CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: STATE MEDICAL BOARD OF OHIO

Regulation/Package Title: Controlled Substance Prescribing-Limits for Prescribing of Opioids for Acute Pain

Rule Number(s): 4731-11-01, 4731-11-02 and New 4731-11-13

Date:

Rule Type:

- xNew
- xAmended
- ☐ 5-Year Review
- ☐ Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

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Section 3719.062 of the Revised Code (effective 4-6-17) allows health related licensing boards to adopt rules limiting the amount of an opioid analgesic that may be prescribed pursuant to a single prescription by an individual licensed by the board. The Medical Board is proposing amendments to two existing rules and one new rule.

(1) Rule 4731-11-01:
- Adds definitions for acute pain, morphine equivalent dose, minor, extended-release or long-acting opioid analgesic, opioid analgesic, palliative care and terminal condition.

(2) Rule 4731-11-02
- Adds requirement that physicians and physician assistants must follow Rules 4729-5-30 and 4729-5-13, Ohio Administrative Code. This will include the requirement that prescriptions for controlled substances will need to include the diagnosis.

(3) New Rule 4731-11-13
- Limits prescriptions for opioid analgesics to treat acute pain to no more than a seven-day supply for adults and a five-day supply for minors. If the physician determines that the pain is expected to persist for longer than seven days, the physician may prescribe for a longer period, but the reason for exceeding the limits and for prescribing an opioid analgesic must be documented in the patient's medical record. The prescription is also limited to average daily dose of 30MED (Morphine Equivalent Dose) and provides an exception in limited circumstances.
- Requires that the patient and the parent or guardian of a minor patient is advised of the benefits and risks of the opioid analgesic, including the potential for addiction.
- Allows for exceptions for prescriptions for opioid analgesics used to treat patients receiving hospice or palliative care, cancer and terminal illness, and medication assisted treatment for addiction.

The provisions of these proposed rules will be applicable to physician assistants through Rule 4730-2-07, Ohio Administrative Code, Standards for Prescribing. The other healthcare boards (Board of Nursing and Dental Board) are promulgating rules with the same provisions. The Board of Pharmacy is promulgating rules consistent with these limits.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

The rules are authorized by Sections 3719.062 and 4731.05, Ohio Revised Code.

3. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

   The rules do not implement a federal requirement.

4. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   This question is not applicable.

5. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   Ohio is experiencing an opioid epidemic that negatively impacts public health resulting in profound consequences to Ohio's economy and way of life. The Governor has directed that the state's professional licensing boards take action by rule to help affect change and improve health outcomes. The public purpose for the rule package is to reduce the frequency and amount of opioids prescribed for acute pain, while preserving the ability for providers to prescribe beyond limits specified in the rule when clinically appropriate and with proper documentation. The rule package also seeks to significantly limit the amount of unused opioids that are available for diversion.

6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

Outcomes reflecting the impact of the limits on opioid prescribing resulting in benefits for public safety will be measured by OARRS data, public health and law enforcement statistics. The success of the regulations will also be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees, medical practices and medical facilities regarding the provisions of the rule.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

   Governor Kasich and his Governor's Cabinet Opiate Action Team (GCOAT) were instrumental in reviewing state and federal standards and OARRS trends that

indicated now is the right time to move forward in collaboration with government and public stakeholders to establish certain standards for opioid use in the treatment of acute pain. Directors and staff from the Board of Nursing, Dental Board, Board of Pharmacy and State Medical Board have all met to discuss the need for consistent standards of practice reflective of a common goal to reduce the frequency and amount of opioids prescribed for acute pain, while preserving the ability for providers to prescribe beyond limits specified in the rule when clinically appropriate and with proper documentation.

The draft rules were discussed at the Medical Board's Policy Committee meeting on April 12, 2017. This meeting is open to the public. The draft rules were provided to the Physician Assistant Policy Committee and discussed at the May 9, 2017 meeting, which is also open to the public.

On April 13, 2017, the rules were circulated to the Medical Board's prescriber licensees (allopathic, osteopathic and podiatric physicians and physician assistants) via an e-news blast. The rules were placed on the Board's website and were circulated to associations and other interested parties via e-mail.

The public and interested parties had the opportunity to comment on the enclosed draft rules from April 13, 2017 through the close of business on April 28, 2017. The State Medical Board received 189 comments on the draft rules through email and the website.

On May 10, 2017, the draft rules, comments received and suggested amendments to the draft rules were discussed with the Medical Board's Policy Committee and the full Board. Both meetings were open to the public.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

The Medical Board received 189 comments from interested parties, including physicians and associations. A spreadsheet outlining the comments is attached. A summary of the comments is set forth below. Please note that the numbers are approximate and that some responses contained comments in more than one category. Twenty-nine comments were generally supportive of the rules, with no suggested changes.

1. Thirty-five comments were generally not in favor of the rules, but provided no specific recommendations for changes.
2. One hundred and six comments raised concerns that the prescribing limits (5-7days or 30MED) were too restrictive for certain procedures or conditions. (Post-surgery, post-fracture and post-trauma were the most often cited examples).
3. Twenty-seven comments raised privacy or technical concerns regarding the inclusion of diagnosis codes on the prescriptions for controlled substances.

