
Topics in Ohio Pharmacy Law for Pharmacists

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Program Number: 036-367-15-001-H03 C.E.U.s: 0.1 Contact Hours: 1 hour

Release Date: 03/15/2015 Expiration Date: 3/15/2017

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This program is approved by the Ohio Board of Pharmacy for Jurisprudence Credit.

The cost for this program is \$20.00.

Learning Objectives

- 1) Discuss the legal requirements of pharmacists when opioids are prescribed to minors
- 2) Discuss the legal requirements for multiple prescriptions for schedule II drugs
- 3) Describe the legal requirements for prescribing controlled substances to family members
- 4) Describe the legal requirements for prescription transfers
- 5) Discuss other issues related to the practice of pharmacy in Ohio

Prescribing Opioids to Minors (ORC 3719.061)

As of September 17, 2014, House Bill 314 requires all prescribers (physicians, PAs, APNs, optometrists, dentists, and podiatrists) to obtain explicit informed consent prior to issuing a prescription for any drug classified as an opioid. The new law states that informed consent has three components: 1) assessing the minor's mental health and substance abuse history, 2) discussing with the minor and their parent, guardian, or other authorized adult the risks and dangers when taking an opioid, and 3) obtaining the signature of a parent, guardian, or authorized adult on a consent form. Note: If the minor is accompanied by another authorized adult other than the parent or guardian, the prescriber is limited to prescribing not more than a 72-hour supply of an opioid. Another adult authorized to consent to the minor's medical treatment is defined as an adult to whom a minor's parent or guardian has given written authorization to consent to the minor's medical treatment. The law does specify instances when the informed consent requirement does not apply. These include:

- 1) The minor's treatment is associated with or incident to a medical emergency.
- 2) The minor's treatment is associated with or incident to surgery, regardless of whether the surgery is performed on an inpatient or outpatient basis.
- 3) In the prescriber's professional judgment, fulfilling the law's informed consent requirement would be a detriment to the minor's health or safety.
- 4) The minor's treatment is provided in a hospital, emergency facility, ambulatory surgery facility, nursing home, pediatric respite care program, residential care facility, freestanding rehab facility, or similar institutional facility. This exemption does not apply when the treatment is given in the prescriber's office that is located on the premises of or adjacent to any of these facilities mentioned above.
- 5) The prescription is for a compound that is a controlled substance containing an opioid that a prescriber issues to a minor at the time of discharge from a facility or other location described in number "4" above.

Even though most of the responsibility for this new law falls on the prescriber, pharmacists have a responsibility as well. What do pharmacists need to know and do regarding this new law? Pharmacists have a corresponding responsibility to ensure that a prescription issued by a prescriber is for a legitimate medical purpose and in accordance with all state and federal laws. The physician should document on the prescription that informed consent was obtained or attach a copy of the informed consent form with the prescription. If the minor meets any of the exemptions listed above, the pharmacist can safely assume using their own professional judgment that no consent form is required. However, if a pharmacist receives a prescription with no documented consent for an opioid for a minor and these exemptions do not apply, then

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he/she should verify with the prescriber that a consent form was completed prior to dispensing the prescription. It is strongly recommended that the pharmacist document the informed consent or the reason why it is not required in the patient record. NOTE: The pharmacist must ultimately decide what is in the best interest of the patient and the lack of informed consent does not preclude a pharmacist from dispensing an opioid prescription to a minor. Always do what's best for the patient using your own professional judgment.

