CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio State Board of Pharmacy

Regulation/Package Title: Impaired Pharmacists / Continuing Education / Dangerous Drugs

Rule Number(s): Amended: 4729-6-01; 4729-6-03; 4729-7-06; 4729-9-14; 4729-9-21

Date: 5/16/2014

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✓ Amended	Rescinded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.

Proposed Rule Changes

- **4729-6-01:** Changes references from the Ohio Department of Alcohol and Drug Addiction Services to the Ohio Department of Mental Health and Addiction Services.
- **4729-6-03:** Changes references from the Ohio Department of Alcohol and Drug Addiction Services to the Ohio Department of Mental Health and Addiction Services.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov

- **4729-7-06 (5-Year Review):** Changes the requirement that in-state continuing education providers submit their participant lists to the Board. Instead, providers will be required to maintain those records. In addition, in-state providers will no longer have to send notification to the Board before or within fourteen days after a program has been presented.
- **4729-9-21:** Requires drugs compounded in a pharmacy to meet national compounding standards as well as meet all requirements of federal law.
- **4729-9-26 (5-Year Review):** Corrects a typo in the criminal records check for pain management clinics section of the OAC.
- **4729-9-14 (5-Year Review):** Updates references to measurement standards. In addition, requires all prescribers or terminal distributor of dangerous drugs who store controlled substances to conduct an inventory of these drugs annually to detect for theft or diversion.

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

The proposed rules are authorized by sections 4729.26, 3719.28 and 4729.552 of the Ohio Revised Code. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 3719.12, 4729.01, 4729.18, 3719.121, 4729.12, 3715.521, 3715.63, 3715.64, 3719.05, 4729.28, 4729.55, 4776.02 and 4776.04.

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 rule does 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 the pharmacy profession has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the Ohio State Board of Pharmacy. The Ohio State Board of Pharmacy regulates all aspects of pharmacy practice, including admission to practice, standards of practice, dispensing and storage of drugs and the discipline of pharmacists. While the Food and Drug Administration closely regulates the manufacture and distribution of prescription drugs, the day-

to-day practice of pharmacy, including the dispensing of drugs by licensed prescribers, traditionally has been left to state boards.

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 Codes authorizes the state board of pharmacy to adopt rules governing the practice of pharmacy and the dispensing of dangerous drugs, including compounded medications. Section 3719.28 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules governing controlled substances in order to prevent the improper acquisition, use or diversion into illicit channels. Section 4729.552 of the Ohio Revised Code requires the state board of pharmacy to adopt rules regarding the licensure of pain management clinics. The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in Chapter 4729 of the Ohio Revised Code to promote the public's safety. Without these regulations, the Ohio State Board of Pharmacy would not be able to:

- Provide the requirements for impaired pharmacists to seek treatment for substance abuse.
- Provide the uniform requirements to ensure quality in-state continuing education for Ohio pharmacists.
- Ensure that pharmacies adhere to best practices and federal law when preparing compounded drugs.
- Provide uniform background check requirements for facilities licensed by the Board of Pharmacy as pain management clinics.
- Ensure that locations keep records regarding controlled substances stored on-site, including the requirement that these locations perform inventories to detect theft or diversion.

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 prescribers of dangerous drugs 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 were reviewed and approved by the Ohio State Board of Pharmacy's Rules Review Committee. The committee is comprised of a broad array of stakeholders including:

- OhioHealth
- Trumbull Memorial Hospital
- Kroger
- Hock's Pharmacy
- Northeast Ohio Medical University
- Nationwide Children's Hospital
- Giant Eagle
- Absolute Pharmacy
- St Ann's Hospital
- Akron General
- Cedarville University

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 Ohio State Board of Pharmacy Rules Review Committee reviewed the proposed changes. Following the approval of the package by the Rules Review Committee, the Ohio State Board of Pharmacy formally approved the rules.

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. However, input was solicited from registered pharmacists through the Board's Rules Review Committee representing health systems, hospitals and retail practice.

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 the protecting the public's safety by ensuring uniform regulations, the Ohio State 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 the remainder of the rules in this package. It is the Board's responsibility to ensure that regulations pertaining to impaired pharmacists, drug compounding, controlled substances and continuing education are consistent throughout the state. It was the determination of the Board's Rule 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 Legal Affairs reviewed the Ohio Administrative Code to ensure that the regulation does not duplicate an existing Ohio 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 rule 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 quarterly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, monthly 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:

- Pain management clinics.

- Hospitals, long-term care facilities, pharmacies, prescribers and any other location that stores controlled substances.
- Continuing education providers such as colleges, universities and hospitals.
- Pharmacies that compound drugs.

