2008

ACHIEVING BALANCE in State Pain Policy

A Progress Report Card (Fourth Edition)

Pain & Policy Studies Group

University of Wisconsin School of Medicine and Public Health

Paul P. Carbone Comprehensive Cancer Center

www.painpolicy.wisc.edu

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State policies aimed at preventing drug abuse, regulating professional practice, and improving patient care can either enhance or interfere with pain management. Five evaluations over an eight-year period by the University of Wisconsin Pain & Policy Studies Group (PPSG) show continuous improvement in state policies governing the medical use of opioid medications. This *Progress Report Card* (*Progress Report Card 2008*) 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 (Fifth edition)*) (*Evaluation Guide 2008*), the *Progress Report Card 2008* 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 2008* 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.

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The Pain & Policy Studies Group

The mission of the Pain & Policy Studies Group is to achieve more balanced international, national, and state policies so that patients' access to pain medications is not compromised by efforts to prevent diversion and drug abuse.

The following recent contributions of the PPSG are described in publications, available at www.painpolicy.wisc.edu:

- Pain policy workshops for members of state medical boards, and research demonstrating improvements in knowledge and attitudes about pain management and public policy.
- Research showing that state policies improved when boards use a model pain policy.
- Content evaluation of federal and state policy.
- Evaluation of policies influencing the use of controlled substances for treatment of pain in persons with a history of substance abuse.
- Status of state prescription monitoring programs.
- Efforts of state medical boards to improve and communicate pain policies to physicians.
- Commentary on the relation between abuse of prescription pain medications and illegal activity not involving the practitioner-patient relationship.
- Commentary on the relation between pain management and increasing abuse of prescription pain medications.
- Analysis of the extent that pain medications are stolen from the licit drug distribution system.
- A reassessment of trends in medical use and abuse of opioid pain medications.

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EXECUTIVE SUMMARY

In the United States, healthcare professionals, regulatory agencies, and policymakers currently are grappling with how to appropriately and effectively deal with two overlapping issues affecting public health: (1) untreated and undertreated pain, and (2) the abuse and diversion of prescription controlled substances, including opioid pain medications. Although controlled substances are recognized as indispensable medications for many painful conditions, especially when pain is severe, they also have a potential for abuse and these dual characteristics must always be considered concurrently. Importantly, a policy response to one of these issues should not have an unanticipated deleterious impact on the other.

Controlled substances and medical and pharmacy practice policies enacted to govern opioid medications and prevent abuse and diversion come into play when healthcare practitioners prescribe, dispense, or administer opioids to relieve pain. These policies should represent a government's dual obligation not only to establish a system of drug controls to prevent abuse and diversion, but also to ensure the adequate medical availability of needed medications. This is referred to as the Central Principle of Balance, which is the foundation of this research report. Balanced policies have the potential to enhance pain management while avoiding the potential to interfere with such treatment. 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.

Over the last decade, states have made considerable progress in achieving and maintaining more balanced policy. Healthcare regulatory boards in many states have used templates to create policies designed to directly reassure licensees that the mere act of prescribing or dispensing opioids for a legitimate medical purpose, such as pain management, will not result in disciplinary sanction. Such policy development seems to be a conscientious reaction on the part of healthcare licensing agencies to recognize practitioners' long-held concerns about regulatory scrutiny, which can make them reluctant to consider opioids as a viable treatment option. In addition, most if not all states have policies recognizing that pain management and the use of controlled substances is part of quality medical practice. Now more than ever before, state regulations are requiring 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. Finally, the laws establishing many recent prescription monitoring programs, which often is a state's primary diversion control mechanism, are explicitly recognizing that the program's objective is to reduce abuse and diversion while avoiding hampering medication availability and patient care; such language directly conforms to the Central Principle of Balance.

Despite the adoption in recent years of policies intended to encourage the appropriate use of controlled substances for pain management, treating pain using opioids continues to be unduly restricted by some states' laws that reflect medical opinions that were discarded decades ago. Practices that are medically inappropriate by today's standards include considering opioids as a treatment of last resort, equating drug addiction with the prolonged use of opioids to manage pain, requiring "drug holidays" for patients with chronic pain, and restricting the amount of medication that can be prescribed at one time regardless of patient need. Treatment restrictions also are based on certain patient characteristics, such as when a patient has pain but has a pre-existing addictive disease. Although treating patients with an addictive disease or a history of substance abuse calls for special clinical skills, extra monitoring, and possibly a consultation with or referral to an addiction medicine specialist, some states prohibit treating such patients with controlled substances in all circumstances, which creates treatment disparities that can adversely impact patients' health outcomes. Recently-adopted policies

have tended to avoid creating these potential barriers, but such arbitrary or outdated standards remain common in older state laws. For most states, efforts to improve policy must be directed at removing these archaic requirements and limitations from state legislation and regulations.

This report focuses on the extent that controlled substances 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 quality of its pain policy; state grades are presented for 2000, 2003, 2006, 2007, and 2008 to allow study of policy change over time.

The report concludes that state pain policies are becoming more balanced, even compared to last year. Since 2007:

- 13 states adopted new policies containing language that fulfilled at least one evaluation criterion, and in 7 of those states the policy change was sufficient to improve their grade;
- Oregon achieved an A in 2008, and joins Kansas, Michigan, Virginia, and Wisconsin as having the most balanced pain policies in the country;
- Georgia showed the largest grade improvement, increasing from a D+ to a B;
- 88% of states now have a grade above the average (a C); and
- No state's grade decreased in the last year or even since 2000.

The policy improvement that occurred between 2007 and 2008 was largely the result of: (1) state healthcare regulatory boards adopting policies encouraging 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, first reported in 2003, seems to be thriving. This improvement supports the conclusion that government agencies continue to recognize the need to remove regulatory barriers and encourage appropriate treatment of pain, and legislatures are creating laws to address drug abuse and diversion that avoid interfering with legitimate medical practice and patient care. 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 in order to maintain grade improvements.

