

State policy affecting pain management: recent improvements and the positive impact of regulatory health policies

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Abstract

Criteria-driven policy analysis resources from the University of Wisconsin Pain and Policy Studies Group (PPSG) evaluated drug control and professional practice policies that can influence use of controlled substances for pain management, and documented changes over a 3-year period. Additional research was needed to determine the extent of change, the types of messages contained in the policies, and what has contributed to changing policy content. Four research aims guided this study: (1) evaluate change between 2000 and 2003 of state policy that can affect pain relief, (2) describe content differences for statutes, regulations, guidelines, and policy statements, (3) evaluate differences between policies specific to pain management and policies governing general healthcare practice, and (4) compare content of policies specific to pain management created by healthcare regulatory boards to those created by state legislatures. Results showed that more current policies, especially policies regulating health professionals, tend to encourage pain management and avoid language that restricts professional decision-making and patient treatment. In addition, pain policies from healthcare regulatory boards were generally less restrictive than statutes or policies that govern general healthcare practice. These findings suggest that the positive policy change results primarily from state medical, pharmacy, and nursing boards adopting policies promoting pain management and the use of opioids, while containing few if any restrictions. Despite this improvement, further progress can be made when states continue to abrogate additional restrictions or clinically obsolete provisions from policies. PPSG policy evaluations provide guidance to lawmakers, healthcare regulators, and clinicians who are striving to achieve balanced policy, an attainable but redoubtable goal, to benefit patient care.

Keywords: State healthcare policy; Medical decision-making; Opioid prescribing; Policy evaluation; Pain management

1. Introduction

Insufficient pain management is a significant public health concern [1] and adequate relief depends on access to a variety of treatment options, including

the appropriate use of controlled substances when the pain is of moderate or severe intensity [2–5]. U.S. federal and state controlled substances policies and state medical practice policies govern physician prescribing, dispensing, and administering of controlled substances, including opioid analgesics. Controlled substances laws are designed primarily to control the diversion and abuse of drugs, but federal laws (i.e., the

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Table 1
Types of policies

“Legislation” refers to rules of conduct adopted by the legislature that have binding legal force; legislation also can be called “statutes”. The most common legislation affecting the prescribing of controlled substances for pain management at the state level include Controlled Substances Acts, Medical Practice Acts, Pharmacy Practice Acts, and Intractable Pain Treatment Acts

“Regulations” refer to official policy issued by an agency of the executive branch of government pursuant to statutory authority. Regulations have binding legal force and are intended to implement the administrative policies of an agency created by the legislation. For example, regulations from the state medical board establish what conduct is or is not acceptable for physicians licensed in the state. The most common regulations affecting the prescribing of controlled substances for pain management at the state level include Medical Board Regulations and Pharmacy Board Regulations

“Guidelines” refer to official 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 can clarify acceptable practice for those regulated by an agency. Guidelines can also include an officially adopted “policy statement” that appears in a position paper, report, article, letter, or agency newsletter. A number of state medical boards have issued guidelines or policy statements regarding the medical use of controlled substances for treating pain, which define the conduct the board considers to be within the professional practice of medicine

Controlled Substances Act and the Code of Federal Regulations) recognize that opioid analgesics are necessary for the relief of pain and that their availability for medical purposes must be ensured [6–9]. Federal law also acknowledges the value of controlled substances to public health [10] and the Food and Drug Administration approves controlled substances as safe and effective when used under medical supervision [11]. Under federal law, licensed physicians can prescribe controlled substances for legitimate medical purposes when in the usual course of professional practice [12]; the policy also affirms that physicians are responsible for the proper prescribing and dispensing of controlled substances [12]. State controlled substances policy has the potential to conform to federal law by recognizing the dual purpose of drug control policy, which emphasizes the public health importance of prescription medications as well as the need to provide security against their diversion and abuse. However, the necessity of balancing the medical utility of prescription medications with drug control may not be adequately represented in state controlled substances laws, which often place primary emphasis on establishing security requirements to protect the public [13].

Medical practice, including the professional use of opioid analgesics for pain relief and palliative care, is regulated solely by state policies. The policies that govern medical practice at the state level include medical and pharmacy practice legislation and regulations, as well as regulatory boards’ guidelines or policy statements, and are defined in Table 1. The Federation of State Medical Boards of the U.S. (the Federation) of-

fers a model statute called the Modern Medical Practice Act (MMPA) to help guide the creation of medical practice acts; the MMPA defines medical practice to include the treatment of pain [14]. As such, professional practice policy can place the diagnosis and treatment of pain within the ordinary purview of medicine. In addition, medical practice policy can conform to national authoritative sources, such as federal law [8], the Uniform Controlled Substances Act (UCSA) [15], and the Federation [16], by clearly regarding opioid prescribing as a legitimate professional practice.