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

Violation of the rules may result in administrative licensure discipline for a pharmacist or a location licensed as a terminal distributor of dangerous drugs license (TDDD). Discipline might include reprimand, suspension of the license, required course work, and/or revocation of the license or continuing education provider status.

c. Quantify the expected adverse impact from the regulation.

4729-6-01: Changes references from the Ohio Department of Alcohol and Drug Addiction Services to the Ohio Department of Mental Health and Addiction Services in a definitional section. As such, this change should have no expected adverse impact.

4729-6-03: Changes references from the Ohio Department of Alcohol and Drug Addiction Services to the Ohio Department of Mental Health and Addiction Services in a rule that provides the requirements for approved treatment providers for impaired pharmacists. The standards outlined in this rule incorporate minimum standards of current treatment providers licensed by the Ohio Department of Mental Health and addiction services. The only added cost of this rule would be notify the Board if an impaired pharmacist is found in violation of their treatment contract or continues to practice pharmacy.

4729-7-06: This rule would require in-state continuing education providers to maintain a list of participants for 5-years, which would result in increased administrative costs to the providers. However, the rule also removes the requirement that providers send notification to the Board, which would result in decreased administrative costs. The rule overall does require all in-state providers of continuing education to meet certain minimum standards which result in compliance costs to the providers.

4729-9-21: Requires drugs compounded in a pharmacy to meet national standards as well as meet all requirements of federal law. This may result in increased compliance costs for compounding pharmacies that do not meet national standards (i.e. United States Pharmacopeial Convention Chapter 795 and 797). However, the Board has recently conducted several trainings for its inspectors on these national standards and our

compliance specialists will work with compounding pharmacies to ensure compliance. These efforts should help to mitigate overall compliance costs. All compounding pharmacies should be in compliance with federal law and, therefore, the addition of federal law to this rule should not result in increased compliance costs.

4729-9-26 (5-Year Review): This rule requires, pursuant to Ohio law, the physician owner of a pain management clinic to submit to a background check (both FBI and BCI&I). The cost of this regulation includes the following fees: BCI&I - $22, FBI - $24, and some agencies may charge a processing fee (e.g. $5-$40).

4729-9-14 (5-Year Review): This rule includes certain record keeping requirements, including annual inventories, and will result in increased administrative costs to locations that store controlled substances. The costs will vary based on the number of controlled substances stored on-site and the systems in place to keep records and conduct inventories.

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

The Ohio State Board of Pharmacy is committed to ensuring that continuing education and treatment providers meet certain minimum standards to ensure quality education and care for pharmacists. In addition, it is crucial that pain management clinics, compounding pharmacies and locations that store controlled substance drugs adhere to standards that protect the health and safety of all Ohioans.

Regulatory Flexibility

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

This rule does 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 Ohio State 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 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 an update 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.

4729-6-01 DEFINITIONS; IMPAIRED PHARMACISTS (Proposed Change)

As used in Chapter 4729-6 of the Administrative Code:

(A) "Substance abuse/chemical dependency" means 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 who, because of his/her use of psychoactive substances, 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) "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 participates in a process whereby a pharmacist alleged to be impaired is confronted to evaluate the presence of impairment and, if indicated, who refers the pharmacist for assessment and treatment of the problem.

(F) "Referral for assessment" means a process whereby an intervenor who has reason to believe that a pharmacist 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 or an individual who is certified by the Ohio department of ~~alcohol and drug addiction services (ODADAS)~~ mental health and addiction services as a certified chemical dependency counselor 3 or 2 pursuant to ~~section 3793.07 of the Revised Code and~~ division 3793:2 of the Administrative Code and who by training and experience can make an assessment of a pharmacist'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 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 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 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 person" for an approved treatment provider or limited approved treatment provider is an individual who shall be in full and actual charge of the treatment 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 a self-help program such as Alcoholics Anonymous or Narcotics Anonymous which the individual shall be required to personally attend. The minimum attendance required shall not be less than three documented meetings each week.

(N) "Aftercare" is a counselor-facilitated group meeting which directly responds to problems relating to the ongoing treatment and monitoring of the pharmacist's sobriety, and should extend for a minimum of six 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 a positive drug screen or a return to a pattern of impairment activities which affects the pharmacist's ability to practice.

4729-6-03 REQUIREMENTS FOR APPROVED TREATMENT PROVIDERS (PROPOSED CHANGE)

(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 ~~alcohol and drug addiction services (ODADAS)~~ of mental health and addiction services pursuant to Chapter ~~3793~~ 5119. of the Revised Code;

(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.

(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 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 to the board of pharmacy within one working day.

