PAINS PROJECT

TRANSFORMING THE WAY PAIN IS PERCEIVED, JUDGED AND TREATED

POLICY BRIEF

PAIN AND POLICY STUDIES GROUP REPORT CARD, 2012

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POLICY **BRIEF**
PPSG REPORT CARD, 2012

Co-Editors: Aaron Gilson, Asra Husain, Richard Payne, and Bob Twillman

This policy brief is a product of the Pain Action Alliance to Implement a National Strategy (PAINS), in collaboration with the Center for Practical Bioethics, the American Academy of Pain Management (AAPM), and the Pain and Policy Studies Group (PPSG) at the University of Wisconsin. It was funded by the United States Cancer Pain Relief Committee.

INTRODUCTION

Healthcare practice, including pain management, is governed at the state level and not by federal laws. Numerous barriers continue to affect the provision of pain care. A prevalent barrier is the presence of state policies that create undue restrictions or practice ambiguities. Healthcare professionals need to understand the state statutes and regulatory policies that govern practice in their state so that they remain in compliance with, and thoroughly conform to, legal standards.

The University of Wisconsin Pain and Policy Studies Group (PPSG) has created the Progress Report Card to evaluate the ability of state policies to support pain management and palliative care by looking at the language in laws and regulations and assigning a letter grade from A to F. The PPSG examined these policies and laws for language that would impede or enhance practices in healthcare to help alleviate pain in patients. Over the last 12 years, PPSG has published six Progress Report Cards and has found significant improvement in states' policies over time.

BACKGROUND

Drug control laws and medical practices work together to ensure that opioid pain medications are made available to patients with a legitimate medical need, while preventing diversion and abuse of such medications. This two-pronged approach to dealing with opioid medications is known as the ***Principle of Balance*** (herein referred to as "balance"). Balance is grounded in the Single Convention on Narcotic Drugs, which states in its preamble:

> *Recognizing that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes,*
>
> *Recognizing that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind* (Single Convention, Preamble)[1]

This statement shows that it is important to allow for access to pain medications while preventing diversion and abuse of such medicines. Several other high-level international organizations have confirmed that balance is an important goal in effective healthcare and regulation. The World Health Organization (WHO) stated that, "WHO considers the public health outcome to be at its maximum (or "balanced") when the optimum is reached between maximizing access for rational medical use and minimizing substance abuse." (Ensuring Balance 2011)[2]

The United Nations Economic and Social Council (UN ECOSOC) has also issued guidance on this matter. In two separate resolutions, the body has called on its member states to review and revise national legislation so as to "reflect a balance between ensuring availability and preventing diversion and abuse, including by identifying and removing overly restrictive provisions which unnecessarily impede availability." (Paragraph 47b)[3]

At the national level, there has also been significant medical guidance to strive for balanced drug access and control policies. The Institute of Medicine's (IOM) Committee on End of Life Care recommended:

> *"a 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)[4]

Additionally 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)[5]

The American Cancer Society (ACS) Cancer Action Network recommended, "remov[ing] or amend[ing] restrictive or ambiguous language in state statutes and regulations" (p. 1)[6]. Additionally, the National Institutes of Health stated that, "regulatory barriers need to be revised to maximize convenience, benefit and compliance..." (p. 15)[7].

CREATING THE PROGRESS REPORT CARD

The PPSG, a PAINS participant, developed 16 evaluation criteria for the report card. These criteria were split into positive and negative categories, with eight criteria in each category, as shown in **Table 1.**

The PPSG evaluated several types of policies for the Progress Report Card. These include the Controlled Substances Act and its accompanying regulations, as well as state legislation, state regulatory guidelines and other relevant policies. State legislation and regulations included in the review were those that dealt with controlled substances, medical pharmacy, nursing practice, intractable pain treatment acts, prescription monitoring programs and similar laws.

Table 1 — Criteria Used to Evaluate State Pain Policies[8]	
Positive Criteria: Criteria that identify policy language that may enhance safe and effective pain management	**Negative Criteria:** Criteria that identify policy language that may impede safe and effective pain management.
1) Controlled substances are recognized as necessary for public health.	1) Opioids are relegated as only a treatment of last resort.
2) Pain management is recognized as part of general healthcare practice.	2) Medical use of opioids is implied to be outside legitimate professional practice.
3) Medical use of opioids is recognized as legitimate professional practice.	3) Physical dependence or analgesic tolerance are confused with "addiction."
4) Pain management is encouraged.	4) Medical decisions are restricted: **Category A:** Restrictions based on patient characteristics **Category B:** Mandated consultation for all patients **Category C:** Restrictions regarding quantity prescribed or dispensed **Category D:** Undue prescription limitations
5) Practitioners' concerns about regulatory scrutiny are addressed.	5) Length of prescription validity is restricted.
6) Prescription amount alone is recognized as insufficient to determine legitimacy of prescribing .	6) Practitioners are subject to undue prescription requirements.
7) Physical dependence or analgesic tolerance are not confused with "addiction."	7) Other provisions that may impede pain management.
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	8) 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

Positive and negative provisions were identified in accordance with the methods determined in the *Evaluation Guide 2008*.[9] The 16 evaluation criteria, listed in the table above, were used to identify positive and negative policy provisions in each state through December 2012. To determine the grades for each state, the total number of policy provisions was calculated for both positive and negative provisions. Then a range, average and standard deviation for the aggregated positive and negative provisions were determined. Next, the PPSG averaged the number of provisions for both positive and negative policies and found one standard deviation above and below.

