2/27/2017

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 Rules

- 4729-6-04: Creates requirements for a licensee or registrant who enters a monitoring program contract after treatment.
- 4729-6-06: Provides the requirements for a licensee or registrant placed on probation.

Amended

- 4729-6-01: Replaces definition of substance abuse/chemical dependency. Replaces all references to pharmacists with licensee or registrant. Adds conditions to definition of impaired. Adds definition of approved monitoring program. Removes definition of limited approval treatment provider. Adds condition to definition of intervenor. Allows a designated person to initiate a referral for assessment. Changes the definition of responsible person to designated person, and replaces limited approved treatment provider with approved monitoring program in same rule. Adds conditions to definition of twelve-step program. Extends minimum length of aftercare to twelve months. Adds conditions to definition of relapse.
- 4729-6-02: Replaces all references to pharmacists with licensee or registrant. Includes pharmacy technicians in chapter concerning impaired pharmacists. Clarifies requirements for reinstatement. Allows monitoring programs to administer evaluations.
- 4729-6-03: Gives new requirements to become an approved treatment provider. Replaces all references to pharmacists with licensee or registrant.
- 4729-6-05: Replaces all references to limited approved treatment providers with approved monitoring programs. Replaces all references to pharmacists with licensee or registrant.
- 4729-6-10: Replaces all references to pharmacists with licensee or registrant.

Please note: Rules do not apply to terminal or wholesale distributors of dangerous drugs.

Comments on the proposed rules will be accepted until close of business on March 16, 2017. Please send all comments to the following email address:
Cameron.mcnamee@pharmacy.ohio.gov

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

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CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Impaired Licensees, Registrants and Probation

Rule Number(s): New: 4729-6-04; 6-06

Amend: 4729-6-01; 6-02; 6-03; 6-05; 6-10

Date: 2/27/2017

Rule Type:

New	5-Year Review
Amended	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.

New Rules

- 4729-6-04: Creates requirements for a licensee or registrant who enters a monitoring program contract after treatment.
- 4729-6-06: Provides the requirements for a licensee or registrant placed on probation.

Amended

- 4729-6-01: Replaces definition of substance abuse/chemical dependency. Replaces all references to pharmacists with licensee or registrant. Adds conditions to definition of impaired. Adds definition of approved monitoring program. Removes definition of limited approval treatment provider. Adds condition to definition of intervenor. Allows a designated person to initiate a referral for assessment. Changes the definition of responsible person to designated person, and replaces limited approved treatment provider with approved monitoring program in same rule. Adds conditions to definition of twelve-step program. Extends minimum length of aftercare to twelve months. Adds conditions to definition of relapse.
- 4729-6-02: Replaces all references to pharmacists with licensee or registrant. Includes pharmacy technicians in chapter concerning impaired pharmacists. Clarifies requirements for reinstatement. Allows monitoring programs to administer evaluations.
- 4729-6-03: Gives new requirements to become an approved treatment provider. Replaces all references to pharmacists with licensee or registrant.
- 4729-6-05: Replaces all references to limited approved treatment providers with approved monitoring programs. Replaces all references to pharmacists with licensee or registrant.
- 4729-6-10: Replaces all references to pharmacists with licensee or registrant.

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

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.

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?

The proposed 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 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.

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)?**

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.

6. **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.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

The rules in this package were reviewed by the Pharmacists Rehabilitation Organization, the Ohio Department of Mental Health and Addiction Services, Ohio Society of Health-System Pharmacists and the Ohio Pharmacists Association.

Prior to filing with CSI, the rules were also reviewed and approved by the Board of Pharmacy.

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

For the proposed rules, the Pharmacists Rehabilitation Organization suggested the following changes:

- In rule 4729-6-01, require the licensee or registrant to attend face-to-face meetings;

- In rule 4729-6-01, change minimum length of aftercare from six to 12 months;
- In rule 4729-6-02, incorporate "free from mind-altering, mood-changing substances" in demonstration of the licensee or registrant's case for reinstatement;
- In rule 4729-6-06, set the probationary period's minimum length at five years;
- In rule 4729-6-06, allow requests for modifications to probationary terms only after three years;

Any proposed feedback agreed to by the committee and approved by the Board was incorporated into the rule package.

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?

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

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?

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.

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 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.

12. 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.

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 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 legislative affairs liaison and feedback from the Board's legal director for every citation submitted.

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 rule package impacts the following:

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

b. Identify the nature of the adverse impact (e.g., license 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.

New Rules

- 4729-6-04: Creates requirements for a licensee or registrant who enters a monitoring program contract after treatment. 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.

- 4729-6-06: Provides the requirements for a licensee or registrant placed on probation. 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.