This *Progress Report Card,* used in conjunction with *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (Fifth edition)*, provides a framework for deciding which policies should be removed, as well as example language to guide the development of new and more balanced policies. 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.

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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.

The results presented herein pertain to identified policies adopted through March 2008. 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 publication is available on the PPSG website at www.painpolicy.wisc.edu. Requests, comments, and suggestions can be directed to:

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INTRODUCTION

Unrelieved Pain Continues to Burden Americans

It is well-documented that unrelieved pain continues to be a serious public health problem for the general population in the United States.[1-8] This issue is particularly salient for children,[9-14] the elderly,[15-18] minorities,[19-25] for patients with active addiction or a history of substance abuse[26-30] or who have developmental disabilities,[31-32] as well as for those with serious diseases such as cancer,[33-40] HIV/AIDS,[9,41-45] or sickle-cell anemia.[46-48] Clinical experience has demonstrated that adequate pain management leads to enhanced functioning and quality of life, while uncontrolled chronic pain contributes to disability and despair.

Pain can be Relieved

There are many effective drug and non-drug approaches to manage pain, which vary according to the individual needs of the patient. However, there is a recognition that controlled substances, including opioid analgesics (sometimes called by the archaic legal name, "narcotic"), are necessary to maintain public health,[49] and that they are a mainstay of pain treatment for cancer and HIV/AIDS, particularly if pain is severe.[33,40,50-54] Although their use for the relief of a variety of chronic non-cancer pain conditions remains controversial,[55] they also can be clinically beneficial.[56-57]

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. A gap exists between what is known about pain management and what is done by healthcare professionals and institutions. Whether a particular patient can obtain adequate pain relief depends on many factors in the healthcare and drug regulatory system; these factors, such as professional and institutional practices, can be influenced either positively or negatively by 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 pain management and consider it and the 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 incorrect scientific knowledge, or establish unnecessary or unduly strict prescribing requirements.

Influence of Drug Abuse Control Policy

Opioid medications also have a potential for abuse. 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.[58-59] Such policies are intended only 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 medical practices and create undue burdens for practitioners and patients.[60-62]

State policies that do not conform to or conflict with current standards of professional practice can interfere with pain management by:

- Unduly restricting the amounts that can be prescribed and dispensed,
- Unduly restricting the period for which prescriptions are valid,
- Denying access to patients with pain who also have a history of substance abuse,
- Requiring special government-issued prescription forms only for the medications that are capable of relieving pain that is severe,
- Requiring opioids to be a treatment of last resort, and
- Using outdated definitions that confuse physical dependence with addiction.

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

- Controlled substances are necessary for the public health (as does federal law).[49]
- Pain management is an integral part of the practice of medicine (as does the Federation of State Medical Board's *Modern Medical Practice Act*).[63]
- 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*).[64-67]
- 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*).[64-67]
- 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*).[64-67]

The Imperative to Evaluate Pain Policy

Many international and national authorities, including the World Health Organization (WHO), the International Narcotics Control Board (INCB), 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).[68]

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.[53,69]

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).[58]

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*" (pp. 198, 267).[2]

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).[71]

In 2001, the ACS stated that "…additional and sustained efforts are needed to ensure that new barriers are not erected and that adequate pain relief for cancer patients is assured" (p. 3).[72] The NIH has concluded that "Regulatory barriers need to be revised to maximize convenience, benefit, and compliance…" (p. 15).[4]

WHY A PROGRESS REPORT CARD?

This Progress Report Card (Progress Report Card 2008), funded by grants from the American Cancer Society and Susan G. Komen for the Cure, and through a cooperative agreement with the Lance Armstrong Foundation, is the latest in a sequence of reports[73-75] 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 policymakers, healthcare professionals, and advocates, to understand the policies in their state that reinforce the right to pain management and that can hinder patient access to effective treatment. Ultimately, policy improvement efforts guided by the *Progress Report Card 2008* will achieve more positive and consistent state policy governing the medical use of controlled substances for pain management (both 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 acting in the usual 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 treatment 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 (IPTA), 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. Although 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. Evaluation of relevant federal policies is available in the *Evaluation Guide 2008,* at www.painpolicy.wisc.edu.

WHY A PROGRESS REPORT CARD?

Based on findings from five separate PPSG evaluations of state pain policies,[76-80] each state has been assigned a grade for 2000, 2003, 2006, 2007, and 2008. To measure progress, the PPSG compared states' grades from 2008 with their grades from 2000, 2003, 2006, and 2007.

The *Progress Report Card 2008* 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 guidelines that PPSG evaluated in each state; these are in the *Evaluation Guide 2008*, which is the companion document to the *Progress Report Card 2008*. 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 right to pain management and 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.htm.

Method to Evaluate Pain Policies

The *Evaluation Guide 2008* describes methods that PPSG has developed with peer review to evaluate pain policies using a central principle, criteria, and procedures to collect policies and identify relevant policy provisions.[80]

The Central Principle of Balance

The Central Principle of Balance, which is defined in Table 2, guides this evaluation of pain policies influencing pain management. The main idea is that drug control and professional practice policies and their implementation should be balanced so that efforts to prevent diversion and abuse do not interfere in the medical use of opioid analgesics for patient care.

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 medical 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 (Fifth edition)*. University of Wisconsin Paul P. Carbone Comprehensive Cancer Center; Madison, WI; 2008.)

[b] The adequacy of *controls* to prevent diversion and abuse of controlled substances is also a valid topic for the evaluation of policy. The purpose of this document is to evaluate policies affecting drug availability, medical practice, and pain management, rather than drug abuse prevention and control.

