

NEW OHIO PHARMACY RULES EFFECTIVE JANUARY 1, 2004

Lesson number 036-368-04-001-H03

Approved for one contact hour of Ohio Jurisprudence by the Ohio State Board of Pharmacy.

Objectives

After reading this lesson, the pharmacist will be able to:

- Discuss changes in Ohio pharmacy law effective January 2004;
- Understand new record keeping requirements for dangerous drugs and controlled substances and sales of dangerous drugs on-line;
- Explain changes to Ohio law regarding NAPLEX score transfer, jurisprudence Examination and continuing education;
- Explain changes to Ohio law regarding laboratories and animal shelters;
- Describe the labeling requirements for compounded parenteral products produced in a fluid therapy pharmacy; and
- Describe the lawful manner of issuance of a prescription.

Introduction

January 1, 2004 saw the introduction of new rules by the Ohio State Board of Pharmacy.

The internet link for these rules at the time of issue of this lesson is

<http://pharmacy.ohio.gov/RulesEffec040101-AM-Sh.htm>. The rules can also be found at the Board website at <http://pharmacy.ohio.gov/> under the “What’s New” link.

These rules affected a wide variety of pharmacy practices and record keeping requirements. This lesson will present some of those new rules. This lesson will also review the February 2003 change in manner of issuance of a prescription.

Terminology for Legal Responsibility

Effective January 1, 2004, the OHIO STATE BOARD OF PHARMACY enacted new terminology for the person legally responsible for a pharmacy. **See Rule 4729-5-11.** The new term for the legally responsible person is now deemed the “responsible person”, not the responsible pharmacist. The term was changed in an attempt to achieve uniformity in the rules regarding laboratories and animal shelters, which also use the term “responsible person.” For a pharmacy, the responsible person must still be a pharmacist. The responsibilities of this pharmacist remains unchanged, and includes at least the following:

- providing "supervision and control" of dangerous drugs [see Ohio Revised Code see 4729.55 (B)],
- providing "adequate safeguards" to prevent the unauthorized sale or other distribution of dangerous drugs [see Ohio Revised Code 4729.55 (C)],
- maintaining all drug records otherwise required, and
- complying with all state and federal laws, regulations, and rules regulating the distribution of drugs.

A pharmacist may be the responsible person for more than one pharmacy - with a written request sent to, and permission granted by, the Board. The written request must explain the circumstances requiring the pharmacist to be responsible for more than one pharmacy

– and the period of time during which the circumstances will exist. The responsible person pharmacist can not simply be a “figure head,” and must be physically present in the pharmacy a sufficient amount of time to provide supervision and control. Changes in a pharmacy’s responsible person must be promptly communicated to the Board. The changed must be communicated within thirty days on a board-approved form and must be sent by certified mail, return receipt requested, or by verified facsimile transmission.

NAPLEX Score Transfer and Jurisprudence Examination

We all know a pharmacist who wants to move from some other state to practice pharmacy in the great state of Ohio, right? They may want to know about the new rules regarding the transfer of NAPLEX scores for Ohio pharmacy licensure. **See Rule 4729-5-31.** Previously, a candidate who wanted to transfer a NAPLEX score was required to pass the Ohio jurisprudence examination within twelve months from the date the board receives the initial application for licensure. Now, the candidate must take the Ohio jurisprudence examination within twelve months from the date the candidate completes the NAPLEX examination. The new rule reads as follows:

Any candidate who has requested to transfer their NAPLEX score to Ohio must ~~receive a passing score on~~ **take** the Ohio jurisprudence examination within twelve months from the date the ~~board receives the initial application or the transfer of their~~ **candidate completed the** NAPLEX **examination or the** score **transfer** will be denied.

Key to changes: *UNDERLINED* = **Add** New Language *LINED THROUGH* = **Remove** Old Language

Continuing Pharmacy Education

The “category” approach to continuing pharmacy education has been modified. **See Rule 4729-7-01.** “Approved continuing education” is defined as participation in an organized and structured continuing pharmacy education experience which has been presented by an approved provider or the state board of pharmacy and which presents information directly related to the practice of pharmacy.

Previously, the pharmacist needed to monitor how many continuing education units were being accumulated in the categories of patient care, and pharmacy management, and pharmacy jurisprudence. The only category that survived the change in law is “pharmacy jurisprudence” – that continuing pharmacy education that deals with current laws, rules, and regulations dealing with the practice of pharmacy.

