# **Important Legal Issues for Ohio Pharmacists**

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### **Learning Objectives**

- 1) Discuss the legal issues when dispensing schedule II controlled substances
- 2) Discuss the legal issues when dispensing an oral schedule II prescription
- 3) Describe the legal requirements when a patient is out of refills
- 4) Discuss the new requirements of using OARRS and how to register
- 5) Discuss other issues related to Ohio pharmacy law

### **Prescriptions for Schedule II Controlled Substances**

{OAC 4729-5-21(A) (G); OAC 4729-5-30 (B)(15); CFR 1306.13(a)}

Some health care providers and pharmacists erroneously believe that there is a more restrictive time limit regarding when a schedule II prescription can be filled. This is just not true. The same rules that apply for non-controlled substance prescriptions apply to schedule II prescriptions. The first fill of the new prescription must take place within six months of the date the prescription was written. However, pharmacists must ensure that the prescription is for a legitimate medical purpose. Under Ohio and federal law, this is known as corresponding liability. This means that 50% of this responsibility is on the pharmacist. Pharmacists cannot hide behind the excuse, "The doctor wrote so I filled it". If a pharmacist is presented with a prescription for Adderall XR<sup>®</sup> 15mg on October 15, 2011 and it was written on September 21, 2011 by the patient's pediatrician, there may be a legitimate medical reason why the patient waited to get this prescription filled. For example: the patient may have had medication left from a previous prescription. If the pharmacist determines in their professional judgment the patient has a legitimate reason for waiting and it is for a legitimate medical purpose, he/she can dispense the prescription. However, if a pharmacist receives a prescription for Oxycontin<sup>®</sup> 20mg on November 3, 2011 and it was written by an emergency department physician on August 10, 2011, the pharmacist should seriously question whether it is for a legitimate medical purpose.

Many pharmacists also believe that every written controlled substance prescription from a prescriber must have his/her DEA number on the prescription. This is a true statement. Federal law requires the prescriber to have their DEA on every controlled substance prescription he/she writes. However, some prescribers are not doing this because DEA numbers are being taken from prescriptions and used to call in fraudulent prescriptions. The important point is that the pharmacists should use good judgment in verifying the authenticity of the prescription and act in the best interest of the patient. Therefore, if you receive a prescription for a controlled substance for a legitimate medical purpose without a DEA number on it, the pharmacist should write it on the prescription to fulfill the legal requirement.

Let's discuss a couple of common situations that can occur when pharmacists are dispensing prescriptions for schedule II drugs. What should a pharmacist do if they do not have enough medication in stock to fill a

prescription for a schedule II drug? For example: The patient presents a prescription for Percocet 2.5/325<sup>®</sup> tablets #90 and the pharmacy only has 45 tablets in stock. In this situation, the pharmacy has 72 hours to dispense the remaining quantity (in this example 45 tablets). The pharmacy must order and obtain the remaining 45 tablets and dispense them within 72 hours. The pharmacist should also document on the front of the prescription the quantity (45 tablets) dispensed. If the pharmacy cannot dispense the remaining 45 tablets within 72 hours, the pharmacist must notify the prescribing practitioner. After 72 hours, no further medication can be dispensed from this original prescription. The patient may have to obtain a new prescription from the prescriber. In another related situation, what if the patient presents a prescription for Percocet 2.5/325<sup>®</sup> tablets #60 and can only afford 30 tablets at this specific time? In this situation, the patient can only receive what they can afford at the time of dispensing. The pharmacist cannot dispense the remaining quantity (30 tablets) at any time in the future. The "72 hour rule" only applies to situations when the pharmacy does not have enough medication in stock. It does not apply to the situation when the patient cannot afford the entire quantity at the time of dispensing. Let's consider the same prescription, Percocet 2.5/325<sup>®</sup> tablets #60, and this time the patient's insurance will only pay for 50 tablets. Can the patient pay cash for the remaining 10 tablets? The answer is "Yes". The patient has a right to entire quantity as long as it is dispensed all together. As long as all 60 tablets are dispensed at the same time, the pharmacist could bill the insurance company for 50 tablets and let the patient pay cash for the remaining 10 tablets. Again, all 60 tablets must be dispensed at the same time.

