10/10/19

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

New:

- 4729:4-1-09: Provides the requirements for terms while under supervision.

Amend:

- 4729:4-1-01: Provides definitions for the licensee probation chapter of the administrative code. The rule is amended to update a reference to the DSM-5, include an approved monitoring program as part of an individualized treatment plan, and added definitions for “business day” and “hemp products.”
- 4729:4-1-02: Outlines reinstatement requirements for a license or registration due to impairment. The rule is amended to include language that the treatment program needs to be approved and or an approved monitoring contract.
- 4729:4-1-04: Creates requirements for a licensee or registrant who enters a monitoring program contract after treatment. Amended to include “hemp products.”
- 4729:4-1-05: Provides the requirements for a licensee or registrant placed on probation. Amended to include language of approval by the board, violation of the term of probation may result in additional action by the board, and probation is unrelated to impairment the board may impose other probationary conditions.
- 4729:4-1-07: Provides the requirements for the summary suspension of a license or registration of an impaired pharmacy professional. Amended to include monitoring contract from an approved treatment provider.

No Change:

- 4729:4-1-03: Provides requirements to become an approved treatment provider for pharmacy professionals.
- 4729:4-1-06: Provides requirements for approved monitoring programs.

Comments on the proposed rules will be accepted until close of business on October 31, 2019. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov

Business Impact Analysis

Agency, Board, or Commission Name: State of Ohio Board of Pharmacy

Rule Contact Name and Contact Information:
Cameron McNamee (cameron.mcnamee@pharmacy.ohio.gov)

Regulation/Package Title (a general description of the rules' substantive content):
Probation Rules

Rule Number(s): 4729:4-1-01, 4729:4-1-02, 4729:4-1-03, 4729:4-1-04, 4729:4-1-05, 4729:4-1-06, 4729:4-1-07, 4729:4-1-09

Date of Submission for CSI Review: 10/10/19

Public Comment Period End Date: 10/31/19

Rule Type/Number of Rules:

New/ 1 rules — No Change/ 2 rules (FYR? Y)

Amended/ 5 rules (FYR? Y) — Rescinded/____ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing

regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   4729:4-1-03: Requires certification by the Department of Mental Health and Addiction Services or the Board.

   4729:4-1-06: Requires Board authorization for approved monitoring programs.

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   4729:4-1-04: Violation of this rule may result in administrative licensure discipline.

   4729:4-1-05: Violations of probation terms in the rule may result in an extension of the probationary period.

   4729:4-1-07: This regulation may result in the immediate suspension of a license or registration of a pharmacy professional.

   4729:4-1-05: The violations of probation terms in the rule may result in additional Board action including revocation of the pharmacy professional's issued license or registration.

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   4729:4-1-03: Requires reporting of infractions by probationers to the Board.

   4729:4-1-04: Requires costs related to drug screens.

   4729:4-1-05: Requires submission of quarterly form to the probation committee.

   4729:4-1-06: Requires approved treatment monitors and report deviations to the Board.

4729:4-1-09: Requires reporting to the Board of any violation of terms of suspension and reporting of information to the Board during the period of suspension.

d. ☐ Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

Regulatory Intent

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

New:

- 4729:4-1-09: Provides the requirements for terms while under supervision.

Amend:

- 4729:4-1-01: Provides definitions for the licensee probation chapter of the administrative code. The rule is amended to update a reference to the DSM-5, include an approved monitoring program as part of an individualized treatment plan, and added definitions for "business day" and "hemp products."
- 4729:4-1-02: Outlines reinstatement requirements for a license or registration due to impairment. The rule is amended to include language that the treatment program needs to be approved and or an approved monitoring contract.
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- 4729:4-1-05: Provides the requirements for a licensee or registrant placed on probation. Amended to include language of approval by the board, violation of the term of probation may result in additional action by the board, and probation is unrelated to impairment the board may impose other probationary conditions.
- 4729:4-1-07: Provides the requirements for the summary suspension of a license or registration of an impaired pharmacy professional. Amended to include monitoring contract from an approved treatment provider.

No Change:

- 4729:4-1-03: Provides requirements to become an approved treatment provider for pharmacy professionals.
- 4729:4-1-06: Provides requirements for approved monitoring programs.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

The proposed rules are authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 4729.18 and 3719.121.

