

## **NEW RULES EFFECTIVE FEBRUARY 2005**

### Objectives

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

- Discuss changes in Ohio pharmacy law effective February 2005
- Describe new requirements for pharmacy interns
- Understand requirements for automated drug delivery systems
- Understand Standards For Compounding Parenteral Or Sterile Product Prescriptions
- Understand Drug Repository Program invoices
- Describe Positive Identification requirements

### Introduction

February 2005 saw the introduction of new law by the Ohio State Board of Pharmacy. These rules affected a wide variety of pharmacy practices, and prescription processing requirements. This lesson will present some of those new rules.

### Interns

Record keeping requirements for pharmacy interns became a bit more rigid. Fortunately, they are still fairly straight forward and easy to follow. The practical experience affidavit now requires reporting of the total number of actual clock hours worked. The actual clock hours worked during the reported time period in question are rounded to the nearest hour. The hours reported must be able to be documented by payroll or other records which may be examined by the board of pharmacy upon reasonable notice. The previous requirement was directed to “hours obtained” and has been modified.

Practical experience affidavits are evidence of practical experience for internship credit. The affidavits must be signed by the preceptor on file with the board of pharmacy. In the event of the unavailability of the preceptor's signature due to extraordinary circumstances and due to no fault of the intern, the board may accept an alternative method for verification of a practical experience affidavit

To apply for registration as a pharmacy intern, the applicant must provide an original transcript certifying that the applicant has in fact successfully completed a minimum of sixty semester or ninety quarter hours of college work. See 4729-3-02 and 4729-3-03. The previous standard was forty eight semester hours or seventy two quarter hours. The applicant must also provide a certificate of enrollment into a school of pharmacy certifying that the person is enrolled in a school of pharmacy and is actively working towards the requirements for licensure as a pharmacist.

For those applicants who have already obtained a first professional degree in pharmacy the Board must now approve equivalencies if the applicant does not have evidence of successful completion of the “Test of Spoken English (TSE).” Previously, the TSE equivalent did not have to be Board approved.

### Dispensing With An Automated Drug Delivery System

Automated drug delivery systems are more prevalent than ever. They have the potential to provide convenience, accuracy, and cost-savings to institutions and patients. Where does the pharmacist fit in? The drug is deemed to have been dispensed when the pharmacist has given final approval to the patient specific prescription in the system. The automated drug delivery system is intended for use by a terminal distributor of dangerous drugs to assist in the dispensing of a drug. See OAC 4729-5-35. The automated drug delivery system must meet the following requirements:

- (A) Each automated drug delivery system must be approved by the board of pharmacy prior to its implementation by the terminal distributor of dangerous drugs;
- (B) The automated drug delivery system must have a documented and ongoing quality assurance program that monitors total system performance and includes the requirement for one hundred per cent accuracy in drug and strength delivered;
- (C) The automated drug delivery system must have adequate security to prevent unauthorized individuals from accessing or obtaining dangerous drugs;
- (D) The records kept by the automated drug delivery system must comply with all board requirements.

### Positive Identification

Positive identification is a method of identifying an individual who prescribes, administers, or dispenses a dangerous drug. As the type and number of “paperless” record keeping systems grow, accountability becomes more difficult. One way to maintain accountability is for individuals to use a means of positive identification.

Previously, a private personal identifier, such as a password, might have sufficed. While a password may still be used, it can no longer be the sole method of identifying the individual who prescribes, administers, or dispenses a dangerous drug. If a password is used, the person must also include a:

1. manual signature on a hard copy record;
2. magnetic card reader;
3. bar code reader;
4. thumbprint reader or other biometric method;
5. proximity badge reader;
6. board approved system of randomly generated personal questions;
7. printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the dangerous drug. The printout must be maintained for three years and made available on request to those individuals authorized by law to review such records; or
8. Other effective methods for identifying individuals that have been approved by the board.

A positive identification method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also

include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system

#### Prescription Format

Many, if not nearly all, written prescriptions are still given to patients on standard prescription blank sized orders. There is only so much information that can fit on that small piece of paper. The potential for errors would seem to increase as hand writing gets smaller or bunched together. The Board has undertaken to address this situation by allowing no more than three noncontrolled substance prescription orders per prescription form. OAC 4729-5-13 requires that no pharmacist may dispense dangerous drugs pursuant to a written outpatient prescription when there are four or more noncontrolled substance prescription orders on a prescription form.

