2012

ACHIEVING BALANCE
in State Pain Policy

A Progress Report Card (CY 2012)

Pain & Policy Studies Group
University of Wisconsin School of Medicine and Public Health
Carbone Cancer Center
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State policies aimed at regulating professional practice and improving patient care can either enhance or interfere with pain management. Six evaluations over a twelve-year period by the University of Wisconsin Pain & Policy Studies Group (PPSG) has shown continuous improvement in state policies governing the medical use of opioid medications. This *Progress Report Card* (*Progress Report Card 2012*) 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 (Sixth edition)*) (*Evaluation Guide 2012*), the *Progress Report Card 2012* 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 2012* 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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EXECUTIVE SUMMARY

In the United States, healthcare professionals, government and regulatory agencies, and policymakers have been grappling with how to appropriately and effectively deal with two overlapping issues affecting public health: (1) untreated and poorly treated pain, and (2) the abuse and diversion of prescription controlled substances, such as opioid pain medications. Of course, successful pain care comprises more than prescription medications (including opioids) and an integrative model of care should be encouraged for all patients. Although controlled substances are recognized as important medications for many painful conditions, especially when pain is severe, they also have a potential for abuse and these dual characteristics must be considered concurrently. Any policy response to one of these issues should avoid contributing to an unanticipated deleterious impact on the other.

Drug control and medical and pharmacy practice policies enacted to govern medication distribution and the mitigation of diversion and abuse come into play when healthcare practitioners prescribe, dispense, or administer opioids to relieve pain. Ideally, these policies represent a government's dual obligation not only to establish a system of drug controls to prevent diversion and abuse, but also to ensure the adequate medical availability of needed medications; under this obligation, medication availability must be limited to legitimate medical use but be restricted from use for non-medical purposes. This is referred to as the Central Principle of Balance, which is substantiated by international and national authoritative sources and which is the conceptual foundation of this research report. As such, the Central Principle of Balance embodies the two objectives of supporting public health by ensuring medication availability for legitimate medical and scientific purposes and protecting public safety through appropriate and effective drug control measures. When applied to a context of pain management, balanced policies have the potential to enhance pain relief while avoiding the potential to interfere with medical decision-making and patient care.

Over more than a decade, states have made considerable progress in achieving and maintaining more balanced policy. Healthcare regulatory boards in many states have developed policies designed to directly reassure licensees that the mere act of prescribing or dispensing opioids for a legitimate medical purpose (e.g., as component of pain care) will not result in disciplinary sanction. Such policy proliferation seems to be a conscientious reaction on the part of healthcare licensing agencies to address practitioners' long-held concerns about regulatory scrutiny when considering pain medications as a treatment option. In addition, most if not all states have policies recognizing that pain management, including the use of pain medications, is part of quality healthcare practice. Now more than ever before, state regulations are defining ways for healthcare facilities, such as hospitals, nursing homes, and hospices, to make pain assessment and treatment an expected element of patient care. Some states – but far from all – have adopted policies recognizing that medical education should address pain management and palliative care, and encourage that a team of professionals manage painful conditions to better address a patient's different and often complex healthcare needs. Finally, laws establishing and implementing many recent prescription drug monitoring programs, which often serve as a state's primary diversion control mechanism, are explicitly recognizing that the program's objective is to reduce abuse and diversion without hampering proper medication use and patient care; such language directly represents the Central Principle of Balance.

Despite the adoption in recent years of policies intended to promote safe and effective pain management, including with the appropriate use of controlled substances, a practitioner's ability to engage in such practice or to effectively employ opioids as a therapeutic modality continues to be unduly impeded by some states' laws. Such restrictions include defining "unprofessional conduct" to include "excessive prescribing" without defining the standards used for such a determination, equating drug addiction with the prolonged use of opioids to manage pain, and severely limiting the period in which prescriptions need to be dispensed before they become invalid. Treatment restrictions or ambiguities also are based on certain patient characteristics, such as when a patient has pain but also has a history of substance abuse. Although it is widely accepted that treating patients with an addictive disease or a history of substance abuse calls for specific clinical skills, extra

monitoring, and possibly a consultation with or referral to an addiction medicine specialist, some states prohibit use of controlled substances with such patients even when deemed clinically warranted, which creates treatment disparities that can adversely impact patients' health outcomes. Recently-adopted policies (even those designed primarily to mitigate non-medical prescription drug use) have tended to avoid creating these potential barriers, but such standards remain common in older state laws. For most states, efforts to improve policy must be directed at removing these outdated requirements and limitations from state legislation and regulations.