Multiple Prescriptions for Schedule II Drugs (21 CFR 1306.04 & 1306.05)

Let's consider this example. A parent takes their child to visit his physician for a follow-up visit regarding their ADHD on March 1, 2015. The child has been taking Adderall[®] XR 10mg, #60, once daily in the morning for 18 months. The parent has seen a dramatic improvement in the child's behavior at home and school. The last visit to the physician was on January 15, 2015 when the parent received a prescription for the same 60 day-supply of drug. The physician knows the patient has enough medication until March 14, 2015. He does not want the parent to have the prescription filled until that date. What should the physician do? The physician may be tempted to post-date the prescription with the date March 14, 2015. This is illegal. Prescriptions must be dated on the day that the physician signs and issues the prescription. Therefore the date on the prescription must be March 1, 2015. Post-dated prescriptions are illegal. The best option for the physician is to write in the directions of the prescription, "Do not fill until March 14, 2015". Federal law allows physicians to issue multiple prescriptions for schedule II drugs. This law allows physicians to issue multiple prescriptions for a schedule II drug with "do not fill until" on them for up to a 90 day supply of medication. Let's consider another example. A physician decides that he/she only needs to see a child every 90 days for his ADHD. The date of the physician visit is March 1, 2015. The physician could write three prescriptions on March 1, 2015 for Adderall XR[®] 5mg, #30, one daily. The first prescription would have nothing additional in the directions. The second prescription would have "Do not fill until March 31, 2015" in the directions, and the third would have "Do not fill until April 30, 2015". All three of these prescriptions would have the date issued as March 1, 2015. With these dates on the prescriptions, pharmacists are prohibited from filling them before these dates. Also, the physician is not required to write these prescriptions in 30 day increments. Another physician may want to issue six prescriptions for a 14 day supply on each with the appropriate "do not fill until" dates on each one. In summary, the total days supply when multiple prescriptions are issued for a schedule II drug with "do not fill until" on it is 90 days. Example: What if the physician does not want to issue three separate prescriptions with do not fill dates on them and wants to write just one prescription for Adderall XR[®] 5mg, #90, one daily? Is this legal? The answer is "Yes" as long as it is for a legitimate medical purpose. Finally, this law does not require physicians to see their patients every 90 days. The length of time between appointments and care that needs to be given is left up to the discretion of the physician. In some cases, patients who are very stable on their therapy may need to be seen only a few times a year.

Practitioners Prescribing of Controlled Substances to Family Members (OAC 4731-11-08)

Many pharmacists have experienced the situation where a physician comes into the pharmacy and asks the pharmacist for prescription pad to write a prescription for a family member. For example: A physician writes a prescription for his wife for levofloxacin 500mg, #7, one tablet daily for a sinus infection. As long as the physician is writing the prescription for a legitimate medical purpose, most pharmacists would fill the prescription. However, what if a physician wanted to write a prescription for his wife for Tylenol #3[®], #120, one tablet every six hours as needed, 5 refills? This is a problem. Ohio law states that accepted and prevailing standards of care presuppose a professional relationship between a patient and practitioner when the practitioner is utilizing controlled substances. First of all, a practitioner may never have such a relationship with himself or herself. Therefore, a practitioner may not self-prescribe or self-administer controlled substances. The law goes even further to state that accepted and prevailing standards of care

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require a practitioner maintain detached professional judgment when utilizing controlled substances in the treatment of family members. "Family members" is defined as spouse, parent, child, sibling, or other individual in relation to whom a practitioner's personal or emotional involvement may render that practitioner unable to exercise this type of detached professional judgment. This means that prescribers may not write prescriptions for controlled substances for any of these individuals except in emergency situations, which must be documented in the patient's record. If a pharmacist receives a prescription for a controlled substance written by a prescriber for one of these types of family members they should speak with the prescriber, discuss if it is indeed an emergency, and document this conversation in the patient's profile or on the back of the prescription. Again, the "acid test" for the pharmacist is whether the prescription is for a legitimate medical purpose and a bona fide emergency.

