
What Every Pharmacist Needs to Know About Controlled Substances in Weight Reduction

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Learning Objectives:

- 1) Discuss the legal requirements for short-term use of controlled substances for weight reduction
- 2) Discuss the legal requirements for the weight loss drugs Qsymia[®] and Belviq[®].
- 3) Explain the requirements of pharmacists regarding the dispensing of controlled substances for weight reduction.
- 4) Discuss patient cases regarding the dispensing of controlled substances for weight reduction.

Pharmacists and Diet Drug Dispensing (OAC 4731-11-03 thru 4731-11-04)

There is still a great deal of confusion regarding the law and requirements of pharmacists when dispensing controlled substances for weight reduction. This problem has only been compounded with the addition of Qsymia[®] and Belviq[®] to the market. These drugs have different restrictions regarding their prescribing for weight reduction than the short-term weight reduction products such as phentermine. Many times pharmacists are looking in the legal statutes and rules promulgated by the Pharmacy Board for this information. The laws and rules regarding the use of controlled substances for weight reduction are actually in the State Medical Board of Ohio section of the Ohio Administrative Code, not the pharmacy board's. Here is a link to those rules if you need further information <http://codes.ohio.gov/oac/4731-11>. This program will discuss the legal requirements and differences in the use of the short-term controlled substances for weight reduction and the two newer agents, which can be utilized for chronic weight management.

The very first thing a pharmacist should determine when receiving a prescription for a controlled substance for weight reduction is whether the prescription is for a legitimate medical purpose. Under Ohio and federal law, the pharmacist has a corresponding responsibility with the physician to ensure that these medications are prescribed for a legitimate medical purpose. In the simplest of terms, 50% of this responsibility is on the physician and 50% of this responsibility is on the pharmacist. Pharmacists cannot justify dispensing a prescription that is NOT for a legitimate medical purpose because, "The doctor wrote it so I filled it. It is not my fault if the prescription is not for a legitimate medical purpose. That's the doctor's problem". If the pharmacist feels there are some issues with a prescription's use for a legitimate medical purpose, he/she should call the physician, discuss the patient's case with him/her, and document the conversation. Even after the conversation with the physician, the pharmacist may still feel the medication is not for a legitimate medical purpose and refuse to fill the prescription.

Before a physician writes a prescription for a controlled substance for weight reduction, the physician must obtain a complete medical history and conduct a thorough medical exam. The physician must determine that the patient has made a good faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on calorie restriction, nutritional counseling, behavior modification, and exercise without the use of controlled substances and that treatment has been ineffective. The physician shall also assess and document the patient's freedom from signs of drug or alcohol abuse and the presence and absence of contraindications and adverse side effects. The patient must have a Body Mass Index (BMI) of at least 30 or a BMI of at least 27 with comorbid factors. These comorbid factors are disease states that would improve if the patient lost weight. Examples of these could be high blood pressure, asthma, diabetes,

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and high cholesterol just to name a few. Once these determinations are made along with other clinical assessments, the physician can write a prescription for a controlled substance for weight reduction.

The physician must meet face-to-face with the patient at a minimum every thirty days and document the patient's efforts to lose weight. The physician shall include the following information in the patient chart: 1) documentation demonstrating the patient's continuing efforts to lose weight, 2) documentation of the patient's dedication to the treatment program, 3) response to treatment, 4) the presence or absence of contraindications and adverse effects, and 5) indicators of possible substance abuse that would necessitate the discontinuation of treatment utilizing controlled substances. Based on this information, the physician can issue a prescription for a controlled substance for weight reduction for no more than a 30 day supply. The patient must receive a new prescription from the physician every 30 days. This 30 day limit per prescription includes Qsymia[®] and Belviq[®] as well, even though these drugs could be used for much longer periods of time. However, this does not mean that controlled substance prescriptions for weight reduction cannot have refills. They can have refills. However, each prescription issued can only be for a maximum of 30 days. The patient needs a new prescription every 30 days from the physician. A prescription for Belviq[®] 10mg, one tablet daily, #15 with one refill is legal. This is a legal prescription because the total length of therapy for this prescription does not exceed thirty days. Pharmacists can also partially dispense a 30-day prescription for a patient that cannot afford the entire quantity or wants to try a small amount first. *For example*, a patient has a prescription for Belviq 10mg[®], one tablet daily, #30. If the patient only wants 15 tablets, the pharmacist can dispense 15 tablets with 1 refill.