Appendix A documents the sources of legal and medical 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 positive and negative provisions in all state[c] statutes, regulations, and official healthcare regulatory guidelines and policy statements (see Table 3 for a list of the individual criteria).

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 opioid availability and pain management*. Appendix B contains a complete explanation of the grading methodology.

Table 3: Criteria Used to Evaluate State Pain Policies

Positive provisions: Criteria that identify policy language with the potential to enhance pain management

1. Controlled substances are recognized as necessary for the public health
2. Pain management is recognized as part of general medical 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 the 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 provisions: Criteria that identify policy language with the potential to impede pain management

9. Opioids are considered 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
    - 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 additional 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

[c] The District of Columbia is treated as a state.

WHY A PROGRESS REPORT CARD?

Two capsules are provided to elucidate the relevance of selected evaluation criteria, showing how policy relates to healthcare practice and patient care.

Capsule 1: Concern about Regulatory Investigation for Prescribing Opioids
Evaluation Criterion #5

Patients

"With everything that is out there with these medicines, aren't you and your license in danger for prescribing this kind of medicine?" (Statement from patient in a large university chronic pain program.)

Physicians

Some physicians report that concern about being investigated by regulatory and licensing agencies when prescribing opioid medications for patients, including those with cancer pain or chronic non-cancer pain, leads them to prescribe lower doses or quantities of pain medication and to authorize fewer refills.[81-82]

Regulators

Some members of state medical boards that license and investigate physicians state believe that prescribing opioids to patients with chronic non-cancer pain *should* be discouraged or investigated.[65,83]

State Pain Policies

In the last decade, 40 state legislatures and medical boards have adopted policies that recognize and address physicians' concerns about being investigated for prescribing opioid pain medications.

Conclusion

Despite a growing effort by policymakers and regulators, the concern about regulatory scrutiny remains a significant impediment to pain relief and will take years of further policy development, communication, and education to overcome.

Capsule 2: Confusion about Addiction-Related Terms
Evaluation Criteria #7 & #11

Patients

"…I was openly accused of being an 'addict' and of falsely reporting chronic pain just to obtain prescription drugs."[84] Some cancer patients refuse pain treatment for fear of becoming addicted.[8,85-86]

Physicians and Pharmacists

Some physicians express concern that addiction or drug abuse will develop when prescribing to patients with cancer or chronic non-cancer pain.[82,87] Some pharmacists lack knowledge of the crucial distinction between addiction, physical dependence, and tolerance.[88-89]

Regulators

Some state medical regulators do not understand the meaning of "addiction," but educational efforts have led to improvements in their knowledge of this concept.[65,83]

State Pain Policies

In the last decade, 37 state healthcare regulatory boards have adopted policies that correctly define addiction-related terms. Despite this progress, 16 states still have inaccurate definitions that would allow pain management to be confused with addiction.[80]

Conclusion

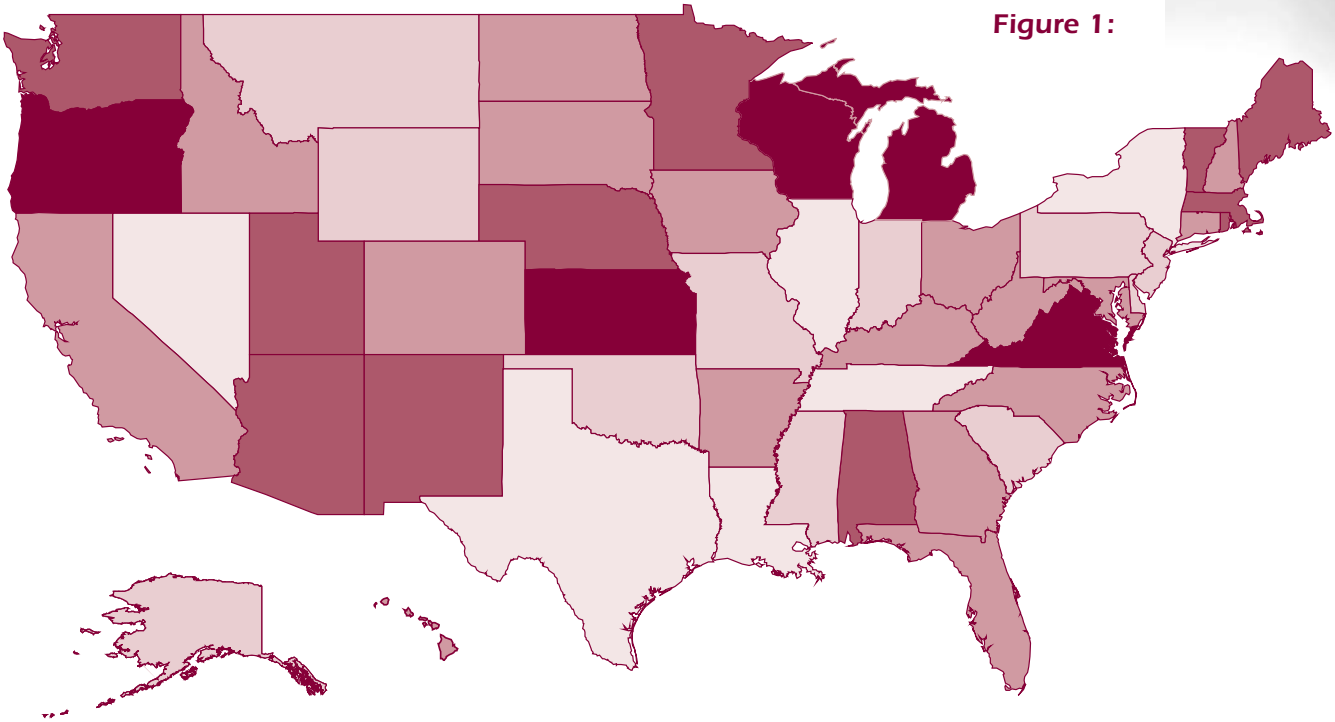
Confusion about addiction leads to overestimation of its prevalence and is a significant impediment to pain relief. Recently-adopted state policies and improved knowledge of regulators are steps in the right direction; however, a much greater systematic effort will be needed to clarify policy and educate policy makers, healthcare practitioners and patients so that concerns about addiction are based on an accurate understanding of this disease and do not interfere with pain management.

