2013

ACHIEVING BALANCE
in State Pain Policy

A Progress Report Card (CY 2013)

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State policies aimed at regulating professional practice and improving patient care can either enhance or interfere with pain management. Seven evaluations over a fourteen-year period by the University of Wisconsin Pain & Policy Studies Group (PPSG) has shown continuous improvement in state policies governing pain treatment, including the medical use of opioid medications. This *Progress Report Card* (*Progress Report Card 2013*) uses evidence from policy research to grade states' policies from A to F. Along with the companion analysis of each state's policies (entitled *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (CY 2013)*) (*Evaluation Guide 2013*), the *Progress Report Card 2013* can be used by state agencies and pain relief advocates to develop plans to further improve state pain policies.

The evidence used to create the *Progress Report Card 2013* comes from a systematic, criteria-based, research evaluation of the best information available to the PPSG. We hope that our findings, conclusions, and recommendations will stimulate individuals, organizations, and state governments to work together to evaluate or re-evaluate their policies regarding pain management and to take the necessary steps to improve and implement them.

The Pain & Policy Studies Group

The Pain & Policy Studies Group (PPSG) is a global research program at the University of Wisconsin Carbone Cancer Center within the School of Medicine and Public Health. The PPSG mission is to improve global pain relief by achieving balanced access to opioids in an effort to enhance the quality of life of people living with cancer and other painful diseases. The PPSG's work, guided by a public health approach, aims to address governmental and regulatory environments governing professional healthcare practice relating to pain management, including barriers to legitimate access of prescription opioid analgesics that are essential for severe pain relief and palliative care. Such efforts are achieved through effective public policy, communications, and outreach efforts. The PPSG is nationally and internationally recognized for its work and leadership to improve availability of opioid pain medicines, having been at the forefront of such efforts since its creation in 1996, since which time it has been the home of a World Health Organization (WHO) Collaborating Center.

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There are important ongoing efforts in the U.S. to address simultaneously two major public health crises — (1) the medical under-treatment of pain and (2) the non-medical use of controlled substances — both of which involve the opioid analgesic class of medications. Patients with pain may receive many pharmaceutical and non-pharmaceutical treatments, depending on the diagnosis, but opioid analgesics are not always needed. However, opioid analgesics remain a very important treatment option, yet are sometimes difficult to obtain when clinically warranted. On the other hand, people who use controlled substances non-medically typically ingest multiple substances, including prescription medications or illicit opioids such as heroin. Policy efforts to address pain relief and non-medical use share the common aim of protecting public health and improving quality of life, either by alleviating pain and its debilitating effects or by addressing substance use disorders and their tragic consequences. If done in a *balanced* manner, both efforts should have measurably effective outcomes and neither should interfere with the other.

As will be seen in this report, achieving balance in the control of medications that are used for pain relief, but which also can be abused, is an undisputed public good that has been well-established in international treaties and U.S. federal drug control policy, and in state professional practice policies. These policies establish the drug approval and drug control systems, creating the parameters in which these systems should function to ensure adequate medication availability for healthcare purposes and to control diversion (i.e., movement of medications from licit to illicit distribution or use). Understanding this policy context is necessary when considering ways to achieve effective and balanced responses both to the problems of unrelieved pain and to diversion and abuse of prescription medications.

Understanding the drug approval and control system

When thinking about drugs for medical use, it is important to distinguish between the federal policies governing drug approval and drug control. Both are established under authority of the U.S. Congress and federal administrative agencies. The Federal Food, Drug, and Cosmetics Act (FFDCA) (21 USC §301 et seq) provides the underlying drug approval framework for non-prescription and prescription medications. The Food and Drug Administration (FDA) administers the FFDCA and approves medications for human use when they are determined to be safe and effective for *their intended medical uses.* Prescription medications, including opioid analgesics, are deemed unsafe for any over-the-counter self-administration; they are lawfully available to legitimate patients only on the prescription of practitioners licensed under state law.

By law, the official labeling for each medication is approved by the FDA and contains the information needed for safe and effective use, including warnings and consequences, contraindications, and adverse reactions. The FDA-approved label provides several examples of non-medical uses of opioid analgesics, such as unauthorized increases in dose, use with alcohol or illicit substances, compromising the integrity of the product (e.g., crushing and using unapproved routes of administration). These uses are common in cases of opioid analgesic-involved overdose and death.

Recently, the Congress authorized the FDA to require pharmaceutical manufacturers to develop Risk Evaluation and Mitigation Strategies (REMS), when warranted, as a means to ensure that the treatment benefits of certain products outweigh their risks. Messages conveyed through Package Inserts, Medication Guides, and REMS specify that use of prescription medications without a valid prescription issued by a properly licensed practitioner for a legitimate medical purpose, or in ways that are contraindicated, is likely to compound the risk of adverse consequences.

EXECUTIVE SUMMARY: POLICY CONTEXT FOR BALANCE

If an approved prescription medication does have an abuse liability, such as with opioid analgesics, it comes under the additional control of the federal Controlled Substances Act (CSA) (21 USC §801 et seq), which is implemented by the Drug Enforcement Administration (DEA). Federal controlled substances laws do not supersede the FDA-approved uses of medications, and the state has the jurisdiction to regulate healthcare professionals and their practice. States have adopted laws, regulations, and guidelines relevant to prescribing medications, including controlled substances, and professional practice.

The CSA establishes a national *drug control system* to distribute approved medications to patients; it is analogous to a pipeline for moving valuable material that should not leak. The drug control system is a "closed" system — that is, all enterprises and individuals involved in production, distribution, prescribing, dispensing, possession, research, and disposal of prescription-only controlled substances must be registered with the DEA and also the state if required. Conditions of registration include:

- adhering to laws and regulations that limit medication availability to legitimate medical uses and patients,
- implementing safeguards against diversion, and
- reporting to the DEA of amounts distributed to all registrants at the retail level, as well as amounts that are lost or stolen.

Physicians can lose their DEA registration and be subject to criminal or civil penalties if they issue prescriptions for non-medical purposes or outside the usual course of medical practice (i.e., to individuals who are not legitimate patients). Many states have policies that acknowledge a practitioner's need to understand and comply with relevant federal and state laws when prescribing controlled substances.

Patients, by virtue of their being recipients of prescription-only controlled medicines, have responsibilities under law. Labeling and Medication Guides caution patients to not transfer the medications prescribed for them to any other person, under penalty of law. It is unlawful for any person to possess controlled substances, including opioid analgesics, without a valid prescription. In addition, it is illegal under federal and state laws to acquire these medications by theft, fraud, or misrepresentation.

Despite all of these legal requirements governing distribution of controlled "prescription drugs"[a] via the closed system, opioid analgesics are diverted from all levels of the pipeline. Once diverted, they become illegally available for sale and non-medical use, which can lead to overdose and death.

Opioid analgesics are often diverted from the pipeline *before* they are prescribed. For example, criminal diversions of large quantities are reported by manufacturers, distributors, and pharmacies, and often involve armed robberies and night break-ins. Thefts, including employee pilferage, occur from pharmacy supplies in nursing homes and hospitals. There also are numerous criminal activities by organizations and individuals, including some patients, to obtain opioid analgesics unlawfully. These include fraud and misrepresentation, such as "doctor shopping," prescription forgery, alteration of prescription forms, and misuse of Medicare and Medicaid drug coverage. "Script doctors" and "Pill Mills" are illegal activities by rogue physicians who still have the necessary authority to prescribe, or to purchase and dispense, controlled substances. Some of these high volume "prescription" practices, though ultimately found to be illegal, nevertheless have contributed to state patterns of controlled medication consumption. Taken together, these methods of diversion are sometimes referred to as an "industry."

[a] It is important to note that some usages of the term "prescription drug" can lead to incorrect conclusions about the source of an abused drug. "Prescription drug" does not necessarily mean a drug that was actually prescribed. When considering a balanced policy approach to abuse or diversion of prescription opioids, determining whether a valid prescription was involved is essential.

EXECUTIVE SUMMARY: POLICY CONTEXT FOR BALANCE

Relatively distinct from overt criminal activities, some physicians and pharmacists prescribe or dispense in a careless or unprofessional manner (which would include practitioners who prescribe more than medically necessary and thus contribute to the volume of unused medications), and are subject to license revocation or other civil penalties defined in federal and state law. Even if opioids are prescribed legitimately, but then are not stored securely, they are vulnerable to diversion through medicine cabinet theft and home burglaries. When people report obtaining opioids from peers or family or from a dispensed prescription, the actual means of diversion from the system remains unknown unless further information is acquired.

There currently is insufficient understanding about the extent to which these numerous sources of diversion contribute to abuse, addiction, overdose, and death. It is obvious that, to effectively address non-medical use of opioid analgesics, a better appreciation is needed about the multiple determinants of diversion by using data and intelligence information to identify specific leaks in the system (which could be communicated through educational programs or public awareness campaigns). Consequently, existing data systems, including those that track theft and drug evidence, burglary, retail drug distribution, prescribing, and health consequences, can be used to inform law enforcement and public health interventions. In this way, sources can be targeted using geographic indicators, just as one would locate the source of the agent in infectious disease control. Once detected, law enforcement or regulatory officials can address the problem with precision. For example, rogue prescribers and pill mills can be identified using information that is available today; intervention would produce immediate reductions in distribution to the retail level in that area, and should take into consideration whether legitimate patients would be affected. Effectively addressing these issues also would be strengthened by broader availability and access to treatment for substance use disorders. Overall, policy or programmatic approaches aimed at only a single diversion source should not be considered sufficient for such a multifaceted issue as diversion.

PPSG Policy Evaluation Research

The policy evaluation research represented in this report and in the companion report, entitled *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (CY 2013)* (*Evaluation Guide 2013*), was designed to help ensure that people with pain who need treatment with controlled medicines are better able to have access, by identifying and assessing balance in current federal and state statutes, regulations, and other official policies. Since the inception of this project in 2000, numerous states have adopted policies to enhance safe and effective pain management while removing regulatory barriers to appropriate treatment. These policies often are modeled after balanced templates developed by the Federation of State Medical Boards. Nevertheless it is possible that new state laws and healthcare regulatory policies aimed at substance abuse could introduce undue requirements, restrictions, or ambiguities that could impede healthcare decision-making and patient care. Examples of current policies affecting pain management are included throughout the *Evaluation Guide 2013*, but especially in Section IX. Adoption of balanced policy responds to the continued call from international and national authoritative bodies representing legal, regulatory, and healthcare communities to promote the reduction of the non-medical use of prescription medications while at the same time addressing inadequate treatment for debilitating pain.

