

STATE BOARD NEWS -- AUGUST 1997 ISSUE
(State Section Only)

LICENSE RENEWAL - 1997-1998

By the time you receive this Newsletter, you should have received the forms to renew your Ohio pharmacist or pharmacy intern license for 1997-1998. If you have not received them by August 15, 1997, contact the Board office immediately at 614/466-4143. Your current license to practice pharmacy in Ohio expires on September 15, 1997. The renewal application must be received at the Board office prior to that date so that you may continue to practice pharmacy in Ohio.

UPCOMING BOARD-APPROVED JURISPRUDENCE PROGRAM:

Cincinnati Police Division / Pharmaceutical Diversion Squad
(Call John Burke or Carol Guffey at 513/352-1610 for details and application)
Drugs of Abuse and the Health Professional - "Avoiding the Pitfalls"
October 14, 1997 - 6:00 p.m. - Cleveland, Ohio

AMENDED RULES EFFECTIVE JULY 1, 1997

Patients and their Prescriptions

Ohio Administrative Code Rule 4729-5-24 (Prescription copy) was amended by the Board during the June 1997 meeting. The Board originally adopted this rule in 1971 in recognition of the fact that the information on a prescription is the property of the patient for whom the prescription was issued.

The Ohio Board of Pharmacy was one of the few boards at the time to allow the transfer of prescription information between pharmacists so that patients could obtain the medications they need when they need them and where it is convenient. This concept is becoming increasingly important with changing business practices that are the result of increasing health care costs and efforts to contain those costs.

The Board has received an increasing number of complaints this past year regarding patients who have not been able to obtain their medications when they need them. The reasons behind these complaints have been several.

One of the reasons is the number of prescriptions for maintenance medications that are being obtained through the mail with the advent of managed care and the proliferation of prescription benefit management companies. Patients have not received their medications when they need them due to delivery problems.

Another reason is that an increasing number of pharmacies do not have the drug in stock or do not have the amount prescribed when a refill is requested. This problem is generally due to tighter inventory controls on the part of businesses in order to control costs.

Patients have attempted to obtain the medications which they need by asking a local pharmacy that has the medications in stock to obtain a copy of their prescriptions which have remaining refills. Prior to the advent of managed care and prescription benefit plans using mail order pharmacies, the Board received very few complaints that patients were unable to obtain their prescription medications when needed. Consequently, the rule regarding the transfer of prescription copies was permissive and allowed pharmacists to transfer prescriptions between pharmacies so that patients could obtain their medication when and where they needed them.

Due to the refusal of many pharmacies to transfer prescriptions when requested by patients or pharmacists on behalf of the patient, the Board amended Ohio Administrative Code Rule 4729-5-24 effective July 1, 1997 by adding the following paragraph in order to ensure that patients are able to obtain the medications that they need when they need them:

- (D) Information on a prescription is the property of the patient and is intended to authorize the dispensing of a specific amount of medication for use by the patient. Original copies of prescriptions shall be maintained by pharmacies for the purpose of documenting the dispensing of drugs to a particular patient.
- (1) In the event that the pharmacy is not able to provide the medication when needed by the patient pursuant to an authorized refill, the pharmacist shall, upon the request of the patient, transfer the prescription information to the pharmacy designated by the patient.
 - (2) No pharmacy shall refuse to transfer information about a previously dispensed prescription to another pharmacy when requested by the patient. Prescription information shall be transferred in accordance with this rule as soon as possible in order to assure that the patient's drug therapy is not interrupted.

The amended rule is in the best interest of not only the patient but also the health professionals caring for the patient. Unnecessary telephone calls to a patient's physician to obtain a new prescription are to be avoided, especially where a valid prescription exists and additional refills are available. Issuing additional prescriptions for the same medications impairs the ability of health care professionals in monitoring the patient's compliance with their drug therapy.

Unnecessary telephone calls in these instances also wastes the time of health care professionals in caring for their patients. Health care professionals need to maximize the time available to engage in productive activities related to the patient's care, such as patient counseling. Time should not be wasted in obtaining a new prescription when authorization to continue the patient's drug therapy exists (i.e., remaining refills).

Pharmacies who refuse to transfer a copy of a prescription pursuant to this rule will be subject to disciplinary action by the Board. The Board may impose a monetary penalty of \$1,000.00 per violation against those pharmacies that do not comply with paragraph (D) beginning July 1, 1997. In amending this rule, it is the Board's intent that patients are able to obtain refills of their medication when needed without having to obtain another prescription from the prescriber.

NAPLEX Examination

Ohio Administrative Code Rule 4729-5-31 (Criteria for licensure by examination) was amended to reflect the new computer-adapted licensure exam – the North American Pharmacist Licensure Examination. This exam was used for the first time in March of this year.

By the time you receive this newsletter, the exam will have been administered to candidates for licensure during a two-week window in June (06/09-21/97) and approximately four weeks in July-August (07/07/97-08/08/97) at Sylvan Testing Centers throughout the United States. The computer-adaptive examination provides the Board with the ability to test candidates more frequently and at many locations throughout the United States. The use of Sylvan Test Centers throughout the United States provides exam candidates with the opportunity to take the exams near home and avoid the expense and time to travel to a centralized location. Additional information regarding the NAPLEX exam may be found under "What's New" on the Board's Home Page on the World Wide Web (page 24 of the 1997 Annual Report).

Ephedrine-containing Product Exception Approved

Ohio Administrative Code Rule 4729-12-09 (Exceptions) was amended to add SnoreStop™ to the current listing of products excepted from Schedule V restrictions on products containing ephedrine.

CONTROLLED SUBSTANCES - UTILIZATION FOR WEIGHT REDUCTION

Reprint of Articles Published in the State Board Newsletter

Editor's Note: Due to the number of questions received on a daily basis by the Board office, the following articles regarding this subject are being reprinted in this issue of the State Board Newsletter. The State Medical Board rules (Ohio Administrative Code Chapter 4731-11) regulate the legal use of controlled substances in medical practice. Ohio Administrative Code Rule 4731-11-04 specifically deals with the use of Schedule III and IV controlled substances for weight control. The State Medical Board rules are included in the current edition of the Drug Laws of Ohio as is the telephone number and address of the State Medical Board. Specific information regarding the application of these rules in medical practice should be directed to the State Medical Board office (614/466-3934).

OBESITY/SCHEDULE III & IV ANOREXIANTS (reprint from February 1992 State Board Newsletter)

Effective November 17, 1986, the State Medical Board declared that a prescription issued by a physician for a Schedule III or IV controlled substance for purposes of weight reduction in the treatment of obesity NOT in accordance with the F.D.A. approved labeling for the product constituted "selling, prescribing, giving away, or administering drugs for other than legal and legitimate purposes." The Medical Board rule also states that:

the physician shall not initiate or shall discontinue utilizing all Schedule III or IV controlled substances immediately upon ascertaining or having reason to believe . . . that the patient has developed tolerance (a decreasing contribution of the drug toward further weight loss) to the anorectic effects of the controlled substance being utilized, or . . .

A review of the FDA-approved labeling that appears in the 1991 issue of the *Physician's Desk Reference* for these products states the following:

Indications:

. . . is indicated in the management of exogenous obesity as a short term adjunct (a few weeks) in a weight regimen of weight reduction based on caloric restriction. The limited usefulness of agents of this class (see ACTIONS) should be measured against possible risk factors inherent in their use such as those described below.

Warnings:

Tolerance to the anorectic effect usually develops within a few weeks. When this occurs, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued . . .

The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of over-dosage.

The dilemma for the prescribing physician and the dispensing pharmacist is what is meant by a "few weeks." Dictionaries and thesauruses state that the adjective "few" means "not many" or "two or three." The 1991 edition of the *USP Drug Information for the Health Care Professional* provides little guidance since it essentially parrots the official labeling, which uses the phrase "a few weeks." The 1980 edition of the *USP DI*, however, states that these drugs are "recommended for short-term use only, since tolerance to the anorectic effect usually develops within 6 to 12 weeks" and provides the only definitive time frame.

DRUG CONSUMPTION AND THE POWER OF THE "LAY PRESS" - FENFLURAMINE & PHENTERMINE
(reprint from November 1995 State Board Newsletter)

Recently, lay publications and nationally televised "news magazine" programs have publicized the latest medical "trend" in appetite control - the simultaneous use of fenfluramine and phentermine. The May 1995 issue of *Reader's Digest* carried a special report originally published in the February 1995 issue of *Allure* entitled "The New Diet Pills". The May 15, 1995 issue of *U.S. News & World Report* also carried an article about these two drugs entitled, "When Willpower Won't - Researchers Now View Obesity as a Disease Requiring Drugs".

The unique feature of this latest medical trend is that these two drugs are said by the proponents to be effective only if taken for life. The *U.S. News and World Report* article stated that, "the [two patients featured in the article] expect their drug therapy to last as long as they do."

The widespread publication of this latest medical trend in weight control has resulted in many patients requesting their physicians to prescribe these two drugs based on the information provided in these articles. As a result, many practitioners are prescribing the drugs and pharmacists are questioning whether or not the two drugs may be prescribed concurrently.

These two drugs have been available for treating obesity for many years. Both drugs are Schedule IV controlled substances that have been approved by the FDA for weight loss. Consequently, the prescribing of these drugs for weight loss is governed by the State Medical Board Administrative Code Rule 4731-11-04.

Since these two drugs have different mechanisms of action and significantly different side effects, it is important that the dispensing pharmacist discuss potential problems when

counseling the patient who is taking the combination for the first time. Performing prospective drug utilization review prior to dispensing the drugs is also important since phentermine is a stimulant and fenfluramine has the ability to potentiate CNS depression producing medications as well as antihypertensives (*USP-DI*, 15th edition).

The State Medical Board published the following article, "Coadministration of Phentermine and Fenfluramine for Weight Loss," in their Summer 1995 newsletter:

Many patients have approached their physicians in recent months requesting weight-loss treatment using a combination of phentermine and fenfluramine (Schedule IV controlled substances), a treatment approach featured in several recent publications and programs in the popular media. Because all phentermine and fenfluramine products are controlled substances, their use is governed by Rule 4731-11-04, Ohio Administrative Code. It is essential for physicians to be familiar with this rule before prescribing these drugs.

The Board adopted Rule 4731-11-04 in 1986 to address a serious and growing substance abuse problem. At the time, U.S. Drug Enforcement Administration (DEA) statistics showed Ohio to be among the top five states in per capita consumption of Schedule II controlled substance stimulants. The Board ultimately adopted a rule banning those drugs for weight reduction. Although numbers were not kept to show levels of distribution of substances in Schedules III and IV, the experience of the State Medical Board, the Board of Pharmacy, the DEA, and law enforcement agencies throughout the state was that stimulant drugs such as phentermine, phendimetrazine, and benzphetamine constituted a major diversion and abuse problem. Testimony at the Board's 1986 rules hearing revealed that controlled substance stimulants in Schedule III and IV were widely sought "on the streets," and were even diverted and abused by impaired health care professionals.

While much evidence in 1986 showed that controlled diet drugs present a serious substance abuse problem, no acceptable studies had been done showing them to be effective at achieving long-term weight loss. In fact, the medical literature showed that patients who lost weight with anorexiants, with or without behavior therapy, later gained the weight back faster than patients who had lost weight using behavior therapy alone.

Based on the available evidence, the State Medical Board adopted Rule 4731-11-04, setting stringent standards for the use of controlled substances to assist in weight reduction. The rule prohibits use of these drugs as a first line of treatment; requires that they be used only in accordance with their FDA approved labeling; prohibits continued use if the patient develops tolerance or stops losing weight; and prohibits their use in the presence of a contraindication, in the treatment of a pregnant patient, or in the treatment of a patient who has a history of or shows a propensity for alcohol or drug abuse. The rule sets other technical requirements, which a physician should learn before prescribing these drugs.

Rule 4731-11-04 has traditionally been viewed as prohibiting coadministration of multiple controlled substances to assist in weight reduction, because coadministration of two CNS stimulants violates the "recognized contraindication" prohibition of the rule. Fenfluramine, however, is unique in that it is the only controlled substance approved by FDA as a weight loss aid that does not usually act as a CNS stimulant. Thus, its use together with another controlled diet drug

does not violate the "recognized contraindication" prohibition, and the State Medical Board has not ruled that a physician may not coadminister fenfluramine and phentermine.

In 1992, Dr. Michael Weintraub, of Rochester, New York, published a study reporting long-term success in achieving and maintaining weight loss using fenfluramine and phentermine in combination. Almost immediately, the State Medical Board began receiving inquiries from physicians excited over the possibilities this treatment approach offered for their obese patients. The Board has had to caution inquiring physicians that, while the coadministration of fenfluramine and phentermine may not constitute a violation per se, the provisions of Rule 4731-11-04 still apply:

- Either or both drugs can still be used only in accordance with their FDA approved labeling, and the labeling for both still limits use to "a few weeks."
- The rule still requires cessation of treatment using either or both drugs if
 - (1) the patient develops tolerance, or
 - (2) fails to lose weight over a 14-day period.

****END OF REPRINTS****.

DISCIPLINARY ACTIONS

The disciplinary actions listed below include only those where the individual's license to practice has been suspended, revoked, or restricted, and does not include those actions where the individual's license to practice has been placed on probation or has been reinstated without restrictions, or a monetary penalty imposed by the board.

Anyone having a question regarding the license status of a particular practitioner, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the licensing board which regulates that profession or activity, as follows:

State Dental Board (614/466-2580);
State Medical Board (614/466-3934);
State Nursing Board (614/466-3947);
State Optometry Board (614/466-5115);
State Pharmacy Board (614/466-4143);
State Veterinary Medical Board (614/644-5281);
Drug Enforcement Administration (216/522-3705).

STATE PHARMACY BOARD:

Order Effective 12/08/95:

Eric Douglas Vogelsong, R.Ph.; Lucasville - License suspended indefinitely, minimum 12 months, and may not be employed by or work in a facility licensed by the Board while suspended.

Order Effective 03/15/96:

Cynthia F. Phurrough, R.Ph.; Cincinnati - License revoked.

Order Effective 10/29/96:

Lisa Katherine Ramirez, R.Ph.; Port Clinton - May not train pharmacy interns or be a preceptor; may not serve as responsible pharmacist; and may not destroy, or may not assist in or witness the destruction of, controlled substances for five years effective 04/18/97.

Settlement Agreement Effective 01/12/97:

Robert J. Dougherty, R.Ph.; Urbana - License suspended indefinitely and may not be employed by or work in a facility licensed by the Board while suspended.

Order Effective 03/13/97:

Jeffrey Scott Dannemiller, R.Ph.; Akron - May not train pharmacy interns or be a preceptor; may not serve as responsible pharmacist; and may not destroy, or may not assist in or witness the destruction of, controlled substances for five years effective 04/17/97.

Settlement Agreement Effective 04/21/97:

Ralph Lee LeVange, R.Ph.; Park Forest, IL- License suspended indefinitely and may not be employed by or work in a facility licensed by the Board while suspended.

Orders Effective 04/24/97:

Jerome Friedman, R.Ph.; Columbus - License suspended indefinitely, minimum two years.