Prescription Transfers (OAC 4729-5-24)

One of the areas that many pharmacists begin to become less diligent about over time is that of proper recordkeeping. One specific area can be the legal requirements regarding prescription transfers, or copies as they are sometimes called. Prescriptions shall be transferred only between two pharmacists. However, an intern can be involved in the transfer process as long as certain rules are followed. The rules regarding the involvement of interns in this process will be discussed in detail later. Non-controlled substances can be transferred more than once as long as the prescription has refills available to be legally filled. Prescriptions for controlled substances can only be transferred one time. However, pharmacies that electronically share a real time, online database may transfer a controlled substance prescription up to the maximum number of refills permitted by law and the prescriber's authorization. The pharmacy receiving a transferred prescription should make sure it is an exact duplicate of the original prescription, containing all the same information as the original prescription. The pharmacy receiving the transferred prescription must make sure that the following information is also included:

- a) the serial prescription number assigned to the prescription
- b) name and address of the pharmacy transferring the copy
- c) date the prescription was issued
- d) date of the original dispensing
- e) original number of refills
- f) date of the last refill
- g) number of valid refills remaining
- h) full name of the transferring pharmacist

In addition, the pharmacist receiving the copy must write the word "transfer" on the face of the prescription and record the date of the transfer on the face of the prescription. Most pharmacies these days are now computerized. If this is the case, the pharmacist transferring a copy of a prescription must include the following information in the prescription record within the computer system. This includes date of the transfer, name of the pharmacist making the transfer, and name and address of the pharmacy receiving the copy. If the transferred prescription is a controlled substance, the pharmacist must also record the DEA number of the pharmacy receiving the transfer. The computer system must also invalidate the prescription within its recordkeeping system. If the prescription being transferred is a controlled substance, the pharmacist must complete another step in the process in addition to including the above information in the pharmacy's computer system. The pharmacist must go to the hardcopy prescription files and pull the original prescription. He/she must write the word "void" on the face of the prescription in such a way to avoid defacing or destroying any original information contained on the prescription. On the back of the original prescription, the pharmacist must record the date of transfer, his/her signature, name, address, DEA number of the pharmacy receiving the transfer, and the full name of the pharmacist at the receiving pharmacy. If a pharmacy does not have a computerized system or other alternative recordkeeping system, this same process must be followed for non-controlled substance transfers as well.

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As pharmacy databases and computer systems become more technologically advanced, centralized databases will continue to become more common. A prescription may be transferred between two pharmacies if the two pharmacies are accessing the same prescription records in a centralized database or the pharmacy computers are linked in any other manner. The pharmacy computer systems must satisfy all the same legal requirements as stated above. This shall also include the invalidation of the prescription record in the system to prevent further dispensing at the original site. Even pharmacies that electronically share a real time, online database or centralized database must record the information on the back original hardcopy prescription for controlled substance prescriptions that are transferred as described above. Here is a situation that occurs all too frequently regarding prescription transfers. A prescription for Jane Doe, amoxicillin 500mg, TID, #30 is called-in to Pharmacy X from Dr. Smith. A few hours later, Pharmacy Y calls Pharmacy X and asks if Pharmacy X received an oral prescription for Jane Doe from Dr. Smith. Pharmacy Y tells Pharmacy X that the patient wants it filled at Pharmacy Y. The pharmacist at Pharmacy X orally gives all the information regarding the prescription for Jane Doe over the phone to the pharmacist at Pharmacy Y and then throws the oral prescription in the trash. Is this legal? The answer is “No”. What should Pharmacy X have done? Pharmacy X should have entered the prescription into their computer system without dispensing it and then transferred it to Pharmacy Y. This prescription will be displayed on Jane Doe’s patient profile at Pharmacy X, and should be filed with all the other hardcopy prescriptions. There should also be 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. This is the correct process for any oral prescription called-in to the wrong pharmacy.