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 and 2012 to allow an understanding of policy change over time.

The report concludes that state pain policies are becoming more balanced, even when compared to the last evaluation in 2008. Since 2008:

- All but 11 states changed policies or adopted new policies containing language that fulfilled at least one evaluation criterion, and in 20 of those states the policy change was sufficient to improve their grade;
- Georgia, Iowa, Maine, Montana, Rhode Island, Vermont, and Washington achieved an A in 2012, and join Kansas, Massachusetts, Michigan, Oregon, Virginia, and Wisconsin as having the most balanced pain policies in the country;
- Delaware, Georgia, Iowa, Montana, and Wyoming showed the largest grade improvement, increasing a full grade level;
- 94% of states now have a grade above the average (a C), compared to 88% in 2008; and
- No state's grade decreased since 2008 or even since 2006.

The policy improvement that occurred between 2008 and 2012 was largely the result of: (1) state healthcare regulatory boards adopting policies to encourage appropriate pain management, and (2) state legislatures repealing restrictive or ambiguous policy language, including repealing problematic language from Intractable Pain Treatment Acts.

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 remove regulatory barriers and encourage appropriate treatment of pain. Legislatures are 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.

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.

EXECUTIVE SUMMARY

This *Progress Report Card*, used in conjunction with *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (CY 2012)*, provides a framework for deciding which policies should be addressed, as well as example language 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, we can establish a more positive legislative, regulatory, and practice environment 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

Acknowledgments

The PPSG wishes to thank the numerous professionals (representing healthcare, regulation, and legal areas) who provided thoughtful and valuable feedback throughout the development of this entire series of policy evaluation reports.

Citation

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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 2012. 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.[1-7] This issue is particularly salient for children,[8-13] the elderly,[14-18] people of racial and ethnic subgroups,[19-23] people with developmental disabilities,[24;25] people in the military or military veterans[26-28] as well as for those with diseases such as cancer,[29-34] HIV/AIDS,[35-38] or sickle-cell disease.[39-41] 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.[42]

Pain Can be Relieved

There are many potentially-effective drug and non-drug approaches to manage pain,[32;43-49] 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.[42] However, controlled substances, including opioid analgesics (sometimes referred to by the outdated legal term, "narcotic"), often are necessary to maintain public health[50] and are a mainstay of pain treatment for cancer and HIV/AIDS, particularly if pain is severe.[49;51-53] Opioid analgesics in the class of morphine have a legitimate medical use[54] and are indicated for the medical management of moderate or severe pain.[49;55] Although their use for the relief of a variety of chronic non-cancer pain conditions continues to evolve,[56] 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.[57-59] Physicians, osteopaths, pharmacists, and nurses (where permitted) must be able, knowledgeable, and confident to prescribe, administer, and dispense opioids according to individual patient needs.[60-62]

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.[42] 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;[63] 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. 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.

