

# **Research Protocol for State Laws and Other Regulatory Policies Related to Pain Care**

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## State Laws and Other Regulatory Policies Related to Pain Care

- I. **Date of Protocol:** December 2017
  
- II. **Scope:** Compile, code, and analyze state-level laws and other regulatory policies governing pain treatment, including for palliative care and end-of-life care; this is a legal content review based only on observable features. The defined policy field for this project encompasses (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 that are meant to govern healthcare practice in the state, but also is designed to identify (4) statutes and regulations establishing practice standards for patient care in healthcare facilities, and (5) statutes and regulations establishing prescription monitoring programs (PMPs). This cross-sectional dataset analyzes important features of state pain-related law and other regulatory policies, including to the prescribing of controlled substances (specifically Schedule II opioid analgesics), definitions creating parameters for healthcare practice, delineating standards for evaluating and improving pain treatment including practitioner expectations for such treatment, and characteristics of state PMPs.
  
- III. **Primary Data Collection**
  - a. **Project Dates:** January 2018 – September 2018.
  
  - b. **Dates Covered in the Dataset:** Laws and policies active as of December 31, 2017. This is a cross-sectional dataset analyzing state pain-related laws and other regulatory policies as they are in effect at one point in time, December 31, 2017. The effective date listed for each state is the date of the most recent version of the statute, regulation, or other regulatory policy within that state. If more than one law or regulation is included in the legal text for a state, the effective date reflects the date of the most recently amended or enacted statute, regulation, and other regulatory policy within the legal text.
  
  - c. **Data Collection Methods:** Staff in the Sonderegger Research Center of the University of Wisconsin-Madison School of Pharmacy comprise the Team who built this dataset. The Team consisted of two policy researchers (Researchers), including one supervisor (Supervisor). This project is unique because the Researchers were also the subject matter experts responsible for defining the scope of the laws and other regulatory policies included in this dataset. Lexis Academic was used to identify which states had state pain-related laws in effect as of December 31, 2017. Non-legal regulatory policies were identified and collected directly from the websites of regulatory boards governing physicians, osteopathic physicians, and pharmacists. As informed by previous data collection and interactions with boards, board policy was considered adopted if an active link was available through the website and when no explicit statement indicated that the policy was not considered to govern professional practice.

Secondary sources were also used to help initially identify state laws governing prescribing limits, continuing education, and PMPs:

- i. Brandeis PDMP Center of Excellence’s PDMP Maps and Tables (content contemporaneousness varied depending on topic)
- ii. Federation of State Medical Boards’ (FSMB’s) Continuing Medical Education by State (current through January 30, 2018)
- iii. National Alliance for Model State Drug Laws’ (NAMSDL’s) State Prescription Monitoring Program Statutes and Regulations List (current through May 2016)
- iv. NAMSDL’s Overview of Pain Management and Prescribing Policies (current through January 2016)
- v. Prescription Drug Abuse Policy System’s (PDAPs’) Prescription Drug Monitoring System database (current through July 1, 2016)

**d. Databases Used:** Research was conducted using Lexis Academic, state-specific medical, osteopathic, and pharmacy board websites, and secondary sources from Brandeis, FSMB, NAMSDL, and PDAPs.

- i. Full text versions of the regulatory guidelines or policy statements collected were pulled from each respective state regulatory board website.

**e. Search Terms:**

- i. Keyword searches: (January 23 & 24, 2018, for Batch 1 – All other searches occurred March 19-28, 2018, unless otherwise specified)

**1. Domain 1: Policy Definitions**

- a. Practice w/100 Pain
- b. Addict!
- c. Substance use
- d. Dependence!
- e. Habitue
- f. Abuse
- g. Nontherapeutic
- h. Issuance
- i. Amount
- j. Dos!
- k. Supply
- l. Equivalence!
- m. Days
- n. Months
- o. Prescri!
- p. Valid
- q. Unprofessional
- r. Discipline!
- s. Revocation
- t. Excess!

- u. Not medically
- v. Endanger
- 2. Domain 2: Establishing a Context for Pain Treatment**
  - a. Harm
  - b. Diversion
  - c. Abuse
  - d. Poisoning
  - e. Overdose
  - f. Death
  - g. Patient care
  - h. Determin!
  - i. Judgement
  - j. Allegations
  - k. Conduct
  - l. Criteria
  - m. Inappropriate
  - n. Review
  - o. Evaluat!
  - p. Case by case
  - q. Individual
  - r. Totality
  - s. Clinical
  - t. Circumstances
  - u. Appropriate strategy
  - v. Achieving w/5 goals
  - w. Prescri!
  - x. Continuing w/5 educat!
  - y. Educat!
  - z. Curricul!
  - aa. Course
  - bb. Standard
  - cc. Accept
  - dd. Web
- 3. Domain 2a: Establishing a Context for Pain Treatment in Health Facilities** – Since laws regulating healthcare facilities can occur outside of the defined policy field, this keyword search was applied to all state laws (conducted on March 19-27, 2018).
  - a. Facility w/250 Pain
  - b. Hospital w/250 Pain
  - c. Hospice w/250 Pain
  - d. Long-term care w/250 Pain
  - e. Nursing home w/250 Pain
  - f. Assisted living w/250 Pain
  - g. Ambulatory care w/250 Pain

