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**P-29980\_00001**

WIS\_PPSG\_007010

P-29980 \_ 00001

# ACHIEVING BALANCE IN STATE PAIN POLICY

A Progress Report Card (CY 2015)

## **Pain & Policy Studies Group**

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July 2016



Supported by:





## THE NATIONAL PROBLEM OF UNRELIEVED PAIN

It is well-documented that unrelieved pain continues to be a serious public health problem for the general population in the United States,<sup>1-8</sup> and especially for certain patient populations.<sup>9,16</sup> This reality is especially troublesome because clinical experience shows that adequate pain management can lead to enhanced functioning and quality of life, while uncontrolled severe pain can contribute to disability and despair.<sup>17</sup> **Many** potentially effective drug and non-drug approaches exist to manage pain,<sup>18-26</sup> the appropriateness of which vary according to the individual needs and characteristics of the patient. In fact, there is a notable consensus that an integrative approach to pain care, using a variety of treatment modalities, should be the goal for all patients.<sup>4;27;28</sup> However, controlled substances, including opioid analgesic medications (sometimes referred to by the outdated legal term, “narcotics”), are considered a mainstay of pain treatment for cancer and HIV/AIDS.<sup>29-32</sup> Opioid medications in the class of morphine are designated as having a legitimate medical use<sup>33</sup> and are indicated for the medical management of pain, especially if pain is severe.<sup>26;34;35</sup> Although their use for the relief of a variety of chronic non-cancer pain conditions continues to evolve,<sup>36;37</sup> and evidence of effectiveness for these conditions is derived largely from clinical experience, there seems to be a general agreement that some patients with such pain can be properly treated with opioid therapy.<sup>38;41</sup> Physicians, osteopaths, pharmacists, and nurses and other healthcare professionals (where permitted) must be able, knowledgeable, and confident to prescribe, administer, and dispense opioid medications according to individual patient needs.<sup>40;45;46</sup>

Of course, opioid medications also have a potential for abuse.<sup>47</sup> For this reason, opioid medications and the healthcare professionals who prescribe, administer, or dispense them are regulated pursuant to federal and state controlled substances policies, as well as under state laws and regulations that govern drug control and professional practice.<sup>48;49</sup> Such policies are intended to prevent illicit trafficking, drug abuse, and substandard practice related to prescribing and patient care. However, in some states these policies go well beyond the usual framework of controlled substances and professional practice policy, and can negatively affect legitimate healthcare practices and create undue burdens for practitioners and patients,<sup>50-54</sup> resulting in interference with appropriate pain management. In addition, a gap often exists between what is known about pain management and what is done by healthcare professionals and institutions, which can be influenced either positively or negatively by state-level policy. Policies that encourage appropriate pain management, and consider it and the justified use

of controlled substances to be an expected part of healthcare practice, are preferable to those policies that provide no positive guidance to professionals treating patients' pain, but especially to those based on outdated terminology or to those that establish unduly strict prescribing requirements or ambiguous treatment standards.

Both international and national authorities, including the World Health Organization (WHO),<sup>56;55;56</sup> the International Narcotics Control Board (INCB),<sup>57;58</sup> the United Nations Economic and Social Council (UN ECOSOC),<sup>59</sup> the Institute of Medicine,<sup>60-62</sup> the American Cancer Society (ACS),<sup>63</sup> and the National Institutes of Health,<sup>64</sup> have called attention to untreated or poorly treated pain and have concluded that it is due in part to drug abuse control policies that impede medical use of opioid medications. These authorities have recommended evaluation and improvement of policies influencing pain management.

Overall, the purpose of this evaluation is to identify state policies affecting medication availability, healthcare practice, and pain management, rather than drug abuse prevention and control specifically (which remains a valid topic for the policy evaluation). Evaluation findings are meant to help achieve more positive and consistent state policy governing pain management (cancer and non-cancer pain), palliative care, and end-of-life care, including the appropriate medical use of controlled substances when warranted. Importantly, the policy changes that are encouraged do not negate the underlying principle that opioid medications may only be provided for legitimate medical purposes by licensed healthcare practitioners in the course of their professional practice<sup>65</sup> to be used only by those to whom they are prescribed and in accordance with practitioner instructions. These tools can help government and non-government organizations, as well as policymakers, healthcare professionals, and advocates, to understand the policies in their state that reinforce the appropriate practice of pain management or that can hinder patient access to effective treatment.

## METHOD TO EVALUATE PAIN POLICIES

**Evaluated Policies** Evaluation results are derived from a systematic, criteria-based analysis of policies that have been adopted by the 50 states and the District of Columbia.<sup>66</sup> State policies that are principal to this project are those that govern drug control, prescribing, and healthcare practice. Specifically, these policies include statutes and regulations related to controlled substances, and medical, osteopathic, and pharmacy practice, other governmental policies

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<sup>a</sup>For the purpose of reporting project findings, the District of Columbia is referred to as a state.

where present, such as state medical board guidelines and official policy statements. In addition, the evaluation encompassed other policies containing language directly mentioning the treatment of pain, such as:

- Policies authorizing or requiring healthcare facilities to assess or treat pain
- Provisions encouraging or requiring medical school education or continuing medical education related to pain management (evaluation is based on the objectives stated in policy, and not on the specific curriculum content)
- Provisions establishing pain commissions, councils, and task forces as governmental vehicles designed to improve pain management and the use of controlled substances (evaluation is based on the objectives stated in policy, and not on the procedures or results of the commission's work)
- Provisions authorizing or requiring regulatory agencies to create and implement rules or guidelines specifically relating to pain management, and communicating these policies to licensees (evaluation is based on the objectives stated in policy, and not on the specific content of the resulting policies, which will be subject to evaluation once adopted)
- Provisions relevant to pain management or medication access in statutes and regulations that create and implement state-level drug control databases such as prescription monitoring programs

[Context for interpreting policy evaluation results.](#) As stated previously, this evaluation is meant to identify relevant language in each state's legislation or regulatory policies that have the potential to influence appropriate treatment of patients with pain, including controlled medication availability. It is expected that people seeking to improve their state's policy can use these evaluation findings to guide their interactions with and messages for policymakers, as a means to provide convincing justification for relevant policy change requests. Of course, this evaluation is limited through its method of "black letter" policy analysis – it focuses on policy content and does not consider the undeclared intention or context within which the policy was developed and adopted. Moreover, policy content may not directly relate either to the degree to which the recommendations or requirements are implemented or the extent that clinical practice conforms to adopted standards. Examining practitioners' compliance with existing policy, and how this relates to patient outcomes, is a critical topic for additional research.

## Examples of Unevaluated Policies

Although many state policies are evaluated for this project, a number of unevaluated policies<sup>b</sup> exist that could affect patient care decisions as well. This analysis also does not account for additional potential influences to consider, including:

- Non-policy actions or resources
- Policies yet to be adopted (e.g., Bills)
- Content of a policy undermining its stated intent
- Perceptions of legal or regulatory oversight that override actual policy content
- Federal/state policy initiatives to reduce non-medical use/diversion of prescription medications
- Positive policy change as only the first step to improve pain management (a thorough description of each of these factors is contained in Section IV of [http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/Evalguide\\_CY2013.pdf](http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/Evalguide_CY2013.pdf))

This evaluation also identified a few potentially relevant policy provisions for which there were no clear relationships to existing criteria. For example, North Carolina established a controlled substances reporting system with a provision stating that the Department of Health may report to the Medical Board about certain prescribing practices and patient outcomes; this provision is analogous to, but more specific than, similar information sharing that is allowed in other states. As another example, Ohio adopted into its Controlled Substances Act (1) requirements for issuing a prescription for opioids to an unemancipated person under 18 years old, and (2) more elaborate standards of care related to the access and use of prescription drug monitoring program information, but without mentioning the importance of effective pain treatment.

Further information also is needed to determine whether these policies have implications for clinical practice and patient treatment, and whether the consequence of such policies stem more from an inadequate understanding of the legal provisions rather than from the requirements established through these policies.

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<sup>b</sup> Unevaluated policies govern such issues as: Other prescribers' practice (e.g., nursing and physician assistants), controlled substances scheduling, prescribing, dispensing, or administering Schedules III-V controlled substances, advance directives or living wills, physician-assisted suicide or euthanasia, reimbursement of therapeutic interventions, worker's compensation, controlled medication importation, and program grants to state agencies.

<sup>c</sup> In recent years, many bills that have been introduced in state legislatures to combat prescription medication abuse have contained requirements that would restrict patient access to medications used for pain care. Fortunately, most of these bills have not passed; for those that have been signed into law, the final legislation has been an improvement, if not completely, over the bill language. Coordinated advocacy activities to respond to these bills create opportunities for increased policymaker awareness of potential unintended consequences, which can better ensure the avoidance of future policy impediments. Efforts must continue to ensure policies that will maintain standards for appropriate treatment while also reducing the potential for abuse and diversion.

Finally, an important prescribing standard was introduced to state policy after the evaluation period had ended. In 2016, the Maine Legislature adopted an aggregate daily dosage standard ( $\leq 100$  morphine milligram equivalents), joining Indiana, Rhode Island, and Washington as having a similar standard codified in state law (although not necessarily the same total amounts). However, Maine's standard is unique because the dosage amount ultimately is a ceiling dose that prescribers cannot exceed when treating chronic pain. In addition, it does not permit opioid treatment to continue even after specific additional requirements are met, as allowed in the other states' policies. No other state currently has such a fixed standard. Such an inflexible dosage restriction, coupled with a loss of treatment discretion around that dosage, has the potential to interfere in clinical decision-making and impede patient care.

**Research Methodology.** Project findings result from methods developed with peer review to evaluate pain policies using a central conceptual principle, policy collection procedures, and 16 criteria used to identify relevant policy provisions (see a previous evaluation report for a description of these methods, in Sections V, VII, and VIII [http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/Evalguide\\_CY2013.pdf](http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/Evalguide_CY2013.pdf)). The Central Principle of Balance, which guides this evaluation of policies influencing pain management, is defined in Table 1 and has been applied to the clinical realm as simultaneously attempting to improve pain management and reduce harms or diversion.<sup>66</sup> Balance was founded in the Single Convention on Narcotic Drugs<sup>67</sup> and is represented in the federal Controlled Substances Act<sup>68</sup> and has been supported historically by the INCB,<sup>69</sup> the WHO,<sup>68</sup> the UN ECOSOC,<sup>69</sup> and the UN Commission on Narcotic Drugs,<sup>70</sup> as well as the American Cancer Society,<sup>71</sup> the Institute on Medicine,<sup>4</sup> the DEA,<sup>72</sup> the National Association of Attorneys General,<sup>73</sup> the Federation of State Medical Boards,<sup>74</sup> the Centers for Disease Control and Prevention,<sup>39</sup> and the White House Office of National Drugs Control Policy.<sup>74</sup> The 16 criteria were developed based on the Central Principle of Balance, and are listed in Table 2. Criteria are divided into two categories and are used to identify relevant policy language in all states' statutes, regulations, and official healthcare regulatory guidelines and policy statements.