4. **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 proposed rules do not implement a federal requirement.

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

   This rule package exceeds federal requirements because the regulation of pharmacy professionals has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the State of Ohio Board of Pharmacy.

6. **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)?**

   Section 4729.26 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

   Section 3719.28 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules to facilitate surveillance of traffic in drugs, to prevent the improper acquisition or use of controlled substances or their diversion into illicit channels.

   The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in the above referenced chapters of the Ohio Revised Code to promote the public's safety and uniformity of care throughout Ohio. Without these regulations, the Ohio State Board of Pharmacy would not be able to ensure pharmacy professionals are monitored to ensure that they are complying with required substance abuse treatment plans.

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

   The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees and registrants regarding the provisions of the rules.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. **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.

This rule package was distributed to stakeholders and posted for public comment and were also reviewed by the Board.

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

The Board did not receive any comments during the public comment period.

11. **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?**

Scientific data was not used to develop or review this rule package.

12. **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?**

As the regulations are essential to protecting the public's health and safety by ensuring uniform regulations related to the treatment of substance abuse amongst pharmacy professionals, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. **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 agency did not consider a performance-based regulation for this rule package. It is the Board's responsibility to ensure uniform regulations across Ohio. At this juncture, it was the determination of the Board and the Rules Review Committee that the rule package did not lend itself to performance-based regulations.

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

The Board of Pharmacy's Director of Policy and Communications and Chief Legal Counsel reviewed the proposed rules to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation.

15. 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 Pharmacy Board's web site, information concerning the rule will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Pharmacy Board staff are also available via phone or email to answer questions regarding implementation of the rule. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Pharmacy Board staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates from the Board's Director of Policy and Communications and feedback from the Board's Chief Legal Counsel for every citation submitted.

Adverse Impact to Business

16. 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; and

The rule package impacts the following:

- Pharmacists;
- Pharmacy interns; and
- Pharmacy technicians.

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

Violation of these rules may result in administrative licensure discipline for a pharmacist, pharmacy intern and pharmacy technician. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

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.

New:

- 4729:4-1-09: Provides the requirements for terms while under supervision. This rule requires prior approval from the Board or the Board's probation committee if leaving the state for more than three days. This requires submission of notification to the Board's legal department and should only take 15-30 minutes to compose and submit. It also requires the individual under probation to provide copies of Board orders and settlement agreements to prospective and current employers. These documents are available online for free so compliance with this requirement will have a minimal impact on the licensee.

Amend:

- 4729:4-1-01: Provides definitions for the licensee probation chapter of the administrative code. The rule is amended to update a reference to the DSM-5, include an approved monitoring program as part of an individualized treatment plan, and added definitions for "business day" and "hemp products". The regulation should have no adverse impact as it is a definition section.
- 4729:4-1-02: Outlines reinstatement requirements for a license or registration due to impairment. The rule is amended to include language that the treatment program needs to be approved and or an approved monitoring contract. This rule authorizes the Board to require the pharmacy professional to receive treatment, the costs of which vary based on the treatment provider and length of stay.
- 4729:4-1-04: Creates requirements for a licensee or registrant who enters a monitoring program contract after treatment. Amended to include "hemp products". The individual will incur the costs of any random, unannounced blood or urine screens, and the costs of a hair sample test in the event of a negative diluted screen. The individual can also incur the costs of professional therapy where indicated.
- 4729:4-1-05: Provides the requirements for a licensee or registrant placed on probation. Amended to include language of approval by the board, violation of the term of probation may result in additional action by the board, and probation is unrelated to impairment the board may impose other probationary conditions. This regulation requires approved treatment monitors monitor and report deviations to the Board. Such requirements would result administrative costs incurred by the monitor.
- 4729:4-1-07: Provides the requirements for the summary suspension of a license or registration of an impaired pharmacy professional. Amended to include monitoring

contract from an approved treatment provider. The adverse impact would be the immediate suspension of a license or registration by the Board.

No Change:

- 4729:4-1-03: Provides requirements to become an approved treatment provider for pharmacy professionals. The regulation would require the approved treatment provider to monitor and report certain infractions to the Board. Such requirements would result administrative costs incurred by the provider.
- 4729:4-1-06: Provides requirements for approved monitoring programs. It will take an estimated 20 to 30 minutes to submit quarterly declaration to the Board of Pharmacy. The individual will incur the costs of any random, unannounced blood or urine screens.