One thing is very clear in the State Medical Board of Ohio's rules, there is no off-label prescribing of controlled substances for weight reduction. A physician may not write a schedule III or IV controlled substance for weight reduction unless the drug has an FDA approved indication for this purpose. If a controlled substance is not FDA approved for weight reduction, it cannot be prescribed for this indication. Schedule II controlled substances can never be used for weight reduction. In addition, a physician cannot exceed the FDA approved dose of the controlled substance for weight reduction. *For example*: The FDA approved labeling for Adipex-P[®] is 37.5mg once daily. A physician cannot write a prescription for a patient for Adipex-P[®] 37.5mg BID. A pharmacist should not fill this prescription. For all controlled substances used for weight reduction that have an the FDA approved indication for use as "for a few weeks" in its labeling, the medical board has included in their rules to interpret this to mean 12 weeks. FDA approved labeling "for a few weeks" = "12 weeks" in Ohio. Currently, therapy with any controlled substance other than Qsymia[®] and Belviq[®] should not exceed 12 weeks. These drugs will be referred to in this program as "short-term" drugs. *For example*: A physician cannot use one short-term controlled substance, such as Didrex[®], for 12 weeks and then switch to another short-term controlled substance, such as Adipex-P[®] for an additional 12 weeks. However, the length of use for Qsymia[®] and Belviq[®] are different. They can be used continuously for longer periods of time because these drugs have an FDA approved indication for long-term use. This will be discussed in greater detail later in this program. It must also be noted that new medications in the future may have FDA approved labeling that allows long-term use. Whenever a new controlled substance for weight reduction becomes available, pharmacists should become extremely familiar with its FDA approved use, dosing, and requirements for use before dispensing to ensure compliance with the Ohio State Medical Board's laws and rules.

Once a patient has been treated with a short-term controlled substance for weight reduction, such as phentermine[®] for 12 weeks, the patient cannot be immediately switched to another short-term use controlled substance for weight loss without a 6 month break in therapy. *For example*: A patient has been taking Didrex[®] for 12 weeks for weight reduction. The physician wants to switch the patient to Adipex-P[®], another short-term use controlled substance. The patient must have a 6-month controlled substance free period before therapy with Adipex-P[®] can begin. Let's assume the last day a patient took a dose of Didrex[®] was October 1, 2013. The patient cannot be re-started on a 12-week course of therapy of Adipex-P[®] until six months later (April 1, 2014). The patient could, however, be switched to either Qsymia[®] or Belviq[®] after 12

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weeks of Didrex[®] therapy. Switching to Qsymia[®] or Belviq[®] will be discussed in greater detail later in the program.

What if the patient experiences an interruption in therapy? *For example:* the patient had a prescription filled at your pharmacy on October 1, 2013 for Adipex-P[®], one tablet QD, #30. He brings in a new prescription for Adipex-P[®] to be filled on November 20, 2013. Can you fill this prescription? The law states that if a patient has an interruption of therapy of more than seven days with **any** controlled substance for weight reduction, the physician should not write a new prescription for a controlled substance for weight reduction, nor should the pharmacist fill it. There are, however, a few circumstances when therapy can continue even after an interruption of 7 or more days:

- 1) illness or injury to the patient justified a temporary cessation of treatment
- 2) the physician was unavailable
- 3) the patient was unavailable for a valid reason and notified the physician of this reason
- 4) the physician believes there is a medically valid reason why therapy should be interrupted and then re-started

However, it must be noted. This interruption in therapy counts towards the total length of therapy. *For example:* If a patient has been taking Adipex-P[®] for 4 weeks and there is a 2-week break in therapy for a medically valid reason, the patient only has 6 weeks worth of therapy left with this drug. The two weeks missed counts toward the total of 12 weeks. In another scenario, a pharmacist may find a patient profile that shows a large gap in treatment. *For example:* A patient had a prescription filled at ABC Pharmacy for phentermine, one tablet daily, #30 on September 1, 2013. The patient brings in a prescription for the same drug on November 1, 2013. When performing prospective DUR, the pharmacist notices a 30-day gap in treatment. What could be the cause? The patient could have had the prescription for the month of October filled at another pharmacy. Therefore, the pharmacist should discuss this with the patient, document it in the patient's profile before dispensing the prescription, and possibly call the other pharmacy to verify it was filled there last month. Instead of calling the other pharmacy, a better solution is to request an OARRS report on the patient. This would alert the pharmacist to any other pharmacies the patient may be using to fill their weight loss medications and provide excellent insight into why there was a 30-day break. OARRS is a great tool for pharmacists to use for those patients presenting controlled substance prescriptions for weight loss to help determine if the prescription is for a legitimate medical purpose.