Readers are referred to the *Evaluation Guide 2008*, 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.

MAKING THE GRADE: HOW DO THE STATES RATE?

State Grades for 2008 : States' grades for 2008 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 opioid availability and pain management (see Appendix B for a complete description of the grading methodology).

Figure 1:



A	B+	B	C+	C	D+	D	F
5 states 10% of US pop.	11 states 13% of US pop.	17 states 38% of US pop.	12 states 16% of US pop.	6 states 23% of US pop.	None	None	None
Kansas Michigan Oregon Virginia Wisconsin	Alabama Arizona Maine Massachusetts Minnesota Nebraska New Mexico Rhode Island Utah Vermont Washington	Arkansas California Colorado Connecticut Florida Georgia Hawaii Idaho Iowa Kentucky Maryland New Hampshire North Carolina North Dakota Ohio South Dakota West Virginia	Alaska Delaware Dist. of Columbia Indiana Mississippi Missouri Montana New Jersey Oklahoma Pennsylvania South Carolina Wyoming	Illinois Louisiana Nevada New York Tennessee Texas			

Table 4: State Grades for 2008

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

Highlights of the 2008 Grades

- 12% of states received an average grade of C, while 88% scored above a C and no states fell below the average (D+, D, or F).
- Oregon received an A, joining Kansas, Michigan, Virginia, and Wisconsin.
- Georgia showed the largest grade improvement, increasing from a D+ to a B.
- Four distinct regional patterns emerged: New England states (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont), states in the northern Midwest (Iowa, Minnesota, Nebraska, North Dakota, South Dakota and Wisconsin), and the Northwestern states of Idaho, Oregon, and Washington, all received a grade of B or above, while the middle Northeastern states of Delaware, New Jersey, New York, and Pennsylvania received a grade of either C or C+.
- The five states achieving an A comprise 10% of the total U.S. population. States with a B or B+ make up around 50% of the U.S. population, largely owing to the influence of there being 28 states in these grade categories (three of the states being California, Florida, and Ohio, which are the 1st, 4th, and 7th most populated states, respectively). Another 39% of the U.S. population live in the 18 states that have a grade of C or C+, primarily owing to the populations of Illinois, New Jersey, New York, Pennsylvania, and Texas.

Did Grades Change from 2000 to 2008?

To evaluate changes that occurred over the last eight years, 2008 grades were compared with the 2000, 2003, 2006, and 2007 grades (see Table 5).

Table 5: State Grades for 2000, 2003, 2006, 2007, and 2008

STATES	2000 GRADES	2003 GRADES	2006 GRADES	2007 GRADES	2008 GRADES	STATES	2000 GRADES	2003 GRADES	2006 GRADES	2007 GRADES	2007 GRADES
AL	B	B	B+	B+	B+	MT	C+	C+	C+	C+	C+
AK	C	C+	C+	C+	C+	NE	B+	B+	B+	B+	B+
AZ	B	B	B	B+	B+	NV	D+	C	C	C	C
AR	C+	C+	B	B	B	NH	C	C+	C+	B	B
CA	C	C	C	B	B	NJ	D+	C	C+	C+	C+
CO	C	C	C+	B	B	NM	B	B+	B+	B+	B+
CT	C	C	C+	B	B	NY	D	C	C	C	C
DE	C+	C+	C+	C+	C+	NC	B	B	B	B	B
DC	D+	D+	C+	C+	C+	ND	C	C	B	B	B
FL	B	B	B	B	B	OH	B	B	B	B	B
GA	D+	D+	D+	D+	B	OK	C+	C+	C+	C+	C+
HI	C	C	B	B	B	OR	C+	C+	B+	B+	A
ID	C	C+	B	B	B	PA	C+	C+	C+	C+	C+
IL	C	C	C	C	C	RI	D+	D+	B	B	B+
IN	C	C+	C+	C+	C+	SC	C+	C+	C+	C+	C+
IA	C+	B	B	B	B	SD	B	B	B	B	B
KS	C+	B+	B+	A	A	TN	D	C	C	C	C
KY	D+	C+	B	B	B	TX	C	C	C	C	C
LA	C	C	C	C	C	UT	C+	C+	B	B	B+
ME	B	B	B	B	B+	VT	C	C+	B+	B+	B+
MD	C+	B	B	B	B	VA	B	B	A	A	A
MA	C	B	B	B+	B+	WA	B	B	B	B	B+
MI	B	A	A	A	A	WV	C+	B	B	B	B
MN	C+	C+	B	B	B+	WI	C	C+	B	A	A
MS	C	C	C+	C+	C+	WY	C	C	C+	C+	C+
MO	D+	C+	C+	C+	C+						

- Almost half (49%) of states received above a C in 2000, increasing to 67% in 2003, 84% in 2006, 86% in 2007, and 88% in 2008.
- Oregon received an A in 2008.
- No state's grade decreased from 2000 to 2008.

How Did Grades Change Between 2007 and 2008?

