# WEST VIRGINIA
# SECRETARY OF STATE
## NATALIE E. TENNANT
# ADMINISTRATIVE LAW DIVISION

Form #3

Do Not Mark In This Box

2011 JUL 25 PM 4:52

## NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
## AND
## FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: West Virginia Board of Osteopathy TITLE NUMBER: 24

CITE AUTHORITY: W. Va. Code §30-1-4

AMENDMENT TO AN EXISTING RULE: YES X NO ___

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 1

TITLE OF RULE BEING AMENDED: Licensing Procedures for Osteopathic Physicians

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ___

TITLE OF RULE BEING PROPOSED: ___

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Ernest Miller DO
Authorized Signature

## QUESTIONNAIRE

*(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)*

DATE: July 27, 2011

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) West Virginia Board of Osteopathy
405 Capitol Street, Suite 402
Charleston, WV 25301

LEGISLATIVE RULE TITLE: Licensing Procedures for Osteopathic Physicians

1. Authorizing statute(s) citation West Virginia Code §30-1-4

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

   June 1, 2011

   b. What other notice, including advertising, did you give of the hearing?

   Postcards with a description of the proposed change were mailed to all licensed physicians. A copy of the entire rule, with the amendment marked, was posted on the Board's website.

   The Board's website also contained a form through which comments could be submitted directly to the Board's office.

   c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

   July 1, 2011

   d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

   Attached X No comments received 6

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

July 28, 2011

f. **Name, title, address and <u>phone/fax/e-mail numbers</u>** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Diana K. Shepard, Executive Director
West Virginia Board of Osteopathy
405 Capitol Street, Suite 402
Charleston, WV 25301
(T) 304-558-6095 (Fax) 304-558-6096
email: wvbdosteo@wv.gov

g. **<u>IF DIFFERENT</u> FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

Doren Burrell, Sr. Assistant Attorney General
West Virginia Board of Osteopathy
405 Capitol Street, Suite 402
Charleston, WV 25301
(T) 304-558-6098 (Fax) 304-558-6096
email: dcb@wvago.gov

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

N/A

b. Date of hearing or comment period:

N/A

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

N/A

d. Attach findings and determinations and reasons:

Attached N/A

**WEST VIRGINIA BOARD OF OSTEOPATHY**

# LICENSING PROCEDURES FOR OSTEOPATHIC PHYSICIANS

**Title 24, Series 1**

## SUMMARY OF PROPOSED AMENDMENT TO LEGISLATIVE RULE

Currently, the West Virginia Board of Osteopathy's licensing rule prohibits the use of certain stimulant drugs for the treatment of obesity or for the goal of weight loss for more than two weeks at a time. The description in the rule only addresses "Schedule II" controlled substances, but the drugs most commonly used for this purpose are listed on Schedule IV in the West Virginia Controlled Substances Act. The Board sought to change the rule to include all sympathomimetic amine drugs which are controlled substances.

Based upon comments received, the Board acknowledges that some medications may be a useful component of a weight loss program and recognizes that the two-week limitation may be counter-productive.

The proposed amendments adopted by the Board now require the screening of patients, and regular monitoring by a physician. Drugs approved by the FDA may only be used for the treatment of obesity when they are a component of a comprehensive program including diet and exercise and they may not be prescribed on a long-term basis unless the individual patient continues to lose weight and remains healthy.

**WEST VIRGINIA BOARD OF OSTEOPATHY**

# LICENSING PROCEDURES FOR OSTEOPATHIC PHYSICIANS

**Title 24, Series 1**

## STATEMENT OF CIRCUMSTANCES FOR FILING PROPOSED CHANGE TO LEGISLATIVE RULE

The Board recognizes that obesity is one of the greatest health concerns for an increasing number of West Virginia citizens and that doctors want tools and methods to deal with this issue.

Several clinics in West Virginia have offered "weight loss" programs and services to their patients. These services may include a program of diet, vitamin supplements, and treatment with drugs that suppress a person's appetite. The most commonly used drug of this type is a stimulant and it is also restricted under the Controlled Substances Act.

There are several risks associated with this type of treatment. Not all people are good candidates for this type of drug because of heart or metabolic problems. Patients and, because of patient demand, their physicians may view the drug as the simple solution instead of following a thorough program of diet, exercise and lifestyle changes. Also, many patients develop a tolerance to the effect of the drugs over time and no longer lose weight even though they keep using the drug. In the worst cases, the Board has seen some clinics passing out these drugs without any real scrutiny or monitoring of patients in situations where the patients are seeing no benefits.

The West Virginia Board of Osteopathy has allowed the use of stimulant drugs for this purpose for brief periods of time under very limited circumstances. However, the existing rule did not apply to the most commonly used drugs of this type. The Board proposed to change the description of drugs to include all such stimulants that were also controlled substances.

Based upon comments received, comparison of rules from other states, and publications in medical literature, the West Virginia Board of Osteopathy chooses to modify its rule to require careful screening of prospective patients, establishment of comprehensive weight loss plans, regular monitoring of the patients' health and weight, and limited periods of use to prevent the patients' tolerance to the drugs involved.

APPENDIX B

# *FISCAL NOTE FOR PROPOSED RULES*

Rule Title: Licensing Procedures for Osteopathic Physicians

Type of Rule: [X] Legislative [ ] Interpretive [ ] Procedural

Agency: West Virginia Board of Osteopathy

Address: 405 Capitol Street, Suite 402
Charleston, WV 25301

Phone Number: 304-558-6095 Email: wvbdosteo@wv.gov

## Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

The proposed amendments to the rule should not have any fiscal impact. These amendments are ntended to follow the state of current medical information regarding the use of certain stimulants to treat dangerous obesity,

## Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

| FISCAL YEAR | | | |
|---|---|---|---|
| Effect of Proposal | Current Increase/Decrease (use "-") | Next Increase/Decrease (use "-") | Fiscal Year (Upon Full Implementation) |
| 1. Estimated Total Cost | 0.00 | 0.00 | 0.00 |
| Personal Services | | | |
| Current Expenses | | | |
| Repairs & Alterations | | | |
| Assets | | | |
| Other | | | |
| 2. Estimated Total Revenues | 0.00 | 0.00 | 0.00 |

Licensing Procedures for Osteopathic Physicians

Rule Title:

Rule Title: _____

**3. Explanation of above estimates (including long-range effect):**
Please include any increase or decrease in fees in your estimated total revenues.

## MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

The proposed amendments to the rule provide a greater and clearer standard for when a physician may prescribe certain drugs. The West Virginia Board of Osteopathy does not anticipate any increased costs because this is simply a refinement of an exisiting rule which the Board has enforced through disciplinary actions. The Board does not anticipate that the number of such actions would increase or decrease merely because of these amendments.

Since the proposed amendments do not relate to fees or administrative charges, this rule will not affect the annual revenues of the Board of Osteopathy.

Date: July 28, 2011

Signature of Agency Head or Authorized Representative

Diane Shepard

# TITLE 24
# LEGISLATIVE RULE
# WEST VIRGINIA BOARD OF OSTEOPATHY

## SERIES 1
## LICENSING PROCEDURES FOR OSTEOPATHIC PHYSICIANS

### §24-1-1. General.

1.1. Scope. -- This rule establishes the operation of the Board and the regulation and licensing of osteopathic physicians.

1.2. Authority. -- W. Va. Code §30-1-4.

1.3. Filing Date. -- April 27, 2010.

1.4. Effective Date. -- April 27, 2010.

### §24-1-2. Application and Enforcement.

This rule implements W. Va. Code §30-14-1, et seq.

### §24-1-3. Definitions.

3.1. Affiliate. -- A member of a group of 2 or more fully accredited health care institutions legally united by an agreement of affiliation, conceived to enhance the potential of all participants in the provision of health care and medical education.

3.2. AOA. -- American Osteopathic Association

3.3. Approved program of post-graduate clinical training. -- a program of clinical training approved by, or subject to approval by, the American Osteopathic Association or approved by the Accreditation Council for Graduate Medical Education for the purposes of intern or resident training;

3.4. Board. -- The West Virginia Board of Osteopathy established in W. Va. Code §30-14-1.

3.5. Crimes involving moral turpitude. -- Those crimes which have dishonesty as a fundamental and necessary element; including, but not limited to, crimes involving theft, embezzlement, false swearing, perjury, fraud or misrepresentation.

3.6. Immediate family -- a person within one degree of kinship of a physician or any relative living in the physician's household.

3.7 Medicine. -- Osteopathic medicine.

3.8. State Boards Examination. -- The examination sponsored and administered by the West Virginia Board of Osteopathy.

3.9. NBOME. -- The National Board of Osteopathic Medical Examiners.

3.10. Probation. -- Conditions and requirements imposed upon a licensee for a period of time that the Board, in its discretion, determines to be justified under any provision of law. A licensee placed on

probation may continue to practice subject to limitations imposed by the Board, including the requirement that the licensee appear before the Board, or an officer or agent of the Board at such times and places as are designated by the Board. A licensee may be placed on probation without a previous or concurrent suspension or revocation of his or her license.

**§24-1-4. Qualifications and Application for a License to Practice Medicine and Surgery.**

4.1. An applicant for a license to practice osteopathic medicine and surgery shall complete an application provided by the Board. The applicant shall complete the application in full prior to the Board's consideration of the application.

4.2. An application for a license to practice medicine and surgery shall include the following:

4.2.a. A photograph taken within the previous 60 days which resembles the applicant;

4.2.b. Evidence of graduation from a medical school approved by the American Osteopathic Association;

4.2.c. A sworn and notarized statement on a form provided by the Board from another physician stating that the applicant is of good moral character, and that the applicant is physically and mentally capable of engaging in the practice of medicine;

4.2.d. Evidence of the completion of a minimum of 1 year of clinical training under either of the following options:

4.2.d.1. Post-graduate, clinical training in a program approved by the American Osteopathic Association, which may also include a program approved under the Association's Resolution 42 procedure;
or

4.2.d.2. Post-graduate, clinical training in a program approved by the Accreditation Council for Graduate Medical Education and 40 hours of continuing medical education in osteopathic medicine with osteopathic manipulative treatment in courses approved, and classified as Category 1A, by the American Osteopathic Association.

4.2.e. Complete payment to the Board of the amount established by the Board under the West Virginia Board of Osteopathy rule Fees for Services Rendered By the Board of Osteopathy, Title 24 CSR 5. If the licensure fee is paid by personal check, the licensing process is not considered complete until the check has cleared the bank.

4.2.f. Any other documents as may be required by the Board.

4.3. An applicant for a license to practice medicine and surgery is required to obtain a passing score on all steps of the COMLEX-USA examination developed by NBOME.

4.4. The Board may accept an equivalent exam given by another Osteopathic State Board if the Board determines it to have equivalent standards to the COMLEX-USA examination developed by NBOME. The Board is not required, however, to accept these exams in lieu of the COMLEX-USA examination.

4.5. The 40 hours of continuing medical education specified in subdivision 4.2.d.2. of this rule may be completed through attendance at several courses, conducted at different times and locations, as long as the total instruction time is at least 40 hours. A single, unbroken course or class is not required.

4.6. All applicants for licensure to practice osteopathic medicine and surgery shall demonstrate their ability to communicate in the English language to the satisfaction of the Board.

4.7. An applicant shall arrange for a personal interview with a member of the Board prior to his or her application being considered by the Board. The Board may require any applicant to appear before the Board at the meeting at which his or her application is to be considered. The purpose of the interview or required attendance at a Board meeting is to clarify information contained in the application. The Board may require production of original documents at the interview or require attendance at a Board meeting.

4.8. The application, together with all photocopied documents submitted with the application, become the property of the Board and shall not be returned.

4.9. The burden of satisfying the Board of the applicant's qualifications for licensure is upon the applicant.

4.10. A license to practice medicine and surgery in this State is valid for a term of 2 years and shall be renewed by June 30 of the second year. The license shall be renewed upon the receipt of a non-refundable fee, established by the Board, together with an application provided by the Board.

**§24-1-5. Duties of Licensees and Permit Holders.**

5.1. All licensees and holders of permits issued by the Board have a duty to provide valid contact information, consisting of a telephone number and a residence address where official notifications may be delivered. If any of the contact information changes, the person must notify the Board of the change in writing within 30 days of the change.

5.2. A licensee or permit holder may also provide an alternate address, such as a business address, to the Board to serve as a public address of record, but the person must still provide a valid residential address.

5.3. The holder of an educational permit has a duty to notify the Board in writing within 5 days if he or she leaves his or her post-doctoral, clinical training program.

**§24-1-6. Qualifications for the Issuance of a License to Practice Medicine and Surgery by Reciprocal Endorsement.**

6.1. An applicant for a license to practice osteopathic medicine and surgery by reciprocal endorsement from another state, or the District of Columbia, shall provide proof of licensure in that jurisdiction under licensure requirements substantially similar to those existing in this State, and proof that he or she has the requisite qualifications to provide the same standard of care as a physician initially licensed in this State. These requirements and qualifications are specifically enumerated in this section. An applicant for a license to practice osteopathic medicine and surgery by reciprocal endorsement shall:

6.1.a. Provide evidence of graduation from an AOA accredited medical school;

6.1.b. Provide proof of successful completion of either:

6.1.b.1. A minimum of 1 year of post-graduate, clinical training in a program approved by the American Osteopathic Association (including programs approved by the Association under its Resolution 42 procedure); or

6.1.b.2. A minimum of 1 year of post-graduate, clinical training in a program approved by

the Accreditation Council for Graduate Medical Education and 40 hours of continuing medical education in osteopathic medicine with osteopathic manipulative treatment in courses approved, and classified as Category 1A, by the American Osteopathic Association.

6.1.c. Provide a sworn notarized statement from another physician that the applicant is of good moral character and is physically and mentally capable of engaging in the practice of medicine and surgery; and

6.1.d. Have successfully passed all steps of the COMLEX-USA examination developed by NBOME, or equivalent state osteopathic exam.

6.2. The 40 hours of continuing medical education specified in subdivision 6.1.b.2. of this rule may be completed through attendance at several courses, conducted at different times and locations, as long as the total instruction time is at least 40 hours. A single, unbroken course or class is not required.

**§24-1-7. License to Practice Medicine and Surgery by Reciprocal Endorsement; Application Required.**

7.1. An applicant for a license to practice medicine and surgery by reciprocal endorsement shall complete an application on forms provided by the Board. The applicant shall complete all parts of the application, in full, prior to being reviewed by the Board.

7.2. An applicant for a license to practice medicine and surgery by reciprocal endorsement shall provide a statement that he or she is in good standing in the jurisdiction in which he or she is licensed, and that he or she has no medical disciplinary action pending against him or her.