Most of the policy development activities identified in this report demonstrate state governments' willingness to cooperate and promote safe and effective pain management and avoid unduly restricting access to controlled medications for the people who need them, while taking precautions against exacerbating non-medical use or diversion. The overall aim is a balanced drug control and healthcare regulatory environment that maintains or improves the well-established closed distribution system of drug control and related information systems. To achieve and sustain balance in a dynamic environment, it is necessary to understand and enforce the closed distribution system, preserving the critical distinction between the many patients who use these medications for therapeutic purposes and those whose

motivations and activities are outside medicine and the law. Appendix B in the *Evaluation Guide 2013* provides an extensive list of recommended readings, of which the articles by Cicero et al., Coleman, Inciardi et al., and Joranson & Gilson are relevant to this issue.

When balance is achieved, patient care decisions can be based only on clinical circumstances, with individualized treatment approaches that are not hampered by legislative or regulatory barriers. Such an approach could help to allay the concern expressed in a recent editorial in the *Journal of Pain Research*:

> "Why should patients with chronic pain who are prescribed necessary opioids for legitimate medical purposes endure the wrath of policy changes and resultant untreated pain due to criminality of others…?"

PPSG Progress Report Card

This report focuses on the extent that drug control and medical and pharmacy practice policies contain language that can potentially enhance or impede pain management. A research methodology was developed to grade each state based on the content of its policy that can affect treatment of patients' pain. State grades are presented for 2006-2008, 2012, and 2013 to allow an understanding of policy change over time.

This report concludes that state pain policies are becoming more balanced, even when compared to the last evaluation in 2012. Since 2012:

- Twenty-four states changed policies or adopted new policies containing language that fulfilled at least one evaluation criterion, and in five of those states the policy change was sufficient to improve their grade;
- Alabama and Idaho achieved an A in 2013, and join Georgia, Iowa, Kansas, Maine, Massachusetts, Michigan, Montana, Oregon, Rhode Island, Vermont, Virginia, Washington, and Wisconsin as having the most balanced pain policies in the country;
- Idaho showed the largest grade improvement between 2008 and 2013, increasing a full grade level;
- 96% of states now have a grade above a C (based on grades calculated in 2000), compared to 88% in 2008; and
- No state's grade decreased since 2012 or even since 2006.

The policy improvement that occurred between 2012 and 2013 was largely the result of: (1) adopting policies to encourage appropriate pain management, palliative care, or end-of-life care, and (2) state legislatures or regulatory agencies repealing restrictive or ambiguous policy language.

The momentum of positive policy change documented in 2006 seems to be continuing. This improvement supports the conclusion that government and regulatory agencies continue to appreciate the need to encourage appropriate treatment of pain without creating barriers to such treatment. Legislatures are additionally adopting laws to prevent drug abuse and diversion at the state level that have tended to eschew requirements that would interfere with legitimate medical practice and patient care. In fact, many of these recent policies contain an objective statement related to both reducing the non-medical use of prescription medication and maintaining their availability for healthcare purposes, which reflects the conceptual framework used for this policy evaluation.

EXECUTIVE SUMMARY: POLICY CONTEXT FOR BALANCE

Experience around the country is showing that a valuable state governmental mechanism to achieve more balanced policy is the use of task forces, advisory councils, and summit meetings to examine the need for changes in state pain policy. Many states now face the challenge not only of adopting positive policies, but of removing restrictive language from legislation or regulations. Even for states that have achieved an A, there remains the potential for additional policy activity (however well-intentioned) that might introduce potentially restrictive requirements or limitations. Continued efforts to enhance pain management through state policy must avoid unintended restrictions or ambiguities that could interfere with legitimate practice.

This *Progress Report Card*, used in conjunction with the *Evaluation Guide 2013*, provides a framework for deciding which policies should be addressed, as well as language from other states to guide the development of new and more balanced policies related to the provision of pain care services. Balance in pain policy can be achieved and maintained if policymakers, healthcare professionals, and regulatory agencies work together and take advantage of available policy resources. In this way, a more positive legislative, regulatory, and practice environment can be established for the relief of pain in all patients, including those who are challenged by cancer, HIV/AIDS, sickle-cell anemia, and other painful conditions.

Acknowledgements, Citation, Notes to Reader

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Notes to the Reader

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This document is one product of the ongoing research program of the Pain & Policy Studies Group. Our purpose for making these data available is to promote education and policy change. However, their use for research purposes is limited to those who are affiliated with the Pain & Policy Studies Group, or by permission.

Policies are in constant flux, and the results presented herein pertain to identified policies adopted through December 2013. Also, the material in this report does not represent legal or medical advice. Individuals interested in using these results to implement change can contact the PPSG office at the address below.

This Progress Report Card, along with its companion Evaluation Guide, is available on the PPSG website at http://www.painpolicy.wisc.edu. Requests, comments, and suggestions can be directed to:

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INTRODUCTION

Unrelieved Pain Continues to Burden Americans

It is well-documented that unrelieved pain continues to be a serious public health problem for the general population in the United States.[1-8] This issue is particularly salient for children,[9-14] the elderly,[15-19] people of racial and ethnic subgroups,[20-24] people with developmental disabilities,[25;26] people in the military or military veterans[27-30] as well as for those with diseases such as cancer,[31-36] HIV/AIDS,[37-40] or sickle-cell disease.[41-43] Clinical experience has demonstrated that adequate pain management leads to enhanced functioning and quality of life, while uncontrolled severe pain contributes to disability and despair.[4;44]

Pain Can be Relieved

There are many potentially-effective drug and non-drug approaches to manage pain,[34;45-52] the appropriateness of which vary according to the individual needs of the patient. In fact, an integrative approach to pain care is encouraged for all patients.[4;53] However, controlled substances, including opioid analgesics (sometimes referred to by the outdated legal term, "narcotic"), often are necessary to maintain public health[54] and are a mainstay of pain treatment for cancer and HIV/AIDS, particularly if pain is severe.[52;55-57] Opioid analgesics in the class of morphine have a legitimate medical use[58] and are indicated for the medical management of moderate or severe pain [b].[52;59] Although their use for the relief of a variety of chronic non-cancer pain conditions continues to evolve,[60;61] and evidence of effectiveness for these conditions is derived largely from consensus standards, there seems to be a general agreement that some patients with such pain can be properly treated with opioid therapy.[62-66] Physicians, osteopaths, pharmacists, and nurses (where permitted) must be able, knowledgeable, and confident to prescribe, administer, and dispense opioids according to individual patient needs.[63;67;68]

The Gap Between Knowledge and Practice

Medical science has contributed important new knowledge about pain management in the last 25 years, but incorporation of this knowledge into practice has been slow and remains incomplete.[4] A gap exists between what is known about pain management and what is done by healthcare professionals and institutions. The provision of pain treatment services to a particular patient depends on many factors in the healthcare and drug regulatory system;[69] these factors, such as professional and institutional practices, can be influenced either positively or negatively by state-level policy. The connection among policy, professional and institutional practices, and patient care is complex, but the overarching public health goal is to develop policies that (if implemented) can enhance healthcare for patients, including pain treatment, and to avoid policies that can interfere in that care. This policy context is outlined in the Executive Summary. Policies that encourage appropriate pain management, and consider it and the warranted use of controlled substances to be an expected part of healthcare practice, are preferable to those policies that provide no positive guidance to professionals treating patients' pain, are based on outdated terminology, or establish unduly strict prescribing requirements or ambiguous treatment standards.

[b] On April 16, 2014, the FDA approved class-wide labeling changes for all extended-release and long-acting (ER/LA) opioid analgesics – such products are indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate" (http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm363722.htm).

Influence of Drug Abuse Control Policy

Opioid medications also have a potential for abuse (a discussion of this important issue is in the Executive Summary and Section III of the *Evaluation Guide 2013*). Consequently, opioid analgesics and the healthcare professionals who prescribe, administer, or dispense them are regulated pursuant to federal and state controlled substances laws, as well as under state laws and regulations that govern professional practice.[70;71] Such policies are intended to prevent illicit trafficking, drug abuse, and substandard practice related to prescribing and patient care. However, in some states these policies go well beyond the usual framework of controlled substances and professional practice policy, and can negatively affect legitimate healthcare practices and create undue burdens for practitioners and patients,[72-76] resulting in interference with appropriate pain management.

Examples of such policy language include:

- Limiting medication amounts that can be prescribed and dispensed for every patient,
- Unduly restricting the period for which prescriptions are valid;
- Unconditionally denying treatment access to patients with pain who also have a history of substance abuse;
- Requiring special government-issued prescription forms only for a certain class of medications;
- Requiring opioids to be a treatment of last resort regardless of the clinical situation,
- Using outdated definitions that confuse physical dependence with addiction; and
- Defining "unprofessional conduct" to include "excessive" prescribing, without defining the standard or criteria under which such a determination is made.

Further, policies that have been recommended to encourage appropriate pain management are frequently absent from state policies. For example, some states have not yet adopted policies recognizing that:

- Controlled substances are necessary for the public health (as does federal law).[54]
- Pain management is an integral part of the practice of medicine (as does the Federation of State Medical Board's *Modern Medical Practice Act*);[77]
- The legitimacy of a practitioner's prescribing is not based solely on the amount or duration of the prescription (as does the Federation of State Medical Board's pain policy templates, including the 2013 *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*);[63;78-80]
- Physicians should not fear regulatory sanctions for appropriately prescribing controlled substances for pain (as does the Federation of State Medical Board's pain policy templates, including the 2013 *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*);[63;78-80]
- Physical dependence or tolerance are not synonymous with addiction (as does the Federation of State Medical Board's pain policy templates, including the 2013 *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*).[63;78-80]

The Imperative to Evaluate Pain Policy

Many international and national authorities, including the World Health Organization (WHO), the International Narcotics Control Board (INCB), the United Nations Economic and Social Council (UN ECOSOC), the Institute of Medicine (IOM), the American Cancer Society (ACS), and the National Institutes of Health (NIH), have called attention to the inadequate treatment of pain and have concluded that it is due in part to drug abuse control policies that impede medical use of opioids. These authorities have recommended evaluation and improvement of policies influencing pain management. For example, following a review of the reasons for inadequate cancer pain relief, the INCB asked all governments in the world to:

> *"...examine the extent to which their health-care systems and laws and regulations permit the use of opiates for medical purposes, identify possible impediments to such use and develop plans of action to facilitate the supply and availability of opiates for all appropriate indications"* (p. 17).[81]

In 2011, the INCB again called for governments to ensure the legitimate availability of opioid medications by focusing on the need to improve their policies:

> *"Governments should determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede the prescribing or dispensing of, or needed medical treatment of patients with, narcotic drugs or psychotropic substances, or their availability and distribution for such purposes, and, should this be the case, make the necessary adjustments." (¶132(g))* [82]

The WHO has stated that better pain management could be achieved throughout the world if governments used evaluation guidelines to identify and overcome regulatory barriers to the availability and appropriate medical use of opioid analgesics.[83;84] The 2011 WHO Guidelines for ensuring medication availability and accessibility called for governments to review its legislation and administrative requirements to determine the extent of barriers to medication availability.