#### **Oral Schedule II Prescriptions** {CFR Sec. 1306.11(d) and ORC Sec. 3719.05(A)(3)}

In some rare circumstance, a prescriber may need to call in an oral prescription for schedule II drug for a patient. Even though this is a very infrequent situation, pharmacists should know the legal requirements. First, many pharmacists think that they can only dispense no more than a 72 hour supply of a schedule II drug on an oral prescription. This is not true. The amount a pharmacist can dispense is defined as "enough for the emergency period". In these situations, the pharmacist and prescriber must discuss the patient's situation and use their collective professional judgment. In certain cases only a 24 hour supply may be necessary, but in other cases more than a 72 hour supply may be necessary. The pharmacist should document this conversation with the prescriber. Requirements of a pharmacist regarding an oral schedule II prescription are as follows: 1) The quantity prescribed and dispensed should be enough for only the emergency period. 2) The pharmacist should immediately reduce the oral prescription to writing and it must contain all of the information required for a written prescription for a controlled substance. 3) The pharmacist must receive the written prescription from the prescriber within 7 days. This written prescription must be attached to the oral prescription taken by the pharmacist. On this written prescription must be the statement "Authorization for Emergency Dispensing". The written prescription may be delivered in person or by mail with the postmark on the envelope within the seven day period. Once software systems are approved by the DEA, an electronic prescription may be sent by the physician to the pharmacy in lieu of a written prescription. 4) If the physician does not provide the written prescription within seven days, the pharmacist should notify the local DEA office.

#### Refilling a Prescription When a Patient is Out of Refills (ORC 4729.281)

Every pharmacist has encountered the following situation. A patient comes into your pharmacy at 5:30pm on Sunday night and needs a refill on their blood pressure medication. The pharmacist checks the computer and finds the patient does not have any refills remaining. The last thing any pharmacist wants is to have a patient go without their blood pressure medicine. However, what does Ohio law allow in this situation? A pharmacist may dispense a prescription drug without a written or oral prescription from a prescriber if all the following conditions are met:

1) The medication cannot be a schedule II drug. A pharmacist cannot dispense a schedule II drug when a patient is out of medication. This makes sense because there are no refills allowed on schedule II medications.

2) The pharmacy at which the pharmacist works has a record of a prescription for the drug in the name of the patient who is requesting it. However, the prescription does not provide for a refill or the refills have expired.

3) The pharmacist is unable to obtain authorization of additional refills from the prescriber responsible for the patient's care or another prescriber responsible for the patient's care.

4) In the pharmacist's judgment, the drug being requested for a refill meets one of the following requirements. a) The drug is essential to sustain the life of the patient or continues therapy for a chronic condition of the patient. b) Failure to dispense the drug could result in harm to the health of the patient. These scenarios can encompass many drugs and many different disease states. The pharmacist needs to act in the best interest of the patient and carefully consider these scenarios.

5) The amount of medication dispensed when the patient is out of refills and the prescriber cannot be contacted should not exceed a 72 hour supply. It should be noted that 72 hours is the maximum supply. In some cases, less than a 72 hour supply may be sufficient.

6) This may be done only once for each prescription.

7) The pharmacist must notify the prescriber who issued the prescription or another prescriber responsible for the patient's care within 72 hours after the medication is dispensed when the patient is out of refills.

8) The pharmacist who dispenses a medication in this situation must also keep certain records of this dispensing including: drug dispensed, name and address of the patient, amount dispensed, and original prescription number. If someone other than the patient is picking up the prescription, the name and address of that individual must be documented as well.

When using these laws as intended, pharmacists can ensure that patients who need medications and are out of refills can continue to receive the therapy that they need.

## **New Requirements of Using OARRS and How to Register** {OAC 4729-5-20 (D)}

With the passage of HB 93, changes have been made regarding pharmacists requirements to review OARRS reports as part of the prospective DUR process. If you are not registered with OARRS, you should complete the application process as soon as possible. Here is a step-by-step guide on how to get registered.

- 1) Go to: <u>www.ohiopmp.gov</u>
- 2) Click on "Register"
- 3) Fill out the form online (make sure there are no mistakes!!)
- 4) Print the form
- 5) Sign it in front of a notary public
- 6) Send in the form, a copy of your pharmacist's ID card, and a copy of your driver's license
- 7) OARRS will send you an e-mail you must respond to (proving it is a legitimate e-mail address)
- 8) You will receive your user ID via e-mail and password via U.S. Mail
- 9) Once you have both, you can access the system

Here are the highlights of the OARRS Prospective DUR requirement that were effective as of 10/27/11. OARRS reported drugs include all controlled substances, tramadol, and carisoprodol.