7.3. An application for a license to practice medicine and surgery by reciprocal endorsement must be received by the Board no later than 30 days prior to the meeting of the Board at which the application will be reviewed.

7.4. An applicant shall arrange for a personal interview with a member of the Board prior to the meeting during which his or her application is to be considered. The purpose of the interview or required attendance at a Board meeting is to clarify any information contained in the application. The Board may require production of original documents at the interview or required attendance at a Board meeting.

7.5. An applicant shall have available for review by a Board member, or by the Board, if the applicant appears at the meeting, the following original documents:

7.5.a. His or her medical school diploma;

7.5.b. A document attesting to the successful completion of the required minimum of 1 year AOA approved postgraduate clinical training;

7.5.c. A certified copy of the scores attained by the applicant on the COMLEX-USA examination developed by NBOME or State Board; the scores shall meet the requirements established in subsection 4.4 of this rule.

7.5.d. A sworn notarized statement on a form provided by the Board stating that the applicant is of good moral character, and is physically and mentally capable of engaging in the practice of medicine and surgery;

7.5.e. A statement that the applicant is in good standing in each jurisdiction in which he or she is licensed to practice and that he or she has no medical disciplinary action pending; and

7.5.f Any other documents required by the Board.

7.6. An applicant for a license to practice medicine and surgery by reciprocal endorsement shall provide all photocopied documents to the Board. The photocopies shall be attached to the application and made a part of the application. The application, together with all photocopied documents submitted with the application, become the property of the Board and shall not be returned.

7.7. An applicant for a license to practice medicine and surgery by reciprocal endorsement shall submit payment of a non-refundable fee, in an amount as established by the Board under the West Virginia Board of Osteopathy rule Fees for Services Rendered By the Board of Osteopathy Title 24 CSR 5. If it is paid by personal check, licensing process is not considered complete until the check has cleared the bank.

7.8. An applicant for a license to practice medicine and surgery by reciprocal endorsement has the burden of demonstrating to the satisfaction of the Board that the applicant has the requisite qualifications of a physician initially licensed in this State.

**§24-1-8. Temporary Permit to Practice Osteopathic Medicine and Surgery; Qualifications.**

8.1. An applicant for a temporary permit to practice medicine and surgery:

8.1.a. Shall submit evidence that he or she is a graduate of a medical school approved by the AOA;

8.1.b. Shall be able to demonstrate to the satisfaction of the Board the ability to communicate in the English language;

8.1.c. Shall submit evidence that he or she is of good moral character and that he or she is physically and mentally capable of engaging in the practice of medicine;

8.1.d. Shall have completed one year of an approved program of postgraduate education; Provided that, if the postgraduate program has only been approved by the ACGME, the applicant shall also have commenced taking a minimum of 40 hours of continuing medical education in osteopathic medicine with osteopathic manipulative treatment in courses approved, and classified as Category 1A, by the American Osteopathic Association.

8.1.e. Shall practice in an area of need, as determined by the Board. The Board may consider specialty need in a given area.

8.2. The issuance of a temporary permit shall not be interpreted or construed as the Board's approval of the applicant for licensure. Each person who seeks licensure shall meet all regular licensure requirements established by law in order to be licensed.

**§24-1-9. Temporary Permit to Practice Osteopathic Medicine and Surgery; Application Required.**

9.1. An applicant for a temporary permit to practice medicine and surgery in West Virginia shall submit an application on a form prescribed and provided by the Board. The form shall be completed and submitted at least30 days in advance of the date on which the expected practice will begin, together with the following documents:

9.1.a. Evidence of graduation from a medical school accredited by the AOA;

9.1.b. A photograph taken within 60 days which resembles the applicant;

9.1.c. A letter from a physician fully licensed to practice osteopathic medicine and surgery in West Virginia who has agreed to supervise the applicant, if considered necessary by the Board;

9.1.d. A non-refundable fee in an amount established by the West Virginia Board of Osteopathy rule Fees for Services Rendered By the Board of Osteopathy, 24CSR5.

9.1.e. A sworn and notarized statement on a form provided by the Board from another physician stating that the applicant is of good moral character, and is physically and mentally capable of engaging in the practice of medicine and surgery;

9.1.f. Proof of completion of one year of an approved program of post-graduate clinical training; and

9.1.g. Any other documents required by the Board.

9.2. The application, together with all photocopied documents submitted with it, become the property of the Board and shall not be returned.

9.3. An applicant for a temporary permit shall arrange for a personal interview with a member of the Board prior to the meeting at which his or her application is to be considered. The Board may require that an applicant be present at the meeting during which his or her application will be reviewed. The purpose of that interview or required attendance at a Board meeting is to clarify any information contained in the application. The Board may require production of original documents at the interview or required attendance at a Board meeting.

**§24-1-10. Temporary Permit to Practice Osteopathic Medicine and Surgery; Conditions of Practice.**

10.1. A physician granted a temporary permit to practice osteopathic medicine shall abide by all acceptable Rules and laws of the State of West Virginia governing the practice of osteopathic medicine and surgery in this State.

10.2. Physicians granted a temporary permit to practice osteopathic medicine and surgery shall practice only in the location specified by the Board and under the supervision of a licensed physician approved by the Board.

10.3. A physician who has been issued a temporary permit to practice osteopathic medicine and surgery may apply to the Board for a new temporary permit if the permit holder wishes to change the conditions of the practice as specified in the original application and as further specified in the permit. The Board considers the application for a new temporary permit a transfer, and the application shall be accompanied by letters setting forth any and all reasons for change in conditions. The required documents shall be completed by all parties as in the original application and shall be sent to the Board, together with the application and a non-refundable fee.

**§24-1-11. Temporary Permit to Practice Osteopathic Medicine and Surgery; Examination Required.**

11.1. Every physician who holds a temporary permit to practice osteopathic medicine and surgery in the State of West Virginia and who has not satisfactorily completed all steps of the COMLEX-USA examination developed by NBOME, or equivalent state osteopathic exam, shall take and pass all uncompleted portions of the COMLEX-USA examination at the next available examination date

following issuance of the temporary permit.

11.2. If the holder of the temporary permit fails to take the required examinations within the time specified in the section, the permit automatically expires.

11.3 If the holder of the temporary permit takes the required examination, but does not pass, the holder may request an extension of the temporary permit until the next available examination date. At the discretion of the Board, additional extensions may be granted, but in no event will the Board extend a temporary permit more than 1 year after the original date of issuance.

**§24-1-12. Application Forms and Processing.**

12.1. Application forms for licensure may include, but not be limited to, requirements for the following information; as considered necessary by the Board:

12.1.a. An AOA bibliographical printout;

12.1.b. A Federation of State licensing Boards derogatory information sheet regarding other state Board actions;

12.1.c. A list of all states where the physician has had a license, even if the license is not active;

12.1.d. A list of all hospitals where the physician has had privileges in the last 5 years;

12.1.e. The applicant's medical school;

12.1.f. A list of all training programs, including post graduate training programs;

12.1.g. The state from which the physician is requesting endorsement, with specific references to that state's examination and grades;

12.1.h. A copy of the individual's birth certificate, passport or baptismal, to be used in identifying the applicant and the appropriate spelling of his or her name;

12.1.i. A copy of a marriage license, divorce decree or court order, to document a name change; and

12.1.j. The place and date of the applicant's birth.

12.2. In the event the Board's staff finds derogatory information during the processing of an application, the information shall be presented to the Board for its review and the determination as to whether an individual should be scheduled for an interview during a regular Board meeting or if the staff should obtain additional information.

12.3. It is the applicant's responsibility to mail all necessary forms to selective institutions for response to the Board.

12.4. Completed verification forms shall be mailed directly from institutions.

12.5. The Board reserves the right to obtain additional information through oral or written examinations, psychiatric evaluation, physical examination or other tests as may be necessary to determine the competency of the applicant. Any additional tests, exams etc., are the financial responsibility of the applicant.

12.6. The Board reserves the right to require applicants who have not sat for or passed a written examination for licensure in the past 10 years to take an oral competency or practical skills examination in their field practice prior to issuing a license or to retake a written exam if considered necessary.

**§24-1-13. Educational Permits.**

13.1. A graduate medical trainee who seeks to participate in a post-graduate, clinical program involving osteopathic practice in this State, and who has not been licensed in this jurisdiction or any other, shall secure an educational permit. The permit grants the graduate medical trainee permission to participate in the training program and restricts him or her to the confines of the training institution, its affiliates and affiliated community hospitals. A graduate medical trainee may not use an educational permit to practice outside of the scope of the training program. Outside practice may only be conducted under a regular license to practice osteopathic medicine and surgery.

13.2. The permits are not a license to practice, nor a promise by the Board to issue a license upon completion of training.

13.3. Specific requirements for an educational permit are as follows:

13.3.a. The applicant shall submit a completed application for an educational permit to the Board 60 days in advance of July 1, or by another date by special permission;

13.3.b. An application for an educational permit shall include proof that the applicant is a graduate of a medical school approved by the AOA;

13.3.c. An application for an educational permit shall include a sworn and notarized statement from another physician that the applicant is of good moral character, and that he or she is physically and mentally capable of engaging in the practice of osteopathic medicine and surgery;

13.3.d. An applicant for an educational permit shall be able to demonstrate to the satisfaction of the Board his or her ability to communicate in the English language; and

13.3.e. An application for an educational permit shall be accompanied by a non-refundable fee in an amount established by the Board under the West Virginia Board of Osteopathy rule Fees for Services Rendered By the Board of Osteopathy Title 24 CSR 5.

13.3.f. An application for an educational permit, or renewal of an educational permit, shall include verification or written acknowledgment from the director of an approved program of post-graduate clinical training that the applicant is a current participant, in good standing, in the program.

13.4. An educational permit expires on the last day of June following issuance of the permit. The permits automatically expire and become void if the trainee leaves the training program for any reason.

13.5. Educational permits may also be suspended or revoked by the Board at any time upon the same grounds as an osteopathic license may be suspended or revoked, as specified in section 24-1-18 of this rule.

13.6. The application, together with the photocopied documents submitted with the application, become the property of the Board and shall not be returned.

13.7. The issuance of an educational permit shall not be interpreted or construed as the Board's approval of an applicant for licensure upon the applicant's completion of the educational training

program. Each person who seeks licensure shall fulfill all requirements established by law in order to be licensed.

13.8. An educational permit is only available for graduates who have never previously been licensed to practice osteopathic medicine in any jurisdiction.

**§24-1-14. Written Examination; Examinee Conduct.**

The conduct of examinees during the examination is governed by written guidelines issued by the NBOME or the State Board.

**§24-1-15. License Renewal; Renewal Applications Form.**

15.1. A licensee shall renew his or her license every 2 years, by submitting a renewal application form and paying a non-refundable renewal fee in an amount established by the Board under the West Virginia Board of Osteopathy rule Fees for Services Rendered By the Board of Osteopathy Title 24 CSR 5. The Board shall mail forms to each known licensee at his or her last known address. However, licensees are solely responsible for acquiring and submitting renewal application forms. A physician who fails to acquire and submit a renewal application may not practice on an expired license. The renewal application, together with all documents submitted with the application, become the property of the Board and shall not be returned.

15.2. The Board's renewal application form shall include a request for the following information:

15.2.a. The applicant's name, date of birth, home and principal business address and telephone numbers;

15.2.b. A statement of the applicant's medical training and work experience;

15.2.c. A statement concerning any disciplinary action taken against the applicant in the last two 2 years;

15.2.d. A statement concerning any civil litigation related to the practice of medicine or any criminal litigation commenced against the applicant in the last 2 years;

15.2.e. A statement describing the applicant's present ability to possess or dispense controlled substances;

15.2.f. A statement regarding disciplinary actions of the other jurisdictions in which the applicant is licensed to practice medicine;

15.2.g. Documentation of a minimum of 32 hours of AOA approved Continuing Medical Education, of which at least 50% must be category 1 or CME hours in standard heart saver courses obtained during the preceding 2 year licensing period pursuant to W. Va. Code §30-14-10.

15.2.h. The number of malpractice settlements made or judgments against the applicant in the last 5 years;

15.2.i. Any treatment received for mental illness, chemical substance, alcohol dependency or other impairment in the last 2 years; and

15.2.j. Any limitations of hospital privileges in the last 2 years.

15.3. A licensee who fails to timely renew his or her license shall submit a new application with required documentation in order to reinstate his or her license pursuant to W. Va.Code §30-14-10.

15.4. A licensee who is deployed outside of the Unites States on active duty in the armed forces of the United States for six months or more of his or her most recent license period may be exempted from the continuing medical education requirement for that license period and his or her application for renewal of license will not be denied for failure to satisfy this requirement.

15.5. A licensee participating in a clinical residency program for more than nine months out of his or her most recent licensing period may substitute a verification of his or her participation in lieu of documentation of the Continuing Medical Education hours specified in subdivision 15.2.g. of this rule.

**§24-1-16. Policy Regarding License Applicants for New Licensure, License Renewal, or License Reactivation Who Have Had a License Revoked or Surrendered in Another State.**

16.1. If an osteopathic physician has had his or her license revoked or surrendered in another state, the Board shall not issue or reactivate a license until the physician shows that he or she is eligible for licensure in the state where the action was taken. This does not include licenses which were not renewed at renewal times and were in good standing.

16.2. This policy is also applicable to physicians applying for an educational permit.

**§24-1-17. License Exemptions.**

17.1. In addition to exemptions provided by law, any duly licensed nonresident physician who participates in a continuing medical education course within the State is not required to be licensed in this state.

17.2. Physicians duly licensed in another state may transmit medical instructions by radio to personnel in this State in emergency situations.