Over the last 15 years, states have developed health policies with the intention to directly enhance pain management and to relieve licensees’ concerns about regulatory oversight when prescribing controlled substances in large quantities or for extended periods. During this time there has been a substantial increase in the number of policies relevant to the use of controlled substances to treat pain, from a total of six policies in 1989 to 91 policies in 2003 [17]. Such policies include Intractable Pain Treatment Acts (IPTAs) and medical board regulations, guidelines, or policy statements. IPTAs are statutes designed to encourage adequate pain relief by providing physicians with a “safe harbor” from discipline by state regulators when prescribing opioid analgesics to treat “intractable pain”. However, IPTAs usually do not contain explicit statements promoting pain management and patient access to appropriate care. Also, IPTAs often pose additional practice requirements and can ultimately restrict the prescribing of opioid analgesics for pain [18–20]. For example, IPTAs historically have man-

dated consultation for every patient, regardless of the primary physician's training or expertise, or they have restricted prescribing to patients who were addicts but who nevertheless required pain management. Given the limitations of these common pain statutes, many states have instead chosen regulatory policy as the way to promote adequate pain treatment and palliative care, with medical, pharmacy, and nursing boards increasingly adopting jointly-prepared guidelines.

Pain continues to be inadequately treated in the U.S. despite the presence, and indeed prevalence, of state controlled substances and professional practice policies. Reasons for continued insufficient pain management can stem from practitioners' remaining reluctant to prescribe even when knowing about positive pain policies in their state, practitioners being unaware of their state policy encouraging pain management, and the presence of state policies with restrictive language. Indeed, national authorities [21–24] have acknowledged that laws, such as IPTAs, can impose potential barriers on the availability and medical use of opioids, and have recommended that restrictive policy language or provisions be repealed as a means of improving pain management [25–27]. The Pain and Policy Studies Group (PPSG), a research program at the University of Wisconsin, has developed a criteria-based evaluation methodology for identifying policy language relevant to pain relief. Using this methodology, policy barriers to physician prescribing and patient access to controlled substances are recognized, and can then be corrected. This work resulted in three recent policy analysis resources funded by the Robert Wood Johnson Foundation: (1) “Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation” (*Evaluation Guide* 2000) [28], (2) “Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (second edition)” (*Evaluation Guide* 2003) [29], and (3) “Achieving Balance in State Pain Policy: A Progress Report Card” (*Progress Report Card*) [30]. The methodology for each document was reviewed and commented on by experts in pain medicine, public health, bioethics, and health and regulatory policy.

1.1. Guides to policy evaluation

In 2000, the PPSG compiled the findings of its comprehensive 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. Results were published in a document entitled “Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation” (*Evaluation Guide* 2000) [28]. The PPSG evaluated state policies governing drug control and medical and pharmacy practice that were in effect as of March 2000 from all 50 states and the District of Columbia.

The central principle of “Balance” formed the foundation of the policy evaluation and asserts that public safety efforts to prevent drug abuse must not interfere with the public health goal of appropriate pain relief when using controlled substances [29]. Consequently, policies that govern medical practice must not be unduly restrictive and should not contradict current professional and scientific knowledge. The principle of balance was used to derive 17 evaluation criteria, each of which was related to one of two categories: (1) positive criteria — policy language that can *enhance* pain relief, and (2) negative criteria — language that can *impede* pain relief. Table 2 lists the criteria. Clinical and policy rationale for each criterion is located at <http://www.medsch.wisc.edu/painpolicy/eguide2003/index/eguide2003.pdf> (in Section VII). A more detailed summary of the policy collection methodology, the rationale for policy evaluation, the principle of balance, the application of the criteria, and the types of policies not included in the evaluation, is published elsewhere [31].

The PPSG replicated its evaluation in 2003 to examine the extent of state policy change since 2000. Policies were collected as of March 2003 and were evaluated using the same methodology as the *Evaluation Guide* 2000. Results from the updated evaluation were published as an electronic document entitled “Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (second edition)” (*Evaluation Guide* 2003) [29].

Using a systematic criteria-based evaluation demonstrated that policies created to prevent drug abuse and substandard prescribing practices contained language that could restrict legitimate medical practice if implemented. Numerous policies were found that failed to conform to, or even conflicted with, current professional practice standards. The PPSG also identified policy language in many states that could improve pain management and patient access to adequate treatment.

The 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). This information was converted to a grade for each state's pain and palliative care policies, which were then detailed in a Progress Report Card.

1.2. Progress Report Card

The PPSG produced "Achieving Balance in State Pain Policy: A Progress Report Card" (*Progress Report Card*) [30] to compare each state, and to measure progress from 2000 to 2003, using a single metric to simplify a complex policy evaluation. Policy data from the state profiles contained in the *Evaluation Guide* 2000 and the *Evaluation Guide* 2003 were used to assign a grade to each state for 2000 and 2003 [30]. A state's grade reflects the quality of state pain policy relating to the principle of balance, and is calculated from the frequency of provisions that meet the evaluation criteria; the methodology used to calculate grades is outlined in [31]. A higher grade represents more balanced policy that is consistent with modern medical standards. Lower grades signify the presence of policy barriers, including language that restricts medical decision-making, contradicts current medical knowledge or conflicts with recommendations from authoritative sources, and fails to communicate appropriate messages about pain management and using controlled substances.

