2006

ACHIEVING BALANCE in State Pain Policy

A Progress Report Card (Second 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. Three evaluations over a six-year period by the University of Wisconsin Pain & Policy Studies Group (PPSG) show improvement in state policies governing the medical use of opioid medications. This *Progress Report Card* (*Progress Report Card 2006*) 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 (Third edition)*) (*Evaluation Guide 2006*), the *Progress Report Card 2006* 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 2006* 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 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

Pain, sometimes severe and debilitating, is associated with a variety of diseases including cancer, sickle-cell anemia, HIV/AIDS, and other chronic conditions. Adequate pain relief contributes to improved health and can restore quality of life. Unfortunately, inadequate relief of pain continues to occur all too often. People often react with disbelief or surprise that painful conditions can go unrelieved with the modern medicine available in the U.S. The devastating effects of chronic pain are tragic and expensive, and ironic in light of existing knowledge about pain management which too often does not reach those in need.

Most if not all pain can be relieved, but only if knowledgeable healthcare professionals are able to properly use the many treatments that are safe and effective. Opioid pain medications have a well-recognized role in managing pain, particularly when it is severe. But opioids also have a potential for abuse. The controlled substances and professional practice policies that have been enacted to govern these medications and prevent abuse always come into play when health professionals use opioids to relieve pain. In fact, governments are obligated not only to establish a system of drug controls to prevent abuse and diversion; they must also ensure their medical availability. This is the Central Principle of Balance, which is the foundation of this research report. Balanced policies include those with a potential to enhance pain management while avoiding the potential to interfere with such treatment.

Some states – but far from all – have adopted policies which recognize that controlled substances are necessary for public health, that pain management is part of quality medical practice, that medical education should include pain management and palliative care, and that patient care facilities have a responsibility to assess and treat pain.

But in some states, pain treatment using opioids is unduly restricted by policies reflecting medical opinions that were discarded decades ago. Practices that would be medical mistakes by today's standards include requiring opioids to be a treatment of last resort, equating the use of opioids to manage pain with drug addiction, requiring "drug holidays," and restricting the amount of medication that can be prescribed at one time regardless of patient need; yet such standards are common in today's state policies. Indeed, many states are now adopting model policies that avoid creating these potential barriers.

In addition, for decades physicians have reported being reluctant to prescribe opioids because of fear of the stress, expense, and consequences of being investigated by licensing agencies or law enforcement. These fears have profound implications for practitioners' willingness to consider these medications as a viable treatment option and can, as a result, hinder patient access to adequate pain relief. A number of states have adopted model policies that reassure licensees; in other states, policy remains silent.

The focus of this report is the extent that policies which influence pain management contain language that potentially enhances or impedes 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, and 2006, to allow study of policy change over time.

The report concludes that state pain policies are becoming more balanced:

- Michigan and Virginia have an A and are the most balanced pain policies in the country
- 82% of states now have a grade above a C
- 19 states had positive grade change since 2003
- Rhode Island showed the greatest improvement, increasing from a D+ to B
- no state's grade decreased over time

EXECUTIVE SUMMARY

The significant amount of policy improvement that occurred between 2003 and 2006 was the result of: (1) state healthcare regulatory boards adopting policies encouraging pain management, palliative care, or end-of-life care, and (2) state legislatures repealing restrictive or ambiguous policy language, including repealing multiple- or single-copy prescription programs.

The momentum for positive policy change, first reported in 2003, has endured, supporting the conclusion that government agencies continue to recognize the need to remove regulatory barriers and encourage appropriate treatment of pain. To achieve more balanced and consistent pain policy, most states face the challenge not only of adopting positive policies, but of removing restrictive language from legislation. Experience around the country is showing that a valuable state governmental mechanism to achieve balanced policy is the use of task forces, advisory councils, and summit meetings to examine state pain policy. This *Progress Report Card*, used in conjunction with *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (Third edition)*, provides a framework for deciding which policies should be removed, as well as models 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 the policy resources that are available. In this way, we can establish a more positive 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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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 policies adopted through March 2006. The material in this report does not represent legal or medical advice. Individuals interested in more current policy information, or 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, [9-12] the elderly,[13-16] minorities,[17-21] patients with active addiction or a history of substance abuse,[22-25] developmental disabilities,[26,27] as well as for those with serious diseases such as cancer[28-33] HIV/AIDS,[9,34-38] or sickle-cell anemia.[39-41] 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 general medical and regulatory consensus that opioid analgesics (sometimes called by the archaic legal name, "narcotics") are necessary to maintain public health;[42] and that they are a mainstay of pain treatment for cancer and HIV/AIDS, particularly if pain is severe.[28,33,43-47] Their use for the relief of a variety of chronic non-cancer pain conditions is also clinically beneficial.[48,49]