**§24-1-18. Causes For Denial, Probation, Limitation, Discipline, Suspension Or Revocation of Licenses of Osteopathic Physicians.**

18.1. The Board may deny an application for a license, place a licensee on probation, suspend a license, limit or restrict a license or revoke any license issued by the Board, upon satisfactory proof that the licensee has:

18.1.a. Knowingly made, or presented or caused to be made or presented, any false, fraudulent or forged statement, writing, certificate, diploma or other material in connection with an application for a license;

18.1.b. Been or is involved in fraud, forgery, deception, collusion or conspiracy in connection with an examination for a license;

18.1.c. Become addicted to a controlled substance;

18.1.d. Become a chronic or persistent alcoholic;

18.1.e. Engaged in dishonorable, unethical or unprofessional conduct of a character likely to deceive, defraud or harm the public or any member of the public;

18.1.f. Willfully violated a confidential communication;

18.1.g. Had his or her license to practice osteopathic medicine in any other state, territory, jurisdiction or foreign nation revoked, suspended, restricted or limited, or otherwise acted against, or has been subjected to any other disciplinary action by the licensing authority thereof, or has been denied licensure in any other state, territory, jurisdiction, or foreign nation;

18.1.h. Been or is unable to practice osteopathic medicine with reasonable skill and safety to patients by reason of illness, drunkenness, excessive use of alcohol, drugs, chemicals or any other type of substance, or by reason of any physical or mental abnormality;

18.1.i. Demonstrated a lack of professional competence to practice osteopathic medicine with a reasonable degree of skill and safety for patients. In this connection, the Board may consider repeated acts of a physician indicating his or her failure to properly treat a patient and may require the physician to submit to inquiries or examinations, written or oral, by members of the Board, or by other physicians licensed to practice medicine in this State, as the Board considers necessary to determine the professional qualifications of the licensee;

18.1.j. Engaged in unprofessional conduct, including, but not limited to, any departure from, or failure to conform to, the standards of acceptable and prevailing medical practice, or the ethics of the osteopathic medical profession, irrespective of whether or not a patient is injured by the conduct, or has committed any act contrary to honesty, justice or good morals, whether the act is committed in the course of his or her practice and whether committed within or without this State;

18.1.k. Been convicted of or found guilty of a crime in any jurisdiction which directly relates to the practice of medicine or to the ability to practice medicine. Any plea of nolo contendere is considered conviction for purposes of this rule;

18.1.l. Advertised, practiced or attempted to practice under a name other than his or her own;

18.1.m. Failed to report to the Board any person whom the licensee knows is in violation of this rule or of provisions of W. Va. Code §§30-14-3 or 30-14A-1;

18.1.n. Aided, assisted, procured or advised any unlicensed person to practice medicine contrary to this rule or the W. Va. Code §§30-14-3 or 30-14A-1;

18.1.o. Failed to perform any statutory or legal obligation placed upon a licensed physician;

18.1.p. Made or filed a report which the licensee knows to be false; intentionally or negligently failed to file a report or record required by state or federal law or willfully impeded or obstructed the filing or induced another person to do so. The reports or records shall include only those which are signed in the capacity as a licensed physician;

18.1.q. Paid or received any commission, bonus, kickback or rebate, or engaged in any split-fee arrangement in any form whatsoever with a physician, podiatrist, organization, agency or person, either directly or indirectly, for patients referred to providers of health care goods and services, including, but not limited to, hospitals, nursing homes, clinical laboratories, ambulatory surgical centers or pharmacies. The provisions of this subdivision shall not be construed to prevent a physician from receiving a fee for professional consultation services;

18.1.r. Engaged in sexual contact with a current patient who is not a spouse of the physician or exercised influence within a patient-physician relationship for purposes of engaging a patient in sexual activity;

18.1.s. Made deceptive, untrue or fraudulent representations in the practice of osteopathic medicine or employed a trick or scheme in the practice of osteopathic medicine when the trick or scheme fails to conform to the generally prevailing standards of treatment in the medical community;

18.1.t. Solicited patients, either personally or through an agent, through the use of fraud, intimidation, undue influence, or by overreaching or vexatious conduct. A solicitation is any communication which directly or implicitly requests an immediate response from the recipient;

18.1.u. Failed to keep written records justifying the course of treatment of the patient, including, but not limited to, patient histories, examination results and test results and treatment rendered, if any;

18.1.v. Exercised influence on the patient or client in such a manner as to exploit the patient or client for the financial gain of the licensee or of a third party, which shall include, but not be limited to, the promoting or selling of services, goods, appliances or drugs and the promoting or advertising on any prescription form of a community pharmacy. For the purposes of this subdivision, it is legally presumed that prescribing, dispensing, administering, mixing or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities, is not in the best interests of the patient and is not in the course of the physician's professional practice, without regard to his or her intent;

18.1.w. Prescribed, dispensed or administered any medicinal drug appearing on any schedule set forth in W. Va. Code §§60A-1-101 to 60A-7-707 by the physician to himself or herself, except one prescribed, dispensed or administered to the physician by another practitioner authorized to prescribe, dispense or administer medicinal drugs;

18.1.x. Engaged in malpractice or failed to practice medicine with that level of care, skill and treatment which is recognized by a reasonable, prudent physician engaged in the same or a similar specialty as being acceptable under similar conditions and circumstances;

18.1.y. Performed any procedure or prescribed any therapy which, by the prevailing standards of medical practice in the community, would constitute experimentation on a human subject, without first obtaining full, informed and written consent from the patient;

18.1.z. Practiced or offered to practice medicine and surgery beyond the scope permitted by law or accepted and performed professional responsibilities which the licensee knows or has reason to know he or she is not competent to perform;

18.1.aa. Delegated professional responsibilities to a person whom the licensee knew or had reason to know is not qualified by training, experience or licensure to perform the responsibilities;

18.1.bb. Violated or attempted to violate any law or lawfully promulgated rule or regulation of this State, any other state, the Board, the United States or any other lawful authority (without regard to whether the violation is criminally punishable), which relates to or in part regulates the practice of osteopathic medicine, when the licensee or applicant knows or should know that the action is violative of the law, rule or regulation; or has violated a lawful order of the Board; or has failed to comply with a lawfully issued subpoena of the Board; or has violated an order of any court entered pursuant to any proceedings commenced by the Board;

18.1.cc. Presigned blank prescription forms;

18.1.dd. Prescribed, ordered, dispensed, administered, supplied, sold or given any drug which is an amphetamine or sympathomimetic amine drug and a compound designated as a ~~Schedule II~~ controlled substance under W. Va. Code §§60A-1-101 to 60A-1-707, to or for any person except for;

18.1.dd.1. The treatment of narcolepsy; attention deficit disorder, which is a behavioral syndrome characterized by inappropriate symptoms of moderate to severe distractibility, short attention span, hyperactivity, emotional liability and impulsivity; or drug-induced brain dysfunction;

18.1.dd.2. The differential diagnostic psychiatric evaluation of depression or the treatment of depression or the treatment of depression shown to be refractory to other therapeutic modalities;

18.1.dd.3. The clinical investigation of the effects of the drugs or compounds when an investigative protocol for the drugs or compounds is submitted to, reviewed and approved by the Board before the investigation is begun; or

18.1.dd.4. The treatment of obesity, when consistent with excessive appetite, ~~for periods not to exceed 2 weeks per six-week period~~ under the following conditions:

A. After conducting prudent screening of the patient's metabolic and cardiac functioning,

B. The medication is prescribed as part of a comprehensive program of management of diet and lifestyle, monitored and documented by the treating physician,

C. Where the medication has been identified by the United States Food and Drug Administration as being appropriate for the treatment of obesity, and

D. In the case of those drugs indicated for "short-term" weight loss, for a period not to exceed twelve weeks out of any six-month span, unless, and only so long as, the patient exhibits continued weight loss and no adverse health effects;

18.1.ee. Knowingly maintained a professional connection or association with any person who is in violation of the W. Va. Code §§30-14-3 or 30-14A-1 or the rules of the Board; or has knowingly aided, assisted, procured or advised any person to practice medicine contrary to the W. Va. Code §§30-14-3 or 30-14A-1 or to the Rules of the Board; or knowingly performed any act which in any way aids, assists, procures, advises or encourages any unlicensed person or entity to practice osteopathic medicine; or has divided fees or agreed to divide fees received for professional services with any person, firm, association, corporation or other entity for bringing or referring a patient; or has engaged in the practice of medicine as an officer or employee of any corporation other than one organized and existing pursuant to the W. Va. Code §30-14-3, except as a licensed physician, intern or resident of a hospital or teaching institution licensed by this State;

18.1.ff. Offered, undertaken or agreed to cure or treat disease by a secret method, procedure, treatment or medicine; or has treated, operated or prescribed for any human condition, by a method, means, or procedure which the licensee has refused to divulge upon demand of the Board;

18.1.gg. Engaged in false or deceptive advertising. "False or Deceptive Advertising" means a statement that includes a misrepresentation of fact, is likely to mislead or deceive because of a failure to disclose material facts, is intended or is likely to create false or unjustified expectations of favorable results or includes representations or implications that in reasonable probability will cause an ordinary prudent person to misunderstand or be deceived; or

18.1.hh. Engaged in advertising that is not in the public interest. Advertising that is not in the

public interest includes the following, with the exceptions specifically listed:

18.1.hh.1. Advertising that has the effect of intimidating or exerting undue pressure;

18.1.hh.2. Advertising that uses testimonials;

18.1.hh.3. Advertising which is false, deceptive, misleading, sensational or flamboyant;

18.1.hh.4. Advertising which guarantees satisfaction or a cure;

18.1.hh.5. Advertising which offers gratuitous services or discounts, the purpose of which is to deceive the public. This subdivision does not apply to advertising which contains an offer to negotiate fees, nor to advertising in conjunction with an established policy or program of free care for patients; and

18.1.hh.6. Advertising which makes claims of professional superiority which a licensee is unable to substantiate.

18.2. As used in section 18.1.e. of this rule, "Dishonorable, unethical or unprofessional conduct of a character likely to deceive, defraud or harm the public or any member thereof" includes, but is not limited to:

18.2.a. Prescribing or dispensing any "Controlled Substance" as defined in W. Va. Code §§60A-1-101 to 60A-1-707:

18.2.a.1. With the intent or knowledge that a controlled substance will be used or is likely to be used other than medicinally or for an accepted therapeutic purpose;

18.2.a.2. With the intent to evade any law with respect to the sale, use or disposition of the controlled substance;

18.2.a.3. For the licensee's personal use,

18.2.a.4. For the use of his or her immediate family for any period of treatment, or sequence of such periods, exceeding 3 days;

18.2.a.5. Without making an in-person examination of the patient at least once out of every 6 months for the duration of the treatment;

18.2.a.6. Without making and keeping documentation of the examination of the patient, diagnosis, basis for treatment, and treatment plan, in a manner consistent with the standards of acceptable and prevailing medical practice;

18.2.a.7. In amounts that the licensee knows or has reason to know, under the attendant circumstances, that the amounts so prescribed or dispensed are excessive under accepted and prevailing medical practice standards; or

18.2.a.8. When the licensee knows, or has reason to know, that an abuse or improper diversion of the prescribed or dispensed substance is occurring or is likely to occur.

18.2.b. Issuing or publishing in any manner whatsoever, representations in which grossly improbable or extravagant statements are made which have a tendency to deceive or defraud the public, or a member of the public, including, but not limited to:

18.2.b.1. Any representation in which the licensee claims that he or she is able to cure or treat manifestly incurable diseases, ailments or infirmities by any method, procedure, treatment or medicine which the licensee knows or has reason to know has little or no therapeutic value; or

18.2.b.2. Any representation in which the licensee claims that he or she is able and willing to treat diseases, ailments or infirmities under a system or school of practice; other than that for which he or she holds a certificate or license granted by the Board; other than that for which he or she holds a degree or diploma from a school otherwise recognized as accredited by the Board; or which he or she professes to be self-taught;

18.2.c. A serious act, or a pattern of acts committed during the course of his or her medical practice which, under the attendant circumstances, would be considered to be gross incompetence, gross ignorance, gross negligence or malpractice, including the performance of any unnecessary service or procedure;

18.2.d. Conduct which is calculated to bring or has the effect of bringing the osteopathic medical profession into disrepute, including, but not limited to, any departure from or failure to conform to the standards of acceptable and prevailing medical practice within the state, and any departure from or failure to conform to the principles of medical ethics of the AOA. For the purposes of this subsection, actual injury to a patient need not be established;

18.2.e. Any charges or fees for any type of service rendered within 72 hours of the initial visit, if the licensee advertises free service, free examination or free treatment;

18.2.f. The administration of anabolic steroids for other than therapeutic purposes;

18.2.g. The use of chelation therapy for diseases and conditions other than acute hypercalcemia, lead poisoning, and intoxications caused by some other heavy metals;

18.2.h. Charging or collecting an excessive, unconscionable fee.

18.2.h.1. The Board shall take into account the following factors:

18.2.h.1.A. The time and effort required for performing services rendered;

18.2.h.1.B. The novelty and difficulty of the procedure or treatment;

18.2.h.1.C. The skill required to perform the procedure or treatment properly;

18.2.h.1.D. Any requirements or conditions imposed by the patient or circumstances;

18.2.h.1.E. The nature and length of the professional relationship with the patient;

18.2.h.1.F. The experience, reputation, and ability of the licensee; and

18.2.h.1.G. The nature of the circumstances under which the services are provided.

18.2.h.2. In any case where it is found that an excessive, unconscionable fee has been charged, in addition to any actions taken, the Board may require the licensee to reduce or pay back the fee.

18.2.i. Failure by a licensee to report a known or observed violation of this rule, and/or the provisions of the W. Va. Code §§30-14-3 or 30-14A-1.

18.3. When the Board finds that any applicant is unqualified to be granted a license or finds that any licensee should be disciplined pursuant to the W. Va. Code §§30-14-3 or 30-14A-1 or rules of the Board, the Board may proceed as described in the West Virginia Board of Osteopathy rule Discplinary and Complaint Procedures Title 24 CSR 6.

WEST VIRGINIA BOARD OF OSTEOPATHY

# RESPONSES TO COMMENTS RECEIVED

## LICENSING PROCEDURES FOR OSTEOPATHIC PHYSICIANS

Title 24, Series 1

The West Virginia Board of Osteopathy received a total of six comments to its proposed amendment to the rule for "Licensing Procedures for Osteopathic Physicians." Three comments were submitted by mail and three comments – two of them anonymously – were submitted to the Board through a form on its website.

The Board's responses are provided below:

**Response to anonymous comment** submitted via website, Sunday June 19, 2011:

This comment expresses confusion about the purpose or effect of the rule. Since the author did not submit a name, the Board was unable to reach this person to address his or her misunderstanding. The Board has no comment in response, other than the Summary of the Rule and the Statement of Circumstances submitted with this filing.

**Response to anonymous comment** submitted via website, Wednesday June 29, 2011:

This comment consisted solely of the statement, "A good many vaulalbes [sic] you've given me." Since this is unintelligible in its meaning and does not address the rule in any substantive way, the Board of Osteopathy sees no need to respond.

**Response to Dr. David Apgar**, Huntington, WV:

Dr. Apgar has objected to the existing two-week limitation on the use of sympathomimetic amine drugs for treatment of obesity. The Board of Osteopathy has incorporated his suggestions for standards that parallel the FDA recommendations and the rule of the State Medical Board of Ohio. The rule as now proposed by this Board is simpler than the Ohio rule, but it does follow the same time guidelines that were recommended by Dr. Apgar.

**Response to Dr. Richard Shorter**, Melrose Family Medicine, Princeton, WV:

Dr. Shorter has offered comments reflecting a balanced approach and conscientious consideration of the available medical information. He urges the Board to remove the two-week limitation as counter-productive to patient health and, indeed, recommends that no fixed time limit be established. Instead he advocates that 'continued weight loss' be the factor for determining how long to use the drugs in question.