Grades were determined for positive provisions and for negative provisions separately. These two grades were then combined to arrive at final grades, which are reported on the table on the back page. Mid-point grades were assigned rather than rounding a grade up or down. For example, a state that received a B for positive provisions and an A for negative provisions received a final combined grade of B+.

REPORT CARD FINDINGS

The PPSG found a positive trend in grades since the first Progress Report Card. In 2006, when the first report card was created, 84% of states received a grade of C or above. In the most recent Progress Report Card, created in 2012, 94% of states received a grade of C or above. Since 2008, 20 states have shown positive grade changes and, remarkably, no state's grade has decreased. The largest grade improvement was seen in Georgia, which went from a D+ to an A. In fact, in this report card, not a single state received a grade of D+ or lower. Georgia was joined by Iowa, Maine, Montana, Rhode Island, Vermont and Washington in achieving a grade of an A for the first time. The map below shows each state's grade for the 2012 report card.

Table 2 — Grading distribution[10]		
Distribution for Positive Provisions	Grade	Distribution for Negative Provisions
1 or more standard deviations above average	A	No negative 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	1 within standard deviations above the average
No positive provisions	F	1 or more standard deviations above the average

POLICIES INFLUENCING FINDINGS

In its review of state policies, the PPSG found that the most prevalent problematic provisions were those that confuse "addiction" with physical dependence. Thirteen states have conflicting information about what constitutes addiction and physical dependence as a result of laws and/or regulations that define the two phenomena identically. This causes problems because a regular patient who is prescribed opioid medications for legitimate use could then be labeled as an addict, even though there is no addiction in place. Such stigmatization can deter medical professionals from prescribing opioids and keep those who legitimately need such medications for pain from using them. These conflicting policies also create confusion for prescribing doctors.

Many state policies also include provisions that imply that opioid use is not a part of professional practice, that make it unclear at what point doctors are able to prescribe opioids, and/or that imply that there is a dosing standard for opioid medications that must be

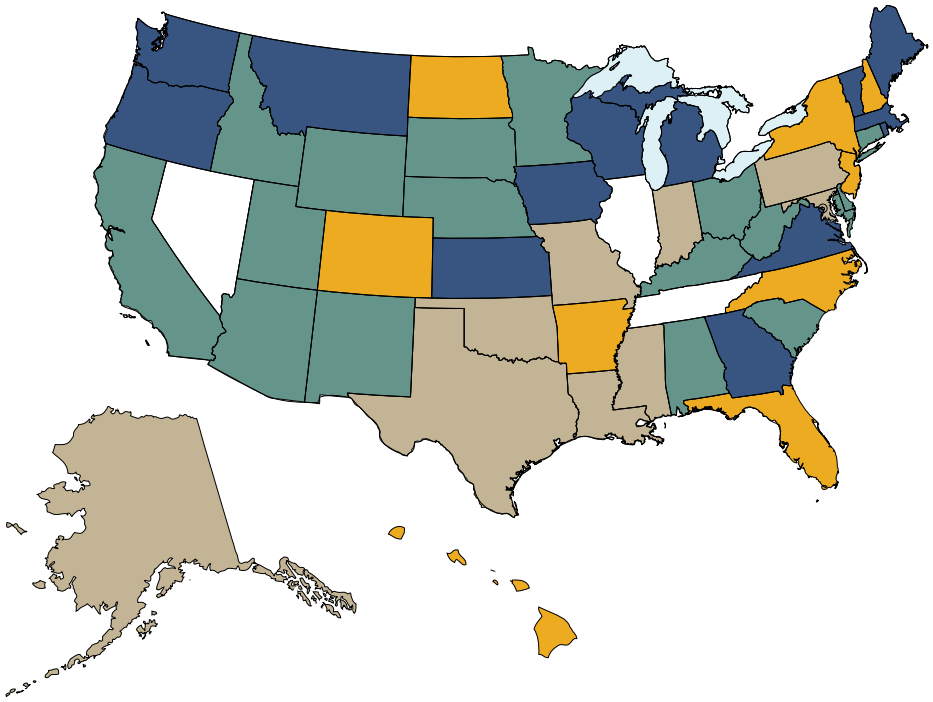

Table 3

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

legally followed. Such policies limit the ability of doctors to provide appropriate medical care using their knowledge and expertise.

IMPLICATIONS

Several states have opportunities for an improved grade simply by adopting or removing language from existing laws in order to improve access to opioid medications. With no ambiguous language in their state policies, Alabama, Alaska and North Dakota are all able to improve access just by adopting additional positive language. A total of 12 states could have improved an entire letter grade simply by repealing one or two negative provisions.

