CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Impaired Practitioners

Rule Number(s): 4731-16-01, 4731-16-02, 4731-16-04, 4731-16-05, 4731-16-06, 4731-16.07, 4731-16-08, 4731-16-09, 4731-16-10, 4731-16-11, 4731-16-12, 4731-16-13, 4731-16-14, 4731-16-15, 4731-16-16, Ohio Administrative Code

Date: August 29, 2017

Rule Type:

- ☐ New
- ☐ Amended
- x5-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- ☐ Rescinded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

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

The rules outline the Board's comprehensive program in addressing licensees who are impaired in their abilities to practice according to acceptable and prevailing standards of care because of habitual or excessive use or abuse of drugs, alcohol, or other substances that imapair ability to practice. The rules apply to licensees of the Board as well as treatment providers approved by the Board for the treatment of impaired practitioners. The following is a listing of the rules.

Rule 4731-16-01 Definitions
Rule 4731-16-02 General Procedures in Impairment Cases
Rule 4731-16-04 Other Violations
Rule 4731-16-05 Examinations
Rule 4731-16-06 Consent Agreements and Orders for Reinstatement
Rule 4731-16-07 Treatment Provider Program Obligations
Rule 4731-16-08 Criteria for Approval
Rule 4731-16-09 Procedures for Approval
Rule 4731-16-10 Aftercare Contracts
Rule 4731-16-11 Revocation, Suspension, or Denial of Certificate of Good Standing
Rule 4731-16-12 Out-of-State Impairment Cases
Rule 4731-16-13 Duty to Report or Refer Practitioner, Execution of Release Forms
Rule 4731-16-14 Caffeine, Nicotine, and Over-The-Counter Drugs
Rule 4731-16-15 Patient Rights
Rule 4731-16-16 Practice Prohibition

The rules are proposed as no change rules at this time.

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

   Sections 4730.07, 4731.05, 4760.19, 4762.19, 4774.11, and 4778.12, 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.

   No, the regulations 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.**

   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)?**

The rules set forth the Board's program for evaluating and monitoring licensees who are unable to practice pursuant to acceptable and prevailing standards of care due to habitual or excessive use or abuse of drugs, alcohol or other substances that impair the ability to practice. The rules set forth the requirements for standardized treatment and monitoring by treatment providers approved by the Board. Impaired licensees can cause serious health and safety issues for their patients and the rules provide a clear requirement for those licensees to cease practice upon a determination of impairment until the licensee is cleared to return to practice.

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

   Success will be measured in terms of compliance by licensees and treatment providers.

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.

   On June 10, 2016, the rules set forth below in Chapter 4731-16, Ohio Administrative Code were circulated to interested parties for comment. These included healthcare associations and treatment providers.

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

With the exception of one comment from Dr. Whitney questioning whether the Board was changing its position on Rule 4731-16-16, the Board did not receive any comments through the rule review process. The portions of these rules that deal with the one-bite reporting exemption for impairment are the subject of discussions and work group meetings with Representative Grossman, Ohio Physicians' Health Program and other associations and H.B. 145 pending in the Senate.

The rules are past the 5-year rule review and need to be updated. We would like to update the rules as no change rules now and then will address the changes needed with the passage of H.B. 145 when it becomes effective.

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 have been in place for many years and are based on best practices for treating individuals with chemical dependency issues.

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 has been working to make changes to the reporting exemption for impaired licensees, and will make rule changes as necessitated under H.B. 145 when it becomes effective. In the meantime, the Board wants to move forward with the rules as no-change in order to update the rules since they are beyond the five-year rule review period.

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 rules are performance based in that they set forth the basic minimum requirements and leave the process up to the treatment providers.

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

    There are no other regulations for the treatment and monitoring of impaired licensees of the Medical Board.

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.**

    Notice of the proposed rules in Chapter 4731-16 will be sent to licensees and interested parties and posted on the Medical Board's website. Medical Board staff will be available to address questions that may arise.

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;**
       Licensees regulated by the Medical Board, including physicians, podiatrists, physician assistants, massage therapists, cosmetic therapists, radiologist assistants, acupuncture and oriental medicine practitioners, genetic counselors, and anesthesiologist assistants.

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

Failure to comply with the Board's rules in Chapter 4731-16 could result in discipline, ranging from a reprimand to permanent revocation. In addition, violation of these rules could result in a fine up to $20,000. Cost of compliance, such as fees for evaluations, treatment and monitoring as well as periodic drug screens are borne by the licensees.

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.

According to the National Institute on Drug Abuse, the costs of drug and alcohol treatment can range anywhere from $5000 to $50,000, with the national average at $18,000 in 2014.

Service fees for licensed practitioners receiving drug screening with FirstSource Solutions, Inc, the third-party administrator used by the Board are as follows:

Option 1	Quest MEDPRO B	$ 36.00
Option 2	Quest MEDPRO B with ETG	$ 61.00
Option 3	Quest MEDPRO E	$ 61.00
Option 4	Quest MEDPRO E with ETG	$ 87.00
Option 5	Quest ETG	$ 31.00
Option 6	Quest panel 23355N	$ 80.50
Option 7	Quest MEDPRO D	$ 52.00
Option 8	Quest MEDPRO D with ETG	$ 77.50
	Quest MEDPRO C	$ 39.25
	Quest MEDPRO C with ETG/ETS	$ 64.75
	Quest panel 21791N	$182.25
	Quest 5 panel blood drug panel 23429N	$241.00
	Quest 7 panel blood drug panel 22945N	$256.00
	Quest 9 panel blood drug panel 23427N	$271.00
	Quest Dextromethorphan panel 24186N	$83.50 stand-alone
	Quest Dextromethorphan panel 112811	$44.50 add-on
	MedTox K2 SPICE panel 191116	$106.00 includes shipping lab to lab
	MedTox Bath Salts panel 2786	$106.00 includes shipping lab to lab

USDTL Phosphatidyl Ethanol (PeTH)	$143.50
USDTL HairStat 5	$ 66.00
USDTL HairStat 7	$ 79.00
USDTL HairStat 9	$ 94.00
USDTL HairStat 10	$139.00
USDTL HairStat 12	$214.00
USDTL HairStat 14	$289.00
Omega Oral Fluid 6 panel	$ 24.25 plus shipping
Omega Oral Fluid 10 panel	$ 27.00 plus shipping
NMS Propofol (Diprivan) in urine panel 4018U	$201.00 includes shipping
NMS GHB Gammahydroxybutyrate panel 9326U	$201.00 includes shipping NMS
Sevoflurane in blood panel 7701	$551.00 plus shipping lab to
lab NMS Lidocaine in blood panel 93117B	$188.50 plus shipping lab to
lab NMS Lidocaine in urine panel 93117U	$146.50 plus shipping lab to
lab	

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

    Licensees who are impaired in their ability to practice due to drugs, alcohol or other substances can cause serious health and safety issues for their patients, which justifies any adverse impact.

Regulatory Flexibility

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

    No. The potential health and safety consequences to the public for not following the rules in Chapter 4731-16 are significant. All licensees and treatment providers are held to the same standards.

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?**

    Given the potential harm to the public for noncompliance with the rules, any waiver would be inappropriate.

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

The Medical Board provides information via email blasts to licensees and posts information on its website. Where needed, guidance documents are created to explain information that is not clear. The Medical Board staff is available via telephone and e-mail.