The Board acknowledges that the two-week limit is likely to be counter-productive and has removed this limit from its rule. However, the Board also knows that a twelve-week period for pharmacologic therapy has emerged as something of a consensus within the medical field and the Board believes it is important to recognize this view. The Board recognizes that patients may respond differently to any given form of therapy and, for this reason, the Board will not set twelve weeks as a firm limit. The Board finds that the best approach is to adopt the twelve-week limit, but to allow for additional treatment beyond this time period as long as the patient continues to experience sustained weight loss with no adverse affects.

**Response to Dr. Colleen Meriwether**, Lewisburg, WV:

Dr. Meriwether objects to imposing a two-week limitation on the use of phentermine, a Schedule IV substance, for treatment of obesity. She suggests that this restriction may be appropriate for Schedule II drugs. Based upon her comment and other comments received, the Board has removed this restriction.

Dr. Meriwether also urges the Board to consider guidelines promulgated by the American Society of Bariatric Physicians (ASBP) and she included a copy of these guidelines with her response. The Board's responses to these guidelines are provided below in answer to the comments received directly from this organization.

Finally, Dr. Meriwether asks the Board to recognize that obesity is a chronic condition and requires a long-term treatment in the same way that hypertension and diabetes require long-term treatment. In response, the Board acknowledges that a long-term treatment is a desirable goal, but there are no drugs of this type that are approved for long-term use. (The FDA has given approval for the long–term use of one drug, Orlistat, but this is not a sympathomimetic amine drug.) After review of several different resources, the Board finds that phentermine is not authorized by the federal government for long-term use and its effectiveness diminishes as the patient develops a tolerance to its effect. Therefore, the Board has adopted an approach that allows the use of such medication when the physician can document that the patient continues to lose weight at a responsible rate and can justify its continued use without observable, negative effects upon the patient.

**Response to the American Society of Bariatric Physicians**, Aurora, CO

This Society has provided an extensive set of documents for the Board's consideration: a cover letter, a position paper on Overweight and Obesity Management and a set of guidelines adopted by this organization for the treatment of overweight or obese patients. Although the Society does mention the use of other forms of treatment for obesity, the bulk of the materials address just one form of therapy – a drug-based treatment to induce weight loss and maintain reduced weight.

The Society does not suggest specific amendments to the proposed rule, but they do object to the Board's provision limiting the use of sympathomimetic amine drugs to just two weeks at a time. As reflected in the Board's responses to other comments, the Board accepts the argument against a limit of two weeks and has amended its rule to remove that limit.

The Board acknowledges that the Society's written guidelines provide helpful information and considerations for a practicing physician who may utilize the drugs that the Society calls "anorectics." These guidelines, although highly detailed, are also quite limited. These guidelines fail to provide any guidance or information about the cessation of treatment or follow-up care and monitoring of a patient. Furthermore, these guidelines mention "other treatment modalities," but fail to discuss these other treatments in any way other than 'counseling.' The guidelines do not address considerations that may favor other approaches or any of the risks and benefits of such alternatives.

In fact, all of the materials presented by the Society reflect a narrow focus on just two drugs – phentermine and sibutramine*. The Board sees these materials as arguing for uses of sympathomimetic amine drugs in ways that have not been approved by the United States Food and Drug Administration. Specifically, the Society argues that phentermine – which only been approved for short-term treatments – should be used on a long-term basis, and may also be used to help a person maintain a low body weight for 'occupational needs' or as a preventative measure for people to avoid gaining weight when they are genetically predisposed to obesity and related diseases. Though <u>some</u> of these may be laudable goals, regulatory authorities have NOT deemed phentermine to be an appropriate drug to accomplish these objectives.

The Society urges the Board to consider that many practicing physicians will use lawful drugs for treatments that have not been specifically-approved by the FDA. This is termed "off-label use." The Society notes that the American Medical Association and the FDA itself have recognized that off-label uses of approved drugs may be acceptable and ethical in the practice of medicine.

While it may be ethical to prescribe a drug for an off-label use, the Board's focus with this rule is its duty to protect the public from <u>unethical</u> uses of drugs or other therapies. The Board's principal concerns are with over-reliance upon stimulant

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* Since the Society's adoption of their written guidelines, sibutramine has been removed from the market because of adverse effects that outweigh the benefits of weight loss.

medications to the detriment of the patients. This may occur when a physician offers these stimulants without addressing issues of the patient's diet and lifestyle. A patient's needs are poorly served when treatment consists of little more than taking vital signs and refilling a prescription. A comparable ill occurs when a physician continues to treat the patient with medication long after the patient has developed a tolerance to the drug and ceased losing weight.

The Society argues that it is just as important to stop gaining weight as it is to lose the weight. While maintenance of a lower weight is important to the continued health of a formerly obese patient, this is best accomplished through modifications of the patient's lifestyle. Long-term treatment with stimulant medication is not in the best interest of the patient, particularly if the actual causes of the patient's weight gain are not addressed and corrected.

For these reasons, the West Virginia Board of Osteopathy declines to allow the use of sympathomimetic amine drugs, and specifically phentermine, for the additional off-label uses advocated by the American Society of Bariatric Physicians.

**Shepard, Diana K**

**From:** Administrator@wvsto.com [Administrator@wvsto.com] **Sent:** Sun 6/19/2011 1:49 PM
**To:** Shepard, Diana K
**Cc:**
**Subject:** Proposed Rule Change Comment
**Attachments:**

this correction is as clear and concise as mud. What exactly are you trying to correct or change?

**Shepard, Diana K**

**From:** Administrator@wvsto.com [Administrator@wvsto.com] **Sent:** Wed 6/29/2011 9:21 PM
**To:** Shepard, Diana K
**Cc:**
**Subject:** Proposed Rule Change Comment
**Attachments:**

A good many vaulalbes you've given me.

**Shepard, Diana K**

**From:** Administrator@wvsto.com [Administrator@wvsto.com] **Sent:** Wed 6/22/2011 5:02 PM
**To:** Shepard, Diana K
**Cc:**
**Subject:** Proposed Rule Change Comment
**Attachments:**

I agree that Phentermine and other sympathomimetic amine drugs need to be regulated to limit abuse. The proposed rule change however is going to treat schedule IV Phentermine the same as schedule II amphetamine. The notice omitted the paragraph D under 18.1.30 "The treatment of obesity, when consistent with excessive appetite, for periods not to exceed two weeks per six week period". First, I don't see how my colleagues can make informed comments on the proposed rule without hearing of the consequences of the rule change. Second, a two week limitation on treatment of obesity with appetite suppressants is contrary to FDA recommendations for use of Phentermine. Third, a two week limitation on treatment of obesity is ridiculous, ineffective, and will eliminate the wellness benefit many patients need and do achieve with weight loss. (i.e. one of my patients lost 19 pounds in four weeks this week) Rather than classify Phentermines by rule the same as amphetamine, I suggest a new rule be written similar to Ohio's regulation of Phentermines. Ohio limits use of Phentermines to three months and they cannot be prescribed again until six months later. This is consitent with the FDA product insert recommendation that the Phentermines be used no more than twelve weeks. It limits dependency, abuse and allows physicians to assist obese patients with appetite control to achieve a healthier weight. Isn't good health what we all want our patients to achieve? The only thing the proposed rule change will achieve is to effectively eliminate the use of appetite suppressants. Patients will visit their local M.D. for help with treatment of their obesity. If this is what the board and West Virginia Osteopathic physicians want, that is what they will get. Sincerely, David Apgar, D.O., C.M.D.

**Melrose Family Medicine**
*A Division of WV / VA Health Care Alliance*
**RICHARD SHORTER, D.O.**
756 Athens Road • Princeton, WV 24740
**(304) 425-0716**
**Fax (304) 487-1322**

June 14, 2011

Diana Shepard, Executive Director
State of West Virginia Board of Osteopathy
405 Capitol St. Suite 402
Charleston, WV 25301

Dear Ms. Shepard:

I would like to thank you for taking the time to speak with me last week regarding the use of the weight loss medication Phentermine. I was unaware that the Board had issued any guidelines for prescribing this agent beyond those issued by the FDA. Your input was very useful in helping me to understand the Board's position on this matter.

As all primary care doctors in West Virginia can attest, obesity and its attendant medical problems are a tremendous issue. We are frustrated by the lack of safe and effective therapies and saddened by observing the toll that obesity takes on the lives of our patients. As a result I have been working over the past several months to try to develop a safe and effective weight loss program which could be beneficial to my patients. This program would incorporate dietary modification, lifestyle counseling, increased physical activity, as well as anorectic medication i.e. Phentermine.

When the FDA approved Phentermine it stipulated that it be used for "short term therapy." However, a definition of "short term" was never provided. A twelve week course of therapy has been referenced several times in the literature though this seems to be based more upon consensus rather than on "hard science." The Board's definition, "periods not to exceed two weeks per six week period" actually would indicate intermittent as opposed to short term therapy and ultimately fails to address total duration of therapy. Based upon my review of the available literature, intermittent therapy does not appear to provide any superiority to continuous therapy either in efficacy or risk for dependency/tolerance.

Based on my experience it would seem that an approach in which a patient was regularly monitored while on medication in order to assure a sustained gradual weight loss (one to two pounds per week on average) until a goal weight is reached or signs of tolerance or dependency were encountered, i.e. diminished rate of weight loss, would be a reasonable approach. This would allow the physician the latitude of being able to continue therapy as long as this was proving effective and not producing any significant untoward effects.

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It would stand to reason that guidelines on the use of drugs such as Phentermine need to take into account the patient's baseline weight/BMI, ideal body weight, as well as any underlying medical conditions, prior history of drug abuse/dependency, capacity for exercise, etc. which could impact the appropriate duration of therapy.

Accordingly I request that you present this letter to the Board for their review and comments. I understand the dilemma that the Board faces in trying to prevent the abuse or misuse of potentially addictive drugs. However I also want to be able to use all the tools available to be able to assist my patients who are suffering from the effects of obesity and its complications. I appreciate any further guidance the Board could offer on this issue. Thank you.

Sincerely,

Richard A. Shorter, D.O.

RAS/dm

June 29, 2011

West Virginia Board of Osteopathy
405 Capital Street
Suite 402
Charleston, WV 25301

Regarding: Proposed Rule Change to W.Va Code 60A-1-101 to 60A-1-707

To the West Virginia Board of Osteopathy,

Please accept this information which I submit for consideration on the Board's proposed rule change in Section 24-1-18.1dd to delete the phrase "Schedule II" from the rule.

I am a West Virginia practitioner and as part of my practice, I treat overweight and obese patients. These patients derive tremendous benefit from using phentermine as an adjunct to their weight loss program. As I interpret the proposed rule, a West Virginia licensee may be subject to discipline if he/she prescribes phentermine (a Schedule IV controlled substance) outside the exception outlined in Section 24-1-18.dd.4 of "periods not to exceed 2 weeks per six-week period". I do not believe that such a limitation on prescribing for that medication would be consistent with current, accepted national guidelines which have been published by the American Society of Bariatric Physicians (ASBP). These guidelines, adopted by ASBP in 2009, set forth evidence based data which supports the long term use of anorectic medications as part of the comprehensive approach to clinical obesity treatment. I have attached a copy of these guidelines to this comment as a valuable resource for your consideration. I understand that ASBP is also submitting a written comment opposing the rule change, and I endorse and support the Society's viewpoint.

The limitations in this rule should only apply to Schedule II drugs which include amphetamines, dextroamphetamines, and methylphenidate (Ritalin). To my knowledge, phentermine is the only drug mentioned in this rule that is not a Schedule II drug, it is a Schedule IV. By definition , the Schedule II anorectic drugs are more stimulating and thus have far more potential for street abuse than does phentermine. These Schedule II medications, therefore, are not recommended for the treatment of overweight and obese patients, and I do not use them with my patients. The Schedule III and IV anorectics offer acceptable alternatives with very little potential for street abuse. Phentermine has proven to be a safe, cost effective, and highly successful medication in the long term treatment of overweight and obese patients. This has certainly been true in my practice.

As we all are too well aware, West Virginia is plagued by one of the highest obesity rates in the U.S. Aggressive measures have to be taken to help these patients. Limiting the use of

phentermine would be counterproductive and possibly harmful to patients. Obesity is a chronic illness and should be treated as one. Short term treatment of this chronic illness is ineffective just as short term treatment of hypertension, diabetes, hypothyroidism, and other chronic diseases is ineffective.

I urge the Board to carefully review and consider the information I have provided and the documentation that will be provided by ASBP. This information is current and the guidelines are the standard of care for the management and treatment of the overweight and obese.

Thank you for the opportunity to be heard on this issue. Your consideration of all the facts pertinent to this matter is greatly appreciated.

Sincerely,

Colleen Meriwether, DO

Colleen Meriwether D.O.

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July 1, 2011

West Virginia Board of Osteopathy
405 Capitol Street
Suite 402
Charleston, WV 25301

Regarding: Proposed Rule Change to W. Va. Code §§60A-1-101 to 60A-1-707

To Whom It May Concern:

The American Society of Bariatric Physicians (ASBP) represents over 1,400 members nationwide who specialize in the treatment of overweight and obese patients. For sixty-one years the ASBP has worked to improve the quality of patient care by developing up-to-date standards of practice and by educating physicians on optimal treatment methods. ASBP is pleased to offer the assistance and expertise of the collective group in guiding the West Virginia Board of Osteopathy as it reviews the obesity treatment regulations.

ASBP understands that the duty of the Board is to protect the public health and safety and commends the Board for its diligence and attention to this duty. We are also aware that there are alarmingly high rates of overweight and obesity among West Virginia citizenry. In fact, the most recently-published CDC statistics show that West Virginia has the sixth highest obesity rate in the United States. ASBP respectfully submits that the current rule which limits the use of obesity medications for periods not to exceed two weeks per six-week period severely inhibits proper overweight and obesity treatment in West Virginia, and discourages bariatric physicians from even attempting to treat the overweight and obese.

Obesity, a chronic illness with numerous adverse metabolic consequences, requires long-term treatment. Current published data does not support restricting patients to a two week supply every six weeks. The old theory that discontinuous pharmacotherapy is as effective as continuous therapy for weight loss has now been thoroughly discredited. Patients treated in this manner almost always regain weight when phentermine is withheld. Discontinuous pharmacotherapy has about as much credibility as giving insulin-dependent diabetics insulin two out of six weeks.