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

The Board determined that the regulatory intent justifies the impact on business because the regulations are intended to protect and promote public safety. In particular, they ensure uniform regulations that allow for the monitoring of pharmacy professionals who suffer from substance abuse or mental illness to ensure that they comply with all requirements of their treatment plan.

Regulatory Flexibility

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

These rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

19. 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?

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the practice of pharmacy or the preparation/distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

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

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations. Additionally, field staff (i.e. compliance officers) is trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

Furthermore, the Board's probation committee can provide additional guidance to licensees/registrants who need additional information.

Chapter 4729:4-1 Probation Committee

4729:4-1-01 Definitions - impaired licensees, registrants and probation.

As used in division 4729:4 of the Administrative Code:

(A) "Substance abuse/chemical dependency" means a substance use disorder as defined by the "Diagnostic and Statistical Manual of Mental Disorders" (DSM-5) or any official supplement thereto (10/~~16~~1/~~2016~~2018).

(B) "Impaired licensee or registrant" means a licensee or registrant who, because of ~~his/her~~the person's mental illness, habitual or excessive use or abuse of drugs or alcohol, use of psychoactive substances, or use of other substances that impair the ability to practice, is rendered unable to practice pharmacy or conduct authorized activities within a pharmacy with requisite judgment, skill, competence, or safety to the public.

(C) "Approved treatment provider" means a designated treatment program pursuant to section 4729.18 of the Revised Code and rule 4729:4-1-03 of the Administrative Code.

(D) "Approved monitoring program" means a board approved and designated monitor pursuant to section 4729.18 of the Revised Code and rule 4729:4-1-06 of the Administrative Code.

(E) "Intervenor" means a person who is employed by or affiliated with an approved treatment provider or an approved monitoring program and participates in a process whereby a licensee or registrant alleged to be impaired is confronted to evaluate the presence of impairment and, if indicated, who refers the licensee or registrant for assessment and treatment of the impairment.

(F) "Referral for assessment" means a process whereby an intervenor or designated person who has reason to believe that a licensee or registrant is impaired directs that individual to be examined for diagnosis and treatment.

(G) "Treatment assessor" means any of the following:

(1) An individual who is licensed under Chapter 4731. of the Revised Code as a doctor of medicine or a doctor of osteopathic medicine and surgery and who is a certified addiction specialist; or

(2) An individual who is licensed by the Ohio chemical dependency professionals board as a licensed independent chemical dependency counselor, licensed chemical dependency counselor 3 or 2 pursuant to Chapter 4758. of the Administrative Code and, who by training and experience, can make an assessment of a licensee or registrant's impairment.

(H) "Individualized treatment plan" is a document which shall provide for inpatient treatment, outpatient treatment, family therapy, psychotherapy, professional support groups, twelve-step programs, aftercare including support and self-help groups, monitoring programs consisting of random, chain of evidence drug screens, and work site review. Such services and other services may be determined by an approved treatment provider or an approved monitoring program.

(I) "Treatment contract" means a document which outlines the individualized treatment plan, the requirement to cease practice, the requirement for compliance by the impaired licensee or registrant, and the requirement for notification of the board for non-compliance or relapse pursuant to section 4729.18 of the Revised Code.

(J) "Inpatient treatment" shall consist of placing the licensee or registrant in an approved treatment provider facility that will provide lodging and food, as well as care and treatment for detoxification and rehabilitation as indicated by the treatment contract.

(K) "Outpatient treatment" shall consist of the licensee or registrant not residing in an inpatient treatment facility but who is participating in aftercare, twelve-step programs, professional support group (if available), and monitoring programs consisting of random, chain of evidence drug screens and work site review, to establish compliance.

(L) "Designated person" for an approved treatment provider or approved monitoring program is an individual who shall be in full and actual charge of the treatment or monitoring program including, but not limited to, the following:

(1) Ensuring the provider has the necessary facilities and personnel to provide services;

(2) Maintaining records; and

(3) Notification of the board when required.

(M) "Twelve-step program" means a self-help program such as alcoholics anonymous or narcotics anonymous or a related organization that addresses substance use disorders and promotes sobriety and recovery through peer group support, self-help, and anonymity, and which is based on an abstinence model of recovery. An impaired licensee or registrant shall be required to personally attend face-to-face twelve-step programs not less than three documented meetings each week, on separate days. Meetings that occur online, telephonically, or via other electronic means shall not be counted towards the minimum requirement.

(N) "Aftercare" is a counselor-facilitated group meeting which directly responds to problems relating to the ongoing treatment and monitoring of the licensee or registrant's sobriety and should extend for a minimum of twelve months.

(O) "Professional support group" is a group of peers meeting to discuss the problems specific to recovery and re-entry to practice of the licensee or registrant.

(P) "Relapse" means any use of, or obtaining for the purpose of using, drugs, alcohol, psychoactive substances, or any use of other substances that impair the ability to practice; it also includes a positive drug screen or a return to a pattern of impairment activities which affects the licensee or registrant's ability to practice. Relapse also refers to a mental health or mental illness episode that impacts or impairs the ability to practice pharmacy or conduct authorized activities within a pharmacy with the requisite judgment, skill or competence to ensure the safety of the public.

(Q) “Business day” means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the offices of the board of pharmacy are not open for business.

(R) “Hemp products” has the same meaning as defined in section 924.212 of the Revised Code.

NOTE: The definition rule will be reorganized in alphabetical order. Therefore, this rule will be rescinded and replaced with the text changes above.

4729:4-1-02 Applicability.

(A) No person, except an approved treatment provider, shall purport to be or operate as a treatment facility for the purpose of administering care in the detoxification and rehabilitation of an impaired licensee or registrant.

(B) The rules in this division of the Administrative Code are applicable to all licensed pharmacists, pharmacy interns, and any other board licensees or registrants, including pharmacy technician trainees, registered pharmacy technicians, and certified pharmacy technicians.

(C) Should the board have reason to believe that a pharmacist, pharmacy intern or other licensee or registrant suffers from impairment because of conduct or behavior committed or displayed by the individual, the board may compel the individual to be examined by an approved treatment provider. If the licensee or registrant fails to submit to an assessment as ordered by the board, or if the assessment discloses impairment, or if there is an admission of impairment, or if the board has other reliable, substantial, and probative evidence demonstrating impairment, the board may:

(1) Refer the licensee or registrant for treatment;

(2) Initiate action against the licensee or registrant pursuant to Chapters 119., 3719.

and 4729. of the Revised Code; or

(3) Summarily suspend the license or registration of an individual pursuant to rule 4729:4-1-07 of the Administrative Code if the licensee or registrant's continued practice poses a danger of immediate and serious harm to others.

(D) Before being eligible to apply for reinstatement of a license or registration suspended because of impairment, the licensee or registrant must demonstrate to the board that ~~he/she~~the licensee or registrant possesses the requisite judgment, skill, and competence to ensure public safety. Such demonstration shall include, but not be limited, to the following:

(1) Certification from an approved treatment provider and/or approved monitoring program that the licensee or registrant:

(a) Has signed an approved treatment and/or approved monitoring contract and is participating in and complying with an individualized treatment plan;

(b) Has successfully completed any required inpatient treatment;

(c) Is actively participating in or has successfully completed an outpatient treatment program;

(d) Has demonstrated ~~he/she~~ the licensee or registrant has continued to be alcohol, drug, and psychoactive drug free, as well as free from mind-altering, mood-changing substances, by

random, chain of evidence drug screens for a period of time as determined by the board at the time of the suspension;

(e) Has been evaluated by an approved treatment provider who has made a clear determination, documented in a written statement, that the licensee or registrant is eligible to return to practice.

(2) Certification that the licensee or registrant has met all requirements of the board order and satisfactory evidence has been submitted to the board, including, but not limited, to the following:

(a) A copy of the signed and agreed to treatment and/or monitoring contract;

(b) Written reports and documentation from the approved treatment program and monitoring program;

(c) Written reports, on a form designated by the board, from the licensee or registrant describing recovery progress.

4729:4-1-03 Requirements for approved treatment providers.

(A) An approved treatment provider, as defined in rule 4729:4-1-01 of the Administrative Code, shall meet or exceed the following requirements:

(1) Certification, as determined by the board, by the Ohio department of mental health and addiction services pursuant to Chapter 5119. of the Revised Code.

(2) Any other treatment provider approved by the board, to include:

(a) An out-of-state provider, when treatment has already been initiated or completed; or

(b) Any provider not certified in accordance with paragraph (A)(1) of this rule.

(3) Any treatment provider must be approved prior to a licensee or registrant participating in the program, unless the board finds exceptional circumstances exist, in which case the board may approve the treatment provider during or after treatment.

(B) An intervenor associated with an approved treatment provider shall:

(1) Respond to information from concerned individuals;

(2) Ascertain validity of the information received;

(3) Assess the situation and, if the licensee or registrant is showing evidence of impairment, the intervenor shall refer the individual for evaluation;

(4) If the licensee or registrant fails to comply within one week to a referral for evaluation, the intervenor must report the name of the individual to the board within one business day.

(C) A treatment assessor associated with an approved treatment provider shall evaluate a licensee or registrant referred to the approved treatment provider to determine if the licensee or registrant has a substance use disorder related impairment.

(1) If such an impairment exists, the approved treatment provider shall formulate the licensee or registrant's individualized treatment plan as defined in rule 4729:4-1-01 of the Administrative Code. The specific requirements shall be determined by an assessment of psychological, physical, developmental, family, social, environmental, recreational, and professional needs. The individualized treatment plan shall be part of a treatment contract which the impaired licensee or registrant must sign. If the impaired licensee or registrant fails to sign the treatment contract and enter treatment within forty-eight hours of the determination that the licensee or registrant needs treatment, the approved treatment provider must report the name of the licensee or registrant to the board within one business day.

(D) The designated person for the approved treatment provider shall:

(1) Establish a system of records that will provide for complete information about an impaired licensee or registrant from intervention through the rehabilitation stage;

(2) Establish treatment contracts meeting the requirements of this division and a system of follow up to determine compliance by the impaired licensee or registrant with the treatment contract;

(3) Ensure the confidentiality of the impaired licensee or registrant, except:

(a) If the licensee or registrant fails to comply within one week to a referral for evaluation;

(b) If the impaired licensee or registrant fails to sign the contract and enter treatment within forty-eight hours of the determination that the licensee or registrant needs treatment;

(c) If the impaired licensee or registrant does not suspend practice on entering treatment;

(d) If the impaired licensee or registrant does not comply with the terms of the treatment contract;

(e) If the impaired licensee or registrant resumes practice before the approved treatment provider or monitoring program has made a clear determination that the licensee or registrant is capable of practicing;

(f) If the impaired licensee or registrant suffers a relapse at any time.

(4) Notify the state board of pharmacy within one business day if the licensee or registrant violates any provision of this rule.

4729:4-1-04 Monitoring contracts.

(A) Within one week of completing treatment, in the absence of extenuating circumstances, the licensee or registrant shall enter into a monitoring contract with an approved monitoring program regardless of whether the licensee or registrant is under a period of suspension or probation.

(B) The monitoring program contract shall include all of the following requirements:

(1) Group therapy, support groups, or, when appropriate, individual counseling, or a combination thereof.

(2) Periodic, random, unannounced blood and/or urine screens at a frequency of at least monthly and sixteen times per year for the length of the contract, unless otherwise approved by the board or the board's probation committee and to provide additional random, observed urine and/or blood samples as may be requested by the intervenor or designated person.

(a) The urine sample must be given within twelve hours of notification.

(b) The dilution standard will be creatinine clearance and/or specific gravity.

(c) Results of all drug screens must be negative and the refusal of a drug screen or a diluted drug screen is equivalent to a positive result. Any positive results, including those which may have resulted from ingestion of food but excluding false positives which resulted from medication legitimately prescribed, indicates a violation of the contract and shall be reported to the board or the board's probation committee.

(d) In the event of a negative diluted screen, a hair sample test must be completed at the cost of the probationer in a time frame consistent with the drug laboratory's recommended policy, but in any event no later than twelve days after the negative diluted screen.

(3) Mandatory participation in alcoholics anonymous, narcotics anonymous, or a similar twelve-step program, or its equivalent, as set forth in rule 4729:4-1-01 of the Administrative Code.

(a) To obtain the signatures of either the secretary or chairperson of the meeting for attendance verification or, in the absence of both, a meeting representative.