- 13 of 51 states (26%) changed their policies in a way that fulfilled at least one evaluation criterion; the policy changes were sufficient in 7 of these states to produce a positive grade change.
- Of the 7 states that improved, Georgia had the largest grade improvement, moving from a D+ to a B, due to adopting Criterion #3 in the pharmacy board regulations and because its medical board replaced its original pain policy (adopted in 1991) with a pain management guideline that repealed three existing restrictive or ambiguous provisions (Criterion #9, Criterion #11, and Criterion #12: Category D) and fulfilled the following seven positive criteria: Criterion #2, Criterion #3, Criterion #4, Criterion #5, Criterion #6, Criterion #7, two instances of Criterion #8 (Category A), and Criterion #8 (Category B) (see Table 3 for a description of the criteria).
- 44 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 March 2007 and March 2008

Positive Change –7 states	No Change – 44 states	
Georgia	Alabama	Montana
Maine	Alaska	Nebraska
Minnesota	Arizona	Nevada
Oregon	Arkansas	New Hampshire
Rhode Island	California	New Jersey
Utah	Colorado	New Mexico
Washington	Connecticut	New York
	Delaware	North Carolina
	District of Columbia	North Dakota
	Florida	Ohio
	Hawaii	Oklahoma
	Idaho	Pennsylvania
	Illinois	South Carolina
	Indiana	South Dakota
	Iowa	Tennessee
	Kansas	Texas
	Kentucky	Vermont
	Louisiana	Virginia
	Maryland	West Virginia
	Massachusetts	Wisconsin
	Michigan	Wyoming
	Mississippi	
	Missouri	

Interesting New Policies

Although often not contributing to the positive grade changes observed between 2007 and 2008, the following policies are of interest:

- 2 states (Minnesota and North Carolina) adopted balanced legislation that established a prescription monitoring program to reduce prescription opioid abuse and diversion. Recent prescription 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.
- 2 states (Alaska and Rhode Island) adopted regulations establishing pain management standards for hospice facilities.
- Michigan adopted legislation mandating continuing education about pain management for pharmacists.
- Utah adopted legislation creating a harm reduction program for prescription opioids, which includes, among other things, a requirement to educate practitioners, patients, insurers, and the public about the appropriate and effective management of chronic pain and the obligation to measure the program's effectiveness; this legislation resulted in the grade improvement for Utah.
- Texas adopted legislation to develop a pain treatment review committee to specifically address how the state's laws can affect pain management and the quality of life for patients with chronic or end-of-life pain.

Improvements in Pain Management Policy

State grades for balanced policy continued to improve notably from 2007 to 2008. As in the previous *Progress Report Card (Progress Report Card 2007)*, the driving force for positive policy change was state healthcare regulatory boards that adopted several types of policies encouraging pain management; however, such policy adoption contributed to grade improvement in only three states. Positive policy change also occurred because of the repeal of restrictive or ambiguous language from statute or regulation.

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)*.[90] 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)*.[64] The revision is substantially similar to the 1998 guidelines, but additionally recommends that state boards consider failure to treat pain as subject to professional discipline. Many state medical regulatory boards have participated in pain management workshops sponsored by the Federation and the PPSG and subsequently adopted the *Model Guidelines* or *Model Policy* to encourage better pain management and to address physicians' concerns about investigation.[61,83,91] The trend of state medical boards adopting policies on pain management has resulted in positive changes in state pain policies[67] and also in efforts to communicate them to practitioners and the public.[92-93]

As of March 2008, a total of 32 states had adopted either the *Model Guidelines* or *Model Policy* in whole or in part.[d] In the last year, four states (Georgia, Minnesota, Missouri, and New York) adopted medical board regulatory policies based on the Federation's model policy templates. The *Model Policy* does not have any negative provisions; states that adopt it fully receive the greatest number of positive provisions (9) from a single policy: Criteria #2, #3, #4, #5, #6, #7, (see Table 3 for a description of the criteria), as well as three provisions that satisfy Criterion #8 (see Appendix D for a description of Criterion #8 categories).

[d] These states are Alabama, Arizona, Colorado, Connecticut, Florida, Georgia, Hawaii, Idaho, Kansas, Kentucky, Maine, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New York, North Carolina, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

Osteopathic Board Policies

The Washington osteopathic board adopted a policy relating to pain management, which fulfilled the following criteria: Criteria #2, #4, #5 (see Table 3 for a description of the criteria) and Criterion #8: Category C (see Appendix D for a description of Criteria #8 categories).

REPEAL OF RESTRICTIVE OR AMBIGUOUS LAWS

Positive policy change also occurred when states repealed negative provisions from statutes or regulations.

Definitions of Intractable Pain

Oregon 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). Fourteen states continue to define "intractable pain" (or "chronic pain") in a way that can convey the ambiguous practice messages described above.[e]

Ambiguities in Intractable Pain Policy

Rhode Island also repealed a legislative provision that seemed to be inconsistent with another provision in the same policy, and created ambiguity about whether a practitioner was permitted to use opioids to treat pain in a person with a history of substance abuse. This policy language fulfilled Criterion #16 (Category C). Missouri is the only state that continues to have such an ambiguity in an Intractable Pain Treatment Act.

Repeal of Restrictive Prescription Validity Periods

Texas repealed from its Controlled Substances Act the overly-restrictive prescription validity period of 7-days (fulfilling Criterion #14). This change completely eliminates in Texas 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. Four states have retained a validity period of less than two weeks.[f]

No Negative Policy Changes

No state added restrictive or ambiguous policy language between 2007 and 2008. Although the frequency of adopting negative provisions has reduced notably in recent years, this is the first time that the policy evaluation identified no new restrictive or ambiguous provisions.

[e] These states are Arkansas, Colorado, Florida, Louisiana, Minnesota, Mississippi, Missouri, Nevada, New Jersey, Ohio, Tennessee, Texas, Washington and West Virginia.

[f] These states are Delaware, Hawaii, Illinois, and Vermont.

CURRENT STATUS OF BALANCE IN STATE PAIN POLICY

Oregon now joins Kansas, Michigan, Virginia, and Wisconsin as having the most balanced pain policies in the country. In the last eight years, these five states took advantage of the Federation's *Model Guidelines* or *Model Policy*, and repealed all excessively restrictive and ambiguous policy. This achievement does not mean the work is finished, because policy needs to be implemented (see next section). 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.