- h. Licensure w/250 Pain
- i. Resident w/250 Pain
- 4. Domain 3: Practitioner Expectations for Pain Treatment**
  - a. Pain
  - b. Integrat!
  - c. Pharmacologic
  - d. Non-pharmacologic
  - e. Collaborat!
  - f. Interdisciplinary
  - g. Multidisciplinary
  - h. Individual care
  - i. Tailored
  - j. Patient function!
  - k. Quality of life
  - l. Shared w/20 deci!
  - m. Benefit
  - n. Risk
  - o. Harm
  - p. Diversion
  - q. Abuse
  - r. Poisoning
  - s. Overdose
  - t. Death
- 5. Domain 4: PMP-Related Content** – After the initial keyword search, it became clear that a broader application was required since many potentially-relevant PMP-related laws remained outside of the defined policy field. The NAMSDL State Prescription Monitoring Program Statutes and Regulations List (current through May 2016) was used to guide identification of PMP laws throughout all states’ statutes and regulations (keyword searches conducted on April 16-18, 2018). These laws were then downloaded and read manually to distinguish applicable language. Also, it should be noted that many states have become participants in the National Association of Boards of Pharmacy’s PMP InterConnect, which facilitates PMP interoperability, despite not having laws explicitly authorizing such data sharing.
  - a. Prescription monitoring
  - b. Prescription drug monitoring
  - c. Dispens!
  - d. Transmi!
  - e. Business
  - f. Day(s)
  - g. Twenty-four (24) hours
  - h. Minutes
  - i. Real time

- j.** Report
- k.** Week
- l.** Daily
- m.** Submit
- n.** Share w/20 data
- o.** Interoperab!
- p.** Regist!
- q.** Reciprocal
- r.** Agreement
- s.** Other
- t.** Another
- u.** Interstate
- v.** Exchang!
- w.** Access
- x.** Database
- y.** Information
- z.** Apply
- aa.** Application
- bb.** Enroll
- cc.** Authori!
- dd.** Certif!
- ee.** Check w/20 prescri!
- ff.** Before prescri!
- gg.** Prior to initial prescri!
- hh.** Query
- ii.** Run w/5 report
- jj.** Before initiating
- kk.** Initial w/10 prescri!
- ll.** First time
- mm.** Prior to starting
- nn.** When starting
- oo.** Continuing w/5 educat!
- pp.** Train
- qq.** Tutorial
- rr.** Educational tutorial
- ss.** Course
- tt.** Review
- uu.** Unprofessional
- vv.** Illegal
- ww.** Misuse
- xx.** Abuse
- yy.** Diversion
- zz.** Violation
- aaa.** Outside w/10 standards

- bbb.** Improper
  - ccc.** Inappropriate
  - ddd.** Breach w/10 standards
  - eee.** Questionable
  - fff.** Parameters
  - ggg.** Indicators
  - hhh.** Criteria
  - iii.** Deviate
  - jjj.** Aberrant
  - kkk.** Patterns
  - lll.** Disciplinary action
  - mmm.** Identify w/10 prescribers
  - nnn.** Harmful
  - ooo.** Abnormal
  - ppp.** Unusual
  - ii.** Key word searches were supplemented by reviewing the table of contents chapters for pain-related statutes and regulations within the defined policy field.
  - iii.** Once all the relevant statutes and regulations were identified for a jurisdiction, a Master Sheet was created for each jurisdiction. The Master Sheet for each jurisdiction includes the most recent policy history for each statute, regulation, or other regulatory policy. The most recent effective dates, or the date when a version of law or regulation becomes enforceable, are recorded for each relevant statute, regulation, and other regulatory policy.
  - iv.** All 51 jurisdictions were 100% independently, redundantly, researched to better ensure that all relevant law was collected by the Researchers.
  - v.** Divergences, or differences between the original research and redundant research, were reviewed by the Supervisor and resolved by Team consensus.
- f. Initial Returns and Additional Inclusion or Exclusion Criteria:** Included laws pertaining to state-level pain care laws.
- i.** The following variables were included in the state pain policy dataset:
    - 1. Domain 1: Policy Definitions**
      - a.** Defining practice of medicine to include pain treatment
      - b.** Defining addiction not based solely on physical dependence or tolerance
        - i.** Statement that physical dependence or tolerance are not considered addiction
      - c.** Defining a maximum amount for a prescription of a controlled substance
      - d.** Defining a duration for which a prescription for a controlled substance is valid
      - e.** Defining “unprofessional conduct” to include excessive prescribing
    - 2. Domain 2: Establishing a Context for Pain Treatment**