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

(D) If such an impairment exists, the approved treatment program shall formulate the pharmacist'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 must sign. If the impaired pharmacist fails to sign the treatment contract and enter treatment within forty-eight hours of the determination that the pharmacist needs treatment, the approved treatment provider must report the name of the pharmacist to the board of pharmacy within one working day.

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

(1) Establish a system of records that will provide for complete information about an impaired pharmacist 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 with the treatment contract;

(3) Assure confidentiality of the impaired pharmacist, except:

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

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

(c) If the impaired pharmacist does not suspend practice on entering treatment;

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

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

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

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

4729-7-06 CRITERIA FOR IN-STATE APPROVED PROVIDERS OF CONTINUING PHARMACY EDUCATION (PROPOSED CHANGE AND 5-YEAR REVIEW)

In-state providers who desire to become approved by the state board of pharmacy must demonstrate ability and willingness to offer quality continuing pharmacy education in a responsible manner and shall submit evidence of this on applications supplied by the board. The minimal criteria include:

(A) There shall be a responsible person charged with the administration of the continuing pharmacy education program and liaison with the board. Unless

otherwise approved by the board, the responsible person shall be a pharmacist licensed to practice pharmacy in Ohio.

(B) Providers shall award continuing pharmacy education credit to successful participants in terms of C.E.U.s.

(C) Providers shall ~~send~~ maintain a list of successful program or experience participants and their Ohio registration numbers ~~to the board within fourteen days of the experience or maintain such records~~ for a five-year period to be made available to the board on request.

(D) Providers shall award a certificate to each successful participant containing at least the following information:

(1) The name of the provider;

(2) The completion date of the experience;

(3) The name of the participant;

(4) The title of the experience;

(5) The number of C.E.U.s the experience has been assigned;

(6) The program or experience identification number according to the numbering system designated by the board; and

(7) The positive identification of the responsible person.

(E) Ohio jurisprudence program providers shall submit a provider program notice or a sample of the program or experience certificate to the board no later than 14 days after a program is presented.

(~~E~~ F) Providers shall develop and employ evaluation techniques that will assess the effectiveness of the continuing pharmacy education experiences with the goal of continual improvement.

(~~F~~ G) Providers should utilize an evaluation mechanism for the purpose of allowing each participant to assess the achievement of personal objectives.

~~(G) Providers shall send notification to the board before or within fourteen days after a program has been presented. The notification shall include the name of the presenter(s) and the items noted in paragraphs (D)(1), (D)(2), (D(4), (D)(5), and (D)(6) of this rule.~~

4729-9-21 DRUGS COMPOUNDED IN A PHARMACY PURSUANT TO A PATIENT SPECIFIC PRESCRIPTION (PROPOSED CHANGE)

(A) In order to compound prescriptions, a pharmacy shall meet the minimum standards for a pharmacy pursuant to rule 4729-9-02 of the Administrative Code.

(B) Parenteral and sterile product prescriptions shall be compounded in accordance with Chapter 4729-19 and/or Chapter 4729-15 of the Administrative Code.

(C) For all compounded prescriptions, the pharmacist shall:

(1) ~~For all non-sterile compounded prescriptions, the pharmacy shall comply~~ Comply with the United States Pharmacopeial Convention Chapter 795 when compounding non-sterile drug products;

(2) ~~For all sterile compounded prescriptions, the pharmacy shall comply~~ Comply with The United States Pharmacopeial Convention Chapter 797 when compounding sterile compounded drug products;

(3) Comply with section 503A of the Federal Food, Drug, and Cosmetic Act (11/27/2013).

~~(1)~~(4) Inspect and approve the compounding process;

~~(2)~~(5) Perform the final check of the finished product.

(D) For all compounded prescriptions, the pharmacist shall be responsible for:

(1) All compounding records;

(2) The proper maintenance, cleanliness, and use of all equipment used in compounding.

(E) Personnel engaged in the compounding of drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel shall be worn as necessary to protect personnel from chemical exposure and drug products from contamination.

(F) A prescription shall be compounded and dispensed only pursuant to a specific order for an individual patient issued by a prescriber. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(G) A compounded prescription that is dispensed to a patient must be labeled according to rule 4729-5-16 of the Administrative Code.

(H) Labels for a compounded prescription that is prepared in anticipation of a prescription drug order shall contain, but not be limited to, the following:

(1) The name, strength, and quantity of each drug used in the compounded prescription;

(2) The identification of the repackager by name or by the final seven digits of its terminal distributor of dangerous drugs license number;

(3) Pharmacy control number;

(4) The pharmacy's expiration date or beyond use date.