Influence of Drug Abuse Control Policy

Opioid medications also have a potential for abuse (a discussion of this important issue is in the *Evaluation Guide 2012*). Consequently, opioids and the healthcare professionals who prescribe, administer, or dispense them are regulated pursuant to federal and state controlled substances policies, as well as under state laws and regulations that govern professional practice.[64;65] 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,[66-70] 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 pain patients 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).[50]
- Pain management is an integral part of the practice of medicine (as does the Federation of State Medical Board's *Modern Medical Practice Act*).[71]
- 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 *Model Policy for the Use of Controlled Substances for the Treatment of Pain*).[61;72-74]
- Physicians should not fear regulatory sanctions for appropriately prescribing controlled substances for pain (as does the Federation of State Medical Board's *Model Policy for the Use of Controlled Substances for the Treatment of Pain*).[61;72-74]
- Physical dependence or tolerance are not synonymous with addiction (as does the Federation of State Medical Board's *Model Policy for the Use of Controlled Substances for the Treatment of Pain*).[61;73;75]

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 pain policies. 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).[76]

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))* [77]

INTRODUCTION

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.[78;79] The most recent 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."* [49]

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))* [80]

> *"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)* [80]

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).[81]

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).[82]

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). [83]

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).[84] The NIH has concluded that "Regulatory barriers need to be revised to maximize convenience, benefit, and compliance…" (p. 15).[85]

WHY A PROGRESS REPORT CARD?

This *Progress Report Card* (*Progress Report Card 2012*), funded by a grant from the American Cancer Society and through a cooperative agreement with Livestrong, is the latest in a sequence of reports[86-89] developed to evaluate state policies that affect pain management.[a] 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 2012* 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. The policy changes that are needed 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.

[a] 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 2012*.

WHY A PROGRESS REPORT CARD?

Based on findings from three previous PPSG evaluations of state pain policies,[90-92] each state has been assigned a grade for 2006, 2007, and 2008. With this report, to measure progress the PPSG compared states' grades from 2012 with their grades from 2006, 2007, and 2008.

The *Progress Report Card 2012* 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.[b] 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 PPSG evaluated in each state; these are in the *Evaluation Guide 2012*, which is the companion document to the *Progress Report Card 2012*. These tools can be used by government and non-government organizations, as well as 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 PPSG provides the complete text of each state's pain-specific (but not pain-related) policies on its website at www.painpolicy.wisc.edu/matrix.

Method to Evaluate Pain Policies

The *Evaluation Guide 2012* describes methods that PPSG has developed with peer review to evaluate pain policies using a central principle, procedures to collect policies, and criteria used to identify relevant policy provisions.[93]

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.[94]

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.

[b] 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?

Appendix A documents the sources of legal and healthcare authority, from which the PPSG derived the Central Principle of Balance.

The Evaluation Criteria

The PPSG developed 16 criteria based on the Central Principle of Balance. They are divided into two categories and are used to identify relevant policy language in all state[c] 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.

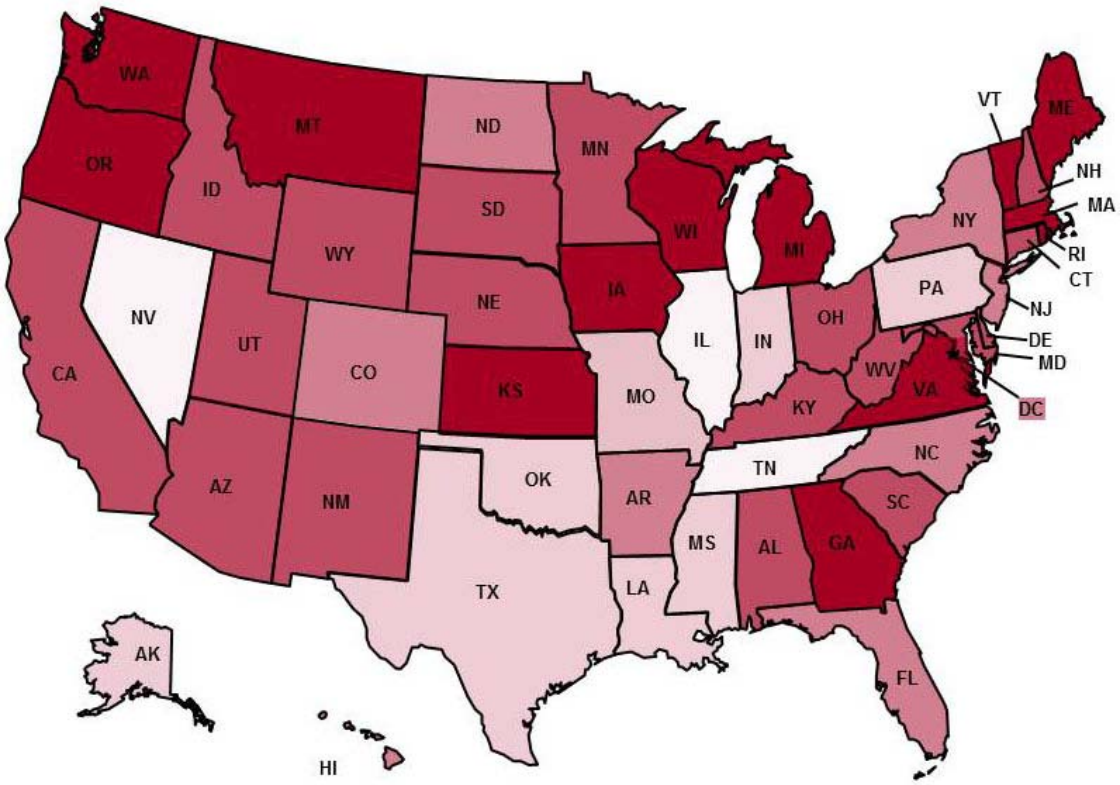
Readers are referred to the *Evaluation Guide 2012*, a companion to this report, for a more detailed discussion of the imperative to evaluate policy, the Central Principle of Balance, the evaluation criteria, the method used to evaluate state policies, and the text of the policy provisions that are identified in each state and on which the grades in the next section are based.

[c] 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 2012: States' grades for 2012 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
13 states 20% of US pop.	18 states 31% of US pop.	9 states 22% of US pop.	8 states 20% of US pop.	3 states 7% of US pop.	None	None	None
Georgia	Alabama	Arkansas	Alaska	Illinois			
Iowa	Arizona	Colorado	Indiana	Nevada			
Kansas	California	Dist. of Columbia	Louisiana	Tennessee			
Maine	Connecticut	Florida	Mississippi				
Massachusetts	Delaware	Hawaii	Missouri				
Michigan	Idaho	New Jersey	Oklahoma				
Montana	Kentucky	New York	Pennsylvania				
Oregon	Maryland	North Carolina	Texas				
Rhode Island	Minnesota	North Dakota					
Vermont	Nebraska						
Virginia	New Hampshire						
Washington	New Mexico						
Wisconsin	Ohio						
	South Carolina						
	South Dakota						
	Utah						
	West Virginia						
	Wyoming						

MAKING THE GRADE: HOW DO THE STATES RATE?

Table 4: State Grades for 2012			
STATES	2012 GRADES	STATES	2012 GRADES
AL	B+	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	B+	PA	C+
IL	C	RI	A
IN	C+	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	C+	WY	B+
MO	C+		

Highlights of the 2012 Grades

- 6% of states received an average grade of C, while 94% scored above a C and no states fell below the average (D+, D, or F).
- Georgia, Iowa, Maine, Montana, Rhode Island, Vermont, and Washington received an A, joining Kansas, Massachusetts, Michigan, Oregon, Virginia, 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 13 states achieving an A comprise 20% of the total U.S. population. States with a B or B+ make up over 50% of the U.S. population, largely owing to the influence of there being 27 states in these grade categories (four of the states being California, New York, Florida, and Ohio, which are the 1st, 3rd, 4th, and 7th most populated states, respectively). Another 27% of the U.S. population lives in the 11 states that have a grade of C or C+, primarily owing to the populations of Texas, Illinois, and Pennsylvania (which are the 2nd, 5th, and 6th most populated states, respectively).

MAKING THE GRADE: HOW DO THE STATES RATE?

Did Grades Change from 2006 to 2012?