- a. Need to reduce harms from controlled substances while maintaining patient care
  - b. Regulatory board will use individual case characteristics to judge validity of pain treatment
  - c. Establishing an education course for practitioners to improve pain treatment
  - d. Establishing methods offered for healthcare facilities to improve pain treatment
- 3. Domain 3: Practitioner Expectations for Pain Treatment**
- a. Expecting practitioners to consider integrative care during pain treatment
  - b. Expecting practitioners to provide individualized care during pain treatment
  - c. Expecting practitioners to assess patient functioning during pain treatment
  - d. Expecting practitioners to engage in shared decision-making with patients when considering pain treatment options
  - e. Expecting practitioners to assess or discuss patient benefits and/or risks before initiating pain treatment
  - f. Expecting practitioners to monitor patient benefits and/or risks during pain treatment
- 4. Domain 4: PMP-Related Content**
- a. Timeframe in which dispensing data is submitted to the PMP after dispensing
  - b. Authorizing the PMP to share data with other state PMPs
  - c. Requiring practitioners to register with the PMP
  - d. Requiring practitioners to check the PMP before initially prescribing a controlled substance
  - e. Requiring teaching practitioner or pharmacist users about the PMP
  - f. Requiring the PMP governing agency to review program information to identify inappropriate use of monitored medications
- ii. Excluded variables include:
1. Any responsibilities or standards that may exist in common law but are not codified in state law
  2. Content from introduced or unadopted bills
  3. Civil or administrative case law, or language from legislative notes
  4. City/local or non-legal institutional policy
  5. Nursing and physician assistants practice
  6. Controlled substances scheduling
  7. Prescribing, dispensing, or administering Schedules III-V controlled substances
  8. Advance directives or living wills



9. Physician-assisted suicide or euthanasia
10. Reimbursement of therapeutic interventions
11. Worker's compensation
12. Controlled medication importation
13. Program grants to state agencies
14. Laws governing pain clinics, since a separate comprehensive analysis (conducted by others, at <http://pdaps.org/datasets/pain-management-clinic-laws>) covers these standards.
15. Clinical practice guidelines, unless one was adopted by a healthcare regulatory board to serve as a guidance document
  - a. In cases where the CDC prescribing guideline was adopted by a regulatory board, only the messages contained in its introduction and guidelines sections were subject to review.

#### **IV. Coding**

- a. **Development of Coding Scheme:** This project began as an update of a criteria-based evaluation of state laws and regulatory policies begun over 20 years ago and implemented periodically until 2015, which included involvement of both the Supervisor and Researcher at various points in time. As a result, the information gathered and refined over the last two decades, including the reports written and issued for each evaluation, served the function of background memoranda broadly outlining the pain, palliative care, and end-of-life care laws and regulatory policies evolving throughout the United States over time. Both the Supervisor and Researcher served as content experts before this project was formulated, thus eschewing the need for formal written summary memoranda as the basis for project conceptualization. Primary conceptualization was accomplished in 2017, with review and feedback from a workgroup of five subject matter experts, which aided in focusing on important thematic domains, narrowing the scope of laws reviewed, and refining and limiting the evaluation criteria. The Supervisor of this project drafted and refined the evaluation criteria (coding questions) throughout 2017 and in early 2018. Laws and regulatory policies were collected for the first Batch of 5 states, and the criteria were applied (activities were recorded in a series of daily research sheets, when necessary). Initial criteria application led to further refinement and then finalization of the coding questions for subsequent states. The finalized questions were then entered into a Microsoft Excel spreadsheet and the Research Team's identification of potentially-relevant policy language was subject to redundant coding (see [www.acscan.org/painscore](http://www.acscan.org/painscore) for a more complete description of the methods). After the laws were reviewed and approved by the Supervisor, relevant laws were saved in Microsoft Word files and the Supervisor and Researcher began independent coding for the next Batch of 5 states. For all subsequent redundant coding of state laws, the results were entered into the corresponding variable fields in the Microsoft Excel spreadsheet for calculating divergence rates.

