

# Research Protocol for Morphine Equivalent Daily Dose Policies

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## Morphine Equivalent Daily Dose Policies

- I. **Date of Protocol:** June 2017; November 2017;
  
- II. **Scope:** A comprehensive survey of state-level Morphine Equivalent Daily Dose (MEDD) threshold policies. A doctoral candidate at Johns Hopkins researched and built this dataset under a dissertation grant from the Agency for Healthcare Research and Quality (AHRQ). To be included, the policy must meet all of the below inclusion criteria. The policy formats and state agencies selected were determined through an iterative process in which state level MEDD policies were searched for online and in the academic literature, and the list of included formats and agencies were updated to include the most common and frequently cited types of policies. The result was a cross-sectional dataset of state-level MEDD policies in effect as of June 1, 2017.
  
- III. **Primary Data Collection**
  - a. **Project Dates:** June 1, 2017 - October 17, 2017. The doctoral candidate conducted preliminary background research for this project May 1, 2015 to May 31, 2016.
  
  - b. **Dates Covered in the Dataset:** January 1, 2007- June 1, 2017. The published dataset only includes the most recent version of each state's policies, thus the published project is a cross-sectional dataset of state-level MEDD threshold policies in effect on June 1, 2017.
  
  - c. **Data Collection Methods:** The research team consisted of the doctoral candidate (Researcher 1) who conducted preliminary background research, compiled the policy set, and coded the policies, a second researcher from the doctoral candidate's institution who independently coded the policies (Researcher 2), and Researcher 1's academic advisor who supervised the project (Supervisor).
  
  - d. **Search Terms:** keyword searches included "Morphine equivalent," "Milligrams morphine", "Opioid dose threshold," and "Opioid dose maximum."
  
  - e. **Databases Used:** Researcher 1 used LexisNexis and Westlaw Next to conduct a comprehensive search of legislative acts in all 50 states and the District of Columbia. Researcher 1 used Google to find non-legislative state-level policy documentation and checked each state's Medicaid Agency, Health Department, Prescription Drug Monitoring Program, Workers' Compensation Board/Division, Medical Board, and Pharmacy Board websites to determine if any other MEDD threshold policies existed.
  
  - f. **Inclusion and Exclusion Criteria:** Policies must be of one of the following formats: "Guideline/Recommendation," "Legislative Act," "Rule/Regulation," "Prior

Authorization,” “Claim Denial,” “Alert System/Automatic Patient Report” and have been implemented by one of the following state-level organizations: “Medicaid Agency,” “Health Department,” “Prescription Drug Monitoring Program,” “State Legislature,” “Workers’ Compensation Board/Division,” “Medical Board,” or “Pharmacy Board.” Policy formats and state-level organizations are defined later in this document.

Policies from any private company, non-profit organization, or from any type of national organization were not included unless they were co-sponsored by one of the above state-level organizations. Policies that reference policies implemented by other organizations (for example, in the background section of a report), but do not endorse the policy were not included. Policies that only limit the MEDD for certain drugs (e.g. non-preferred drugs only or short-acting drugs only) or do not limit cumulative MEDD were not included. Medicaid and Workers’ Compensation prior authorization policies that do not apply to all Medicaid or Workers’ Compensation insurers within the state were not included. Policies which recommend increased follow-up after exceeding a given MEDD with no other recommended course of action were not included. Proposed bills that never became law are not included.

#### **IV. Coding**

**a. Development of Coding Scheme:** Researcher 1 began with policy questions developed during the preliminary background research stage. As Researcher 1 compiled policy documentation and coded the policies, additional questions were added or modified with input from Researcher 2 and the Supervisor.