#### Minimum Standards For Compounding Parenteral Or Sterile Product Prescriptions.

A policy and procedure manual needs to be prepared and maintained regarding the compounding, dispensing, and delivery of sterile product prescriptions. Compounds must have “beyond use” dates to determine when the products are no longer available for use by a patient. The policy and procedure manual must have justification for the chosen beyond use dates of compounded products. The policy and procedure manual must be current and available for inspection and copying by a state board of pharmacy designated agent.

There also needs to be an ongoing quality assurance control program. The program must now monitor the finished compounded drug products. Previously, the quality assurance control program only needed to monitor the personnel performance, equipment, and facilities. There also needs to be written quality assurance programs developed that address, as a minimum,

1. Adequate training and continuing competency monitoring of all personnel in personal cleansing, proper attire, aseptic technique, proper clean room conduct, and clean room disinfecting procedures. Instructors must have the appropriate knowledge and experience necessary to conduct the training;
2. Continued verification of compounding accuracy including physical inspection of end products;
3. Continued verification of automated compounding devices;
4. Continued verification that appropriate beyond use dates are being assigned to compounded products;
5. End product testing including, but not limited to, the appropriate sampling of products if microbial contamination is suspected. Additionally, if bulk compounding of parenteral or sterile products is being performed using nonsterile chemicals, extensive end product testing must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter and testing for pyrogens.
6. There must be written procedures developed requiring appropriate sampling if microbial contamination is suspected.

7. All clean rooms and laminar flow hoods must have environmental monitoring performed at least every six months to certify operational efficiency. There must be a plan in place for immediate corrective action if operational efficiency is not certified. Records certifying operational efficiency must be maintained for at least three years.

#### Drug Repository Programs

Recipient pharmacies, hospitals, or nonprofit clinics can receive donations of dangerous drugs to assist their patients. Donators can be a licensed terminal distributor of dangerous drugs, a licensed wholesale distributor of dangerous drugs or a patient who was legally dispensed a dangerous drug pursuant to a patient-specific drug order. It is too late for a patient to donate dangerous drugs after the dangerous drugs have been taken out of the pharmacy.

A pharmacy, hospital, or nonprofit clinic may elect to participate in the drug repository program, pursuant to sections 3715.87 to 3715.873 of the Revised Code, if all of the following requirements are met:

- (A) Must be licensed as a terminal distributor of dangerous drugs pursuant to section 4729.54 of the Revised Code.
- (B) Must comply with all federal and state laws, rules, and regulations.

The following may donate a dangerous drug, pursuant to the eligibility requirements of rule 4729-35-04, to a pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program:

- (1) A licensed terminal distributor of dangerous drugs.
- (2) A licensed wholesale distributor of dangerous drugs.
- (3) A person who was legally dispensed a dangerous drug pursuant to a patient-specific drug order.

All dangerous drugs, except controlled substances and drug samples, may be donated to a pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program if the drugs meet all of the following requirements:

- (A) The drugs are in their original sealed and tamper-evident unit dose packaging. The packaging must be unopened except that the drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed.
- (B) The drugs have been in the possession of a licensed healthcare professional and not in the possession of the ultimate user.
- (C) The drugs have been stored according to federal food and drug administration storage requirements.
- (D) The drugs must have an expiration date of six months or greater.
- (E) The packaging must list the lot number and expiration date of the drug.
- (F) The drugs must not have any physical signs of tampering or adulteration.
- (G) The drug packaging must not have any physical signs of tampering.

A person electing to donate an eligible dangerous drug shall not have taken custody of the drug prior to the donation. The person may direct the donation through a terminal distributor of dangerous drugs. A person who resides in an institutional facility and was legally dispensed a dangerous drug pursuant to a patient-specific order may elect to sign and date a donor form prior to donating a drug, which shall state "from this day forward I wish to donate all my remaining unused drugs that are eligible, pursuant to rule 4729-35-04, to the drug repository program". A person designated by durable power of attorney, a guardian, or other individual responsible for the care and well-being of a patient may make the decision to donate an eligible dangerous drug.

