An Update on Opioid Policy

Understanding and Navigating the Laws and Regulations Governing Pain Relief With Opioids

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Introduction

Recent reports suggest that many healthcare practitioners express concern about prescribing controlled substances, including opioid analgesics, to patients with chronic pain, especially chronic noncancer pain.[1-4] Two of the primary causes of such concern are the reluctance to contribute to drug abuse, addiction, and diversion,[5-7] and the possibility of being investigated or disciplined by a regulatory agency.[6,8-10] Given the general dearth of specialists to whom patients with chronic pain can be referred, especially if the patient has a history of substance abuse or current addictive disease, many patients with pain remain untreated or undertreated. As a result, efforts to reduce the public health problem of prescription drug abuse can be viewed as exacerbating the public health problem of uncontrolled pain. Likewise, many believe that the call to treat pain has contributed to the recent increase in the nonmedical use of prescription drugs.

These contradictory messages have created a seemingly untenable situation for healthcare practitioners. However, practitioners often can find guidance about prescribing controlled substances for pain management through their state's laws, regulations, and official licensing policies. Although such information is available, evidence demonstrates that practitioners can be unaware of the requirements and recommendations established in state policies.[11,12] Without this knowledge, practitioners cannot take advantage of the guidance that is provided by state legislative or regulatory agencies and, worse, may be vulnerable to regulatory scrutiny by failing to conform to the policies.

Pain Policy Evaluation Resources

To increase awareness of state policy content relating to opioid treatment for pain relief and palliative care, the University of Wisconsin Pain & Policy Studies Group (PPSG) created a series of resource documents, not only for healthcare practitioners but also for lawmakers, regulators, advocates, and other key stakeholders. The basis for this criteria-based policy evaluation research is a fundamental and long-standing national and international principle of drug regulation and medical ethics called "balance." Balance represents a government's dual obligation to establish a system of controls to prevent the abuse, trafficking, and diversion of medications while simultaneously ensuring the availability of medications for legitimate medical purposes.[13] As a result, balanced state policies avoid creating barriers to appropriate healthcare practice and patient care and support both pain management and the legitimate use of controlled substances as essential characteristics of quality medical practice.[14] The principle of balance was used to derive a set of evaluation criteria, with each criterion relating to one of two categories: (1) *positive provisions* -- policy language that can enhance pain relief, and (2) *negative provisions* -- unduly restrictive or ambiguous language that can impede pain relief.

Beginning in 2000 there have been 5 policy evaluations; the results presented in this brief are from the most recent research conducted in 2008 and supported by grants from the American Cancer Society and Susan G. Komen for the Cure and through a cooperative agreement with the Lance Armstrong Foundation. "Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation" (*Evaluation Guide* on the Web site) contains a complete description of the individual criteria, the evaluation methodology, the policy language from all states that satisfies each criterion, and example language that state advocates can use to improve their policies.[15] "Achieving Balance in State Pain Policy: A Progress Report Card" (*Progress Report Card* on the Web site) quantifies the policy content for each state from 2000 to 2008 in the form of grades, which can be used to easily document policy change within a state over time.[16] Both reports are available at www.painpolicy.wisc.edu.

Policy Evaluation Findings

Some states have policies that were adopted to prevent drug abuse and unprofessional conduct, but which go beyond these functions to establish excessive requirements that overly limit healthcare decision-making. Such negative provisions do not conform to and even conflict with current standards of professional practice, such as the following:

- Confuses physical dependence with addiction, thus suggesting that patients with pain who are being treated with opioids may be "addicts" (in 16 states);
- Implies that the medical use of opioids is outside legitimate professional practice (in 10 states);
- Prohibits prescribing to patients with addictive disease or a history of substance abuse, even if they have pain (in 8 states);
- Requires a specialist consultation for every patient who is prescribed schedule II controlled substances (in 8 states);
- Places arbitrary limits on the amount of pain medications that can be prescribed and dispensed at one time (in 8 states);
- Restricts opioids from being used unless other treatments have failed (in 6 states); and
- Limits the amount of time (less than 2 weeks) that a schedule II prescription is valid (in 4 states).

