



Adherence, Inc.® educational module
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Ohio Law & Restrictions on Prescribing Controlled Substances

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Adherence, Inc. is approved as a provider of continuing education by the Ohio State Board of Pharmacy. This module is approved by the Ohio State Board of Pharmacy and may apply towards the continuing educational requirements for jurisprudence in Ohio. Pharmacists in other states should check with their respective licensing boards.

OBJECTIVES AND GOALS:

1. The pharmacist will learn the relationship of the state boards to the public served and the professionals regulated by its rules.
2. The pharmacist will better understand how controversies arise involving board rules, and why they can not readily be solved.
3. The pharmacist will have a better understanding of the restrictions imposed on prescribing controlled substances.
4. The pharmacist will be able to better discuss the legitimate use of controlled substances by prescribers.

All readers: The information contained herein is general in nature and is intended to be used in consultation with your health care providers. The information herein is not meant to replace specific instructions or directions or warnings given to you by your physician, other prescriber, pharmacist, or accompanying this product. The information we have included is selective in nature and it is not claimed that it includes all known in respect to medical therapies, precautions, contraindications, effects, or interactions possibly related to the use of this drug. The information may differ from that contained in the product labeling which is required by law. The information, additionally, is not sufficient to make an evaluation as to the risks and benefits of taking a particular drug in a particular case and is not medical advice for individual problems, and it should not alone be relied upon for these purposes. Since the inclusion (or exclusion) of particular information about a drug is judgmental in nature and since opinion as to drug usage may differ, you may wish to consult additional sources. Should you desire additional information or if you have any questions as to how this information may relate to you in particular ask your doctor, pharmacist, nurse or other health care provider. Since unreported side effects, newly recognized precautions, or other new information about any drug may come to light at any time, it may be necessary to refer to more current resources.

Health professionals: We believe the material presented in this educational module to be accurate and current at the time of publication. We would remind the reader, however, that he or she is responsible for using professional judgement and for confirming or interpreting the findings presented here before utilizing the information.

Laws and controlled substances

Federal, state, and local laws define certain drugs as controlled substances. In general a controlled substance is one that warrants stricter distribution than is common for most other drugs. In comparing the laws or rules of law, those which are more stringent are to be followed.

A statement in the Federal Controlled Substances Act (21 USCA 801) explains the purpose of the more stringent laws to control the availability, utilization, and distribution of controlled substances:

The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.
(Underlined for emphasis)

In federal law controlled substances are separated into five classes (termed “schedules”), as defined in 21 USCA 812. Schedule 1 drugs are those with a recognized high potential of abuse, while Schedule 5 drugs are those with the least abuse potential.

As a general rule states defer to Federal law. Subsection 3719.43 of the Ohio Revised Code (ORC), for example, states the addition, transfer to another schedule, or removal of a drug’s controlled status in the Federal Controlled Substances Act is automatically effected in the corresponding schedule or schedules in the current listing of controlled substances provided in the Ohio Revised Code.

On the other hand, it is impossible for Federal statutes to address all problems that are perceived or evident at the state or local level. States, therefore, act properly in retaining the right to enact laws that are more stringent than federal laws. In Ohio, for instance, Subsection 3719.44 of the ORC states that the state retains the right to add, transfer among schedules, or remove a drug from control provided that the action does not result in less stringent control of the drug.

Legislative laws in Ohio are incorporated into the Ohio Revised Code. Based on these laws state regulatory bodies, e.g. the state boards of medicine and pharmacy, are empowered to establish rules to effect those laws relevant to their profession. These rules then become part of the Ohio Administrative Code (OAC).

The rules adopted by different regulatory bodies may vary among the states, and unfortunately, some professionals directly affected by these rules often look at

them from a mistaken perspective that the state and the state board are purposefully trying to limit professional initiative and autonomy.

It needs to be understood, however, that State boards of pharmacy and medicine have preeminent responsibility to protect the public irrespective of its relationship with the professionals they are authorized to oversee.