> *"Guideline 9: Governments should examine their drug control legislation and policies for the presence of overly restrictive provisions that affect delivery of appropriate medical care involving controlled medicines. They should also ensure that provisions aim at optimizing health outcomes and take corrective action as needed. Decisions which are ordinarily medical in nature should be taken by health professionals."* [52]

In addition, the UN ECOSOC has called for governments to identify and address regulatory barriers in the narcotics control policies:

> *"Review and revise national legislation, regulation and policies, in order to ensure that they reflect a balance between ensuring availability and preventing diversion and abuse, including by identifying and removing overly restrictive provisions which unnecessarily impede availability." (¶47(b))* [85]

> *"UNODC will commence a process of examination of its model laws to ensure that they reflect an appropriate balance between the measures to ensure availability of controlled medications for medical and scientific purposes and the measures to reduce illicit manufacture, illicit trade, and diversion. If required, revisions will be made to remove or modify provisions that create impediments to medical and scientific use and do not advance the objectives of the Conventions." (¶49)* [85]

INTRODUCTION

In the U.S., the IOM Committee on Opportunities in Drug Abuse Research called for:

> *"...additional research on the effects of controlled substance regulations on medical use and scientific research. Specifically, these studies should encompass the impact of such regulations and their enforcement on prescribing practices and patient outcomes in relation to conditions such as pain...[and]... for patients with addictive disorders"* (p. 259).[86]

The IOM Committee on Care at the End of Life recommended:

> *"...review of restrictive state laws, revision of provisions that deter effective pain relief, and evaluation of the effect of regulatory changes on state medical board policies..." [and] "reform [of] drug prescription laws, burdensome regulations, and state medical board policies and practices that impede effective use of opioids to relieve pain and suffering"* (p. 198, 267).[87]

The IOM Committee on Cancer Control in Low- and Middle-Income Countries recently restated the need to address the negative impact that overly-restrictive drug control efforts can have on medical availability:

> *"Governments should collaborate with national organizations and leaders to identify and remove barriers to ensure that opioid pain medications, as well as other essential palliative care medicines, are available under appropriate control. The INCB and WHO should provide enhanced guidance and support, and assist governments with this task"* (p. 250). [88]

In 2007, the ACS Cancer Action Network offered the following recommendation "…Remove or amend restrictive or ambiguous language in state statutes and regulations" (p. 1).[89] The NIH has concluded that "Regulatory barriers need to be revised to maximize convenience, benefit, and compliance…" (p. 15).[90]

WHY A PROGRESS REPORT CARD?

This *Progress Report Card* (*Progress Report Card 2013*), funded by a grant from the American Cancer Society and through a cooperative agreement with the Livestrong Foundation, is the latest in a series of reports[91-94] developed to evaluate state policies that affect pain management.[c] It is a tool that can be used by government and non-government organizations, as well as by policymakers, healthcare professionals, and advocates, to understand the policy in their state that reinforces the appropriate practice of pain management or that can hinder patient access to effective treatment. Ultimately, policy improvement efforts guided by the *Progress Report Card 2013* will achieve more positive and consistent state policy governing the medical use of controlled substances for pain management (acute, cancer, and non-cancer pain), palliative care, and end-of-life care. Such policy changes do not interfere with the underlying principle that opioid analgesics may only be provided for legitimate medical purposes by licensed healthcare practitioners in the course of their professional practice. The policy research terms used in this report are defined in Table 1.

Table 1: Policy Research Terms

Pain policy refers to federal or state policy that relates to pain management, and is generally found in two categories:

- ***Pain-specific*** policies directly address pain and its management, such as medical board pain management guidelines.
- ***Pain-related*** policies do not directly address pain management but contain provisions that could ultimately affect its treatment, such as state acts that address generally the prescribing and dispensing of controlled substances.

Within pain policies are:

Provisions: policy language that was identified as satisfying an evaluation criterion, and include

- ***positive provisions,*** which are those parts of a policy identified in the evaluation that have the potential to enhance pain management, and
- ***negative provisions,*** which are those parts of a policy identified in the evaluation that have the potential to impede pain management.

Policy change is the addition or removal of provisions; sufficient policy change in a state will produce a ***grade change*** for that state.

Policy Types

Law is a broad term that refers to rules of conduct with binding legal force adopted by a legislative or other government body at the international, federal, state or local levels. Law can be found in treaties, constitutional provisions, decisions of a court, and include both statutes and regulations. The most common laws are the statutes enacted by a legislature, such as an Intractable Pain Treatment Act, or those that create prescription monitoring programs or pain advisory councils, or license healthcare facilities.

Regulation is an official policy issued by an agency of the executive branch of government pursuant to statutory authority. Regulations are found in the state administrative code. Regulations have binding legal force and are intended to implement the administrative policies of a statutorily-created agency. For example, regulations issued by licensing boards according to a state's administrative procedures statute govern professional conduct, and establish what conduct is or is not acceptable for those regulated by the agency (such as physicians, pharmacists, and nurses). Regulations of state agencies may not exceed the agency's statutory authority.

Guideline means an officially adopted policy issued by a government agency to express the agency's attitude about, or position on, a particular matter. While guidelines do not have binding legal force, they may help those regulated by an agency to better understand the regulating agency's standards of practice. A number of state medical boards have issued guidelines regarding the medical use of opioid analgesics, which describe conduct the board considers to be within the professional practice of medicine (some pharmacy and nursing boards have issued similar guidelines.) "Guidelines" may also include an officially adopted position statement that appears in a position paper, report, article, letter or agency newsletter.

[c] Federal policy is not included in this report card because such policy does not regulate professional practice. Also, laws and regulatory policies governing nurses' prescriptive authority and pain management practice were not used as part of this methodology to grades states based on policy content. An evaluation of relevant federal policies, as well as nursing practice policies, is available in the *Evaluation Guide 2013*.

WHY A PROGRESS REPORT CARD?

Based on findings from four previous PPSG evaluations of state pain policies,[95-98] each state has been assigned a grade for 2006, 2007, 2008, and 2012. With this report, states' grades from 2013 are compared with their grades from 2006, 2007, 2008, and 2012 to measure progress.

The *Progress Report Card 2013* is the result of policy research and is not a "position statement" about a state's pain policies. The use of a single index to compare states can draw the attention of state policy-makers and healthcare professionals to the need to evaluate and improve the regulatory policy environment for pain management.[d] We recognize that a grade may oversimplify the interpretation of a state's policies. Therefore, we are making available detailed information about the specific statutes, regulations, and other policies that were evaluated in each state; these are in the *Evaluation Guide 2013*, which is the companion document to the *Progress Report Card 2013*. These tools can be used by members of government and non-government organizations, as well as by policymakers, healthcare professionals, and advocates, to understand the policies in their state that reinforce the appropriate practice of pain management or that can hinder patient access to effective treatment. In addition, the complete text of each state's pain-specific (but not pain-related) policies is provided on the PPSG website at www.painpolicy.wisc.edu/matrix.

Method to Evaluate Pain Policies

The *Evaluation Guide 2013* describes methods developed with peer review to evaluate pain policies using a central principle, policy collection procedures, and criteria used to identify relevant policy provisions.[98]

The Central Principle of Balance

The Central Principle of *Balance*, which is defined in Table 2, guides this evaluation of policies influencing pain management. The main idea is that the content of drug control and professional practice policies, and ideally their implementation, should be balanced so that efforts to prevent diversion and abuse do not interfere with patient pain care, including the medical use of pain medications.[99]

Table 2: The Central Principle of Balance

The ***Central Principle of Balance*** represents a dual obligation of governments to establish a system of controls to prevent abuse, trafficking, and diversion of narcotic drugs while, at the same time, ensuring their medical availability.

Medical Availability

- While opioid analgesics are controlled drugs, they are also essential drugs and are absolutely necessary for the relief of pain.
- Opioid analgesics should be accessible to all patients who need them for relief of pain.
- Governments must take steps to ensure the adequate availability of opioids for medical and scientific purposes, including:
  - empowering healthcare practitioners to provide opioids in the course of professional practice,
  - allowing them to prescribe, dispense and administer according to the individual medical needs of patients, and
  - ensuring that a sufficient supply of opioids is available to meet medical demand.

Drug Control

- When misused, opioids pose a threat to society.
- A system of controls is necessary to prevent abuse, trafficking, and diversion, but the system of controls is not intended to diminish the medical usefulness of opioids, nor interfere in their legitimate medical uses and patient care.

Adapted from Pain & Policy Studies Group. *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (CY 2012).* University of Wisconsin Carbone Cancer Center. Madison, WI; 2013.

Appendix A documents the sources of legal and healthcare authority supporting the Central Principle of Balance.

[d] The adequacy of *controls* to prevent diversion and abuse of controlled substances is also a valid topic for the evaluation of policy. This is not the purpose of this document, however, which is to evaluate policies affecting drug availability, healthcare practice, and pain management, rather than drug abuse prevention and control specifically.

WHY A PROGRESS REPORT CARD?

The Evaluation Criteria

Sixteen criteria were developed based on the Central Principle of Balance. They are divided into two categories and are used to identify relevant policy language in all state[e] statutes, regulations, and official healthcare regulatory guidelines and policy statements (see Table 3 for a list of the individual criteria).

Table 3: Criteria Used to Evaluate State Pain Policies

Positive Criteria: Criteria that identify policy language that may enhance safe and effective pain management	
# 1	Controlled substances are recognized as necessary for public health
# 2	Pain management is recognized as part of general healthcare practice
# 3	Medical use of opioids is recognized as legitimate professional practice
# 4	Pain management is encouraged
# 5	Practitioners' concerns about regulatory scrutiny are addressed
# 6	Prescription amount alone is recognized as insufficient to determine legitimacy of prescribing
# 7	Physical dependence or analgesic tolerance are *not* confused with "addiction"
# 8	Other provisions that may enhance pain management
	Category A: Issues related to healthcare professionals
	Category B: Issues related to patients
	Category C: Regulatory or policy issues
Negative Criteria: Criteria that identify policy language that may impede safe and effective pain management	
# 9	Opioids are relegated as only a treatment of last resort
#10	Medical use of opioids is implied to be outside legitimate professional practice
#11	Physical dependence or analgesic tolerance are confused with "addiction"
#12	Medical decisions are restricted
	Category A: Restrictions based on patient characteristics
	Category B: Mandated consultation for all patients
	Category C: Restrictions regarding quantity prescribed or dispensed
	Category D: Undue prescription limitations
#13	Length of prescription validity is restricted
#14	Practitioners are subject to undue prescription requirements
#15	Other provisions that may impede pain management
#16	Provisions that are ambiguous
	Category A: Arbitrary standards for legitimate prescribing
	Category B: Unclear intent leading to possible misinterpretation
	Category C: Conflicting or inconsistent policies or provisions

Quantifying the Quality of State Pain Policies

The state grades measure the quality of state policy influencing pain management, in relation to the Central Principle of Balance, and are based on the frequency of provisions in a state that meet the evaluation criteria; *the higher the grade, the more balanced are a state's policies regarding pain management, including the appropriate use of pain medications.* Appendix B contains a complete explanation of the grading methodology.