4729-9-26 CRIMINAL RECORDS CHECK FOR PAIN MANAGEMENT CLINICS (PROPOSED CHANGE AND 5-YEAR REVIEW)

Pursuant to division (B) of section 4729.552 of the Revised Code, a new terminal distributor of dangerous drug license with a pain management clinic classification will not be issued until the physician owner(s), or if incorporated the physician officers, of the pain management clinic submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check. Additionally, a criminal records check is required every time there is a change in ownership for each new owner(s) or officer(s). The criminal records check shall consist of both a BCI&I criminal records check and a federal bureau of investigations (FBI) records check. The results of the criminal records check must be sent directly to the Ohio state board of pharmacy from BCI&I. To be considered valid, the criminal records check must have been performed within the past twelve months. After the board receives the results of all of the required criminal records checks the license process will proceed. The physician owner(s) or physician officers must submit electronic fingerprint impressions pursuant to rule 4729-5-12 of the Administrative Code. Physician owner(s) or physician officers are required to have all employees submit to a BCI&I and FBI criminal records check to ensure that no person has been previously convicted of, or pleaded guilty to a theft offense that would constitute a felony as described in division (K)(3) of section 2913.01 of the Revised Code ~~of~~ or a felony drug abuse offense as defined in section 2925.01 of the Revised Code. Employees must submit electronic fingerprint impressions to the physician owner(s) or physician officers pursuant to rule 4729-4-04 of the Administrative Code.

4729-9-14 RECORDS OF CONTROLLED SUBSTANCES (5-YEAR RULE REVIEW)

(A) Each prescriber or terminal distributor of dangerous drugs shall keep a record of all controlled substances received, administered, dispensed, sold, destroyed, or used. The acts of prescribing, administering, dispensing, and destroying of a controlled substance must be documented with the positive identification of the responsible individual pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code. These records may be kept electronically if the method is approved by the state board of pharmacy and the records are backed-up each business day.

(1) Records of receipt shall contain a description of all controlled substances received, the kind and quantity of controlled substances received, the name and address of the persons from whom received, and the date of receipt.

(2) Records of administering, dispensing, or using controlled substances shall contain a description of the kind and quantity of the controlled substance administered, dispensed, or used, the date, the name and address of the person to whom or for whose use, or the owner and identification of the animal for which, the controlled substance was administered, dispensed, or used.

(3) Records of drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the name and address requirements of paragraph (A)(2) of this rule.

(4) Destruction of controlled substances shall be conducted in accordance with rule 4729-9-06 of the Administrative Code.

(B) Each prescriber or terminal distributor of dangerous drugs shall maintain an inventory of all controlled substances as follows:

(1) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.

(a) The name of the substance.

(b) The total quantity of the substance.

(i) Each finished form (e.g., ten-milligram tablet or ten-milligram concentration per ~~fluid ounce or~~ milliliter).

(ii) The number of units or volume of each finished form in each commercial container (e.g., one-hundred-tablet bottle or ten-milliliter vial).

(iii) The number of commercial containers of each such finished form (e.g., three one-hundred-tablet bottles or ten one-milliliter vials).

(c) If the substance is listed in schedule I or II, the prescriber or terminal distributor of dangerous drugs shall make an exact count or measure of the contents.

(d) If the substance is listed in schedule III, IV, or V, the prescriber or terminal distributor of dangerous drugs may make an estimated count or measure of the contents, unless the container holds more than one thousand tablets or capsules in which an exact count of the contents must be made.

(2) A separate inventory shall be made for each place or establishment where controlled substances are in the possession or under the control of the prescriber or terminal distributor. Each inventory for each place or establishment shall be kept at the place or establishment.

(3) An inventory of all stocks of controlled substances on hand on the date the prescriber or terminal distributor first engages in the administering, dispensing, or use of controlled substances. In the event the prescriber or terminal distributor of dangerous drugs commences business with no controlled substances on hand, this fact shall be recorded as the initial inventory.

(4) Each prescriber or terminal distributor of dangerous drugs shall take a new inventory of all stocks of controlled substances on hand every ~~two~~ year~~s~~ following the date on which the initial inventory is taken.

(5) When a substance is added to the schedule of controlled substances by the federal drug enforcement administration or the state board of pharmacy, each prescriber or terminal distributor of dangerous drugs shall take an inventory of all stock of such substance on hand at that time.

(C) All records of receipt, distribution, administering, dispensing, inventory, destruction, or using controlled substances shall be kept for a period of three years at the place where the controlled substances are located. Any terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send a written request to the state board of pharmacy. The request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy will send written notification to the terminal distributor of dangerous drugs documenting the approval or denial of the request. A copy of the board's approval shall be maintained with the other records of controlled substances. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov