CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Controlled Substances: Prescribing for Subacute and Chronic Pain

Rule Number(s): 4731-11-01(Amended); 4731-11-02 (Amended) and 4731-11-14 (New)

Date: June 14, 2018

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- ☐ Rescinded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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The proposed rules apply to the prescription of controlled substance medications for subacute and chronic pain. These rules build on the 2013 chronic prescribing guidelines and take an additional step to stop addiction before it starts by introducing a rule for prescription opioids for the treatment of long-term pain (lasting 12 weeks or more) and subacute pain (lasting more than 6 weeks and less than 12 weeks). The following is a description of the rules:

- **Rule 4731-11-01 Definitions**

Adds definitions for medication therapy management, subacute pain and chronic pain.

Modifies the definition of acute pain to clarify that it lasts six weeks or less.

- **Rule 4731-11-02 General Provisions**

Corrects the reference to Pharmacy Board rules which must be followed for controlled substance prescriptions.

- **New rule 4731-11-14 Prescribing for subacute and chronic pain**
    - Requires a consideration of non-medication and non-opioid treatment options prior to or when continuing to treat subacute and chronic pain.
    - Requires review, assessment, OARRS check, treatment plan and discussion of risks and benefits prior to prescribing opioids for subacute or chronic pain.
    - Requires the physician to offer a naloxone prescription to a patient receiving opioids under certain circumstances.
    - At 50 Morphine Equivalent Dose ("MED"), physicians will be required to re-evaluate the patient, update or formulate a new treatment plan, if necessary, obtain written informed consent and consider consultation with a specialist or a medication therapy management review by a pharmacist.
    - At 80MED, the physician and patient enter into a written pain agreement, the physician offers a naloxone prescription, and the physician obtains a consultation with a specialist in the area of the body affected by the pain, a pain management specialist, or specialist in addiction medicine or addiction psychiatry, or a medication therapy management review.
    - The consultation requirements when the prescription meets or exceeds 50 or 80 MED do not apply if the patient was receiving an opioid at that dose prior to the effective date of the rule.
    - At 120 MED, physicians will be required to have a pain management specialist as prescriber or consultant, unless the patient was at that dose prior to the effective date of the rule. A consult is needed if the dose escalates.
    - Periodic follow-up assessment is required if the dose is below 50 MED.
    - Follow-up assessment is required at least every three months if the dose is at 50 MED or above.
    - The rule does not apply to opioid prescriptions for patients in hospice care or with terminal cancer or another terminal condition.
    - The rule does not apply to inpatient prescriptions under Pharmacy Board statutes.

The provisions of these proposed rules will be applicable to physicians and physician assistants through Rule 4730-2-07, Ohio Administrative Code, Standards for Prescribing.

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

   The rules are authorized by Sections 3719.062, 4731.05 and 4731.052, 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 establish standards and checkpoints between the physician and patient when prescribing opioids for the treatment of subacute or chronic pain. The new rules will not take away medication for those in need, but instead strengthen communication between physicians and patients by establishing check points for additional assessment to ensure that patients receiving opioids for subacute or chronic pain are more carefully managed.

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

   Outcomes reflecting the impact on subacute and chronic 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 subacute and chronic 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 establish consistent standards and checkpoints between the prescriber and patients when prescribing opioids for subacute and chronic pain.

The draft rules were discussed at the Medical Board's Policy Committee meeting on May 9, 2018. This meeting is open to the public. The draft rules were provided to the Physician Assistant Policy Committee and discussed at the June 11, 2018 meeting, which is also open to the public.

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 draft rules from May 11, 2018 through the close of business on May 25, 2018. Late comments were also reviewed. The State Medical Board received 17 comments on the draft rules through email and the website.

On June 13, 2018, 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?**

Seventeen groups or individuals provided comments. A spreadsheet outlining the comments received is attached.

For the most part, the commenters were supportive of the rules.

a. Two commenters (Dr. Parran and Dr. Gibbs) were supportive of the rules as written.
b. Two commenters and patients (Mari Beth Cerech and Sandra Sizemore) indicated that the rules would have a negative impact on chronic pain patients.
c. Seven commenters (Seth Dobbelaer, Marcie Seidel, Anahi Ortiz, M.D., Debbie Burrell, Pamela Knight, Trish Perry, and Cheri Bryson) recommended changing the

language to include a co-prescription for naloxone at 50MED to reflect the CDC guidelines.

d. Four commenters (OSMA, Ohio Health, John Naveau, M.D., and Jennifer Barnhouse) expressed concerns that pain management specialists may not be available. OSMA and Ohio Health suggested considering elimination of the face-to-face visit requirement.
e. OSMA recommended the elimination of written informed consent and expressed concerns regarding the use of OARRS data for the enforcement of the rule.
f. Ohio Health had some questions regarding the applicability of the grandfather provisions.

The comments were discussed in detail at the June 13, 2018 Policy Committee meeting and the Board meeting later that day. The Board determined to make a change to Rule 4731-11-14 to add a provision at paragraph (C)(5) to require a physician to consider offering a naloxone prescription at 50MED to mitigate risk of overdose.

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 Ohio Guidelines for Prescribing opioids for the Treatment of Chronic Non-Terminal Pain 80 Mg of a Morphine Equivalent Daily Dose (MED) "Trigger Point" developed by GCOAT and adopted by the Medical Board in 2013 and Guideline for Prescribing Opioids for Chronic Pain adopted by the Centers for Disease Control and Prevention in 2016 were relied upon as foundational sources for the rules in this package. The Board also reviewed and relied upon similar rules developed in the states of Virginia and Washington.

OARRS data from the Ohio Board of Pharmacy indicates that as of September 2017, Ohio patients were receiving opioids in the following doses:

50MED: 106,389 patients
80MED: 55,309 patients
120MED: 24,427 patients

The risk of overdose increases as the dose exceeds 50MED and this informed the need for a rule that established safety procedures and checkpoints for patients as the dosage increased.

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 is rescinding its existing rules on chronic pain prescribing as part of this rule package. In addition, 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 subaute and chronic pain will need to be aware of the checkpoints at 50, 80 and 120 MEDand may need to more frequently see the patients receiving these prescriptions. In addition, prescribers will need to obtain consultations with specialists and implement drug screening in certain circumstances. A naloxone prescription may need to be offered to the patient in certain circumstances. 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 2016, 4,050 Ohio residents died from unintentional drug overdoses, a 32.8 percent increase compared to 2015. The state is interested in limiting the number of opioid analgesics that are available and providing additional care and resources to patients receiving high amounts of opioids for six weeks or

longer. Requiring prescribers to offer a naloxone prescription, a drug that reverses opioid overdose, to patients at risk of overdose is one of the key components of the rules. The State has a compelling interest in promoting safe treatment of pain while avoiding risks of harm to patients.

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.