

274. 42 C.F.R. § 410.38(f). A transcutaneous electrical nerve stimulation (“TENS”) is a type of electrical nerve stimulator that is attached to the surface of the patient’s skin over the peripheral nerve to be stimulated. CMS COVERAGE ISSUES MANUAL, *supra* note 268, at § 60-20. Medicare pays for a TENS unit that is determined to be medically necessary and that is ordered by the beneficiary’s physician or a specialty physician on referral from the beneficiary’s physician and the written order is furnished to the supplier before the delivery

In addition, Medicare Part B provides coverage for medication supplied incidental to a physician's professional services and for those drugs that cannot be self-administered.²⁷⁵ However, Medicare does not provide payment, for oral medication in an outpatient setting, including pain medication that is supplied pursuant to a physician's prescription.²⁷⁶

of the unit to the beneficiary. 42 C.F.R. § 410.38(f)(1), (2). *See also* CMS COVERAGE ISSUE MANUAL, *supra* note 268, at § 45-19 (identifying requirements for transcutaneous electrical nerve stimulation for acute post-operative pain); *id.* at § 60-20 (explaining coverage of TENS for chronic pain under the durable equipment benefit).

275. 42 U.S.C. § 1395k(a)(2)(B) (providing Medicare Part B coverage for medical and other health services); 42 U.S.C. § 1395x(s)(2) (defining "medical and other health services" to include drugs which are not usually self-administered by the patient); 42 C.F.R. § 410.26 (explaining Medicare Part B coverage for drugs); CMS, DHHS, MEDICARE CARRIERS MANUAL § 2049, available at <http://www.cms.hhs.gov/manuals> (last modified Nov. 26, 2003).

276. On November 25, 2003, after months of contentious negotiations between House and Senate conferees, Congress approved a bill that will assist Medicare beneficiaries to pay for the costs of outpatient prescription drugs. *See Congress Approves Drug Benefit Bill, Sending Legislation to President Bush*, BNA HEALTH PLAN & PROVIDER REP. (BNA, Inc., Washington, D.C.), Dec. 3, 2003, at 1223 [hereinafter BNA Report]. *See also* Medicare Prescription Drug, Modernization and Improvement Act of 2003, Pub. L. No. 108-173, available at <http://thomas.loc.gov>. Although the drug benefit will begin in 2006, a prescription drug discount card will be made available beginning the spring of 2004. BNA Report at 1223. The bill is estimated to cost \$395 million over the next 10 years. *Id.* The full drug benefit will require beneficiaries to pay an estimated \$35 monthly premium and a \$250 annual deductible for the drug benefit. *Id.*

Prior to this bill, signed by President George W. Bush on December 8, 2003, Medicare Part B did not provide payment or medication in an outpatient setting. *See* Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173 (2003). Thus, prior to this Act, where a physician gave a patient pills or other oral medication, such medication was excluded from coverage since the form of the drug given to the patient was usually self-administered. *See* CMS COVERAGE ISSUES MANUAL, *supra* note 268, at § 2049.2. In addition, oral drugs incident to physician services were considered self-administered and, thus, were not covered under Medicare Part B. *Id.* at § 2049.2. *See also* 42 C.F.R. § 410.27 (2003).

In 1988 and 1994, initial congressional attempts to provide a Medicare prescription benefit failed. *See, e.g.,* The Medicare Catastrophic Act of 1988, Pub. L. No. 100-360, 102 Stat. 683, *repealed by* Medicare Catastrophic Repeal Act of 1989, tit. II, Pub. L. No. 101-234; American Health Security Act of 1994, H.R. 3960, 103rd Cong. (1994). A few years later, the 106th Congress introduced several bills that proposed to provide a Medicare prescription drug benefit. *See, e.g.,* Seniors Prescription Insurance Coverage Equity (SPICE) Act of 1999, H.R. 2782, S. 1480, 106th Cong. (1999). *See also* Amy J. Dilcher, *Congress Proposes to Expand Medicare to Include Coverage for Outpatient Prescription Drugs*, at www.law.uh.edu/healthlawperspectives/Medicare/20000518Congress.html (summarizing prescription drug legislation). In the 107th Congressional session, Congress introduced at least twenty-three bills that would have provided a Medicare prescription benefit or addressed Medicare's lack of coverage for prescription drugs by alternative means. None of these bills passed. Although The Medicare Modernization and Prescription Act of 2002, which proposed to provide a voluntary prescription drug coverage under the Medicare program, passed in the House, it ultimately died in the Senate. *See* The Medicare Modernization and Prescription Act, H.R. 4954, 107th Cong. (2002).

Consequently, Medicare beneficiaries can be admitted to a hospital, skilled nursing facility, or hospice, and receive Medicare coverage for care that may cost thousands of dollars; however, the program will not cover a patient's monthly prescription costs for oral pain medication, which may amount to several hundred dollars every month. The high cost of oral pain medication is necessarily a problem for elderly persons on fixed incomes who have several prescriptions. In 1996, for example, the average annual out-of-pocket expense for medication per elderly person was \$405, a ninety-one percent increase in comparison to 1987.²⁷⁷ When seniors with limited budgets must decide which prescriptions to fill, they are more likely to fill their prescriptions for blood pressure or diabetes medication, rather than medicine for pain relief, which may they consider non-essential medication. As such, Medicare's reimbursement policy for oral medication impedes pain management for Medicare beneficiaries who are suffering in pain and who are not in settings in which pain medication is reimbursed by Medicare.

Medicare Part A also provides coverage for hospice services.²⁷⁸ In 2001, the total number of hospice users was 579,801.²⁷⁹ Hospice benefits provide for the management of terminal illness and related conditions, including pain relief. To qualify for hospice benefits, a beneficiary must be considered "terminally ill" and must voluntarily elect hospice care.²⁸⁰ A beneficiary is considered "terminally ill" if a physician certifies that the beneficiary has a life expectancy of six months or less.²⁸¹ Once a beneficiary elects hospice care, the individual must waive the right to Medicare payment for all curative treatment for the terminal illness and related conditions.²⁸² In return, the patient is eligible for a variety of

277. DHHS, HEALTH AND INJURY CHARTBOOK, at 12 & tbl.119 (2001). A recent study by the Commonwealth Fund found that the average Medicare enrollee in Medicare+Choice plan (Medicare's private plan option) will spend approximately \$512 in out-of-pocket expenses for prescription drugs in 2003. Cf. Marsha Gold & Lori Achman, THE COMMONWEALTH FUND, ISSUE BRIEF NO. 667, AVERAGE OUT-OF-POCKET HEALTH CARE COSTS FOR MEDICARE+CHOICE ENROLLEES INCREASE 10 PERCENT IN 2000 (Aug. 2003) (noting the increase in out-of-pocket expenses from 1999-2003), at http://www.cmf.org/programs/medfutur/gold_averageoocosts_ib_667.pdf.

278. 42 U.S.C. § 1395d(a)(4) (2000) (explaining scope of benefits).

279. HOSPICE ASS'N OF AM., HOSPICE FACTS & STATISTICS 1 (Nov. 2002) (citing CMS, OFFICE OF THE ACTUARY, CTR. FOR HEALTH PLANS & PROVIDERS (Oct. 2002), available at <http://www.nahc.org/Consumer/hpstats.html>).

280. 42 U.S.C. § 1395d(d).

281. 42 C.F.R. § 418.22(b) (2003); 42 C.F.R. § 418.20 (2003) (describing election periods); 42 C.F.R. § 418.22 (providing requirements for certification of terminal illness).

