OPA Student Law Review 2020

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Key Ohio Pharmacy Statues to Study

1) Pharmacy Practice Act: 4729.01 to 4729.99
2) Controlled Substance Act 3719.01 to 3719.99
3) Pure Food and Drug Law 3715.01 to 3715.99
4) State Board of Pharmacy Rules OAC 4729-1 to 4729-37
5) State Board of Pharmacy Rules OAC 4729:1 thru 4729:6
6) Medical Board Rules 4731-11
7) Medical Marijuana Laws ORC 3796
8) Medical Marijuana Dispensaries OAC 3796:6

I. Test Taking Tips

1) Read the question thoroughly.
2) Don't over-analyze the questions.
3) Don't think about that one case in a million that may change the answer.
4) Try not to rely on what you do at work
5) When in doubt, your first response is usually the correct one.
6) For each question, eliminate those choices you know are wrong.
7) Don't let a couple of obscure questions frustrate you. Remember 33% of the questions you get are "test" questions for future exams.
8) You have approximately 1 minute & 30 seconds per question. Take your time.
9) Look for subtle word changes in the question, but don't try to "read into" the question.
10) When trying to decide between federal and state law, always choose the state law.
11) Relax, and work slowly but steadily.
12) Download the DEA's Pharmacist's Manual
    How to do it:
    a) www.deadiversion.usdoj.gov
    b) Click on "Resources"
    c) Click on "Publications and Manuals"
    d) Click on "Manuals"
    e) Click on "Pharmacist Manual"
    f) You can save it as a PDF
13) The Ohio Board of Pharmacy issues many guidance documents that help clarify and interpret different issues in the practice of pharmacy. I suggest you read and study these. Much of this information is included in this booklet. Here is a link to this information: https://pharmacy.ohio.gov/Pubs/Special.aspx

14) If you would like additional information to study on the most recent law changes. Most of this information is included in this booklet. Here is a link: https://pharmacy.ohio.gov/LawsRules/RuleChanges.aspx
15) It is also a good idea to read the "Recent Updates" on the home page of the Ohio Board of Pharmacy Website. Here is a link: https://pharmacy.ohio.gov/
16) If the law has changed, answer the question based on what the new law is currently.
17) It is a well-known fact that student who have only worked in hospital or institutional pharmacies tend to struggle more with the Ohio law exam. For these students, I suggest you read and study these two sections from the Ohio law statues thoroughly. Here is a link to them:

https://pharmacy.ohio.gov/LawsRules/OAC.aspx

The Ohio MJPE and NAPLEX have begun to add more multiple-multiple choice questions. These questions will make the student "pick" which of the following answers are correct from a choice of five answers. The student must correctly pick all the correct answers that apply or the entire question is wrong. Here is an example:

Question: Which of the following are true?

a) An applicant has 3 attempts to pass the NAPLEX.
b) A pharmacist must notify the Board of Pharmacy of a change of name within 30 days.
c) A pharmacist license must be renewed by September 15th.
d) A pharmacy must notify the Board within 10 days when there is a change in responsible pharmacist.
e) A pharmacy must notify the Board 20 days prior to discontinuing business.

Things students forget to study

1) Misbranded vs. adulterated
2) OTC labeling requirements
3) Labels of IVs
4) Drug schedules
5) OARRS requirements
6) sterile compounding guidelines (refer to your lab notes)
7) Compounding Drugs for Physician Use
8) Focus on outpatient laws
9) Big focus on community pharmacy and controlled substances
10) Security of drugs in an institutional pharmacy

Ohio Administrative Code
Most of the information from the Ohio Administrative Code (OAC) related to pharmacy is contained in this booklet in summary form and prepares you well for the Ohio MJPE exam. However, based on previous student comments, I suggest you study the sections listed below that you feel "weak" or "unsure" of. I have categorized these sections based on my assessment of priority level. Use this as a guide based on the time you have available to study. Remember, all

information in the Ohio pharmacy laws is important. This is just a guide. Here is a link to these sections of the Ohio Administrative Code: https://pharmacy.ohio.gov/LawsRules/OAC.aspx