Amended

- 4729-6-01: The regulation should have no adverse impact as it is a definition section.
- 4729-6-02: Replaces all references to pharmacists with licensee or registrant. Includes pharmacy technicians in chapter concerning impaired pharmacists. Clarifies requirements for reinstatement. Allows monitoring programs to administer evaluations. This regulation requires the compiling of data to demonstrate to the Board a pharmacy professional's ability to resume practice. In addition, 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.
- 4729-6-03: Gives new requirements to become an approved treatment provider. Replaces all references to pharmacists with licensee or registrant. 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.
- 4729-6-05: Replaces all references to limited approved treatment providers with approved monitoring programs. Replaces all references to pharmacists with licensee or registrant. This regulation requires approved treatment monitors monitor and report deviations to the Board. Such requirements would result administrative costs incurred by the monitor.
- 4729-6-10: Replaces all references to pharmacists with licensee or registrant. Includes provisions whereby a licensee or registrant may be summarily suspended by the Board as it relates to impairment. The adverse impact would be the immediate suspension of a license or registration by the Board.

15. 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 to ensure that they comply with all requirements of their treatment plan.

Regulatory Flexibility

16. 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.

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?

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.

18. 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 4729-6 Impaired Licensees, Registrants and ~~Pharmacists~~ Probation

4729-6-01 Definitions; impaired pharmacists.

As used in Chapter 4729-6 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 (10/16/2016). ~~a condition involving the use of alcohol or other drugs to a degree that it interferes in the functional life of the licensee, as manifested by physical health, family, job, legal, financial, or emotional/psychiatric problems.~~

(B) "Impaired ~~pharmacist~~" means a ~~pharmacist~~ licensee or registrant who, because of his/her mental illness, habitual or excessive use or abuse of drugs, alcohol, use of psychoactive substances, or use of other substances that impair the ability to practice is rendered ~~is~~ unable to practice 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 4729-6-03 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 4729-6-05 of the Administrative Code.

~~(D) "Limited approved treatment provider" means a board approved and designated treatment program pursuant to section 4729.18 of the Revised Code and rule 4729-6-05 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 ~~pharmacist~~ licensee or registrant alleged to be impaired is confronted to evaluate the presence of impairment and, if indicated, who refers the ~~pharmacist~~ licensee or registrant for assessment and treatment of the problem.

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

(G) "Treatment assessor" means 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 ~~addictionist~~ addictionologist or an individual who is certified by the Ohio department of mental health and addiction services as a certified chemical dependency counselor 3 or 2 pursuant to division 3793:2 of the Administrative Code and who by training and experience can make an assessment of a ~~pharmacist's~~ licensee or registrant’s impairment.

(H) "Individualized treatment plan" is a written 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. The above services and other services may be determined by an approved treatment provider.

(I) "Treatment contract" means the document which outlines the individualized treatment plan, the requirement to cease practice, the requirement for compliance by the impaired licensee or registrant ~~pharmacist~~, 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 ~~pharmacist~~ 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 ~~pharmacist~~ 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) "~~Responsible~~ Designated person" for an approved treatment provider or approved monitoring program ~~limited approved treatment provider~~ is an individual who shall be in full and actual charge of the treatment or monitoring program; including but not limited to, assuring the provider has the necessary facilities and personnel to provide services, maintaining records, and notification of the board when required.

(M) "Twelve-step program" ~~is~~ 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. ~~which the individual~~ An impaired licensee or registrant shall be required to personally attend face-to-face twelve-step programs~~. The minimum attendance required shall~~ not be 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 ~~pharmacist's~~ sobriety, and should extend for a minimum of ~~six~~ 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 licensed professional.

(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, for a substance not approved by the treatment or monitoring

program, or a return to a pattern of impairment activities which affects the licensee or registrant's ~~pharmacist's~~ ability to practice. Relapse also refers to a mental health or mental illness episode that impacts or impairs the ability to practice pharmacy with the requisite judgment, skill, competence, or safety to the public.

4729-6-02 Applicability.

(A) No person, except an ~~licensed~~ 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 ~~pharmacist~~.

(B) The rules in Chapter 4729-6 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. ~~For the purposes of this chapter only, the word "pharmacist" shall include pharmacy interns and other individuals licensed by the board.~~

(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 ~~pharmacist~~ individual, the board may compel the individual to be examined by an approved treatment provider. If the licensee or registrant ~~pharmacist~~ 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;

(3) Summarily suspend the license or registration of an individual ~~pharmacist~~ pursuant to rule 4729-6-10 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 ~~pharmacist~~ licensee or registrant must demonstrate to the board that he/she possesses the requisite judgment, skill, and competence to ensure public safety in the practice of pharmacy. Such demonstration shall include but not be limited to the following:

(1) Certification from an approved treatment provider that the licensee or registrant ~~pharmacist~~:

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

(b) Has successfully completed ~~the~~ any required inpatient treatment;

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

(d) Has ~~been shown to be~~ demonstrated he/she has continued to be alcohol, ~~and~~ 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 or monitoring program who has made a clear determination, documented in a written statement, that the licensee or registrant ~~pharmacist~~ is eligible to return to practice ~~capable of practicing~~.