4. Five comments raised concerns that documentation requirements were overly burdensome.
5. Six comments raised concerns that non-opioid pain relief, including NSAIDs are not appropriate for certain patient populations.
6. Four comments raised concerns with having a prescription limit or consent process that was different for minors.
7. One comment raised concerns that the exception language for allergy will allow diversion.
8. One comment raised concerns that the exception for cancer pain should be amended to except only those patients with active cancer pain.

Many of the comments received on this issue address the concern that patients may require doses higher than a 30MED average to adequately address pain following orthopedic surgery, burns, amputations, or another serious trauma. Based on the comments, the Medical Board approved amendments to 4731-11-13, OAC, that allows for some limited circumstances in which the physician may exceed the 30MED average daily dose.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

The rules were developed through input from physicians and professionals at the Department of Mental Health and Addiction Services, Department of Medicaid, the State Medical Board's Policy Committee, the Ohio Board of Nursing, the Ohio Dental Board and the Ohio Board of Pharmacy. The Acute Guidelines developed by GCOAT in 2016 and OARRS data were relied upon as foundational sources for the rules in this package, including the day dose limits and the corresponding 30 MED limits. OARRS data suggests that the state could see an estimated reduction of 109 million opiate doses once the new rules are in effect.

In addition to Ohio, the following states have proposed or finalized legislation, regulations or executive orders limiting opioid prescriptions:

Arizona, Connecticut, Kentucky, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont.

Senate Bill 892, limiting opioid prescriptions for the initial treatment of acute pain to a 7-day supply or the limit established under state law, was recently introduced in the U.S. Senate.

10. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

    The Board assisted the Governor and GCOAT in Ohio's collaborative efforts to curb use of opioids unless medically necessary. Ohio has authored several written guidelines in its efforts to assist prescribing licensees, the public and other stakeholders change practice patterns that result in increased risk of opioid abuse. Considering the continuing opioid epidemic and public protection concerns and to further consistency in prescribing practices, and the common direction of the other healthcare licensing boards in this focused effort, the Board did not consider further regulatory alternatives.

11. **Did the Agency specifically consider a performance-based regulation? Please explain.** ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

    The Board did not propose performance-based regulations in this rule package due to the necessity of setting established processes and standards to achieve its public protection mandate.

12. **What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

    The Medical Board coordinated the rule amendments to reflect requirements for controlled substance prescriptions in rules promulgated by the Board of Pharmacy, and in coordination with the Governor, stakeholder Cabinet agencies, and other healthcare licensing agencies.

13. **Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

The rules will be posted on the Medical Board's website, information concerning the rules will be included in informational materials e-mailed to licensees, and notices will be sent to associations, individuals, and groups. Medical Board staff members are available by telephone and e-mail to answer questions. Medical Board staff members also give presentations to groups and associations who seek an update on physician practice regulations.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

The scope of the impacted business community would be licensees of the Medical Board who are authorized to prescribe controlled substances, including opioids. This includes physicians holding a M.D., D.O., or D.P.M. license and physician assistants who are authorized to prescribe.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

Prescribers who prescribe opioids for acute pain will need to be aware of the limits and may need to more frequently see the patients receiving these prescriptions. In addition, prescribers will need to add a diagnosis code to the prescription and will need to provide more documentation if the five or seven day and 30 MED limits are exceeded. Physicians and physician assistants who are found to have violated these rules could be subject to a disciplinary action, which could include a monetary fine.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

Individuals who receive formal disciplinary action for violating these rules will be subject to civil penalties as set forth in 4731.225, Ohio Revised Code.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

Ohio is in the midst of a serious opioid epidemic. In CY 2014, 2,482 Ohio residents died from unintentional drug overdoses. Based on law enforcement drug seizures, Ohio has seen a major increase in drug reports involving fentanyl, a more lethal opiate, more than 30-50 times more potent than heroin. Key to reversing this trend is reducing the abuse and diversion of opiate prescriptions. Many individuals who are addicted to opioids received their first pill through a prescription opioid, either from a valid prescription or diverted from a friend or family member. The state is interested in limiting the number of opioid analgesics that are available and placing the limits on the prescribing of opioids for acute pain will help to limit the number of opioids available for diversion and improper use. Research also shows that the majority of acute pain issues resolve in 5-7 days. The State has a compelling interest in promoting safe treatment of acute pain while avoiding risks associated with the diversion, theft of opioids.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

Treatment of patients with opioids is a complex matter which impacts the health and safety of patients. The public safety requirements relevant to these rules require consistency in their application to all licensees and are not amenable to exemptions or alternative means of compliance for small businesses.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

Due process requires the Medical Board to consistently apply its rules regarding controlled substance prescribing such that all prescriber licensees are equally treated.

18. **What resources are available to assist small businesses with compliance of the regulation?**

Medical board staff members are available by telephone and e-mail to answer questions. Personnel from the Nursing Board, Dental Board and Board of Pharmacy will also be available to provide information to their affected licensees.