**b. Dataset Terminology:**

- i.** “Morphine Equivalent Daily Dose Policies” (hereafter “policy” or “policies”) represent policies which seek to limit overall opioid prescribing above a certain Morphine Equivalent Daily Dose (MEDD).
- ii.** “MEDD” represents a measurement that converts opioid prescriptions to their equivalent dose in morphine and divides the total prescription by days supply (the number of days the prescription is intended to last). Policies may also refer to MEDD as Milligrams Morphine Equivalent (MME).
- iii.** “Guideline/recommendation” provides a recommended threshold over which prescribers should not exceed or should only exceed if special precautions are taken. Guidelines/recommendations have no mechanism of enforcement.
- iv.** “Rules/regulations” are similar to guidelines, but are stated as an imperative (e.g. “must” “shall”) and may or may not have an explicit means of enforcement.
- v.** “Legislative Act” is any law passed by the state’s legislative body which has gone into effect. Proposed bills that never became law are not included.
- vi.** “Prior Authorization” is a requirement that mandates prior approval from a third party before prescriptions above a given MEDD threshold may be filled.
- vii.** “Alert System/Automatic Patient Report” is a mechanism by which targeted, unsolicited letters or alerts sent either by mail or electronically and inform

prescribers that patients under their care have exceeded a given MEDD threshold. Follow-up action may or may not be required.

- viii. “Claim Denial” is a mechanism by which a third party denies prescription fills above a given MEDD threshold. In cases where Prior Authorization documentation explicitly states that prescriptions above a given MEDD threshold will not be approved, Prior Authorization and Claim Denial may be coded as two distinct policies.
- ix. “MEDD threshold level” refers to the number of cumulative milligrams of morphine equivalent per day as outlined in a given policy.
- x. “Types of patients” refers to any patient population for whom the policy does not apply.
- xi. “Short course” refers to opioid prescriptions that are below a given days supply and are intended for short-term use.
- xii. “Days supply” refers to the maximum number of days the prescription(s) is intended to last.
- xiii. “Specialist” refers to any specified (e.g. pain specialist, orthopedic specialist) or unspecified specialized physician.
- xiv. “Prescription Drug Monitoring Programs” (PDMP) refers to programs which collect prescribing and/or dispensing data of controlled substances, including opioids. Physicians or other authorized users may use these programs to view a patient’s prescribing history and possibly detect doctor shopping.
- xv. “Pain contract/patient education” refers to the action of developing a contract with a patient regarding proper use of opioids, educating patients on the risks of opioid use, working with patients to set realistic expectations about pain relief and practice self-management techniques, or any other risk mitigation strategy or change in treatment plan.
- xvi. “Drug testing” refers to the action of testing a patient for narcotics use.

- c. **Coding Methods:** Policy questions were reviewed by the Supervisor and questions were edited for clarity. Researcher 2 suggested additional modifications to questions during a preliminary coding of the first three state’s policies. Modifications were agreed upon by both Researchers.

Below are coding rules that apply generally to the coding questions throughout the dataset:

- Policies were coded for each state and each state may have multiple policies. Where states have multiple policies, they are presented beginning with the policy with the most recent effective date.
- The text coded was limited to MEDD Policies as previously defined. Other policies that were cited or cross-referenced in the policies were not coded or included in the policy source text.

Below are coding rules that apply specifically to the coding questions throughout the dataset:

- **Question: “What is the type of policy?”**

- Legislation which establishes a prior authorization requirement was coded as “Prior Authorization” and caution noted.
- In cases where Prior Authorization documentation explicitly states that prescriptions above a given MEDD threshold will not be approved, Prior Authorization and Claim Denial were coded as two distinct policies.
- If any other organization not in the inclusion criteria additionally co-sponsored the policy, the “other” option was checked and the information was caution noted.
- **Question: “What is the MEDD threshold level?”**
  - If a range of MEDD values was given, the highest value in the range was used and the range was caution noted.
  - Policies that have a baseline MEDD threshold for all opioids, and then lower (stricter) MEDD thresholds for certain types of opioids were coded according to the baseline threshold. Where different threshold levels were associated with different patient group exemptions or different circumstances under which a threshold may be exceeded, each threshold level was coded as a separate policy.
  - If two different thresholds were mentioned with no explicit differences in exemptions or circumstances under which the threshold should be exceeded, the lower of the two thresholds was coded.
- **Question: “Which types of patients, if any, are exempt from the policy?”**
  - For prior authorization, “types of patients” specifically refers to individuals who do not need to go through the prior authorization process, regardless of whether these individuals will ultimately receive approval for the prescription.
  - “Acute/etiologic pain patients” was coded if the policy states that it does not apply to acute pain, that it does not apply to pain with a clear etiology or cause, or that it applies only to chronic pain.
  - “Terminal/hospice/palliative care patients” was coded if the policy states that it does not apply to any of the following: pain from a terminal condition, or individuals receiving hospice, palliative, or end-of-life care.
  - “Cancer/malignant pain patients” was coded if the policy states that it does not apply to patients with either cancer pain or malignant pain.
  - “Long-term care facility/nursing home patients” was coded if the policy states that it does not apply to patients residing in either long-term care facilities or nursing homes.
  - “Patients with recent opioid use” was coded if the policy states that it specifically applies to opioid naïve patients or new opioid prescriptions.
- **Question: “How are short courses defined in number of days supply?”**
  - Where the length of the course of opioids was defined in months, this was converted to number of days with 30 days to a month assumed (e.g. 3 months = 90 days).
- **Question: “Under which circumstances may the MEDD threshold be exceeded?”**