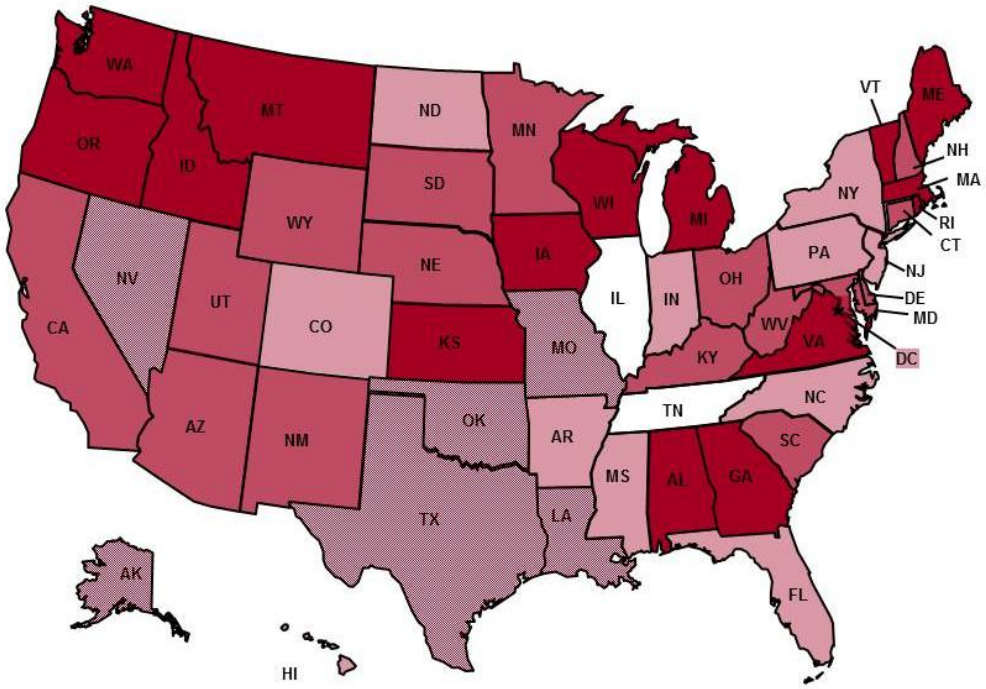
Readers are referred to the *Evaluation Guide 2013*, a companion to this report, for a more detailed discussion of the imperative to evaluate policy, the Central Principle of Balance, the evaluation criteria, the method used to evaluate state policies, and the text of the policy provisions that are identified in each state and on which the grades in the next section are based.

[e] For the purpose of this report, the District of Columbia is referred to as a state.

MAKING THE GRADE: HOW DO THE STATES RATE?

State Grades for 2013: States' grades for 2013 are presented in Figure 1 and Table 4. Again, a state's grade represents the quality of its policies affecting pain treatment, based on the Central Principle of Balance, and is calculated from the total number of provisions in a state fulfilling the evaluation criteria; higher grades mean more balanced state policies influencing pain management, including with the medical use of opioid analgesics (see Appendix B for a complete description of the grading methodology).

Figure 1



A	B+	B	C+	C	D+	D	F
15 states 22% of US pop.	16 states 29% of US pop.	12 states 29% of US pop.	6 states 14% of US pop.	2 states 6% of US pop.	None	None	None
Alabama	Arizona	Arkansas	Alaska	Illinois			
Georgia	California	Colorado	Louisiana	Tennessee			
Idaho	Connecticut	Dist. of Columbia	Missouri				
Iowa	Delaware	Florida	Nevada				
Kansas	Kentucky	Hawaii	Oklahoma				
Maine	Maryland	Indiana	Texas				
Massachusetts	Minnesota	Mississippi					
Michigan	Nebraska	New Jersey					
Montana	New Hampshire	New York					
Oregon	New Mexico	North Carolina					
Rhode Island	Ohio	North Dakota					
Vermont	South Carolina	Pennsylvania					
Virginia	South Dakota						
Washington	Utah						
Wisconsin	West Virginia						
	Wyoming						

CURRENT STATUS OF BALANCE IN STATE PAIN POLICY

Table 4: State Grades for 2013			
STATES	2013 GRADES	STATES	2013 GRADES
AL	A	MT	A
AK	C+	NE	B+
AZ	B+	NV	C+
AR	B	NH	B+
CA	B+	NJ	B
CO	B	NM	B+
CT	B+	NY	B
DE	B+	NC	B
DC	B	ND	B
FL	B	OH	B+
GA	A	OK	C+
HI	B	OR	A
ID	A	PA	B
IL	C	RI	A
IN	B	SC	B+
IA	A	SD	B+
KS	A	TN	C
KY	B+	TX	C+
LA	C+	UT	B+
ME	A	VT	A
MD	B+	VA	A
MA	A	WA	A
MI	A	WV	B+
MN	B+	WI	A
MS	B	WY	B+
MO	C+		

Highlights of the 2013 Grades

- 6% of states received a grade of C, while 94% scored above a C and no states achieved a grade of D+, D, or F — Appendix C shows each state's grades for both positive and negative provisions.
- Alabama and Idaho received an A, joining Georgia, Iowa, Kansas, Maine, Massachusetts, Michigan, Montana, Oregon, Rhode Island, Vermont, Virginia, Washington, and Wisconsin.
- Generally, there was notable grade variability within U.S. Census Bureau-defined regions, but a few clear patterns emerged: three West South Central states (Louisiana, Oklahoma, and Texas) received a grade of C+, all South Atlantic states (Delaware, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, and West Virginia) received a grade of B or above, while all New England States (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont) received either a B+ or an A.
- The 15 states achieving an A comprise 22% of the total U.S. population. States with a B or B+ make up almost 60% of the U.S. population, largely owing to the influence of there being 28 states in these grade categories (five of the states being California, New York, Florida, Pennsylvania, and Ohio, which are the 1st, 3rd, 4th, 6th, and 7th most populated states, respectively). Another 20% of the U.S. population lives in the eight states that have a grade of C or C+, primarily owing to the populations of Texas and Illinois (which are the 2nd and 5th most populated states, respectively).

CURRENT STATUS OF BALANCE IN STATE PAIN POLICY

Did Grades Change from 2006 to 2013?

To evaluate changes that occurred over the eight-year evaluation timeframe, 2013 grades were compared with the 2006, 2007, 2008, and 2012 grades (see Table 5).

Table 5: State Grades for 2006, 2007, 2008, 2012, and 2013

STATES	2006 GRADES	2007 GRADES	2008 GRADES	2012 GRADES	2013 GRADES	STATES	2006 GRADES	2007 GRADES	2008 GRADES	2012 GRADES	2013 GRADES
AL	B+	B+	B+	B+	A	MT	B	B	B	A	A
AK	C+	C+	C+	C+	C+	NE	B+	B+	B+	B+	B+
AZ	B	B+	B+	B+	B+	NV	C	C	C	C	C+
AR	B	B	B	B	B	NH	C+	C+	B	B+	B+
CA	C	B	B	B+	B+	NJ	C+	C+	B	B	B
CO	C+	B	B	B	B	NM	B+	B+	B+	B+	B+
CT	C+	B+	B+	B+	B+	NY	C+	C+	C+	B	B
DE	C+	C+	C+	B+	B+	NC	B	B	B	B	B
DC	C+	C+	C+	B	B	ND	B	B	B	B	B
FL	B	B	B	B	B	OH	B	B	B	B+	B+
GA	D+	D+	B	A	A	OK	C+	C+	C+	C+	C+
HI	B	B	B	B	B	OR	B+	B+	A	A	A
ID	B	B	B	B+	A	PA	B	B	B	B	B
IL	C	C	C	C	C	RI	B	B	B+	A	A
IN	C+	C+	C+	C+	B	SC	B	B+	B+	B+	B+
IA	B	B	B	A	A	SD	B	B	B	B+	B+
KS	B+	A	A	A	A	TN	C	C	C	C	C
KY	B	B	B	B+	B+	TX	C	C	C+	C+	C+
LA	C	C	C	C+	C+	UT	B	B	B+	B+	B+
ME	B	B	B+	A	A	VT	B+	B+	B+	A	A
MD	B	B	B	B+	B+	VA	A	A	A	A	A
MA	B+	A	A	A	A	WA	B	B	B+	A	A
MI	A	A	A	A	A	WV	B	B	B	B+	B+
MN	B	B	B+	B+	B+	WI	B	A	A	A	A
MS	C+	C+	C+	C+	B	WY	C+	C+	C+	B+	B+
MO	C+	C+	C+	C+	C+						

- 88% of states received above a C in 2006, increasing to 90% in 2007, 92% in 2008, 94% in 2012, and 96% in 2013.
- Alabama and Idaho received an A in 2013.
- Idaho demonstrated the largest grade improvement, increasing from a B to an A between 2006 and 2013.
- No state's grade decreased from 2006 to 2013.

CURRENT STATUS OF BALANCE IN STATE PAIN POLICY

How Did Grades Change Between 2012 and 2013?

- 24 of 51 states (47%) changed their policies in a way that represented at least one evaluation criterion; the policy changes were sufficient in five of these states to produce a positive grade change.
- Of the five states with grade improvements, all demonstrated the same extent of grade change since the last assessment (increasing a half-grade level [e.g., from a B to a B+]). Such grade improvements were accomplished by various methods:
  - Alabama added language to its Pain Management Act regarding practitioner education, involving completion of credits from a medical curriculum in pain treatment as a requirement for Medical Directors of Pain Clinics;
  - Idaho deleted an outdated definition of "drug dependence" from its Pharmacy Board regulations;
  - Indiana added a medical board regulation regarding the treatment of pain, which recognized that the goal of pain treatment should include improvements in patient functioning and quality of life, and encouraged physicians to discuss with patients the benefits and risks of treatment (which can better ensure the clinical indication of such treatment and that opioids will be used for medical purposes);
  - Mississippi changed its hospice standards to include additional positive language; and
  - Nevada added a continuing education requirement for pain management to its Medical Practice Act.
- 46 states made no policy changes sufficient to make a difference in their grade (see Table 6).