282. 42 U.S.C. § 1395d(d)(2)(A); 42 C.F.R. § 418.24(d) (2003) (stating that election for hospice benefit requires waiver of all other Medicare benefits). The individual may revoke the election at any time. 42 U.S.C. § 1395d(d)(B)(i); 42 C.F.R. § 418.28(a) (2003).

palliative care services.²⁸³ Many experts suggest that access to hospice care under Medicare is limited and that enrollment in hospice often occurs too late.²⁸⁴ From 1992 to 2002, for instance, the number of hospice patients dying within one week of admission increased from twenty-one percent to thirty percent.²⁸⁵ Consequently, the data suggest that patients are not receiving the totality of an important Medicare benefit - at least six months of hospice services - that Congress intended the terminally ill to receive.

In a 2002 report to Congress, the Medicare Payment Commission ("MedPac") concluded that the difficulty in predicting the course of illness, even with today's advanced technology, causes late enrollment in hospice programs.²⁸⁶ Research suggests that only twenty percent of prognoses of terminal illness were accurate and sixty-three percent overestimated the survival time of beneficiaries.²⁸⁷ Given the difficulty in predicting a patient's death, most patients referred to hospice die within only three weeks of their admission to a hospice.²⁸⁸ Recognizing this, Congress

283. 42 C.F.R. § 418.202 (2003). Covered hospice services include nursing care, medical social services, physicians' services, counseling, home health aid services, physical, occupational, and speech therapy. *Id.*

284. See generally David E. Joranson, *Are Health-Care Reimbursement Policies a Barrier to Acute and Cancer Pain Management?*, 9 J. PAIN & SYMPTOM MGMT. 244 (1994), available at <http://www.medsch.wisc.edu/painpolicy/publicat/94jpsma.htm>. Short-term admissions result in increased health care costs to the hospice. *Id.*

285. MEDICARE PAYMENT ADVISORY COMM., MEDICARE BENEFICIARIES' ACCESS TO HOSPICE, REPORT TO THE CONGRESS, at 6 (May 2002). A delay in admission to hospice care has serious implications. For instance, patients in the last six months of life are likely to need pain management services, particularly those with terminal illness. Beneficiaries who remain in environments other than the hospice setting (for example, community, skilled nursing facilities, home health agencies) often do not receive appropriate management of pain because the focus in those systems is on providing curative treatment as compared to palliative care in hospice settings. Since beneficiaries who elect the hospice benefit must waive payment for all curative treatment, hospices are in the unique position to be able to focus solely on the comfort level of the patients in their dying days.

286. *Id.* (concluding that one of the main causes of late referrals to hospice included the difficulty of making prognoses of death within six months).

287. *Id.*

288. Jost, *supra* note 266, at 294 (citations omitted). Professor Jost suggests that the declining length of stay is a result of several factors. Increased pressure is being placed on doctors to refrain from referring patients to hospices until death is almost certain. *Id.* Additionally, Medicare hospital reimbursement, "which both discourages hospitals from admitting patients until their condition is grave and encourages hospitals to discharge patients as rapidly as possible, making it tempting for discharge planners to make a quick home health referral rather than a more time-consuming hospice referral." *Id.* Further, advances in technology often permit patients to remain in the community with symptoms controlled for a much longer time than previously, followed by a swift death when treatments finally fail. *Id.* Finally, other Medicare providers such as SNFs and home health agencies, may be reluctant to refer patients to hospices until the patient is in the final stages of dying because the hospice benefit is exclusive of other Medicare services. *Id.*

recently amended the Social Security Act to clarify that the certification of a terminal illness “shall be based on the physician’s or medical director’s clinical judgment regarding the normal course of the individual’s judgment.”²⁸⁹ According to MedPac, additional time may be required for the health care industry to familiarize itself with this standard and apply it.²⁹⁰

Another reason for delayed admissions to hospice care is physicians’ concern with investigations into Medicare certifications for patients who did not expire as early as predicted.²⁹¹ Investigative agencies such as the Office of Inspector General (“OIG”) have conducted retrospective reviews of terminal illness certifications.²⁹² Federal government audits of hospice certifications deter physicians from making referrals to hospice at the appropriate time²⁹³ because physicians do not wish to trigger OIG scrutiny of their medical practice (with potential charges, including Medicare fraud, at issue).²⁹⁴ Accordingly, these investigations substitute retrospective governmental scrutiny for medical judgment and are thus a barrier to the adequate management of pain.

Medicare payment rates for hospice services are yet another barrier to adequate pain management. Hospice services for both Medicare and Medicaid are paid on four prospective per diem rates, with each rate determined by the level of service and whether it is provided on an inpatient or outpatient basis.²⁹⁵ While beneficiaries are not precluded from receiving

289. Benefits Improvement and Protection Act (BIPA) of 2000, Pub. L. No. 106-554, 114 Stat. 2763 (2000) (amending § 1814(a)(7) of the Social Security Act, Subtitle C, § 322).

290. MEDICARE PAYMENT ADVISORY COMM., *supra* note 285, at 7.

291. Jost, *supra* note 266, at 295-95.

292. Jost, *supra* note 266, at 295. See also OFFICE OF THE INSPECTOR GEN. (OIG), DHHS, PUB. NO. A-05-97-00015, OIG AUDIT, BENEFICIARY HOSPICE ELIGIBILITY AT SAMARITAN CARE, INC., SOUTHFIELD, MICHIGAN, (Sept. 11, 1998), available at <http://oig.hhs.gov/oas/reports/region5/5970015.pdf>; OIG, DHHS, PUB. NO. A-02-94-01030, OIG AUDIT, REVIEW OF HOSPICE BENEFICIARY ELIGIBILITY AT HOSPICIO EN EL HOGAR DE MANATI (June 9, 1995), available at <http://oig.hhs.gov/oas/reports/region2/29401030.pdf>.

293. See, e.g., OIG, DHHS, PUB. NO. A-04-95-0211, OIG AUDIT, OPERATION RESTORE TRUST, REVIEW OF HOSPICE ELIGIBILITY AT THE HOSPICE OF THE FLORIDA SUNCOAST, INC. (Aug. 1996), available at <http://oig.hhs.gov/oas/reports/region4/4900211.pdf> (recommending recoupment of \$8.9 million relating to beneficiaries who the OIG determined were not eligible for Medicare hospice benefits). The Health Care Financing Administration (HCFA) (now the Centers for Medicare and Medicaid Services) subsequently agreed to reassess the OIG’s findings. HCFA, DHHS, MANAGEMENT REPORT ON FINAL ACTION FOR FISCAL YEAR 1999, SECTION VI (1999), available at http://www.hhs.gov/of/reports/account/acct99/sect6/sect6_5.html; HCFA, DHHS, MANAGEMENT REPORT ON FINAL ACTION FOR FISCAL YEAR 2000 (2000), available at <http://www.hhs.gov/of/reports/account/acct00/sect6/sect6b.html>.