(2) Certification that the ~~pharmacist~~ 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:

(a) A copy of the signed and agreed to treatment 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 ~~pharmacist~~ describing ~~progress towards~~ recovery progress.

4729-6-03 Requirements for approved treatment providers.

(A) An approved treatment provider, as defined in rule 4729-6-01 of the Administrative Code, shall meet or exceed the following requirements:

(1) Certification by the Ohio department of mental health and addiction services pursuant to Chapter 5119. of the Revised Code; or

~~(2) Accreditation by the appropriate accrediting agency(s); and~~

~~(3) Have certified personnel including but not limited to intervenor, treatment assessor, and responsible person as defined in rule 4729-6-01 of the Administrative 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 other provider not certified as set forth in (A)(1).

(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 ~~pharmacist~~ licensee or registrant is showing evidence of impairment, the intervenor shall refer the individual for evaluation;

(4) If the pharmacist fails to comply within one week to a referral for evaluation, the intervenor must report the name of the ~~pharmacist~~ individual to the board of pharmacy within one ~~working~~ business day.

(C) A treatment assessor associated with an approved treatment provider shall evaluate a ~~pharmacist~~ licensee or registrant referred to the approved treatment provider to determine if the ~~pharmacist~~ licensee or registrant has a substance abuse/chemical dependency related impairment.

(D) If such an impairment exists, the approved treatment program shall formulate the ~~pharmacist's~~ licensee or registrant's individualized treatment plan as defined in rule 4729-6-01 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 ~~pharmacist~~ licensee or registrant must sign. If the impaired ~~pharmacist~~ licensee or registrant fails to sign the treatment contract and enter treatment within forty-eight hours of the determination that the ~~pharmacist~~ licensee or registrant needs treatment, the approved treatment provider must report the name of the ~~pharmacist~~ licensee or registrant to the board of pharmacy within one ~~working~~ business day.

(E) The ~~responsible~~ designated person for the approved treatment provider shall:

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

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

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

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

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

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

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

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

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

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

4729-6-05 Requirements for ~~limited approved treatment providers~~ approved monitoring programs.

(A) ~~A limited approved treatment provider~~ An approved monitoring program, as defined in rule 4729-6-01 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 ~~responsible~~ designated person as defined in rule 4729-6-01 of the Administrative Code.

(B) An intervenor associated with an approved monitoring program ~~a limited 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 ~~pharmacist~~ licensee or registrant is showing evidence of impairment, the intervenor shall refer the individual for evaluation;

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

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

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

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

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

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

4729-6-04 Monitoring contracts. (NEW)

(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, an individual counseling, or a combination of the above;

(2) Periodic, random, unannounced blood or urine screens, or both 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, 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 timeframe consistent with the drug lab'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 4729-6-01(M);

(a) to obtain the signatures of either the secretary or chairperson of the meeting for my 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 4729-6-01(M) 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 another person so authorized by law 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, except in the event of an emergency as determined by the physician, and provide documentation of the need for any medication (to include a copy of the prescription or note from the prescribing physician) within 48 hours of receipt of treatment, if any mood altering and/or potentially addictive medications are required or recommended by the physician;

(b) to renew verification with the Intervenor or Designated Person every 90 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 filling own prescriptions;

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

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

(i) alcohol free wine or beer;

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

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

(iv) foods or beverages containing alcohol;

(v) any other form of ethyl alcohol.

(5) Acknowledgment of the relinquishment of the right to self-medicate other than single entity over-the-counter non-steroidal anti-inflammatory and acetaminophen;

(6) Regular contact with a certified alcoholism or other addiction 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 problems;

(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 during 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 does 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 his or her designee;

(14) Maintenance of a log of all controlled substances, and other drugs if directed by the board, which the practitioner prescribes, orders, personally furnishes, or administers, where appropriate.

4729-6-10 Summary suspension, license of impaired licensee or registrant ~~pharmacist~~.

(A) An impaired licensee or registrant ~~The license of the pharmacist~~ may be summarily suspended without a prior hearing pursuant to section 3719.121 of the Revised Code if, in the opinion of the board, ~~an~~ the impaired ~~pharmacist~~ 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 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 ~~determination~~ that the ~~pharmacist~~ licensee or registrant is capable of practicing;

(4) A relapse, as defined in rule 4729-6-01 of the Administrative Code, of substance abuse/chemical dependency at any time.

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

4729-6-06 Probation (NEW)

(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 4729-6-07;

(6) Prior notification to 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 probationary term, 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 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 and all persons and entities that provide the individual chemical dependency treatment or monitoring; and

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

(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 them 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; and

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

(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, or 30 days, whichever is greater. Subsequent violations will toll the probationary period for a minimum of 60 days. The board may implement additional disciplinary action in addition to or instead of tolling probation.