Table 6: Grade Change in State Pain Policy Between 2012 and 2013

Positive Change (5 states)	No Change (46 states)	
Alabama	Alaska	Nebraska
Idaho	Arizona	New Hampshire
Indiana	Arkansas	New Jersey
Mississippi	California	New Mexico
Nevada	Colorado	New York
	Connecticut	North Carolina
	Delaware	North Dakota
	Dist. of Columbia	Ohio
	Florida	Oklahoma
	Georgia	Oregon
	Hawaii	Pennsylvania
	Illinois	Rhode Island
	Iowa	South Carolina
	Kansas	South Dakota
	Kentucky	Tennessee
	Louisiana	Texas
	Maine	Utah
	Maryland	Vermont
	Massachusetts	Virginia
	Michigan	Washington
	Minnesota	West Virginia
	Missouri	Wisconsin
	Montana	Wyoming

CURRENT STATUS OF BALANCE IN STATE PAIN POLICY

Interesting New Policies

Although not always contributing to the positive grade changes observed between 2012 and 2013, the following policy adoption is notable:

- 5 states (Kentucky, Massachusetts, New Jersey, Texas, and Utah) adopted legislation or regulations mandating continuing education about pain management or palliative care for licensees;
- 3 states (Colorado, New Hampshire, and Rhode Island) adopted legislation or regulations adopted or expanded its hospice or palliative standards;
- 3 states (Idaho, Virginia, and West Virginia) adopted the Federation of State Medical Board's *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain* created in July, 2013, while another 3 states (Kentucky, Oregon, and Tennessee) added other statutes or regulatory policies governing pain management;
- 2 states (Texas and Vermont) created an advisory council or a work group as a mechanism to determine effectiveness of the state prescription drug monitoring program; and
- 2 states (Arkansas and Georgia) added laws with language that directly supports the Central Principle of Balance.

Improvements in Pain Management Policy

State grades for balanced policy continued to improve notably between 2012 and 2013. As in the previous *Progress Report Card* from 2012, the driving force for positive policy change was state healthcare regulatory boards that adopted several types of policies encouraging pain management (although they may not have resulted in a state's grade change). Positive policy change also occurred because of the repeal of restrictive or ambiguous language from statute or regulatory policy.

HEALTHCARE REGULATORY BOARD POLICIES

The Federation's Model Policies

To promote consistency in state medical board policy, in 1998 the Federation of State Medical Boards of the U.S. (the Federation) adopted *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (*Model Guidelines*).[100] In May 2004, the Federation's House of Delegates unanimously adopted a revision of the *Model Guidelines*, called the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (*Model Policy*).[101] The revision was substantially similar to the 1998 guidelines, but additionally considered the "inappropriate treatment of pain" to include "nontreatment," "overtreatment," "undertreatment," and the "continued use of ineffective treatments" – which conveyed to state boards that a failure to treat pain could be subject to professional discipline just as other substandard practice might be. In July, 2013, the Federation's House of Delegates approved a thorough content update of this policy, making it specific to opioid therapy for chronic pain (entitled *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*[63] available at http://www.fsmb.org/pdf/pain_policy_july2013.pdf).

Many state medical regulatory boards subsequently adopted the *Model Guidelines* or *Model Policies* to encourage better pain management and to address physicians' concern about investigation.[71;74;102] This trend has resulted in positive changes in state pain policies[103;104] and also in efforts to communicate them to practitioners and the public.[105;106]

CURRENT STATUS OF BALANCE IN STATE PAIN POLICY

As of December 2013, a total of 35 state medical or pharmacy boards had adopted either the 1998 *Model Guidelines*, the 2004 *Model Policy*, or the 2013 *Model Policy* in whole or in part.[f] Since 2012, three states (Idaho, Virginia, and West Virginia) replaced older healthcare regulatory board policies with one based on the Federation's 2013 *Model Policy* template. The model policy templates do not have any negative provisions; states that adopt them completely receive the greatest number of positive provisions from a single policy (see Appendix D for a listing of the types of Criteria #8 categories fulfilled).

REPEAL OF RESTRICTIVE OR AMBIGUOUS POLICIES

Positive policy change, but not necessarily a grade change, also occurred when states repealed negative provisions from statutes or regulatory policy. For example:

Definitions of "Drug Dependent Person"

Colorado and Idaho repealed the term "drug dependent person" from state law. These definitions of "drug dependent person" could be fulfilled only by the presence of physical dependence. As a result, because the definitions occur in law, they could legally classify a person who is being treated with opioid pain medications. Thirteen states continue to define "drug dependent person" (or "narcotic dependent person," "chemical dependency," "addict," "narcotic addict," or "habitué") in law, which has the potential to stigmatize patients with pain and restrict prescribing practices, which could lead to inadequate pain management.[g]

No Negative Policy Change

No state added restrictive or ambiguous policy language sufficient to change state grades between 2012 and 2013. However, the last legislative session in a number of states had bills that were introduced containing requirements or restrictions that have the potential to establish barriers to appropriate pain treatment when implemented into practice. Although these bills were not passed, the introduction of such bills requires ongoing attention and increased policy-maker awareness about the potential unintended consequences, in an effort to avoid future policy impediments.

[f] These states are Alabama, Arizona, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Iowa, Kansas, Kentucky, Maine, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New York, North Carolina, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.
[g] These states are Arizona, Hawaii, Indiana, Louisiana, Maryland, Missouri, Nevada, New Jersey, North Carolina, Oklahoma, Pennsylvania, Tennessee, and Wyoming.

CURRENT STATUS OF BALANCE IN STATE PAIN POLICY

Alabama and Idaho now join Georgia, Iowa, Kansas, Maine, Massachusetts, Michigan, Montana, Oregon, Rhode Island, Vermont, Virginia, Washington, and Wisconsin as having the most balanced policies in the country related to pain management, including with the appropriate use of pain medications for legitimate medical purposes. Over time, these 15 states took advantage of available policy templates and resources, and repealed all excessively restrictive and ambiguous policy. This achievement does not mean that their work is finished, because policy needs to be properly implemented (see next section). Importantly, there is no ceiling on policy quality, so states with high grades should continue to explore how additional policy can help to improve access to pain management while avoiding the adoption of restrictive requirements or limitations. In fact, 25 states that achieved an A for positive language in the past have continued to adopt policy language promoting appropriate pain management during this evaluation timeframe.[h]

Since 2012, legislatures and healthcare regulatory agencies in five states modified their relevant policies sufficiently to improve their grade for Balance. Of these states, Alabama, Indiana, Mississippi, and Nevada only evidenced a grade change in the last year, while Idaho had more than one grade improvement over the other four assessment periods since 2006; these changes demonstrate some continuing efforts to enhance pain policies that can affect professional practice and patient care. To this end, Idaho demonstrated the largest grade improvement since the last assessment (increasing a full grade level [i.e., from a B to an A]). These grade changes were accomplished by various methods:

- Alabama added language to its Pain Management Act regarding practitioner education, involving completion of credits from a medical curriculum in pain treatment as a requirement for Medical Directors of Pain Clinics;
- Idaho deleted an outdated definition of “drug dependence” from its Pharmacy Board regulations;
- Indiana added a medical board regulation regarding the treatment of pain, which recognized that the goal of pain treatment should include improvements in patient functioning and quality of life, and encouraged physicians to discuss with patients the benefits and risks of treatment (which can better ensure the clinical indication of such treatment and that opioids will be used for medical purposes);
- Mississippi changed its hospice standards to include additional positive language; and
- Nevada added a continuing education requirement for pain management to its Medical Practice Act.

Importantly, there were no states for which changes in policy resulted in a reduced grade. Overall, the evidence in this report paints a positive picture of progress towards Balance. Looking ahead, several states have special opportunities to achieve the highest grade for balanced policies, while others face special challenges.

[h] These states are Arizona, Arkansas, California, Colorado, Florida, Georgia, Kentucky, Massachusetts, Minnesota, Missouri, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, and Wisconsin.

Implications for Future Policy Change Actions

Special Opportunities

Some states are in a unique position of being able to achieve significant policy change either by adopting positive policy or repealing restrictions. Alaska and North Dakota currently have no restrictive or ambiguous language in their state's policies influencing pain management. These states could achieve an A simply by adopting additional positive language. Another 16 states (Arizona, California, Connecticut, Delaware, Kentucky, Maryland, Minnesota, Nebraska, New Hampshire, New Mexico, Ohio, South Carolina, South Dakota, Utah, West Virginia, and Wyoming) would have received an A in 2013 had one or two restrictive or ambiguous provisions been repealed.

Special Challenges

By the end of 2013, all but two states (96%) had a grade above a C; this is a substantial improvement since 2006, when 86% of states had a grade exceeding a C. Such progress is significant but, for many states to achieve more balanced and consistent pain policy, they face the challenge of removing long-outdated negative provisions from state statutes and regulations, some of which have been present for 30 years or more. Negative provisions unduly restricting professional practice are not a necessary part of the laws needed for drug control. To be sure, states may enact laws or other governmental policies that are stricter than federal law, and should be free to experiment and differ in their approaches to public policy. However, it is necessary to ensure that all such policies are balanced and that do not create barriers to healthcare practice and patient care decisions requiring medical expertise.

Only one of the five states achieving a grade change since 2012 did so by removing restrictive or ambiguous policy language.[i] In addition, of the 24 states with identified substantive policy change in the last year, only two states corrected potential legislative or regulatory impediments. This recent pattern of policy change suggests a decline in legislative and regulatory consideration about reducing policy barriers to patient care. This situation is particularly challenging because, importantly, 28 states (78%), of those remaining 36 states that do not have an A, can achieve a positive grade change *only* by repealing restrictive or ambiguous policy language.[j] Appendix E shows the number of states with statutes, regulations, or guidelines or policy statements that contain language meeting criteria for both types of policy provisions. The presence of any of these provisions in a specific state can be determined by consulting the *Evaluation Guide 2013*.

One of the most frequent negative provisions remaining in state policy is terminology that confuses physical dependence with addiction. Although 41 states have adopted language that clarifies the distinction between these clinical phenomena, which usually is contained in healthcare regulatory guidelines or policy statements, the statutes of 11 states and the regulation of two states continue to classify physical dependence as synonymous with addiction. Consequently, 11 states have conflicting standards about what constitutes addiction, which are present in different policies and can create confusion for practitioners.[k] Also, a definition of addiction (or drug dependence) in law, which can be established solely by the presence of physical dependence, can legally classify as an "addict" a patient who is being treated with opioid pain medications. When such a standard is applied in practice, it has the potential to stigmatize pain patients and restrict prescribing practices, leading to inadequate pain management. Most states' statutory definitions of addiction were modeled after the definition found in the federal Public Health and Welfare Act (42 USCS

[i] This state is Idaho.
[j] These states are Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Kentucky, Maryland, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, West Virginia, and Wyoming.
[k] These states are Arizona, Hawaii, Louisiana, Maryland, Missouri, Nevada, North Carolina, Oklahoma, Pennsylvania, Tennessee, and Wyoming.

§201), which is still present and was created over 40 years ago. Special attention should be given to repealing this prevalent state statutory or regulatory definition that no longer conforms to the current medical and scientific understanding of addiction.