**b. Coding Modifications:** After preliminary coding began, the team met on March 21, 2018, to discuss the process up to and until that point. The team reviewed in great detail the difficulty in applying the coding questions related to practitioners' considerations about benefits and risks, and harms, during treatment. Difficulty resulted from brief mentions of these concepts occurring frequently throughout an entire policy governing pain treatment. For interpretive and coding clarity, it was decided to code specifically for provisions that establish a responsibility for practitioners to access or discuss benefits or risks before treatment, as well as for the responsibility to monitor for benefits or risks during treatment. Another coding change was eventually made, moving away from a practitioner's expectation to provide integrative pain care to consider such care, as a means to recognize a greater latitude of practice. The same need for clarity was also found for the question relating to the various criteria that a board uses to judge prescribing for pain treatment. It was decided to focus solely on individual case characteristics (e.g., the totality of clinical circumstances) to determine treatment legitimacy. Finally, on April 3 it was decided to limit a question about providing informational resources to practitioners to improve pain management to establishing an education course only.

**c. Coding Methods:** Below are specific rules used when coding the questions and responses in the state pain policy dataset:

**Domain 1: Policy Definitions**

○ **Question: “Does the practice of medicine include the treatment of pain?”**

- States were coded as “Yes” if the treatment of pain was included in the practice of medicine.
- Where the policy was silent on whether the practice of medicine included the treatment of pain, “No” was coded.
- “Practice of medicine” includes other healthcare practices (e.g., osteopathy and pharmacy) or the healing arts generally.
- The following phrase was scoped out: Definitions of “medical services.”

○ **Question: “Does a policy define addiction not based solely on physical dependence or tolerance?”**

- States were coded as “Yes” if a policy defined addiction or related term accordingly.
- Where the policy was silent on the definition of addiction, or if addiction is defined based solely on physical dependence or tolerance, “No” was coded.
- “Addiction” includes such terms as Substance Use Disorder, Drug Dependence, Dependence, Habitué, Substance Abuse.
- The following was scoped out: Statements about addiction that were not included in a definition of the term, if a relevant definition was also present.

**Child Question: “Is there a statement that physical dependence or tolerance are not considered addiction?”**

- States were coded as “Yes” if a policy includes such a statement.

- Where the policy was silent on the statement about addiction, “No” was coded.
- This question can be fulfilled by a statement that physical dependence or tolerance were not considered to be met for patients taking opioid medications solely under appropriate medical supervision or for pain treatment.
- **Question: “Does the policy define a maximum amount for a prescription of a controlled substance?”**
  - States were coded as “Yes” if the policy defined a maximum amount for a prescription of a controlled substance.
  - Where the policy was silent on whether the policy defined a maximum amount for a prescription of a controlled substance, “No” was coded.
  - When states had different requirements for various schedules of controlled substances, they were coded according only to the Schedule II controlled substance requirement.
  - “Prescription” means a prescription for a medication that is dispensed in the general course of professional practice, and does not include those issued for an emergency situation, for partial dispensing, or other specific clinical circumstances.
- **Child Question: “What is the maximum amount for a prescription of a controlled substance?”**
  - This question was coded whenever the law explicitly stated the maximum amount for which a prescription for a controlled substance could be written, in the metric reported (e.g., number of dosage units, numbers of days supply, or morphine equivalence). The current mutually-exclusive verbatim categories are:
    - 7-day supply
    - 30-day supply
    - 30-day supply, 100 MME
    - 31-day supply
    - 31-day supply or 100 dosage units, whichever is greater 1 month supply
    - 34-day supply
    - 90-day supply
  - When states had different requirements for various schedules of controlled substances, they were coded according only to the Schedule II controlled substance requirement.
  - “Prescription” means a prescription for a medication that is dispensed in the general course of professional practice, and does not include those issued for an emergency situation, for partial dispensing, or other specific clinical circumstances.
- **Question: “Does the policy define a duration for which a prescription for a controlled substance is valid?”**

- States were coded as “Yes” if the policy defined a duration for which a prescription for a controlled substance is valid.
- Where the policy was silent on whether the policy defined a duration for which a prescription for a controlled substance is valid, “No” was coded.
- When states had different requirements for various schedules of controlled substances, they were coded according only to the Schedule II controlled substance requirement.

**Child Question: “What is the duration for which a prescription for a controlled substance is valid?”**

- This question was coded whenever the law explicitly stated the duration for which a prescription for a controlled substance is valid, in the metric reported (e.g., days, weeks, months, etc.). The current mutually- exclusive verbatim categories are:

3 days

7 days

14 days

21 days

30 days

60 days

90 days

120 days

6 months

- When states had different requirements for various schedules of controlled substances, they were coded according only to the Schedule II controlled substance requirement.