Legal Requirements for Qsymia[®] and Belviq[®]

After Meridia[®] was removed from the market and before Qsymia[®] and Belviq[®] became available, the legal requirements for using controlled substances for weight reduction was easy. Twelve weeks maximum and 6-months controlled substance free for all therapy options. With the addition of these two drugs, the legal requirements regarding their use and in combination with short-term drugs like phentermine became much more complicated. Qsymia[®] and Belviq[®] are FDA approved for chronic weight management and potential long-term use. Before dispensing either of these two drugs, pharmacists should become very familiar with their clinical use in patients trying to lose weight. This is especially true for Qsymia, as the dosing of this drug can be very complex. The State Medical Board of Ohio has recognized the potential for these drugs to be beneficial to patients for long-term use. Therefore, based on the FDA approved labeling, the Medical Board has concluded that these two drugs can be used indefinitely for chronic weight management. This means there is no limit on the amount of time a patient can be on these drugs as long as the physician is properly monitoring and documenting the progress of the patient's weight loss program. In addition, the physician must meet with the patient face-to-face every 30 days to make these clinical determinations. Even though these two medications can be used for long periods of time, the patient must receive a new prescription every thirty days, just like with phentermine. There are, however, some complex situations regarding the use of Qsymia[®] and Belviq[®] and the switching back and forth between these drugs and the short-term use drugs like phentermine. Some patient cases regarding the use of these drugs are discussed below. Finally, these laws and rules for weight reduction only apply to controlled substances.

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They do not apply for the drug Xenical[®]. Xenical[®] is a lipase inhibitor and blocks the absorption of fat in the gastrointestinal track and is not a controlled substance. Therefore, physicians can prescribe non-controlled substances for weight reduction for long periods of time with multiple refills.

Summary for Pharmacists

- 1) The maximum days supply per prescription of **any** controlled substance for weight reduction is 30 days. A new prescription is needed every 30 days.
- 2) Pharmacists do not have to document that the patient is losing weight. Also, the pharmacist does not have to weigh the patient or calculate their body mass index (BMI). Pharmacists should use their own judgment and not fill a prescription for a controlled substance for weight reduction if a patient obviously does not meet the BMI requirements.
- 3) Do not dispense any controlled substance for weight reduction for more than 12 weeks for any drug except Qsymia[®] or Belviq[®].
- 4) Do not dispense any schedule II controlled substances for weight reduction or any controlled substance without FDA approval for weight reduction.
- 5) These regulations do not apply to Xenical[®] or any other non-controlled substance used for weight loss.
- 6) If there is a question about the validity of a prescription, do not hesitate to contact the patient's physician, discuss any issues you may have, and document the conversation.
- 7) Advance Practice Nurses (APNs) and Physician Assistants (PA) **cannot** write prescriptions for controlled substances for weight reduction.

Patient Cases:

- 1) A patient has been taking phentermine for 12 weeks. Can the physician switch them to either Qsymia[®] or Belviq[®]? For how long can the patient be switched to Qsymia[®] or Belviq[®]?
- 2) A patient has been taking Qsymia[®] or Belviq[®] for 6 months, can the patient be switched to phentermine for 12 weeks?
- 3) A patient has been taking Qsymia[®] or Belviq[®] for 6 months, then the patient took phentermine for 12 weeks. Can the patient be immediately switched back to Qsymia[®] or Belviq[®]?
- 4) A patient has been taking Qsymia[®] or Belviq[®] for 6 months, then the patient took phentermine for 12 weeks, and then the patient took Qsymia[®] or Belviq[®] for 2 months. Now the physician wants to prescribe phentermine. Is this legal?
- 5) Does the prescription from the physician have to be a "written" prescription for a controlled substance for weight reduction?
- 6) A physician writes a prescription for Qsymia 3.75/23mg[®] #15, one daily, 1 refill. Can a pharmacist refill the prescription?
- 7) A patient has been taking Belviq[®] for twelve weeks. The patient brings in a new prescription for a 30 day supply of Belviq[®]. Does the pharmacist have to request and review an OARRS report on the patient?
- 8) A physician writes a prescription for methylphenidate 10mg for weight reduction. Is this legal?
- 9) A physician writes a prescription for phentermine 37.5mg, #90, BID for narcolepsy with 3 refills. Can a pharmacist fill this?