294. Jost, *supra* note 266, at 295.

295. 42 U.S.C. § 1395f(i) (2000); 42 C.F.R. § 418.302-0.309 (2003). See also 42

hospice services in excess of six months, the hospice benefit is capped at a specific amount each year regardless of the services provided.²⁹⁶ In 1997, the OIG found that hospice patients residing in nursing homes received fewer services than similar patients who received hospice services in their homes, even though the reimbursement rates for both types of patients were the same.²⁹⁷ While hospice payment rates are adjusted for inflation annually, the rates are based on information from a Medicare demonstration project completed in the early 1980s and are thus inconsistent with the costs that efficient hospices incur in furnishing care to patients.²⁹⁸ In its report to Congress, MedPac recommended evaluating hospice payment rates to ensure that they are consistent with the costs of providing appropriate care.²⁹⁹

2. Medicaid Reimbursement

In addition to Medicare, a major payer of services, Medicaid is a joint federal and state program also providing coverage for pain management.³⁰⁰ The Medicaid program provides coverage for health-related services for the poor and for individuals over the age of sixty-five who are dually eligible for Medicaid.³⁰¹ Because Medicaid is run by the states, Medicaid coverage policies for pain management differ from state to state. In general,

U.S.C.A. § 195f(i) (West 2003).

296. For fiscal year ending October 31, 2001, the hospice cap amount was \$16,650.85. See Palmetto GBA, Change in Hospice Payment Rates, Update to the Hospice Cap, Revised Hospice Wage Index and Hospice Pricer, available at <http://www.palmettogba.com>; Memorandum from Thomas E. Hamilton, CMS Director of the Disabled and Elderly Health Programs Group, to all Associate Regional Administrators of the Division of Medicaid and State Operations 1-2 (date not provided) (establishing Medicare payment rates for FY 2002). Section 1814(i)(1)(C)(ii) of the Social Security Act provides for an annual increase in the payment rates for hospice care services. See 42 U.S.C. § 1395f. Section 1814(i)(2)(B) of the Act provides for an annual increase or decrease in the hospice cap amount. See 42 U.S.C. § 1395f. Should a beneficiary receive hospice services that exceed the capped amount, Medicare will not pay additional hospice services. See 42 U.S.C. § 1395f. For FY 2001, the average number of hospice days utilized was 49.9 days per client. See HOSPICE ASS'N OF AM., *supra* note 279.

297. OIG, DHHS, PUB. NO. OEI-05-95-00250, HOSPICE PATIENTS IN NURSING HOMES (Sept. 1997), available at <http://oig.hhs.gov/oei/reports/oei-05-95-00250.pdf>. According to its FY 2003 work plan, the OIG plans to follow up its examination of the financial implications of Medicare hospice payments for nursing home residents. See OIG, DHHS, OIG WORK PLAN 2003, available at <http://oig.hhs.gov/publications/docs/workplan/2003/2cms%20FY03.pdf>.

298. MEDICARE PAYMENT ADVISORY COMM., *supra* note 285, at 7.

299. *Id.* at 8.

300. 42 U.S.C. § 1396a (2000). See also 42 U.S.C.A. § 1396a (West 2003).

301. Dual eligibility means that the beneficiary is eligible to receive benefits under both the Medicare and Medicaid programs. See www.cms.hhs.gov/dualeligibles/bbadadef.asp.

Medicaid provides coverage for inpatient services,³⁰² outpatient care,³⁰³ skilled nursing facility care,³⁰⁴ and physician services.³⁰⁵

The most significant Medicaid issue is prescription drug coverage. Medicaid has historically filled the gap in Medicare's lack of a prescription drug benefit by providing coverage for drugs to beneficiaries.³⁰⁶ Medicaid has also played a "key role" in bridging the gaps in Medicare for those beneficiaries who are dually eligible under both government programs.³⁰⁷ However, the Medicaid statute allows states to impose copayments on beneficiaries to limit coverage.³⁰⁸ Studies have shown that copayments of as little as one dollar per prescription have led to a five to ten percent decline in drug use, including both essential and nonessential drugs.³⁰⁹

Federal law also permits states to limit the minimum or maximum quantities per prescription or the maximum number of refills of the medication.³¹⁰ As of 1998, approximately half of the states imposed limits on the quantity of drugs that could be dispensed and/or the number of refills per prescriptions.³¹¹ More significantly, eight states limited the number of prescription refills a recipient may obtain in one month, while other states limit the number of dispensing fees that a pharmacist could receive in a month for filling a particular recipient's prescriptions.³¹² Because pain patients often require frequent dosages of medication - upwards of thirty to fifty pills a day - these limitations are likely to impede pain management.³¹³ Attempts to limit Medicaid coverage of pain medication through restrictions on the quantity of drugs have an adverse effect on pain management because patients are unable to obtain the medication they need and are left to find either another source of payment or to suffer in pain.³¹⁴

302. 42 U.S.C. § 1396d(a)(1) (2000). *See also* 42 U.S.C.A. § 1396d(a)(1) (West 2003).

303. 42 U.S.C. § 1396d(a)(2). *See also* 42 U.S.C.A. § 1396d(a)(2).

304. 42 U.S.C. § 1396d(a)(4). *See also* 42 U.S.C.A. § 1396d(a)(4).

305. 42 U.S.C. § 1396d(a)(5). *See also* 42 U.S.C.A. § 1396d(a)(5).

306. KAISER COMM'N ON MEDICAID & THE UNINSURED, HENRY J. KAISER FAMILY FOUND., A PRESCRIPTION DRUG BENEFIT IN MEDICARE: IMPLICATIONS FOR MEDICAID AND LOW-INCOME MEDICARE BENEFICIARIES 2 (Sept. 2003).

307. *Id.* at 1.

308. 42 U.S.C. § 1396o(a)(2), (3) (2000); 42 C.F.R. § 447.53-54 (2003) (providing that services cannot be denied to a recipient who is unable to pay a copayment); 42 U.S.C. § 1396o(e). As of 1998, twenty-seven states imposed copayments on prescriptions, which ranged from \$0.50 to \$3.00 per prescription. Jost, *supra* note 266, at 297.

309. Jost, *supra* note 266, at 297.

310. 42 U.S.C. § 1396o(a)(2), (3); 42 C.F.R. § 447.53-.54 (2003).

311. Jost, *supra* note 266, at 297.

312. *Id.*

313. *Id.*; JORANSON ET AL., *supra* note 2, at 495.

314. Jost, *supra* note 266, at 297.

Because the Medicare and/or Medicaid programs may limit the ability of patients to access controlled substances or hospice services for pain relief, the programs are barriers to pain management. Any policy that purports to improve pain management should: (1) eliminate the Medicare requirement that a physician certify that an individual has six months or less to live and require that physicians certify terminal illness by another standard to be determined by Centers for Medicare and Medicaid Services with input from physicians; (2) provide a safe harbor from federal and state fraud investigations for health care providers and institutions who, in good faith, certify Medicare beneficiaries for hospice services; (3) establish a requirement that OIG audits of hospice care eligibility determinations are performed by physicians who specialize in patients with terminal illness; (4) address Medicare payment rates for hospice services; and (5) prohibit states from placing limitations on the quantity of prescription drugs dispensed to Medicaid beneficiaries.

E. Civil Liability for the Undertreatment of Pain

While there are a multitude of barriers that impede adequate pain management, until recently, there were no external incentives for providers to treat pain. Traditionally, state medical boards have declined to pursue disciplinary actions against health care providers for the undertreatment of pain. For example, the family of an elderly man who died of lung cancer filed a complaint with the Medical Board of California against a physician for failing to prescribe adequate pain medication prior to his death.³¹⁵ While the Board's medical consultant agreed that "the pain care was indeed inadequate," it concluded that, "there is insufficient evidence at this time to warrant pursuing further action."³¹⁶ The family subsequently filed a lawsuit in California state court asserting medical malpractice and elder abuse.³¹⁷

Today, however, the threat of civil liability is emerging as an incentive for providers to treat pain. While there are only a few cases alleging the undertreatment of pain as the basis for a medical malpractice claim, two recent cases indicate that these actions may be on the rise. While health

315. COMPASSION IN DYING FED'N, UNDERTREATING PAIN CAN AMOUNT TO ELDER ABUSE (Feb. 3, 2000), available at <http://www.compassionindying.org/releases/elderabuse.html>; Susan Okie, *Doctor's Duty to Ease Pain at Issue in California Lawsuit*, WASH. POST, May 8, 2001, at A3, available at <http://www.washingtonpost.com/wp-dyn/health/A51818-2001May6.html>. For a description of this case, see *infra* text accompanying notes 330-53.