○ **Question: “Does a policy define 'unprofessional conduct' to include excessive prescribing?”**

- States were coded as “Yes” if the "unprofessional conduct" standard included excessive prescribing.
- Where the policy was silent on whether "unprofessional conduct" included excessive prescribing, or if “unprofessional conduct” was defined but did not include excessive prescribing, “No” was coded.
- “Unprofessional conduct” often is defined in a specific section of law and means a violation of a legal standard that creates grounds for professional discipline or revocation of a practitioner’s license.
- “Excessive prescribing” includes amounts considered not medically necessary, advisable, or justified, that endanger a patient or the public, or in excess of approved labeling or medically recognized quantities, but with no exceptions or no information to unambiguously define “excessive.”
- The following was scoped out: Mentions of excessive prescribing outside of unprofessional conduct provisions.

**Child Question: “Does the policy include factors determining excessive prescribing?”**

- States were coded as “Yes” if factors were listed to determine excessive prescribing.
- Where the policy was silent on factors determining excessive prescribing, “No” was coded.
- Factors determining excessive prescribing can include dispensing for no legitimate medical purpose, amounts not reasonably related to proper medical management patient's illnesses or conditions, the size and frequency of orders, or the type and size of the patient.
- The following was scoped out: Ambiguous standards (e.g., “accepted medical standards” without identifying the specific standards).

## **Domain 2: Establishing a Context for Pain Treatment**

- **Question: “Does a policy state the need to reduce harms from controlled substances while maintaining patient care?”**
  - States were coded as “Yes” if a statement was present representing the need to reduce harms from controlled substances while maintaining patient care.
  - Where the policy was silent on whether a statement was present representing the need to reduce harms from controlled substances while maintaining patient care, “No” was coded.
  - “Harms” include diversion, abuse, addiction, poisoning, overdose, and death.
  - “Patient care” includes access to needed treatments (e.g., appropriate availability of controlled substances) and improved treatment outcomes.
  - The following was scoped out: Laws that state the need either to reduce harms or maintain patient care separately, but not together in a single statement, paragraph, or in proximity.
- **Question: “Does a policy establish that a regulatory board will use individual case characteristics to judge validity of pain treatment?”**
  - States were coded as “Yes” if a regulatory board uses individual case characteristics to judge validity of pain treatment.
  - Where the policy was silent on a regulatory board using individual case characteristics to judge validity of pain treatment, “No” was coded.
  - “Pain treatment” relates to chronic pain conditions only and can include opioid therapy when clinically indicated.
- **Question: “Does the policy establish an education course for practitioners to improve pain treatment?”**
  - States were coded as “Yes” if an expectation to participate in an education course is established for practitioners to improve pain treatment.
  - Where the policy was silent on whether an expectation to participate in an education course is established for practitioners to improve pain treatment, “No” was coded.
  - “Education course” means formal continuing education about pain management, prescribing or dispensing controlled substances, or diversion control, mandatory professional curricula about pain management or controlled substances, or training requirements. Also, an education course

- could cover a variety of topics, including pain management, opioid prescribing, diversion reduction strategies, and abuse/addiction reduction strategies.
- The following were scoped out: Provision of non-course-related information or materials (e.g., pain commission or advisory committee responsibilities and written pamphlets), or required education for only subsets of practitioners or pharmacists (e.g., those involved in disciplinary proceedings).
  - **Question: “Does the policy establish methods offered for healthcare facilities to improve pain treatment?”**
    - States were coded as “Yes” if methods are offered for healthcare facilities to improve pain treatment.
    - Where the policy was silent on whether methods are offered for healthcare facilities to improve pain treatment, “No” was coded.
    - Multiple methods (e.g., pain care standards, written pain care plans, short-term inpatient care protocols, discharge planning, care transition plans, facility policies, staff training, educational materials, and multidisciplinary team protocols) could be identified in the same healthcare facility or across different facilities.
    - The general category of healthcare facilities or programs, and related institutions can include programs providing palliative care or end-of-life care services. Cumulatively, healthcare facilities relevant to this project are:
      - Hospice care programs, including inpatient hospice services, hospice inpatient facilities, home hospice care, and hospice house, residential hospice facilities, and homecare organizations or other agencies licensed to provide hospice services
      - Hospitals, including those providing hospice services, short-term hospitals, rehabilitation hospital centers, specialized hospitals, ambulatory surgical facilities, ambulatory care facilities
      - Long-term care facilities, including nursing homes, nursing care facilities (e.g., nursing and specialized facilities), and assisted living facilities (e.g., special needs or enhanced assisted living residences)
      - Residential care facilities, including residential treatment and rehabilitation facilities, enhanced adult residential care, community-based residential facilities
      - Comprehensive care facilities, including comprehensive personal care homes
      - Extended care facilities
      - Community-based health programs
      - Adult day healthcare facilities, including community living homes and those with specialized Alzheimer’s Services
      - Elder group homes, including homes for the terminally ill
      - Home health care agencies, including homecare organizations and in-home services agencies

- Outpatient diagnostic or treatment centers
- HIV supportive living centers
- End-stage regional dialysis clinics
- Alzheimer's/dementia special care facilities or units.
- The following were scoped out: Mental health and substance use disorder treatment facilities (e.g., behavioral health facilities), therapeutic community residences, maternal and child care facilities providing healthcare services to children and adolescents, and facilities providing healthcare services through state insurance plans.