A particular challenge continues to be in those few states that have a considerable number of positive provisions but also have many negative provisions.[l] Since the last evaluation, none of these states repealed restrictive legislative or regulatory language, but many continued to adopt policy language that could enhance pain management. As a result, such changes, although positive and encouraged, will not improve their grade because of the number of negative provisions remaining. For these states, there must be a continued focus on reducing the number of restrictive or ambiguous provisions for any positive grade change to occur.

In addition, there are a few states (Alaska, Illinois, and North Dakota) in which neither the medical nor pharmacy boards have issued policies addressing the use of controlled substances for treating pain. In these states, clinicians have not been provided guidance from their licensing agency about what is considered acceptable approaches related to pain treatment, including the use of pain medications for legitimate medical purposes.

Finally, six states (12%) now face the challenge not only of adopting positive policies, but of removing restrictive or ambiguous language from legislation or regulations, to achieve a grade of A.[m] Even for states that have achieved an A, there remains the potential for additional policy activity (however well-intentioned) to introduce potentially restrictive or unclear requirements. Continued efforts to enhance pain management through state policy must avoid unintended restrictions or ambiguities in order to maintain grade improvements.

[l] These states are Missouri, Nevada, Oklahoma, and Tennessee.
[m] These states are District of Columbia, Illinois, Indiana, Louisiana, Mississippi, and Pennsylvania.

CONCLUSION

Overall, the positive progress in the adoption of balanced state pain policy has been ongoing in the new decade. Such momentum apparently is in response to increasing national and state-level recognition that improving or removing provisions that can influence professional practice and patient care is a necessary step in improving pain management for patients with cancer, HIV/AIDS, and other diseases or conditions. It is apparent that state professionals or groups have used policy evaluation resources and/or model policies to guide positive policy change efforts.

This trend even has occurred throughout a period of increase in the abuse and diversion of opioid pain medications.[99;107-116] It is important to understand that the policy improvement represented in this report does not undermine the basic prohibitions against drug trafficking and diversion established in controlled substances or healthcare regulatory policies (see Executive Summary); states that improve their grades do not weaken their ability to prevent drug abuse and diversion or to deal with unprofessional conduct. Nevertheless, there must be continued efforts by governments and healthcare professionals to address drug abuse while not interfering with legitimate healthcare practices and patient access to appropriate pain care. A public health approach to preventing prescription drug abuse is needed that is compatible with the Central Principle of Balance,[117] as seen with the 2011 White House Office of National Drug Control Policy strategy (see the *Evaluation Guide 2013* for a detailed discussion of this strategy in Section IV, Item F).[113] Policy across the nation that seeks to balance legitimate availability of medications with abuse mitigation can be achieved and maintained if policymakers and healthcare practitioners work together, use the Central Principle as a guide, and take advantage of the policy resources that are available. Indeed, much of the state-level policy designed to address the non-medical use of prescription opioids, which has been adopted in the last eight years, has avoided restrictive or ambiguous requirements while also maintaining a context of medication availability for medical purposes. The PPSG contribution to this process is policy research and technical assistance to government agencies, professionals, and groups working to improve policy governing pain, palliative care, and end-of-life care.

RECOMMENDATIONS FOR IMPROVING STATE GRADES

1. Establish a policy evaluation mechanism

The extent to which a state's policies acknowledge a government's dual obligation to prevent the abuse and diversion of controlled medicines while maintaining their legitimate availability can either contribute to or detract from a positive professional practice and drug regulatory environment for pain management, palliative care, and end-of-life care. Recognizing that the improvement of state pain policies ultimately requires government concurrence, a number of states have successfully developed ad hoc policy evaluation mechanisms that are associated with state government – these include task forces, commissions, advisory councils, and summit meetings.[118-121] The terms of reference for such a body often include evaluation of the state's pain policies, and membership to the body should comprise governmental and non-governmental stakeholders with dedicated staffing to achieve objectives. The guidance available from international and national authorities can help to make the case for establishing a task force to examine pain policy; these sources can be found in the section of this report, entitled "The Imperative to Evaluate Policy," and in the *Evaluation Guide 2013*.

Once established, a state task force can take advantage of several resources to review state policy, including:

(a) internet access to the full text of its own and every other state's pain-specific policies (http://www.painpolicy.wisc.edu/matrix.htm),

(b) a State Profile that identifies each specific provision found during the PPSG 2013 evaluation, arranged according to the policy in which it was found and the criterion it satisfied (contained in the *Evaluation Guide 2013*), and

(c) this *Progress Report Card 2013*, which shows the distribution and details about the grades for each state for 2006-2008, 2012, and 2013.

For example, task force members could be interested in understanding how their state's grade compares to other states, in particular contiguous states. Task force members also might want to know in greater detail the specific categories of criteria that are fulfilled by their state's current policies (from the *Evaluation Guide 2013* State Profiles section) and how this compares with the policy content in other states. Appendix E shows the total number of states with policies that fulfill each evaluation criterion. Such comparisons could answer the following questions:

- Does state policy specifically encourage pain management (as it does in 40 states), or not?
- Does state policy directly address practitioners' concerns about being investigated (as it does in 42 states), or not?
- Does state policy define "drug dependent person" so that it could be confused with physical dependence that may develop when using opioids to treat pain (as it does in 13 states), or not.
- Does state policy contain provisions that create unclear standards or requirements for practitioners when treating a patient with pain (as it does in 24 states), or not?

After a state's pain policies have been studied, corrective proposals can be developed. A primary resource to assist with this process is the *Evaluation Guide 2013*, which identifies language from every state that could contribute to improved pain-related policy. A quick perusal of another state's current policy content can provide valuable examples of language that could be relevant for use in your state where it is lacking or when wanting a particular provision to be present in a different type of policy. Alternatively, such a process could identify provisions to avoid or improve upon.

2. Make a commitment to implementing policy

Policy change without implementation has little value. Many licensed practitioners are not fully aware of the policies that govern controlled substances prescribing and pain management.[102;122-124] Professional licensing boards should disseminate widely and frequently the policies that affect practitioners and pain management. Once a state's policy has been improved, it should also be communicated to those who implement the policy and are affected by it, including practitioners and the public, but also administrators, investigators and attorneys. Policy content must also be understood and adhered to.

The goal is to promote understanding that the state's policy is to encourage legitimate pain management practices, and that healthcare professionals who responsibly provide controlled pain medications should have nothing to fear from regulatory or law enforcement agencies in the state. For example, the medical licensure boards in North Carolina and Minnesota historically have excelled in their efforts to communicate pain management policy to licensed physicians.[125-127] The Maryland Board of Physician Quality Assurance produced a video titled "A Sense of Balance: Treating Chronic Pain,"[128] which was required viewing for new licensees. Some states, including the District of Columbia, Iowa, Kentucky, Massachusetts, Michigan, New Mexico, New York, Ohio, Oregon, Texas, Vermont and Wyoming, have adopted laws that require or encourage healthcare regulatory agencies to periodically educate their licenses about pain management or palliative care issues through continuing education activities. In addition, several state medical licensing boards, including those in California, Delaware, Georgia, Minnesota, New York, Ohio, Rhode Island, Utah, and Wyoming, have (or have had in the past) prominent links on the home page of their websites that provide information to licensees about pain management issues, including the use of pain medications.

APPENDICES

Appendix A: Authoritative Sources for the Central Principle of Balance

INTERNATIONAL AUTHORITIES

United Nations Single Convention on Narcotic Drugs of 1961

"the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering...adequate provision must be made [by governments] *to ensure the availability of narcotic drugs for such purposes"* (Article 4).

"The Parties [national governments] *shall take such legislative and administrative measures as may be necessary...to limit exclusively to medical and scientific purposes the production, manufacture...distribution... and possession of drugs"* (Article 9(4)).

"The Board, in co-operation with Governments, and subject to the terms of this Convention, shall endeavour to limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes, to ensure their availability for such purposes and to prevent illicit cultivation, production and manufacture of, and illicit trafficking in and use of, drugs" (Article 9(4)).

International Narcotics Control Board

"One of the objectives of the Single Convention on Narcotic Drugs, 1961, and of that Convention as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961, is to ensure the availability of opiates, such as codeine and morphine, that are indispensable for the relief of pain and suffering, while minimizing the possibility of their abuse or diversion" (INCB, 1989, ¶1).

"…[the Board], in conjunction with WHO, undertook to identify possible medical needs for opiates which were currently not being met for a variety of reasons. Information was gathered from various sources, including drug regulators, health system managers, medical specialists, pharmacists and specialized units within WHO, to determine how countries are assessing their medical needs for opiates, the extent to which those needs are being met, what impediments have arisen, and what short-, medium- and long-term strategies may be deployed to overcome those impediments" (INCB, 1989, ¶5).

"International drug control treaties not only recognize the dangers associated with abuse of and trafficking in narcotics drugs, but they also recognize that they are indispensable for the relief of pain and suffering…The [INCB], in cooperation with Governments, endeavours to ensure that there is an adequate supply of narcotic drugs for medical and scientific purposes and to limit their production and use only to such purposes in order to prevent illicit narcotic drug production, trafficking and use" (INCB,1996, Summary, p. iii).

"The Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol establishes a dual drug control obligation for Governments: to ensure adequate availability of narcotic drugs, including opiates, for medical and scientific purposes, while at the same time preventing the illicit production of, trafficking in and use of such drugs" (INCB, 1996, ¶1).

"The Board believes that an efficient national drug control regime must involve not only a programme to prevent illicit trafficking and diversion, but also a programme to ensure the adequate availability of narcotic drugs for medical and scientific purposes…Controls should not be such that for all practical purposes they eliminate the availability of narcotic drugs for medical purposes" (INCB, 1996, ¶48).

"The International Narcotics Control Board is the successor to drug control bodies the first of which was established by international treaty over sixty years ago. A series of treaties confer on the Board specific responsibilities. The Board 'shall endeavor to limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes' and 'to ensure their availability for such purposes'" (INCB, 1997, Forward, p. iii).

The principal objective of the Single Convention on Narcotic Drugs of 1961 and previous international conventions to limit the use of narcotic drugs to legitimate medical and scientific purposes reflects the consensus among all Governments that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes…Adequate availability and limitation were considered by the State parties to the 1961 Convention…as two complementary, not mutually exclusive, aims and were thus incorporated in the control provisions of those Conventions. In adopting such aims, Governments were motivated by two complimentary humanitarian considerations, namely the need to provide optimal help and relief for pain and suffering and the need to protect the individual and society from drug dependence and its detrimental consequences" (INCB, 2000, (¶1).

"If the underlying principles of the international drug control treaties are correctly and fully implemented, they can provide the necessary international basis for Governments to guarantee the availability of narcotic drugs and psychotropic substances with accepted medical use to all those who need them. Those principles can also provide the necessary mechanism for preventing the inappropriate use and abuse of those narcotic drugs and psychotropic substances. The correct interpretation of the two complementary aims, namely ensuring and at the same time limiting the availability of those controlled drugs which are essential for medical purposes, is gaining wider acceptance" (INCB, 2000, ¶38).