Since 2007, legislatures and healthcare regulatory agencies in 7 states modified their relevant policies sufficiently to improve their grade for Balance. Three of these states (Georgia, Maine, and Washington) only evidenced a grade change in the last year, while the other four states had more than one grade improvement over the four assessment periods; these changes demonstrate continuing efforts to enhance pain policies that can affect professional practice and patient care. Georgia demonstrated the largest grade improvement in the last year (from a D+ to a B) and had undergone its first grade change since 2000. This grade change was accomplished by replacing the oldest existing medical board guideline (adopted in 1991 and containing three restrictive provisions) with a policy based on the Federation's Model Policy (which contains no restrictive provisions). There have been no states since 2000 where 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.

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, Maine, 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 policies. Nine other states (Arizona, Massachusetts, Minnesota, Nebraska, New Mexico, Rhode Island, Utah, Vermont, and Washington) would have received an A in 2008 had one or two restrictive or ambiguous provisions been repealed, which is up from six states being in this position in 2007.

Special challenges

In 2008, 88% of the states achieved a grade above a C; this is a substantial improvement since 2003, when two-third of states had a grade exceeding the average. Such progress is significant, but for states to achieve more balanced and consistent pain policy, they face the challenge of removing many long-outdated negative provisions from state statutes, some of which have been present for 30 years or more. Negative provisions are not a necessary part of the laws needed for drug control or the regulation of professional practice. 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 patient care decisions requiring medical expertise are not unduly restricted by governmental regulation aimed instead at preventing drug abuse.

For example, in the last eight years there was a 27% reduction in negative provisions from the nearly 200 that were present in 2000, compared to a 75% increase in positive provisions during the same period; this raises a question as to whether repeal of negative provisions from law has been receiving less attention compared to efforts with professional licensing boards to adopt positive policy. Twenty-three states (45%) can achieve a positive grade change *only* by repealing restrictive or ambiguous policy language.[g] Appendix E shows the number of states with statutes, regulations, or guidelines or policy statements that contain language meeting criteria for both positive and negative provisions. The presence of any of these provisions in a specific state can be determined by consulting the *Evaluation Guide 2008*.

One of the most frequent negative provisions remaining in state policy is terminology that confuses physical dependence with addiction. Although 37 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 14 states and the healthcare regulations of two states continue to classify physical dependence as synonymous with addiction. Consequently, 12 states have conflicting standards about what constitutes addiction, which are present in different policies and can create confusion for practitioners.[h] 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 chronic opioid therapy. When such an archaic 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 almost 40 years ago. Special attention should be given to repealing this prevalent state statutory or regulatory definition that no longer conforms to the current medical and scientific understanding of addiction.

A particular challenge continues to be in those states that have a considerable number of positive provisions but also have many negative provisions.[i] In the last four years, New York and Texas repealed restrictive legislative or regulatory language, but such changes have not improved their grade because of the large 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, Delaware, Illinois, and Indiana) in which neither the medical nor pharmacy boards have issued policies addressing the use of controlled substances for treating pain. Of these states, Delaware and Illinois have had no grade improvements in the last eight years.

Finally, 19 states (37%) now face the challenge not only of adopting positive policies, but of removing restrictive language from legislation or regulations, to achieve a grade of A.[j] Even for states that have achieved an A, there remains the potential for additional policy activity (however well-intentioned) to introduce potentially restrictive requirements or limitations. Continued efforts to enhance pain management through state policy must avoid unintended restrictions or ambiguities in order to maintain grade improvements.

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[g] These states are Arizona, Arkansas, California, Colorado, Florida, Hawaii, Massachusetts, Minnesota, Missouri, Nebraska, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Rhode Island, Tennessee, Texas, Utah, Vermont, Washington, and West Virginia.

[h] These states are Arizona, Colorado, Hawaii, Idaho, Louisiana, Maryland, Missouri, Nevada, North Carolina, Oklahoma, Pennsylvania, and Tennessee.

[i] These states are New York, Tennessee, and Texas.

[j] These states are Connecticut, Delaware, District of Columbia, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maryland, Mississippi, Montana, Nevada, New Hampshire, Pennsylvania, South Carolina, South Dakota, and Wyoming.

CONCLUSION

Overall, the momentum for positive change in state pain policy continues into 2008, apparently in response to increasing national recognition that improving or removing provisions that can influence professional practice and patient care is an important step in improving pain management for patients with cancer, HIV/AIDS, and other diseases. Importantly, for the first time, no state adopted relevant policies in the last year that contained any restrictive or ambiguous provisions. The use of policy evaluation resources and model policies by state groups to guide positive policy change efforts is apparent.

This trend has occurred during a period of increase in the abuse and diversion of opioid pain medications.[94-96] It is important to understand that the policy improvement represented in this report does not undermine the basic prohibitions against drug trafficking and diversion of controlled substances or healthcare regulatory policies; states that improve their grades do not weaken their ability to prevent drug abuse and diversion or deal with unprofessional conduct. In the future, there must be continued efforts by governments and healthcare professionals to address drug abuse while not interfering with legitimate medical 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.[97] A more balanced national policy can be achieved and maintained if policymakers and advocates work together, use the Central Principle as a guide, and take advantage of the policy resources that are available. The PPSG contribution to this process is policy research, model development, and technical assistance to government agencies and groups working to improve Balance in pain policy.

RECOMMENDATIONS FOR IMPROVING STATE GRADES

1. Establish a policy evaluation mechanism

The extent to which a state's policies are balanced or unbalanced can either contribute to or detract from a positive professional practice and drug regulatory environment for pain management. 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.[98-100] The terms of reference for such a body should include evaluation of the state's pain policies, the membership should include governmental and non-governmental stakeholders, and dedicated staffing should be available. The guidance available from 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 2008*.