### **Domain 3: Practitioner Expectations for Pain Treatment**

- **Question: “Are practitioners expected to consider integrative care during pain treatment?”**
  - States were coded as “Yes” if practitioners are expected to consider integrative care during pain treatment.
  - Where the policy was silent on whether practitioners are expected to consider integrative care during pain treatment, “No” was coded.
  - “Integrative care” means the use of either pharmacologic or non-pharmacologic therapies, or both, and can be referenced as collaborative care, integrated care, interdisciplinary care, or multidisciplinary care.
- **Question: “Are practitioners expected to provide individualized care during pain treatment?”**
  - States were coded as “Yes” if practitioners are expected to provide individualized care during pain treatment.
  - Where the policy was silent on whether practitioners are expected to provide individualized care during pain treatment, “No” was coded.
  - “Individualized care” includes tailored care, and can relate to the type and causes of the patient’s pain, the preferences of the practitioner and the patient, the resources available at the time of care, and other concurrent issues encompassing the totality of the clinical circumstances.
- **Question: “Are practitioners expected to assess patient functioning during pain treatment?”**
  - States were coded as “Yes” if practitioners are expected to assess patient functioning during pain treatment.
  - Where the policy was silent on whether practitioners are expected to assess patient functioning during pain treatment, “No” was coded.
  - “Patient functioning” includes quality of life and is meant to be assessed in addition to pain scores.
- **Question: “Are practitioners expected to engage in shared decision-making with patients when considering pain treatment options?”**
  - States were coded as “Yes” if practitioners are expected to engage in shared decision-making with patients when considering pain treatment options.



- Where the policy was silent on whether practitioners are expected to engage in shared decision-making with patients when considering pain treatment options, “No” was coded.
- **Question: “Are practitioners expected to assess or discuss patient benefits and/or risks before initiating pain treatment?”**
  - States were coded as “Yes” if practitioners are expected to assess or discuss patient benefits and/or risks before initiating pain treatment.
  - Where the policy was silent on whether practitioners are expected to assess or discuss patient benefits and/or risks before initiating pain treatment, “No” was coded.
- **Question: “Are practitioners expected to monitor patient benefits and/or risks during pain treatment?”**
  - States were coded as “Yes” if practitioners are expected to monitor patient benefits and/or risks during pain treatment.
  - Where the policy was silent on whether practitioners are expected to monitor patient benefits and/or risks during pain treatment, “No” was coded.

#### **Domain 4: PMP-Related Content**

- **Question: “Does the policy require a timeframe in which dispensing data is submitted to the PMP after dispensing?”**
  - States were coded as “Yes” if the policy requires a timeframe in which dispensing data is submitted to the PMP after dispensing.
  - Where the policy was silent on whether the policy requires a timeframe in which dispensing data is submitted to the PMP after dispensing, “No” was coded.
- **Child Question: “What is the timeframe in which dispensing data is submitted to the PMP after dispensing?”**
  - This question was coded whenever the law explicitly stated the timeframe in which dispensing data is submitted to the PMP after dispensing, in the metric reported (e.g., in days, next business day, real time, etc.). The current verbatim categories are:
    - real time
    - 24 hours daily
    - 1 business day
    - next business day
    - 72 hours
    - 3 business days
    - 7 days weekly
    - 8 days
    - Monthly
- **Question: “Does the policy authorize the PMP to share data with other state PMPs?”**
  - States were coded as “Yes” if the policy authorizes the PMP to share data with other state PMPs.