Highest Priority
OAC 4729-5 Pharmacy Practice
OAC 4729-9 Dangerous Drugs
OAC 4729-11 Controlled Substances
OAC 4729-16 Drug Compounding
OAC 4729-17 Institutional Facilities
OAC 4729-37 Drug Database (OARRS)
OAC 4729:1 Pharmacists
OAC 4729:2 Pharmacy Interns
OAC 4729:5 Terminal Distributors of Dangerous Drugs sections 1-10
OAC 4729:8 Drug Database
OAC 4729:9 Controlled Substances and Drugs of Concern

Moderate Priority
OAC 4729-8 Drug Take Back
OAC 4729-15 Nuclear Pharmacies
OAC 4729:3 Pharmacy Technicians
OAC 3796:6 Dispensaries (Medical Marijuana)
OAC 4729:6 Drug Distributors (Manufacturers, Wholesalers, 3PL, Repackagers, etc),
OAC 4729:10 Prescription Drug Collection

Lower Priority
OAC 4729-7 Severability
OAC 4729-2 Meetings
OAC 4729-18 Office Based Opioid Treatment
OAC 4729:4 Impaired Licensees and Registrants
OAC 4729:5 Terminal Distributors of Dangerous Drugs sections 11-23

Very Low Priority
OAC 4729-13 Approved Laboratories
OAC 4729-14 Animal Shelters
OAC 4729:11 Home Medical Equipment Service Providers

II. Cancer Drugs and Drug Repository Program

Orally administered cancer drugs that are not in original, sealed, tamper evident packaging can be donated under the drug repository laws. These drugs include:

a) oral drugs used to treat cancer or cancer-related side effects
b) oral drugs used to treat the side effects of a drug used to treat cancer
c) controlled substances in long-acting or extended release form used for the treatment of opioid dependence or addiction

For oral cancer drugs that are not in the original sealed and tamper evident unit dose packaging the following must occur:

1) The repository program must have developed and implemented standards and procedures to determine that the drugs appear to be unadulterated, safe, and suitable for dispensing. This may be done by visual inspection.
2) The drugs have been stored appropriately.
3) Expiration date of 6 months or longer
4) No physical signs of tampering or adulteration
5) No controlled substances or samples
6) Drugs that require refrigeration, freezing, or storage at a special temperature are not eligible

III. Definition of to Practice Pharmacy in Ohio

Practice of pharmacy - means providing pharmacist care requiring specialized knowledge, judgment, and skill derived from the principles of biological, chemical, behavioral, social, pharmaceutical, and clinical sciences. Pharmacist care includes the following:

1) Interpreting prescriptions

2) Dispensing drugs and drug therapy related devices

3) Compounding drugs

4) Counseling individuals with regard to their drug therapy, recommending drug therapy related devices, and assisting in the selection of drugs and appliances for treatment of common diseases and injuries and providing instruction in the proper use of the drugs and appliances

5) Performing drug regimen reviews with individuals by discussing all of the drugs that the individual is taking and explaining the interactions of the drugs

6) Performing drug utilization reviews with licensed health professionals authorized to prescribe drugs when the pharmacist determines that an individual with a prescription has a drug regimen that warrants additional discussion with the prescriber

7) Advising an individual and the health care professionals treating an individual with regard to the individual's drug therapy

8) Acting pursuant to a consult agreement with one or more physicians

9) Engaging in the administration of immunizations

10) Engaging in the administration of drugs (long-acting injectables)

IV. Duty to Report by Pharmacists, Interns, and Technicians

1) Pharmacists, interns and technicians are now required to report the following to the Board of Pharmacy:

a) Conduct indicating any pharmacist, intern or technician is addicted to or is suspected of abusing alcohol, drugs, or any other chemical substance that renders an individual unfit to carry out their professional duties. This includes physical or mental impairment as well. You are not required to report these instances if you are treating one of these individuals or the pharmacist has access to the individual's protected health information (PHI).

b) A pharmacist, intern, technician, or licensed entity (wholesaler, pharmacy, etc) attempts to violate or aids in the violation of any of the Ohio Board of Pharmacy laws and/or rules.

c) Conduct by a pharmacist, intern, or technician that is defined as unprofessional conduct or dishonesty by the Board.

2) The required reporting of these "instances" must be made in writing by mail, the Board's online compliant form, or by telephone. The complaint shall include: name of the individual who committed the violation, the violation which is believed to have occurred, & dates and places of the occurrence.