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 (www.painpolicy.wisc.edu/matrix.htm), (b) a State Profile that identifies each specific provision found during the PPSG 2008 evaluation, arranged according to the policy in which it was found and the criterion it satisfied (contained in the *Evaluation Guide 2008*), and (c) this *Progress Report Card 2008*, which shows the distribution and details about the grades for each state for 2000, 2003, 2006, 2007, and 2008.

The task force might be interested in learning, for example, how its grade compares to other states, in particular contiguous states. The task force might also be interested in which positive or negative criteria are fulfilled by the state's current policy (from the *Evaluation Guide 2008* State Profiles section) and how this compares with the policies from other states. Appendix E shows the total number of states with policies that fulfill each evaluation criterion. Such comparisons could answer such questions as:

- Does my state policy specifically encourage pain management (as it does in 39 states), or not?
- Does my state policy directly address practitioners' concerns about being investigated (as it does in 40 states), or not?
- Does my state policy define addiction so that it could be confused with physical dependence that may develop when using opioids to treat pain (as it does in 16 states), or not.
- Does my state policy contain provisions that create unclear standards or requirements for practitioners when treating a patient with pain (as it does in 15 states), or not?

After a state's pain policies have been studied, corrective proposals can be developed. The main resource to assist with this process is the *Evaluation Guide 2008*, which contains a section entitled "Example Language to Improve Pain-Related Policy," and is available on the internet at www.painpolicy.wisc.edu. This section includes recommended language from the Federation's *Model Policy* and other models, as well as example language from other states.

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.[87,89,101] 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. Balanced policy must be understood and respected as such.

The goal is to promote understanding that the state's policy is to encourage pain management, 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 have excelled in their efforts to communicate pain management policy to licensed physicians.[102-104] The Maryland Board of Physician Quality Assurance has produced a videotape titled "A Sense of Balance: Treating Chronic Pain,"[105] which is required viewing for new licensees. Some states, such as Michigan, Oregon, Texas, and Wyoming have adopted laws that require healthcare regulatory agencies to periodically educate their licenses about pain management issues. Several state medical licensing boards, including those in California, Minnesota, New York, Ohio, and Rhode Island, have sections on their websites that provide information to licensees about the use of controlled substances for pain management.

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" (UN, 1977, p. 13).

"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" (UN, 1977, pp. 18-19).

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).

"These [Evaluation] Guidelines can be used by governments to determine whether their national drug control policies have established the legal and administrative framework to ensure the medical availability of opioid analgesics, according to international treaties and the recommendations of the INCB and the WHO… [and] to encourage governments to achieve better pain management by identifying and overcoming regulatory barriers to opioid availability" (WHO, 2000, pp. 1-2).

"…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 Narcotics 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).

United Nations Economic and Social Council

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

World Health Assembly

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

References

(1) United Nations. *Single Convention on Narcotic Drugs, 1961, As Amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961*. New York, NY: United Nations; 1977. (Available at http://www.incb.org/e/ind_conv.htm).

(2) World Health Organization. *The Use of Essential Drugs: Eighth Report of the WHO Expert Committee (Technical Report Series 882)*. Geneva, Switzerland: World Health Organization; 1998.

(3) World Health Organization. *Cancer Pain Relief: With a Guide to Opioid Availability*. Second ed. Geneva, Switzerland: World Health Organization; 1996. (Available at http://whqlibdoc.who.int/publications/9241544821.pdf).

(4) World Health Organization. *Achieving Balance in National Opioids Control Policy: Guidelines for Assessment*. Geneva, Switzerland: World Health Organization; 2000. (Available at http://www.painpolicy.wisc.edu/publicat/00whoabi/00whoabi.htm).

(5) World Health Organization Executive Board. Cancer control: Report by the Secretariat. 114th Session. EB114/3. Geneva, Switzerland: World Health Organization, 2004.

(6) World Health Organization. WHO Expert Committee on Drug Dependence (Thirty-fourth Report). Geneva, Switzerland: World Health Organization, 2006.

(7) United Nations Economic and Social Council. *Treatment of Pain Using Opioid Analgesics; Resolution 2005-25*. Report on the forty-eighth session of the Commission on Narcotic Drugs E/2005/28; 19 March 2004 and 7-11 March 2005; issued 22 July 2005. (Available at http://www.un.org/docs/ecosoc/documents/2005/resolutions/Resolution%202005-25.pdf.)

(8) World Health Assembly. *Cancer Prevention and Control*. WHA 58.22. Geneva, Switzerland: World Health Organization; 2005. (Available at http://www.who.int/gb/ebwha/pdf_files/WHA58-REC1/english/A58_2005_REC1-en.pdf.)

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).

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).

References

(1) Controlled Substances Act. Pub L No. 91-513, 84 Stat 1242, 1970.

(2) Drug Enforcement Administration, Last Acts, Pain & Policy Studies Group, et al. *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act*. Washington, DC: Last Acts; 2001. (Available at http://www.painpolicy.wisc.edu/dea01.htm).

(3) Federation of State Medical Boards of the United States Inc. *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Dallas, TX: Federation of State Medical Boards of the United States Inc; 2004. (Available at http://www.fsmb.org).

(4) National Association of Attorneys General. *Resolution Calling for a Balanced Approach to Promoting Pain Relief and Preventing Abuse of Pain Medications*. Adopted at the National Association of Attorneys General Spring Meeting; Washington, DC; March 17-20, 2003.

(5) National Association of Attorneys General. *Improving End-of-Life Care: The Role of Attorneys General*. Washington, DC: National Association of Attorneys General, 2003.