# QUANTIFYING THE QUALITY OF STATE PAIN POLICIES

Findings from the criteria-based evaluation are then converted into a grade for each state. State grades measure the quality of state policy influencing pain management, in relation to the Central Principle of Balance, and are based on the frequency of provisions in a state that meet the evaluation criteria; the higher the grade, the more balanced are a state's policies regarding pain management, including the appropriate use of pain medications. Grades are based on the total number of positive and negative provisions contained in all states' policies in effect by the end of 2015.

We recognize that a single grade may oversimplify the interpretation of a state's policies. As a result, detailed information is available about the specific statutes, regulations, and other governmental policies that were evaluated in each state; the individual policy profiles for all states can be found at [http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/State\\_Policy\\_Profiles\\_CY2015.pdf](http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/State_Policy_Profiles_CY2015.pdf). In addition, each state's pain-specific policy, in its entirety, is contained on the following website: <http://www.painpolicy.wisc.edu/database-statutes-regulations-other-policies-pain-management>

## CURRENT STATUS OF BALANCE IN STATE PAIN POLICY

States' grades as of December 31, 2015, are presented in Table 3. Again, a state's grade represents the quality of its policies affecting pain treatment, based on the Central Principle of Balance, and is calculated from the total number of provisions in a state fulfilling the evaluation criteria; higher grades mean more balanced state policies influencing pain management, including with the medical use of opioid medications. Table 4 shows each state's separate grades for positive and negative provisions. Again, the specific language identified in all evaluated policies that contributed to the grades for each state is at [http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/State\\_Policy\\_Profiles\\_CY2015.pdf](http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/State_Policy_Profiles_CY2015.pdf)

### HIGHLIGHTS OF THE 2015 GRADES

- Only one state has a grade of C, while 98% scored above a C and no states fell below the average (D+, D, or F).
- 13 states have an A: Alabama, Georgia, Idaho, Iowa, Kansas, Maine, Michigan, Oregon, Rhode Island, Vermont, Virginia, Washington, and Wisconsin.

- Generally, there is notable grade variability within U.S. Census Bureau-defined regions, but a few clear patterns emerged: three of four West South Central states (Louisiana, Oklahoma, and Texas) have a grade of C+, all three Middle Atlantic states (New Jersey, New York, and Pennsylvania) have a grade of B or B+, all nine South Atlantic states (Delaware, the District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, and West Virginia) received a grade of B or above, as did all six New England states (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont), all five East North Central states (Illinois, Indiana, Michigan, Ohio, and Wisconsin), and all five Pacific states (Alaska, California, Hawaii, Oregon, and Washington).
- The 13 states achieving an A comprise 19% of the total U.S. population. States with a B or B+ make up almost 65% of the U.S. population, largely owing to the influence of there being 31 states in these grade categories (with seven of the states being California, Florida, New York, Illinois, Pennsylvania, Ohio, and North Carolina, which are the 1<sup>st</sup>, 4<sup>th</sup>, 5<sup>th</sup>, 6<sup>th</sup>, and 7<sup>th</sup>, and 9<sup>th</sup> most populated states, respectively). Another 16% of the U.S. population live in the seven states that have a grade of C or C+, primarily owing to the population of Texas (which is the 2nd most populated state).

## NEW POLICIES

The following policy adoption is notable from the past few years:

- 11 states (Connecticut, Delaware, Florida, Georgia, Kentucky, Mississippi, Nevada, South Carolina, Tennessee, Utah, and West Virginia) adopted legislation or regulations mandating continuing education about prescribing controlled substances or opioid medications, pain management, or palliative care for licensees or for those who prescribe as staff of pain clinics.
- 8 states (Arizona, the District of Columbia, North Carolina, Pennsylvania, South Carolina, Utah, Vermont, and Wisconsin) adopted, adopted by reference or adopted based on, or updated to the Federation of State Medical Board's 2013 Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain (see following section), while another 10 states (Alaska, California, Colorado, Minnesota, New Hampshire, New Mexico, Oklahoma, Rhode Island, Tennessee, and Texas) added or updated other statutes or regulatory policies governing pain management, and another 2 states (Arkansas and Indiana) now require the development of rules governing prescribing for pain.