316. Okie, *supra* note 315, at A3.

317. Bergman v. Eden Med. Ctr., No. H205732-1 (Alameda County Ct. filed June 13, 2002). See also Barry R. Furrow, *Pain Management and Provider Liability: No More Excuses*, 29 J.L. MED. & ETHICS 28, 28 (2001).

care providers may need an incentive to provide pain medicine, in the current system these providers are placed in a difficult position where both the treatment and the overtreatment of pain may result in penalties. If they prescribe pain medication to treat pain, they are subjecting themselves to potential disciplinary or criminal actions. Under controlled substance laws, there is clearly an incentive to avoid prescribing narcotics for pain relief, including the potential for a reprimand, fines, suspension or revocation of the professional licenses, criminal penalties, jail time, and loss of liberty. However, if providers do not prescribe controlled substances, they may now face administrative disciplinary actions by state medical boards, civil actions for the undertreatment of pain, malpractice awards, increased insurance costs, and publication of such information on databases available to various health care entities and the public. The physician is forced to choose between the lesser of two evils, notwithstanding his or her wishes to provide relief from pain.

An Oregon case, the only instance to date in which a state medical board disciplined a health care provider for under-prescribing pain medication, may signal a shift in attitudes toward imposing liability for undertreating pain. In September 1999, the Oregon Board of Medical Examiners cited Dr. Paul Bilder, a fifty-four year old pulmonary specialist, for unprofessional or dishonorable conduct and gross or repeated acts of negligence for failing to adequately treat six seriously ill or dying patients with pain medication from 1993 to 1998.³¹⁸ In at least three of the cases, Dr. Bilder purportedly failed to prescribe controlled substances for pain relief for fear that pain medication would suppress the respiratory drive of his patients despite medical research reflecting appropriate titration of controlled substances does not depress patient respirations.³¹⁹ In one case, for example, Dr. Bilder refused to prescribe sedatives for a thirty-five year old woman with pulmonary disease and instead prescribed a paralytic agent, which relaxes the breathing muscles to accommodate the breathing tube.³²⁰ Dr. Bilder refused to prescribe pain medications or sedatives later that day

318. See Or. Bd. of Med. Examiners, Guide to Licensing Action Report (Aug. 14, 2003), available at www.bme.state.or.us/licensactionrpt.html (lists legal actions that have been taken by the Oregon Board of Medical Examiners). See also Erin Hoover Barnett, *Case Marks Big Shift in Pain Policy*, OREGONIAN, Sept. 2, 1999. Oregon's disciplinary action against Dr. Bilder comes more than one and a half years after a national nonprofit patient advocacy group, Compassion in Dying, called upon all fifty states medical boards and the Federation of State Medical Boards to penalize physicians who failed to give adequate pain control to terminally ill patients. *Medical Boards Urged to Penalize Docs Who Give Little Pain Relief to Dying*, MED. & HEALTH, Jan. 19, 1998, available at 1998 WL 10321284.

319. Barnett, *supra* note 318.

320. *Id.*

when the patient became restless and fought the ventilator.³²¹ When the woman subsequently pulled out her breathing tube, Dr. Bilder failed to respond to requests to re-intubate the patient.³²² While the Board did not suspend or revoke Dr. Bilder's license to practice medicine, it required him to complete a one-year program in which another pulmonary specialist worked with him to assess his practice and make improvements; it also required him to attend a continuing medical education course on physician-patient communication and to meet with a psychiatrist who would give regular reports to the Board for at least one year.³²³

Dr. Bilder's case demonstrates the extent to which providers' lack of knowledge about the appropriate use of narcotics to manage pain may negatively impact their use of narcotics to relieve pain or discomfort. Further, Dr. Bilder's story sends a message to providers that state medical boards may impose sanctions, pursuant to administrative actions, for undertreating pain. Accordingly, both the treatment and undertreatment of pain may prospectively result in penalties and the loss of external rewards (i.e., loss or suspension of license, fines, etc.). Nevertheless, health care providers may continue to perceive the potential penalties for undertreatment by medical boards less onerous than those penalties imposed when a provider overtreats, given that Oregon's medical board did not suspend or revoke Dr. Bilder's medical license but merely imposed continuing medical education, physician mentoring, and psychiatric visits. Accordingly, providers may continue to undertreat pain.

Aside from disciplinary actions, two other cases illustrate the potential civil penalties that providers may face for undertreating pain. In *Estate of Henry James v. Hillhaven*, a 1990 case, the court found a health care provider liable for failing to treat pain appropriately.³²⁴ Mr. James was admitted to Hillhaven nursing home with less than six months to live as a result of prostate cancer that had metastasized to his left femur and spine. Although a physician had ordered doses of oral morphine elixir every three hours as needed for pain, a Hillhaven nurse, based on her assessment that Mr. James was "addicted to morphine," substituted a mild tranquilizer and delayed or withheld altogether the administration of the oral morphine

321. *Id.*

322. *Id.* An on-call physician eventually reinserted the breathing tube.

323. Or. Bd. of Med. Examiners, *supra* note 318 available at www.bme.state.or.us; Barnett, *supra* note 318.

324. Robyn S. Shapiro, *Health Care Providers' Liability Exposure for Inappropriate Pain Management*, 24 J.L. MED. & ETHICS 360, 361 (1996) (describing the unreported decision of *Estate of Henry James v. Hillhaven Corp.*, No. 89CVS64 (Super. Ct. Div. N.C. Nov. 20, 1990)).

without the physician's authorization.³²⁵

Mr. James' family filed a lawsuit alleging that the failure of the nurse and the nursing home to ensure the proper administration of pain medication in appropriate doses caused Mr. James to experience "inhuman treatment" inflicted "without regard to the consequences and without care as to whether or not the patient received analgesic relief and without care that the result and procedures were torture of the human flesh."³²⁶ During the trial, medical and nursing experts testified about the proper standard of care for the administration of opioid analgesics and specifically about the administration of morphine for the relief of intractable pain.³²⁷ In addition, a nurse specializing in quality assurance for nursing homes testified that health care institutions have an obligation to ensure that their health care providers properly manage pain.³²⁸ The jury awarded fifteen million dollars in damages to the family of Mr. James, which was subsequently resolved by settlement among the parties in an undisclosed amount. In his summary statement approving the settlement, Judge Grant reiterated that Mr. James' family "does not allege that the conduct of the defendants caused the death of [Mr. James], but only that the conduct of the defendants caused [him] increased pain and suffering[.]"³²⁹

It was not until eleven years after *Hillhaven* that a jury found another health care provider liable for the undertreatment of pain. *Bergman v. Eden Medical Center* is the first case in which a physician was held liable for elder abuse under California's Bill of Patient's Rights for the undertreatment of pain based on the physician's failure to prescribe sufficient medication for a terminally ill patient.³³⁰ William Bergman, eighty-five years old, presented to Eden Medical Center in Northern California with complaints of severe back pain.³³¹ Mr. Bergman had

325. *Id.*

326. *Id.*

327. *Id.*

328. *Id.*

329. *Id.*

330. *Bergman v. Eden Med. Ctr.*, No. H205732-1 (Alameda County Ct. filed June 13, 2000). Dr. Chin was not the first physician sued under the California Elder Abuse Act for inadequate treatment. In May 2000, a physician at a nursing home was found liable for elder abuse for concealing a patient's bedsore, opposing her hospitalization when it was medically necessary, and then withdrawing from her case shortly before her death. *Mack v. Soung*, 95 Cal. Rptr. 2d 830, 835-36 (Ct. App. 2000). Like *Bergman*, the case was premised on the fact that the California Elder Abuse Act covers the failure to provide medical care for health needs. CAL. WELF. & INST. CODE § 15610.57 (West 2003).