"A well-functioning national and international system for managing the availability of narcotic drugs and psychotropic substances has to fulfill, inter alia, the following functions: (a) To provide for relief from pain and suffering by ensuring the safe delivery of the best affordable drugs to those patients who need them and, at the same time, preventing the diversion of drugs for the purpose of abuse" (INCB, 2000, ¶41(a)).

"The Single Convention is the result of the recognition by the United Nations of the fact that the adequate provision of narcotic drugs for medical purposes is indispensable for the welfare of mankind, as well as of the fact that drug addiction is a worldwide social and economic threat…Therefore, the Single Convention aims to restrict the use of narcotic drugs to medical and scientific purposes and to prevent their diversion and abuse, while at the same time ensuring their availability for legitimate purposes. It includes control measures over the cultivation of plants that serve as sources of raw material of narcotic drugs, provisions regarding the obligations of national authorities in the application of control measures over the production, manufacture, trade, and distribution of narcotic drugs, as well as provisions for the medical treatment and rehabilitation of addicts" (INCB, 2005, ¶2).

"Another objective of the international drug control treaties is to ensure the availability of narcotic drugs and psychotropic substances for medical treatment and to promote the rational use of controlled drugs" (INCB, 2006, ¶649).

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"The primary objective of the 1961 and 1971 Conventions is to ensure the availability of controlled drugs for medical and scientific purposes and to prevent the non-medical use of those drugs" (INCB, 2009, ¶20).

"One of the fundamental objectives of the international drug control treaties is to ensure the availability of narcotic drugs and psychotropic substances for medical and scientific purposes and to promote the rational use of narcotic drugs and psychotropic substances" (INCB, 2009, ¶770).

"Ensuring the availability of internationally controlled substances for treatment in accordance with article 9 of the Single Convention on Narcotics Drugs of 1961 (1961 Convention), as amended by the 1972 Protocol, and the preamble of the 1971 Convention on Psychotropic Substances (1971 Convention) is a mandate of the International Narcotics Control Board" (INCB, 2011, ¶1).

"The conventions established a control regime to serve a dual purpose: to ensure the availability of controlled substances for medical and scientific ends while preventing the illicit production of, trafficking in and abuse of such substances. The 1961 Convention, while recognizing that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to humankind, affirms that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes…The implementation of the international drug control treaties by parties is monitored by the Board, whose responsibilities under article 9 of the 1961 Convention expressly include the responsibility to ensure the availability of narcotic drugs for medical and scientific purposes" (INCB, 2011, ¶3).

"The international drug control treaties recognize that narcotic drugs and psychotropic substances are indispensable for medical and scientific purposes. However, despite numerous efforts by the Board and the World Health Organization (WHO), as well as non-governmental organizations, their availability in much of the world remains very limited, depriving many patients of essential medicines. The Board continues to monitor the worldwide availability of narcotic drugs and psychotropic substances and has made their availability one of the main topics of its dialogue with Governments on adequate treaty implementation" (INCB, 2011, ¶4).

"By becoming parties to these conventions, States accept the obligation to implement in their national legislation the provisions of the [international drug control] conventions…(¶1)…The international drug control conventions were elaborated in recognition of the fact that certain substances, while being of great benefit to mankind, also had the potential to cause harm, such as dependence syndrome. Therefore, the conventions established a control regime that would ensure the availability of controlled substances for medical and scientific purposes while preventing their illicit production, trafficking and abuse…(¶2)…WHO also provides guidance to Governments on policies and legislation on the availability, accessibility, affordability and control of medicines made from controlled substances (¶4)" (INCB, 2012).

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World Health Organization

"Decisions concerning the type of drug to be used, the amount of the prescription and the duration of therapy are best made by medical professionals on the basis of the individual needs of each patient, and not by regulation" (WHO, 1996, p. 58).

"those [drugs] that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms..." (WHO Expert Committee on Essential Drugs, 1998, p. 2).

"…access to pain relief and palliative care services is often limited, even in high-resource settings, because of…excessive regulation of opioids…[and] urges Member States…to ensure the medical availability of opioid analgesics according to international treaties and recommendations of WHO and the International Control Board" (WHO, 2004, pp. 3-6).

"During the discussions, factors limiting the availability of drugs for medical use were identified, including barriers inadvertently created by the application of laws and regulations. There are countries where stricter measures are applied than are required by the Conventions. This is permissible, as the requirements of the Conventions are minimum requirements. However, the aims of the Conventions are to ensure availability for medical use as well as the prevention of abuse. It should be noted therefore that the Conventions do not require the parties to implement specific licensing for prescribing and dispensing controlled substances for medical use, nor require permits for receiving these substances therapeutically. Applying stricter measures than those required by the Conventions may hamper rational use of medicines. The appropriate national authorities should carefully consider whether any such measure currently in force could be modified to permit access for patients in need…The Committee requested the WHO Secretariat to suggest including on the proposed agenda of the next Committee meeting, a discussion of the impact of scheduling on the balance between medical availability of controlled substances and the prevention of their abuse" (WHO, 2006, pp.20-21)

"The central principle of 'balance' represents a dual obligation of governments to establish a system of control that ensures the adequate availability of controlled substances for medical and scientific purposes, while simultaneously preventing abuse, diversion and trafficking. Many controlled medicines are essential medicines and are absolutely necessary for the relief of pain, treatment of illness and the prevention of premature death. To ensure the rational use of these medicines, governments should both enable and empower healthcare professionals to prescribe, dispense and administer them according to the individual medical needs of patients, ensuring that a sufficient supply is available to meeting those needs. While misuse of controlled substances poses a risk to society, the system of control is not intended to be a barrier to their availability for medical and scientific purposes, nor interfere in their legitimate medical use for patient care" (WHO, 2011, p. 11).

"Countries have a dual obligation with regard to these medicines based on a quadruple imperative, which is based on legal, political, public health and moral grounds. They must ensure that these substances are available for medical purposes and they must protect their populations against abuse and dependence. Indeed, here lies the challenge for both public-health and drug-control authorities. WHO promotes policies that simultaneously strive for minimizing substance abuse and maximizing access for rational medical use. The combination that leads to the maximum public health outcome is the optimum between these two elements, and a policy leading to this optimum can be called a 'balanced policy'" (WHO, 2011, p. 11).

United Nations Economic and Social Council

"…Recognize[s] that the medical use of narcotic drugs, including opiates, is indispensable for the relief of pain and suffering [and]…the need to balance the global licit supply of opiates against the legitimate demand for opiates used to meet medical and scientific needs is central to the international strategy and policy of drug control" (UN ECOSOC, 2005, p. 1).

"Urges all Governments to continue to contribute to maintaining a balance between the illicit supply of and demand for opiate raw materials used for medical and scientific purposes…" (UN ECOSOC, 2005, p. 2).

"Recognizes the importance of improving the treatment of pain, including by the use of opioid analgesics, as advocated by the World Health Organization, especially in developing countries, and calls upon Member States to remove barriers to the medical use of such analgesics, taking fully into account the need to prevent their diversion for illicit use." (UN ECOSOC, 2005, p. 2)

"Affirming that the international drug control conventions seek to achieve a balance between ensuring the availability of narcotic drugs and psychotropic substances under international control for medical and scientific purposes and preventing their diversion and abuse" (UN ECOSOC, 2010, p. 1).

"Noting the medical and scientific needs for internationally controlled substances worldwide to be met within a regulatory and legal framework that prevents their diversion and abuse" (UN ECOSOC, 2010, p. 2).

"Requests the United Nations Office on Drugs and Crime to continue its efforts to ensure the adequate availability of internationally controlled drugs for medical and scientific purposes, cooperating, as appropriate, through the Access to Controlled Medications Programme of the World Health Organization, while continuing its activities to prevent diversion and abuse" (UN ECOSOC, 2010, p. 4).

"Invites Member States to ensure that the International Narcotics Control Board and the United Nations Office on Drugs and Crime are funded adequately, as appropriate, to support their activities to ensure adequate availability of narcotic drugs and psychotropic substances for medical and scientific purposes, including the development and implementation of guidelines to assist Governments in estimating their requirements for internationally controlled substances and to address the risk of the diversion and abuse of those substances" (UN ECOSOC, 2010, pp. 5-6).

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United Nation Commission on Narcotic Drugs

"The reason that opioids are controlled under the international drug control Conventions is the harm associated with misuse and abuse. As the Commission affirmed in Resolution 53/4, the Conventions seek to achieve a balance between ensuring the availability of narcotic drugs and psychotropic substances under international control for medical and scientific purposes and preventing their diversion and abuse. Both sides of this balance — ensuring availability and preventing diversion and abuse — are concerned with the protection and promotion of health and public safety. As the World Health Organization (WHO) states, the public health outcome is "at its maximum" when 'the optimum is reached between maximizing access for rational medical use and minimizing hazardous or harmful use'" (UN CND, 2011, ¶13).

"This recognition of the international drug control Conventions as concerned primarily with health was articulated by the former Executive Director of the United Nations Office on Drugs and Crime (UNODC), in his report to the review of the twentieth special session of the General Assembly, in which he said 'we must bring public health — the first principle of drug control — back to centre stage' and 'drug control, and the implementation of the drug Conventions, must proceed with due regard to health and human rights'" (UN CND, 2011, ¶14).

"Opioid analgesics are essential for sufficient pain management, but should never be the only available substance type for the treatment of pain, particularly for the treatment of mild to moderate pain. Both opioid and non-opioid analgesics should be made available for appropriate pain management and their rational use should follow an appropriate clinical assessment, criteria for proportional interventions and pharmacological rules for the integration in a complex therapeutics approach. If appropriately used, opioid medicines are safe and the patients rarely become dependent on opioid analgesia" (UN CND, 2011, ¶23).

"The control provisions of the Conventions are designed 1) to ensure that controlled medications are prescribed for legitimate medical purposes and safely reach patients through a controlled distribution chain and 2) to combat illicit manufacture, trade and distribution. They are designed to serve what the INCB has described as the overall goal of a 'well-functioning national and international system for managing the availability of narcotic drugs and psychotropic substances' namely 'to provide relief from pain and suffering by ensuring the safe delivery of the best affordable drugs to those patients who need them and, at the same time, to prevent the diversion of drugs for the purpose of abuse'" (UN CND, 2011, ¶32).

World Health Assembly

"to ensure the medical availability of opioid analgesics according to international treaties and recommendations of WHO and the International Narcotics Control Board and subject to an efficient monitoring and control system" (WHA, 2005, p. 3).

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NATIONAL AUTHORITIES

Controlled Substances Act

"Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people" (Title 21 Controlled Substances Act §801(1)).