The pharmacist still needs to be able to document successful completion of continuing pharmacy education sixty contact hours every three years. Three of these contact hours need to be in the area of pharmacy jurisprudence. Continuing pharmacy education completed in the area of pharmacy jurisprudence must be completed via providers and content specifically approved by the Board.

Records of Controlled Substances

Record keeping requirements for controlled substances have changed. **See Rule 4729-9-14.** Each prescriber or terminal distributor of dangerous drugs must maintain an accurate

inventory of all controlled substances. The old rule said that for schedule III, IV, or V, controlled substances, the prescriber or terminal distributor of dangerous drugs shall 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. The new rule states that for schedule III, IV, or V, controlled substances, 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. Under the new rule, either an exact count or an estimated count may be made.

The records of receipt, distribution, administering, dispensing, inventory, or using controlled substances must be kept for a period of three years. The records must be kept at the place where the controlled substances are located. If the prescriber or terminal distributor of dangerous drugs wants to maintain the records at a location other than where the controlled substances are located the prescriber or terminal distributor must first send notification to the Board. The Board is deemed to have consented to the request if the Board does not contest the matter within sixty days.

Records of Dangerous Drugs

Record keeping requirements for dangerous drugs have also changed. **See Rule 4729-9-22.** Each prescriber or terminal distributor of dangerous drugs must now keep a record of all dangerous drugs received, administered, dispensed, distributed, sold, destroyed, or used. The new rule requires a record to be kept of dangerous drugs “destroyed.” Previously, dangerous drugs “destroyed” might be legally unaccounted for. That loophole has been closed.

As with the records of controlled substances, Ohio law requires these dangerous drugs records to be kept for a period of three years and at the place where the controlled substances are located. Ohio law also allows these dangerous drugs records be kept at a location other than where the dangerous drugs are located if the required notification is sent to the Board. The Board is deemed to have consented to the request if the Board does not contest the matter within sixty days.

Sales of Dangerous Drugs On-Line

Dangerous drugs may be sold at retail or wholesale in Ohio by those entities licensed or registered with the Board as a dangerous drug distributor. **See Rule 4729-9-24.** Such sales are typically transacted at “Internet” sites and must be distributed in accordance with Ohio's drug laws. In the course of conducting such sales, personal information from the public (by questionnaire forms or e-mail) is often collected. The new law requires the “Internet” site to provide information regarding how the personal information will be used, pursuant to all federal and state laws, rules, and regulations. One example of such a federal law would be the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA limits how health plans and covered providers may use individually identifiable health information. The dangerous drug distributor must also ensure that such information is not used for purposes not disclosed without the written informed consent of the patient or person submitting personal information.

Board Approval of Laboratories

The Board may issue a terminal distributor of dangerous drugs license to certain laboratories. **See Rule 4729-13-02.** The labs may purchase, possess, and utilize dangerous drugs for scientific and clinical purposes and for purposes of instruction at the establishment or place described in the application. The responsible person whose name appears on the terminal distributor of dangerous drugs license must sign the license and maintain the license in a readily available place in the principal location of the business. Previously, the license had to be posted in the establishment or place described in the license. The responsible person is responsible for maintaining adequate supervision and control over the dangerous drugs and controlled substances acquired, utilized, destroyed, or administered by the approved laboratory and maintaining all records required by law.

Security Controls for Animal Shelters

Controlled substances may be stored in approved animal shelters. **See Rule 4729-14-05.** Previously, the controlled substances were required to be kept in a securely locked stationary cabinet. Now, the controlled substances may be kept in a securely locked and “substantially constructed” cabinet. The Board has modified the storage requirement to allow for the use of properly constructed mobile cabinets. This change is welcome for those animal shelters that have only a single controlled substances cabinet that needed to be wheeled or moved around to different locations in a facility where the controlled substances were stored.