3) Pharmacists are required to self-report the following within 10 days:

a) Any criminal conviction, except for minor traffic violations (examples: parking tickets, speeding, red light, expired license, failure to signal, etc)

b) The individual is convicted, pled guilty, subject to a judicial finding of eligibility for intervention in lieu of conviction, or the equivalent in another jurisdiction.

c) The individual is granted entry into a diversion program, deferred prosecution program, or equivalent

d) Any arrest for a felony within ten days after the arrest

e) Any disciplinary action taken by another state including those pending an appeal

f) A medical error that is the result of reckless behavior or unprofessional conduct and meets the following:

i) An error that may have contributed to or resulted in temporary harm to the patient and required intervention

ii) An error that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization

iii) An error that may have contributed to or resulted in permanent patient harm

iv) An error that required life-saving intervention

v) An error that may have contributed to or resulted in patient death

4) The person makes a report to the Board of Pharmacy is not liable to any person for damages in a civil action as a result of the report, as long as, the report was made in good faith and not fraudulently.

V. Dispensing Naltrexone without a Prescription

Ohio Revised Code section 4729.283 allows pharmacists to dispense naltrexone without a prescription under the following circumstances:

1) The pharmacist must be able to verify the record of a prescription for injectable, long acting naltrexone for the patient that does not have any remaining refills. You can dispense the drug if it was filled at another pharmacy. However, you must contact the dispensing pharmacy and verify their prescription record.

2) The pharmacist is unable to obtain authorization for additional refills at that time.

3) In the pharmacists' professional judgment:
   a) the drug is necessary to continue therapy for substance use disorder
   b) failure to dispense the drug could result in harm to the patient

4) The pharmacist shall offer the patient the choice of the oral form or long-acting injectable form if both are available at the time of patient's request or within one day after the request. If the oral form is dispensed, a 5-day supply is the maximum. With regards to the injectable form, the pharmacist shall decide how much to dispense.

5) The pharmacist may administer the long-acting form if he/she meets the requirement under the laws regarding "administering injections" (4729.45).

6) If naltrexone is dispensed without a prescription, the pharmacist must notify the prescriber within 5 days.

7) There is no limit how many times it can be dispensed without additional refill authorizations. The pharmacist must use his/her professional judgment.

8) Records of this dispensing must be kept for at least one year and include: drug dispensed, amount dispensed, form dispensed, original prescription number, name and address of the patient, and name and address of the individual receiving the drug if not the patient.

9) When dispensing naltrexone in these situations, you must create a new prescription document and assign it a number. However, there is no guarantee that the patient's insurance will cover it.

10) When dispensing naltrexone in these situations, it must be reported to OARRS.

VI. Important Dates (Know these!!)

a) 30 days notice change of name
b) 30 days notice change of address
c) 30 days notice change of employment
d) 10 days notice change in responsible pharmacist
f) 30 day in advance to discontinuing business
g) Terminal distributor's license renewal – April 1st
h) Wholesalers license renewal - July 1st
i) Pharmacist license renewal – September 15th
j) Intern license renewal - September 15th
k) Laboratory terminal distributor's license renewal – April 1st
l) A new application and fee is required to be submitted to the Board within 30 days when there is a change in ownership, business name, trade name, category, or address of a pharmacy or wholesaler.

VII. Generic Substitution

A pharmacist cannot dispense a generic drug if the prescriber has written is his/her own handwriting: "DAW", "dispense as written", "medically necessary", "brand only", or any wording indicating this intent on the prescription. Any wording used to indicate the brand name must be dispensed can be used to prevent generic substitution on oral prescriptions as well.

Definition of generic drug:

a) identical active ingredients,
b) meets the identical compendial or other applicable standard of identity, strength, quality, purity, potency, and where applicable content uniformity, disintegration times, or dissolution rates, and
c) it has not been listed by the FDA as having proven bioequivalence problems

Examples: Preprinted DAW on the script, the pharmacist can dispense the generic.
DAW is typed on the prescription, the pharmacist can dispense the generic.
The nurse writes the prescription and DAW, but the doctor signs the Rx, the pharmacist can dispense the generic.

a) Oral "DAW" is officially recognized under Ohio law
b) Must have a label on the bottle "Generic Substitution Made"
c) Patient has the right to refuse
d) Brand name or generic manufacturer on Rx and bottle
e) No greater liability
f) The prescriber may indicate on the prescription not to vary from the quantity written on the prescription.