At times this focus on serving citizens of the state can either benefit or seemingly burden professionals whose activities are regulated by the board and some professionals will focus on the later.

The bad: The requirement for triplicate order forms, with required distribution to various regulatory offices, seems like an unnecessary burden to some professionals. On the other hand, this strict procedure is meant to ultimately protect the public by preventing illegal distribution of certain drugs.

The good: The professional boards decide the qualifications of the licensed professionals in the state they oversee. Since professionals who lack required qualifications are not allowed to practice, this activity certainly benefits the public. This would perhaps be the primary purpose of the law; but by limiting professional practice (jobs) only to those qualified, it also benefits professionals.

Prescribing Schedule II Substances

This medical board rule 4731-11-03 is clear in explaining how Schedule II stimulants **may** be used to treat certain health conditions. The prescriber **may** utilize Schedule II stimulants to treat:

- (1) Narcolepsy;
- (2) Abnormal behavioral syndrome (attention deficit disorder, hyperkinetic syndrome), and/or related disorders of childhood;
- (3) Drug-induced or trauma-induced brain dysfunction;
- (4) For differential diagnostic psychiatric evaluation of depression;
- (5) For depression shown to be refractory to other therapeutic modalities, including pharmacologic approaches, such as tricyclic antidepressants and MAO inhibitors;
- (6) To treat chronic severe pain or depression, as adjunctive therapy, in the terminal stages of diseases which are accompanied by severe pain;
- (7) And in clinical investigation of the effects of such drugs, in which case the physician shall submit to the board a written investigative protocol for its review

and approval before the investigation has begun. The investigation shall be conducted in strict compliance with the investigative protocol, and the physician shall, within sixty days following the conclusion of the investigation, submit to the board a written report detailing the findings and conclusions of the investigation.

Use of a Schedule II controlled substance would not be appropriate in any of the above cases unless the following conditions are met:

(1) Before initiating treatment utilizing a schedule II controlled substance stimulant, the physician obtains a thorough history, performs a thorough physical examination of the patient, and rules out the existence of any recognized contraindications to the use of the controlled substance stimulant to be utilized.

(2) The physician shall not utilize any schedule II controlled substance stimulant when he knows or has reason to believe that a recognized contraindication to its use exists.

(3) The physician shall not utilize any schedule II controlled substance stimulant in the treatment of a patient who he knows or should know is pregnant.

(4) Upon ascertaining or having reason to believe that the patient has a history of or shows a propensity for alcohol or drug abuse, or that the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions, the physician shall reappraise the desirability of continued utilization of schedule II controlled substance stimulants and shall document in the patient record the factors weighed in deciding to continue their use. The physician shall actively monitor such a patient for signs and symptoms of drug abuse and drug dependency.

The Ohio rules on anorexiants drugs

Section B of rule 4731-11-03 discussed above specifically states that "a physician **shall not utilize** a *schedule II* controlled substance for purposes of weight reduction or control". This ruling thus prohibits the use of methamphetamine (Desoxyn[®]) for such purposes by Ohio physicians even though it is still approved by the F.D.A. for weight reduction in the exogenous obesity.

Though no Schedule II drugs can be used for weight reduction, there are some Schedule III and IV substances that are approved for weight reduction. The use of these substances is addressed specifically in the medical board rule 4731-11-04 discussed below.

We believe the following represents controlled drugs that are available and approved for weight reduction:

Benzphetamine (Didrex ®) CIII

Tablets (U.S.)

Diethylpropion (Tenuate ®, Tepanil ®) CIV

Tablets (U.S. and Canada)

Extended-release tablets (U.S. and Canada)

Phendimetrazine (Bontril ®) CIII

Extended-release capsules (U.S.)

Tablets (U.S.)

Phentermine (Ionamin ®, Adipex P ®) (CIV)

Capsules (U.S.)

Resin capsules (U.S. and Canada)

Tablets (U.S.)