It is good practice to use phentermine long-term for maintenance even though the patient may regain some weight. In some cases the drugs help to retard

weight gain. One example of such use is in patients who are taking drugs that powerfully induce weight gain such as prednisone. The addition of phentermine treatment during a course of prednisone may help limit weight gain. Another example is the use of these anti-obesity agents in post-operative bariatric surgery patients who are beginning to regain weight. Physicians at the long-term bariatric surgery follow-up clinic at Massachusetts General Hospital now routinely start their post-operative patients on an anti-obesity drug at one year in an attempt to retard weight gain. They continue pharmacotherapy therapy even when the patients gain weight, provided the physician thinks the medicine is having a beneficial effect on eating behavior.

It must be noted that there is a common misconception that phentermine is dangerously addictive. On the contrary, phentermine is safe and effective. It is safer than nearly every medicine listed in the PDR – safer even than aspirin. Phentermine has zero addiction potential. In 51 years of worldwide use not a single confirmed case of addiction to phentermine has been published. A recent research study using modern addictive medicine metrics found patients treated with long-term phentermine did not develop amphetamine-like addiction signs or symptoms or amphetamine-like withdrawal.(1) Therapeutic use of sympathomimetic class III and IV drugs does not induce drug-seeking behavior. Patients do not attempt to use intravenous or inhalation routes of administration to enhance stimulant effects as do addicts of crystal methamphetamine or methylenedioxymethamphetamine (MDMA; "ecstasy"). Patients do not engage in binge use of the medicine as true amphetamine addicts do with the drugs of abuse. Therefore current research supports the use of phentermine as a safe and effective anti-obesity medication.

Included with this letter please find the Overweight and Obesity Evaluation and Management guidelines. This comprehensive document represents a current, evidence-based approach to the evaluation and treatment of obesity. The ASBP strongly encourages the members to take the information in this document into careful consideration when reviewing the current rules, as the ultimate goal of sharing this information is to assist physicians in successfully treating obesity.

We understand the intent of the legislation is to provide benefit for and to protect the citizens of West Virginia. However, in our opinion, the current regulations restricting the use of anorectic agents are not consistent with scientific knowledge of overweight and obesity treatment. Nor are they consistent with the best practices of experienced clinicians in the field of bariatric medicine. ASBP supports the Board's desires to control the misuse of sympathomimetics and believes that anorectic usage should only be implemented as part of a comprehensive weight loss program. ASBP believes the current restrictions are detrimental to the physicians practicing bariatric medicine in West Virginia and more importantly, the overweight and obese citizens of your state.

As a fellow Doctor of Osteopathy as well as ASBP's next President, Dr. Bryman would welcome the opportunity to meet with the West Virginia Board of Osteopathy in order to discuss current research and propose new legislation. He has worked extensively with numerous state medical boards in order to provide them with guidance as they review

obesity treatment rulings. Please contact ASBP's Executive Director, Laurie Traetow, at laurie@asbp.org in order to arrange this meeting.

Sincerely,

David Bryman, DO, State Medical Board Task Force Chairman and ASBP President-Elect

Allen Rader, MD, State Medical Board Task Force Member and Former ASBP Secretary / Treasurer

Reference:

1. Hendricks EJ, Greenway FL. A Study of Abrupt Phentermine Cessation in Patients in a Weight Management Program. Am J Ther. 2010 Mar 2 DOI 10.1097/MJT.0b013e3181d070d7.

# American Society of Bariatric Physicians ™

## Overweight and Obesity Evaluation and Management

### Background

The art and science of treating overweight and obesity continues to evolve and improve. Condensing the clinical knowledge and skills of American Society of Bariatric Physicians (ASBP) membership into written guidelines continues to be a work in progress. The introduction of new medications, the continued use of conventional ones, changes to the Physicians Desk Reference (PDR) labeling of some medications, and evolving changes to the treatment of overweight and obesity treatment have generated the need to produce a new set of evaluation and treatment guidelines.

ASBP, organized in 1950, is a national non-profit organization of physicians and interested affiliates who have a special interest in the study and treatment of patients with obesity and associated conditions. The primary goal of the ASBP is to advance and improve the practice and quality of professional service in the field of bariatric medicine. We assert that "*Bariatrics*" is a term that should only apply to the practice of medicine by physicians relating to the areas stated. This would not include a clinic or site that prescribes or dispenses medication without the appropriate examination and continued monitoring and follow-up by a qualified physician. The ASBP does not endorse, support, teach, or promote prescribing controlled substances on the Internet for weight loss.

The ASBP is a member of the Specialty and Service Society of the American Medical Association. The ASBP is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education (CME) for physicians and offers CME at annual and regional meetings of the Society, as well as Internet-based CME.

Membership in the ASBP currently includes approximately 1,100 physicians, both MDs and DOs, from throughout the United States and some foreign countries. ASBP also has approximately 100 NPs and PAs as members. Customary medical specialties represented within the ASBP include family practice, emergency medicine, ob-gyn, internal medicine, surgery, neurology, pathology, pediatrics and psychiatry. Just as members' backgrounds are varied, so are their views on obesity therapy. Agreement should be reached among the membership that long-term lifestyle changes are necessary for long-term success. Just as physicians in other areas of medicine may differ in their choices of therapeutic modalities, ASBP members may utilize similar freedom of choice when treating obesity.

The Obesity Evaluation and Management Committee of the ASBP in drafting these guidelines recommends changing the name of this document from the previous "Anorectic Usage Guidelines" to "Overweight and Obesity: Evaluation and Management." This name change reflects the ASBP's comprehensive approach to

clinical obesity treatment, which includes advice and recommendations for dietary management, behavioral modification, counseling, exercise and appropriate use of medications when indicated, as part of a long-term weight control maintenance program ("weight control" refers to managing excess adipose tissue).

The original Anorectic Usage Guidelines, recent revisions and the new Overweight and Obesity Management Guidelines state that physicians should consider using the Schedule III and IV anorectics as part of a multifaceted obesity treatment program after an appropriate initial patient evaluation and with appropriate ongoing supervision. In addition, for patients who need them, these anti-obesity agents reasonably may be used for maintenance in excess of the manufacturer's labeling of a "few weeks" and, in some cases, in combinations or dosages different from that described on current labeling.

We offer the following recommendations and supporting statements for evaluation and treatment guidelines from peer-reviewed literature and believe these recommendations represent the currently accepted medical practice of bariatric medicine. Any deviation by a practitioner from these guidelines may be appropriate and must be decided by the individual practitioner in caring for the patient. Thus, the bariatrician must not rely on these guidelines or on any other guidelines to provide an infallible blueprint for patient treatment. It is not the intent of these guidelines to limit the bariatrician's judgment in adjusting the therapy based on the patient's condition, medical problems or therapeutic response. These guidelines are not intended to provide specific requirements to be followed by the treating bariatrician.

Another purpose in producing these evaluation and management guidelines is to serve as a recourse based on practical clinical information, current research, and scientific publications from which state medical and pharmacy boards may update any existing obesity management guidelines or requirements and remove antiquated codes or laws that do not represent current evidence-based clinical guidelines. Some state regulatory boards have evaluated physicians' bariatric practices that are based on PDR information that is more than 50 years old. As a result, some boards have taken action against physicians' licenses.

Overweight or obesity and associated metabolic conditions should be viewed on a chronic disease spectrum that produces life-threatening complications. In light of the current obesity epidemic, we believe it is not in the best interest of obese patients to place restrictions on the scientifically valid use of pharmacotherapy in the treatment of obesity.

## Pharmacologic Therapy in Overweight and Obesity

Obesity management should be treated similarly to Attention Deficit Disorder (ADD) in which schedule II controlled substances are frequently prescribed yet no special or detailed rules exist. Similarly, we believe that no specific rules are necessary for treatment of overweight or obesity with the much safer schedule III or IV anorectic medications. Years of experience and additional research have shown these medications

to be both effective and considerably safer than was recognized when the scheduling of anorectic medications was initially instituted.

The strict recommendations seen in the past regarding the use of anorectic medication are perhaps a result of the National Institute of Health's (NIH) review of 769 articles,[1] dates of which ranged from the 1980s to the early 1990s, at the height of phentermine/fenfluramine (phen/fen) prescribing. In a later report, [2] the NIH acknowledged that:

> "Pharmacotherapy, which has generally been studied along with lifestyle modification including diet and physical activity, using dexfenfluramine, sibutramine, Orlistat, or phen/fen, results in weight loss in obese adults **when used for 6 months to 1 year**." (p. 53) (emphasis added)
>
> "Since obesity is a chronic disorder, the short-term use of drugs is not helpful. The health professional should include drugs only in the context of a long-term treatment strategy." (p.86)

Although fenfluramine and dexfenfluramine were removed from the market, the other drugs cited were found to be useful in weight loss if used over a longer period of time. The NIH recommendations published more than ten years ago are outdated and do not reflect current medical knowledge. Sixty thousand (60,000) research studies on obesity have been published since the formulation of the NIH guidelines. A substantial and growing body of evidence suggests that treatment based solely on Body Mass Index (BMI) thresholds is inappropriate and that early, more aggressive treatment is warranted.[3] Other methods of measuring obesity-associated risk and excess adiposity are now available. Physicians should be allowed to treat patients with chronic illnesses based on the most recent evidence and modern thinking, whether it is in the treatment of hypertension, depression, glaucoma, or obesity.

Some examples of more modern thinking can be read in an excellent series of articles written by Dr. Bays in 2006. Dr. Bays discusses a pathological accumulation of fat in susceptible patients that he terms "dysfunctional fat" or "adiposopathy".[4-6] According to Dr. Bays "pathological abnormalities in fat function are more directly related to the onset of excessive fat related metabolic diseases (EFRMD)". Furthermore Dr. Bays explains that "in some cases, weight loss therapeutic agents may even affect metabolic parameters and adipocyte function independently of weight loss alone, suggesting that the benefit of these agents in improving EFRMD may go beyond their efficacy in weight reduction." (Reference: *Expert Rev. Cardiovasc. Ther.* 4(6), 871–895 (2006).

As research accumulates on more accurate descriptions of the etiologies and pathophysiology of obesity, more obesity interventions will be developed. This modern approach to the treatment of obesity incorporates medical intervention, dietary, behavioral, and pharmacologic (when indicated) treatments at an earlier stage of the disease and continues therapy for a longer duration of time. Also, aggressive surgical interventions are becoming more common and more appropriate in severe cases.

Overweight, overfat, and obesity are variations of a recurrent life-long disease that carries a high risk of diabetes, prediabetes, metabolic syndrome, cardiovascular disease and ultimately a risk of premature death and debility if left untreated.[7] Overweight and obesity in the U.S. have increased by more than 75 percent in the past three decades.[8] Patients seeking advice from bariatric physicians are typically told that they should expect a weight reduction of approximately 10 percent of their body weight over a six-month period. This can be accomplished by behavioral counseling, diet modification, exercise programs and medication. Weight loss leads to improvement of sleep apnea, diabetes, arthritis pain, improvement of lipids, reduced cardiovascular risk and an increased life expectancy. Also, it may be reasonable to continue some medication for a longer time in selected patients to assure maintenance of weight loss.

Phentermine has proven to be a safe, cost effective and highly successful medication in the treatment of overweight and obese patients.[9] Unfortunately, many of the current guidelines for prescribing it reflect recommendations that are more than 50 years old rather than current evidence of efficacy and safety. There has been an unrealistic and unjustified fear that phentermine is a highly addictive medication.

The Drug Abuse Warning Report of 2006 (DAWN) illustrates that anorectic medications have one of the lowest drug misuse/abuse rates per 100,000 emergency room visits -- even lower than Ibuprofen.[10] See reference below:

DAWN REPORT 2006

| **Drug** | **# of visits** | **Rate/100,000** |
|---|---|---|
| Antidepressants | 98,789 | 32.7 |
| Opiates/opioids specified | 279,510 | 92.5 |
| Opiates/opioids, unspecified | 55,674 | 18.4 |
| Amphetamine-Dextroamphetamine | 5,608 | 1.9 |
| Ibuprofen | 25,774 | 8.5 |
| Naproxen/combinations | 8,080 | 2.7 |
| Acetaminophen/combinations | 53,835 | 17.8 |
| Anticonvulsants | 36,467 | 12.1 |
| Antimigraine agents | 1,391 | 0.5 |
| **Anorexiants** | **1,327** | 0.4 |
| Total ED visits | 1,742,887 | |
| Total Drug Reports | 3,086,984 | |

## Duration of Pharmacologic Therapy

For the majority of the drugs included in the PDR, no duration of treatment is suggested. The duration of use of a medication in any patient is a matter of clinical judgment in each individual case. It is self-evident that putting time limits on use of medications used in treating a chronic illness is inappropriate when the risk of taking the medication is less than the risk of leaving the illness untreated. In the case of chronic diseases, the FDA does not dictate how long a physician can use insulin in a diabetic, an antihistamine in a patient with allergies, an anti-hypertensive in a patient with hypertension, or a benzodiazepine in a patient with anxiety, etc.

Even more pertinent are the statements regarding long-term use of drugs used in treating ADD in children. The PDR usage statements for these category II drugs do not limit the length of usage. The 2003 PDR entry for Ritalin states "patients requiring long-term therapy should be carefully monitored." This statement has been modified in the 2006 PDR, but there is still no injunction to halt therapy after a few weeks. The entry (2003 edition) for Concerta, a newer preparation of methylphenidate, states "the effectiveness of Concerta for long term use, i.e., for more than four weeks, has not been systematically evaluated in controlled trials. Therefore the physician who elects to use Concerta for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient." This too has been changed in the 2006 PDR, but the duration of therapy is left to the physician's discretion. The PDR entry (2006 edition) for Dexedrine (Glaxo Smith Kline's dexamphetamine), does not discuss duration of therapy except to state "when possible, drug administration should be interrupted occasionally to determine if there is a recurrence of behavioral symptoms sufficient to require continued therapy." The 2006 PDR entry for Adderall, another dextroamphetamine, has similar language. These are category II drugs. In fact, the PDR does not address limiting duration of medication usage for any chronic illnesses except for obesity.

Regarding the treatment of obesity, the ASBP believes that a restriction of medication for 12 weeks to treat this life-long chronic disease is unreasonable, just as a restriction that requires physicians to treat diabetes or hypertension for only 12 weeks is unreasonable. No such regulations exist that restrict ADD pharmacotherapy be limited to 12 weeks. Based on a national survey of ASBP membership, physicians report that anorectic medications are one of the more effective tools available to the clinician.[11] In another recently published study these medications were noted to be safe and effective over the long term.[12]

Weight loss is life saving for many patients, as evidenced by a Journal of the American Medical Association (JAMA) article in 2003.[13] According to this study a black male age 20 with a BMI of 45 will have a life expectancy of only 60 years. This patient would obviously benefit from aggressive treatment that would include diet, behavior modification, medication or even surgical intervention. Limiting treatment to 12 weeks would be detrimental to long-term survival and normal life expectancy.

