
Progress to Achieve Balanced State Policy Relevant to Pain Management and Palliative Care: 2000-2003

Aaron M. Gilson
David E. Joranson
Martha A. Maurer
Karen M. Ryan
Jody P. Garthwaite

ABSTRACT. State laws and regulatory policies govern healthcare practice, including the prescribing, dispensing, and administering of opioid analgesics to treat pain. A number of national healthcare and law enforcement organizations have identified drug regulatory policy as a potential barrier to pain relief and palliative care, and have called for evaluation and removal. This article summarizes and discusses the results of an innovative evaluation methodology that was used to produce three policy analysis tools, including one report that graded and ranked states based on the quality of their policies related to pain management and palliative care (called a Progress Report Card [PRC]). The PRC development and implementation was a first-of-a-kind study that compared pain policies in all states over a three year period according to the same evaluation criteria. Results demonstrate significant progress to improve policy in a number of states during the study period, but also showed that most state policies are characterized by a lack of “balance.” In addition to providing examples of policy change in particular states, the relevance of these findings to current policy issues, including the importance of communicating and implementing new policies is discussed. The need for partnerships between the healthcare and law enforcement communities is emphasized to create a more positive regulatory environment for pain relief and palliative care, which ultimately will benefit patient care.

KEYWORDS: Policy, law, regulation, pain, palliative care, evaluation, methodology, report card

Article copies are available from <http://www.HaworthPress.com> using Copyright Clearance Center's Rightslink service.

Aaron M. Gilson, PhD, is Assistant Director, David E. Joranson, MSSW, is Director, and Martha A. Maurer, BS, Karen M. Ryan, MA, and Jody P. Garthwaite, BA, are Policy Analysts, Pain & Policy Studies Group, Comprehensive Cancer Center, University of Wisconsin Medical School.

Address correspondence to: Aaron M. Gilson, PhD, Pain & Policy Studies Group, 406 Science Drive, Suite 202, Madison, WI 53711-1068 (E-mail: amgilson@wisc.edu).

Journal of Pain & Palliative Care Pharmacotherapy, Vol. 19(1) 2005
<http://www.haworthpress.com/web/JPPCP>

INTRODUCTION

Although there are many safe and effective ways to relieve pain, which is an essential component of palliative care,¹ it is well known that opioid analgesics are important for such treatment.^{2,3} Because opioids also have a potential for abuse, their prescribing is subject to federal and state controlled substances policies in addition to their regulation as prescription drugs.^{4,5} Further, healthcare professionals who prescribe, administer, or dispense opioids are regulated by state laws, regulations, and boards that govern professional practice with controlled substances.

THE CALL TO EVALUATE POLICIES

It is not well known that a number of national and international authorities have recognized that there are barriers to pain management and palliative care in some policies governing controlled substances and professional practice, and have called for their identification and removal. These authorities include the World Health Organization (WHO), the International Narcotics Control Board (INCB), the American Medical Association (AMA), the Institute of Medicine (IOM) of the United States National Academy of Sciences, the American Cancer Society (ACS), the National Institutes of Health (NIH), the National Association of Attorneys General (NAAG), and the Federation of State Medical Boards of the United States, Inc. (FSMB).

At the international level, the INCB is the principal United Nations agency that monitors adherence of national governments to the international narcotics control treaties. It has asked all governments to:

. . . determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede prescribing, dispensing or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and should make the necessary adjustments. (p. 15)⁶

The INCB also recommended that the WHO “develop methods that can be used by governmental and non-governmental organizations to identify impediments to the appropriate medical availability of narcotic drugs” (p. 18).⁶ The WHO subsequently produced guidelines for policy evaluation based on a principle called “balance,”⁷ which will be discussed later. The WHO has recommended use of the guidelines throughout the world to identify regulatory barriers in national opioids control policies.⁷

In the United States, the IOM Committee on Opportunities in Drug Abuse Research called for studies to determine:

. . . 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)⁸

Similarly, the IOM Committee on Care at the End of Life concluded there was a need for:

. . . 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)⁹

The AMA House of Delegates issued a resolution that recognizes the potential impact of a restrictive regulatory environment:

. . . physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain should not be subject to the burdens of excessive regulatory scrutiny, inappropriate disciplinary action, or criminal prosecution. It is the policy of the AMA that state medical societies and boards of medicine develop or adopt mutually acceptable guidelines protecting physicians who

appropriately prescribe and/or administer controlled substances to relieve intractable pain before seeking the implementation of legislation to provide that protection . . . (p. 1)¹⁰

The ACS has issued a policy statement supporting the need for “. . . additional and sustained efforts . . . to ensure that new barriers are not erected and that adequate pain relief for cancer patients is assured” (p. 3),¹¹ and an NIH Consensus Development Program concluded that “Regulatory barriers need to be revised to maximize convenience, benefit, and compliance . . .” (p. 15).¹²

In addition to medical and scientific organizations, national regulatory bodies have called for removal of restrictive policies. In 2003, the President of NAAG pointed to the emerging role of Attorneys General to “eliminate legal and policy barriers” (p. 2) as a means of protecting consumer health.¹³ The FSMB has encouraged state medical boards in cooperation with their states’ attorneys general to:

. . . evaluate their state pain policies, rules, and regulations to identify any regulatory restrictions or barriers that may impede the effective use of opioids to relieve pain. (p. 1)¹⁴

Together, these authoritative bodies have agreed that some drug regulatory policies interfere with pain management and that these barriers should be identified and addressed. Researchers are thus presented with a challenge to develop methods to identify specific barriers in regulatory policy and approaches to address them.