Sibutramine (Meridia ®) CIV

Capsules (U.S. and Canada)

Rule 4731-11-04

(A) A physician shall not utilize a schedule III or IV controlled substance for purposes of weight reduction unless it has an F.D.A. approved indication for this purpose and then only in accordance with all of the provisions of this rule.

(B) Before initiating treatment for weight reduction utilizing any schedule III or IV controlled substance:

(1) The physician shall determine through review of the physician's own records of prior treatment, or through review of the records of prior treatment which another treating physician or weight-loss program has provided to the physician, that the patient has made a substantial good-faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling, behavior modification, and exercise, without

the utilization of controlled substances, and that said treatment has been ineffective.

(2) The physician shall obtain a thorough history, perform a thorough physical examination of the patient, determine that the patient has a BMI of at least thirty, or at least twenty-seven with co-morbid factors, and rule out the existence of any recognized contraindications to the use of the controlled substance to be utilized.

(3) The physician shall assess and document the patient's freedom from signs of drug or alcohol abuse, and the presence or absence of contraindications and adverse side effects.

It is ultimately the patient's responsibility to conform to those diet and life-style changes necessary to ensure continued weight loss or weight loss maintenance. The goal of therapy is that weight loss does not remain solely dependent on drug use.

(C) A physician may utilize a schedule III or IV controlled substance, that bears appropriate F.D.A. approved labeling for weight loss or the maintenance of weight loss, in the treatment of obesity only as an adjunct, in a regimen of weight reduction based on caloric restriction, provided that:

The emphasis in (C) above is that the scheduled drug is at all times to be considered ADJUNCT to diet and life-style changes, which are appropriately the responsibility of the patient. .

(1) The physician shall personally meet face-to-face with the patient, at a minimum, every thirty days when controlled substances are being utilized for weight reduction, and shall record in the patient record information demonstrating the patient's continuing efforts to lose weight, the patient's dedication to the treatment program and response to treatment, and the presence or absence of contraindications, adverse effects, and indicators of possible substance abuse that would necessitate cessation of treatment utilizing controlled substances.

Once again, notice that the responsibility is placed on the patient. The physician is required to document the patient's continuing efforts to lose weight. If there is no effort or interest in effecting change on the behalf of the patient, continued drug therapy would be inappropriate.

(2) The controlled substance is prescribed strictly in accordance with the F.D.A. approved labeling;

(A) If the F.D.A. approved labeling of the controlled substance being utilized for weight loss states that it is indicated for use for “a few weeks”, the total course of treatment using that controlled substance shall not exceed twelve weeks. That time period includes any interruption in treatment that may be permitted under paragraph (C)(3) of this rule; and

Meridia ® (sibutramine) is the only controlled substance drug approved for long-term use. Its safety and efficacy, however, has not been studied beyond two years. Its effectiveness in a particular patient is usually evident within the first 4 weeks of therapy. If the patient has not lost at least 4 pounds during this period the physician is advised to reevaluate continued use of the drug. In addition, sibutramine is likely to elevate both diastolic and systolic blood pressure and the patient must be carefully monitored.

(B) If the F.D.A. approved labeling of the controlled substance being utilized for weight loss states that it is indicated for use for maintenance of weight loss, that use cannot exceed the time period indicated as effective as reported in the clinical studies' information contained in the F.D.A. approved labeling. That time period includes any interruption in treatment permitted under paragraph (C)(3) of this rule.

As mentioned above, the approved labeling for sibutramine indicates that safety and efficacy have not been determined beyond two years. It is inappropriate, therefore, for a patient to be treated for a longer period of time.