Studies exist in the medical literature that support longer-term use of phentermine than the treatment recommended in the PDR. One such study suggests "Long-term pharmacotherapy when combined with appropriate behavioral approaches to improve diet

and increase physical activity, helps some obese patients lose weight and maintain weight loss for **at least a year**.[14] (emphasis added) The major promise of pharmacotherapy lies not in its ability to improve the amount of weight loss, but in its potential to enhance longer-term maintenance of weight loss with conventional therapies."[5] One continuing major barrier in the use of medication to treat obesity is "licensing boards that persecute physicians for alleged misuse of appetite suppressing drugs."[15]

In another study[12] patients were treated safely for more than 10 years of continuous use with phentermine. There was no abuse noted. Even the NIH states that as long as medicine is working, there is no time line on how long one should prescribe it.[16] As far as the perceived potential addictive properties of phentermine, in 49 years of world-wide use, there has never been a case of addiction reported in the peer-reviewed medical literature. (PubMed search 6/17/2008)

When phentermine was approved by the FDA in 1959, it was classified as a Category IV drug with potential for addiction because of the close similarity in molecular structure to amphetamine. Phentermine, in practice, has proven to have little or no potential for addiction. While addiction specialists have described well-defined addiction or abuse syndromes and withdrawal syndromes for cocaine, amphetamine and other stimulant substances, neither an addiction nor a withdrawal syndrome has ever been described for the category III or IV weight management drugs. (Diagnostic and Statistical Manual of Mental Disorders, DSM-IV). Phentermine does not create cravings for illicit drugs or alcohol in patients with a history of substance abuse. In fact, recent studies suggest that phentermine actually is beneficial in reducing cravings for alcohol and is promising as an adjunct to decrease cravings in patients recovering from cocaine addiction.[12]

Dr. Xavier Pi-Sunyer, one of America's pre-eminent obesity authorities, has stated "the image of drug therapy for obesity has been blemished by the past use of 'diet drugs' such as amphetamine, with harmful or addictive potential. Because amphetamine is addictive, it was presumed that the entire class of B-phenylethlamine compounds shared this trait. **However, other drugs in this class, namely phentermine and sibutramine have no abuse potential.**" (Emphasis added) Furthermore, he states that "obesity is a chronic relapsing disease for which there is no foolproof cure. Therefore pharmacological therapy should be viewed as a useful adjunct to lifestyle modification."[17,18]

## Off-Label Use

Physicians commonly prescribe a wide variety of drugs off-label; one recent estimate was that 21 percent of all prescriptions were for off-schedule use.[19] The same study found that 46 percent of cardiac drugs were prescribed off-label. In regard to off-label usage, the following is quoted from the forward of the 2008 edition of the Physicians' Desk Reference:

> "The FDA has also recognized that the FD&C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may choose to prescribe it for uses or in

treatment regimens or patient populations that are not included in approved labeling. The FDA also observes that accepted medical practice includes drug use that is not included in approved labeling."

Concerns that weight management medications are being prescribed off-label are out of place in view of the fact that the health risks of obesity are so serious. These drugs are now known to be safe and efficacious, particularly in the hands of well-trained practitioners. In a time when public support of patient-centered medicine is growing, it is inappropriate for public officials to place restrictions on the right of physicians and their patients to make informed choices in managing their health risks.

## Use in Maintenance

Utilization of anorectic agents for long term as part of a lifelong maintenance program, should be conditional on achieving a clinical response, which may be defined as: (1) loss of weight (fat mass) (an average of at least 1.4 kg per month of therapy has been suggested), (2) loss of 10 percent of maximum (non-pregnant) weight in a healthy patient qualifying for initiation criteria, or (3) loss of 5 percent of maximum (non-pregnant) weight in patients who are at increased risk because of associated co-morbidities. Several researchers, citing a number of articles, [19, 20] conclude that a 5-10 percent decrease in body weight can be clinically significant.

Williamson[21] has noted the tendency for obese patients to gain 0.5 – 1 kg of additional weight per year. Practicing bariatricians treating obese patients have noted the same weight gain tendency with age. Thus, for some patients stopping or at least slowing age-related weight gain may in and of itself constitute a clinical response. Paramount in the treatment with anorectic agents is the physician's responsibility for tailoring the therapy to the individual patient and appropriately documenting therapy and achievements in weight (fat mass) loss and patient health.

## Barriers to Appropriate Use

Currently, there are certain barriers to the appropriate use of anorectic medications. These include the following:

- **The perception by the public and some medical professionals that obesity is caused by lack of willpower.**
- **Anorectic medications are held to a higher standard in defining desired outcomes than are other medicines.**
- **The Schedule III and IV anorectics have a tarnished reputation because of their structural relationship to amphetamines and because of inappropriate prescribing by ill-trained or inexperienced physicians using the medications without a comprehensive program.**
- **There is an inappropriate fear of the "dangers" of anorectics and their potential for abuse by patients.**

- **Outdated information and rigid adherence to PDR labeling prevent appropriate "off-label" use of anorectics.**
- **Many physicians, because of a lack of treatment guidelines and the existence of outdated and/or antiquated federal and or state laws, fear regulatory retaliation if they prescribe anorectic medications.**
- **There has been a failure to recognize that adverse metabolic conditions may develop with even small amounts of fat gain or abnormalities in fat cell function.**
- **The positive psychological effect of weight loss and maintenance as an additional benefit of anorectic usage is often overlooked or ignored.**

These barriers will now be addressed individually:

- **Barrier: The perception by the public and some medical professionals that obesity is caused by lack of willpower.**

**Comment:** As noted by Weintraub and Bray,[22] "obesity is stigmatized and the obese are perceived as lazy, lacking willpower, and being less motivated than others. In a survey on societal views of obesity, students at Michigan State University indicated that they would prefer marrying a cocaine user, a shoplifter, or a Communist over marrying an obese person. The non-obese majority, having no difficulty controlling their weight, finds evidence for the character weakness of the obese in everyday life."

Accusations of gluttony have not been substantiated in a number of studies. In particular, the *Human and Nutritional Evaluation Survey I* (HANES I)[23] which surveyed, among other things, the eating habits of 20,749 individuals across the U.S., found that the obese actually ate *less* than their normal-weight counterparts. To lose weight and to maintain a reduced weight by means of caloric restriction, these individuals must reduce their food intake even further in relation to energy expenditure. To reach and maintain a normal weight, many obese people are forced to live with chronic hunger. Enduring this level of discomfort on a long-term basis is often more than the patient can bear and the weight is regained.

The regaining of lost weight tends to occur not only after the stopping of the anorectic agents but following the cessation of any weight control intervention, whether that involves diet alone, protein-supplemented fasts, exercise, jaw wiring, surgery or other means. Thus, a return back toward baseline weight is a normal response of the body and not related just to medication.

Not only is the treatment of obesity often unsuccessful from the patient's standpoint, but also is frequently demoralizing from the treating physician's standpoint. Someone has said that the physician usually buries his failures, but here is a living failure that keeps returning. For ego protection, the physician is prone to pass out a diet sheet with the admonition to push away from the table. When the patient is unsuccessful, the physician feels relieved of responsibility since the patient only needed to follow instructions, which the patient did not do. For many patients, the physician's advice

that eating less will cure obesity is about as helpful as telling hypertensive patients that relaxing will take care of their problem. Without additional help, change usually does not happen.

- **Barrier: Anorectic medications are held to a higher standard in defining desired outcome than are other medications.**

**Comment:** Weintraub and Bray [22] note, "the view that obese people need 'only to close their mouths' has caused us to demand a higher standard for medication use in treating obesity than we do for treatments of any other chronic condition. We accept the fact that serum cholesterol values will rise following cessation of therapy. We accept that ulcers will often recur following cessation of H2-blocking medications. We understand that rising intraocular pressure when pilocarpine treatment is stopped means that glaucoma has been controlled but not cured. Even in the absence of cure, patients and physicians still view ocular medication, anti-hypertensive agents, cholesterol-lowering medication, and H2-blockers as valuable. All of these failures to *cure* a problem of mal-regulation in human organisms are acceptable."

They continue, "obesity is the only analogous clinical setting where failure of medications to achieve cure is unacceptable."

- **Barrier: The Schedule III and IV anorectics have a tarnished reputation because of their structural relationship to amphetamines and because of inappropriate prescribing by ill-trained or inexperienced physicians using the medications without a comprehensive program.**

**Comment**: All anorectics are phenylethylamines. By definition, the Schedule II anorectic drugs are more stimulating and thus have more potential for street abuse. These medications are therefore not recommended for the treatment of overweight and obese patients. The Schedule III and IV anorectics offer acceptable alternatives with very little potential for street abuse.

In some cases, physicians and other practitioners have utilized anorectic medications *as* the treatment for obesity rather than using the anorectic medications *in* the treatment of obesity. The educational efforts of the ASBP through the years, plus the efforts of regulatory agencies, have substantially curtailed this type of activity. Therefore, these guidelines indicate that anorectic medications should only be used *in conjunction with* a program of weight management inclusive of behavior modification, nutritional counseling and appropriate exercise recommendations.

At a minimum treatment should include direct physician contact at the time of initiating therapy and at reasonable intervals thereafter. If local laws allow refills by a physician extender, the physician generally should be available for consultation regarding the patient.

- **Barrier: There is an inappropriate fear of the "dangers" of the anorectics and their potential for abuse by patients.**

**Comment**: Both short- and long-term studies have not validated these concerns. It is exceedingly rare for a patient receiving anorectics in a reasonably supervised program to demonstrate even psychological dependence. However, some patients may need the anorectic medications on an ongoing basis to help achieve the needed reduction in food intake.

Although the majority of the published anorectic studies have run for no more than 12 weeks, there are a number of studies that have continued treatment for longer periods of time. These studies indicate both the safety and effectiveness of the anorectic medications. Douglas and Munro,[24] and Sullivan and Comai[25] and Goldstein and Potvin[26] in their review articles cite multiple reports of the continuous use of anorectics for 14 to 60 weeks. In addition, these review articles summarize adverse effects of the Schedule III & IV anorectics as adapted from Bray.[27] Side effects occasionally seen with Schedule III and IV anorectics are nervousness, insomnia, headaches, dizziness, nausea and constipation. With appropriate starting doses, attentive monitoring and judicious dosage titration depending upon a patient's clinical response, even these listed side-effects can be avoided in most cases.

In 1992 Michael Weintraub, MD,[28] of the University of Rochester School of Medicine and Dentistry, published a study using anorectic medications for up to three and one-half years in the treatment of obesity. In this study patients utilizing active medication lost more weight than those on placebo. There was no tolerance or drug dependence noted and relatively few side effects.

Richard & Lasagna[29] cite the Griffiths, et. al.,[30] review of the literature on five Schedule III and IV anorectic drugs which concluded that they "were all associated with relatively low or zero anorectic-reinforcement ratios: "Clinically, all of the latter five compounds have anorectic properties...there are, however, relatively few case reports involving abuse of these drugs."

Considering the large amounts of Schedule III and IV anorectics that have been prescribed in the U.S. and abroad, the reported incidents of serious side effects is low indeed, and in some of the case reports, it is impossible to establish for certain that the anorectic medications are primary causes of the reported incidents.

- **Barrier: Outdated information and rigid adherence to PDR labeling prevent appropriate "off-label" use of anorectics.**

**Comment:** Until 1999 anorectic medication labeling had not changed significantly since 1974. The original labeling with recommendations dating from 1974 was generally based on short-term studies (12 weeks or less) and was the result of negotiations between the drug companies and the FDA. The studies on what this labeling was based included about 200 double blind studies, which were analyzed by

Scoville of the FDA.[31] These indicated weight loss of about one pound per week with the anorectic medications versus 1/2 pound per week with the placebos. Using the anorectics for only a few weeks may indeed make the results trivial.

Since that time, a number of long-term studies, as noted previously, have been completed and testify to both the efficacy and safety of the anorectics when used on a long-term basis. More than 50 percent of the members of the ASBP responding to a society survey have had patients on anorectic treatment for time spans measured in multiple years without significant side effects occurring.[11]

2008 ASBP Survey
Poster v3 (2).pdf

The North American Association for the Study of Obesity has stated in their *Guidelines for the Approval and Use of Drugs to Treat Obesity:*[32]

> "Tolerance is a misnomer if a medication continues to have a sustained effect in maintaining a lower body weight. As long as a drug helps to maintain a significant clinical response the medicine should be considered efficacious, even if no further additional weight loss occurs. Continuation of the medication and the dosage should depend on maintaining a beneficial balance between the health benefits of the maintenance of weight loss and the side effects of the medicine."

Albert Stunkard,[33] professor of psychiatry at the University of Pennsylvania Medical School, argued as early as 1982 that appetite suppressants act primarily by lowering the body weight set point and only secondarily by suppressing appetite. The evidence, he contends, does not support the development of tolerance to the anorectics. He concludes that regarding appetite suppressant medication, patients should "use it on a chronic basis or not at all." He later stated in the publication *The Salmon Lecture-Some Perspectives on Human Obesity:*[34]

> "For many years it has been established practice to prescribe appetite suppressant medication for only limited periods of time. The evidence for this belief is obscure, and a set point interpretation of tolerance makes clear its limitation. In terms of body weight, tolerance to appetite suppressants does not develop, which means that the old argument against their use (a loss of efficacy) is no longer valid. These agents retain their efficacy. Paradoxically, it is precisely this maintenance of efficacy that argues against their short term use.
>
> "If any benefits of appetite suppressants are lost when the medication is discontinued, then such medication should not be used on a short term basis. Current policy appears to be diametrically opposed to rational use of appetite suppressant medication, and current practice appears wholly unwarranted.

Furthermore, the myth of tolerance seems to have prevented use of appetite suppressants in precisely those situations in which they are indicated which is over the long term.

> "There are strong positive indications for the long term use of appetite suppressants. Many obese hypertensive and diabetic patients can control their conditions by weight loss. Unfortunately, however, many of them cannot lose weight by diet alone. As a result, they are forced to rely on long term use of medication to control their hypertension, diabetes, and other conditions. If these patients must receive long-term medication, they may well be better off on appetite suppressants than on the usual remedies. At the very least, weight loss will control their complications in a more physiologic manner. Over the long term, the risks of treatment with appetite suppressant medication may be less than those of the medications they are now taking. Long term studies of the safety of appetite suppressant medication are needed. If they can be shown to be safe, major changes in the treatment of obesity-related disorders could result."