Pharmacists must notify the physician within 5 business days when an interchangeable biological product is substituted including the product name and manufacturer. This is not required on refills. Notifications can be by telephone, fax, electronic communication, or any other prevailing means of communication.

Orange Book: FDA generic bioequivalence book
Purple Book: FDA list of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations

VIII. Misbranding vs. Adulterated

a) Adulterated -
   1) Physical conditions of the drugs, environment in which they were manufactured, anything unsanitary or damaged.
   2) If a drug leaves the pharmacy and is then re-dispensed, it is adulterated.
   3) Outdated drugs are adulterated. A compounded drug is considered adulterated if it exceeds the beyond use date listed in USP chapters 795, 797, USP 38 - NF33, manufacturer's product labeling, or appropriate literature sources or direct testing
   4) "beyond use date" and "expiration date" means the same thing

b) Misbranded –
   1) dispensed without a prescription
   2) OTC without proper labeling
   3) improper refills
   4) false advertising
   5) wrong drug dispensed
   6) anything wrong or incorrect on the prescription label
   7) insulin and antibiotics must be batch certified or they are misbranded
   8) drugs that do not have some type of ID, code, or marking that identifies them

IX. Pharmacist, Intern, and Technician Administered Testing (4729:1-3-01)

A pharmacist, intern, or certified pharmacy technician may administered laboratory testing if the following conditions are met:

a) The intern or certified pharmacy technician must be under the direct supervision of a pharmacist.

b) The pharmacy is a licensed terminal distributor and certified by the U.S. Department of Health and Human Services as a clinical laboratory thru CLIA.

c) The tests do not require a prescriber's order and the pharmacy has obtained a CLIA waiver.

d) The responsible pharmacist must ensure that all personnel conducting these tests have been properly trained to conduct them in a safe and effective manner.

e) A pharmacist or intern may evaluate the results of these tests when advising a patient or health care professional if it relates to the patient's drug therapy.

f) This rule does not restrict a pharmacist to order and evaluate tests based on a consult agreement.

X. Diet Drugs

Definition of Obesity:

A patient must have a Body Mass Index (BMI) of 30 to initiate the use of controlled substances for weight reduction, or have a BMI of 27 with an existing comorbid factor such as diabetes, heart disease, etc.

Prescribing of Controlled Substances for Weight Reduction

a) Physicians can prescribe a 30 days supply of a controlled substance for weight reduction.
b) C-II's still cannot be prescribed for weight reduction.
c) Package inserts for weight reduction medications describe duration of use as a "few weeks". The new law defines a "few weeks" as 12 weeks of therapy. (short-term)
d) A patient may restart a weight reduction program with a controlled substance 6 months after the last date a short-term controlled substance was taken for weight reduction.

Example: Patient X takes Adipex-P, a controlled substance, for weight reduction for 12 weeks. The last date the patient took this medication was July 1, 2019. Patient X cannot take another short-term controlled substance for weight reduction till January 1, 2020.

Weigh Loss Drug Prescribing For Chronic Weight Loss Management

a) Both Qsymia and Belviq are schedule IV controlled substances
b) Qsymia has very complex dosing instructions including those for escalation and discontinuing the drug. You should become very familiar with these before dispensing the drug.
c) Belviq should be discontinued if 5% weight loss is not achieved by week 12 of therapy.

Key: According to Mr. William Schmidt of the Ohio State Medical Board, both Qsymia and Belviq can be used for an indefinite period of time as long as the patient has met the weight loss goals in the FDA approved package insert.

This means the 12 week limit does not apply to these drugs. Even though the clinical studies in the FDA approved package insert were conducted for a period of either one or two years, the Medical Board is interpreting the law to allow use for an indefinite period of time based on the physician carefully monitoring the patient.

The complete rules for topic can be found at OAC 4731-11-04.1

The main change to this rule has been with the use of controlled substances for weight loss for chronic weight management. Currently this affects the use and prescribing of Qsymia and Belviq.

a) The physician must meet with the patient face-to-face for the initial visit and at least ever thirty days during the first three months of treatment.

b) After the initial visit and two follow-up visits, the physician may authorize refills for the controlled substance for chronic weight loss management up to five times within a six month period after the initial prescription date.

c) The treatment may be provided by a physician assistant (PA) as long as the drug is on their formulary. If being treated by a PA, the supervising physician shall personally review the medical records of each patient following each visit. A physician assistant shall not initiate utilization of a different controlled substance for weight loss, but may recommend a change for the supervising physician's initiation.

d) A physician shall discontinue prescribing a controlled substance for chronic weight loss management if the patient has repeated failed to comply with the physician's treatment recommendations or the patient is pregnant.