- Unless caution noted, it was assumed that the MEDD threshold may be exceeded if any of the indicated circumstances apply. Where multiple circumstances must apply in order for the threshold to be exceeded (e.g. Patient must receive drug testing and have pain contract/patient education) this was caution noted.
- “Specialist consulted” was coded where a specialist must be consulted either prior to writing prescription(s) exceeding the MEDD threshold or that filling prescription(s) in excess of the MEDD threshold should trigger a specialist referral.
- “Evidence of tapering” was coded where prescriptions in excess of the MEDD threshold may be written if the patient is receiving consecutively lower MEDD over time or the physician has put in place a plan to gradually lower the patients MEDD.
- “Patient has improved pain or function” was coded where prescriptions in excess of the MEDD threshold may be exceeded provided that the patient is experiencing decreased pain or increased function at the higher doses.
- “Clinical judgment” was coded where it was indicated that the MEDD threshold may be exceeded if the prescriber believes that there is a medical justification to do so.
- “PDMP is checked” was coded where it was indicated that the state’s PDMP should be checked either prior to writing prescription(s) exceeding the MEDD threshold or that filling prescription(s) in excess of the MEDD threshold should trigger checking the PDMP.
- “Stable pain and function with non-escalating doses” was coded when it was indicated that patients may exceed the MEDD threshold if they are not experiencing worse pain and function and if their MEDD has not increased.
- “Legitimacy of prescription verified” applies specifically to policies for pharmacists. This was coded when the pharmacist should verify the prescription with the patient’s physician prior to dispensing the prescription if the MEDD exceeds a given threshold.

## V. **Quality Control**

- a. **Quality Control – Research:** The comprehensiveness of the citation list was verified in several ways. First, the list was checked against existing secondary sources that cite compilations of policies including, the AHRQ Guideline Clearinghouse, The Brandeis Prescription Drug Monitoring Program (PDMP) Center of Excellence’s 2016 report on PDMPs with unsolicited reporting, the National Alliance for Model State Drug Laws 2016 report on State Pain Management and Prescribing Policies, and The University of Wisconsin Pain and Policy Studies Group’s Database of Statutes, Regulations, & Other Policies for Pain Management.
- b. Second, Medicaid policies were checked against Medicaid Drug Utilization Review Annual Report Surveys, which lists states with Medicaid agencies responding “yes” to

the question, “Have you set recommended maximum morphine equivalent daily dose measures?” Third, the list was checked against academic literature using the above search terms, for references to MEDD threshold policies. Finally, for the 28 states with no MEDD threshold policy found, at least one representative from a relevant state health agency was contacted to confirm the lack of a formal policy.

- c. Quality Control – Redundant Coding:** Researchers 1 and 2 redundantly coded 100% of the policies. Divergence rates were calculated and divergences were resolved by the Supervisor. Research 1 and 2 independently coded the first eight policies (alphabetically by state) and had a divergence rate of 33%. Divergences were discussed and resolved and clarifying edits were then recorded in the research protocol. The two researchers then independently coded the remaining 23 policies and had a divergence rate of 21% on October 23, 2017 and repeated the process of resolving divergences. When answers to questions were ambiguous in a policy as noted by one or both coders, an attempt was made to clarify the coded element with a representative of the relevant state organization.
- d. Quality Control – Final Check:** The final list was reviewed by Researcher 1 prior to publication to ensure the completeness and accuracy of all responses, citations, and caution notes.