Appendix B: Method to Assign Grades

(1) ***Identification of provisions:***
The positive and negative provisions in state pain policies from 2000, 2003, 2006, and 2007 had already been identified in the *Evaluation Guide 2007*. The criteria were then used to identify positive and negative provisions in policies current through March 2008.

(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 2008*. Each provision was given equal weight.

In 2000, the total number of positive provisions for all states ranged from 0 to 33; the average number of positive provisions per state was 10 and the standard deviation (the extent that the values deviate from the average) was 6. Despite the large range of total positive provisions, 44 states had 14 or 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 a total of 5 to 10 positive provisions. Negative provisions ranged from 0 to 16, with an average of 4 and a standard deviation of 3. The averages and standard deviations were used to calculate the grades. The same grading system was then applied to the total number of positive and negative provisions contained in all states' policies present in 2003, 2006, 2007, and 2008 (relevant policies present in 2008 are contained in the *Evaluation Guide 2008*); so, states' grades in 2000, 2003, 2006, 2007, and 2008 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–2000, 2003, 2006, 2007, & 2008

STATES	(+) 2000	(+) 2003	(+) 2006	(+) 2007	(+) 2008	(-) 2000	(-) 2003	(-) 2006	(-) 2007	(-) 2008
AL	C	C	B	B	B	A	A	A	A	A
AK	D	D	D	D	D	B	A	A	A	A
AZ	B	A	A	A	A	B	C	C	B	B
AR	C	C	A	A	A	B	B	C	C	C
CA	A	A	A	A	A	F	F	F	C	C
CO	B	B	B	A	A	D	D	C	C	C
CT	D	D	C	B	B	B	B	B	B	B
DE	C	C	C	C	C	B	B	B	B	B
DC	F	F	C	C	C	B	B	B	B	B
FL	A	A	A	A	A	C	C	C	C	C
GA	D	D	D	D	B	C	C	C	C	B
HI	D	D	A	A	A	B	B	C	C	C
ID	C	C	B	B	B	C	B	B	B	B
IL	D	D	D	D	D	B	B	B	B	B
IN	C	C	C	C	C	C	B	B	B	B
IA	C	B	B	B	B	B	B	B	B	B
KS	C	A	A	A	A	B	B	B	A	A
KY	D	B	B	B	B	C	C	B	B	B
LA	C	C	C	C	C	C	C	C	C	C
ME	C	C	C	C	B	A	A	A	A	A
MD	C	B	B	B	B	B	B	B	B	B
MA	C	B	B	A	A	C	B	B	B	B
MI	A	A	A	A	A	C	A	A	A	A
MN	C	C	B	B	A	B	B	B	B	B
MS	C	C	B	B	B	C	C	C	C	C
MO	C	A	A	A	A	D	D	D	D	D
MT	C	B	B	B	B	B	C	C	C	C
NE	A	A	A	A	A	B	B	B	B	B
NV	C	B	B	B	B	D	D	D	D	D
NH	D	C	C	B	B	B	B	B	B	B
NJ	C	B	A	A	A	D	D	D	D	D
NM	B	A	A	A	A	B	B	B	B	B
NY	C	A	A	A	A	F	F	F	F	F
NC	B	B	A	A	A	B	B	C	C	C
ND	C	C	C	C	C	C	C	A	A	A
OH	A	A	A	A	A	C	C	C	C	C
OK	A	A	A	A	A	D	D	D	D	D
OR	B	B	A	A	A	C	C	B	B	A
PA	C	C	C	C	C	B	B	B	B	B
RI	B	B	A	A	A	F	F	C	C	B
SC	B	B	B	B	B	C	C	C	C	C
SD	B	B	B	B	B	B	B	B	B	B
TN	C	A	A	A	A	F	F	F	F	F
TX	A	A	A	A	A	F	F	F	F	F
UT	B	B	B	B	A	C	C	B	B	B
VT	C	B	A	A	A	C	C	B	B	B
VA	B	B	A	A	A	B	B	A	A	A
WA	B	B	B	B	A	B	B	B	B	B
WV	B	A	A	A	A	C	C	C	C	C
WI	D	D	C	A	A	B	A	A	A	A
WY	D	D	C	C	C	B	B	B	B	B

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

Model Policy	***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
Model Guidelines	***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
Pharmacy Board policies	***Category A:*** Identifies pseudoaddiction as an important barrier to the appropriate use of opioid analgesics ***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:*** 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:*** Recognizes 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 2008 with Policy Language Having Potential to Enhance or Impede Pain Management

Positive provisions	Number of states
1. Controlled substances are recognized as necessary for the public health	4
2. Pain management is recognized as part of general medical practice	46
3. Medical use of opioids is recognized as legitimate professional practice	51
4. Pain management is encouraged	39
5. Practitioners' concerns about regulatory scrutiny are addressed	40
6. Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing	34
7. Physical dependence or analgesic tolerance are not confused with "addiction"	37
8. Other provisions that may enhance pain management	
Category A: Issues related to healthcare professionals	48
Category B: Issues related to patients	23
Category C: Regulatory or policy issues	49
Negative provisions	**Number of states**
9. Opioids are considered a treatment of last resort	6
10. Medical use of opioids is implied to be outside legitimate professional practice	10
11. Physical dependence or analgesic tolerance are confused with "addiction"	16
12. Medical decisions are restricted	
Category A: Restrictions based on patient characteristics	8
Category B: Mandated consultation	8
Category C: Restrictions regarding quantity prescribed or dispensed	8
Category D: Undue prescription limitations	5
13. Length of prescription validity is restricted	4
14. Practitioners are subject to additional prescription requirements	6
15. Other provisions that may impede pain management	4
16. Provisions that are ambiguous	
Category A: Arbitrary standards for legitimate prescribing	15
Category B: Unclear intent leading to possible misinterpretation	20
Category C: Conflicting (or inconsistent) policies or provisions	8

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