Record keeping requirements have changed. An invoice must be created by the donor location. The invoice must include at least the following information:

1. The name and address of the donor location.
2. The brand name of the drug donated, or the generic name and list either the name of the manufacturer or the national drug code number (NDC#).
3. The strength of the drug.
4. The quantity of the drug.
5. The date the drug was sent to a pharmacy, hospital, or nonprofit clinic.
6. The name and address of the recipient pharmacy, hospital, or nonprofit clinic.

No longer are the lot number and expiration of the drugs required on the invoice. A copy of the invoice must be maintained for a minimum of three years by both the donor location, which includes a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or an institutional facility, and the recipient location, which includes a pharmacy, hospital, or nonprofit clinic.

#### Manner of Processing a Prescription 4729-5-21

A prescription, to be valid, 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 pharmacist when dispensing a prescription must:

- (1) Ensure that patient information is profiled pursuant to rule 4729-5-18;
- (2) Perform prospective drug utilization review pursuant to rule 4729-5-20;
- (3) Ensure that the drug is labeled pursuant to rule 4729-5-16;
- (4) Ensure that a patient is given an offer to counsel pursuant to rule 4729-5-22; and
- (5) Ensure that a prescription is filed pursuant to rule 4729-5-09.

When a pharmacist dispenses a drug pursuant to an original prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or, if approved by the state board of pharmacy, enter his/her

positive identification into the computerized record keeping system pursuant to rule 4729-5-27. If an alternate record keeping system is being used pursuant to rule 4729-5-27, the record of dispensing must also be recorded in the alternate record keeping system.

When a pharmacist dispenses a drug pursuant to an authorized refill of a prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or enter such information in an alternate record keeping system or, if approved by the state board of pharmacy, enter his/her positive identification into a computerized record keeping system pursuant to rule 4729-5-27.

Oral prescriptions are valid provided the following rules are followed:

- (1) The pharmacist shall make a record of the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent, on the original prescription and, if used, on the alternate system of record keeping. The pharmacist is responsible for assuring the validity of the source of the oral prescription.
- (2) Upon receiving a prescription from a recording device, the pharmacist must remove the prescription from the recorder and reduce it to writing. The pharmacist must document on the original prescription the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent. The pharmacist is responsible for assuring the validity of the prescription removed from the recorder.

A licensed pharmacy intern may receive telephone prescriptions if the pharmacist on duty who is supervising the activity of the intern determines that the intern is competent to perform this function. The intern shall immediately reduce the prescription to writing, document the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent, and shall review the prescription with the supervising pharmacist. Prior to dispensing, positive identification of the intern and the supervising pharmacist shall be made on the prescription to identify the responsibility for the receipt of the oral order. The supervising pharmacist on duty is responsible for the accuracy of the prescription. The supervising pharmacist on duty must be immediately available to answer questions or discuss the prescription with the caller.

Facsimile prescriptions are valid provided the following rules are followed:

- (1) A facsimile shall only be valid as a prescription if a system is in place that will allow the pharmacist to maintain the facsimile as a part of the prescription record including the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent as well as identification of the origin of the facsimile.
- (2) The pharmacist must record the prescription in writing pursuant to section 4729.37 of the Revised Code or store the facsimile copy in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.

A pharmacist may not dispense a dangerous drug for the first time beyond six months from the date of issuance of a prescription.

#### Out-Patient Record Keeping 4729-5-27

There must be positive identification of the pharmacist or pharmacists responsible for performing all activities relating to the practice of pharmacy including, but not limited to:

- (1) Prescription information entered into the record keeping system;
- (2) Prospective drug utilization review;
- (3) Dispensing;
- (4) Patient counseling;
- (5) Administering adult immunizations;
- (6) Prescription information reduced to writing from an order received by telephone, facsimile, or recording device.

Records of dispensing must provide accountability and ensure that patients do not receive more drugs than intended by the prescriber. All records relating to the practice of pharmacy shall be uniformly maintained for a period of three years, be readily available, and promptly produced upon request for inspection by a state board of pharmacy officer, agent, and/or inspector during regular business hours.