(b) To be responsible for keeping a personal record of names and phone numbers of the persons signing attendance verification at meetings.

(c) To record meeting attendance dates in a chronological order and collect the attendance verification signatures at the meeting.

(d) To attend another meeting that same week in order to meet the quota of meetings for the week if attendance verification is not obtained.

(e) To obtain a sponsor and home group in a twelve-step program, or its equivalent, as set forth in rule 4729:4-1-01 of the Administrative Code that is not a representative of the monitoring program by a date specified by the approved monitor.

(4) Abstinence from use of alcohol and from use of drugs, except those prescribed, administered or personally furnished by a licensed prescriber who has knowledge of the patient's history and of the disease of addiction, or those administered by another person so authorized by law during a medical emergency.

(a) To notify the intervenor or designated person in advance and provide documentation of the need for any medication (to include a copy of the prescription or note from the prescriber) within forty eight hours of receipt of treatment, if any mood altering and/or potentially addictive medications are required or recommended by the prescriber.

(b) To renew verification with the intervenor or designated person every ninety days if the need for medication is ongoing.

(c) To update medication list with the intervenor or designated person any time a new prescription or over-the-counter medication is added.

(d) To abstain from dispensing own prescriptions.

(e) To avoid exposure to anything that may cause drug screen tests to be positive, including "hemp oil," "hemp products," "coca tea," and poppy seeds.

(f) To abstain from using ethyl alcohol in any form including, but not limited to, the following:

(i) Alcohol free wine or beer;

(ii) Over-the-counter drugs containing alcohol, cough syrups or their similar drugs or supplements;

(iii) Mouthwash or other hygiene products containing ethanol, including sanitizing hand or body gels;

(iv) Foods or beverages containing alcohol; and

(v) Any other form of ethyl alcohol.

(5) Acknowledgment of the relinquishment of the right to self-medicate other than use of single entity over-the-counter non-steroidal anti-inflammatories or acetaminophen.

(6) Regular contact with a licensed chemical dependency counselor, or with a physician qualified by training or experience, or both, to treat chemically dependent persons, who assumes

responsibility for monitoring defined aspects of aftercare contract compliance, and who agrees to:

(a) Report any noncompliance to the approved monitoring program; and

(b) Report any relapse to the approved monitoring program and the board.

(7) A length of contract specified with a minimum of at least five years and at least fifty-two weekly aftercare sessions, with missed sessions to be made up.

(8) Professional therapy, where indicated, to resolve family and work-related issues.

(9) Treatment of any ongoing medical problems to be managed by a licensed prescriber. Treatment of any conditions requiring the use of a mind-altering, mood-changing substance shall require consultation with a physician qualified by training or experience, or both, to provide medical care to chemically dependent persons.

(a) Agreement to identify a single primary care physician and utilize that physician (or physician to whom referred) exclusively for all medical care for the duration of the contract.

(b) Agreement for identified physician to share with approved monitor information on any drugs prescribed or, if over-the-counter drugs, approved, and the information pertinent to recovery and/or compliance with the contract.

(c) Intervenor or designated person approved surgery packet prior to any non-emergency medical procedures.

(10) Referral to other forms of extended care, when indicated.

(11) Any required supervision or restrictions of practice during aftercare.

(12) Personal contact with the assigned intervenor once a week, leaving a message shall not meet the personal contact requirement.

(13) An agreement to attend the pharmacist peer assistance group meetings each month for the duration of the contract, unless otherwise excused by the designated person or the designated person's designee.

4729:4-1-05 Probation.

(A) Probation will be reviewed by members of the board's probation committee and board staff. When a licensee or registrant is placed on probation, the board shall require, at a minimum, the following probationary and limiting terms:

(1) Compliance with all federal, state, and local laws, and all rules governing practice in Ohio.

(2) Submission of quarterly declarations on a form approved by the board or the board's probation committee stating, under penalty of perjury, whether there has been compliance with all conditions of probation and, if applicable, treatment.

(3) Periodic appearances before the board or its representatives as requested.

(4) A minimum five-year contract with an approved monitoring provider, unless otherwise exempted by the board.

(5) Compliance with all terms of the approved monitoring contract, which shall include all terms set forth in rule 4729:4-1-04 of the Administrative Code.