- 4 states (Maryland, South Dakota, Texas, and West Virginia) adopted legislation or regulations initiating or expanding their pain management, hospice, or palliative care standards in various healthcare facilities.
- 2 states (California and Massachusetts) added a law with language that directly supports the Central Principle of Balance.
- 1 state (Alabama) adopted regulations for offering addiction treatment services in the office that not only provides a definition of “addiction” that distinguishes it from physical dependence or tolerance, but also explicitly acknowledges that physical dependence occurring with a “patient on long-term opioid analgesics for pain” is distinct from ICD-10 or DSM diagnostic classification systems.
- 1 state’s (Illinois) statute governing the Prescription Drug Monitoring Program (PDMP) will now offer educational information to the program website and will regularly send updates of such information to registered program users, while 1 state’s (Vermont) PDMP regulations now offer training on how to use program information to practitioners and pharmacists, and their delegates, as well as other users.
- 1 state (Louisiana) now appears to allow pharmacists to dispense not more than a 10-day supply of a Schedule II or Schedule III opioid medication from prescription issued by an out-of-state practitioner, rather than prohibiting any such prescriptions. In doing so, the pharmacist must notify the practitioner of the partial dispensing.
- 1 state (Massachusetts) initiated an interdisciplinary advisory council within the Department of Health as a mechanism to create, maintain, and evaluate state palliative care initiatives.

## HEALTHCARE REGULATORY BOARD POLICIES

[The Federation’s Model Policies](#). To promote consistency in state medical board policy, in 1998 the Federation of State Medical Boards of the U.S. (the Federation) adopted *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Model Guidelines)*.<sup>5</sup> In May 2004, the Federation’s House of Delegates unanimously adopted a revision of the *Model Guidelines*, called the *Model Policy for the Use of Controlled Substances for the Treatment of Pain (Model Policy)*.<sup>6</sup> The revision was substantially similar to the 1998 guidelines, but additionally considered the “inappropriate treatment of pain” to include “nontreatment,” “overtreatment,” “undertreatment,” and the “continued use of ineffective treatments” – which conveyed to state boards that a failure to treat pain could be subject to professional discipline, just as persistent

prescribing despite unsuccessful treatment outcomes and other substandard practice might be. In July 2013, the Federation's House of Delegates approved a thorough content update of this policy, making it specific to opioid therapy for chronic pain (title *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*<sup>40</sup>). This model policy is currently under review to identify the need to improve guidance based on more recent literature.

Many state medical regulatory boards subsequently adopted *Model Guidelines* or *Model Policies* to encourage better pain management and to address physicians' concern about investigation.<sup>49:51,77</sup> This trend has resulted in positive changes in state pain policies and also in efforts to communicate them to practitioners and the public.<sup>78:81</sup>

As of December 2015, a total of 47 state medical or other healthcare regulatory boards or agencies had adopted policies related to pain management or prescribing for pain care, with 33 states using either the 1998 Model Guidelines, the 2004 Model Policy, or the 2013 Model Policy in whole or in part.<sup>81</sup> Most recently, 8 states (Arizona, the District of Columbia, North Carolina, Pennsylvania, South Carolina, Utah, Vermont, and Wisconsin) replaced older healthcare regulatory board policies with one based on, or else seeming to adopt by reference, the Federation's 2013 Model Policy template. The model policy templates do not have any negative provisions; states that adopt them completely receive the greatest number of positive provisions from a single policy.

Alternatively, 6 states (Kentucky, Massachusetts, Missouri, Montana, South Dakota, and West Virginia) repealed existing policy related to pain treatment or end-of-life care but, by December 31, 2015, had not transitioned to a similar regulatory policy. However, only for Missouri, Montana, and South Dakota was this repeal substantive.

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<sup>40</sup>These states are Alabama, Arizona, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Idaho, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

## REPEAL OF RESTRICTIVE OR AMBIGUOUS POLICIES

States also repealed a number of negative provisions from statutes or regulatory policy, including:

**Prescription Validity Period.** Illinois eliminated its 7-day period from its controlled substances regulation. Such change eliminates an unrealistically short number of days (Criterion #13) within which the prescription must be dispensed following its issue. A short validity period can impede a patient's ability to obtain medications without having to make arrangements that are sometimes expensive, especially when travel, slow mail delivery, or other extenuating circumstances exist. Exceeding a prescription's validity period necessitates issuance of a new prescription and possibly a return visit to the physician. Only two states continue to have a validity period of less than two weeks.

**Unprofessional Conduct Standard.** New Hampshire deleted the requirement (Criterion #15) for "unprofessional conduct" to be met by a failure to strictly adhere to prescribing standards that do not allow treatment flexibility. Making any deviation a basis for "unprofessional conduct" does not allow for treatment flexibility based on reasonable cause and imposes a potential for professional liability based on clinical practice guidelines that may not apply to all patients and clinical situations. No other state has the same or similar requirement.

**Ambiguities in Prescription Filling Standard.** North Carolina repealed the requirement for pharmacists to determine that a prescription is harmful or not in the best interest of a patient, as a means of questioning the prescription's validity, which introduced ambiguity about how the pharmacist's determinations would be made or supported (Criterion #16: Category A). No other state has the same or similar requirement.