All prescriptions or other records relating to the practice of pharmacy, which are required to be kept for three years according to section 4729.37 of the Revised Code, may be microfilmed or placed on electronic, magnetic media. The microfilm or electronic, magnetic media used for this purpose must comply with the "International Standards Organization" standards of quality approved for permanent records. Such records are subject to all other paragraphs of this rule.

Any pharmacy intending to maintain records relating to the practice of pharmacy at a location other than the place licensed with the state board of pharmacy must first send written notification to the state board of pharmacy by mail or facsimile. The state board of pharmacy office will send written notification of the approval or disapproval of the request. Only after receiving the notice of the board's approval may the records be placed in the new location.

All computerized record keeping systems must be capable of providing immediate retrieval (via CRT display and hard copy printout or other mutually agreeable transfer medium) of patient profile information for all prescriptions filled within the previous twelve months and retrieval within three working days, excluding weekends and holidays, of all prescriptions dispensed within the previous three years. This information shall include at least, but is not limited to, the following data:

- (1) The original prescription number;
- (2) Date of issuance of the original prescription order by the prescriber;
- (3) Date of dispensing by the pharmacist;
- (4) Full name and address of the patient;
- (5) Full name and address of the prescriber;
- (6) Directions for use;
- (7) The name, strength, dosage form, and quantity of the drug prescribed;
- (8) The quantity dispensed if different from the quantity prescribed;

- (9) If utilizing a board approved system, there must be positive identification documented within the system of the pharmacist responsible for prescription information entered into the computer system, the pharmacist responsible for prospective drug utilization review as defined in rule 4729-5-20, and the pharmacist responsible for dispensing;
- (10) The total number of refills authorized by the prescriber; and
- (11) The refill history of the prescription.

The refill history of the prescription must include, but is not limited to:

- (1) The prescription number;
- (2) The name and strength of the drug dispensed;
- (3) The date of refill;
- (4) The quantity dispensed;
- (5) If utilizing a board approved system, there must be positive identification documented within the system of the pharmacist responsible for prospective drug utilization review as defined in rule 4729-5-20 and the pharmacist responsible for dispensing for each refill; and
- (6) The total number of refills dispensed to date for that prescription order.

Hard copy documentation as required must be provided by each individual pharmacist who makes use of such system by a hard copy printout or tamper evident log book. A hard copy printout of each day's prescription refill data that shall include, at a minimum, the following data:

- (a) Date of dispensing;
- (b) Prescription number;
- (c) Patient name;
- (d) Name, strength (if applicable), and quantity of drug;
- (e) Identification of pharmacy and pharmacist;
- (f) Identification of controlled substances.

This printout must be verified, dated, and signed by each individual pharmacist who dispensed a prescription that day. The pharmacist must verify that the data on the printout is complete and correct and sign a statement to that effect on the document as he/she would sign a check or legal document (e.g., J. H. Smith or Jane H. Smith). These documents must be maintained in chronological order in a separate file at the licensed location where the drug was dispensed for a period of three years from the date of dispensing. If the printout is prepared at a location other than that where the drug was dispensed, the printout must be provided to the licensed location within three working days, excluding holidays and weekends, of the date on which the drugs were dispensed. Such printouts must be verified and signed by each pharmacist who dispensed drugs within twenty-four hours of the date the printout is received;

A tamper evident log book must include the date of dispensing and prescription number. The dispensing pharmacist must manually record his/her name or initials on each log book entry at the time of dispensing each refill; or each individual pharmacist involved in

dispensing drugs must enter into a tamper evident log book, at a minimum, the following data for each prescription refilled:

- (a) Date of dispensing;
- (b) Prescription number;
- (c) Patient name;
- (d) Name, strength (if applicable), and quantity of drug;
- (e) Identification of the pharmacist;
- (f) Identification of controlled substances.

Each individual pharmacist involved in dispensing drugs must review this information at the end of each day and then must sign a statement in the log book attesting to the fact that the prescription information entered into the computer that day and recorded in the log book has been reviewed and is correct as shown.

Any computerized record keeping system must have the capability of producing a printout by any data field which the user pharmacy is responsible for maintaining pursuant to federal and state laws and their implementing regulations and rules within three working days of a request being submitted by an individual authorized by law to access such records.