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

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

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

* grades do not conform to previous reports because of evaluation changes (described in the *Evaluation Guide 2012*)

- 84% of states received above a C in 2006, increasing to 86% in 2007, 88% in 2008, and 94% in 2012.
- Georgia, Iowa, Maine, Montana, Rhode Island, Vermont, and Washington received an A in 2012.
- Georgia demonstrated the largest grade improvement, increasing from a D+ to an A between 2006 and 2012.
- No state's grade decreased from 2006 to 2012.

MAKING THE GRADE: HOW DO THE STATES RATE?

How Did Grades Change Between 2008 and 2012?

- 41 of 51 states (80%) changed their policies in a way that fulfilled at least one evaluation criterion; the policy changes were sufficient in 20 of these states to produce a positive grade change.
- Of the 20 states with grade improvements, Delaware, Georgia, Iowa, Montana, and Wyoming demonstrated the largest grade change since the last assessment (a full grade level [e.g., from a B to an A]). Such grade improvements were accomplished by various methods:
  - Delaware adopted medical board regulations based on the Federation's Model Policy of 2004, as well as added language in the Controlled Substances Act specifying that the state prescription drug monitoring program must not interfere with the legal (appropriate) use of controlled substances;
  - Georgia deleted an outdated definition of "drug dependence" from the Controlled Substances Act, and also adopted policy language that, if implemented, could enhance appropriate patient pain care;
  - Iowa added positive policy language, including repealing a 2002 pharmacy board policy statement (which contained an ambiguous provision) and adopting a joint policy statement from the medical pharmacy, nursing, and physician assistant boards;
  - Montana replaced an existing 1996 medical board guideline (containing restrictive provisions) with a policy based on the Federation's Model Policy (which contains no restrictive provisions); and
  - Wyoming replaced a 2005 medical board policy statement with a policy based on the Federation's Model Policy.
- 31 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 2008 and 2012

Positive Change (20 states)	No Change (31 states)	
California	Alabama	Nebraska
Delaware	Alaska	Nevada
District of Columbia	Arizona	New Jersey
Georgia	Arkansas	New Mexico
Idaho	Colorado	North Carolina
Iowa	Connecticut	North Dakota
Kentucky	Florida	Oklahoma
Louisiana	Hawaii	Oregon
Maine	Illinois	Pennsylvania
Maryland	Indiana	South Carolina
Montana	Kansas	Tennessee
New Hampshire	Massachusetts	Texas
New York	Michigan	Utah
Ohio	Minnesota	Virginia
Rhode Island	Mississippi	Wisconsin
South Dakota	Missouri	
Vermont		
Washington		
West Virginia		
Wyoming		

Interesting New Policies

Although not always contributing to the positive grade changes observed between 2008 and 2012, the following policies are of interest:

- 9 states (Alabama, Connecticut, Maryland, New Hampshire, New Jersey, Oklahoma, South Dakota, Vermont, and Wisconsin) adopted regulations establishing mechanisms to enhance pain management in licensed healthcare facilities.
- 8 states (Arizona, Delaware, Florida, Iowa, Maryland, Minnesota, Mississippi, and Vermont) adopted balanced legislation that established a prescription drug monitoring program to reduce prescription opioid abuse and diversion. Recent prescription drug monitoring programs cover multiple schedules of medications (e.g., Schedules II-IV), and often recognize that these programs are created to prevent the illegal use of controlled substances and are not to infringe on legitimate professional practice and patient care; this statement directly supports the Central Principle of Balance. One state (Texas) continues to require a government-issued prescription form for Schedule II controlled substances only.
- 8 states (District of Columbia, Iowa, Kentucky, Massachusetts, New Mexico, New York, Ohio, and Vermont) adopted legislation or regulations mandating continuing education about pain management or palliative care for licensees.
- 6 states (Indiana, New York, Oklahoma, South Carolina, Tennessee, and West Virginia) adopted laws establishing a responsibility for Opioid Treatment Program staff to either assess for pain or to refer methadone-maintained patients who have chronic pain for the treatment of their pain.
- New York adopted legislation requiring healthcare practitioners to provide patients, who are diagnosed with a terminal illness or condition, with information and counseling about palliative care or end-of-life care options, including pain and symptom management. If practitioners are unwilling to provide such information, they must arrange for another clinician to provide the information or refer the patients to another practitioner who is willing to do so.