(3) A physician shall not initiate a course of treatment utilizing a controlled substance for purposes of weight reduction if the patient has received any controlled substance for purposes of weight reduction within the past six months. **However, the physician may resume utilizing a controlled substance following an interruption of treatment of more than seven days if the interruption resulted from one or more of the following:**

(a) Illness of or injury to the patient justifying a temporary cessation of treatment;
or

(b) Unavailability of the physician; or

(c) Unavailability of the patient, if the patient has notified the physician of the cause of the patient's unavailability; or

(d) If the physician utilizes a controlled substance that bears F.D.A. approved labeling for “weight loss and the maintenance of that weight loss” and based on sound medical judgment believes that an interruption of that treatment was

medically indicated so long as its use is in accordance with paragraph (C) of this rule.

(4) After initiating treatment, the physician may elect to switch to a different controlled substance for weight loss based on sound medical judgment, but the total course of treatment for any combination of controlled substances each of which is indicated for “a few weeks” shall not exceed twelve weeks.

This would include all drugs listed on page six of this program except for sibutramine (Meridia ®), which could actually be used for up to two years, the maximum length of clinical studies addressing safety and efficacy. Sibutramine use, even though not restricted to use for a “few” weeks still needs to be carefully monitored. Sibutramine blocks the reuptake of the neurotransmitters norepinephrine, serotonin, and dopamine. Its active metabolites, on the other hand, do not significantly release endogenous monoamines. Yet, the end result may be that the level of circulating catecholamines is consistently increased over time and this may prove to be cardiotoxic. This might explain why Canada and other countries continue to carefully monitor adverse effects associated with the use of sibutramine.

(5) If the patient has continued to lose weight under the short term treatment, the physician may continue therapy utilizing a controlled substance that bears F.D.A. approved labeling for “weight loss and the maintenance of that weight loss” so long as its use is in accordance with paragraph (C) of this rule.

(6) The physician shall not initiate or shall discontinue utilizing all controlled substances for purposes of weight reduction immediately upon ascertaining or having reason to believe:

(a) That the patient has a history of or shows a propensity for alcohol or drug abuse, or has made any false or misleading statement to the physician relating to the patient’s use of drugs or alcohol; or

(b) That the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician’s directions.

(7) The physician shall not initiate or shall discontinue utilizing all schedule III or IV controlled substances that do not bear F.D.A. Approved labeling which permits long-term use immediately upon ascertaining or having reason to believe:

(a) That the patient has failed to lose weight while under treatment with a controlled substance or controlled substances over a period of thirty days during the current course of treatment, which determination shall be made by weighing the patient at least every thirtieth day, except that a patient who has never before received treatment for obesity utilizing any controlled substance who fails

to lose weight during the first thirty days of the first such treatment attempt may be treated for an additional thirty days; or

(b) That the patient has repeatedly failed to comply with the physician's treatment recommendations.

(8) The physician shall not utilize any schedule III or IV controlled substance for purposes of weight reduction in the treatment of a patient the physician knows or should know is pregnant.

(D) A violation of any provision of this rule, as determined by the board, shall constitute "failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in DIVISION (B)(2) of section [4731.22](#) of the Revised Code; "Selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section [4731.22](#) of the Revised Code; and "a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section [4731.22](#) of the Revised Code.

State Board Update

Compliance Bulletin 98-001 (October, 1998)¹ suggests that pharmacists:

- ? Do not dispense any controlled substance drug for weight reduction beyond 12 weeks at this time, except for Meridia[®].
- ? Document through prospective drug review that the patient has not exceeded twelve weeks of therapy with a controlled substance, other than Meridia[®], or that it has been six months since the last therapy ended.
- ? Do not dispense more than a thirty-day supply for any controlled substance used for weight reduction. The maximum quantity dispensed is based on the package insert's directions for use.
- ? The State Medical Board rule does not require a pharmacist to document or ask for the patient's BMI or weight loss since the last prescription.
- ? However, if the patient personally presents the prescription and obviously does not meet the standards of a BMI of 30, or 27 with comorbid factor, for the first dispensing – DO NOT FILL THE PRESCRIPTION. THIS IS NOT A VALID PRESCRIPTION.

To date this compliance bulletin has not been modified in any way.