Douglas and Munro[24] summarize some of the long-term studies with mean durations running from 10-16 months. They write:

> "A number of studies have suggested that diethylpropion, phentermine, fenfluramine and mazindol can be given for periods of up to several years with reasonable safety and without weight regain occurring. As the risk increases with the degree of obesity, long term therapy could be most readily justified in the most overweight."

Even though use of long-term and combination anti-obesity medications does not appear in FDA approved labeling of the drugs involved, it is consistent with the American Medical Association's (AMA) policy of off-label use.[35] It is the consensus of the ASBP that short-term labeling for other anti-obesity pharmacological agents should be updated. However, since there are insufficient monetary incentives for long-term pharmaceutical studies of generic anorectic medications, such studies are unlikely to occur.

Although not described in approved labeling, it may be appropriate to use anti-obesity agents in combination with one another or with other medications (e.g. anti-depressants), which has been described in various articles, books and shared clinical experiences. A recently published article of a multi-center survey among ASBP members, studied varied combinations of sympathomimetics and SSRI and other antidepressants (excluding monoamine oxidase inhibitors MAOI's) and found not one documented case of the feared serotonin syndrome from combining the medications.[36] Such use is consistent with the FDA policy as elucidated in the Physicians Desk Reference:

"The FDA has also recognized that the FD&C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may choose to prescribe it for uses or in treatment regimes or patient populations that are not included in approved labeling. The FDA also observes that accepted medical practice includes drug use that is not reflected in approved drug labeling."

- **Barrier: Many physicians, because of a lack of treatment guidelines and the existence of outdated and/or antiquated federal and or state laws, fear regulatory retaliation if they prescribe anorectic medications.**

**Comment:** Unfortunately, fear of confrontation with regulatory agencies is often a barrier to the appropriate use of controlled drugs. Since the introduction of the original *Anorectic Usage Guidelines* in 1990 and in light of recent medical and scientific research and opinion, several state medical regulatory agencies have changed previously outdated and antiquated policies overly restricting or banning anorectic medications. The ASBP is proud to have been the first major organization to advocate for the patient to both the medical community and state regulatory agencies regarding modern day pharmacological treatment of obesity. In producing this set of peer-reviewed guidelines, ASBP hopes to continue to educate those involved in the treatment of obesity and those involved in the regulation of obesity evaluation and management.

- **Barrier: There has been a failure to recognize that adverse metabolic conditions may develop with even small amounts of fat gain or abnormalities in fat cell function.**

**Comment:** BMI, although a reasonable epidemiologic measurement tool, does not measure any specific metabolic abnormality. Therefore BMI alone may not be the best tool for deciding appropriate weight loss therapy. The potential benefits of weight control or weight maintenance, including the use of antiobesity agents should be considered appropriate at any weight where metabolic or other conditions pose present or future health risks to an individual.

Bays, et.al.[3] document that in some individuals, excess fat related metabolic diseases (EFRMD) may occur in individuals who are overfat and in individuals with normal fat amounts but abnormally functioning fat, but still within ranges considered to be normal weight. Anti-obesity agents may play an important role in usage in these individuals.

Obesity and the metabolic conditions associated with obesity should be viewed as a disease spectrum. To preclude the treatment of overweight or the metabolic abnormalities associated with abnormal functioning adipose tissue with any means available could be compared to not treating hypertension to prevent ischemic heart disease or congestive heart failure. Therefore, using BMI alone as qualifying criteria

for treatment would restrict treatment from many individuals who would otherwise benefit from it.

As noted previously there is a tendency for untreated overweight individuals to gain one and a half to three pounds or more a year until senility is reached, after which there may be some spontaneous weight loss. Hence, the prevention of weight gain may be warranted particularly if the patient has co-morbidities or if the patient's close relatives tend to develop diabetes mellitus and/or to become significantly more obese as they age.

- **Barrier: The positive psychological effect of weight loss and maintenance as an additional benefit of anorectic usage is often overlooked or ignored.**

**Comment:** The Lasik procedure is used so that patients with otherwise perfectly good eyes can discard their glasses. Botox is used repeatedly over time to temporarily erase skin wrinkles. Plastic surgeons perform cosmetic surgery or liposuction. Human growth hormone has been approved for repeated injections into short children to modestly increase height. None of these procedures is without risk. None of these procedures reduce health risks. Yet all are considered ethical treatments because they add to the quality of life. Similarly, helping modestly overweight patients attain and maintain a more cosmetically pleasing weight may appropriately, in and of itself, be considered a clinical response.

Over the past several decades obesity has moved from being considered a problem of gluttony to that of being an illness or a disease. It is now time to consider that it is not just a health problem but also a cosmetic problem worthy of being addressed on that basis.

# Overweight and Obesity
# Evaluation and Management Guidelines

**The American Society of Bariatric Physicians Guidelines on Overweight and Obesity Evaluation and Management (approved 2009) replace the Anorectic Usage Guidelines statement on the use of Schedule II, III & IV controlled anorectics in the treatment of obese patients as approved by the ASBP Board of Trustees in 1990, and revised October 17, 1996, December 4, 1998, October 4, 2000, and January 30, 2004.**

These guidelines on overweight and obesity evaluation and management replace and supersede any and all previous ASBP position statements and/or guidelines on the use of Schedule II, III & IV controlled anorectics in the treatment of obese patients. These guidelines are not intended to endorse the use of controlled substances, but rather to recognize appropriate use of these medications as part of a comprehensive bariatric program. Obesity is a chronic condition that may be controlled but is rarely cured. For most patients, optimal results will not be achieved on a short-term basis. Long-term treatment and follow-up of months to years may be required.

**The bariatrician must not rely on these guidelines, or on any other guidelines to provide an infallible blueprint for patient treatment. It is not the intent of these guidelines to limit the bariatrician's right to alter the therapy based on the patient's condition, medical problems or therapeutic response. These guidelines are not intended to provide specific requirements to be followed by the treating bariatrician.**

Because of the Schedule II anorectics' potential for street abuse and the acceptable Schedule III & IV alternatives, the ASBP feels that there is currently no indication for the use of the federally regulated Schedule II anorectics in any obesity treatment program. When properly used as part of treatment for obesity, and not as a sole treatment for obesity, Schedule III & IV anorectic drugs (anorectics) can often be useful in helping patients to lose weight and to maintain a reduced weight. The Schedule III and IV anorectics by definition have a low-level of risk and little potential for addiction or psychological dependence when carefully prescribed by a physician in a properly supervised medical practice.

The bariatrician should weigh the benefits and risks of any treatment modality or medication used. Significant sources of information to direct therapeutic interventions include but are not limited to published clinical trials in medical literature; presentations at medical meetings; recommendations of respected independent university-based reviewers and colleagues; practice-based, carefully evaluated clinical experience derived from treating other patients; anorectic labeling and textbook information. All of these sources can provide information, but no single source should be used to the exclusion of others. Unfortunately, the information contained in standard textbooks is often out of date. In addition, it should be noted that while anorectic labeling may be helpful, it is

simply another source of information that often does not reflect the latest published data. Labeling is a legal document developed by lawyers from the Food and Drug Administration and the manufacturer of the medication. Therefore, while ostensibly based on reliable data, often legal issues supersede medical and scientific issues. ASBP advises all practitioners to be fully aware of local and state medical and pharmacy boards and federal regulations involving the treatment of obesity.

These guidelines provide suggestions for the work-up and follow-up of the bariatric patient. They are not intended to replace, and indeed cannot replace, the bariatrician's judgment regarding a particular patient's treatment. Neither are they intended to represent legal requirements for providing good medical practice. The bariatrician is the one most capable of determining what is or is not appropriate for an individual patient.

## A. Initial patient work-up

The course of treatment should be based on the patient's history, appropriately completed physical examination, laboratory work and other testing as indicated.

1. *History*

   A history of each patient should be taken and recorded. It should include an evaluation of dietary status, a weight history and a history of mental status. Whenever this is a self-fill-in or computerized history, or one taken by assistants, the bariatrician should personally evaluate significant positive responses and make appropriate notations.

   Items considered appropriate for medical history should be obtained and document and may include but are not limited to:

   - Patient's and caregivers' stage of readiness to change
   - Past medical and surgical history
   - Co-morbid medical conditions
   - Social history
   - Mental health history
   - Review of systems
   - Weight history
   - Dietary history
   - Substance abuse history
   - Family structure
   - Prior eating disorders
   - Focused family history related to obesity
   - Present physical activity level
   - Food and drug allergies and intolerances
   - Current supplement consumption
   - Current medications
   - Past medication known to affect weight
   - Prior prescribed medications for weight loss
   - Current primary care provider
   - Source of referral
   - Patient's goals

**A. Initial patient work-up (continued)**

2. *Physical examination*
   Items considered appropriate for physical exam should be examined or obtained and documented and may include but are not limited to:
   - General appearance
   - Height
   - Weight
   - Blood pressure
   - Pulse
   - Head and neck exam
   - Thyroid exam
   - Lung exam
   - Cardiovascular exam
   - Abdominal exam
   - Abdominal circumference
   - BMI
   - Extremity exam
   - General neurologic exam
   - Body composition testing of some type (examples: waist to hip ratio, bio-impedance, infra red, Dexa-scanning)

**A. Initial patient work-up (continued)**

3. *Diagnostic studies*
   When prior medical records can be obtained indicating any of the diagnostic studies have recently been completed, the bariatrician may avoid unnecessary duplication by performing only those exams needed to complete the bariatric work-up.

   a. Laboratory work
      Items considered appropriate for initial laboratory testing may include but are not limited to:
      - Comprehensive metabolic profile including basic chemistries including glucose, lipid profile, CBC and liver function testing
      - Thyroid functions including TSH and free T4

   b. Electrocardiogram
      ECG is required if there is reasonable evidence of present or past significant cardiac disease. In addition, the potential value of an ECG should be considered if coronary heart risk factors are present, e.g. hypertension, hyperglycemia, dyslipidemias, metabolic syndrome or a strong family history of cardiac disease. A personal history of syncope unexplained or a family history of unexplained death under age 40 may indicate a risk for prolonged Qtc syndrome, and in this situation an ECG should strongly be considered.

   c. Other optional tests
      Items considered appropriate for optional testing may include but are not limited to:
      - A fasting and/or two-hour insulin test
      - Two- or three-hour Glucose tolerance testing with insulin levels
      - Hemoglobin A1c
      - Vitamin D level
      - Advanced lipid testing
      - B12 level
      - RBC Folate level
      - 24-hour urinary cortisol or other form of cortisol testing
      - Prolactin level
      - Cardiac stress testing
      - Sleep apnea study
      - Physical fitness testing
      - Advance psychological testing
      - Echocardiogram

**A. Initial patient work-up (continued)**

4. *Initial patient management*
   Education may be done individually or in a group setting, and may be done by appropriate clinic staff as determined by the clinic supervising MD.

   Items considered appropriate for initial patient management may include but are not limited to:
   - Review history, physical findings and laboratory data
   - Establish and document a diagnosis list or problem list
   - Obtain written informed consent
   - Determine need for additional testing
   - Determine age-appropriate goals for weight loss and review patient's own goals
   - Provide a nutritional plan (see patient counseling dietary therapy below)
   - Recommend a food diary
   - Identify appropriateness for medication therapy
   - Educate regarding:
     - Appropriate eating habits
     - Exercise
     - Behavioral modification
     - Complications of overweight and obesity.
     - Benefits, risks and possible side effects of medication if used
     - Role of vitamins, minerals, and hormone balance
   - Discuss and document surgical options when appropriate.
   - Establish initial follow-up schedule

   Patient Counseling

   a. Dietary therapy
      ASBP recognizes that multiple studies exist of the advantages and disadvantages of different nutritional weight loss plans.[37,38,39] These types of nutritional therapy may include any combination of macronutrient guidelines, including controlled calorie, controlled fat, controlled carb, adequate protein and any combination of fixed meal plan programs and free choice meal planning. **It is unlikely that one diet is optimal for all overweight and obese people. Dietary guidance should be individualized to allow for specific food preferences and individual approaches to reducing energy intake.**

      Dietary needs may change as the patient loses weight. Several options of plans might be made available to the patient. In 2007 the American Diabetes Association included a low carb diet as appropriate along with controlled calorie diets in working with diabetics.[40]

b. Exercise therapy

The importance of physical activity and weight loss maintenance is well documented.[41,42] ASBP recognizes there is no definite recommendation that works for all people and the exercise advice should be individualized to the likes and needs of each individual patient. However, ASBP recognizes the American College of Sports Medicine's advice that people should participate in approximately 30 or more minutes of physical activity on most days of the week.[42]

c. Maintenance, relapse prevention, and treatment counseling

Any bariatric program must include a maintenance plan for long-term weight management. Strategies for life-long weight maintenance include counseling for the patient, ideas, actions and therapeutic involvement to prevent regain. An intervention plan must be in place when relapse and weight gain occurs. The long-term nature of obesity should be emphasized to any patient at the start of any weight loss program.

d. Medications and other therapeutic modalities (see section B)

**A. Initial patient work-up (continued)**

5. *Ongoing patient management*
   Items considered appropriate for ongoing patient management should be evaluated and documented and may include but are not limited to:
   - Progress of weight loss or maintenance of loss
   - Changes in eating behaviors
   - Changes in activity level
   - Effectiveness of pharmacotherapy
   - Monitor for side effects of medications
   - Monitor for side effects of weight loss
   - Monitor for needed changes in routine medicines affected by weight loss
   - Develop a long-term monitoring and relapse prevention and intervention program
   - Review food diaries when indicated
   - Reassess patient's long term goals and objectives
   - Establish regular follow-up schedule

   a. Interval between visits
      Following the initial visit, patients should be seen by the bariatrician at reasonable intervals. The frequency of these visits may vary from bariatrician to bariatrician and from patient to patient within a single practice. The most common frequency of return bariatric visits in the U.S. is four weeks for patients receiving anorectics. With more severe calorie-restricted, carbohydrate-restricted, or ketogenic diets, the visit interval may be shorter.

      Regardless of the interval between patient visits, the therapy of a patient receiving anorectics requires active involvement by the bariatrician, including reasonable availability between patient visits both during weight loss and during maintenance.

   b. Ongoing services
      The patient should be weighed and have pulse rate and blood pressure checked on follow-up visits, all of which may be performed by a qualified assistant or nurse. The bariatrician should inquire about and evaluate potential medical problems or side effects of the treatment program and/or the anorectics and give appropriate medical counsel or treatment. Physiologic parameters, which could be affected by anorectic use, should be assessed from time to time by the bariatrician, and appropriate notations should be made in the patient's records by the bariatrician. Notations in the records by the nurses or assistants may also be appropriate.