Drug Enforcement Administration

"This section is not intended to impose any limitations on a physician or authorized hospital staff to...administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts" (Title 21 Code of Federal Regulations §1306.07(c)).

"The CSA requirement for a determination of legitimate medical need is based on the undisputed proposition that patients and pharmacies should be able to obtain sufficient quantities...of any Schedule II drug, to fill prescriptions. A therapeutic drug should be available to patients when they need it..." (53 Federal Register 50593, 1988).

"Preventing drug abuse is an important societal goal, but there is consensus, by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients' ability to receive the care they need and deserve…Undertreatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death. Effective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively…For many patients, opioid analgesics – when used as recommended by established pain management guidelines – are the most effective way to treat their pain, and often the only treatment option that provides significant relief…Drug abuse is a serious problem. Those who legally manufacture, distribute, prescribe and dispense controlled substances must be mindful of and have respect for their inherent abuse potential. Focusing only on the abuse potential of a drug, however, could erroneously lead to the conclusion that these medications should be avoided when medically indicated – generating a sense of fear rather than respect for their legitimate properties" (Drug Enforcement Administration, Last Acts et al. 2001).

Federation of State Medical Boards of the U.S.

"Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice, when current best clinical practices are met." (FSMB, 2013, p. 7).

"…principles of high-quality medical practice dictate that the people...have access to appropriate, safe and effective pain management...All physicians and other providers should be knowledgeable about assessing patients' pain and function...opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes n, and familiar with methods of managing pain. Physicians also need to understand and comply with federal and state requirements for prescribing opioid analgesics... The diagnosis and treatment of pain is integral to the practice of medicine" (FSMB, 2013, p. 7-8).

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Institute of Medicine

"…pain raises societal issues that extend beyond individuals and their suffering. Specifically, the opioid medications that are effective for many people with pain also are subject to misuse and abuse, and ensuring that they are available for those who need them and not available to abusers necessitates cross-governmental efforts at all levels" (IOM, 2011, p. 2-1).

National Association of Attorneys General

"…there is a consensus among law enforcement agencies, health care practitioners, and patient advocates that the prevention of drug abuse is an important societal goal that can and should be pursued without hindering proper patient care; and…it is crucial that public health, law enforcement, and government officials continue to develop strategies and methods to prevent the abuse and diversion of prescription drugs, while safeguarding the right of those suffering from severe and chronic pain to continue to have access to appropriate medications." (NAAG, 2003, p. 1)

"The National Association of Attorneys General encourages states to ensure that any such programs or strategies implemented to reduce abuse of prescription pain medications are designed with attention to their potential impact on the legitimate use of prescription drugs" (NAAG, 2003, p. 2).

"…the Attorney General should actively promote the concept of balance that legitimate law enforcement goals should be pursued without adversely affecting the provision of quality end-of-life care." (NAAG, 2003, p. 20)

Office of National Drug Control Policy

"…any policy response [to the prescription drug abuse problem] must be approached thoughtfully, while acknowledging budgetary constraints at the state and Federal levels. The potent medications science has developed have great potential for relieving suffering, as well as great potential for abuse. There are many examples: acute medical pain treatment and humane hospice care for cancer patients would be impossible without prescription opioids; benzodiazepines are the bridge for many people with serious anxiety disorders to begin the process of overcoming their fears; and stimulants have a range of valuable uses across medical fields. Accordingly, any policy in this area must strike a balance between our desire to minimize abuse of prescription drugs and the need to ensure access for their legitimate use…" (ONDCP, 2011, pp. 1-2)

"Research and medicine have provided a vast array of medications to cure disease, ease suffering and pain, improve the quality of life, and save lives. This is no more evident than in the field of pain management. However, as with many new scientific discoveries and new uses for existing compounds, the potential for diversion, abuse, morbidity, and mortality are significant. Prescription drug misuse and abuse is a major public health and public safety crisis. As a Nation, we must take urgent action to ensure the appropriate balance between the benefits these medications offer in improving lives and the risks they pose…" (ONDCP, 2011, p. 10)

APPENDIX B: METHOD TO ASSIGN GRADES

(1) Identification of provisions:

The positive and negative provisions in state pain policies from 2006, 2007, 2008, and 2012 had already been identified in the *Evaluation Guide 2012*. The criteria were then used to identify positive and negative provisions in policies current through December 2013.

(2) Grading:

The grading method was established using the total number of positive and negative provisions identified with the policy evaluation methodology explained in the *Evaluation Guide 2013*. Each provision was given equal weight.

In 2000, the total number of positive provisions was calculated for every state, with a range, an average, and a standard deviation (the extent that the values deviate from the average) for the aggregate number of positive provisions identified from all states. Despite the large range of total positive provisions, most states had fewer provisions, which represented extreme skewness. To adjust for the fact that few states had a large number of positive provisions in 2000, we defined the grade of C by a range including, and extending a standard deviation below, the average – a C was earned by states having around the average number of positive provisions. The same methodology was used for the total number of negative provisions identified in all states, and the averages and standard deviations were used to calculate the grades. This grading system was then applied to the total number of positive and negative provisions contained in all states' policies present in 2003, 2006-2008, 2012, and 2013 (relevant policies present in 2013 are contained in the *Evaluation Guide 2013*); so, in this report, states' grades for 2006, 2007, 2008, 2012, and 2013 are based on the same evaluation and grading methodology.

Grading System for Positive and Negative Provisions

Distribution for Positive Provisions	Grade	Distribution for Negative Provisions
1 or more standard deviations above the average	A	0 provisions
Within 1 standard deviation above the average	B	Within 1 standard deviation below the average
Around the average	C	Around the average
1 or more standard deviations below the average	D	Within 1 standard deviation above the average
0 provisions	F	1 or more standard deviations above the average

The separate positive and negative grades can be found in Appendix C and are averaged to arrive at a state's final grade; unless otherwise specified, the term "grade" refers to the final grade. Mid-point grades were calculated (B+, C+, D+), rather than rounding up or down, in an effort to reflect more precisely each state's unique combination of positive and negative provisions. For example, if a state received an A for positive provisions and a B for negative provisions, the final grade would be a B+.

Appendix C: State Grades for Positive & Negative Provisions – 2013

States	(+) 2013	(-) 2013
Alabama	A	A
Alaska	D	A
Arizona	A	B
Arkansas	A	C
California	A	B
Colorado	A	C
Connecticut	A	B
Delaware	A	B
District of Columbia	B	B
Florida	A	C
Georgia	A	A
Hawaii	A	C
Idaho	A	A
Illinois	D	B
Indiana	B	B
Iowa	A	A
Kansas	A	A
Kentucky	A	B
Louisiana	B	C
Maine	A	A
Maryland	A	B
Massachusetts	A	A
Michigan	A	A
Minnesota	A	B
Mississippi	B	B
Missouri	A	D
Montana	A	A
Nebraska	A	B
Nevada	B	D
New Hampshire	A	B
New Jersey	A	C
New Mexico	A	B
New York	A	C
North Carolina	A	C
North Dakota	C	A
Ohio	A	B
Oklahoma	A	D
Oregon	A	A
Pennsylvania	B	B
Rhode Island	A	A
South Carolina	A	B
South Dakota	A	B
Tennessee	A	F
Texas	A	D
Utah	A	B
Vermont	A	A
Virginia	A	A
Washington	A	A
West Virginia	A	B
Wisconsin	A	A
Wyoming	A	B

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Appendix D: How Language from Healthcare Regulatory Policy has Fulfilled the Categories of Criterion #8

Medical Board Policies based on the Federation of State Medical Board's *Model Policy* templates	***Category A:*** Identifies the potential impact of important barriers on the provision of effective pain care ***Category A:*** Recognizes inadequate treatment of pain as subject to disciplinary action just as other substandard practices might be ***Category A:*** Recognizes that the goals of pain treatment should include improvements in patient functioning and quality of life ***Category A:*** Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice ***Category A:*** Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes ***Category B:*** Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management ***Category C:*** Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the balanced approach represented by federal law and the laws in many states
Pharmacy Board Policies	***Category A:*** Clarifies for pharmacists the important distinction between drug-seeking behaviors resulting from poorly treated pain (i.e., pseudoaddiction) and drug-seeking behaviors related to abuse or addiction; this language identifies a potential clinical situation and attempts to lessen its impact on patient treatment ***Category A:*** Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice ***Category A:*** Recognizes the need for a multidisciplinary approach to pain management ***Category C:*** Represents the principle of Balance, which states that efforts to reduce the abuse and diversion of controlled substances should not interfere with legitimate medical use
Joint Board Policies	***Category A:*** Identifies concerns of drug diversion as an important barrier to access to appropriate pain relief ***Category A:*** Identifies the potential impact of important barriers on the provision of effective pain care ***Category A:*** Recognizes inadequate treatment of pain as subject to disciplinary action just as other substandard practices might be ***Category A:*** Recognizes the need for a multidisciplinary approach to pain management ***Category A:*** Recognizes that the goals of pain treatment should include improvements in patient functioning and quality of life ***Category A:*** Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice ***Category A:*** Recognizes a practitioner's responsibility to provide patient's information about pain management and palliative care when considering treatment options ***Category B:*** Acknowledges that a patient's prior history of drug abuse does not necessarily contraindicate appropriate pain management ***Category C:*** Represents the principle of Balance, which states that efforts to reduce the abuse and diversion of controlled substances should not interfere with legitimate medical use

Appendix E: Number of States in 2013 with Policy Language Having Potential to Enhance or Impede Pain Management	
Positive provisions	**Number of states**
1. Controlled substances are recognized as necessary for public health	4
2. Pain management is recognized as part of general healthcare practice	47
3. Medical use of opioids is recognized as legitimate professional practice	51
4. Pain management is encouraged	40
5. Practitioners' concerns about regulatory scrutiny are addressed	42
6. Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing	38
7. Physical dependence or analgesic tolerance are *not* confused with "addiction"	41
8. Other provisions that may enhance pain management	
Category A: Issues related to healthcare professionals	48
Category B: Issues related to patients	45
Category C: Regulatory or policy issues	50
Negative provisions	**Number of states**
9. Opioids are relegated as only a treatment of last resort	1
10. Medical use of opioids is implied to be outside legitimate professional practice	6
11. Physical dependence or analgesic tolerance are confused with "addiction"	13
12. Medical decisions are restricted	
Category A: Restrictions based on patient characteristics	5
Category B: Mandated consultation for all patients	5
Category C: Restrictions regarding quantity prescribed or dispensed	0
Category D: Undue prescription limitations	3
13. Length of prescription validity is restricted	3
14. Practitioners are subject to additional prescription requirements	5
15. Other provisions that may impede pain management	1
16. Provisions that are ambiguous	
Category A: Arbitrary standards for legitimate prescribing	16
Category B: Unclear intent leading to possible misinterpretation	13
Category C: Conflicting or inconsistent policies or provisions	3

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