In the event that the computerized record keeping system experiences down time, a record of all refills dispensed during such time must be recorded on the back of the original prescription. The refill information must be entered into the computerized record keeping system as soon as it is available for use. During the time the computerized record keeping system is not available, prescriptions may be refilled only if, in the professional judgment of the pharmacist, the number of refills authorized by the prescriber has not been exceeded.

A pharmacy purging a computerized record keeping system of prescription records must develop a method of record keeping capable of providing retrieval (via CRT display, hard copy printout, or other mutually agreeable transfer medium) within three working days, excluding holidays and weekends, of prescription order information for all prescriptions filled or refilled within the previous three years. This information shall include, at a minimum, the following data:

- (1) Pharmacy name and address;
- (2) Original prescription number;
- (3) Date of issuance of the original prescription order by the prescriber;
- (4) Date of original dispensing by the pharmacist;
- (5) Full name and address of the patient;
- (6) Full name and address of the prescriber;
- (7) Directions for use;
- (8) Name, strength, dosage form, and quantity of the drug prescribed;
- (9) Quantity dispensed if different from the quantity prescribed;
- (10) Total number of refills authorized by the prescriber;
- (11) Total number of refills dispensed to date for that prescription order;
- (12) Date of each refill; and

(13) Name or initials of each individual dispensing pharmacist.

A log must be maintained of all changes made to a prescription record after the prescription has been dispensed. Such log may be accessible to the pharmacist for review, but shall be protected from being altered in any way. The log must contain at least, but is not limited to, the following:

- (1) Date and time of change;
- (2) Changes made; and
- (3) Pharmacist making the change.

Prescriptions entered into a computer system but not dispensed must meet all of the following conditions:

- (1) The complete prescription information must be entered in the computer system;
- (2) The information must appear in the patient's profile;
- (3) There is positive identification, in the computer system or on the hard copy prescription, of the pharmacist who is responsible for entering the prescription information into the system; and
- (4) The original prescription is filed according to rule 4729-5-09.

Records shall be maintained for three years on all adult immunizations administered pursuant to section 4729.41 of the Revised Code and must include at least the following information:

- (1) Full name and address of the patient;
- (2) Patient's date of birth or age;
- (3) Patient's gender;
- (4) Patient's applicable allergy information;
- (5) Date of administration by the pharmacist;
- (6) Name, strength, and dose of the adult immunization administered;
- (7) Lot number and expiration date of the immunization;
- (8) Route of administration;
- (9) Location of the injection site;
- (10) Positive identification of the administering pharmacist; and
- (11) Documentation of patient informed consent.

A pharmacist who administers adult immunizations pursuant to section 4729.41 of the Revised Code shall maintain and immediately make available, upon the request of the state board of pharmacy, the following records:

- (1) Documentation of the successful completion of a board approved course in the administration of adult immunizations;
- (2) Documentation of current certification to perform basic life support procedures pursuant to division (B)(2) of section 4729.41 of the Revised Code.

#### MANNER OF ISSUANCE OF A PRESCRIPTION 4729-5-30

A prescription, to be valid, 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.

All prescriptions issued by a prescriber shall:

- (1) Be dated as of and on the day when issued.
- (2) Contain the manually printed, typewritten, or preprinted full name and address of the prescriber.
- (3) Indicate a telephone number where the prescriber can be personally contacted during normal business hours.
- (4) Indicate the full name and address of the patient.
- (5) Indicate the drug name and strength.
- (6) Indicate the quantity to dispense.
- (7) Indicate the appropriate directions for use.
- (8) 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.
- (9) Not authorize any refills for schedule II controlled substances.
- (10) Authorize refills for schedules III and IV controlled substances only as permitted by section 3719.05 of the Revised Code.
- (11) 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.
- (12) Identify the trade name or generic name of the drug(s) in a compounded prescription.
- (13) Not be coded in such a manner that it cannot be dispensed by any pharmacy of the patient's choice.
- (14) For prescriptions issued to a patient by a prescriber, be:
  - (a) Manually signed on the day issued by the prescriber in the same manner as he/she would sign a check or legal document.
  - (b) Issued in compliance with rule 4729-5-13.
- (15) Be issued in compliance with all applicable federal and state laws, rules, and regulations.