While each state must determine the best way to create a public policy on opioid medications that best fits its unique identity, it is important that these policies do not regulate healthcare practices to the point of restricting actions that require medical expertise. Laws, regulations and policies do not need to legislate medical decisions in order to accomplish effective drug control. Doing so creates barriers to access to pain management for patients across the spectrum.

THE WAY FORWARD

The sixth Progress Report Card indicates that further action is still needed by states to improve pain policies. Several states have a significant number of both positive and negative policy provisions. They could improve with more positive provisions being put into place, but this would still not achieve a balanced policy and would not warrant a change in grade. These states need to focus on continuing to reduce the negative provisions while increasing the number of positive provisions to improve access to pain management. In a few states there is no guidance from the licensing authority for clinicians as to what constitutes an acceptable approach to pain management. Policies issued by medical or pharmacy boards regarding controlled substances would correct this problem and help improve grades in Alaska, Illinois, Indiana, and North Dakota.

Several additional factors should be taken into account in crafting policies to improve patient pain care:

- **Other Policy Areas** – Reimbursement, health facility standards and living wills or advance directives can all affect patient pain care.
- **Clinical Activities and Practice Guidelines** – They often implicate pain management through policies.
- **Dichotomy Between Policy Intent and Content** – It is not uncommon for the intent of a policy to not match the actual content of the policy, leading to overly restrictive policies. An example of this is found in states that offer a "patient bill of rights" that allows physicians to refuse to

Table 4 — Grading distribution[10]
State Grades for 2006, 2008, 2010, 201211

State	2006	2008	2010	2012	State	2006	2008	2010	2012
AL	B+	B+	B+	B+	MT	B	B	B	A
AK	C+	C+	C+	C+	NE	B+	B+	B+	B+
AZ	B	B	B	B	NV	C	C	C	C
AR	B	B	B	B	NH	C+	C+	B	B+
CA	C	B	B	B+	NJ	C+	C+	B	B
CO	C+	B	B	B	NM	B+	B+	B+	B+
CT	C+	B+	B+	B+	NY	C+	C+	C+	B
DE	C+	C+	C+	B+	NC	B	B	B	B
DC	C+	C+	C+	B	ND	B	B	B	B
FL	B	B	B	B	OH	B	B	B	B+
GA	D+	D+	B	A	OK	C+	C+	C+	C+
HI	B	B	B	B+	OR	B+	B+	A	A
ID	B	B	B	B+	PA	C+	C+	C+	C+
IL	C	C	C	C	RI	B	B	B+	A
IN	C+	C+	C+	C+	SC	B	B+	B+	B+
IA	B	B	B	A	SD	B	B	B	B+
KS	B+	A	A	A	TN	C	C	C	C
KY	B	B	B	B+	TX	C	C	C+	C+
LA	C	C	C	C+	UT	B	B	B+	B+
ME	B	B	B+	A	VT	B+	B+	B+	A
MD	B	B	B	B+	VA	A	A	A	A
MA	B+	A	A	A	WA	B	B	B+	A
MI	A	A	A	A	WV	B	B	B	B+
MN	B	B	B+	B+	WI	B	A	A	A
MS	C+	C+	C+	C+	WY	C+	C+	C+	B+
MO	C+	C+	C+	C+					

prescribe opioid medications for pain. These laws do not protect the right to pain management for the patient; rather they take away this right.

- **Laws and Regulations** – Laws and regulations influence how healthcare professionals practice medicine. Cognizant of the rules surrounding prescribing and usage of medicines, healthcare professionals may, therefore, be overly cautious when laws are ambiguous. Policies should not remove medical decisions from healthcare professionals' practice. Instead, such policies should guide the legal aspect of drug control while allowing healthcare professionals the ability to appropriately provide adequate pain management to their patients.

It is important to be aware of the policies outlined in the Progress Report Card so that changes may be made to improve medical treatment for patients. Ensuring availability of pain medication for patients is just as important as preventing the abuse and diversion of those same medications. This can only be accomplished when policies are balanced.

For further information about the PPSG's Progress Report Card and its accompanying evaluation guide, please visit the University of Wisconsin Pain and Policy Studies Group website at http://www.painpolicy.wisc.edu/ppsg-releases-new-progress-report-card-and-evaluation-guide. For further information about PAINS, visit http://www.painsproject.org.

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PAINS' mission is to transform the way pain is perceived, judged and treated.

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Co-Editors:
Richard Payne, MD
John B. Francis Chair
Center for Practical Bioethics
www.practicalbioethics.org

Bob Twillman, PhD, FAPM
Deputy Executive Director
American Academy of Pain Management
www.aapainmange.org

Primary Author of Issue 3:
S. Asra Husain, JD, MA
Policy and Legal Analyst
Pain & Policy Studies Group
University of Wisconsin
www.painpolicy.wisc.edu

Editors:
Trudi Galblum
Communications Consultant
Center for Practical Bioethics

Cindy Leyland
PAINS Project Director
Center for Practical Bioethics

Designer:
Ryan W. Kramer
RWK Studios

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