The responsible person whose name appears on the terminal distributor of dangerous drugs license for the animal shelter must sign the license and maintain the license in a readily available place in the principal location of the business. Previously, the license had to be posted in the establishment or place described in the license. The responsible person is responsible for maintaining adequate supervision and control over the dangerous drugs

Labeling Compounded Parenteral Products

Labeling requirements for compounded parenteral products produced in a fluid therapy pharmacy have changed. **See Rule 4729-31-03.** A fluid therapy pharmacy is defined as a pharmacy where the primary purpose is to compound and dispense parenteral compounded sterile product prescriptions. Compounded sterile product prescriptions include, but are not limited to, the following preparations:

- (1) Total parenteral nutrition (TPN) solutions;
- (2) Parenteral analgesic drugs;
- (3) Parenteral antibiotics;
- (4) Parenteral antineoplastic agents;
- (5) Parenteral electrolytes;
- (6) Parenteral vitamins;
- (7) Irrigating fluids;
- (8) Ophthalmic preparations.

The labels for these compounded sterile product prescriptions from a fluid therapy pharmacy no longer must contain the name or initials of the pharmacist. The labels affixed to the containers for such preparations must include at least the following:

- name and address of the pharmacy
- name of the patient
- name of the prescriber
- beyond use date
- directions for use – including route of administration
- date of dispensing
- any cautions which may be required by federal or state law
- storage conditions
- name and amount of the drug(s) added
- name and volume of the parenteral solution
- quantity of drug dispensed, if appropriate

Manner of Issuance of a Prescription

All prescriptions **must** include certain information to be valid in the State of Ohio. See **Rule 4729-5-30**. To be valid, a prescription must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

A valid prescription must (in addition to other requirements):

- Be dated as of and on the day when issued;
- **Contain the manually printed, typewritten, or pre-printed full name and address of the prescriber;**
- **Indicate a telephone number where the prescriber can be personally contacted during normal business hours;**
- Indicate the full name and address of the patient;
- Indicate the drug name and strength;
- Indicate the quantity to dispense;
- Indicate the appropriate directions for use;
- Specify the number of times or the period of time for which the prescription may be refilled. If no such authorization is given, the prescription may not be refilled except in accordance with section 4729.281 of the Revised Code. A prescription marked "Refill P.R.N." or some similar designation is not considered a valid refill authorization.
- Not authorize a refill beyond one year from the date of issuance for schedule V controlled substances and for dangerous drugs that are not controlled substances; and
- Be manually signed on the day issued by the prescriber in the same manner as he/she would sign a check or legal document if issued to the patient by the prescriber

These are legal (read “mandatory”) requirements for issuance a valid prescription. If the prescription does not contain the manually printed, typewritten, or pre-printed full name

and address of the prescriber, it should not be filled as is. If the prescription does not indicate a telephone number where the prescriber can be personally contacted during normal business hours, it should not be filled as is. The benefits of the rule are clear – if the prescriber information is clearly provided on the prescription, it is more likely to be accurately entered into a pharmacy computer database, provided on the prescription label, and submitted to a third party payor. Likewise, calling a prescriber to clarify a prescription is much easier if the phone number is provided on the prescription. The pharmacist should not, and legally does not, have to guess at the identity of the prescriber when filling a prescription.

Invalid prescriptions continue to be a problem, despite the February 2003 rule by the Board of Pharmacy. One reason prescribers continue to issue the invalid prescriptions is that pharmacists continue to fill them. Would you fill a prescription for Oxycontin or Percocet without a legal DEA number or legal signature on that prescription? The prescriber name, address, and phone number requirements are no less “required” than the DEA number and signature requirements. You may send copies of invalid prescriptions and report offending physicians to:

State Medical Board of Ohio

77 South High Street, 17th Floor

Columbus, Ohio 43215-6127.

Phone: 614-466-3934

Complaint Line: 1-800-554-7717

Fax: 614-728-5946

While it may take some time to report these invalid prescriptions, doing so may save time in correcting prescriber errors in the long run. To be on the safe side, you may want to make a copy of the invalid prescriptions and black out or remove the patient’s name, address, phone, and date of birth before the invalid prescription copies are sent to the to State Medical Board of Ohio – to guard patient privacy. After all, the identity of the patient and the identity of the pharmacy are not necessary to report the violations. A courtesy copy of the invalid prescription may also be sent to the prescriber – but is not necessary.

This lesson does not convey, and should not be relied upon as, legal advice. Only a full discussion of the particular facts of a particular matter with a qualified attorney having done the appropriate legal research can yield legal advice.