Before dispensing a prescription, at a minimum, the pharmacist shall request and review an OARRS report covering at least a 1 year time period (and/or another state's report) if the pharmacist becomes aware of a patient meeting any of the following conditions below.

a) Receiving OARRS reported drugs from multiple prescribers,

b) Receiving OARRS reported drugs for more than 12 consecutive weeks,

c) Abusing or misusing OARRS reported drugs (Examples: early refills, over-utilization, patient appears overly sedated or intoxicated when presenting an Rx, or an unfamiliar patient requesting an OARRS reported drug by specific name, street name, color, or identifying marks.) "Give me 'Dans' form of carisoprodol", "Give me the Bars", "I want the purple", etc.

d) Prescriptions for OARRS reported drugs from a prescriber the pharmacist is unfamiliar with (prescriber is out-of-state or prescriber is out of the area from which the pharmacy regularly sees prescriptions), ore) Patient presents a Rx for an OARRS reported drug and resides outside the usual geographic area of the pharmacy.

After obtaining the initial OARRS report, the pharmacist must use his/her professional judgment based on standards of practice to decide when and how frequently other OARRS reports will be requested for each patient. In the rare event that a report is not available on a specific patient, you must use your professional judgment whether or not you should dispense a prescription, including consideration of what is in the best interest of the patient. Remember, the information in an OARRS report is only as good as the pharmacists who have entered the information in the computer based on prescriptions they have dispensed. There may be more than one patient represented in a single OARRS report, even though the software attempts to minimize this from happening. OARRS is just one tool to use in the decision making process of performing prospective DUR. Talking to the patient, prescriber, other pharmacies, and reviewing the patient's profile should also be considered. You now have the option to see if a patient has prescriptions listed in the Indiana prescription monitoring program. Just select the box for Indiana when requesting an OARRS report. You will receive one report with both Ohio and Indiana prescriptions. Michigan and Virginia will be added to the system soon. Eventually, you will be able to search multiple states when requesting an OARRS report.

### **Discussion of Other Issues Related to Ohio Pharmacy Law**

1) Can I give a copy of an OARRS report to a physician? The answer is "No". The physician must request their own OARRS report if they want a copy. However, pharmacists can discuss an OARRS report with a physician without the physician requesting their own copy.

2) Will prescriptions filled by the Veteran's Affairs (VA) outpatient pharmacies show up in an OARRS report. The answer is "No". This is a federal institution and is not required to report prescriptions it dispenses to OARRS.

3) How many times can a non-controlled substance prescription be transferred? This law has been changed back to its original form. Non-controlled substance prescriptions can be transferred an unlimited number of times. (OAC 4729-5-24, effective date 6/16/11)

4) A patient calls my pharmacy with a valid prescription and wants a price for the generic Vicodin<sup>®</sup> tablets #120. Do I have to give the patient a price? The answer is "Yes". A pharmacy shall disclose price information to any patient requesting such information. Price information disclosure shall be provided by means of verbal disclosure on the premises of the retail seller or by means of telephone to any person having a valid prescription that identifies themselves and requests such information. Price information disclosure shall not be required for those schedule II controlled substances where lives or property could be endangered by such disclosure. (ORC 4729.361)

**5**) What needs to be done when a new responsible pharmacist takes over at a specific pharmacy location? The Board of Pharmacy must be notified by the new responsible pharmacist within 30 days on a Board of Pharmacy approved form. This form can be obtained at <u>www.pharmacy.ohio.gov/change-rp-t-0603-</u>

<u>0308.pdf</u>. Additionally, a complete controlled substance inventory must be taken with the new responsible pharmacist who then becomes responsible for this inventory. Do not send a copy of this inventory to the Board of Pharmacy. It should be kept with all other records at the pharmacy.  $\{OAC 4729-5-11 (B) (3) and (4)\}$ 

The views contained 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 on the last page, 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 2-3 weeks of receiving your answer sheet. You must return the answer sheet prior to November 10, 2013 to receive credit.