THE PAIN AND POLICY STUDIES GROUP RESEARCH PROGRAM

In response to the mounting call for positive policy change, the University of Wisconsin Pain and Policy Studies Group (PPSG) has developed a research program to improve U.S. drug control and professional practice policies related to pain management and palliative care. The program was created in several stages, sponsored largely by grants from the Robert

Wood Johnson Foundation, and included (1) national surveys of medical board members, (2) educational workshops for medical board members, (3) evaluation of federal and state policies, (4) guideline development, (5) monitoring adoption of regulatory policy, and (6) policy databases and resources available on the internet.¹⁵⁻¹⁸

The initial PPSG research into regulatory and policy matters informed efforts by the Medical Board of California¹⁹ and the FSMB to improve the quality and consistency of state medical board pain policy. In 1998, the FSMB created “Model Guidelines for the Use of Controlled Substances for the Treatment of Pain” (*Model Guidelines*).²⁰ Organizations from healthcare and law enforcement have endorsed the *Model Guidelines* and have called for their adoption by state medical boards. The Federation prefers that adequate pain relief be promoted by medical regulators and practitioners, rather than by state legislatures.²¹ Twenty-two states have either adopted or adapted the *Model Guidelines*. In May 2004, the Federation’s House of Delegates unanimously adopted a revision of the *Model Guidelines*, called the *Model Policy*.¹⁴ The revision is not substantially different from the 1998 guidelines, but addresses more clearly emerging issues such as inadequate treatment of pain.

Increased policy development, as well as a growing recognition of the need to identify barriers and improve the regulatory environment, has stimulated the PPSG to create a systematic methodology for policy evaluation. The purpose of this article is to describe the methodologies used to evaluate and grade state policies related to pain management and palliative care, summarize the results, discuss implications, and present recommendations for the future.

A GUIDE TO EVALUATION

In July 2000, the PPSG published the first use of its methodology, a comprehensive evaluation of national policy, entitled “Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation” (*Evaluation Guide 2000*).²² The *Evaluation Guide 2000* presented the results of a criteria-based evaluation of federal and state policies relating to pain management,

and palliative and end-of-life care, in particular the use of opioid analgesics. The PPSG evaluated state statutes and regulations governing drug control, and medical and pharmacy practice, as well as other policies from healthcare regulatory organizations, such as state medical and pharmacy boards. We identified approximately 300 policies that were in effect as of March 2000 from all 50 states and the District of Columbia.

Identifying and collecting relevant policies involved several stages, including the use of an electronic legal database (Lexis®) to download policies and conduct keyword searches, contacting relevant state governmental agencies for those policies not available through Lexis, and reviewing websites of regulatory boards or contacting boards directly to request policies. We also used a number of other, non-systematic, methods to ensure the comprehensiveness of our data collection process: (1) periodic review of all medical and pharmacy board newsletters that are available on the internet; (2) periodic updates from the National Association of State Controlled Substances Authorities and the Federation; (3) review of newsletters such as the National Conference of State Legislatures' "State Health Notes," and email list serves; and (4) personal contacts.

We focused our evaluation on drug control and professional practice policies, and did not consider some other policies that states can adopt to improve patient access to adequate pain management and symptom relief. Some states have initiated legislative and regulatory activities that have the potential to impact pain management, such as "Pain as a 5th Vital Sign" legislation, but which fall outside our defined policy parameters. We did not collect policies such as controlled substances scheduling, reimbursement, worker's compensation, educational requirements, importation, Internet prescribing, or provisions related to hospice care, living wills, advance directives, or power-of-attorney. Criminal, civil, or administrative case law also was not evaluated.

THE CENTRAL PRINCIPLE OF BALANCE

"Balance" is a principle that is fundamental to drug regulation and medical ethics and was used to guide the evaluation of policies (see Table 1). The principle asserts that efforts to control misuse of narcotic drugs, such as opioid analgesics, should not interfere with the relief of pain and suffering, and that drug regulatory policy should not contradict medical and scien-

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

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. The belief that opioids hasten death is perpetuated
 12. Physical dependence or analgesic tolerance are confused with "addiction"
 13. Medical decisions are restricted. 13.1. Restrictions based on patient characteristics. 13.2. Mandated consultation. 13.3. Restrictions regarding quantity prescribed or dispensed
 14. Length of prescription validity is restricted
 15. Practitioners are subject to additional prescription requirements
 16. Other provisions that may impede pain management
 17. Provisions that are ambiguous
-

tific knowledge. The principle is stated in Figure 1 and explained in more detail elsewhere.²³ In short, to be “balanced,” a state’s policies should not have barriers, and should also contain provisions that support controlled substances and medical practice concerning pain management and palliative care.

To be balanced, drug control policies will have a high potential to identify and address the specific sources of diversion and a low, perhaps zero, potential to interfere with legitimate availability of pain medications, medical practice, and patient care. An example of a balanced drug control policy can be found in the federal Controlled Substances Act (CSA), which regulates the production and distribution of medications while prohibiting their non-medical use; the CSA clearly recognizes that controlled substances are necessary for public health and production of opioids must be sufficient to meet medical needs. Federal law, unlike some state laws, recognize the medical use of opioids for pain, and does not contain restrictive prescription requirements that can limit medical decision-making about individual patient care.²⁴ Also, the American Alliance of Cancer Pain Initiatives²⁵ has recently developed a policy statement outlining the characteristics of a more balanced state prescription monitoring program (PMP) to reduce drug abuse and diversion while protecting patient care; recommendations include:

- Use of government-issued multiple-copy or single-copy serialized prescription forms should be avoided;
- All controlled substances in Schedules II, III, and IV under both federal and state law should be included;
- Such programs should be administered by the state agency responsible for regulating health care, rather than by the agency responsible enforcing the laws of the state;
- Assurances should be given that legitimate prescribing and dispensing is protected, through the use of a multidisciplinary medical review group. A medical review group could serve the following specific functions:
 - Supervision of the management and uses of data collected by the PMP;

- Development and review of mechanisms to facilitate effective and efficient means of targeting suspicious prescribing and dispensing patterns;
- Review of individual healthcare providers’ prescribing practices to assist in determining if they are participants in drug abuse or diversion;
- Review of individual patient data to assist in differentiating between people with inadequately treated pain and people seeking drugs for abuse and/or diversion; and
- Oversight of the preparation and dissemination of annual data-based performance reports;
- Patient confidentiality should be protected to the greatest extent possible;
- Individual healthcare professionals should have access to PMP data concerning their individual patients for purposes of evaluating those patients’ use of controlled substances;
- Law enforcement agencies should have access to the data when probable cause justifies such access in the course of investigating possible abuse or diversion.²⁵

Adoption of these program characteristics, coupled with the development of educational programs sponsored by all relevant regulatory agencies, to minimize healthcare professionals’ questions or concerns about regulatory scrutiny when using controlled substances as part of legitimate medical practice, would result in a more balanced PMP.

EVALUATION CRITERIA

In order to operationalize the central principle of balance, 17 evaluation criteria were de-

FIGURE 1. The Central Principle of Balance

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. Balance should underlie all drug control policies so that they recognize that efforts to prevent abuse should not interfere in the medical use of opioid analgesics for patient care. As a result, such policies must not be unduly restrictive.

rived to enable researchers to identify: (1) positive provisions-policy language that can *enhance* pain relief, and (2) negative provisions-language that can *impede* pain relief (see Table 1 for the complete list of the criteria). *The positive criteria identify policy language that recognizes the legitimacy of controlled substances prescribing, encourages and supports pain management practice, and reflects the prevailing medical standard. Conversely, negative provisions represent restrictions to healthcare practice, and are inconsistent with current medical knowledge or practice. A balanced policy will contain a number of positive provisions and few if any negative provisions.* The clinical relevance and sources of authority for each criterion is located at <http://www.medsch.wisc.edu/painpolicy/eguide2003/index/eguide2003.pdf> (in Section VII).

Three policy analysts at the PPSG studied systematically all the policies that had been collected, looking for provisions that satisfied any of the criteria. Criteria could be met only if explicit language was present, not by what we thought the language implied or intended. This is called “black letter policy” evaluation. For example, one might assume that the overall intent of a policy is to encourage pain management, but an explicit statement to that effect must be present to satisfy Criterion #4, which identifies policy language that encourages pain management. This rule applied to all but Criterion #10, which is satisfied by language suggesting that medical use of opioids is outside of legitimate professional practice, and might therefore be considered illegal; the rationale for having Criterion #10 relate to implied language can be found at <http://www.medsch.wisc.edu/painpolicy/eguide2003/index/eguide2003.pdf> (in Section VII).

If a criterion was satisfied multiple times in the same policy, we identified only one provision that met the criterion. As a result, any effort to revise a policy must include careful examination of the entire policy to identify all occurrences of a provision. Provisions satisfying Criteria #8 (other positive provisions), #16 (other negative provisions), and #17 (ambiguous provisions), given the nature of these criteria, could be counted more than once in the same policy because they were entirely different in meaning.

The *Evaluation Guide 2000* used the criteria to identify policy provisions having the potential to enhance or impede pain management, and presented the provisions that were identified in the form of a profile for each state’s policies. PPSG presented suggestions for using the findings, as well as model language from several authoritative sources that could be used to improve policy. The *Evaluation Guide 2000* was disseminated to state pain and regulatory organizations; it was discussed in a number of publications and conferences, and it was placed on the PPSG website for easy access. We assisted a number of state groups to apply the evaluation and recommendations in an effort to improve state policies.

Three years later, the PPSG replicated its evaluation of state policies to document policy changes since 2000. This is a reasonable timeframe for the re-evaluation because we have observed that the policy change process in a number of states occurred within three years, including adoption of model guidelines by medical boards, medical board policy development, and revision of state laws. The same types of policies were collected as of March 2003 and were evaluated using the same methodology. The results were published as an electronic document entitled “Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Second edition)” (*Evaluation Guide 2003*).²³

SUMMARY OF FINDINGS FROM THE EVALUATION GUIDES

Policies designed to prevent drug abuse and substandard prescribing practices can ultimately restrict legitimate medical practices and create excessive burdens on caregivers and patients. For the first time, the PPSG used a systematic criteria-based policy evaluation to identify state policy that could interfere with pain management and palliative care. Numerous policy provisions were found that failed to conform to, or even conflicted with, current standards of professional practice, including provisions that:

- Place arbitrary limits on the amount of pain medications that can be prescribed and dispensed at one time,

- Confuse physical dependence with addiction, thus suggesting that pain patients being treated with opioids may be “addicts,”
- Restrict opioids from being used unless other treatments have failed,
- Exaggerate risks of opioids, including the suggestion that therapeutic use of opioids by patients with terminal illness hastens death, and
- Prohibit prescribing to patients with addictive disease or a history of substance abuse, even if they have pain.

In addition, although frequently absent from state policies, the PPSG identified policy language in some states that had the potential to enhance pain management and access to patient care. For example, some state policies recognized that pain management or the use of controlled substances is an integral part of medical practice, and that controlled substances are necessary for the public health. Governmental authorities have recommended these provisions for inclusion in controlled substances and medical practice policy.^{26,27} Also, the PPSG found a number of states having^{15,28-30} policy language that addresses directly physicians’ concerns about regulatory scrutiny, a particularly relevant issue in recent years.

These evaluations resulted in a list of policy language for each state that satisfies the relevant criteria (see <http://www.medsch.wisc.edu/painpolicy/eguide2003/index/eguide2003.pdf> for state-specific profiles of identified policy language from the *Evaluation Guide 2003*). The 2000 policy data were used in part by Last Acts to rank states for a report on dying in America.³¹ It is this information that was converted into “grades” for a subsequent progress report by the PPSG.

A PROGRESS REPORT CARD

In an effort to simplify and draw attention to what might be seen as a complex policy evaluation, to compare the states, and to measure progress from 2000 to 2003, the PPSG produced “Achieving Balance in State Pain Policy: A Progress Report Card” (Progress Report Card).³² Using the policy data from the state

profiles, each state was assigned a grade for 2000 and 2003.²³

The following methodology was used to calculate grades. Each provision identified in the criteria-based evaluation received equal weight. Beginning with the 2000 policy data set, we totaled the number of positive provisions identified in each state’s policies (Criteria 1-8). Using this distribution (which ranged from 0-28), we calculated the average and standard deviation and used it to determine a grading scale for positive provisions. The same method was used on the distribution of negative provisions (which ranged from 0-19) to determine a grading scale. Each state’s grades for positive and negative provisions were averaged to calculate the state’s final grade for the Progress Report Card. A high grade meant a state had a high number of positives and a low number of negatives. Mid-point grades (e.g., B+, C+, D+) were used to characterize more precisely each state’s 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+ (we did not use D-, C-, B-, or A-grades). The averages and standard deviations calculated for 2000 were then applied to the 2003 distributions of positive and negative provisions to measure changes in states’ grades from 2000 to 2003.

The *Progress Report Card* grades states on the extent that their drug control and professional practice policies enhance or impede pain management. A state’s grade is a measure of the quality of state pain policy in relation to the principle of balance, and is based on the frequency of provisions that meet the evaluation criteria. The higher the grade, the more balanced and consistent with modern medicine a state’s policies are. A lower grade means that a state’s policies contain barriers (i.e., provisions that contradict current medical knowledge, are not consistent with the recommendations of authoritative sources of policy guidance, and do not communicate the appropriate messages about pain management to professionals, patients, and the public).

The *Progress Report Card* is the quantification of a systematic policy evaluation, rather than a statement of a “position” about a state’s pain policies. Although a grade oversimplifies a state’s policy environment, the use of a single

index to compare states is useful and can draw the attention of state policy-makers and health-care professionals to the need to evaluate and improve the regulatory policy environment for pain management. As such, the *Progress Report Card* was designed as a tool to be used by government and non-government organizations to achieve more positive and consistent state policy on the use of controlled substances for pain management, palliative care, and end-of-life care. The concept of balance, which underlies the policy evaluation, assures that resulting policy change would not undermine the requirement of licensed healthcare practitioners to use opioid analgesics only for legitimate medical purposes and in the course of their professional practice.

PROGRESS REPORT CARD FINDINGS

Individual state grades for 2000 and 2003 are presented in the *Progress Report Card* (see http://www.medsch.wisc.edu/painpolicy/2003_balance/prc2003.pdf/), demonstrating that the quality of state policies varied greatly between states. In 2003, 35% of states scored around the average (a grade of C), while 41% scored above the average and 24% fell below the average; no state received a grade of A or F. Alabama, Kansas, Massachusetts, Nebraska, and New Mexico achieved the highest grades (B+) and therefore the most balanced policies. Alternatively, New Hampshire, New Jersey, and Rhode Island had the lowest grades (D) and the least balanced policies. The reader can access the *Evaluation Guide 2003 Profile* to view the text of the policies that were identified for any state (<http://www.medsch.wisc.edu/painpolicy/eguide2003/index/eguide2003.pdf/>).

Between the years 2000 and 2003, 16 states modified in their policies sufficiently to produce improvement in their grade. Of the 16 states that had positive policy change, Massachusetts made the greatest improvement, increasing from a D+ to a B+ between 2000 and 2003. The state medical board adopted the Federation's *Model Guidelines*, and removed an unduly restrictive requirement that physicians consult with pain specialists when using controlled substances to treat patients with pain, re-

gardless of the patient's needs or the physician's expertise.

APPLICATION OF PPSG POLICY RESOURCES

During the study timeframe, several state governmental and non-governmental agencies used PPSG resources and technical assistance with positive results. For example, Kansas healthcare professionals collaborated with the PPSG to increase the number of positive policy provisions and achieved a higher grade (B+). The Kansas medical board adopted the *Model Guidelines* and issued a joint policy statement relating to the use of controlled substances for the treatment of pain, which was developed collaboratively with the boards of pharmacy and nursing, and in cooperation with the state cancer pain initiative.

Michigan improved its grade from a D+ to a C+ because the state legislature repealed two unduly restrictive prescription requirements (rather than by adding positive policy language) in cooperation with the Michigan Hospice and Palliative Care Organization, the Michigan Controlled Substances Advisory Commission, and the Michigan Cancer Pain Initiative. The legislature replaced the state's burdensome serialized prescription program with a paperless electronic data transfer (EDT) system, eliminated its 5-day prescription validity period, and deleted all references to the term "intractable pain" from statute. In addition, the state medical board repealed a requirement that physicians always consult with pain specialists when using controlled substances to treat patients with pain, regardless of the physician's expertise.