NEW OHIO PHARMACY LAW RULES EFFECTIVE JANUARY 1, 2004

Questions – choose the one best answer. A passing score and one contact hour will be given for all persons who achieve seventy percent or more correct.

1. The individual responsible for the practice of the profession of pharmacy, including but not limited to supervision and control of dangerous drugs, is the:
 - a. Responsible Pharmacist
 - b. Responsible Person
 - c. Pharmacist in Charge
 - d. Pharmacy Manager

2. If the individual identified in question number one desires to supervise more than one pharmacy, that individual;
 - a. can not legally do so under any circumstances.
 - b. must obtain prior written permission from the Ohio State Board of Pharmacy.
 - c. must outline the circumstances requiring that individual to be responsible for more than one pharmacy and the period of time during which the circumstances will exist.
 - d. must be physically present in the pharmacy a sufficient amount of time to provide supervision and control.
 - e. b and c are correct
 - f. b, and c, and d are correct

3. The Ohio State Board of Pharmacy must be notified within thirty days by certified mail, return receipt requested, when there is a change of responsible person for all locations licensed as a terminal distributor of dangerous drugs.
 - a. true
 - b. false

4. Any candidate who has requested to transfer their NAPLEX score to Ohio must receive a passing score on the Ohio jurisprudence examination within twelve months from the date the candidate completed the NAPLEX examination or the score transfer will be denied.
 - a. true
 - b. false

5. The Ohio State Board of Pharmacy requires “approved continuing education” related to the practice of pharmacy:
 - a. in the area of patient care
 - b. in the area of pharmacy jurisprudence
 - c. in the area pharmacy management
 - d. in the area of pharmacy administration

6. Each prescriber or terminal distributor of dangerous drugs must maintain an inventory of all substances listed in schedule III, IV, or V, and 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
 - a. true
 - b. false

7. Prior to January 2004, a terminal distributor of dangerous drugs was not required to keep a record of all dangerous drugs _____.
 - a. received
 - b. administered
 - c. dispensed
 - d. distributed
 - f. destroyed

8. Under Ohio law prior to January 2004, a registered dangerous drug distributor requesting personal information from the public by way of the "Internet" site did not have to provide provide information regarding how the personal information would be used, pursuant to all federal and state laws, rules, and regulations.
 - a. true
 - b. false

9. The responsible person whose name appears on the limited terminal distributor of dangerous drugs license for an approved animal shelter must sign and maintain the license in a readily available place in the principal location of the business.
 - a. true
 - b. false

10. When prepared in a fluid therapy pharmacy, a compounded parenteral product prescription may be dispensed unless a label is affixed to the container in which such drug is dispensed and such label does not have to include:
 - a. the name and address of the pharmacy.
 - b. the name of the patient for whom the drug is prescribed.
 - c. the name or initials of the pharmacist.
 - d. directions for use of the drug which must include route of administration.
 - e. the date of dispensing.
 - f. any cautions which may be required by federal or state law.



Lesson number 036-368-04-001-H03 Answer Sheet: Expires September 30, 2007

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Answer Sheet – circle the one correct best answer

Question	Answer	Question	Answer
1	A B C D	6	True False
2	A B C D E F	7	A B C D E F
3	True False	8	True False
4	True False	9	True False
5	A B C D	10	A B C D E F



Please return by mail with check for \$15 payable to James Lindon at:

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Rocky River, Ohio 44116

Phone 440-333-0011

Fax 419-710-4925

Please fax, e-mail, or mail [specify one, please] my continuing education certificate to:

Pharmacist Name _____

Street Address _____

City _____ State _____ Zip _____

E-Mail _____

Phone _____

Ohio Pharmacist License Number _____

Check one:

Yes, Please e-mail me your **free** pharmacy law newsletter

No, Do not e-mail me your **free** pharmacy law newsletter

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Program Evaluation (circle one response to each question):

- How would you rate this educational program overall?
 excellent | very good | Good | Fair | Poor
- How well did this program achieve its educational objectives?
 excellent | very good | Good | Fair | Poor
- How well did this program improve your knowledge of the subject matter?
 excellent | very good | Good | Fair | Poor
- How useful and relevant will this lesson be in your practice?
 Very | Somewhat | Not much | Not at all
- About how much time did it take you to complete the lesson and exam?
 30 minutes | 45 minutes | 60 minutes | 90 minutes | Over 90 minutes