331. Okie, *supra* note 315, at A3. See Matthew Yi, *Doctor Found Reckless for Not Relieving Pain, \$1.5 Million Jury Verdict for Family of Cancer Patient Who Went Home to Hayward to Die*, S.F. CHRON., June 14, 2001. See also Janice Lynch, *Will California Court Find Elder Abuse in Case of Inadequate Pain Management?*, at <http://ww.mywhatever.com/>

recently lost weight and had been suffering pain from a compression fracture of a spinal bone; a chest x-ray also revealed possible lung cancer.³³² Dr. Wing Chin, an internal medicine specialist who had not previously treated Bergman, admitted him to the hospital for tests and prescribed intravenous Demerol, a narcotic for pain, to be given in twenty-five to fifty milligram doses as needed.³³³

Nurses at the hospital periodically asked Mr. Bergman to rate his pain on a scale of one to ten and recorded his responses. All of the ratings in Mr. Bergman's medical chart ranged from seven to ten, corresponding with moderate to severe pain. However, progress notes recorded at other times by Dr. Chin and respiratory therapists indicated that Mr. Bergman said he "felt okay" or that his back pain was tolerable.³³⁴ Mr. Bergman underwent a procedure to obtain lung tissue—although not definitive, the results were suggestive of lung cancer. Subsequently, Mr. Bergman chose to forego treatment for lung cancer and returned home from the hospital for palliative care.³³⁵ Upon discharge, Mr. Bergman rated his pain a ten for which Dr. Chin prescribed Vicodin tablets, even though Mr. Bergman could not swallow pills and even though this medication had been ineffective for his back pain on previous occasions.³³⁶ Mr. Bergman's daughter complained that her father required stronger pain medication; accordingly, Dr. Chin ordered a single injection of Demerol and a slow-release patch containing fentanyl, a narcotic.³³⁷ After three days at home, a hospice nurse assessed Mr. Bergman's pain at level ten and called Dr. Chin to ask him to prescribe liquid morphine.³³⁸ According to court records, Dr. Chin did not prescribe the morphine.³³⁹ Later that afternoon, a doctor who had previously treated Mr. Bergman prescribed a single dose of morphine, which brought him immediate relief. Mr. Bergman died the next day.³⁴⁰

Mr. Bergman's family sued both Eden Medical Center and Dr. Chin alleging violation of California's Elder Abuse and Dependent Adult Civil Protection Act Remedies, which allows patients to ask for painkillers of

cifwriter/content/19/abcd1592.html; James Hattori, *Doctor Found Guilty of Elder Abuse* (June 12, 2001), available at <http://www.cnsf.com/storyofweek.html>.

332. Okie, *supra* note 315, at A3.

333. *Id.*

334. *Id.*

335. *Id.*

336. *Id.*

337. *Id.*

338. Okie, *supra* note 315, at A3.

339. *Id.*

340. *Id.*

their choice.³⁴¹ The act provides that “abuse” of an elder includes “neglect,” which is defined to include the failure to provide medical care for physical and mental health needs.³⁴² It allows for both criminal prosecutions³⁴³ and civil suits³⁴⁴ against those accused of elder abuse. It also allows a victim’s family to bring a lawsuit, even after the victim’s death.³⁴⁵ Because California’s malpractice laws do not allow pain and suffering for the deceased, Mr. Bergman’s family brought a lawsuit for elder abuse.³⁴⁶

The jury found Dr. Chin liable for elder abuse and reckless negligence by not giving Mr. Bergman enough pain medication. Although the jury awarded Mr. Bergman’s family \$1.5 million in general damages, it did not find that Dr. Chin acted with malice or that he had intentionally caused emotional distress that would have supported an award of punitive damages.³⁴⁷ Subsequently, the trial judge reduced the \$1.5 million damages to \$250,000, applying California’s medical malpractice cap,³⁴⁸ notwithstanding that the case had been characterized as one of abuse rather than malpractice. In April 2002, Judge Robert Hunter of the Superior Court of California for Alameda County denied defense motions to set aside the verdict and demand a new trial. The court also awarded attorney’s fees to the plaintiff and applied a 1.5 multiplier to the fee award to emphasize the importance of the case to the public interest.³⁴⁹

The *Bergman* decision has had a tremendous impact on the management of pain in California.³⁵⁰ Reacting to the case, California passed legislation³⁵¹ requiring physicians to complete continuing medical education every four years. As stated by Dr. Russell Portenoy, former president of the American Pain Society and head of the pain management department of Beth Israel Medical Center in New York City, the *Bergman* case also sends a wake-up call to physicians that there are potential civil penalties for undertreating pain: “[i]t begins to create the reality of (punishment) . . . for

341. CAL. HEALTH & SAFETY CODE §§ 15600-15675 (West 2001).

342. CAL. HEALTH & SAFETY CODE § 15610.57.

343. CAL. WELF. & INST. CODE § 15656.

344. CAL. WELF. & INST. CODE § 15657-15657.3.

345. CAL. WELF. & INST. CODE § 15657.3(c)-(d).

346. Lynch, *supra* note 331; Hattori, *supra* note 331.

347. Yi, *supra* note 331; Matthew Yi, *Elder Abuse Verdict Challenges Physicians on Pain: Doctors Must Balance Relief Against Addiction*, S.F. CHRON., June 15, 2001.

348. CAL. CIV. CODE § 3333.2(b) (West 2001).

349. Yi, *supra* note 331; Hattori, *supra* note 331.

350. Yi, *supra* note 331; Hattori, *supra* note 331.

351. CAL. BUS. & PROF. CODE § 2190 (West 2002) (codifying Bill AB 487, which was enacted Jan. 1, 2002).

physicians who don't respond to patients who have severe pain."³⁵²

Professor Barry Furrow suggests that cases similar to *Hillhaven* and *Bergman* are likely to continue and even increase in the near future given the number of "politically savvy aging babyboomers with lower back pain," the sound scientific evidence for the proper assessment of pain, and the proliferation of practice management guidelines.³⁵³ Furrow and other scholars have proposed that pain management guidelines may be utilized as a tool by plaintiff's attorneys to establish the standard of care for pain management.³⁵⁴ Practice guidelines are standardized suggestions based on a consensus of current medical research about how to treat a particular medical condition. These guidelines assist health care providers and guide patient decisions about managing a particular condition.³⁵⁵