**Intractable Pain Treatment Act (IPTA).** Tennessee repealed the entire IPTA from statute. The definition of "intractable pain," because it occurred in law, implied that the medical use of opioids is outside legitimate professional practice (Criterion #10) and suggested that physicians would not qualify for the immunity provided by the law if they prescribe opioids as a treatment of first choice for patients, even if the patient is suffering from severe pain (Criterion #16: Category B). However, the definition of "intractable pain" remains in the medical board regulations. The IPTA also contained a definition of "chemical dependency" that could be established only by the presence of physical dependence (Criterion #11, see below), as well as

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<sup>e</sup> These states are Delaware and Hawaii.

ambiguous statements (Criterion #16: Category B) related to the term “severe chronic intractable pain” and the extent that provisions provide specific rights to pain management. Eight states continue to define “intractable pain” (or “chronic pain”) in law that can convey the ambiguous practice messages described above.<sup>8</sup>

**Opioids Mandated as Last Resort** Tennessee repealed language that requires patients to undergo other treatment modalities before being prescribed opioids and other controlled substances, regardless of the clinical circumstance (Criterion #9). No other state has the same requirement.

**Definitions of “Drug Dependent Person.”** Wyoming repealed the term “drug dependent person,” while Tennessee repealed “chemical dependency” from statute and “dependence” from a 1995 medical board policy statement (Criterion #11). Such definitions could be established only by the presence of physical dependence. When the definitions occur in law, such as was in Tennessee and Wyoming, they could legally classify a person who is being treated with opioid pain medications. Twelve states continue to define “drug dependent person” (or “narcotic-dependent person,” “addict,” “active addiction,” “narcotic addict,” or “habitué”) in law, which has the potential to stigmatize patients with pain and restrict prescribing practices, which could lead to inadequate pain management.

## **NEW RESTRICTIVE OR AMBIGUOUS POLICY LANGUAGE**

A few states adopted restrictive or ambiguous policy language in the past few years:

- Codifies prescribing limits in pain clinic regulations, which replicates the limits established in statute but fails to allow the exception found in statute and, therefore, additionally creates an inconsistent standard (Louisiana),
- Introduced into regulations a series of requirements specific only to prescribing a hydrocodone-only extended-release medication that is not an abuse-deterrent formulation, which requires, among other things, a Letter of Medical Necessity. Although states can be more restrictive than Federal law, there is no basis for comparison of such a requirement, especially in relation to a single FDA-approved medication. In addition, the regulation states that nothing in this new standard “shall alter the standard of care a licensee must use when prescribing any [emphasis added]

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<sup>8</sup> These states are Arkansas, Colorado, Minnesota, Mississippi, Missouri, Nevada, Ohio, and Texas.

<sup>9</sup> These states are Arizona, Hawaii, Indiana, Louisiana, Maryland, Missouri, Nebraska, Nevada, New Jersey, North Carolina, Oklahoma, and Pennsylvania.

Schedule II, III, or IV controlled substance.” Since hydrocodone-only extended-release medication is classified in Schedule II, the stated implication of this provision therefore seems ambiguous. The requirement of a Letter of Medical Necessity also is replicated in the pharmacy board regulations (Massachusetts),

- Mandates consultation (Texas) and
- Establishes a requirement for obtaining an “appropriate consultation,” when providing pain management services to a person with a substance use disorder, without specifying the meaning of “appropriate” or who makes this determination (in New Mexico osteopathic medicine board regulations).

Table 5 shows the number of states with statutes, regulations, or guidelines or policy statements that contain language which meets the criteria for both types of policy provisions. It is important to note that each criterion, but especially criteria #8, 15, and 16, could be fulfilled multiple times in the cumulative policies from a single state.

## IMPLICATIONS FOR FUTURE POLICY ACTIONS

### SPECIAL OPPORTUNITIES

Some states are in a unique position of being able to achieve significant policy change either by adopting positive policy or repealing restrictions. Alaska, Illinois, and North Dakota currently have no restrictive or ambiguous language in their state’s pain policies. These states could achieve an A simply by adopting additional positive language. Another 13 states could have received an A had one or two restrictive or ambiguous provisions been repealed.

### SPECIAL CHALLENGES

By the end of 2015, all but one state (98%) had a grade above a C, which represents an overall positive policy environment across the nation. However, for many states to achieve more balanced and consistent pain policy, they face the challenge of removing long-outdated negative provisions from state statutes and regulations, some of which have been present for 30 years or more. Negative provisions restricting professional practice are not a necessary part of the laws needed for drug control. To be sure, states may enact laws or other governmental policies that are stricter than federal law, and should be free to experiment and differ in their

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<sup>h</sup> These states are Arizona, California, Connecticut, Delaware, Kentucky, Maryland, Minnesota, New Hampshire, Ohio, South Carolina, Utah, West Virginia, and Wyoming.

approaches to public policy. However, it is necessary to ensure that all such policies do not unduly restrict healthcare practice and patient care decisions.

Only five states corrected potential legislative or regulatory impediments in the past few years. Such limited policy change suggests a decline in legislative and regulatory consideration about reducing policy barriers to patient care. This situation is particularly challenging because, importantly, 32 states (84%), of those remaining 38 states that do not have an A, can achieve a positive grade change only by repealing restrictive or ambiguous policy language.