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) and suggest that the quality of pain policies varied greatly among states. During the 3-year time frame, 16 states had policy improvement sufficient to improve their grade, and no state's grade decreased. In 2003, 35% of states scored a grade of C, while 41% scored above a C and 24% fell below a C; no state received a grade of A or F. Four states (Alabama, Kansas, Massachusetts, Nebraska, and New Mexico) achieved the highest grade of B+, which represents the most balanced policies. New Hampshire, New Jersey, and Rhode Island were shown to have the lowest grade (D) and therefore the least balanced policies.

Although the *Evaluation Guides* and the *Progress Report Card* were designed as educational and policy change tools to achieve more positive and consistent state policy, and have been successfully used as such, these resources are not formatted to easily determine the extent of change for individual evaluation criterion. It is important to examine the specific policy content that has been changing the most during the 2000–2003 timeframe. Such an analysis was conducted recently [32] to examine the evolution of medical board policy content and to determine the influence of the Federation's 1998 model policy (called *Model Guidelines*) [16], which meets Criteria 2–8 and has no negative criteria (see Table 2 for the list of criteria).

The *Model Guidelines* were determined to have a substantial effect on the regulatory policy content, with policies adopted after the *Model Guidelines* showing more positive provisions and having no negative provisions when compared to policies adopted prior [32]. In addition, when criteria were analyzed individually, policies created after the *Model Guidelines* were significantly more likely to include language that met the following criteria:

- *Criterion 2*: Recognizing pain management as part of medical practice.
- *Criterion 4*: Encouraging pain management.
- *Criterion 6*: Recognizing that prescription amount or duration is insufficient to determine legitimacy.
- *Criterion 7*: Not confusing addiction with physical dependence or tolerance.

There were, however, differential effects depending on policy type; the *Model Guidelines* seemed to have the most influence on medical board guideline content, as opposed to regulations and policy statements. Despite overall improvements in pain management policies over time, it was evident that some boards developed policies that did not rely on the Federation's model. These policies tended to contain language having the potential to impede pain management by regulating it strictly.

Despite empirical evidence that regulatory pain policies are improving, there remains a need to statistically analyze all the policy information used to create the *Evaluation Guides*. Such an analysis extends beyond regulatory policy specific to pain management and palliative care to also include regulatory policies that govern general healthcare practice, as well as drug

Table 2

Criteria used to evaluate all state policies

Positive criteria: 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 criteria: policy language with the potential to impede pain management	
9	Opioids are considered to be a last resort
10	Medical use of opioids is implied to be outside of 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

control statutes and regulations and pain statutes such as IPTAs. Four research aims guide this study. First, we evaluated changes from the content of policies contained in the *Evaluation Guide* 2000 to those used for the *Evaluation Guide* 2003. Second, we compared the content of the different types of policy, whether statutes, regulations, guidelines, or policy statements, independent of when they were adopted. Third, we evaluated the differences between pain policies and policies governing general healthcare practice. Finally, we compared the content of pain policies created by healthcare regulators to those created by state legislatures.

2. Methodology

Policy collection and content evaluation methodology is detailed in the *Evaluation Guide* 2003 (see <http://www.medsch.wisc.edu/painpolicy/eguide2003/index/eguide2003.pdf>), but is described here briefly. The PPSG evaluated state statutes and regulations governing the use of controlled substances, and medical and pharmacy practice. Also evaluated were other governmental policies such as state medical board

guidelines and official policy statements. As such, only policies pertaining directly to the physician/patient relationship were considered.

Three PPSG policy researchers independently evaluated each policy using the 17 criteria, and decided whether or not each criterion was fulfilled. As mentioned previously, the criteria are divided into two groups (see Table 2): (1) "positive" criteria to identify policy language with the potential to enhance pain management (Criteria 1 through 8) and (2) "negative" criteria for policy language with the potential to impede pain management (Criteria 9 through 17). The "positive" criteria relate to policies reflecting current legal and medical principles that promote adequate pain relief. Within this category of criteria, "Other" (Criterion 8) identifies policy language that could contribute to better pain treatment but is not covered by the explicit positive criteria. "Negative" criteria comprise policy language that is outdated or would otherwise restrict medical use of controlled substances and pain relief. As with Criterion 8, "Other" (Criterion 16) and "Ambiguous" (Criterion 17) identify additional potential restrictions to pain management. Policy language was judged to satisfy a criterion based on explicit statements (called "black letter" policy evaluation), not by implication or

intent, and was counted only once per policy despite the number of times the criterion could be satisfied. However, Criteria 8, 16, and 17 could occur multiple times if the identified language represented different concepts.