Prior to and including the time of the *Hillhaven* case, practice guidelines for the management of pain did not exist, which would explain the absence of other undertreatment cases. Proving negligent pain management has been difficult for plaintiffs given the failure of the medical profession to implement pain management standards. In 1992, the U.S. Department of Health and Human Services Agency for Health Care Policy and Research ("AHCPR") released its Acute Pain Management Guidelines, and in 1994, it released its Cancer Pain Management Guidelines.³⁵⁶ Other groups have since released guidelines for the management of different types of pain, including peri-operative pain,³⁵⁷ low back pain,³⁵⁸ and acute and chronic pain in sickle cell disease.³⁵⁹ The Agency for Health Care Policy and Research has also issued guidelines for a variety of patient groups, including injured workers,³⁶⁰ the elderly,³⁶¹ and long-term care residents.³⁶²

352. Yi, *supra* note 331.

353. Furrow, *supra* note 317, at 30.

354. Shapiro, *supra* note 324, at 362; Furrow, *supra* note 317, at 31.

355. Furrow, *supra* note 317, at 31.

356. AGENCY FOR HEALTH CARE POLICY & RESEARCH, DHHS, PUB. NO. 92-0032, ACUTE PAIN MANAGEMENT: OPERATIVE OR MEDICAL PROCEDURES & TRAUMA, CLINICAL PRACTICE GUIDELINE (1992); AGENCY FOR HEALTH CARE POLICY & RESEARCH, DHHS, PUB. NO. 94-0592, MANAGEMENT OF CANCER PAIN, CLINICAL PRACTICE GUIDELINE (1994).

357. AM. SOC'Y OF ANESTHESIOLOGISTS, PRACTICE GUIDELINES FOR ACUTE PAIN MANAGEMENT IN THE PERIOPERATIVE SETTING (1995), at <http://www.asahq.org/publications/AndServices/pain.html>.

358. INST. FOR CLINICAL SYS. IMPROVEMENTS, ADULT LOW BACK PAIN (1999) (revised May 2001), at <http://www.guideline.gov.html>.

359. AM. PAIN SOC'Y, GUIDELINE FOR THE MANAGEMENT OF ACUTE AND CHRONIC PAIN IN SICKLE CELL DISEASE (1999), at www.guideline.gov.

360. WASH. STATE DEPT. OF LABOR & INDUS., GUIDELINES FOR OUTPATIENT PRESCRIPTION OF ORAL OPIOIDS FOR INJURED WORKERS WITH CHRONIC, NONCANCER PAIN (2000), at <http://www.guideline.gov/summary>.

361. *The Management of Persistent Pain in Older Persons*, 50 J. AM. GERIATRIC SOC'Y

Clinical practice guidelines potentially offer an authoritative and settled statement of what the standard of care should be for the treatment of pain.³⁶³ Elder abuse/neglect provisions similar to California's Patient's Bill of Rights, under which the suit against Dr. Chin was brought, combined with medical guidelines outlining proper treatment of pain in sick and dying patients, offer ways to impose responsibility for failures in pain and symptom management.³⁶⁴

While cases premised on the undertreatment of pain are likely to continue, it is unlikely that these cases alone will be sufficient to diminish physician reluctance to manage pain with controlled substances given the factors that work in concert to impede pain management. Consequently, a comprehensive solution that addresses each of the barriers to pain management is needed to shift the environment to one that treats pain adequately.

III. THE NEED FOR A COMPREHENSIVE APPROACH TO PAIN MANAGEMENT AND THE CONQUERING PAIN ACT OF 2003

There is a clear call for Congress to develop a comprehensive pain management policy. Despite advances in technology, changes to state pain policies, and the proliferation of practice guidelines for pain management, the inadequate treatment of pain continues to be a significant problem in this country. The problem is rooted in several causes: fear of disciplinary action and criminal investigations; patient and provider attitudes; and inadequate reimbursement, among others. To date, efforts to address this problem have treated only one or two components of the problem.

These solutions, which are less than comprehensive, have failed to affect an improvement in the management of pain. For example, while some state legislatures have improved state laws and regulations (i.e., the creation of IPTAs), inadequate pain management continues. Despite improvements in reimbursement policies, pain management remains a problem. The key to

205, 205 (2002), available at <http://www.guideline.gov/summary>.

362. AM. MED. DIRS. ASS'N., CHRONIC PAIN MANAGEMENT IN THE LONG-TERM CARE SETTING (1999), at <http://www.guideline.gov/summary>.

363. Furrow, *supra* note 317, at 32.

364. For instance, the Commonwealth of Pennsylvania charged Alterra Assisted Living, Inc. ("Alterra"), an assisted living facility, with three felony counts of neglect and one misdemeanor count of neglect. See Hearing Transcript, Commonwealth of Pennsylvania v. Alterra Assisted Living, Inc., CR-0000702-01(Centre County 2002) (preliminary hearing testimony of the State's expert witness, Marie Boltz, R.N.). One felony count against Alterra was based, in part, on allegations that it failed to provide adequate pain management to one resident. *Id.* After a three-day preliminary hearing, all charges against Alterra were dismissed. *Id.* (District Justice's order dated Jan. 31, 2002).

affecting an improvement is a coordinated course of action that addresses each component that contributes to the inadequate management of pain. A comprehensive approach addressing each barrier to pain management—federal and state laws; federal and state investigation and enforcement of controlled substances laws; patient and physician attitudes; inadequate education; and reimbursement policies—is needed.

A promising plan introduced in the 108th Congress, the Conquering Pain Act of 2003 (“CPA”), is a significant attempt to address a number of the barriers to pain management.³⁶⁵ Similar versions of the bill were introduced in 1999 and 2001, but met an unceremonious demise, having been referred to House and Senate committees and subcommittees but going no further.³⁶⁶ Though disappointing, in light of the myriad of political and financial issues that have confronted Congress over the past four years, it is not surprising that the CPA has not come to the forefront.³⁶⁷ However, inadequate pain management continues to be a problem with more than fifty million individuals currently suffer from chronic pain, resulting in a cost of \$100 billion dollars to society in lost productivity and increased health care costs.³⁶⁸ The management of pain deserves Congress’ attention now and the CPA is a noteworthy effort to address the inadequate treatment of pain.

First and foremost, the CPA recognizes that untreated and undertreated pain is a serious health problem in America. Congress has identified and focused on the particular problem of undertreatment of pain and, in so doing, has recognized not only the pain suffered by individual patients and the burdens suffered by many providers but also the financial burdens placed on society.³⁶⁹ Through the Act, Congress also acknowledges that providers are inadequately trained in pain management and that the treatment of pain is suboptimal because the medical model focuses on a cure rather than on symptom management.³⁷⁰ Because all of these factors have been identified as contributing to the undertreatment of pain, the CPA is more comprehensive than past legislative efforts and addresses issues including, education, attitudes, regulation, and reimbursement.

365. The Conquering Pain Act of 2003, S. 1278, H.R. 2507, 108th Cong. (2003).

366. The Conquering Pain Act of 1999, S. 941, H.R. 2188, 106th Cong. (1999); The Conquering Pain Act of 2001, S. 1024, H.R. 2156, 107th Cong. (2001).

367. While other pressing issues have occupied Congress’ time, it does not necessarily follow that there is a lack of interest in these bills. To the contrary, Congress spent a good deal of time over the last session evaluating one impediment to adequate pain management—Medicare reimbursement policies of prescription drugs. This resulted in the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. See Pub. L. No. 108-173 (2003).

