State Pain Policy Rating
2018 Methodology

On August 9,2018, the American Cancer Society Cancer Action Network (ACS CAN), American Cancer Society (ACS) and the Sonderegger Research Center at the University of Wisconsin School of Pharmacy released its 2018 State Pain Policy Rating. The detailed information on states' pain policy ratings can be found at www.acscan.org/painreportcard. Following are details regarding the methodology used to determine state ratings.

Updating the Methodology

Previous versions of state ratings used a methodology established more than a decade ago. In 2017, a process began to update this methodology to incorporate the latest model policies and the current policy environment. Stakeholders convened a workgroup of pain or policy experts, who met a total of six times to discuss: (1) a description of the project and process, and expected outcomes, (2) review and comments about initial criteria, including ideas for new criteria, (3) review of new and modified criteria, (4) initial ideas about developing a state rating methodology, and (5) review of a pilot test of the initial rating methodology. Decisions were made via workgroup consensus.

The resulting methodology includes a process conforming to formal ***Policy Surveillance*** methodology, new organizational structure of the data, new content (including data on prescription monitoring programs), and a new 3-category rating classification. As such, ***please note that the ratings provided now and in the future cannot be compared to previous state ratings.***

2018 Methodology

Phase 1 – Policy Identification: For the purpose of this evaluation, the types of policies evaluated comprise:

- ***Statutes*** - are laws created by a legislative body;
- ***Regulations*** - an official policy issued by an agency of the executive branch of government pursuant to statutory authority. Regulations are found in the state administrative code. Regulations have binding legal force and are intended to implement the administrative policies of a statutorily-created agency; and
- ***Guidelines -*** an officially adopted policy issued by a government agency to express the agency's attitude about, or position on, a particular matter. While guidelines do not have binding legal force, they may help those regulated by an agency to better understand the regulating agency's standards of practice. Guidelines do not include clinical practice guidelines, unless adopted as such by a regulatory agency.

Cumulatively, the policy population studied for this surveillance project is relevant to pain management, palliative care, or end-of-life care, including the use of controlled pain medications. For the purpose of this evaluation, the policies evaluated are (1) controlled substances statutes and regulations, (2) medical, osteopathic, and pharmacy practice statutes and regulations, (3) guidelines (or policy statements) from the boards of medicine, osteopathy, and pharmacy, (4) statutes and regulations establishing practice standards for patient care in healthcare facilities, and (5) statutes and regulations establishing prescription monitoring programs (PMPs). The evaluation of provisions governing controlled substances (e.g., opioid analgesics) included only those relevant to Schedule II. Importantly, of these statutes and regulations, the policy surveillance does not extend to sections of law governing

pain management clinics, since a separate analysis (conducted by others, at http://pdaps.org/datasets/pain-management-clinic-laws) covers these standards. Also, these various policies do not include local or non-legal institutional policies.

The laws relevant to this project were subjected to a keyword search of words or phrases extracted from each criterion. All keywords were applied to the statutes and regulations governing controlled substances, medical, osteopathic, and pharmacy practice, since these comprised the focal policy population used for this study. In addition, a separate keyword search was used to identify laws related to pain management and healthcare facilities from within all state's statutes and regulations, since experience has proven that relevant content for such topics could occur outside the original narrow policy scope chosen for this project. Keyword searches were not used for non-legal policies collected from regulatory board websites, given that many of these documents were not downloadable in a searchable format. Rather, the entire content of guidelines or policy statements were identified and read manually.

Phase 2 – Policy Collection: Researchers used LexisNexis® Academic, an electronic legal database, to identify the specific statutes and regulations (outlined in Phase 1) for each state. All state healthcare regulatory board websites (i.e., for the medical, osteopathic, and pharmacy boards) also were explored to determine if they contain official relevant guidelines or policy statements that were adopted by the board and remain in effect; if such policies were identified, they were electronically downloaded and added to the collection for review. All relevant policies were collected if they were current as of December 31, 2017.

Phase 3 – Policy Review: All relevant policies that were in force and available as of December 31, 2017, were examined for this evaluation.[1] This process involves reviewing policy to extract information based only on observable features (i.e., a black letter review of policy that does not consider its implication or intent). Two researchers independently reviewed all policies to become knowledgeable about their content.

Phase 4 – Application of Criteria to Policy: To evaluate policies for this report card, 21 separate criteria were used, categorized into 4 domains:

Domain 1 *Policy Definitions and Prescription Limits*	**Domain 2** *Efforts to Assess and Improve Pain Treatment*	**Domain 3** *Expectations of Healthcare Practitioners for Pain Treatment*	**Domain 4** *Prescription Monitoring Programs*
5 criteria	4 criteria	6 criteria	6 criteria

See Figure 1 for a full listing of the criteria guiding the state ratings.

Criteria were chosen based on model statutes or regulatory policies. ***Model statutes or regulatory policies*** are created by national organizations for the specific purpose of providing guidance to

[1] Despite the systematic policy collection method used for this surveillance project, it is possible that policies language that was relevant and had an effective date within the project timeframe was inadvertently overlooked. Also, policies in effect on or after January 1, 2018, were not reviewed for this project. However, such policies were noted and will be included in future ratings.

legislatures and regulatory agencies during drafting and promulgation of relevant laws or policies. Model laws or policies in effect during the timeframe of this evaluation are:

- Federation of State Medical Boards *Essentials of a State Medical and Osteopathic Practice Act* and *Guidelines for the Chronic Use of Opioid Analgesics* (http://www.fsmb.org/globalassets/advocacy/policies/guidelines-for-the-structure-and-function-of-a-state-medical-and-osteopathic-board.pdf);
- The Joint Commission on Accreditation of Health Care Facilities facility standards (https://www.jointcommission.org/topics/pain_management.aspx);
- National Alliance for Model State Drug Laws *Model Prescription Monitoring Program Act* (http://www.namsdl.org/library/A7108378-A300-A79A-8A711DB342E275F6/);
- National Association of Boards of Pharmacy *Model State Pharmacy Act and Model Rules* and *Model Prescription Monitoring Program Act* (https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/);
- National Association of State Controlled Substances Authorities *Model Prescription Monitoring Program Act* (http://nascsa.org/nascsaPMP/nascsaPMPmodelAct/NASCSApmpmodelAct2016.pdf);
- National Conference of Commissioners on Uniform State Laws *Uniform Controlled Substances Act* (http://www.uniformlaws.org/shared/docs/controlled%20substances/UCSA_final%20_94%20with%2095amends.pdf); and
- Current Federal statutes (Controlled Substances Act https://www.deadiversion.usdoj.gov/21cfr/21usc/index.html) and regulations (Code of Federal Regulations https://www.deadiversion.usdoj.gov/21cfr/cfr/index.html).

Using a redundant coding procedure, in compliance with a health policy research methodology created at the Temple University's Beasley School of Law Center for Public Health Law Research, two researchers independently coded all reviewed policies, in batches of five states, to conclude whether provisions fulfilled any criterion. Aggregate coding agreement scores also were calculated to measure rating divergence across the review timeframe. Divergence scores consistently were below 5 percent, achieving the threshold established by the Center for Public Health Law Research standards. Whenever rating discrepancies were identified, reasons were discussed (e.g., did the discordance stem from interpretive differences or merely oversight?), and rating consensus was achieved.

Phase 5 – Rating Policy Based Content: As mentioned previously, the conceptual framework underlying this policy surveillance project represents the relationship of the criteria to model statutes or regulatory policies. That is, all criteria are informed by the contents of at least one federal or national model policy that is now relevant to the subject of a specific criterion.

Three factors characterize the *unweighted summative index* approach used to calculate the state ratings. First, there is presently an insufficient evidence basis to guide value allocation for most criteria based on their potential effects, so criteria weights could not be validly conceptualized. As a result, all criteria are assigned equal weights (i.e., each criterion was assigned 1 point – except that *education for practitioners* and *methods for healthcare facilities* could achieve a maximum of 2 points). Second, no "value" distinction was made based on the type of policy in which a criterion is found because evidence does not exist demonstrating that laws influence practice behaviors more than guidance documents issued directly from an authoritative regulatory board. As a result, point allocation did not differ depending on whether the criterion was fulfilled by statute, regulation, or guideline. Finally, the correspondence of detail between statutes and regulations is highly variable across states, with some states replicating requirements in both types of laws while other states do not. As a result, credit is given only once when a state fulfills a criterion, regardless of the total number of times that criterion is similarly fulfilled throughout all existing policies (i.e., statutes, regulations, and guidelines). Given these

three considerations, ratings are based on each state's total points earned within a range determined by the cumulative number of criteria and point allocations. Total points range from 0 to 24, with a maximum of 6 points possible for each of the 4 domains. A three-category state rating classification is used to reflect the degree to which a state's policies are consistent with recommendations from current model policies that are most relevant to the topic of this project. The 3 categories of ratings are:

Below 50% match to model policy	***50%-80% match to model policy***	***Above 80% match to model policy***
Represented as red in map	Represented as yellow in map	Represented as green in map

Figure 1

Domain 1: Policy Definitions

1. Does the **practice of medicine** include the treatment of pain?

2. Does the **policy** define **addiction** not based solely on physical dependence or tolerance?

    Is there a statement that physical dependence or tolerance are not considered addiction?

3. Does the policy avoid defining a maximum amount for a **prescription** of a **controlled substance**?

    What is the maximum amount for a prescription of a controlled substance?
    Fulfilled by maximums of < 30 day supply or those including a dosage limit with no exceptions

4. Does the policy avoid defining a duration for which a prescription for a controlled substance is valid?

    What is the duration for which a prescription for a controlled substance is valid?
    Fulfilled by maximums of < 2 weeks with no exceptions

5. Does the policy avoid defining "**unprofessional conduct**" to include **excessive prescribing**?

    Does the policy include factors determining "excessive prescribing"?

Domain 2: Establishing a Context for Pain Treatment

1. Does the policy state the need to reduce **harms** from controlled substances while maintaining **patient care**?

2. Does the policy establish that a regulatory board will use individual case characteristics to judge the validity of **pain treatment**?

3. Does the policy establish an **education course** for **practitioners** or pharmacists to improve pain treatment?

4. Does the policy establish methods for **healthcare facilities** to improve pain treatment?

Domain 3: Practitioner Expectations for Pain Treatment

1. Are practitioners expected to consider **integrative care** during pain treatment?

2. Are practitioners expected to provide **individualized care** during pain treatment?

3. Are practitioners expected to assess **patient functioning** during pain treatment?

4. Are practitioners expected to engage in shared decision-making with patients when considering pain treatment options?

5. Are practitioners expected to assess or discuss patient benefits and/or risks before initiating pain treatment?

6. Are practitioners expected to monitor patient benefits and/or risks during pain treatment?

Domain 4: PMP-Related Content

1. Does the policy require that dispensing data be submitted to the PMP no later than the next business day after dispensing?

2. Does the policy authorize the PMP to share data with other state PMPs?

3. Are practitioners required to register with the PMP?

4. Are practitioners required to check the PMP before initially prescribing a controlled substance?

5. Does the policy require teaching practitioner or pharmacist users about the PMP?

6. Does the policy require the PMP governing agency to review program information to identify **inappropriate use** of monitored medications?