Prescribing drugs to enhance athletic ability

It would require a physician or other prescriber of very questionable character to even consider prescribing drugs to enhance athletic ability. Nevertheless, OAR 4731-11-05 is very clear that a physician “**shall not utilize anabolic steroids, growth hormones, testosterone or its analogs, human gonadotropin (HCG), or other hormones for the purpose of enhancing athletic ability.**” The rule perhaps hints at the fact that steroid abuse is a serious and pervasive problem, even among very young athletes.

The DEA is certainly aware of the problem and has a very good educational brochure that discusses steroid abuse. The brochure points out that “Anabolic steroids are primarily used by bodybuilders, athletes, and fitness “buffs” who claim steroids give them a competitive advantage and/or improve their physical performance. Also, individuals in occupations requiring enhanced physical strength (body guards, construction workers, and law enforcement officers) are known to take these drugs. Steroids are purported to increase lean body mass, strength and aggressiveness. Steroids are also believed to reduce recovery time between workouts, which makes it possible to train harder and thereby further improve strength and endurance. Some people who are not athletes also take steroids to increase their endurance, muscle size and strength, and reduce body fat which they believe improves personal appearance.”

The concern is not only for anabolic steroids but their precursors and their availability to the public – and especially to children. The use among students doubled between 1991 and 2002. In addition, the 2002 survey also determined how easy it was for school aged children to obtain steroids. The “Monitoring the Future” 2002 survey of students indicated that 22% of eighth graders, 33.2% of tenth graders, and 46.1% of twelfth graders surveyed in 2002 reported that steroids were “fairly easy” or “very easy” to obtain.

The brochure is available at the following website:

(<http://www.deadiversion.usdoj.gov/pubs/brochures/steroids/professionals/index.html>).

As indicated in the DEA brochure, the problems associated with steroid abuse can be immediate and long lasting:

Short-Term Adverse Physical Effects of Anabolic Steroids in Men

- ? Acne
- ? Skin tissue damage at the site of injection
- ? Shrinkage of the testicles
- ? Decreased sperm production and motility

- ? Decreased semen volume
- ? Frequent or continuing erections
- ? Enlargement of the breast (gynecomastia)
- ? Elevated blood pressure
- ? Increased LDL cholesterol levels
- ? Decreased HDL cholesterol levels
- ? Fluid retention leading to swelling
- ? Abnormal liver function
- ? Prostate enlargement
- ? Bleeding (usually nose)

Short-Term Adverse Physical Effects of Anabolic Steroids in Prepubertal Boys

- ? Precocious sexual development
- ? Penis enlargement
- ? Painful, prolonged penile erections
- ? Increased frequency of penile erections
- ? Premature closure of the growth plates in long bones resulting in a decrease in the total height achieved
- ? Fluid retention leading to swelling

Short-Term Adverse Physical Effects of Anabolic Steroids in Women

- ? Acne
- ? Oily skin
- ? Tissue damage at injection site
- ? Deepening of the voice
- ? Increased body and facial hair growth
- ? Enlargement of the clitoris
- ? Male pattern baldness

- ? Decreased breast size
- ? Menstrual irregularities (missed periods or no periods)
- ? Fluid retention leading to swelling

Adverse Cardiovascular Effects of Anabolic Steroids in Men and Women

- ? Increased blood pressure -----> potential coronary artery disorder
- ? Increased LDL cholesterol -----> potential coronary artery disorder
- ? Enlargement of the heart
- ? Actual death of heart cells
- ? Heart attacks (cardiac infraction)
 - o - Spasms of the coronary arteries
 - o - Increased blood clotting
- ? Stroke

Possible Long-Term Consequences of Anabolic Steroid Abuse in Men and Women

- ? Adverse cardiovascular effects
- ? Liver dysfunction
- ? Liver tumors
- ? Liver cancer
- ? Cancer of the prostate (men only)