- Where the policy was silent on whether the policy authorizes the PMP to share data with other state PMPs, “No” was coded.
- **Question: “Are practitioners required to register with the PMP?”**
  - States were coded as “Yes” if practitioners are required to register with the PMP.
  - Where the policy was silent on whether practitioners are required to register with the PMP, “No” was coded.
  - “Register” means either the need for each individual practitioner to actively register with the PMP or the need to register to gain access to program data.
  - The following was scoped out: When the registration of practitioners was as part of the licensing or DEA registration process or other automatic registration process.
- **Question: “Are practitioners required to check the PMP before initially prescribing a controlled substance?”**
  - States were coded as “Yes” if practitioners are required to check the PMP before initially prescribing a controlled substance.
  - Where the policy was silent on whether practitioners are required to check the PMP before initially prescribing a controlled substance, “No” was coded.
  - “Initially prescribing” includes the requirement to check the PMP before issuing an initial prescription, and perhaps then periodically thereafter.
  - The following was scoped out: A requirement to check the PMP before issuing every prescription.
- **Question: “Does the policy require teaching practitioner or pharmacist users about the PMP?”**
  - States were coded as “Yes” if the policy requires teaching practitioner or pharmacist users about the PMP.
  - Where the policy was silent on whether the policy requires teaching practitioner or pharmacist users about the PMP, “No” was coded.
- **Question: “Does the policy require the PMP governing agency to review program information to identify inappropriate use of monitored medications?”**
  - States were coded as “Yes” if the policy requires the PMP governing agency to review program information to identify inappropriate use of monitored medications.
  - Where the policy was silent on whether the policy requires the PMP governing agency to review program information to identify inappropriate use of monitored medications, “No” was coded.
  - “Inappropriate use” can include suspicious or statistically outlying prescribing, dispensing, or purchasing activity or patient behaviors involving obtaining controlled substances for multiple practitioners or pharmacies.
  - The following was scoped out: Evaluations of inappropriate use that are not conducted by the PMP governing agency, development of threshold criteria without an indication of their use, general statements that the PMP is designed to identify inappropriate use of monitored medications, and the

requirement for the development of rulemaking to identify inappropriate use without adoption of the final rule.

## V. **Quality Control**

**a. Quality Control – Background Research:** All 51 jurisdictions were 100% redundantly researched to better ensure that all relevant laws were identified and collected by the Researchers. The Researchers also consulted secondary sources to verify whether states had relevant state-level laws within the scope of the dataset.

**i.** The research showed that all 51 jurisdictions had some form of laws relevant to the project topic.

### **b. Quality Control – Coding**

**i. Original Coding:** Quality control of the original coding consisted of the Supervisor exporting the data into a Microsoft Excel document every time the Researchers completed coding of each Batch to examine the data for any missing entries, citations, and caution notes.

**ii. Redundant Coding:** The redundant coding process is 100% independent, redundant, coding by two Researchers of each jurisdiction (i.e., each state). Redundant coding means that each jurisdiction (a record) is assigned and coded independently by the two Researchers. Divergences, or differences between the original coding of each Batch and redundant coding, are resolved through consultation and discussion with the Team.

Quality control of the redundant coding consisted of the Supervisor exporting the data into a Microsoft Excel document every time the Researchers completed redundant coding of each Batch to calculate divergence rates. 100% of the records were redundantly coded throughout the life of the project.

After coding the first 5 jurisdictions (Batch 1), the rate of divergence was 22.78%. A coding review meeting was held and all divergences were resolved. Questions that were causing confusion were edited for clarity and then checked across the dataset to make sure coding was consistent. The Supervisor assigned the next 5 jurisdictions (Batch 2) for redundant coding and the rate of divergence dropped to 1.60%. Again, a coding review meeting was held and all divergences were resolved. The divergence rates for the remaining Batches were: 1.60% (Batch 3), 4.00% (Batch 4), 1.60% (Batch 5), 1.60% (Batch 6), 0% (Batch 7), 3.20% (Batch 8), 1.60% (Batch 9), 0.67% (Batch 10). Divergences were discussed and resolved for all Batches.

**iii. Post-production Quality Control:** To ensure reliability of the data, a statistical quality control (SQC) procedure typically is run at the completion of the dataset. To conduct SQC, the Supervisor takes a random sample of variables from the dataset for the Researchers to code blindly. SQC is run until divergences are below 5%. If not below 5%, divergences are reviewed and resolved and another round of SQC is run until the divergence rate falls below 5%. However, given

that all the divergence rates calculated after Batch 1 were less than 5%, and all Batches were redundantly coded and divergences were resolved (see Sec. V(b)(ii): Redundant coding, above), the SQC procedure was not necessary for this project.

- iv. **Final Data Check:** Once all of the coding was completed, the Researchers checked the final coding results against secondary sources where possible. The secondary sources used for comparison are listed in Sec. III(c). Prior to publication, the Supervisor conducted a final review of coding answers, statutory and regulatory citations, and caution notes. All unnecessary caution notes were deleted and all necessary caution notes were edited for publication.