368. Glajchen, *supra* note 16, at 211-18.

369. S. 1278; H.R. 2507.

370. S. 1278 § 2(6)-(7); H.R. 2507 § 2(6)-(7).

A. Title I

Under Title I, section 102, the Secretary of Health and Human Services (the “Secretary”) is required, through the Agency for Health Research and Quality (“AHRQ”), to ensure that health care facilities make available a website established by AHRQ to all health care personnel providing care or services at the health care facility.³⁷¹ The health care facilities would also be required to ensure that the website is accessible to health care providers, patients, and families.³⁷² This provision specifically addresses the inadequate education of those involved in pain management and will likely improve the knowledge of pain management groups by ensuring that these groups have access to practice guidelines.

Section 102 of Title I requires the administrators of several federal government programs, i.e., Medicare, Medicaid, the Public Health Service, and others, to inform beneficiaries that they should “expect to have their pain assessed and should expect to be provided with effective pain and symptom relief, when receiving benefits under such program.”³⁷³ While this provision will create patient expectations of pain assessment and pain relief, it falls short of requiring providers to provide pain relief for beneficiaries of these programs.

Under section 103, the Secretary is required to provide funds for the implementation of special education projects for providers, in as many states as practicable, to improve the quality of pain and symptom management.³⁷⁴ These projects would place “an emphasis on improving pain and symptom management at the end of life,” and could also include efforts to increase the quality of services delivered to chronic pain patients and the chronically ill for whom pain may be a significant symptom.³⁷⁵ This provision has the potential to improve pain management by educating providers about the management of pain.

Section 104 requires Medicare + Choice plans to provide information to beneficiaries about the “organization’s coverage of pain and symptom

371. S. 1278 tit. I, § 101(a) H.R. 2507 tit. I, § 101(a) (“Websites in existence . . . may be used if such websites meet the requirements of this section.”). The website at www.guideline.gov, which is organized and managed by the Agency on Health Care Research, will likely meet the requirements of this section.

372. S. 1278 tit. I, § 101(c)(2)(A)-(C); H.R. 2507 tit. I, § 101(c)(2)(A)-(C).

373. S. 1278 tit. I, § 102(a); H.R. 2507 tit. I, § 102(a). Government health programs include the Medicare and Medicaid program under Titles XVIII and XIX of the Social Security Act, programs through the Public Health Service Act, the Indian Health Service, the Federal Employee Benefits Program, the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), and other programs administered by Secretary of Health and Human Services. See S. 1278 tit. I, § 102(b)(1)-(7); H.R. 2507 tit. I, § 102(b)(1)-(7).

374. S. 1278 tit. I, § 103; H.R. 2507 tit. I, § 103.

375. S. 1278 tit. I, § 103; H.R. 2507 tit. I, § 103.

management” and to evaluate the plan’s performance with respect to access to, and quality of, pain and symptom management.³⁷⁶ Similar to section 102 of Title I, this provision creates patient expectations of pain assessment and pain relief. However, it similarly falls short of providing a right to pain relief for beneficiaries of these programs.

Under Section 105, the Surgeon General is required to prepare and submit to the appropriate congressional committees a report concerning the state of pain and symptom management in the United States, which includes a description of the legal and regulatory barriers to the treatment of pain.³⁷⁷ This provision is important because it recognizes that multiple barriers including inadequate education, patient differences, attitudes and stringent laws and regulations, impede the management of pain. The report by the Surgeon General makes the information available to both the appropriate congressional committees and to the public and thus increases awareness regarding pain management.³⁷⁸ However, while the Surgeon General’s report may ultimately lead to specific actions to address barriers to appropriate pain management, the provision, as written, falls short of taking specific action to remove the barriers to the management of pain.

B. Title II

Title II awards grants for the establishment of six “National Family Support Networks in Pain and Symptom Management” to serve as national models for improving access and quality of pain and symptom management.³⁷⁹ The Networks cater to chronic pain patients and individuals in need of pain management at the end of life and provide assistance to family members and caregivers. Although the provision attempts to improve patient access to pain management and patient-physician communication by establishing six networks, it fails to address physician fears of regulatory scrutiny. Consequently, even if patient access and communication is improved, the physician’s fear of investigations and sanctions for overprescribing pain medication will perpetuate the inadequate treatment of pain.

C. Title III

Section 301 of Title III of the CPA requires MedPac to conduct a study and submit a report to appropriate congressional committees concerning the

376. S. 1278 tit. I, § 104(a)(1), (2)(C); H.R. 2507 tit. I, § 104(a)(1), (2)(C).

377. S. 1278 tit. I, § 105(1); H.R. 2507 tit. I, § 105(1).

378. S. 1278 tit. I, § 105; H.R. 2507 tit. I, § 105.

379. S. 1278 tit. II, § 201(a); H.R. 2507 tit. II, § 201(a). Congress would allocate \$18 million toward this effort. See S. 1278 tit. II, § 201(e); H.R. 2507 tit. II, § 201(e).

reimbursement barriers to pain management.³⁸⁰ Section 302 of Title III would require the General Accounting Office to conduct a survey of public and private health insurance providers, including managed care entities, to determine whether reimbursement policies of these insurers inhibits access to pain and symptom management of chronic pain patients.³⁸¹ Sections 301 and 302 recognize that reimbursement and insurance policies present barriers to the management of pain. However, the provisions fall short of taking specific action to improve known reimbursement barriers to the management of pain, such as the prescription drug benefit or the hospice eligibility requirement.

D. Title IV

Section 401 of Title IV requires the Secretary to establish an advisory committee to make recommendations to the Secretary concerning a coordinated federal agenda on pain and symptom management.³⁸² The advisory committee must prepare and submit recommendations concerning the need for a federal agenda on pain and symptom management to the Secretary. The committee will also report on ways to better coordinate the activities of entities within the Department of Health and Human Services and other federal entities charged with responsibility for the delivery of health care services and research on pain and symptom management.³⁸³ Under section 402, the Secretary, with the assistance of the Institute of Medicine, will be required to review research regarding legal and regulatory barriers that impact patient access to pain and symptom management.³⁸⁴

Title IV enhances pain management for several reasons. First, it recognizes that various barriers, including federal and state legal and regulatory policies, exist to impede the management of pain. Second, Title IV implies that the medical use of opioids is appropriate and a legitimate professional practice. Third, Title IV recognizes that a comprehensive policy and a coordinated effort is necessary to improve the management of pain. However, while Title IV may ultimately lead to specific actions to address barriers to pain management, the provision, like the other provisions, falls short of taking specific action to remove the barriers to the management of pain or to address the adverse impact that federal and state enforcement of controlled substance laws has on the management of pain.

380. S. 1278 tit. III, § 301(1); H.R. 2507 tit. III, § 301(1).

381. S. 1278 tit. III, § 302(a); H.R. 2507 tit. III, § 302(a).

382. S. 1278 tit. IV, § 401(a); H.R. 2507 tit. IV, § 401(a).

383. S. 1278 tit. IV, § 401(e); H.R. 2507 tit. IV, § 401(e).

384. S. 1278 tit. IV, § 402(a)(3); H.R. 2507 tit. IV, § 402(a)(3).

E. Title V

Under Title V, the Secretary, acting through the Health Resources and Services Administration awards grants for the establishment of five or more demonstration projects to determine effective methods to measure improvement in the skills, knowledge, attitudes, and beliefs of health care personnel in pain and symptom management. Additionally, five or more demonstration projects that implement care models for individuals at the end of life are authorized under the provision. This provision, like Title I section 102, specifically addresses the inadequate education of health care providers, patients, and families regarding the management of pain and assists educators in determining how best to educate providers. However, while Title V may lead to specific actions to educate providers about pain management, this provision, as written, does not advance specific action to address the inadequate education of providers.