Other Potential Risks Faced by Anabolic Steroid Abusers in Men and Women

- ? Skin infections
- ? HIV infection (needle sharing) -----> AIDS
- ? Hepatitis infections
- ? Violent trauma

Psychological Effects of Anabolic Steroid Abuse in Men and Women

Psychotic and Manic Reactions (rare occurrence)

- ? Most likely seen in people with prior mental illness

Anger, Hostility, Aggression and/or Violent Behavior

- ? Occurs in some but not all anabolic steroid users
- ? Unpredictable who will respond
- ? Increased likelihood with higher doses
- ? Minor provocations evoke exaggerated responses
- ? Presents danger to spouse, family, and friends
- ? Presents danger to law enforcement

Pharmacists are often asked about protein supplements and “steroids” used for muscle development. The information above should make it clear why the law prohibits physicians from prescribing any drug to enhance athletic ability. The pharmacist can use the same information to counsel patients who ask for their advice or recommendations.

Prescribing controlled substances for self and family members

There are a couple of underlying principles that prevail in determining the appropriateness of prescribing controlled substances for self or family members. First, the effectiveness of treatment in part requires professional judgment not influenced by emotional attachment to the patient. Secondly, under normal circumstances it is assumed that there must be a professional relationship between the prescriber and patient.

OAC 4731-11-08 is very clear and embodies these principles:

(A) Accepted and prevailing standards of care presuppose a professional relationship between a patient and physician when the physician is utilizing controlled substances. By definition, a physician may never have such a relationship with himself or herself. Thus, a physician may not self-prescribe or self-administer controlled substances. This paragraph does not prohibit a physician from obtaining a schedule five controlled substance for personal use in conformance with state and federal laws, in the same manner that a non-physician may obtain a schedule five controlled substance.

(B) Accepted and prevailing standards of care require that a physician maintain detached professional judgment when utilizing controlled substances in the treatment of family members. A physician shall utilize controlled substances

when treating a family member **only in an emergency situation** which shall be documented in the patient's record.

The pharmacist is certainly entitled to ask about the nature of the emergency and this should be documented on the prescription for future reference.

(C) For purposes of this rule, "family member" means a spouse, parent, child, sibling or other individual in relation to whom a physician's personal or emotional involvement may render that physician unable to exercise detached professional judgment in reaching diagnostic or therapeutic decisions.

Paragraph C above may include some relationships that are not obvious. If this seems the case the pharmacist can certainly ask questions. The prescriber might not be aware that his or her activity is questionable and may border on violation of this rule. If a question persists it may be necessary to contact the Boards of Pharmacy and/or Medicine for guidance.

Prescribing for persons never seen

A physician prescribing for a patient he or she has never seen can certainly be problematical. It is not uncommon, especially with controlled substances, for individuals to use various ruses to get physicians and other prescribers to provide prescriptions. In many cases the pharmacist will recognize such individuals and their methods used to obtain controlled substances. It is important that pharmacists be proactive in stopping such activities. OAC 4731-11-08 discussed above states that a professional relationship must exist between a prescriber and patient. A separate rule (OAC 4731-11-09) allows for circumstances when this is not the case. The pharmacist should be aware of this rule so he or she can provide guidance to the prescriber. The rule covers both controlled and non-controlled dangerous drug prescribing. Notice that the rule starts with a comprehensive list of exceptions.

One ruse, perhaps less common today than in the past, involved an individual calling a prescriber away from the office and declaring him or herself as a new patient with a office appointment at some future date and asking for some controlled substance to relieve an acute medical problem. The prescriber may actually want to help the patient under such circumstances, and it may be up to the pharmacist to inform the prescriber that it might be a ruse.

4731-11-09 Prescribing to persons not seen by the physician.

(A) Except in institutional settings, on call situations, cross coverage situations, situations involving new patients, protocol situations, situations involving nurses practicing in accordance with standard care arrangements, and hospice settings, as described in paragraphs (D) and (E) of this rule, a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substance to a person who the physician has never personally physically examined and diagnosed.