As a result, the data for this study are the policy language identified by three policy researchers as meeting one or more criteria. The policy analysts conducted individual evaluations of each relevant policy. The policy analysts then met to discuss and compare their findings, and to identify any lack of agreement or discrepancies. Our content analyses of policies in 2000 and 2003 have yielded unweighted Cohen's κ coefficients (inter-rater reliability coefficients) of 0.86 and 0.93, respectively; an unweighted κ was calculated because the number of raters exceeded two [33]. Discrepancies usually resulted from oversight or minor difference in interpretation. Consensus was ultimately achieved on the evaluation of each policy. The two samples of policies analyzed were those adopted prior to March 2000 (contained in the *Evaluation Guide* 2000) and those adopted as of March 2003 (contained in the *Evaluation Guide* 2003).

2.1. Statistical analysis

Frequency distributions were calculated for each positive and negative criterion identified, as well as the cumulative number of positive and negative criteria. The frequencies for Criteria 1–7 and 9–15 were dichotomous and represented whether or not a criterion was met. For Criteria 8, 16, and 17, the frequencies also were dichotomous, indicating either that the criterion was not met or that it occurred one or more times. Cumulative totals for positive and negative criteria were recoded as the three categories of no provisions found, one or two found, or three or more found. These non-normal frequency distributions required using a non-parametric method for independent samples for all analyses. χ^2 -tests of association were used to compare: (1) the content of the sample of policies from the *Evaluation Guide* 2000 to the sample from the *Evaluation Guide* 2003 (Research Aim #1), (2) the content across types of policies (i.e., statutes, regulations, and guidelines/policy statements) (Research Aim #2), (3) pain policies to policies governing general healthcare practice (Research Aim #3), and (4) pain policy by healthcare regulatory boards to pain legislation (Research Aim #4).

3. Results

3.1. Policy provisions

The total sample of policies contained in both *Evaluation Guides*, each with provisions having the potential to impact pain management and palliative care, was 389, comprising 229 statutes, 87 regulations, 43 guidelines, and 30 policy statements. Table 3 shows the number and frequency of individual policies identified in 2000 and 2003. All 50 states and the District of Columbia were represented, with a mean of 3.76 policies per state in 2000 and 3.94 in 2003.

The frequency of positive and negative provisions varied for each policy. The total number of positive provisions found in each policy in 2000 ranged from 0 to 7, while the negative provisions ranged from 0 to 5. In 2003, the number of positive and negative policy provisions ranged from 0 to 8 and from 0 to 7, respectively. Table 4 contains the number and frequency with which individual criteria were identified in each sample of policies.

Post hoc power analyses for the χ^2 -tests demonstrated superior power for all analyses. For Research Aims #1–3, using the parameters of a 0.05 α level, a total sample size of 389, 1 degree of freedom, and a small effect size (0.2), the level of power was 0.9762. Research Aim #4, analyzing a policy subset, used a 0.05 α level, a total sample size of 139, 1 degree of freedom, and a medium effect size (0.3) to achieve a power level of 0.9426.

3.1.1. Research Aim #1: policy change between 2000 and 2003

The sample of 192 policies adopted by March 2000 was compared to the 197 policies in effect as of March 2003. The significant χ^2 results were associated with no cells having expected counts of less than 5 and a minimum expected count of greater than 1, except for the

Table 3
Number of different policies analyzed in 2000 and 2003

Policy type	2000 [# (%)] (N = 192)	2003 [# (%)] (N = 197)
Statutes	115 (59.9)	114 (57.9)
Regulations	45 (23.4)	42 (21.3)
Guidelines	19 (9.9)	24 (12.2)
Policy statements	13 (6.8)	17 (8.6)

Table 4
Criteria identified in all policies

Criterion	2000 policies [# (%)] (N=192)	2003 policies [# (%)] (N=197)
1	4 (2.1)	4 (2.0)
2	56 (29.2)	63 (32.0)
3	50 (26.0)	58 (29.4)
4	29 (15.1)	39 (19.8)
5	43 (22.4)	52 (26.4)
6	25 (13.0)	30 (15.2)
7	21 (10.9)	30 (15.2)
8	38 (19.8)	49 (24.9)
9	9 (4.7)	11 (5.6)
10	17 (8.9)	16 (8.1)
11	14 (7.3)	16 (8.1)
12	19 (9.9)	20 (10.2)
13.1	7 (3.6)	7 (3.6)
13.2	17 (8.9)	14 (7.1)
13.3	14 (7.3)	13 (6.6)
14	12 (6.3)	8 (4.1)
15	10 (5.2)	5 (2.5)
16	19 (9.9)	22 (11.2)
17	60 (31.3)	57 (28.9)

analysis of all positive provisions, for which 16.7% of cells had an expected count lower than 5 but remained acceptable.

As expected, policies adopted by 2003 were more likely than previous policies to contain positive provisions ($\chi^2(2)=15.456, p<.0001$). When analyzed separately, however, only two criteria demonstrated statistical significance: Recognizing the use of opioids as legitimate professional practice (Criterion 3) ($\chi^2(1)=11.689, p<.001$) and directly addressing physicians' concerns about regulatory oversight (Criterion 5) ($\chi^2(1)=6.443, p<.011$).