Interns and Prescription Transfers (OAC 4729-5-24)

Licensed interns can send or receive copies of most prescriptions. However, under no circumstances can interns take or give copies for controlled substances. This information has to be directly communicated between two pharmacists. Interns can take or give copies under the following circumstances:

- 1) The pharmacist who is supervising the activity of a particular intern will determine if that intern is competent to send or receive a prescription copy. Again, this decision for each intern is made by each individual pharmacist and may be different for different interns.
- 2) The pharmacist who is supervising the intern is responsible for the accuracy of the prescription copy that is sent or received.
- 3) The supervising pharmacist must be immediately available to answer questions or discuss the prescription copy with the caller.
- 4) The pharmacist or intern receiving a prescription copy must document the full names of the intern giving the copy and of his/her supervising pharmacist. The intern giving a prescription copy must give his/her full name and the full name of the supervising pharmacist to the person receiving the prescription copy.
- 5) When an intern receives a copy, he/she must immediately reduce the prescription copy to writing and review it with the supervising pharmacist. Before dispensing the prescription, positive identification (signature or initials for example) must be made on the prescription of both the intern and the supervising pharmacist who received the copy.

Other Pharmacy Practice Issues

1) A dentist wrote a prescription for a codeine cough syrup for a patient. The dentist claims he could not work on the patient’s teeth because of the patient’s cough. Is this legal? No. In Ohio, dentists are considered to be limited prescribers. Therefore, a dentist could only prescribe medications within the course of his/her practice as it relates to dentistry. Limited prescribers are authorized to prescribe drugs only within the course of their professional practice. Limited prescribers in Ohio are: podiatrists, optometrists, veterinarians, advance practice nurses, and physician assistants. Another question is, can an MD write a prescription for the family pet for something as simple as amoxicillin 250mg? The answer to this question is

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“No”. The best way to remember this is with a simple saying: “People doctors are for people and animal doctors are for animals”. “Don’t let people doctors write for animals or animal doctors write for people.” (OAC 4729-5-15)

2) Can I take a faxed prescription for a schedule II controlled substance from an assisted living facility? No. Prescriptions for schedule II controlled substances may not be transmitted by fax except for a resident of a long term care facility, a compounded sterile product prescription for a narcotic substance, or a narcotic prescription for a patient enrolled in a hospice. {CFR Sec. 1306.11 and OAC Sec. 4729-5-30(E)(3)}

3) I received a prescription from an APN. The APN did not have her Certificate To Prescribe (CTP) number on the prescription. Is this required? Yes. Every prescription written by an APN or PA must have his/her CTP number written on the prescription. {OAC Rule 4729-5-30(B)(16)}

4) Does a pharmacist have to do Drug Utilization Review before dispensing a refill? Yes. Before dispensing any prescription, a pharmacist shall review the patient profile for over-utilization or under-utilization, therapeutic duplication, drug-drug interactions, incorrect drug dosage, drug-allergy interactions, abuse/misuse, or inappropriate duration of drug treatment. Upon recognition any of the above, the pharmacist, shall take appropriate action to avoid or resolve the potential problem, which may include consulting with the prescriber and/or consulting with the patient. (OAC Rule 4729-5-20)

5) What are considered the professional duties of a licensed pharmacy intern? Interns and technicians have always had different duties and activities they could perform under the direct supervision of a pharmacist. The Board of Pharmacy has defined several different professional duties an intern could perform in addition to assisting the pharmacist with technician functions. The pharmacist supervising the activity of a particular intern will determine if an intern is competent to perform any of these professional functions. In addition to assisting a pharmacist with technical functions, a pharmacy intern may perform the following professional functions under the direct supervision of a pharmacist. These activities must be documented with positive identification of both the supervising pharmacist and the pharmacy intern. These include: a) the sale of schedule V controlled substances, b) the receipt of oral prescriptions, c) the transfer of a non-controlled substance prescriptions, d) the act of patient counseling, e) the administration of immunizations pursuant to sections 4729.41, 4729-5-36, 4729-5-37, and 4729-5-38 of the Revised Code, and f) the documentation of informed consent to administer an immunization.