*1*) A prescription for a schedule II controlled substance must be filled within \_\_\_\_\_ of the date it was written. (Assume the prescription is for a legitimate medical purpose.)

- a) 7 days
- b) 30 days
- c) 3 months
- d) 6 months
- e) 1 year

2) A patients brings a prescription to the pharmacy for Concerta<sup>®</sup> 27mg #60 (schedule II). The pharmacy only has 30 tablets in stock. How long does the pharmacy have to order and dispense the remaining 30 tablets?

- a) 24 hours
- b) 48 hours
- c) 72 hours
- d) 7 days
- e) 30 days

3) A patient comes to the pharmacy with a prescription for Nucynta<sup>®</sup> 50mg #100 (schedule II). The patient does not have insurance. The patient wants to get 50 tablets now and 50 tablets in two weeks. Can the pharmacist legally do this?

a) Yes

b) No

*4*) If a physician calls in an emergency oral prescription for Percocet<sup>®</sup> 5/325 (schedule II), she has to get the written original prescription to the pharmacy.

- a) 24 hours
- b) 72 hours
- c) 7 days
- d) 30 days
- e) 60 days

5) A physician needs to call in an emergency oral prescription for a patient for morphine sulfate 15mg tablets (schedule II). How many days supply of morphine can the physician call in for this situation?

- a) 24 hour supply
- b) 48 hour supply
- c) 72 hour supply
- d) 7 day supply
- e) enough for the emergency period

5

- 6) When a patient is out of refills on their lisinopril 10mg, the pharmacist can dispense a maximum \_\_\_\_\_\_ until the prescriber can be contacted for further refill authorization. (Assume the prescriber is unavailable)
- a) 24 hour supply
- b) 48 hour supply
- c) 72 hour supply
- d) 7 day supply
- e) 30 day supply

7) A patient is out of refills on their atenolol 50mg. The pharmacist dispenses one tablet to him until the prescriber can be contacted for authorization of more refills. The pharmacist has 72 hours to notify physician of this dispensing.

a) True

b) False

8) According to the new requirements of using OARRS, a pharmacist must request and review an OARRS report covering at least 1 year if which of the following conditions are met:

- a) The patient is receiving OARRS reported drugs for more than 12 weeks.
- b) The patient is receiving OARRS reported drugs from multiple prescribers.
- c) The prescriber of the prescription is from out of state.
- d) b and c only
- e) a, b, and c

9) A pharmacist calls a physician to tell her that one of the physician's patients is receiving controlled substances from 6 different doctors. The pharmacist tells the physician this information was obtained from an OARRS report. The physician wants a copy of this report from the pharmacist. Can the pharmacist legally give the physician a copy of the report?

a) Yes

b) No

10) Which of the following statements are true?

- a) Non-controlled substances can only be transferred one time.
- b) Prescriptions filled by VA outpatient pharmacies will show up in an OARRS report.

c) When a new responsible pharmacist takes over, he/she must notify the Board of Pharmacy within 30 days on a Board of Pharmacy approved form.

- d) a and c are true
- e) b and c are true

## **Continuing Education Test Answer Sheet**

# "Important Legal Issues for Ohio Pharmacists"

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1) A	В	С	D	Е				6)	А	В	С	D	E
2) A	В	С	D	E				7)	А	В	С	D	E
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<b>Program Evaluation:</b> Did this program meet its objectives? 1 2 3 4 5 (1 = poor and 5 = excellent) Please rate the content of this program							Pharmacy Education Unlimited has additional Ohio Board of Pharmacy approved Jurisprudence Continuing Education programs for Pharmacists. <b>Please send to me the following Ohio programs:</b>						
1 2 3 4 5 (1 = poor and 5 = excellent) Please rate the applicability to my practice 1 2 3 4 5 (1 = low and 5 = high)								<i>"Topics in Pharmacy Technician and Intern</i>					
Any other comments about this program:							<i>Laws for Ohio Pharmacists.</i> " Expiration date: 02/23/2012 Cost: \$20.00						
							<i>"Topics in Ohio Pharmacy Law."</i> Expiration date: 01/05/2013 Cost: \$20.00						
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Pharmacy Education Unlimited P.O. Box 383 Columbus, OH 43216 A certificate of completion will be mailed to								Just let us know which programs you are interested in and we will send them out to you at no obligation. You only need to send a check for payment if you return the program for continuing education credit.					
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