Improvements in Pain Management Policy

State grades for balanced policy continued to improve notably between 2008 and 2012. As in the previous *Progress Report Card* (*Progress Report Card 2008*), the driving force for positive policy change was state healthcare regulatory boards that adopted several types of policies encouraging pain management. 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*).[95] 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*).[61] 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.

Many state medical regulatory boards subsequently adopted the *Model Guidelines* or *Model Policy* to encourage better pain management and to address physicians' concern about investigation.[65;68;96] This trend has resulted in positive changes in state pain policies[97;98] and also in efforts to communicate them to practitioners and the public.[99;100]

As of December 2012, a total of 36 state medical or pharmacy boards had adopted either the *Model Guidelines* or *Model Policy* in whole or in part.[d] Since 2008, nine states (Delaware, Iowa, Kentucky, Maine, Missouri, Montana, South Carolina, Washington, and Wyoming) adopted healthcare regulatory board policies based on the Federation's model policy templates. The *Model Policy* does not have any negative provisions; states that adopt it 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).

Osteopathic Board Policies

The Washington osteopathic board adopted a regulation relating to prescribing for chronic non-cancer pain, which fulfilled the following criteria: Criterion #7 (see Table 3 for a description of the criterion) and Criterion #8: Category A and Criterion #8: Category B (see Appendix D for a listing of the types of Criteria #8 categories fulfilled).

Joint Board Policies

Four other states (Iowa, Maine, South Carolina, and Wyoming) adopted or revised a joint policy statement relating to the use of controlled substances for the treatment of pain, which was developed collaboratively by several regulatory boards such as medicine, pharmacy, and nursing. Such policies, which represent a consensus of the boards that govern such healthcare practice as medicine, pharmacy, and nursing, are a unique and credible way to emphasize the importance of multidisciplinary treatment of pain. Cumulatively, the following positive provisions were represented among the policies: Criteria #2, #3, #4, #5, #6, and #7 (see Table 3), and nine instances of Criterion #8: Category A and three instances of Criterion #8: Category B (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 Intractable Pain

Ohio and West Virginia repealed the term "intractable pain" from statute. The definition of "intractable pain," because it occurred in law, implied that the medical use of opioids is outside legitimate professional practice (Criterion #10) and suggested that physicians would not qualify for the immunity provided by the law if they prescribe opioids as a treatment of first choice for patients, even if the patient is suffering from severe pain (Criterion #16: Category B). Eight states continue to define "intractable pain" (or "chronic pain) in law that can convey the ambiguous practice messages described above.[e]

[d] 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.

[e] These states are Arkansas, Colorado, Minnesota, Missouri, Nevada, Ohio, Tennessee, and Texas.

Ambiguities in Law

California repealed from statute the remaining standard that links unprofessional conduct to "excessive" prescribing (Criterion #16: Category A); "excessive" was undefined and created uncertainty for practitioners about the specific standard that determines the legitimacy of a particular prescribing practice and who sets that standard. Currently, eight states use the term "excessive prescribing" (or related standards such as "improper" or "inappropriate") within a context of unprofessional conduct or other licensure standard.[f]

Repeal of Restrictive Prescription Validity Periods

Illinois repealed from its Controlled Substances Act, and Vermont repealed from its pharmacy board regulation, the overly-restrictive prescription validity period of 7 days (which fulfilled Criterion #13). This change completely eliminates in Vermont the barrier of an unrealistically short validity period (i.e., the number of days within which the prescription must be dispensed following its issue), which can make it difficult for a patient to obtain medications without having to make sometimes expensive arrangements, especially when travel, slow mail delivery, or other extenuating circumstances exist; exceeding a prescription's validity period necessitates issuance of a new prescription and a likely return visit to the physician. Three states have retained a validity period of less than two weeks, including Illinois which retains similar language in the Electronic Prescription Monitoring Program regulation.[g]

Opioids as a Last Resort

Three states (Mississippi, Montana, and Washington) repealed language that seemed to require that patients always undergo other treatment modalities before being prescribed opioids, regardless of patient need or other clinical considerations (Criterion #9). Tennessee is the only state with a policy that continues to represent such a standard, which is contained in a 1995 medical board policy statement.