      Bariatrics is the practice of medicine by physicians relating to the treatment of obesity and associated conditions and requires direct doctor-patient contact, even though it is legal in some states to delegate the initial exam and follow-up visits to the nursing staff. At a minimum, treatment should include direct

physician contact at the time of initiating therapy and follow-up by a qualified physician at reasonable intervals thereafter consistent with local standards of care. If follow-up visits are delegated to legally recognized physician extenders, the supervising bariatrician should be available for consultation regarding the patients.

In addition, the patient should receive counseling from the bariatrician and/or the nurses or assistants as indicated regarding the nutritional, behavioral, exercise components and psychological aspects of the treatment program.

c. Laboratory follow-up
Some bariatricians assume a primary care role for the patient while others limit their care more narrowly to the obesity-related issues. Either style is appropriate as long as the patient is clear about the limits of the doctor-patient relationship. Generally, those patients in extended treatment whose laboratory tests have been normal should have these tests repeated at twelve-month intervals. Abnormal values may require more frequent monitoring or referral for follow-up. If the patient has laboratory testing done by an outside laboratory or physician, the bariatrician should record the results in the patient's record when results are made available.

## B. Medications and other therapeutic modalities

The bariatrician should weigh the potential benefits and risks of any medication or modality used. Significant sources of information include these ASBP OOEM guidelines, journal articles, experiences of colleagues, textbooks, and personal education training and experience. Each of these sources may provide valuable information, and no single source should be used to the exclusion of others.

When appropriate, the bariatrician should provide information on the benefits and risks of the proposed treatment modalities to be used and should inquire as to the patient's understanding of the benefits and risks.

When medications are dispensed, they should be packaged and labeled in accordance with applicable laws and statutes, and appropriate records should be kept.

1. *Informed Consent*

   Although the risks associated with the use of anorectics in a prudent manner for weight reduction and weight maintenance are very low, these risks have been more thoroughly evaluated in the dosages and for time periods indicated in the anorectic labeling. Although the probability of psychological dependence is low when anorectics are used in medical weight reduction and maintenance programs appropriately supervised by bariatricians, there should be an awareness of this possibility and the patient should be monitored accordingly, especially when anorectics are used in higher doses and/or on a long-term basis. Monitoring for non-therapeutic use, diversion to unsupervised individuals, and observation for signs of psychological and physical dependence should be ongoing.

   When the anorectics are used in doses exceeding labeled recommendations and suggested treatment time periods and/or in combination therapy, it is suggested that the bariatrician inform the patient that the anorectics are being used in an "off-label" manner, and as such the risks associated with this type of usage have been less systematically evaluated and thus, may be increased over the risks seen with usage in compliance with labeled suggestions. A suggested form of notification to the patient could be through a consent form prepared in cooperation with the bariatrician's professional legal advisors. Such consent form, if used, should be signed by the patient and should indicate the patient's awareness of alternative therapies, possible increased risks associated with off-label use of the anorectics and the patient's explicit decision to proceed with the proposed treatment plan.

**B. Medications and other therapeutic modalities (continued)**

2. *Initiation of anorectic medication therapy*
   At the time of this update, there are no universally accepted minimum criteria for appropriate usage of anorectic agents. The scientific and medical community is well aware that there are multiple factors contributing to obesity, as well as several physiologic parameters, which have been shown to contribute to increased health risks (morbidity and mortality). Such parameters may include ideal body weight (Metropolitan tables), BMI, percent body fat, visceral fat distribution, waist circumference, and/or waist-to-hip ratio. These should be taken into account by the bariatrician and patient considering anorectic agent therapy.[43,44] It is recognized that BMIs may appear high in athletic individuals who are not obese and low in individuals with a low lean body mass (sarcopenia). Therefore, BMI must be combined with clinical correlation.

   It is important to realize that the minimum age of treatment with medication is unknown. Unfortunately, adolescent and childhood obesity has increased dramatically in the U.S. since the 1960s. Adult-related obesity conditions are now commonly diagnosed in adolescence. Therefore, it is up to the individual medical provider to determine a safe age to begin use of anorectic medication in children and adolescents based upon careful historical and physical examination and review of individual patient risks and benefits of such intervention.

   a. Initial parameters
      The ASBP recognizes that there are several acceptable anorectic agent usage criteria for patients including but not limited to at least one of the following parameters:
      - BMI ≥ 30.0 in a normal, otherwise healthy individual
      - BMI ≥ 27.0 in an individual with associated co-morbidities (e.g. type II diabetes, hypertension, abnormal glucose tolerance, atherosclerosis, cardiovascular disease, stroke, hyperlipidemia, hypercholesterolemia, osteoarthritis, gall bladder disease, breast cancer, or sleep apnea)
      - Current body weight ≥ 120 percent of a well documented, long-standing, healthy weight that the patient maintained after age 18
      - Body Fat ≥ 30 percent in females
      - Body Fat ≥ 25 percent in males
      - Waist-hip ratio or waist circumference such that the individual is known to be at increased cardiovascular and/or co-morbidity risk because of abdominal visceral fat
      - Presence of a co-morbid condition or conditions aggravated by the patient's excessive adiposity

      Anorectic agent use may also be appropriate in a number of other situations including but not limited to:
      - Prevention of regain in a person who has lost weight,
      - Occupational needs for maintaining a low body weight,

- Prevention of weight gain in patients with a familial/genetic predisposition to obesity and associated co-morbidities.

b. Dosages
Since there are significant differences in response by various patients to medications, including the anorectics, initial doses should be conservative and should be increased step wise, if and only if needed, and provided there are no significant adverse side effects related to the anorectics.

Dosages suggested on anorectic labeling are primarily based on information obtained from the relatively short-term studies done prior to their approval by the FDA. As such, these dosages may not be appropriate for longer-term therapy. If a clinical response is obtained, it may be appropriate to increase the dose of anorectic medication over time. The bariatrician must determine the magnitude of increased dosages on an individual basis. Bariatricians utilizing dosages in excess of labeled dosages and/or for periods exceeding labeled suggestions and/or using anorectic agents in combination with one another or in combination with other medications are under an additional duty to carefully monitor the patient's progress and potential problems and to continue weighing the benefits and risks associated with the increased dosage and/or longer treatment periods. The decision to use any medication in a specific way should be appropriately documented in the patient's medical record.

c. Use of anorectic medications in obese patients having associated medical conditions
Certain medical problems often associated with obesity, such as diabetes, hypertension and most serum lipid abnormalities, usually respond favorably to weight loss. The anorectics may be useful in helping patients with these conditions achieve meaningful weight loss. *The NIH guidelines for usage of medicines for weight loss use the presence of co- as indication to use medicines at a lower beginning weight.*[43] As noted by Albert Stunkard, M.D., Professor of Psychiatry, University of Pennsylvania:

> "There are strong positive indications for the long term use of appetite suppressants. Many obese, hypertensive and diabetic patients can control their conditions by weight loss. Unfortunately, however, many of them cannot lose weight by diet alone. As a result, they are forced to rely on long term use of medication to control their hypertension, diabetes, and other conditions. If these patients must receive long term medication, they may well be better off on appetite suppressants than on the usual remedies."

The ASBP suggests that the bariatrician carefully weigh the benefits and risks of using anorectics with these patients and if the choice is made to use them, recommends the following:

- Diabetes
  The anorectics may be of value in helping obese patients with diabetes achieve and maintain a meaningful weight loss. Reductions in food intake, carbohydrate intake, and in body weight may reduce the need for insulin and/or hypoglycemic agents. The bariatrician should be alert to these possible changes and their management. The patient should be counseled accordingly. *This condition requires closer monitoring and must include counseling on the prevention and risks of hypoglycemic reactions as well as appropriate medication adjustment by either the bariatrician or primary care physician. Clear communication between these physicians regarding who is responsible for monitoring medication response and changing dosage is required.*

- Serum dyslipidemias
  Obese patients with dyslipidemias are best treated with appropriate dietary changes and weight reduction. The anorectics may well be of value in helping these patients to achieve appropriate dietary changes, weight reduction and weight maintenance.

- Hypertension
  Sympathomimetic amine anorectic-induced hypertension has never been described in the peer-reviewed medical literature. Although there is a widely-held opinion that sympathomimetic amine anorectics induce increases in blood pressure, yet no evidence to support this hypothesis has ever been published. In fact, data from clinical trials with phentermine and diethylpropion indicate that blood pressure falls as patients lose weight just as blood pressure falls in patients who lose weight without pharmacotherapy.

  In considering anorectics in obese patients, bariatricians should be aware of the JNC 7 blood pressure diagnostic categories: optimal or normal BP 119/79 or less; prehypertension BP 120-139/80-89; hypertension BP $\geq$ 140/90; Stage I hypertension BP 140-159/90-99; Stage II hypertension BP $\geq$ 160/100. Typically blood pressures in obese patients with pre-hypertension and hypertension fall if they lose weight. Anorectics may be used safely in obese patients with optimal BP or pre-hypertension. They may also be safely used in patients with either stage I or stage II hypertension on anti-hypertensive medication provided the blood pressure is in control and at or below 140/90 when an anorectic is prescribed. Caution should be exercised in prescribing a sympathomimetic amine anorectic to patients with untreated hypertension. Bariatricians should consider either waiting for weight loss to lower blood pressure or prescribing a diuretic first to lower blood pressure and then adding an anorectic when blood pressure is at or below 140/90. Hypertensive patients on anti-hypertensive medication who omit their medication on the day of examination can be expected to have a blood pressure > 140/90.

Anorectics may be prescribed in such patients with the admonition that they must take their blood pressure medication daily, monitor their own blood pressure and omit the anorectic if their BP is > 140/90. These cautions are suggested more to protect the bariatrician from criticism and censure rather than to protect the patient since there is no evidence that sympathomimetic amine anorectants in therapeutic doses affect blood pressure or any other cardiovascular parameter.

- Cardiovascular disease
  Although there is no evidence anorectics have any effect on cardiac status, many physicians assume otherwise. To protect themselves against criticism or censure, bariatricians should exercise caution in prescribing anorectics in patients with known cardiovascular disease, monitor such patients carefully, and obtain cardiology consultation when appropriate.

  If a pre-treatment ECG is obtained, the Qtc should be evaluated. It had previously been propagated among bariatric practitioners that the upper limit Qtc for anorectic therapy was 440 msec. However, extensive review of medical literature and discussions among practitioners have proven that using Qtc 440 msec is not justifiable or supported in the medical literature. Although a PubMed search does not document any connection between anorectic usage and prolongation of Qtc, an acceptable approach that could be supported includes:

**QTC INTERVALS**

| | 1 to 15 yrs. | Men | Women |
|---|---|---|---|
| **Normal** | 0.44 sec | <0.43 sec | <0.45 sec |
| **Borderline** | 0.44 to 0.46 sec | 0.43 to 0.45 sec | 0.45 to 0.47 sec |
| **Prolonged (upper 1%)** | >0.46 sec | >0.45 sec | >0.47 sec |

**If normal, no contraindications.**

**If borderline**

**No hx of syncope or unexplained family sudden death < age 40**

**Evaluate and add supplement if appropriate: Potassium, Calcium and Magnesium prior to prescribing sympathomimetic anorectic agents.**

**POSITIVE Hx of syncope or unexplained family sudden death < age 40**

**Withhold sympathomimetic anorectic agents for the first month of therapy. Evaluate and add supplement if appropriate: Potassium, Calcium and Magnesium prior to prescribing sympathomimetic anorectic agents. Repeat ECG in one month and check for normalization.**

**If prolonged**

**No hx syncope unexplained family death < age 40**

**Delay prescribing sympathomimetic anorectic agents. Evaluate and add supplement if appropriate: Potassium, Calcium and Magnesium prior to prescribing sympathomimetic anorectic agents. Repeat ECG in one month**

**POSITIVE hx syncope or family sudden death**

**Withhold sympathomimetic anorectic agents and refer for cardiac workup.**

## References for Qtc


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3. Haning W, Goebert D. Electrocardiographic abnormalities in methamphetamine abusers. Addiction (Abingdon, England) 2007;102 Suppl 1:70-5.
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- Psychiatric Disorders

  The obese patient may be prone to depression. In such cases the anorectics may be helpful in the patient's weight loss program, which in turn may help with the depressive state. Patients with significant depressive symptoms should be considered for antidepressant therapy. If antidepressants or other psychiatric drugs are used concurrently with anorectics, the patient should be monitored for potential drug interactions and adverse effects.

## B. Medications and other therapeutic modalities (continued)

3. *Continuation of anorectic medication therapy*
   The continuing use of anorectics should be based on the patient's response to treatment and on an ongoing beneficial benefit-to-risk ratio. Benefit is assumed if the patient is actively losing weight or maintaining an amount of loss associated with statistical reduction of associated risks (five to 10 percent of initial body weight has been shown to provide such benefit).[20] In addition, prevention of weight regain is an appropriate use of medications. In some patients an anorexiant drug may prevent weight gain without producing weight loss. The anorectic drug may be continued if the bariatrician and the patient agree an anorectic is beneficial in preventing weight gain. Bariatric care should be patient-centered; decisions regarding benefit/risks should always be decisions between the physician and the patient.

   As discussed previously in this document and supported by numerous studies and references, long-term sympathomimetic usage for weight loss and relapse prevention and intervention is justifiable and medically indicated.[11,12,14,15,19,20,22,24,26,28,32,33,34,35,36,]

   The AMA states in its 1995 policy and compendium, "the AMA reiterates that it is appropriate and legal for physicians to prescribe approved drugs for uses not included in their official labeling when they can be supported as rational and accepted medical practice."

   **It is important that the patient not feel abandoned during any period of non-anorectic use. Other appropriate therapies may be indicated and on-going support should be continued.**

4. *Health benefits associated with fat loss*
   Although ideally the bariatrician would like to have obese patients lose and maintain a normal weight, this frequently does not happen. However, the evidence is increasingly strong that significant health benefits may occur with a five to 10 percent weight loss that is maintained.[20] In addition, helping patients avoid the tendency to gradually increase weight while getting older may, in and of itself, be a significant health benefit. Also, even a modest weight loss is frequently associated with an increased sense of self worth.

## Conclusions

The Overweight and Obesity Evaluation and Management Task Force of the ASBP respectfully submits this product of work following months of efforts and numerous contributions from the ASBP Board of Trustees for consideration for adoption as the ASBP Overweight and Obesity Evaluation and Management guidelines.

## *Disclaimer*

These guidelines are an educational tool designed to assist practitioners in providing appropriate bariatric care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the ASBP cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources or advances in knowledge or technology subsequent to the publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. It should be recognized; therefore, that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

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The OOEM guidelines were developed by the OOEM task force. The guidelines were evaluated, amended, and revised a total of 17 times prior to achieving the final document. ASBP would like to thank the following for their contributions to these guidelines.

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