The views in this program are not intended as legal advice. Pharmacists should always consult their own attorney or the Ohio Board of Pharmacy when questions or issues regarding the practice of pharmacy arise.

Continuing Education Test Questions. Using the test answer sheet, please circle the correct response for each question. A passing grade of 70% must be obtained to receive continuing education credit. CE statements of credit will be mailed within 1-2 weeks of receiving your answer sheet. You must return the test answer sheet prior to March 15, 2017 to receive credit.

- 1) Informed consent for an opioid prescription for a minor does not apply if...
- a) The minor’s treatment is associated with an inpatient surgery.
 - b) The minor’s treatment is associated with a medical emergency.
 - c) The minor’s treatment is provided in a pediatric respite care program.
 - d) a and b only
 - e) a, b, and c

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- 2) On Friday night, a pharmacist receives a prescription for a 17 year old patient for twenty Tylenol #3® tablets written by an orthopedic physician. The patient has a severely broken arm. There is no documentation of informed consent on the prescription. The physician's office is closed and cannot be contacted until Monday morning. Could the pharmacist dispense this prescription?
- a) Yes b) No
- 3) A physician can write "Do Not Fill Until" on one or more schedule II prescriptions for up to.....
- a) 30 days d) 6 months
b) 60 days e) This cannot be done under any circumstances.
c) 90 days
- 4) A patient comes to the physician's office for his appointment on February 19, 2015. A physician wants to write a prescription for the patient for oxycodone 5mg. The patient currently has enough of the drug from a previous prescription to last them until March 1, 2015. The physician does not want the patient to get the new prescription filled early, so he dates the new prescription March 1, 2015. Is this legal?
- a) Yes b) No
- 5) ABC Pharmacy is transferring a prescription for furosemide 40mg to XYZ Pharmacy. What information does the pharmacist at ABC Pharmacy have to enter into their computer system?
- a) date of transfer
b) name and address of the pharmacy they are transferring the prescription to
c) name of the pharmacist receiving the transferred prescription
d) a and b only
e) a, b, and c
- 6) Which of the following are true?
- a) The pharmacist receiving a prescription transfer must write "transfer" on the face of the prescription.
b) Controlled substances prescriptions cannot be transferred, even if the pharmacies share a real time, online database
c) Interns can receive transferred prescriptions for controlled substances.
d) a and b only
e) a, b, and c
- 7) Can a physician prescribe a controlled substance for his father in a non-emergency situation?
- a) Yes b) No
- 8) An intern takes a prescription from a nurse for Dr. Smith for atorvastatin 20mg. Which of the following statements are true regarding this prescription?
- a) The pharmacist supervising the intern is responsible for accuracy of the prescription.
b) The intern must review the prescription with the pharmacist.
c) Only the pharmacist must sign or initial the prescription.
d) a and b only
e) a, b, and c
- 9) Which of the following are true?
- a) Dentists can write prescriptions for diabetes medications.
b) A physician can write a prescription for the family pet.
c) An APN's certificate to prescribe number must be on a written prescription.
d) a and c are true
e) a, b and c are true
- 10) Pharmacists do not have to conduct drug utilization review on refilled prescriptions.
- a) True b) False

Continuing Education Test Answer Sheet
“Topics in Ohio Pharmacy Law for Pharmacists.”

Program Number: 036-367-15-001-H03
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C.E.U.s: 0.1

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- 1) A B C D E
- 2) A B C D E
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- 4) A B C D E
- 5) A B C D E

- 6) A B C D E
- 7) A B C D E
- 8) A B C D E
- 9) A B C D E
- 10) A B C D E

Name: _____

Address: _____

City, State, and Zip: _____

Email: _____ *Ohio Pharmacist License #* _____

CPE e-profile #: _____ *Date of birth (mm/dd)* _____

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Please send to me the following Ohio programs:

_____ *“What Every Pharmacist Needs to Know About Controlled Substances in Weight Reduction.”*
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