No statistically significant differences emerged for the total number of negative criteria, or for provisions satisfying any individual negative criterion.

3.1.2. Research Aim #2: comparison of policy types

Analyses were conducted to determine whether the frequency of provisions varies according to policy type, independent of the year they were adopted. For this research aim, guidelines and policy statements were combined into one category ($n=73$), because both are less formal than legislation or regulations and neither has the force of law. This group was then compared to statutes and regulations as a single group ($n=316$),

both of which have binding legal force. For these analyses, the statistically significant χ^2 results presented in this section had no cells with expected counts of less than 5 and a minimum expected count of greater than 1.

χ^2 analyses revealed that guidelines and policy statements were more likely than statutes and regulations to recognize that pain management is legitimate professional practice (Criterion 2) ($\chi^2(1)=9.039, p<.003$), recognize that opioid use is legitimate professional practice (Criterion 3) ($\chi^2(1)=55.677, p<.0001$), directly encourage pain management (Criterion 4) ($\chi^2(1)=153.525, p<.0001$), address physician fear of regulatory scrutiny (Criterion 5) ($\chi^2(1)=77.751, p<.0001$), recognize that prescription amount alone is insufficient to determine the legitimacy of treatment (Criterion 6) ($\chi^2(1)=77.883, p<.0001$), not confuse addiction with either physical dependence or tolerance (Criterion 7) ($\chi^2(1)=111.373, p<.0001$), and have one or more "other" provisions with the potential to enhance pain management (Criterion 8) ($\chi^2(1)=11.064, p<.001$). In addition, a statistical comparison between the two groups showed that guidelines and policy statements had a greater total number of positive provisions than did state laws ($\chi^2(2)=114.384, p<.0001$).

Although guidelines and policy statements were more likely to have no negative provisions when compared to statutes and regulations ($\chi^2(2)=14.701, p<.001$), provisions mandating consultation when treating a patient with pain (Criterion 13.2) were found more often in guidelines and policy statements ($\chi^2(1)=11.862, p<.001$). Alternatively, statutes and regulations were significantly more likely to perpetuate the belief that opioid treatment hastens death (Criterion 11) ($\chi^2(1)=7.510, p<.006$), restrict the quantity or duration of prescribing (Criterion 13.3) ($\chi^2(1)=6.703, p<.010$), and have more ambiguous language (Criterion 17) ($\chi^2(1)=13.460, p<.0001$).

3.1.3. Research Aim #3: comparison of pain policies with other policies

The criteria fulfilled by policies designed specifically to address pain management and palliative care (called "pain policies" for the purpose of these analyses, $n=138$) were compared to those policies governing

general professional practice and the use of controlled substances (called “other policies”, $n = 251$). Again, all statistically significant χ^2 -tests had no cells with expected counts of less than 5 and a minimum expected count of greater than 1.

Policies were first compared according to their total number of positive and negative provisions. Pain policies had a significantly greater number of positive provisions ($\chi^2(2) = 215.834$, $p < .002$), while other policies were more likely to contain negative provisions ($\chi^2(2) = 54.701$, $p < .0001$).

The two categories of policies also were compared according to the prevalence of individual provisions. Pain policies were more likely than other policies to consider both pain management and the use of opioids to be a legitimate professional practice (Criteria 2 and 3) ($\chi^2(1) = 32.489$, $p < .0001$ and $\chi^2(1) = 106.871$, $p < .0001$, respectively), encourage pain management (Criterion 4) ($\chi^2(1) = 123.799$, $p < .0001$), address physicians’ concerns about regulatory oversight (Criterion 5) ($\chi^2(1) = 186.057$, $p < .0001$), rec-

ognize that prescription amount alone is insufficient to determine the legitimacy of treatment (Criterion 6) ($\chi^2(1) = 80.443$, $p < .0001$), not confuse addiction with either physical dependence or tolerance (Criterion 7) ($\chi^2(1) = 106.757$, $p < .0001$), and have one or more “other” provisions that could improve pain management when applied (Criterion 8) ($\chi^2(1) = 44.183$, $p < .0001$).