Some Restrictive or Ambiguous Policy Changes

Policy change, but ultimately no grade changes, occurred because a few states adopted restrictive or ambiguous policy language between 2008 and 2012. Four states added the following policy language:

- By expanding the validity period for prescriptions for Schedule II controlled substances (from 3 to 7 days), created an inconsistency with prescription standards from another law (in Hawaii controlled substances regulations),
- Establishes a system of reporting licensees for "improper or inappropriate" prescribing or dispensing without specifying the characteristics that would meet the standard of "improper or inappropriate" (in the Kentucky Controlled Substances Act),
- Defines "unprofessional conduct" to include failing to adhere to certain clinical practice guidelines, which does not seem to allow for treatment flexibility based on reasonable cause and relevant clinical factors (in New Hampshire medical board regulations), and
- Establishes a requirement for obtaining an "appropriate consultation," when providing pain management services to a person with a substance use disorder, without specifying the meaning of "appropriate" or who makes this determination (in New Mexico medical board regulations).

[f] These states are Arkansas, Kentucky, Missouri, Nebraska, New York, Oklahoma, Tennessee, and Texas.
[g] These states are Delaware, Hawaii, and Illinois.

CURRENT STATUS OF BALANCE IN STATE PAIN POLICY

Georgia, Iowa, Maine, Montana, Rhode Island, Vermont, and Washington now join Kansas, Massachusetts, Michigan, Oregon, Virginia, 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 13 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, 16 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 2008, legislatures and healthcare regulatory agencies in 20 states modified their relevant policies sufficiently to improve their grade for Balance. Fourteen of these states (Delaware, District of Columbia, Idaho, Iowa, Kentucky, Louisiana, Maryland, Montana, New York, Ohio, South Dakota, Vermont, West Virginia, and Wyoming) only evidenced a grade change in the last year, while the other six states had more than one grade improvement over the other three assessment periods since 2006; these changes demonstrate many continuing efforts to enhance pain policies that can affect professional practice and patient care. Delaware, Georgia, Iowa, Montana, and Wyoming demonstrated the largest grade improvement since the last assessment (a full grade level [e.g., from a B to an A]). These grade changes were accomplished by various methods:

- Delaware adopted medical board regulations based on the Federation's Model Policy of 2004, as well as language in the Controlled Substances Act specifying that the state prescription drug monitoring program must not interfere with the legal (appropriate) use of controlled substances;
- Georgia deleted an outdated definition of "drug dependence" from the Controlled Substances Act, and also adopted policy language that, if implemented, could enhance appropriate patient pain care;
- Iowa, like Georgia, added positive policy language, including repealing a 2002 pharmacy board policy statement (which contained an ambiguous provision) and adopting a joint policy statement from the medical pharmacy, nursing, and physician assistant boards;
- Montana replaced an existing 1996 medical board guideline (containing restrictive provisions) with a policy based on the Federation's Model Policy (which contains no restrictive provisions); and
- Wyoming replaced a 2005 medical board policy statement with a policy based on the Federation's Model Policy.

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, California, Colorado, Florida, Massachusetts, Minnesota, Missouri, New Jersey, New Mexico, New York, Oklahoma, Oregon, South Carolina, Tennessee, Texas, 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. Alabama, Alaska, and North Dakota currently have no restrictive or ambiguous language in their state's pain policies. These states could achieve an A simply by adopting additional positive language. Another 12 states (Arizona, Connecticut, Delaware, Idaho, Kentucky, Maryland, Minnesota, Nebraska, New Mexico, South Carolina, South Dakota, and Utah) would have received an A in 2012 had one or two restrictive or ambiguous provisions been repealed.