Alternatively, policy language that promotes various aspects of appropriate pain management can enhance patient access to effective pain care and appears most often in regulatory policies rather than in legislation. Fortunately, the frequency with which positive provisions appear in state policy largely exceeds that of the negative provisions, including:

- Recognizes medical use of opioids as legitimate professional practice (in all states);
- Recognizes pain management as part of general medical practice (in 46 states);
- Addresses practitioners' concerns about regulatory scrutiny (in 40 states);
- Encourages pain management (in 39 states);
- Distinguishes addiction from physical dependence or analgesic tolerance (in 37 states); and
- Recognizes that medication amount or duration is insufficient to determine legitimacy of a prescription (in 34 states).

State policies that lack positive provisions and contain negative provisions are considered unbalanced because they fail to acknowledge the medical benefit of opioid analgesics and limit their use regardless of their clinical appropriateness. Such policies can ultimately create barriers to

effective patient care and should be changed.

Progress Report Card Findings

The policy evaluation results described above are quantified into a grade, ranging from A to F, which represents the quality of a state's policy content. The higher a state's grade, the more balanced are its policies relating to the use of controlled substances for pain management, palliative care, and end-of-life care.

Results show that the quality of pain policies continues to vary greatly across states but has improved over time. By 2008, 12% of states scored around the average (a grade of C), while 88% scored above the average and no state received below the average (a grade of D+, D, or F).[16] The Table contains the complete list of states' grades for 2008. These present grades demonstrate significant change over time because almost half (49%) of states received above a C in 2000.

Between 2007 and 2008, 13 states adopted new policies containing language that fulfilled at least one evaluation criterion and, in 7 of those states, the change was sufficient to improve their grade. Oregon achieved the highest grade (A) and joined Kansas, Michigan, Virginia, and Wisconsin as having the most balanced policies in the country. Georgia demonstrated the largest improvement, increasing from a D+ to a B. This was accomplished primarily through the medical board repealing its 1991 pain policy (the oldest existing medical board pain policy) with a guideline that repealed 3 existing negative provisions and contributed 7 positive provisions. Importantly, no state's grade decreased from 2007 to 2008, or since the policy evaluations were begun in 2000; in the last year, state legislatures and regulatory agencies have completely avoided adopting new policies that could impede pain management and the medical use of controlled substances.

Conclusions

The momentum for state policy change that began in 2000 has continued into 2008. The improvement documented in recent years results largely from state healthcare regulatory boards adopting guidelines or policy statements that encourage safe and effective pain management. Less frequently, but equally important, state legislatures have repealed restrictive and often archaic language from statutes.[17]

As policies become more balanced across the nation, practitioners must recognize the policies as balanced. Healthcare practitioners who become informed about the content of their state's policies will better understand the extent to which their legislatures or regulatory boards promote appropriate pain care, how they reassure practitioners that they need not be concerned about scrutiny for their prescribing practices, and the extent to which they avoid requirements that limit medical decision-making or reflect outdated medical and scientific knowledge. Practitioners who learn that their state's policies are silent about various aspects of pain management services, or actually contain negative provisions, have become advocates for policy change and these practitioners have used the policy evaluation resources described above to justify efforts to improve policy content.

Of course, policy change alone will not solve the problem of unrelieved pain. Untreated or undertreated pain is widely considered a multifactorial issue stemming from many diverse causes. Successfully removing undue legislative and regulatory restrictions and additional policy barriers does not obviate the need to determine whether other impediments exist that can hinder pain management. However, improving policy remains an essential component of patient access to effective pain relief.

Table 1. State Grades for 2008

STATE	2008 GRADE	STATE	2008 GRADE
Alabama	B+	Montana	C+
Alaska	C+	Nebraska	B+
Arizona	B+	Nevada	C
Arkansas	B	New Hampshire	B
California	B	New Jersey	C+
Colorado	B	New Mexico	B+
Connecticut	B	New York	C
Delaware	C+	North Carolina	B
District of Columbia	C+	North Dakota	B
Florida	B	Ohio	B
Georgia	B	Oklahoma	C+
Hawaii	B	Oregon	A
Idaho	B	Pennsylvania	C+
Illinois	C	Rhode Island	B+
Indiana	C+	South Carolina	C+
Iowa	B	South Dakota	B
Kansas	A	Tennessee	C
Kentucky	B	Texas	C
Louisiana	C	Utah	B+

Maine	B+	Vermont	B+
Maryland	B	Virginia	A
Massachusetts	B+	Washington	B+
Michigan	A	West Virginia	B
Minnesota	B+	Wisconsin	A
Mississippi	C+	Wyoming	C+
Missouri	C+		

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