When forms are used that create multiple copies of a prescription issued to a patient by a prescriber, the original prescription that bears the actual signature of the prescriber must be issued to the patient for dispensing by a pharmacist. Oral transmission by the prescriber or the prescriber's agent of original prescriptions and refills authorized by a prescriber, pursuant to the requirements of this rule, may be transmitted by telephone only to:

- (1) A pharmacist.
- (2) A recording device within the pharmacy if the pharmacist is unavailable. The pharmacist must remove the prescription from the recorder and reduce it to writing. The pharmacist is responsible for assuring the validity of the prescription removed from the recorder.

(3) A licensed pharmacy intern if the pharmacist on duty who is supervising the activity of the intern determines that the intern is competent to receive telephone prescriptions.

The prescriber's agent must provide his/her full name when transmitting an oral prescription. Original written prescriptions authorized and signed by a prescriber may be transmitted by the prescriber or the prescriber's agent by facsimile machine to a pharmacy pursuant to the following:

(1) The facsimile of the prescription must include the full name of the prescriber and if applicable the full name of the prescriber's agent transmitting the prescription to the pharmacy.

(2) The original prescription signed by the prescriber from which the facsimile is produced shall not be issued to the patient. The original prescription signed by the prescriber must remain with the patient's records at the prescriber's office or the institutional facility where it was issued.

(3) Prescriptions for schedule II controlled substances may not be transmitted by facsimile except for:

(a) A resident of a long term care facility pursuant to rule 4729-17-09.

(b) A narcotic substance issued for a patient enrolled in a hospice. The original prescription must indicate that the patient is a hospice patient. The facsimile transmission must also meet the other requirements of this rule.

(c) A compounded sterile product prescription for a narcotic substance pursuant to rule 4729-19-02.

(4) A facsimile of a prescription received by a pharmacy in any manner other than transmission directly from the prescriber or the prescriber's agent shall not be considered a valid prescription.

A prescription may be transmitted by means of a board approved electronic prescription transmission system, without further verification by the pharmacist of the prescriber's identity, provided that:

(1) The system shall require positive identification of the prescriber as defined in rule 4729-5-01 and the full name of any authorized agent of the prescriber who transmits the prescription.

(2) The computer data must be retained for a period of three years at the prescriber's office.

## Questions

1. To apply for registration as a pharmacy intern, the applicant must provide an original transcript certifying that the applicant has in fact successfully completed a minimum forty eight semester hours.
  - a. True
  - b. false
2. To apply for registration as a pharmacy intern the applicant needs be enrolled in a pre-pharmacy program and actively working towards the requirements for licensure as a pharmacist.
  - a. True
  - b. false
3. When an automated drug delivery system is employed, the drug is deemed to have been dispensed when the pharmacist has given final approval to the patient specific prescription in the system.
  - a. True
  - b. false
4. The positive identification printout of transactions verified and manually signed within must be maintained for two years.
  - a. True
  - b. false
5. The automated drug delivery system must have a documented and ongoing quality assurance program that monitors total system performance and includes the requirement for substantial accuracy in drug and strength delivered.
  - a. True
  - b. false
6. Positive identification is a method of identifying an individual who prescribes, administers, or dispenses a dangerous drug.
  - a. true
  - b. false
7. Which of the following can not be used with a password for positive identification.
  - a. magnetic card reader
  - b. bar code reader
  - c. thumbprint reader or other biometric method
  - d. facility approved system of randomly generated personal questions
  - e. proximity badge reader
8. No pharmacist may dispense dangerous drugs pursuant to a written outpatient prescription when there are four or more noncontrolled substance prescription orders on a prescription form.
  - a. true
  - b. false
9. To comply with the law, an ongoing quality compounding assurance control program only needs to monitor the personnel performance, equipment, and facilities.
  - a. true
  - b. false
10. An invoice for a drug repository program must include the lot number and expiration of the drugs donated.
  - a. true
  - b. false



Lesson number 036-368-05-001-H03 Answer Sheet: Expires January 30, 2009  
 Approved for one contact hour of Ohio Jurisprudence by the Ohio State Board of  
 Pharmacy

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Answer Sheet – circle the one correct best answer

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



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

Pharmacist Name \_\_\_\_\_

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