IV. RECOMMENDATIONS

The Conquering Pain Act of 2003 is an admirable effort by Congress to address the inadequate management of pain. It raises the public's awareness of this issue and recognizes that multiple barriers impede pain management. Additionally, the CPA acknowledges that a coordinated and comprehensive effort is required to adequately address the management of pain. As such, it devotes valuable federal resources, namely time and funds, to further research this issue. However, despite its attempts, the Act does not go far enough to attack the problem because it fails to adequately address several significant issues that are known to impede the management of pain.

A. Investigations and Enforcement

Adding a provision that addresses the barriers created by government investigations and the enforcement of controlled substance laws would strengthen the CPA. The proposed law does not contain any provisions that address this issue, even though the fear of regulatory scrutiny is a primary barrier to pain management. Health care providers are reluctant to relieve the pain of their patients even if they know it might be the best course of action. The reticence on the part of providers is understandable given the severity of the potential penalties: loss or revocation of license, fines, jail time, and loss of liberty. The CPA should support the notion that effective pain management can be achieved and that those who provide appropriate pain management have little to fear from the law.

The Act could achieve this goal in two ways.³⁸⁵ First, the CPA should be amended to provide a “safe harbor,” like those found in the state Intractable Pain Treatment Acts that immunize health care providers and health care institutions that prescribe, dispense, or administer controlled substances for the purpose of relieving pain when the provider or institution demonstrates compliance with an established practice guideline. Compliance with an applicable practice guideline for pain management would provide a defense in an administrative, civil, or criminal action under the CSA.

Second, the CPA should also be amended to address the problems with federal investigations and enforcement actions. Generally speaking, federal and particularly state investigations and enforcement actions for overprescribing pain medications are triggered by the quantity of drug prescribed to a patient, rather than a qualitative review of the patient’s condition, the length of the drug therapy, and the patient’s response to drug therapy. For this reason, the CPA should require the DEA and states to follow specific guidelines for investigations and enforcement of controlled substance laws. These guidelines should be determined with input from investigators and health care providers who prescribe controlled substances to manage pain. For example, neither federal nor state investigations should be triggered solely by the quantity of drug prescribed. Both federal and state investigators should be trained in the appropriate use of controlled substances. Further, investigators should be required to have both quantifiable and qualifiable information and documentation prior to bringing charges against any health care provider or institution for overprescribing controlled substances, and should be required to review patient medical records. This would create a presumption that the provider is acting in the best interest of the patient, which is consistent with the goal of managing pain. Investigators should also be required to consult with an expert in pain management to evaluate the patient’s medical records. On the other side, providers and institutions should ensure that they have diligently and sufficiently documented their assessments, telephone conversations with patients, and the medical necessity of prescriptions for narcotics. Adequate documentation should be utilized to refute charges of overprescribing narcotics and to demonstrate compliance with the standard of care established by practice guidelines.

B. Health Care Facility Inspection Requirements

The CPA should be amended to require that health care institutions that

385. Frank-Stromborg & Christensen, *supra* note 201, at 236.

participate in federal government health care programs assess and adequately provide pain relief for beneficiaries of those federal programs. While the CPA, as written, would create patient expectations of pain assessment and pain relief, it falls short of requiring health care facilities to provide pain relief for beneficiaries of these programs. The CPA should provide civil money penalties and other punishments for health care facilities who fail to comply with this requirement. The providers who demonstrate compliance with an established practice guideline for the management of pain necessarily would demonstrate compliance with the requirement.

C. Reimbursement

The CPA should be amended to address four well-documented reimbursement barriers to pain management.³⁸⁶

First, Congress should amend the hospice provision in the Medicare Act to eliminate the requirement that a physician certify that an individual has six months or less to live. Instead, the Act should require that physicians certify terminal illness by another standard to be determined by Centers of Medicare and Medicaid Services with input from physicians and other health care providers. The difficulty of predicting the course of illness or time of death makes the physician certification of terminal illness requirement unworkable. Consequently, hospice admissions are often delayed, and patients are not receiving the full hospice benefit (i.e., six months) that Congress intended them to receive.

Second, Congress should provide a safe harbor from federal and state fraud investigations for health care providers and institutions who have, in good faith, certified Medicare beneficiaries for hospice services. Congress should expressly require that OIG audits of hospice care eligibility determinations are performed by physicians who specialize in patients with terminal illness. Physicians' concerns about investigations of their certifications of terminal illness for hospice services delay admissions of Medicare beneficiaries to hospice care and impede pain management.

Third, Congress should require that the Centers for Medicare and Medicare Services evaluate Medicare payment rates for hospice services in light of MedPac's recommendations, and report to Congress with the results of the evaluation on specific date. Currently, hospice rates are based on information obtained from the early 1980's, which is outdated and thus inconsistent with the costs that efficient hospices incur in furnishing care to

386. The absence of a prescription drug benefit was formerly a reimbursement barrier, but Congress has recently addressed this issue with the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. See Pub. L. No. 108-173 (2003).

patients.

Fourth, Congress should include a provision in the CPA amending the Medicaid statute to prohibit states from placing limitations on the quantity of prescription drugs dispensed to Medicaid beneficiaries. As previously discussed, coverage limitations on the quantity of prescription drugs impedes pain management.

D. Education

While the CPA contains provisions that would improve the education of patient, families, and providers, it should go further to combat the problem of inadequate pain management. For example, the CPA should be amended to make the receipt of federal money by professional schools and universities contingent upon compliance with a requirement that schools incorporate pain management and the use of controlled substances into their curricula. This would ensure that future health care professionals attending federally funded schools are, at the very least, exposed to pain management earlier in their careers. Moreover, Congress should allocate funds to provide grants to academic institutions and professional schools to provide pain management education. Further, Congress should make DEA registration to prescribe controlled substances contingent upon continuing medical education on the use of controlled substances to manage pain.

The CPA and the proposed revisions, taken together, represent a comprehensive policy addressing the multiple components that impede the management of pain. Given the fifty million patients who exhibit pain in America and the exorbitant costs related to untreated pain, Congress should reintroduce the CPA with the proposed revisions.

V. CONCLUSION

Despite progress in the medical community's understanding of how to treat pain, health care providers continue to underprescribe opioids to manage pain. This practice is a result of several factors, including fear of disciplinary and enforcement actions; negative attitudes of health care providers, patients, and the public about the use of controlled substances to treat pain; inadequate education in pain management; and Medicare and Medicaid reimbursement policies. Recent decisions holding physicians accountable for the inadequate treatment of pain are insufficient to change the reluctance of health care providers to prescribe controlled substances to manage pain. Until this point, efforts to improve the pain management problem have been piecemeal and have consequently failed to achieve an improvement in the management of pain.

A comprehensive public policy that addresses the multiple barriers is

needed to address the inadequate management of pain in America. While the Conquering Pain Act of 2003 is a commendable effort to improve pain management, it fails to adequately address several significant issues that are known to impede the management of pain. Congress should pass the CPA in accordance with the proposed revisions in this congressional session. Only then will it be possible for the millions of patients who suffer in pain to obtain adequate pain management. Society will benefit from a policy that adequately addresses pain management through decreased health care spending and disability and worker's compensation costs, and increased productivity. It is for these reasons that there is a need for Congress to develop and implement a comprehensive policy such as the CPA with the proposed revisions to put an end to the epidemic of pain that currently exists in this country.