Requirements of Pharmacists

a) A pharmacist is not responsible for documentation of total weight loss or of maintenance of weight loss.
b) However, if a patient personally presents a prescription for weight loss and obviously doesn't meet the BMI standards of 30 or 27 with a comorbid factor for the first filling, DO NOT

FILL THE PRESCRIPTION. However, the patient may drop below this BMI if diet, exercise, medication, and etc are working and therapy can continue.

c) Do not dispense any controlled substance for weight reduction (except Qsymia and Belviq) beyond 12 weeks.
d) In general, no refills are permitted on controlled substances for short term weight reduction beyond 30 days. However, a physician can write refills on a prescription for a controlled substance for weight reduction, but the pharmacist must contact the physician before dispensing each refill to make sure the physician has had a face-to-face meeting with the patient every 30 days. It may be easier to just get a new prescription every 30 days.
e) No more than a 7 day interruption in therapy unless specific circumstances are met as per Ohio State Medical Board rules for short-term weight loss medications
f) Contrave and Saxenda are not controlled substances and are not subject to these rules.
g) The Ohio Medical Board is currently allowing Vyvanse to be used for binge eating disorder (BED).

XI. PDMP Checklist

- Type of drugs prescribed (number of CNS depressants and stimulants)
- Duplicate therapy or duplicate classes of drugs
- Strengths of medication prescribed
- Quantity
- Days supply per prescription
- Number of physicians the patient is seeing (watch same address)
- Number of pharmacies the patient is using
- Are they using urgent care centers, minute clinics, ERs, and/or other prescribers?
- Are they getting things filled early?
- Are doses, quantities, and/or strengths escalating?
- Method of payment by patient
- There may be errors in the data

XII. Thoughts on Prescription Drug Diversion

- Take care of your patients first. Don't become that pharmacist who looks at every patient that comes into the pharmacy with a controlled substance prescription with a "suspicious eye".
- Safety of yourself, your staff and your customers comes first
- Don't take it personal
- Don't drive yourself crazy trying to be perfect
- Experience is on your side.
- Prescription diverters are becoming very sophisticated.
- Don't put legitimate pain patients at risk by refusing to fill prescriptions.
- A patient is going to "get one by you" from time to time. Do the best you can.
- Don't let one "bad" experience influence how you treat the rest of your patients.

Cases

Case: An APN with a CTP number is employed by the hospital. Can she use the hospital's DEA number with a suffix to write controlled substances for patients being discharged from the hospital?

Case: How long do track and trace records have to kept?

Case: How much can a pharmacy compound of a drug product in advance?

Case: A patient comes into your pharmacy on a Saturday night. He is out of his Lipitor 20mg. The physician's office is closed. How much Lipitor could you dispense to this patient?

Case: When a drug expires, how much of the potency remains?

Case: When a drug expires on 03/20, when does it actually expire?

Case: Can a registered technician obtain additional refills from a physician?

Case: A patient brings you a prescription for Vicodin tablets, one tablet QID, prn #100 with 4 refills. The patient only wants to get 50 tablets at a time. How many times can the pharmacist fill this prescription with a quantity of 50?

Case: Patient comes into the pharmacy with a prescription for methylphenidate 10mg, #60. They only want 30 tablets. They want to get the other thirty tablets in two weeks. Can the pharmacist fill the remaining 30 tablets in two weeks?

Case: What letter does the DEA number begin with for a physician to prescribe buprenorphine for drug addiction?

Case: Can a physician write a prescription for buprenorphine for pain?

Case: Can a pharmacist fill a prescription written for buprenorphine for the sister of a physician?

Case: Can a nurse sign a faxed refill request at the authorization of a physician?

Case: How many days does a patient have to fill a alprazolam 1mg prescription?

Case: How many days does a patient have to fill a tramadol 50mg prescription?

Case: What is the intern to pharmacist ratio for immunizations?