Rule 4729-17-01 define an "Institutional facility" as a hospital as defined in section [3727.01](#) of the Revised Code, or a facility licensed by the Ohio state board of pharmacy and the Ohio department of health, the Ohio department of rehabilitation and correction, or the Ohio department of mental retardation and developmental disabilities at which medical care is provided on site and a medical record documenting episodes of care, including medications ordered and administered, is maintained, including but not limited to:

- (1) Convalescent homes;
- (2) Developmental facilities;
- (3) Long term care facilities;
- (4) Nursing homes;
- (5) Psychiatric facilities;
- (6) Rehabilitation facilities;
- (7) Mental retardation facilities.

(B) Except in institutional settings, on call situations, cross coverage situations, situations involving new patients, protocol situations, situations involving nurses practicing in accordance with standard care arrangements, and hospice settings, as described in paragraphs (D) and (E) of this rule, a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any dangerous drug which is not a controlled substance to a person who the physician has never personally physically examined and diagnosed, except in accordance with the following requirements:

- (1) The physician is providing care in consultation with another physician who has an ongoing professional relationship with the patient, and who has agreed to supervise the patient's use of the drug or drugs to be provided; and
- (2) The physician's care of the patient meets all applicable standards of care and all applicable statutory and regulatory requirements.

(C) A physician shall not advertise or offer, or permit the physician's name or certificate to be used in an advertisement or offer, to provide any dangerous drug in a manner that would violate paragraph (A) or paragraph (B) of this rule.

(D) Paragraphs (A) and (B) of this rule do not apply to or prohibit the provision of drugs to a person who is admitted as an inpatient to or is a resident of an institutional facility. For purposes of this rule, “institutional facility” has the same meaning as in rule 4729-17-01 of the Administrative Code. This paragraph does not authorize or legitimize practices that would violate other applicable standards or legal requirements.

(E) Paragraphs (A) and (B) of this rule do not apply to or prohibit:

(1) The provision of controlled substances or dangerous drugs by a physician to a person who is a patient of a colleague of the physician, if the drugs are provided pursuant to an on call or cross coverage arrangement between the physicians;

(2) The provision of controlled substances or dangerous drugs by a physician to a person who the physician has accepted as a patient, if the physician has scheduled or is in the process of scheduling an appointment to examine the patient and the drugs are intended to be used pending that appointment;

(3) The provision of controlled substances or dangerous drugs by emergency medical squad personnel, nurses, or other appropriately trained and licensed individuals, in accordance with protocols approved by the state board of pharmacy pursuant to rule 4729-5-01 of the Administrative Code; or

(4) The provision of controlled substances or dangerous drugs by a nurse practicing in accordance with a standard care arrangement that meets the requirements of Chapter 4723 of the Revised Code and rules promulgated by the board of nursing pursuant thereto.

(5) The provision of controlled substances or dangerous drugs by a physician who is a medical director or hospice physician of a hospice program licensed pursuant to Chapter 3712 of the Revised Code, to a patient who is enrolled in that hospice program. This paragraph does not authorize or legitimize practices that would violate other applicable standards or legal requirements.

SUMMARY:

Professional regulatory bodies, such as the state boards of pharmacy and medicine, exist in order to **protect the public**. On the other hand, they do not take lightly, as discussed, the task of incorporating rules that restrict professional initiative and autonomy. When an unpopular rule does exist practitioners must abide by it or present valid reasons that the rule be rescinded. It is the author’s experience that board members are very open minded to thoughtful criticism and helpful suggestions.

Body Mass Index

BMI is preferred reference to weight alone because it correlates well with an individual's height. A person who stands 5 feet in height and weighs 153 pounds is obese based on the BMI, whereas an individual standing 5 foot 5 inches and weighing 153 pounds is of normal weight.