## VI. State Ratings

- a. **Background:** For over a decade, the American Cancer Society, the American Cancer Society Cancer Action Network, and the University of Wisconsin have tracked and rated state pain policies. State ratings were most recently published in 2015. In 2017, the organizations underwent a process to update the methodology of this analysis to better reflect the current policy environment, the results of which are represented throughout this report. The purpose of this phase is to rate legal content found in state-level policies governing pain treatment, including for palliative care and end-of-life care, according to its degree of match to model statutes or regulatory policies (see Section b, below). Coding question findings were then compiled for an overall rating for each state (see Sections c & d, below).
- b. **Use of Model Laws and Policies:** Coding questions described above were chosen based on model statutes or regulatory policies, which are created by national organizations for the specific purpose of providing guidance to legislatures and regulatory agencies during drafting and promulgation of similar laws or policies. Relevant model laws or policies in effect during the timeframe of this evaluation were:
  - i. Federation of State Medical Boards *Essentials of a State Medical and Osteopathic Practice Act* (<http://www.fsmb.org/globalassets/advocacy/policies/guidelines-for-the-structure-and-function-of-a-state-medical-and-osteopathic-board.pdf>) and *Guidelines for the Chronic Use of Opioid Analgesics* ([http://www.fsmb.org/siteassets/advocacy/policies/opioid\\_guidelines\\_as\\_adopted\\_april-2017\\_final.pdf](http://www.fsmb.org/siteassets/advocacy/policies/opioid_guidelines_as_adopted_april-2017_final.pdf))
  - ii. the Joint Commission on Accreditation of Health Care Facilities facility standards ([https://www.jointcommission.org/topics/pain\\_management.aspx](https://www.jointcommission.org/topics/pain_management.aspx))
  - iii. National Alliance for Model State Drug Laws *Model Prescription Monitoring Program Act* (<http://www.namsdl.org/library/A7108378-A300-A79A-8A711DB342E275F6/>)
  - iv. National Association of Boards of Pharmacy *Model State Pharmacy Act and Model Rules and Model Prescription Monitoring Program Act*

[\(https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/\)](https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/)

- v. National Association of State Controlled Substances Authorities *Model Prescription Monitoring Program Act*  
<http://nascsa.org/nascsaPMP/nascsaPMPmodelAct/NASCsApmpmodelAct2016.pdf>
- vi. National Conference of Commissioners on Uniform State Laws *Uniform Controlled Substances Act*  
[http://www.uniformlaws.org/shared/docs/controlled%20substances/UCSA\\_final%2094%20with%2095amends.pdf](http://www.uniformlaws.org/shared/docs/controlled%20substances/UCSA_final%2094%20with%2095amends.pdf)
- vii. 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>)

With this, the conceptual framework underlying this policy surveillance project represents the relationship of the coding questions to model statutes, regulations, or other regulatory policies. That is, all coding questions are informed by the contents of at least one federal or national model policy that is now relevant to the subject of a specific coding question.

- c. **Calculating State Ratings:** 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 for “Yes” and 0 points for “No” – 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:

<p><b>Below 50% match to model policy</b></p> <p>Represented as red in map</p>	<p><b>50%-80% match to model policy</b></p> <p>Represented as yellow in map</p>	<p><b>Above 80% match to model policy</b></p> <p>Represented as green in map</p>
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**d. Unique Coding for Questions:** The method used to collect, search, code, and record that was described in Section I-V are the basis for state ratings, except the use of these three child coding questions, instead of the parent questions, to conform to the point allocation required for this project (described above in Section VI(c)):

- **Question: “What is the maximum amount for a prescription of a controlled substance?”**
  - States were coded as “1” if the policy avoided defining the maximum amount for a prescription of a controlled substance, or if the maximum amount was greater than or equal to a 30-day supply with no dosage limits.
  - Where the policy defined the maximum amount for a prescription of a controlled substance, and if the maximum amount was less than a 30-day supply and/or had a dosage limit, “0” was coded.
- **Question: “What is the duration for which a prescription for a controlled substance is valid?”**
  - States were coded as “1” if the policy avoided defining the duration for which a prescription for a controlled substance is valid, or if the duration was greater than or equal to 2 weeks.
  - Where the policy defined the duration for which a prescription for a controlled substance is valid, and if the duration was less than 2 weeks, “0” was coded.
- **Question: “What is the timeframe in which dispensing data is submitted to the PMP after dispensing?”**
  - States were coded as “1” if the policy requires that dispensing data be submitted to the PMP no later than the next business day after dispensing, or an equivalent timeframe (e.g., 24 hours).
  - Where the policy was silent on whether the policy requires that dispensing data be submitted to the PMP, or if the timeframe was later than the next business day after dispensing, “0” was coded.

In addition, one coding question was reworded to conform to the point allocation required for this project (described above in Section VI(c)):

- **Question: “Does the policy avoid defining 'unprofessional conduct' to include excessive prescribing?”**
  - States were coded as “1” if the policy avoids defining “unprofessional conduct” to include excessive prescribing.

- Where the policy did not avoid defining “unprofessional conduct” to include excessive prescribing, “0” was coded.