One of the most frequent negative provisions remaining in state policy is terminology that confuses physical dependence with addiction. Although 38 states have adopted language that clarifies the distinction between these clinical phenomena, which usually is contained in healthcare regulatory guidelines or policy statements, the statutes of 11 states and the regulations in two states continue to classify physical dependence as synonymous with addiction. Consequently, eight states have conflicting standards about what constitutes addiction, which are present in different policies and can create confusion for practitioners. Also, a definition of addiction (or drug dependence) in law, which can be established solely by the presence of physical dependence, can legally classify as an “addict” a patient who is being treated with opioid pain medications. When such a standard is applied in practice, it has the potential to stigmatize pain patients and restrict prescribing practices, leading to inadequate pain management. Most states’ statutory definitions of addiction were modeled after the definition of “drug dependent person” found in the federal Public Health and Welfare Act (42 USCS § 201), which is still present and was created over 45 years ago. Special attention should be given to repealing this prevalent state statutory or regulatory definition that no longer conforms to the current medical and scientific understanding of addiction.

A particular challenge continues to be in those few states that have a considerable number of positive provisions but also have many negative provisions. For these states, there must be a continued focus on reducing the number of restrictive or ambiguous provisions for any positive grade change to occur.

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<sup>i</sup> These states are Illinois, New Hampshire, North Carolina, Tennessee, and Wyoming.

<sup>j</sup> These states are Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Indiana, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Utah, West Virginia, and Wyoming.

<sup>k</sup> These states are Arizona, Hawaii, Louisiana, Maryland, Nebraska, Nevada, North Carolina, and Oklahoma.

<sup>l</sup> These states are Louisiana, Missouri, Nevada, Oklahoma, Tennessee, and Texas.




In addition, there are a few states (Missouri, Montana, North Dakota, and South Dakota) for which policies addressing the treatment of pain, including the use of controlled substances, are present for neither the medical nor pharmacy boards. In these states, clinicians are not provided guidance from their licensing agency about what is considered acceptable approaches related to pain management, including the use of pain medications for legitimate medical purposes.

Finally, only two states (Missouri and South Dakota) now face the challenge not only of adopting positive policies, but of removing restrictive or ambiguous language from legislation or regulations, to achieve a grade of A. Even for states that have achieved an A, there remains the potential for additional policy activity (however well-intentioned) to introduce potentially restrictive or unclear requirements. Continued efforts to enhance pain management through state policy must avoid unintended restrictions or ambiguities in order to maintain grade improvements.

## CONCLUSIONS

Policy adoption in the past few years represents continued momentum apparently in response to increasing national and state-level recognition that policy change in relation to professional practice and patient care is a necessary step in improving pain management for patients with cancer, HIV/AIDS, and other diseases or conditions. Modifying policy also has occurred during a period of increase in the abuse and diversion of prescription medications, including opioid pain medications.<sup>74;82-91</sup> Importantly, the policy characteristics represented in this evaluation are not designed to undermine the basic prohibitions against drug trafficking and diversion established in drug control or healthcare regulatory policies; it is not likely that states with higher grades have weakened their ability to prevent prescription medications abuse and diversion or to deal with unprofessional conduct. As a result, improving policies related to pain care does not have to threaten the viability of existing abuse- and diversion-control systems.

A public health approach to preventing prescription drug abuse is needed that is compatible with the Central Principle of Balance,<sup>66;92;93</sup> as seen with the 2011 White House Office of National Drug Control Policy strategy,<sup>74</sup> and with subsequent strategies.<sup>94;95</sup> Policy across the nation that seeks to balance medication abuse mitigation with appropriate pain management can be achieved and maintained if policymakers and healthcare practitioners work together, use the Central Principle as a guide, and take advantage of available policy resources. Indeed,



much of the state policy designed to address the non-medical use of prescription opioids, which has been formally adopted in the past five years, has avoided restrictive or ambiguous requirements while also maintaining a context of medication availability for medical purposes. Given the prevalent state-level activity focusing solely on prescription medication abuse, however, it is likely that potentially restrictive policies are on the horizon for patients with pain, as exemplified by Maine's 2016 legislation establishing a daily dosage ceiling when treating non-cancer pain – a codified dosing amount that cannot be exceeded and is explained in more detail in the Examples of Unevaluated Policies section. It remains critical for people with pain, especially those experiencing severe pain, that efforts by members of government and regulatory agencies, as well as healthcare professionals, must continue addressing abuse and diversion while not interfering with legitimate healthcare practices and patient access to appropriate pain care. Findings from this policy research are intended to inform technical assistance to government agencies, professionals, and groups working to improve policy governing pain, palliative care, and end-of-life care.

## Table 1: The Central Principle of Balance

The **Central Principle of Balance** represents a dual obligation of governments to establish a system of controls to prevent abuse, trafficking, and diversion of narcotic drugs while, at the same time, ensuring their medical availability.

### **Medical Availability**

- While opioid analgesics are controlled drugs, they are also essential drugs and are absolutely necessary for the relief of pain.
- Opioid analgesics should be accessible to all patients who need them for relief of pain.
- Governments must take steps to ensure the adequate availability of opioids for medical and scientific purposes, including:
  - Empowering healthcare practitioners to provide opioids in the course of professional practice,
  - Allowing them to prescribe, dispense and administer according to the individual medical needs of patients, and
  - Ensuring that a sufficient supply of opioids is available to meet medical demand.

### **Drug Control**

- When misused, opioids pose a threat to society.
- A system of controls is necessary to prevent abuse, trafficking, and diversion, but the system of controls is not intended to diminish the medical usefulness of opioids, nor interfere in their legitimate medical uses and patient care.

Adapted from Pain & Policy Studies Group *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation* (CY 2013) University of Wisconsin Carbone Cancer Center. Madison, WI; 2014.