Special Challenges

By the end of 2012, all but three states (94%) had a grade above a C; this is a substantial improvement since 2006, when 84% of states had a grade exceeding the average. 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 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 healthcare practice and patient care decisions requiring medical expertise are not unduly restricted.

Half of all states achieving a grade change since 2008 did so, at least in part, by changing policy that removed restrictive or ambiguous language.[i] This pattern of policy change seems to represent unprecedented legislative and regulatory consideration about reducing potential policy barriers. Importantly, however, 28 states (74%), of those remaining 38 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 2012*.

One of the most frequent negative provisions remaining in state policy is terminology that confuses physical dependence with addiction. Although 42 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 12 states and the regulations of three states continue to classify physical dependence as synonymous with addiction. Consequently, 13 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 § 201), which is still present and was created over 40 years ago. Special attention should be given to repealing

[i] These states are California, Georgia, Iowa, Montana, New York, Ohio, Rhode Island, Vermont, Washington, and West Virginia.
[j] These states are Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Kentucky, Maryland, Minnesota, Missouri, Nebraska, 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, Colorado, Hawaii, Idaho, Louisiana, Maryland, Missouri, Nevada, North Carolina, Oklahoma, Pennsylvania, Tennessee, and Wyoming.

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 most continued to adopt policy language that could enhance pain management. As a result, such changes, although positive and encouraged, have not improved 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, Indiana, 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, seven states (14%) 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, Oklahoma, Tennessee, and Texas.
[m] These states are District of Columbia, Illinois, Indiana, Louisiana, Mississippi, Nevada, and Pennsylvania.

CONCLUSION

Overall, the positive progress in the adoption of balanced state pain policy has continued into 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.[101-109] 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; 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,[110] as seen with the 2011 White House Office of National Drug Control Policy strategy (see the *Evaluation Guide 2012* for a detailed discussion of this strategy).[106] 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 four 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.[111-114] 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 2012*.

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 2012 evaluation, arranged according to the policy in which it was found and the criterion it satisfied (contained in the *Evaluation Guide 2012*), and

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

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 2012* 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 41 states), or not?
- Does state policy directly address practitioners' concerns about being investigated (as it does in 41 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 15 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 2012*, 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.[96;115-117] 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.[118-120] The Maryland Board of Physician Quality Assurance produced a video titled "A Sense of Balance: Treating Chronic Pain,"[121] 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)).

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)

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" (p. 1).[122]

"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." (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" (p. 1).United Nations Economic and Social Council, 2010

"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" (p. 2).

"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" (pp. 5-6).

"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" (¶23). [123]

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" (p. 3).WHA, 2005

APPENDICES

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.

"…principles of quality medical practice dictate that the people...have access to appropriate and effective pain relief...physicians [should] view pain management as a part of quality medical practice for all patients with pain...All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances...controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins" (FSMB, 2004, p. 5).

"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" (FSMB, 2004, p. 6).

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." (p. 2-1)

APPENDICES

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…" (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…" (pp. 1-2)

APPENDICES

APPENDIX B: METHOD TO ASSIGN GRADES

(1) Identification of provisions:

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

(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 2012*. 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, and 2012 (relevant policies present in 2012 are contained in the *Evaluation Guide 2012*); so, in this report, states' grades for 2006, 2007, 2008, and 2012 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 – 2012

States	(+) 2012	(-) 2012
Alabama	B	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	B
Illinois	D	B
Indiana	C	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	C	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	C	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

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

Medical Board Policies based on the *Model Policy*	***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 B:*** Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management
Medical Board Policies based on the *Model Guidelines*	***Category A:*** Identifies the potential impact of important barriers on the provision of effective pain care ***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 B:*** Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management
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 2012 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	41
5. Practitioners' concerns about regulatory scrutiny are addressed	41
6. Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing	39
7. Physical dependence or analgesic tolerance are *not* confused with "addiction"	42
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	49
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"	15
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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