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Answers to Patient Cases:

- 1) Yes. Qsymia[®] or Belviq[®] can be used as long as the physician determines is medically necessary for the chronic weight management of the patient.
- 2) Yes, the patient can take phentermine for 12 weeks after taking Qsymia[®] or Belviq[®] and does not need a 6-month controlled substance free period.
- 3) Yes
- 4) No, before phentermine can be restarted, the patient must have been “off” phentermine for 6 months.
- 5) The answer to this is “No”. A physician may “phone-in” an oral prescription for a controlled substance for weight loss and a pharmacist can legally fill it. However, the pharmacist must ask himself, “Is this prescription for a legitimate medical purpose?” If the pharmacist determines that it is, nothing in the law precludes a physician from issuing a prescription for a controlled substance for weight reduction orally.
- 6) Yes, because the prescription in total was not written for more than a 30 day supply. The patient needs a new prescription every thirty days. This type of prescription may be common because the drug is so expensive. The patient may want a smaller amount to determine if they can tolerate it or not.
- 7) Yes, any patient taking a controlled substance for more than 12 consecutive weeks must have an OARRS report requested, reviewed, and a documented assessment of that report by a pharmacist.
- 8) No, schedule II controlled substances cannot be written for weight reduction. In addition, methylphenidate is not FDA approved for weight reduction.
- 9) Yes, because this prescription is not written for weight reduction, so those rules do not apply. However, the pharmacist better make sure this prescription is for a legitimate medication purpose.

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 October 10, 2015 to receive credit.

- 1) For a patient to begin therapy with a controlled substance for weight loss, he must have a BMI of _____ or a BMI of _____ with a comorbid factor that would improve if the patient lost weight.
 - a) 27; 27
 - b) 30; 27
 - c) 27; 30
 - d) 30; 30
 - e) 30; 15
- 2) Which of the following are true?
 - a) The physician must meet with the patient face-to-face at a minimum every 60 days.
 - b) Phentermine can be used continuously for no more than 16 weeks.
 - c) Adderall XR[®] cannot be prescribed for weight reduction.
 - d) a and b are true
 - e) b and c are true
- 3) A patient was taking phentermine for 12 weeks. The physician wants to switch the patient to Belviq[®]. Can the physician immediately switch the patient and begin therapy with Belviq[®]?
 - a) Yes
 - b) No

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- 4) What is maximum amount of time a patient can take Qsymia[®] for chronic weight management? (Assume the physician is following all the legal requirements.)
- a) 6 weeks
 - b) 12 weeks
 - c) 6 months
 - d) one year
 - e) Qsymia[®] can be used indefinitely.
- 5) If a patient has more than a _____ day break in therapy with a controlled substance for weight reduction, the physician should not write a new prescription.
- a) 1 day
 - b) 3 day
 - c) 5 day
 - d) 6 day
 - e) 7 day
- 6) Which of the following are true?
- a) APNs cannot write prescriptions for Qsymia[®].
 - b) A physician can legally prescribe Adipex-P[®], one tab TID, #90 for weight loss.
 - c) Patients need a new prescription every 30 days for a controlled substance for weight reduction.
 - d) a and c are true
 - e) a, b and c are true
- 7) A patient took Adipex-P[®], a controlled substance, for weight reduction for 12 weeks. The last date the patient took this medication was June 1, 2013. When can the patient start taking phentermine again?
- a) June 2, 2013
 - b) July 1, 2013
 - c) December 1, 2013
 - d) February 1, 2013
 - e) June 1, 2014
- 8) A patient has been taking Belviq[®] for 9 months, then the patient took phentermine for 12 weeks. Can the patient be immediately switched back to Belviq[®]?
- a) Yes
 - b) No
- 9) A new controlled substance for weight loss is now available. The drug's FDA approved labeling states it is to be used for "a few weeks of therapy". What is the maximum amount of time a patient can continuously take this drug for weight loss?
- a) 30 days
 - b) 60 days
 - c) 12 weeks
 - d) one year
 - e) The drug can be used indefinitely.
- 10) A patient has a new prescription for Qsymia[®] 3.75 mg/23 mg, one capsule daily, #30. The patient only wants to get 15 filled because it is expensive. Can the pharmacist dispense 15 capsules with one refill?
- a) Yes
 - b) No

Continuing Education Test Answer Sheet

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

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3) A B C D E 8) A B C D E
4) A B C D E 9) A B C D E
5) A B C D E 10) A B C D E

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