**Table 2: Criteria Used to Evaluate State Pain Policies**

***Positive Criteria: Criteria that identify policy language that enhance safe and effective pain management***

- # 1 Controlled substances are recognized as necessary for public health
- # 2 Pain management is recognized as part of general healthcare 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 legitimacy of prescribing
- # 7 Physical dependence or analgesic tolerance are not confused with "addiction"
- # 8 Other provisions that may enhance pain management
  - Category A: Issues related to healthcare professionals
  - Category B: Issues related to patients
  - Category C: Regulatory or policy issues

***Negative Criteria: Criteria that identify policy language that impede safe and effective pain management***

- # 9 Opioids are relegated as only a treatment of last resort
- # 10 Medical use of opioids is implied to be outside legitimate professional practice
- # 11 Physical dependence or analgesic tolerance are confused with "addiction"
- # 12 Medical decisions are restricted
  - Category A: Restrictions based on patient characteristics
  - Category B: Mandated consultation for all patients
  - Category C: Restrictions regarding quantity prescribed or dispensed
  - Category D: Undue prescription limitations
- # 13 Length of prescription validity is restricted
- # 14 Practitioners are subject to undue prescription requirements
- # 15 Other provisions that may impede pain management
- # 16 Provisions that are ambiguous
  - Category A: Arbitrary standards for legitimate prescribing
  - Category B: Unclear intent leading to possible misinterpretation
  - Category C: Conflicting or inconsistent policies or provisions

**Table 3: State Grades for 2015**

<b>STATES</b>	<b>2015GRADES</b>
Alabama	A
Alaska	B+
Arizona	B+
Arkansas	B
California	B+
Colorado	B
Connecticut	B+
Delaware	B+
District of Columbia	B
Florida	B
Georgia	A
Hawaii	B
Idaho	A
Illinois	B
Indiana	B+
Iowa	A
Kansas	A
Kentucky	B+
Louisiana	C+
Maine	A
Maryland	B+
Massachusetts	B
Michigan	A
Minnesota	B+
Mississippi	B+
Missouri	C
Montana	C+
Nebraska	B
Nevada	C+
New Hampshire	B+
New Jersey	B
New Mexico	B
New York	B
North Carolina	B+
North Dakota	B
Ohio	B+
Oklahoma	C+
Oregon	A
Pennsylvania	B+
Rhode Island	A
South Carolina	B+
South Dakota	B
Tennessee	C+
Texas	C+
Utah	B+
Vermont	A
Virginia	A
Washington	A
West Virginia	B+
Wisconsin	A
Wyoming	B+

**Table 4: State Grades for Positive & Negative Provisions – 2015**

<b>STATES</b>	<b>(+) 2015</b>	<b>(-) 2015</b>
Alabama	A	A
Alaska	B	A
Arizona	A	B
Arkansas	A	C
California	A	B
Colorado	A	C
Connecticut	A	B
Delaware	A	B
District of Columbia	A	B
Florida	A	C
Georgia	A	A
Hawaii	A	C
Idaho	A	A
Illinois	C	A
Indiana	A	B
Iowa	A	A
Kansas	A	A
Kentucky	A	B
Louisiana	A	D
Maine	A	A
Maryland	A	B
Massachusetts	A	C
Michigan	A	A
Minnesota	A	B
Mississippi	A	B
Missouri	B	D
Montana	D	A
Nebraska	A	C
Nevada	A	D
New Hampshire	A	B
New Jersey	A	C
New Mexico	A	C
New York	A	C
North Carolina	A	B
North Dakota	C	A
Ohio	A	B
Oklahoma	A	D
Oregon	A	A
Pennsylvania	A	B
Rhode Island	A	A
South Carolina	A	B
South Dakota	B	B
Tennessee	A	D
Texas	A	D
Utah	A	B
Vermont	A	A
Virginia	A	A
Washington	A	A
West Virginia	A	B
Wisconsin	A	A
Wyoming	A	B

**Table 5: Number of States in 2015 with Policy Language Having Potential to Enhance or Impede Pain Management**

<b>Positive provisions</b>	<b>Number of states</b>
1. Controlled substances are recognized as necessary for public health	4
2. Pain management is recognized as part of general healthcare practice	45
3. Medical use of opioids is recognized as legitimate professional practice	51
4. Pain management is encouraged	40
5. Practitioners' concerns about regulatory scrutiny are addressed	39
6. Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing	32
7. Physical dependence or analgesic tolerance are not confused with "addiction"	38
8. Other provisions that may enhance pain management	
Category A: Issues related to healthcare professionals	47
Category B: Issues related to patients	44
Category C: Regulatory or policy issues	50
<b>Negative provisions</b>	<b>Number of states</b>
9. Opioids are relegated as only a treatment of last resort	0
10. Medical use of opioids is implied to be outside legitimate professional practice	6
11. Physical dependence or analgesic tolerance are confused with "addiction"	12
12. Medical decisions are restricted	
Category A: Restrictions based on patient characteristics	5
Category B: Mandated consultation for all patients	7
Category C: Restrictions regarding quantity prescribed or dispensed	1
Category D: Undue prescription limitations	2
13. Length of prescription validity is restricted	2
14. Practitioners are subject to additional prescription requirements	6
15. Other provisions that may impede pain management	0
16. Provisions that are ambiguous	
Category A: Arbitrary standards for legitimate prescribing	14
Category B: Unclear intent leading to possible misinterpretation	14
Category C: Conflicting or inconsistent policies or provisions	5