Although other policies tended to contain a greater total number of negative provisions, pain policies were shown to satisfy three individual criteria more often than other policies. Pain policies were more likely to consider opioids to be a treatment of last resort (Criterion 9) ($\chi^2(1) = 38.348$, $p < .0001$), imply that the medical use of opioids is outside legitimate professional practice (Criterion 10) ($\chi^2(1) = 53.844$, $p < .0001$), and mandate consultation when treating a patient with pain (Criterion 13.2) ($\chi^2(1) = 30.024$, $p < .0001$). In contrast, other policies contain language reinforcing the misperception that opioids hasten death (Criterion 11) ($\chi^2(1) = 11.786$,

Table 5
Summary of results for each research aim

	Aim #1 (2000 policies vs. 2003 policies)	Aim #2 (statutes and regulations (S&R) vs. guidelines and policy statements (G&PS))	Aim #3 (pain policies (PP) vs. other policies)	Aim #4 (medical pain policies (MPP) vs. legislative pain policies (LPP))
Total positive criteria	2003 > 2000	G&PS > S&R	PP > other	ns ^a
Total negative criteria	ns	G&PS = 0	Other > PP	MPP = 0
Criterion 1	ns, ne ^b	ns, ne	ns, ne	ne
Criterion 2	ns	G&PS > S&R	PP > other	ns
Criterion 3	2003 > 2000	G&PS > S&R	PP > other	ns
Criterion 4	ns	G&PS > S&R	PP > other	MPP > LPP
Criterion 5	2003 > 2000	G&PS > S&R	PP > other	ns
Criterion 6	ns	G&PS > S&R	PP > other	MPP > LPP
Criterion 7	ns	G&PS > S&R	PP > other	MPP > LPP
Criterion 8	ns	G&PS > S&R	PP > other	ns
Criterion 9	ns	ne	PP > other	MPP > LPP
Criterion 10	ns	ns	PP > other	LPP > MPP
Criterion 11	ns	S&R > G&PS	Other > PP	ne
Criterion 12	ns	ns	Other > PP	ns, ne
Criterion 13.1	ns	ns, ne	ns, ne	ne
Criterion 13.2	ns	G&PS > S&R	PP > other	ns
Criterion 13.3	ns	S&R > G&PS	Other > PP	ns, ne
Criterion 14	ns	ne	Other > PP	ns
Criterion 15	ns	ns, ne	Other > PP	ns
Criterion 16	ns	ns	ns	ns
Criterion 17	ns	S&R > G&PS	ns	LPP > MPP

^a Not statistically significant.

^b Not evaluable due to greater than 20% of χ^2 cells having an expected count of less than 5.

$p < .001$), confuse addiction with physical dependence or tolerance (Criterion 12) ($\chi^2(1) = 9.719$, $p < .002$), restrict the quantity or duration of prescribing (Criterion 13.3) ($\chi^2(1) = 9.986$, $p < .002$), restrict length of prescription validity (Criterion 14) ($\chi^2(1) = 11.593$, $p < .001$), and creating additional prescription requirements (Criterion 15) ($\chi^2(1) = 8.578$, $p < .003$).

3.1.4. Research Aim #4: comparison of medical pain policies to legislative pain policies

Medical pain policies (i.e., policies created by medical, pharmacy, and nursing regulatory boards to promote effective pain management, $n = 100$) were compared to legislative pain policies (i.e., statutes created by state legislatures, $n = 39$). The comparisons were conducted to determine differences in the quality of policies created primarily by healthcare professionals and state lawmakers. As with the previous analyses, the significant χ^2 results presented in this section had no cells with expected counts of less than 5 and a minimum expected count of greater than 1.

Although there were no statistically significant differences between the policy categories for total positive criteria, medical pain policies were more likely than legislative pain policies to avoid provisions that could ultimately restrict prescribing or medical decision-making ($\chi^2(2) = 10.252$, $p < .006$).

When examining differences with provisions meeting individual criteria, the following results emerged. Medical pain policies were more likely than legislative pain policies to include language that encouraged pain management (Criterion 4) ($\chi^2(1) = 18.079$, $p < .0001$), recognized amount or duration of prescribing as insufficient to determine legitimacy of prescribing (Criterion 6) ($\chi^2(1) = 14.839$, $p < .0001$), and did not confuse addiction with physical dependence or tolerance (Criterion 7) ($\chi^2(1) = 23.249$, $p < .0001$). In terms of negative provisions, regulatory pain policies tended to consider opioids to be a treatment of last resort (Criterion 9) ($\chi^2(1) = 9.111$, $p < .003$).

Legislative pain policies were significantly more likely to imply that opioids are not considered legitimate medical practice (Criterion 10) ($\chi^2(1) = 15.513$, $p < .0001$) and contain ambiguous policy language (Criterion 17) ($\chi^2(1) = 26.382$, $p < .0001$).

Table 5 contains a summary of the statistically significant results for all research aims.

4. Discussion

The study findings demonstrate that state policies with the potential to impact pain management practice and the use of controlled substances have been improving. More recent policies tend to have a greater amount of positive language that encourages adequate pain relief and drug availability for legitimate use, while not containing many provisions that could restrict such practice. Regulatory health policies created by state medical, pharmacy, and nursing boards seem to have contributed the positive language found in more recent policies, with much of the improvement resulting from guidelines and policy statements. As suggested by previous research [32], the Federation's *Model Guidelines* were the likely source of the positive policy language found in regulatory guidelines and policy statements. The *Model Guidelines* were created to convey to licensees the messages that adequate pain relief and judicious use of controlled substances should be considered an expected part of legitimate professional practice and to promote consistency in states' policies [34]; these messages were maintained in the Federation's recent revision of the *Model Guidelines* [26].