Hawaii and Idaho were the only states for which positive policy change was achieved solely through state legislative action to repeal a number of unduly restrictive prescription requirements. The Hawaii Cancer Pain Initiative and the Community State Partnership worked together with the Narcotics Enforcement Division to replace the state's burdensome duplicate prescription program with a paperless EDT system. Hawaii eliminated its 3-day prescription validity period. In addition, the Idaho legislature replaced its duplicate prescription pro-

gram with a paperless EDT system, and extended its 7-day prescription validity period to 30 days.

DISCUSSION

The challenge set forth by international and national bodies has stimulated development of research methods and systematic policy evaluations, which in turn have assisted non-governmental organizations (i.e., state pain initiatives and community-state partnerships) to work with state legislatures and regulatory boards in a number of states to improve the regulatory policy environment for pain management and palliative care.³³ This progress has been accomplished by repealing archaic provisions and by adopting new policies that are more in keeping with modern medical and regulatory principles, as well as the public health objective of improving pain management and palliative care. It is a good beginning, but there is a long way to go. Because no state received either an A or an F, there is great opportunity for positive policy change, as well as a chance for state policies to worsen.

The quality of state policies that govern medical practice, including the use of prescription pain medications, bears directly on medical decision-making and, ultimately, patient care. Policies containing positive language that encourages pain management can support professionals whose use of pain medications is hampered by concerns about the risks inherent in oversight by drug law enforcement and regulatory agencies. Alternatively, restrictive policies can make professionals unwilling to use pain medications and make it difficult for patients to obtain adequate pain relief. Improving state policy is one important part of the multifaceted approach to improving pain management and symptom control which includes securing against the abuse and diversion of pain medications.³⁴

The total number of both positive and negative provisions determines a state's grade. Making state policy more balanced generally requires that states: (1) adopt language that promotes pain management, and (2) remove language that can impede pain management. To achieve a grade of A, state agencies and organizations should first examine the 2003 grades for posi-

tive and negative provisions (found in Appendix B of the *Progress Report Card*, located at http://www.medsch.wisc.edu/painpolicy/2003_balance/prc2003.pdf/). The more the grades deviate from an A, the more change is needed. The PPSG provides guidance for improving state policy in the *Evaluation Guide 2003* (<http://www.medsch.wisc.edu/painpolicy/eguide2003/index/eguide2003.pdf/>).

Adding Positive Language

Improving a state's "positives" has several components. Significant, but not complete, improvement to state policy can be made by adopting the Federation's *Model Guidelines*, which contain seven positive provisions and no negative provisions. Ten states adopted in full the *Model Guidelines*, while a number of others have only adopted parts of the Model.¹⁶ The *Model Guidelines* encourage physicians not only to learn more about pain management and opioid prescribing, but also to continually monitor for abuse and diversion when treating patients with pain. If states adopt the *Model Guidelines*, physicians would benefit from regulatory guidance about these important issues. Adoption of policies that make pain management an expectation for all physicians may make adequate relief more accessible to all people with pain,³⁵ which is a principle that continues to be represented by the Federation's new *Model Policy*.¹⁴

A state's Uniform Controlled Substances Act (USCA) should contain language that expresses that controlled substances are necessary for the public health, as does the federal Controlled Substances Act²⁷ and the international treaties to which the U.S. is a party.³⁶ Without such a provision, a state's UCSA focuses primarily on abuse and trafficking of controlled substances and is not balanced. In addition, a state's Medical Practice Act or regulations should contain language clearly recognizing that pain management is a part of medical practice, consistent with the Modern Medical Practice Act³⁷ recommended to all the states by the Federation.

In fact, the primary source of positive policy language observed in the *Progress Report Card* was healthcare regulatory boards' adoption of guidelines and policy statements, often cumu-

lately satisfying Criteria #2, #3, #4, #5, #7, and #8. Between 2000 and 2003:

- five states approved medical board policies based on the Federation's *Model Guidelines*, three states adopted joint policy statements relating to the use of controlled substances for pain management,
- two states adopted a pharmacy board policy statement relating to pain management, and
- one state medical board developed a palliative care guideline to educate physicians about the treatment of terminally-ill patients.

Repealing Negative Language

Negative provisions tend to be more difficult to address because they typically occur in laws, which requires a legislative process to amend or repeal the language. Because some of these policies restrict medical decision-making, their repeal may be essential to a state's ability to achieve balanced policy.

There were many instances during the three-year period in which repealing negative provisions improved state grades. Three states removed their requirement for a multiple- or single-copy prescription form (Criterion #15) and substituted a less intrusive method to monitor physicians' prescribing (usually an EDT system that does not require a special government-issued prescription form); this change is consistent with recommendations from the AACPI³⁸ and others.³⁹ Four states modified overly restrictive prescription validity periods (Criterion #14) from controlled substances statutes and regulations. Finally, three states repealed provisions mandating that physicians consult with pain specialists in every instance of using controlled substances to treat patients with pain (Criterion #13.2).

Another important source of negative language is Intractable Pain Treatment Acts (IPTAs), which are policies that began to be adopted more than a decade ago with the intention to improve access to pain management by providing statutory immunity to physicians who prescribe opioids to patients with "intractable pain." However, the language in IPTAs often poses more requirements and restrictions on the pre-

scribing of opioids for pain. Some IPTAs suggest that the use of opioids for intractable pain is not within the ordinary practice of medicine (Criterion #10), opioid therapy cannot occur without a consultation (Criterion #13.2), or that patients who use drugs nontherapeutically cannot be treated (Criterion 13.1). These mandates have the effect of greater rather than less governmental regulation over the use of controlled substances to manage pain. In addition, the safe harbor policy may not apply to patients whose pain does not satisfy the narrow definition of "intractable pain." The AACPI recently has issued a policy statement outlining cautions about IPTAs, and suggests policy alternatives with similar objectives and a greater potential to improve pain relief.⁴⁰ Nevertheless, IPTAs continue to be a prevalent response to pain management issues, having been passed by 12 state legislatures since 1989.

Removing excessively strict prescription requirements will ease the burden on prescribers and patients. However, it is also important to recognize that other barriers in the healthcare, reimbursement, and medical education system should be identified and addressed.⁴¹⁻⁴⁴

Making policy changes to improve a state's grade does not interfere with the underlying control system for controlled substances, or undermine the requirement that healthcare practitioners provide opioid analgesics only for legitimate medical purposes and in the course of professional practice. Improving balance in a state's policy does not "liberalize" prescribing; it is not going "soft on drugs," nor does it encourage misuse. Rather, better balance improves the consistency of a state's policy with modern drug regulation, medical knowledge, and professional practice for the benefit of the patient.

CONCLUSION: BALANCED STATE POLICY— ONLY THE FIRST STEP

Positive state policy is one necessary, but not sufficient, factor to consider when improving professional practice relating to pain management and symptom control. There are some states in which grass-roots initiatives have succeeded in making pain management a higher

healthcare priority, in spite of an absence of policies that clearly support such practice.⁴⁵

In addition, adopting more balanced policy will have an impact only to the extent that it is implemented and understood. Balanced policy with no implementation has little practical value. To be most effective, a state's policies need to be disseminated and communicated widely to physicians, pharmacists, nurses and the public; there are many examples of states that have accomplished this, including Kansas, Minnesota, North Carolina, Ohio, and West Virginia. For example, in the mid-1990s members and investigative and legal staff from the North Carolina Medical Board participated in an educational workshop about pain management and regulatory policy. The workshop was followed by a local radio show addressing patient pain relief. Later, the Board adopted a new position statement that was published in the board newsletter that reaches all licensed physicians and surgeons. From 1996 to 2000, the Board continued to develop policy, provided education, and communicated these efforts to licensees and the public.⁴⁶ Another example is the Minnesota Board of Medical Examiners, which endorsed the Federation's Model Guidelines in 2001, and then sponsored a series of 10 educational seminars across the state to educate healthcare professionals about pain management and the Board's supportive attitude.

The purpose of the policy change tools developed by the PPSG is to draw attention to the potential positive and negative impact of policy on pain relief and to promote the removal of excessive regulatory barriers to physician prescribing and patient care. However, this is only one side of the balance equation. We too are concerned about the abuse and diversion of pain medications, which is why we promote balanced policies-policies designed to prevent abuse and diversion of pain medications while, at the same time, ensuring their medical availability. Systems of control to prevent drug abuse and diversion are established in controlled substances policies, which are contained in sections distinct from those evaluated, and would not be affected by our policy improvement recommendations.

If pain medications are diverted and abused, the principle of balance dictates that the sources of diversion should be dealt with directly with-

out interfering with availability, legitimate medical practice, or patient care. Taking this one step further, the principle of balance can be used to clarify, ideally, the roles of healthcare professionals and law enforcement officials: practitioners who treat pain must avoid contributing to diversion, and law enforcement agencies who work to stop diversion must not interfere with pain management. Thus, the principle of balance outlines a framework for common ground and, indeed, the complementary interest of healthcare and law enforcement; this interest in a balanced approach to pain management is exemplified by a recent and unprecedented collaboration between healthcare and law enforcement. The partnership of these diverse organizations began in 2001 when The Drug Enforcement Administration, Last Acts Partnership, and the Pain & Policy Studies Group at the University of Wisconsin worked together to develop a consensus statement entitled *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act* (found at www.aacpi.org/regulatory/consensus.pdf).⁴⁷ This consensus statement, which has been endorsed by 42 other health care organizations, calls for addressing both the necessity of medical access to prescription pain medications and active approaches to prevent abuse and diversion. After releasing the statement, the group met to discuss the compelling need to educate both the health care community and the law enforcement and regulatory communities. Another more specific document was produced in 2004: *Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals, and Law Enforcement Personnel*.⁴⁸ The FAQ is intended as a resource to provide primary care clinicians and law enforcement officers with current medical information so that both groups can better understand the treatment of pain and can effectively prevent prescription pain medications from being diverted and becoming a source of public harm, without interfering with pain management.

Given the increased public awareness of unrelieved pain, as well as a better understanding of the systemic barriers that adversely impact patient care, there is a growing national recognition of the need, even the imperative, to achieve balance. Pain control and drug control

need not be contradictory public health objectives. To implement a balanced approach requires a broad-based, multidisciplinary engagement process that involves developing effective communication and partnerships between the law enforcement and healthcare communities.^{17,49,50} These efforts must extend beyond the purview of healthcare professionals and their organizations to include national law enforcement agencies, associations of district attorneys, sheriffs, police chiefs, and medical examiners. In fact, many national law enforcement and regulatory organizations have already endorsed the principle of balance, including the U.S. Drug Enforcement Administration, the Federation of State Medical Boards of the U.S., the National Association of Attorneys General, the National Association of Drug Diversion Investigators, and the National Association of State Controlled Substances Authorities. Formal consensus of such organizations, coupled with their commitment to sustained implementation of self-education regarding a balanced approach to pain management, drug regulation, and law enforcement, would facilitate a more positive regulatory environment for pain relief and palliative care. An engagement process like this could effectively address physicians' concerns about regulatory scrutiny and would narrow what Passik describes as the "gap between the philosophy espoused by top members of the law enforcement community and what is happening on the ground" (p. 200).⁵¹ Positive policy change, and effective communication of such change, is necessary for this important clinical and regulatory evolution.

REFERENCES

1. Arnold R, Berger A, Billings JA, et al. Clinical Practice Guidelines for Quality Palliative Care. Brooklyn, NY: National Consensus Project for Quality Palliative Care; 2004. (Available at <http://www.nationalconsensusproject.org/guideline.pdf>)
2. American Academy of Pain Medicine and American Pain Society. The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement. Glenview, IL: American Academy of Pain Medicine and American Pain Society; 1997. (Available at <http://www.painmed.org/productpub/statements/opioidstmt.html>)
3. World Health Organization Cancer and Palliative Care Unit. Cancer Pain Relief: A Guide to Opioid Availability. WHO Collaborating Center for Symptom Evaluation in Cancer Care; Madison, Wisconsin, USA. 1992 (Monograph).
4. Noah L. Challenges in the federal regulation of pain management technologies. *J Law Med Ethics*. 2003; 31(1):55-74.
5. Gilson AM, Joranson DE. U.S. policies relevant to the prescribing of opioid analgesics for the treatment of pain in patients with addictive disease. *Clin J Pain*. 2002; 18(4 suppl):S91-S98. (Available at <http://www.medsch.wisc.edu/painpolicy/publicat/02cjpri/index.htm>)
6. International Narcotics Control Board. Report of the International Narcotics Control Board for 1995: Availability of Opiates for Medical Needs. New York, NY: United Nations; 1996. (Available at http://www.incb.org/e/ind_ar.htm)
7. World Health Organization. Achieving Balance in National Opioids Control Policy: Guidelines for Assessment. Geneva, Switzerland: World Health Organization; 2000. (Available at <http://www.medsch.wisc.edu/painpolicy/publicat/00whoabi/00whoabi.htm>)
8. Institute of Medicine Committee on Opportunities in Drug Abuse Research. Pathways of Addiction: Opportunities in Drug Abuse Research. Washington, DC: National Academy Press; 1996. (Available at <http://www.nap.edu/catalog/5297.html>)
9. Institute of Medicine Committee on Care at the End of Life. Approaching Death: Improving Care at the End of Life. Washington, DC: National Academy Press; 1997. (Available at <http://books.nap.edu/catalog/5801.html>)
10. American Medical Association-House of Delegates. Protection for Physicians Who Prescribe Pain Medication H-120.960. Chicago, IL: American Medical Association; 2003.
11. Cancer Pain Management Policy Review Group. American Cancer Society Position Statement on Regulatory Barriers to Quality Cancer Pain Management. National Government Relations Department, American Cancer Society; 2001.
12. National Institutes of Health Consensus Development Program. Symptom Management in Cancer: Pain, Depression and Fatigue. Statement prepared following a National Institutes of Health State-of-the-Science Conference on Symptom Management in Cancer; Bethesda, MD; July 15-17, 2002. (Available at http://consensus.nih.gov/ia/022/022_intro.htm)
13. National Association of Attorneys General. Improving End-of-Life Care: The Role of Attorneys General. Edmondson WAD, editor. Washington, DC: National Association of Attorneys General; 2003.
14. 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.fsb.org>)
15. Gilson AM, Joranson DE. Controlled substances and pain management: Changes in knowledge and attitudes of state medical regulators. *J Pain Symptom Man-*

- age. 2001; 21(3):227-237. (Available at <http://www.medsch.wisc.edu/painpolicy/publicat/01jpsm/index.htm>)
16. Gilson AM, Joranson DE, Maurer MA. Improving state medical board policies: Influence of a model. *J Law Med Ethics*. 2003; 31(1):119-129. (Available at <http://www.medsch.wisc.edu/painpolicy/publicat/03jlme/index.htm>)
17. Joranson DE, Gilson AM, Dahl JL, Haddox JD. Pain management, controlled substances, and state medical board policy: A decade of change. *J Pain Symptom Manage*. 2002; 23(2):138-147. (Available at <http://www.medsch.wisc.edu/painpolicy/publicat/02jpsm1/index.htm>)
18. Joranson DE, Gilson AM, Nischik JA. North Carolina, pain management and end-of-life care: Communicating the policy. *Fed Bull, J Med Licen & Disc*. 2002; 88(3):116-119. (Available at <http://www.medsch.wisc.edu/painpolicy/publicat/02fsmb/index.htm>)
19. Medical Board of California. New, easy guidelines on prescribing. *Action Report*. 1994; 51:1,8.
20. Federation of State Medical Boards of the United States Inc. *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Euless, TX: Federation of State Medical Boards of the United States Inc; 1998. (Available at <http://www.fsmb.org>)
21. Federation of State Medical Boards of the United States Inc. *Position of the Federation of State Medical Boards in support of adoption of pain management guidelines*. 2000.
22. Joranson DE, Gilson AM, Ryan KM, et al. *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation*. Madison, WI: Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center; 2000. (Available at <http://www.medsch.wisc.edu/painpolicy/eguide2000/index.html>)
23. Pain & Policy Studies Group. *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation, Second Edition*. Madison, WI: University of Wisconsin Comprehensive Cancer Center; 2003. (Available at http://www.medsch.wisc.edu/painpolicy/2003_balance/)
24. Dahl JL, Joranson DE. Cancer pain: the US reports. *Palliat Med*. 1992; 6:94-97.
25. Dahl JL, Joranson DE, Weissman DE. The Wisconsin cancer pain initiative: a progress report. *Am J Hospice Care*. 1989; 6(6):39-43.
26. National Conference of Commissioners on Uniform State Laws. *Uniform Controlled Substances Act*. NCCUSL; Chicago, IL. Adopted at its Annual Conference Meeting in its One-Hundred-and-Third-Year; Chicago, IL; July 29-August 5, 1994.
27. *Controlled Substances Act*. Pub L No. 91-513, 84 Stat 1242, 1970.
28. *Controlled Substances Act*. Title 21 USC §801(1). (Available at <http://www.deadiversion.usdoj.gov/21cfr/21usc/211ausct.htm>)
29. Joranson DE, Gilson AM. Controlled substances, medical practice, and the law. In: Schwartz HI, ed. *Psychiatric Practice Under Fire: the Influence of Government, the Media, and Special Interests on Somatic Therapies*. 1st ed. Washington DC: American Psychiatric Press, Inc.; 1994:173-194. (Available at <http://www.medsch.wisc.edu/painpolicy/publicat/94appcs.htm>)
30. Joranson DE. Federal and state regulation of opioids. *J Pain Symptom Manage*. 1990; 5(Suppl.)(1):S12-S23. (Available at <http://www.medsch.wisc.edu/painpolicy/publicat/90jpsmf.htm>)
31. *Last Acts. Means to a Better End: A Report on Dying in America Today*. Washington, DC: Last Acts National Program Office; 2002. (Available at <http://www.lastacts.org/>)
32. Pain & Policy Studies Group. *Achieving Balance in State Pain Policy: A Progress Report Card*. Madison, WI: University of Wisconsin Comprehensive Cancer Center; 2003. (Available at http://www.medsch.wisc.edu/painpolicy/2003_balance/)
33. Dahl JL, Bennett ME, Bromley MD, Joranson DE. Success of the State Pain Initiatives. *Cancer Pract*. 2002; 10(Suppl. 1):S9-S13. (Available at <http://www.aacpi.wisc.edu/images/SPI.pdf>)
34. 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.medsch.wisc.edu/painpolicy/dea01.htm>)
35. Hoffmann DE, Tarzian AJ. Achieving the right balance in oversight of physician opioid prescribing for pain: The role of state medical boards. *J Law Med Ethics*. 2003; 31(1):21-40. (Available at http://www.aslme.org/pub_jlme/index_31.php)
36. United Nations. *Single Convention on Narcotic Drugs, 1961*. Geneva, Switzerland: United Nations; 1973.
37. Federation of State Medical Boards of the United States Inc. *A Guide to the Essentials of a Modern Medical Practice Act*. 9th ed. Dallas, TX: Federation of State Medical Boards; 2000. (Available at <http://www.fsmb.org/>)
38. American Alliance of Cancer Pain Initiatives. *Statement on State Prescription Monitoring Programs*. Madison, WI: AACPI; 2002. (Available at <http://www.aacpi.wisc.edu/regulatory/regulatory.html>)
39. Brushwood DB. Maximizing the value of electronic prescription monitoring programs. *J Law Med Ethics*. 2003; 31(1):41-54. (Available at <http://www.aslme.org/mayday.php>)
40. American Alliance of Cancer Pain Initiatives. *Statement on Intractable Pain Treatment Acts (IPTA)*. Madison, WI: AACPI; 2004.
41. Hawryluck LA, Harvey WRC, Lemieux-Charles L, Singer PA. Consensus guidelines on analgesia and sedation in dying intensive care unit patients. *BMC Med Ethics*. 2002; 3:1-9. (Available at <http://www.biomedcentral.com/1472-6939/3/3>)
42. Institute of Medicine National Cancer Policy Board. *Improving Palliative Care for Cancer*. Foley KM, Gelband H, editors. Washington, DC: National Academy Press; 2001. (Available at <http://www.nap.edu/catalog/10149.html>)

43. Meisel A, Snyder L, Quill T. Seven legal barriers to end-of-life care: Myths, realities, and grains of truth. *JAMA*. 2000; 284(19):2495-2501.
44. Zerzan J, Stearns S, Hanson L. Access to palliative care and hospice in nursing homes. *JAMA*. 2000; 284(19):2489-2494.
45. Dahl JL. Working with regulators to improve the standard of care in pain management: The U.S. experience. *J Pain Symptom Manage*. 2002; 24(2):136-146.
46. Ferrante FM. Principles of opioid pharmacotherapy: practical implications of basic mechanisms. *J Pain Symptom Manage*. 1996; 11(5):265-273.
47. Furstenberg CT, Ahles TA, Whedon MB, et al. Knowledge and attitudes of health-care providers toward cancer pain management: a comparison of physicians, nurses, and pharmacists in the State of New Hampshire. *J Pain Symptom Manage*. 1998; 15(6):335-349.
48. Drug Enforcement Administration, Last Acts, Pain & Policy Studies Group. Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel. Washington, DC: Drug Enforcement Administration; 2004. (Available at http://www.deadiversion.usdoj.gov/faq/pain_meds_faqs.pdf)
49. Gregoire CO. When the law is good medicine. *J Law Med Ethics*. 2002; 30(3):41-44.
50. Ziegler SJ, Lovrich NP. Pain relief, prescription drugs, and prosecution: a four-state survey of chief prosecutors. *J Law Med Ethics*. 2003; 31(1):75-100.
51. Passik S. Letter to the Editor: Same as it ever was? Life after the Oxycontin Media Frenzy. *J Pain Symptom Manage*. 2003; 25(3):199-201.