(6) Prior ~~notification~~ approval ~~-~~of the board or ~~to the board or~~ the board's probation committee ~~or full board~~ of departures or absences in excess of three days from Ohio. Periods of departure or absence shall not reduce the probationary term, unless otherwise determined by motion of the board or the board's probation committee.~~,~~ F~~f~~or absences of three months or longer in instances where the board can be assured that probationary monitoring is otherwise being performed.

(7) Inability to engage in a consult agreement, unless otherwise approved by the board or the board's probation committee.

(8) As designated in the board's order, submission of observed urine, blood, or hair samples upon request of the approved monitoring program or board, and without prior notice, at the cost of the licensee or registrant.

(9) Compliance with any employer provided drug or alcohol screens.

(10) When deemed appropriate by the board or the board's probation committee, undertaking psychiatric evaluation, and, where appropriate, continuing treatment acceptable to the board, with evidence of compliance to be provided in each quarterly report.

(11) Copies of the board order or settlement agreement to be provided by the individual to all of the following during the effective period of the board order or settlement agreement:

(a) All employers or prospective employers,

(b) ~~and a~~All persons and entities that provide the individual chemical dependency treatment or monitoring; and

(~~b~~c) By certified mail, the proper licensing authority of any state or jurisdiction in which the individual holds or applies for any professional license, excluding the state of Ohio board of pharmacy.

(12) Continuing compliance with the terms of the monitoring contract entered into with the treatment provider and approved monitoring provider, provided, that where terms of the monitoring contract conflict with the terms of the settlement agreement or board order, the terms of the settlement agreement or board order shall control.

(13) Continuing authorization, through appropriate written consent forms, for disclosure by the treatment provider and/or approved monitor to the board, to treating and monitoring physicians, and to others involved in the monitoring process, of information necessary for those individuals to fulfill their respective duties and obligations.

(14) Minimum probationary term of at least five years, unless otherwise approved by the board.

(15) No requests by the probationer for modifications to probationary terms for at least three years, however, limited, isolated deviations from the probationary terms may be granted with the approval by the board or its probation committee in exceptional circumstances.

(16) Self-reporting of any violation of one or more terms of probation.

(17) Maintain a current address with the Board.

(B) Periods during which the probationer is not in compliance with all probationary terms shall toll the length of time of probation during which the probationer was out of compliance. The board shall issue a resolution setting forth the minimum length of time each violation will toll the probationary term. The resolution shall be updated as necessary and available on the board's web site, www.pharmacy.ohio.gov. The board may implement additional disciplinary action in addition to or instead of tolling probation.

(C) Violation of any term of probation may result in additional action before the board up to and including revocation of the registrant or licensee's pharmacy board issued license or registration.

(D) In the event the probation is unrelated to impairment as defined in 4729:4-1-01, the Board may impose any other probationary conditions as it warrants applicable to the individual facts pertaining to discipline.

4729:4-1-06 Requirements for approved monitoring programs.

(A) An approved monitoring program, as defined in rule 4729:4-1-01 of the Administrative Code, must be approved by the state board of pharmacy and shall meet or exceed the following requirements:

(1) Have board approved policies and procedures which shall include, but not be limited to, the following:

(a) The program's standards and procedures for care;

(b) The program's standards and training/approval process for personnel.

(2) Have personnel including, but not limited to, an intervenor and a designated person as defined in rule 4729:4-1-01 of the Administrative Code.

(B) An intervenor associated with an approved monitoring program shall:

(1) Respond to information from concerned individuals;

(2) Ascertain validity of the information received;

(3) Assess the situation and, if the licensee or registrant is showing evidence of impairment, the intervenor shall refer the individual for evaluation;

(4) If the licensee or registrant fails to comply within one week to a referral for evaluation, the intervenor must report the name of the licensee or registrant to the board within one business day.

(C) The designated person for the limited approved treatment provider shall:

(1) Ensure confidentiality of the impaired licensee or registrant, except:

(a) If the licensee or registrant fails to comply within one week to a referral for evaluation; or

(b) If the impaired licensee or registrant suffers a relapse at any time during or following rehabilitation.

(2) Notify the state board of pharmacy within one business day if the licensee or registrant violates any portion of this rule.

4729:4-1-07 Summary suspension of a licensee or registrant.

(A) An impaired licensee or registrant may be summarily suspended without a prior hearing pursuant to section 3719.121 of the Revised Code if, in the opinion of the board, the impaired licensee or registrant poses a danger of immediate and serious harm to others by:

(1) Refusing to seek evaluation, treatment, and rehabilitation for a substance abuse/chemical dependency related impairment;

(2) Not signing and/or complying with the treatment and/or monitoring contract from an approved treatment provider or monitoring program;

(3) Resuming practice before the approved treatment provider or monitoring program has made an assessment and recommends that the licensee or registrant is capable of practicing;

(4) A relapse, as defined in rule 4729:4-1-01 of the Administrative Code, of substance abuse/chemical dependency at any time.

(B) An impaired licensee or registrant may be summarily suspended without a prior hearing pursuant to section 3719.121 of the Revised Code if a the licensee or registrant is guilty of a felony drug abuse offense as defined in section 2925.01 of the Revised Code.

4729:4-1-09 Terms while under suspension. (NEW)

(A) When a licensee or registrant is placed on an indefinite or other term of suspension, the board shall require, at a minimum, the following terms in its suspension order:

(1) Compliance with all federal, state, and local laws.

(2) Submission of quarterly declarations on a form approved by the board or the board's probation committee stating, under penalty of perjury, whether there has been compliance with all conditions of suspension and, if applicable, treatment.

(3) Periodic appearances before the board, the board's probation committee, or its representatives as requested.

(4) A minimum five-year contract with an approved monitoring provider, unless otherwise exempted by the board.

(5) Compliance with all terms of the approved monitoring contract, which shall include all terms set forth in rule 4729:4-1-04 of the Administrative Code.

(6) Prior approval by the board or the board's probation committee of departures or absences in excess of three days from Ohio. Periods of departure or absence shall not reduce the term of suspension, unless otherwise determined by motion of the board or the board's probation committee. For absences of three months or longer in instances where the board can be assured that suspension monitoring is otherwise being performed.

(7) As designated in the board's order, submission of observed urine, blood, or hair samples upon request of the approved monitoring program or board, and without prior notice, at the cost of the licensee or registrant.

(8) Compliance with any employer provided drug or alcohol screens.

(9) When deemed appropriate by the board or the board's probation committee, undertaking psychiatric evaluation, and, where appropriate, continuing treatment acceptable to the board, with evidence of compliance to be provided in each quarterly report.

(10) Copies of the board order or settlement agreement must be provided by the individual to all of the following during the effective period of the board order or settlement agreement:

(a) All employers or prospective employers,

(b) All persons and entities that provide the individual chemical dependency treatment or monitoring; and

(c) Law enforcement and court personnel if suspended licensee or registrant has court involvement related to suspension such as drug court, intervention in lieu of treatment, or diversion program;

(d) By certified mail, the proper licensing authority of any state or jurisdiction in which the individual holds or applies for any professional license, excluding the state of Ohio board of pharmacy.

(11) Continuing compliance with the terms of the monitoring contract entered into with the treatment provider and approved monitoring provider, provided, that where terms of the monitoring contract conflict with the terms of the settlement agreement or board order, the terms of the settlement agreement or board order shall control.

(12) Continuing authorization, through appropriate written consent forms, for disclosure by the treatment provider and/or approved monitor to the board, to treating and monitoring physicians, and to others involved in the monitoring process, of information necessary for those individuals to fulfill their respective duties and obligations.

(14) Self-reporting of any violation of one or more terms of suspension.

(15) Maintain a current address with the Board.

(B) Periods during which the suspended licensee or registrant is not in compliance with all terms of suspension shall toll the length of time of suspension during which the suspended licensee or registrant was out of compliance. The board shall issue a resolution setting forth the minimum length of time each violation will toll the suspension term. The resolution shall be updated as necessary and available on the board's web site, www.pharmacy.ohio.gov. The board may implement additional disciplinary action in addition to or instead of tolling suspension.

(C) Violation of any term of suspension may result in additional action before the board up to and including revocation of the registrant or licensee’s pharmacy board issued license or registration.

(D) In the event the suspension is unrelated to impairment as defined in 4729:4-1-01, the Board may impose any other suspension conditions as it warrants applicable to the individual facts pertaining to discipline.