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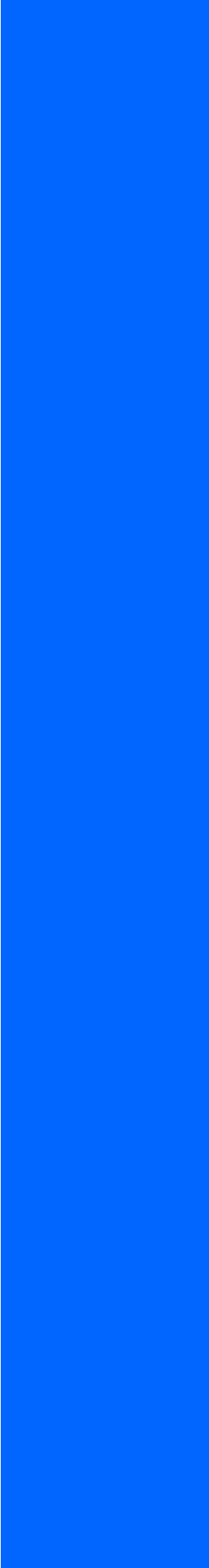
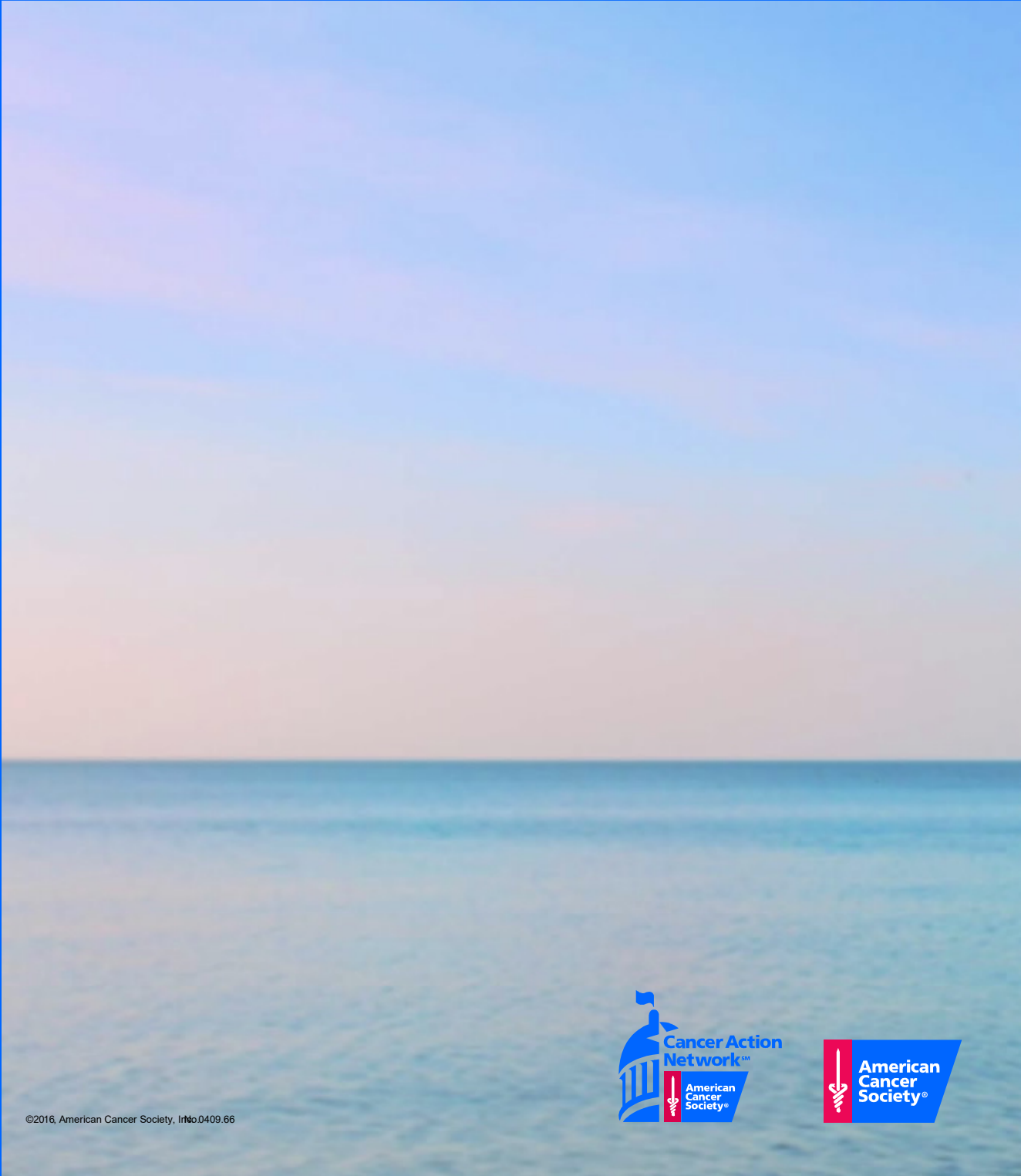


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