When pain statutes, regulations, and guidelines and policy statements were analyzed against all other policies, which were not related specifically to pain relief and palliative care, more positive provisions were found in the pain policies. Language that could ultimately restrict pain treatment was normally identified in policies governing general medical practice and medication prescribing; such provisions perpetuate the misperception that opioids hasten death, confuse addiction with the physiological phenomena of physical dependence and tolerance, limit quantities of drugs prescribed or dispensed, limit prescription validity periods, or require the use of government-issued serialized prescription forms. The occurrence of these negative provisions can hamper physicians' flexibility in the management of patients with pain. Such policy language appears to regulate, rather than guide, pain care and medical practice with controlled substances, and do so more strictly than federal law and the policies in most other states.

The influence of the *Model Guidelines*, promulgated in 1998, is perhaps most evident when examining the occurrence of Criterion 5, which addresses physicians' fears of regulatory scrutiny. A primary objective

of the *Model Guidelines* was to alleviate concern about unwarranted regulatory oversight of physician prescribing, which the federation considered to be an important barrier to pain relief [34]. Provisions meeting this criterion also are common in healthcare board regulations, guidelines, and policy statements adopted before the 1998 *Model Guidelines*. They also are common in IPTAs because legislatures wanted physicians to be able to prescribe opioids for “intractable pain” without risk of disciplinary sanction. Consequently, Criterion 5 differentiates:

- 2000 policies from 2003 policies (because the positive policy change found between 2000 and 2003 was mostly the result of state healthcare boards adopting policies based on the *Model Guidelines*) [30];
- statutes and regulations from guidelines and policies statements (because almost all guidelines and policy statements satisfy this criterion) [32]; and
- pain policies from other policies (Criterion 5 is identified predominantly in pain policies) [29].

In addition, there was no statistically significant difference between pain statutes and regulatory pain policies in the extent that Criterion 5 was fulfilled. All pain statutes are created to provide immunity from disciplinary action to physicians who prescribe controlled substances, which addresses directly concerns about regulatory scrutiny. As a result, pain statutes, regulations, and guidelines and policy statements are the primary sources of language aimed at reducing physicians’ fears of sanctions for prescribing controlled substances, which is considered a significant barrier to effectively treating patients with pain.

Further consideration is warranted about the statistical significance of a few individual criteria across the research aims. Criteria 1 and 13.1 did not occur frequently enough in any type of state policy to achieve statistical significance in any research context. State policies tend not to recognize controlled substances as necessary for public health (Criterion 1), which is not surprising. Criterion 1 originates from language in federal law, later present in the UCSA that represents the principle of balance but has not been widely adopted [29]. Without such balancing language, controlled substances statutes focus predominantly on the abuse potential of controlled substances to the exclusion of their public health utility [15].

Limitations on prescribing to certain patient populations (Criterion 13.1) were found exclusively in pain statutes that otherwise create “safe harbors” for physicians who treat patients with “intractable pain”; this finding was significant in Research Aim #4, but was not reported because more than 20% of the expected values in the χ^2 table were less than 5. These state policies typically prohibit prescribing to the class of patients with pain who also have an addictive disease (i.e., “addicts”, “drug dependence persons”, or “habitual users”), but who may nevertheless need opioids to relieve their symptoms [35]. To be balanced, healthcare practice and prescribing policies should permit medical decisions to be made by physicians based on patient needs and not by government.

Definitions that confuse addiction with physical dependence or tolerance (Criterion 12) occurred much more frequently in statutes not designed specifically to address pain management and palliative care, such as state Controlled Substances Acts. Most of these definitions are largely based on terminology about “drug dependence” created by the World Health Organization in 1964. The 40-year-old definition now represents an antiquated view of addiction and physical dependence, which is inconsistent with current medical and scientific knowledge, can stigmatize patients with pain, and erroneously suggests that the chronic medical use of opioids for pain results in drug dependence [36]. To be most effective and not create the potential to restrict medical practice, state policy needs to conform to the medical community’s current scientific and clinical understanding of issues. In addition, overly restrictive prescription validity periods (less than 2 weeks; Criterion 14) occur outside of pain policy, and are another example of how language in state statutes can create the potential for barriers to adequate pain relief. Unrealistically short validity periods can make it difficult for a patient to obtain medications without having to make extraordinary arrangements, especially when travel, slow mail delivery, or other extenuating circumstances exist.

Finally, Criterion 15, which relates to provisions mandating use of government-issued serialized prescription forms when prescribing medications in certain schedules, does not exist in any medical board or pain policies, but are found in controlled substances statutes and related regulations. Studies have shown

that the adoption of this requirement precedes a notable decline in the prescribing of those drugs being monitored and an increase in the prescribing of medications not monitored, even though the substituted drugs are in lower schedules and may not be clinically effective [37]. The requirement of government-issued serialized prescription forms are being replaced by electronic prescription monitoring programs that do not mandate use of a special form, or requires a forgery-resistant prescription form for a greater selection of schedules, thus reducing the likelihood of “down scheduling” [38]. Criterion 15 clearly has the potential to stigmatize certain treatment options, thereby reducing a practitioner’s flexibility to respond appropriately to an individual patient’s care requirements.