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 between 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 to be an expected part of healthcare practice are preferable to those policies that provide no positive guidance to professionals treating patients' pain, or which are based on incorrect scientific knowledge and that 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.[50,51] 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.[52-54]

Some 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,
- Restricting access to pain patients 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 pain management 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).[42]
- Pain management is an integral part of the practice of medicine (as does the Federation of State Medical Board's *Modern Medical Practice Act*).[55]
- Controlled substances are an essential part of legitimate professional practice (as does the Federation of State Medical Board's *Model Policy for the Use of Controlled Substances for the Treatment of Pain*).[56]
- 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*).[56]
- 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*).[56]

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.[a] 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).*[57]

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.[46]

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

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).[59] The NIH concluded that "Regulatory barriers need to be revised to maximize convenience, benefit, and compliance…" (p. 15).[4]

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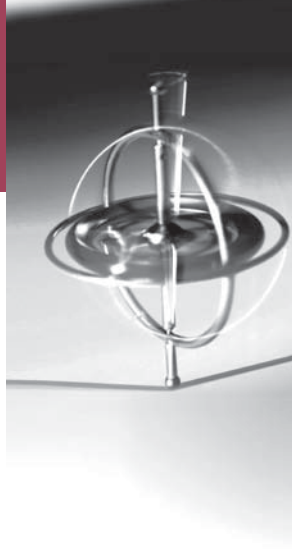
[a] The Agency for Healthcare Policy and Research is no longer included as an authoritative source because its clinical practice guidelines on acute pain (1992) and cancer pain (1994) have been withdrawn.

WHY A PROGRESS REPORT CARD?



This *Progress Report Card (Progress Report Card 2006)*, supported by grants from the American Cancer Society and the Susan G. Komen Breast Cancer Foundation, and through a cooperative agreement with the Lance Armstrong Foundation, is the latest in a sequence of reports[60] developed to evaluate state policies that affect pain management.[b] It is a tool that can be used by government and non-government organizations to achieve more positive and consistent state policy on 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 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.

[b] Federal policy was not included in this report card because such policy does not regulate professional practice. Evaluation of federal policies is available in the *Evaluation Guide 2006*, at www.painpolicy.wisc.edu.

WHY A PROGRESS REPORT CARD?

Based on findings from three separate PPSG evaluations of state pain policies,[61-63] each state has been assigned a grade for 2000, 2003 and 2006. To measure progress, the PPSG compared states' grades from 2006 with their grades from 2000 and 2003.

The *Progress Report Card 2006* is the result of policy research and is not a "position" 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.[c] We recognize that a grade may oversimplify 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 2006*, which is the companion document to the *Progress Report Card 2006*. 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 2006* describes methods that PPSG has developed with peer review to evaluate pain policies using a central principle and criteria as well as procedures to collect policies, and identify and quantify relevant policy provisions.[63] Based on feedback about previous reports, the evaluation methodology used for this report was expanded to include a broader variety of policies (e.g., those governing osteopathic practice, licensure of healthcare facilities, and education of healthcare professionals) (see the *Evaluation Guide 2006* for a complete description of the changes to the evaluation methodology).

The Central Principle of Balance

The Central Principle of *Balance*, which is defined in Table 2, guides this evaluation of pain policies. The main idea is that drug control and professional practice policies and their implementation should be balanced so 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, Third Edition*. Madison, WI: Pain & Policy Studies Group, University of Wisconsin Paul P. Carbone Comprehensive Cancer Center; 2006.)

[c] 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 statutes, regulations, and guidelines and official governmental policy statements (see Table 3 for a list of the individual criteria).[d] The state grades measure the quality of state pain policy 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.*

To assign grades, the PPSG: (1) identified the positive and negative policy provisions in each state, and (2) assigned grades based on the total number of provisions, the average, and the standard deviation. 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

[d] 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: Fear of 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.[64,65]

Regulators

Some members of state medical boards that license and investigate physicians declare that prescribing opioids to patients with chronic non-cancer pain *should* be discouraged or investigated.[66,67]

State Pain Policies

In the last decade, 39 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 fear of 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."[68] Some cancer patients refuse pain treatment for fear of becoming addicted.[69,70]

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.[65,71] Some pharmacists lack knowledge of the crucial distinction between addiction, physical dependence, and tolerance.[72,73]

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.[66,67]

State Pain Policies

In the last decade, 36 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.[63,74]

Conclusion

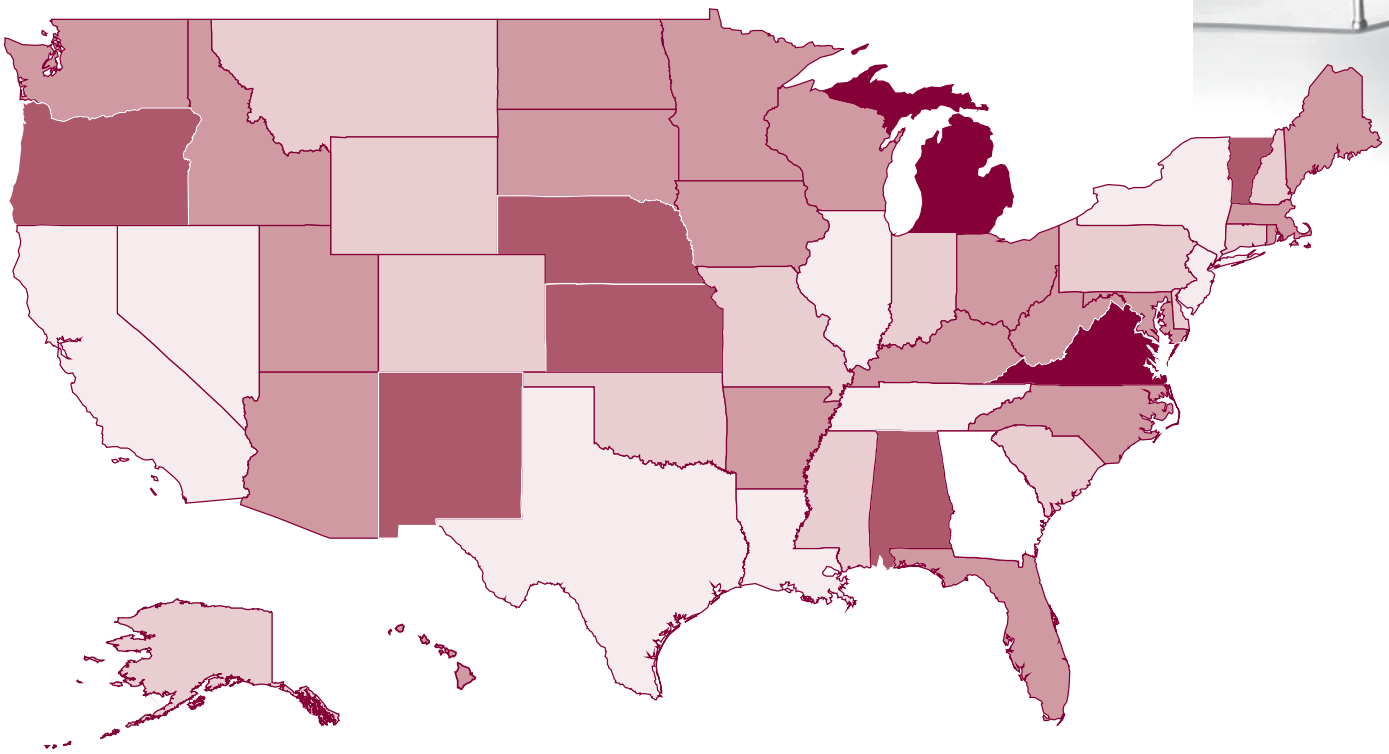
Confusion about addiction leads to overestimation of its prevalence and is a significant impediment to pain relief. Recently-adopted state policies and improved knowledge of regulators are steps in the right direction; however, a much greater systematic effort will be needed to clarify policy and educate 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 2006*, 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 were identified in each state.

MAKING THE GRADE: HOW DO THE STATES RATE?

State Grades for 2006 : States' grades for 2006 are presented in Figure 1 and Table 4.

Figure 1:



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

Table 4: State Grades for 2006

STATES	2006 GRADES	STATES	2006 GRADES
AL	B+	MT	C+
AK	C+	NE	B+
AZ	B	NV	C
AR	B	NH	C+
CA	C	NJ	C
CO	C+	NM	B+
CT	C+	NY	C
DE	C+	NC	B
DC	C+	ND	B
FL	B	OH	B
GA	D+	OK	C+
HI	B	OR	B+
ID	B	PA	C+
IL	C	RI	B
IN	C+	SC	C+
IA	B	SD	B
KS	B+	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	B
MS	C+	WY	C+
MO	C+		

Highlights of the 2006 Grades

- 16% of states received an average grade of C, while 82% scored above a C and only 2% fell below the average.
- Michigan and Virginia were the only states to receive an A; no state received a D or F.
- Only two distinct regional patterns emerged: States in the northern Midwest (Iowa, Minnesota, North Dakota, South Dakota and Wisconsin) received Bs, as did three Northwestern states (Idaho, Oregon, and Washington);
- The three states with the largest population (California, New York, and Texas), representing approximately a quarter of the U.S. population, each earned average grades of C.

Did Grades Change from 2000 to 2006?

To evaluate changes that occurred over the last six years, 2006 grades were compared with the 2000 and 2003 grades[e] (see Table 5).

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

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

- Almost half (49%) of states received above a C in 2000, increasing to 67% in 2003 and 82% in 2006.
- Michigan and Virginia received an A in 2006.
- No state's grade decreased from 2000 to 2006.

[e] 2000 and 2003 grades were re-calculated using the 2006 methodology to allow comparison and measure progress over time (see Appendix B: Method to Assign Grades); the grades in this report are in some cases not the same as those contained in the first, and now obsolete, *Progress Report Card*.

How Did Grades Change from 2003 to 2006?

- 35 of 51 states (69%) changed their policies; the policy changes were sufficient in 19 of these states to produce a positive grade change.
- Of the 19 states that improved, Rhode Island had the greatest improvement, moving from a D+ to a B. Although a positive provision was added to the state Intractable Pain Treatment Act (Criterion #3; see Table 3), the improvement was due primarily to the repeal from statute of six restrictive or ambiguous provisions: Criteria #10, #11, #13, #14, #16 (Category A), and #16 (Category B) (see Table 3 for a description of the criteria).
- 32 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 2003 and March 2006

Positive Change –19 states	No Change – 32 states
Alabama	Alaska
Arkansas	Arizona
Colorado	California
Connecticut	Delaware
District of Columbia	Florida
Hawaii	Georgia
Idaho	Illinois
Kentucky	Indiana
Minnesota	Iowa
Mississippi	Kansas
New Jersey	Louisiana
North Dakota	Maine
Oregon	Maryland
Rhode Island	Massachusetts
Utah	Michigan
Vermont	Missouri
Virginia	Montana
Wisconsin	Nebraska
Wyoming	Nevada
	New Hampshire
	New Mexico
	New York
	North Carolina
	Ohio
	Oklahoma
	Pennsylvania
	South Carolina
	South Dakota
	Tennessee
	Texas
	Washington
	West Virginia

Interesting New Policies

In 2006, we expanded our evaluation to other policies. Although those policies did not contribute greatly to the positive grade changes observed between 2003 and 2006, the following information is of interest:

- 9 states (18%) have adopted laws that either mandate or encourage healthcare practitioners to obtain continuing education about pain management issues.
- 26 states (51%) have adopted regulations establishing pain management standards for healthcare facilities, including hospitals, hospices, and nursing homes.
- In those states where the osteopathic board is separate from the medical board, 38% have adopted policies that encourage the appropriate use of controlled substances for pain management.

Reasons for the Improved Grades

State grades for balanced policy continued to improve significantly from 2003 to 2006. As in the previous *Progress Report Card* (*Progress Report Card 2003*), the driving force for positive policy change was state healthcare regulatory boards that adopted several types of policies encouraging pain management or palliative care. Less frequent sources of positive policy change were legislative adoption of pain-specific statutes and repeal of restrictive or ambiguous language.

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)*.[75] 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)*.[56] 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' fear of investigation.[53,76] The trend of state medical boards adopting policies on pain management has resulted in positive changes in state pain policies[77] and also in efforts to communicate them to practitioners and the public.[78,79]

As of March 2006, a total of 28 states had adopted either the *Model Guidelines* or *Model Policy* in whole or in part.[f] Twelve states (Colorado, Connecticut, Idaho, Massachusetts, Missouri, Nebraska, North Carolina, Oklahoma, Utah, Vermont, Virginia, and West Virginia) adopted medical board regulatory policies based on the Federation's *Model Policy*. The *Model Policy* does not have any negative provisions; states that adopt it 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).

Three state medical board regulatory boards (Hawaii, Kentucky, and Michigan[g]) approved policies based on the Federation's previous *Model Guidelines*. States that fully adopt the *Model Guidelines* are credited with eight positive provisions and no negative provisions: Criteria #2, #3, #4, #5, #6, #7 (see Table 3), and two instances of Criterion #8 (see Appendix D for a description of Criterion #8 categories).

Finally, medical boards in four other states (California, the District of Columbia, Oregon, and Wyoming) had unique policies that were not based on either of the Federation's models. These policies are distinct from one-another and contain provisions that meet a range of positive criteria.

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

[g] Michigan's pain management policy was a product of collaboration between the medical and osteopathic boards.

Pharmacy Board Policies

Three state pharmacy boards (Florida, Michigan, and Wisconsin) adopted policies relating to pain management; those in Florida and Michigan were based on the Federation's model policies. Collectively, the following criteria were fulfilled: Criteria #2, #3, #4, #5, #7 (see Table 3), and four instances of Criterion #8 (see Appendix D for a description of Criteria #8 categories).

Joint Board Policies

Four states (Florida, Michigan, Minnesota, and New Mexico) approved joint policy statements relating to the use of controlled substances for the treatment of pain, which were developed collaboratively by several regulatory boards such as medicine, osteopathy, pharmacy, and nursing. These policies, which represent a consensus of boards that govern healthcare practice, are a unique and credible way to emphasize the importance of multidisciplinary treatment of pain. Collectively, the following positive provisions were added: Criteria #2, #3, #4, #5, #7 (see Table 3), and numerous instances of Criterion #8 (see Appendix D for a description of Criterion #8 categories).

PAIN-SPECIFIC STATUTES

Arkansas adopted an Intractable Pain Treatment Act (IPTA) and Hawaii adopted Pain Patient's Bill of Rights legislation, both of which added a total of 17 positive provisions. Although three negative provisions were added as well, these statutes are improvements over similar past legislation containing numerous instances of restrictive or ambiguous policy language.

REPEAL OF RESTRICTIVE OR AMBIGUOUS LAWS

Positive policy change also occurred when states repealed negative provisions from laws that establish prescription monitoring programs, short prescription validity periods, required consultation, and opioids as a treatment of last resort.

Changes in Prescription Monitoring Programs

Two states (California and New York) repealed their requirement for a government-issued multiple- or single-copy prescription form for Schedule II controlled substances only (although New York's requirement included Benzodiazepines in Schedule IV) (Criterion #14). California replaced its triplicate program with an Electronic Data Transfer (EDT) system that does not require a special government-issued prescription form; California's EDT program requires the use of a serialized security form for medications in Schedules II-V. New York expanded its EDT program with an easy-to-obtain single-copy government-issued form for all prescription medications, including all controlled substances. Such changes are thought to eliminate a barrier to pain management because they reduce practitioners' reluctance to obtain and use the forms, are a less intrusive method to monitor physicians' prescribing, and do not stigmatize the Schedule II medications that are so important for managing severe pain. One state (Texas) continues to have single-copy prescription form requirement only for Schedule II controlled substances. In addition, we found that some policies establishing prescription monitoring programs include language recognizing that the program is not intended to interfere with medical practice, thus directly supporting the Central Principle of Balance.

Restrictive Prescription Validity Period

Two states modified overly restrictive prescription validity periods of less than two weeks (Criterion #13) from controlled substances statutes and/or regulations. Rhode Island eliminated its 7-day period; Texas eliminated a 7-day period from a regulation, but it remains present in the Controlled Substances Act. Such changes eliminate an unrealistically short number of days within which the prescription must be dispensed following its issue. Short validity periods can impede a patient's ability 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 possibly a return visit to the physician. Five states, including Texas, continue to have a validity period of less than two weeks.[h]

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

Mandated Consultation Provisions

Five states (California, Colorado, Idaho, Oregon, and Vermont) repealed provisions *mandating* that physicians always consult with specialists when using controlled substances to treat patients with pain if they want immunity from disciplinary sanction (Criterion #12: Category B). Although there is no question that physicians should seek consultation when needed, such a requirement is not necessary for every case, especially if the practitioner is knowledgeable about pain management. In addition, such a requirement does not allow for patients who need immediate treatment. Ten states currently mandate consultation under certain circumstances when using opioids to treat patients with pain, including California and Colorado that retained this provision in other policies.[i]

Opioids as a Last Resort

Seven states (Colorado, Kentucky, New Mexico, North Dakota, Rhode Island, Virginia, and West Virginia) repealed language that either required that patients undergo other treatment modalities before being prescribed opioids (Criterion #9) or suggested that medical use of opioids is considered, as a matter of policy, a treatment of last resort (Criterion #16: Category B). Currently, 21 states have policies that characterize opioids as a treatment of last resort.[j]

Some Negative Policy Changes

Policy change, but no grade changes, occurred because a few states added restrictive or ambiguous policy language between 2003 and 2006. Six states added the following negative provisions:

- Restricts prescribing to patients with an addictive disease (Arkansas),
- Suggests that physicians would not qualify for immunity if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain (Arkansas),
- Mandates consultation (District of Columbia),
- Within the "Pain Patient's Bill of Rights," permits physicians to refuse to prescribe opioid medications, which appears to conflict with the standard recognizing that opioids are necessary for public health and are a part of medical practice; this language falls short of providing any patient rights and thus may establish a false expectation for adequate pain management (Hawaii),
- Restricts the quantity of medication prescribed or dispensed (Louisiana),
- Permits pharmacists to refuse to fill a prescription if potential harm is based solely on the quantity of medication prescribed (North Carolina),
- Although adopting the Federation's *Model Policy*, additional policy language contradicts the flexibility standard inherent in the policy (Utah).

[i] These states are Arizona, California, Colorado, District of Columbia, Mississippi, Nevada, New York, Ohio, Oklahoma, and Rhode Island.

[j] These states are Arizona, Arkansas, California, Colorado, District of Columbia, Georgia, Louisiana, Maryland, Minnesota, Missouri, Mississippi, Montana, Nevada, New Jersey, Ohio, Oregon, Tennessee, Texas, Vermont, Washington, and West Virginia.

CURRENT STATUS OF BALANCE IN STATE PAIN POLICY

Michigan and Virginia now have the most balanced pain policies in the country. In the last six years, these two states took advantage of the Federation's *Model Guidelines* and *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 negative policies.

Since 2003, in the rest of the country, legislatures and healthcare regulatory agencies in 19 states modified their policies sufficiently to improve their grade for Balance. Five of those states (Idaho, Kentucky, New Jersey Vermont, and Wisconsin) improved their pain policies between 2000 and 2003, and did so again between 2003 and 2006, demonstrating that some states have continuing efforts to enhance pain policies that can affect professional practice and patient care. There have been no states since 2000 where changes in policy result 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; other states 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, North Dakota, and Wisconsin currently have no restrictive or ambiguous language in state pain policies. These states could achieve an A simply by adopting additional positive policies. Five other states (Kansas, Nebraska, New Mexico, Oregon, and Vermont) would have received an A in 2006 had one or two restrictive or ambiguous provisions been repealed.

Special challenges. In 2006, over 80% of the states achieved a grade above a C; this was 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.

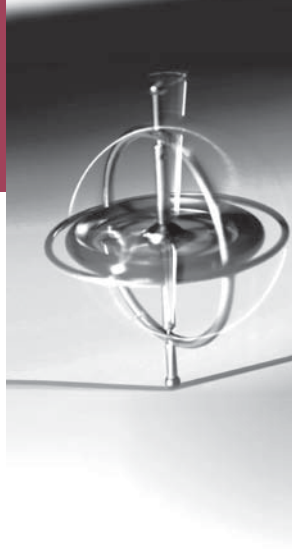
For example, in the last six years there was only a 13% reduction in negative provisions from the nearly 200 that were present in 2000, compared to almost a 60% increase in positive provisions during the same period; this raises a question as to whether repeal of negative provisions in statutes is receiving less attention compared to efforts with professional licensing boards to adopt positive policy. 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 particular state can be determined by consulting the *Evaluation Guide 2006*.

A particular challenge may be in those states that have a considerable number of positive provisions but also have many negative provisions.[k] In the last three years, California, New York, and Texas repealed restrictive legislative 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.

Finally, 47% of states will need to repeal restrictive provisions *and* adopt additional positive language to achieve a grade of A.

[k] These states are California, New Jersey, New York, Tennessee, and Texas.

CONCLUSION



Overall, the momentum for positive change in state pain policy continues into 2006, 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. The use of policy evaluation resources and model policies by state groups to guide positive policy change efforts is apparent.

This trend has even occurred during a period of increase in the abuse and diversion of opioid pain medications.[80-82] In the future, it will be important that efforts by governments and healthcare professionals to address drug abuse not interfere with legitimate medical practices and patient access to appropriate pain care. A public health approach to preventing prescription drug abuse is needed and is compatible with the Central Principle of Balance.[83] 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.[84-86] 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 2006*.

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 2006 evaluation, arranged according to the policy in which it was found and the criterion it satisfied (contained in the *Evaluation Guide 2006*), and (c) the *Progress Report Card 2006*, which shows the distribution and details about the grades for each state for 2000, 2003, and 2006.

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 2006* State Profiles section) and how this compares with the policies from other states. Appendix E shows the total number of states with pain 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 38 states), or not?
- Does my state policy directly address practitioners' fears of being investigated (as it does in 39 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 22 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 2006*, 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 relevant language from the Federation's *Model Policy* and other models, and example language from other states.

2. Make a commitment to implementing policy

Policy change without implementation has little value. Balanced policy must also be understood and respected as such. Many licensed practitioners are not fully aware of the policies that govern controlled substances prescribing and pain management.[73,87] 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.

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.[88-90] The Maryland Board of Physician Quality Assurance has produced a videotape titled "A Sense of Balance: Treating Chronic Pain,"[91] which is required viewing for new licensees. Some states, such as Michigan and Texas, 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 Minnesota and Ohio, 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, p. 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, p. 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).

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) 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.)

(7) 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).

continued

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 in 2000 and 2003 had already been identified for the *Evaluation Guide 2000* and *Evaluation Guide 2003*.[l] The PPSG updated its policy database in using the methodology explained in the *Evaluation Guide 2006*. The criteria were then used to identify positive and negative provisions in policies current through March 2006.

(2) ***Grading:*** The grading method was established using the total number of positive and negative provisions identified with the new policy evaluation methodology explained in the *Evaluation Guide 2006*.[m] As a result of the methodology changes, the state grades in this report for 2000 and 2003 may be different from those contained in the previous *Progress Report Card* from 2003.[n] 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 and 2006 (relevant policies present in 2006 are contained in the *Evaluation Guide 2006*); so, states' grades in 2000, 2003, and 2006 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

Each state's separate grades for positive and negative provisions 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 average 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+.

[l] In 2006, we expanded our evaluation to include other types of policies. Such policies would not have appeared in the 2000 or 2003 *Evaluation Guides*. However, we determined the adoption date for all policies new to the evaluation in 2006. Those policies found to be in effect as of March 2000 were included in the calculation of grades for 2000. As a result, the 2000 state grades are based on the contents of the policies new to the evaluation and those originally contained in the *Evaluation Guides*. The same process was used to calculate grades for 2003, using all policies in effect as of March 2003.

[m] Grades for 2000 and 2003 are based on revisions to the information contained in the *Evaluation Guides* published in 2000 and 2003.

[n] The *Progress Report Card* from 2003 is now considered obsolete and has been removed from our website.

Appendix C: State Grades for Positive and Negative Provisions–2000, 2003, and 2006

STATES	(+) GRADE 2000	(+) GRADE 2003	(+) GRADE 2006	(-) GRADE 2000	(-) GRADE 2003	(-) GRADE 2006
AL	C	C	B	A	A	A
AK	D	D	D	B	A	A
AZ	B	A	A	B	C	C
AR	C	C	A	B	B	C
CA	A	A	A	F	F	F
CO	B	B	B	D	D	C
CT	D	D	C	B	B	B
DE	C	C	C	B	B	B
DC	F	F	C	B	B	B
FL	A	A	A	C	C	C
GA	D	D	D	C	C	C
HI	D	D	A	B	B	C
ID	C	C	B	C	B	B
IL	D	D	D	B	B	B
IN	C	C	C	C	B	B
IA	C	B	B	B	B	B
KS	C	A	A	B	B	B
KY	D	B	B	C	C	B
LA	C	C	C	C	C	C
ME	C	C	C	A	A	A
MD	C	B	B	B	B	B
MA	C	B	B	C	B	B
MI	A	A	A	C	A	A
MN	C	C	B	B	B	B
MS	C	C	B	C	C	C
MO	C	A	A	D	D	D
MT	C	B	B	B	C	C
NE	A	A	A	B	B	B
NV	C	B	B	D	D	D
NH	D	C	C	B	B	B
NJ	C	B	A	F	F	F
NM	B	A	A	B	B	B
NY	C	A	A	F	F	F
NC	B	B	A	B	B	C
ND	C	C	C	C	C	A
OH	A	A	A	C	C	C
OK	A	A	A	D	D	D
OR	B	B	A	C	C	B
PA	C	C	C	B	B	B
RI	B	B	A	F	F	C
SC	B	B	B	C	C	C
SD	B	B	B	B	B	B
TN	C	A	A	F	F	F
TX	A	A	A	F	F	F
UT	B	B	B	C	C	B
VT	C	B	A	C	C	B
VA	B	B	A	B	B	A
WA	B	B	B	B	B	B
WV	B	A	A	C	C	C
WI	D	D	C	B	A	A
WY	D	D	C	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 extend beyond pain scores to 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 extend beyond pain scores to 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 extend beyond pain scores to 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 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 2006 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	45
3. Medical use of opioids is recognized as legitimate professional practice	51
4. Pain management is encouraged	38
5. Practitioners' concerns about regulatory scrutiny are addressed	39
6. Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing	31
7. Physical dependence or analgesic tolerance are not confused with "addiction"	36
8. Other provisions that may enhance pain management	
Category A: Issues related to healthcare professionals	47
Category B: Issues related to patients	18
Category C: Regulatory or policy issues	39
Negative provisions	**Number of states**
9. Opioids are considered a treatment of last resort	8
10. Medical use of opioids is implied to be outside legitimate professional practice	13
11. Physical dependence or analgesic tolerance are confused with "addiction"	16
12. Medical decisions are restricted	
Category A: Restrictions based on patient characteristics	9
Category B: Mandated consultation	10
Category C: Restrictions regarding quantity prescribed or dispensed	9
Category D: Undue prescription limitations	6
13. Length of prescription validity is restricted	5
14. Practitioners are subject to additional prescription requirements	6
15. Other provisions that may impede pain management	3
16. Provisions that are ambiguous	
Category A: Arbitrary standards for legitimate prescribing	17
Category B: Unclear intent leading to possible misinterpretation	22
Category C: Conflicting (or inconsistent) policies or provisions	9

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