Calculation:

Calculations approximate using 2.2 Kg per pound and 0.0254 M per inch.

$$\mathbf{Metric} = \text{weight (Kg)} / \text{height (m)}^2$$

$$\text{BMI for the individuals above:} \quad 69.54/2.32 = 29.9 \quad \text{and} \\ 69.54/2.72 = 25.6$$

$$\mathbf{Non-Metric} = [\text{weight (pounds)} / \text{height (inches)}^2] \times 704.5$$

$$\text{BMI for the individuals above:} \quad 153/3600 \times 704.5 = 29.9 \quad \text{and} \\ 153/4225 \times 704.5 = 25.5$$

The key BMI measures to remember are 30 to initiate therapy for any patient, or 25 for those with comorbid health conditions. The key BMI associated with continuing medication after weight loss has ceased is 35 measured at the beginning of treatment. Refer to Rule 4731-11-04(C)(10) for full explanation.

Questions: there is one best answer for the questions below. Send you answer sheet and the appropriate administrative fee to: Adherence, Inc. PO Box 42407 Cincinnati, Ohio 45242-0497.

1. In respect to prescribing controlled substances state law must defer to federal law.
 - a. true
 - b. false

2. State medical board rules clearly state that schedule II stimulants may be prescribed for all but _____.
 - a. Narcolepsy
 - b. The differential diagnosis of depression
 - c. Weight reduction control
 - d. Depression that has proved refractory to conventional therapies

3. Rule 4731-11-04 is a rule written by the Ohio State Board of Pharmacy.
 - a. true
 - b. false

4. Rules 4731-11-04 is as equally concerned with diet and life-style changes associated with successful weight loss as with the drug therapy utilized.
 - a. true
 - b. false

5. A BMI of _____ is required for a patient to be considered for therapy utilizing a controlled substance approved for weight reduction.
 - a. 25
 - b. 30
 - c. 35
 - d. any of the above

-
6. A controlled substance approved for weight reduction for "a few weeks" may be prescribed for a maximum of _____ weeks.
- 12 weeks
 - 15 weeks
 - 24 weeks
 - 48 weeks
7. A patient who weighs 180 pounds and stands 67 inches tall has a BMI of
- 25
 - 28
 - 30
 - 33
8. A controlled substance approved for weight reduction can be prescribed for a maximum of _____ units.
- 14
 - 14 day supply
 - 30
 - 30 day supply
9. A patient completing one treatment round with a controlled substance for weight reduction may be restated on a new round of drug therapy after:
- 3 months
 - 6 months
 - 9 months
 - 12 months
10. The following drug or drugs may not be prescribed for the purpose of enhancing athletic ability
- Anabolic steroids
 - Testosterone
 - Human gonadotropin hormone
 - All the above

-
11. A prescriber may order a controlled substance for him/her self
- In an emergency situation
 - When the regular prescribing physician cannot be reached
 - When the medication has been prescribed on a continuous basis by another physician and there are no signs of abuse
 - Never
12. What % of twelfth graders in the “Monitoring the Future” 2002 survey reported that steroids were easy to obtain?
- 30
 - 46
 - 63
 - 75

Adherence, Inc. ®
Ohio Law & Restrictions on Prescribing Controlled Substances

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Credit: 1 Hr (0.1 CEUs)

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Evaluation Question: Please help us evaluate this program by answering the following:

	POOR/	FAIR /	SATIS /	GOOD
1. QUALITY OF INFORMATION	1	2	3	4
2. USEFULNESS IN MY PRACTICE	1	2	3	4
3. READABILITY & PRESENTATION	1	2	3	4
4. How long did it take you to complete this program :	_____ hours			

Continuing Education Answer Sheet: Please circles the appropriate answer for each question.

1. A B C D

5. A B C D

9. A B C D

2. A B C D

6. A B C D

10. A B C D

3. A B C D

7. A B C D

11. A B C D

4. A B C D

8. A B C D

12. A B C D

SIGNATURE: _____

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Please take the time for helpful comments. We are especially interested in knowing topics that would interest you for future modules.