It is noteworthy that a few restrictive provisions tended to occur more frequently in policies designed to encourage effective pain management. Considering opioids a treatment of last resort (Criterion 9) is found in older healthcare policies, usually adopted before 1998 [32]. These policies recommend, and in some cases mandate, that physicians document that all reasonable alternative treatments have been explored before prescribing controlled substances. Such policy language is inconsistent with current medical knowledge and limits clinical decision-making about when a physician can legitimately use opioids. The implicit message that the medical use of opioids is not part legitimate medical practice (Criterion 10) is mainly a function of definitions from IPTAs [30]. Definitions of “intractable pain” suggest that using opioids is outside the “generally accepted course of medical practice”, which is the reason physicians need immunity for prescribing. Physicians may therefore be subject to discipline unless the patient’s pain is deemed to satisfy the definition of “intractable pain” and all the conditions of the policy are met. Finally, specialist consultation when treating a patient with pain (Criterion 13.2), although appropriate and important when the clinical situation warrants, should not be mandated. This type of policy language again appears in older policies [32] and disregards the skill and expertise of the prescribing physician. If followed for every patient with chronic pain, such policies have the potential to limit patient access because of the increased time and administrative burden for the physician and increased patient cost.

5. Conclusions

Criteria-based policy research shows that state drug, health, and regulatory policies governing the medical use of controlled substances, which bear directly on clinical decision-making and ultimately patient care, have been improving. Policies containing positive language that encourages pain management can support professionals who are willing to use pain medications but are concerned about regulatory oversight [26]. Restrictive policies can make professionals unwilling to use pain medications and make it difficult for patients to obtain adequate pain relief [21,23]. As a result, abrogating excessively strict prescription requirements will ease the burden both on prescribers and patients.

Adoption of policies that make pain management an expectation for all physicians may make adequate relief more accessible to all people with pain. But this will occur only when there are no other barriers in the healthcare system that will obstruct patient access to these important medications, such as the knowledge and attitudes of healthcare providers or restrictive reimbursement policies. Balanced state policy, like other factors, is insufficient by itself to enhance pain management, but it is a necessary component to achieving this important objective [32]. In addition, policy will have an impact only to the extent that it is understood and implemented by licensees. Positive policy, with no implementation or professional training, has little chance of affecting healthcare practice [31,39].

Creating balanced policy must be viewed as an integral part of a multifaceted approach to improving pain management, while at the same time securing against the abuse and diversion of pain medications. The concept of balance allows not only for the identification of policy provisions that either compliment or conflicts with current medical standards, but also for helping to define the roles of healthcare professionals, regulators, and law enforcement officials. Practitioners who treat pain should adopt risk assessment strategies when they deem them clinically necessary (i.e., use of a written agreement between physician and patient outlining patient responsibilities, periodic use of urine/serum screenings, etc.) to avoid contributing to diversion, while law enforcement agencies’ efforts to prevent diversion must not interfere with pain management [40,41]. Healthcare and law enforcement professionals ultimately share a common responsibility

and, increasingly, a common interest: protecting public health by minimizing diversion of prescription pain medications but ensuring their availability for legitimate medical purposes.

The above messages are clearly stated in the Federation's recent revision of the *Model Guidelines* (entitled *Model Policy for the Use of Controlled Substances for the Treatment of Pain [Model Policy]*), which was passed unanimously by their House of Delegates on 30 April 2004 [26]. In the introduction to the *Model Policy*, its stated goal is:

“... to provide state medical boards with an updated template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations ... The *Model Policy* is designed to communicate certain messages to licensees: that the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will be not sanctioned solely for prescribing opioids analgesics for legitimate medical purposes. *This policy is not meant to constrain or dictate medical decision-making.*” (emphasis added) (p. 1) [26].

With this policy, as with the original *Model Guidelines*, the Federation is promoting consistent and balanced policy. The policy objective is to encourage adequate pain relief, to educate healthcare licensees that pain management, including with controlled substances, is within the bounds and indeed an expectation of quality professional practice and to relieve physicians' concern about regulatory oversight from their licensing board.

In a heretofore unparalleled effort, regulators, law enforcement officials, lawmakers, clinicians, and grass-roots organizations have expressed their commitment to enhancing pain management [31,42,43]. Many of these policy activities have used PPSG policy analysis resources. Leadership at the state level, coupled with readily available information to guide policy change decisions, will likely facilitate a better-coordinated and more effective approach to reducing policy barriers and

adopting balanced policy. The challenges to improving patient pain treatment are formidable, but the objective is truly a matter of public health.

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