Daniel T. Zachman, R.Ph.; Shelby - License revoked.

Settlement Agreement Effective 06/16/97:

Frederick J. Weik, R.Ph.; Lambertville, MI - May not serve as responsible pharmacist for one year.

Summary Suspension of Licenses:

Henry B. Eyman, R.Ph.; Springfield - 04/23/97.

Elizabeth R. Murcia, R.Ph.; Indian Spring - 04/23/97.

David P. Sano, R.Ph.; Alliance - 06/09/97.

STATE MEDICAL BOARD:

Talivaldis Berzins, M.D.; Columbus - License revoked - 10/18/96.

David H. Brown, D.O.; North Lima - License revoked - 01/16/97.

Christopher Edward Bryniarski, D.P.M.; Mayfield Heights - Summary Suspension of License - 10/10/96. License revoked - 04/11/97.

Jessica Beatrice Campbell, M.D.; Zanesville - Summary Suspension of License - 02/14/97. License suspended indefinitely, minimum one year - 06/10/97.

Albert Burton Cinelli, M.D.; Youngstown - License revoked - 10/11/96.

Valerie Shearman Gilreath, D.O.; Pontiac, MI - License suspended indefinitely, minimum six months - 02/04/97.

Lewis Leonard Horvitz, M.D.; Euclid - License restoration permanently denied - 10/08/96.

Enrique N. Kaufman, M.D.; Cincinnati - License suspended indefinitely, minimum two years, effective 04/11/97 - 02/12/97.

Daniel Martin Kavanaugh, D.P.M.; Akron - Summary Suspension of License - 09/12/96. License revoked - 01/16/97.

David E. Little, D.O.; Pickerington - Summary Suspension of License - 04/17/96. License revoked - 07/11/96.

William Patrick Maher, D.O.; Westerville - License revoked - 04/11/97.

Samuel Meyers, M.D.; Gallipolis - License retired permanently - 11/28/96.

Michael Joseph Mignona, D.P.M.; Cleveland - License revoked - 02/11/97.

Emil William Mozola, M.D.; Independence - License revoked - 04/19/96.

Gregory S. Mynko, M.D.; Avon Lake - License suspended indefinitely, minimum two years - 12/03/96.

Kolli Mohan Prasad, M.D.; Boardman - License suspended indefinitely - 02/12/97.

William Anthony Price, M.D.; Boardman - License suspended indefinitely, minimum one year - 09/26/96.

Ramachandra Pudupakkam, M.D.; Lima - License suspended indefinitely, minimum three years - 11/30/96.

Luis E. Quiroga, M.D.; Cincinnati - License suspended indefinitely, minimum six months - 11/30/96.

Victor L. Ramos, M.D.; Novelty - License suspended 90 days - 09/26/96.

Michael D. Reynolds, M.D.; Lima - License suspended indefinitely, minimum six months - 02/16/97.

Benjamin H. Saunders, Jr., M.D.; Findlay - License retired permanently - 12/03/96.

Jeffrey C. Spencer, M.D.; Lyndhurst - License suspended indefinitely, minimum one year to be calculated from June 12, 1996 - 12/17/96.

Frank Joseph Swiger, D.P.M.; Willowick - Summary suspension of license effective 10/10/96. License revoked - 04/11/97.

Tina Marie Thomas-McCauley, M.D.; Cleveland - License suspended indefinitely, minimum two years - 12/05/96.

Darrell Keith Wells, M.D.; Westerville - License revoked - 12/03/96.

Jerome Arthur Wensinger, M.D.; Marion - License suspended thirty days effective 04/03/97 through 05/02/97 - 11/23/96.

Summary Suspension of Licenses:

Patricia Joan Bonitatibus, M.D.; Wheeling - 04/14/97.

Gordon Bailey, M.D.; Zanesville - 11/01/96.

Thomas Warren Carrigan, M.D.; Troy - 04/14/97.

Samson D. Reyes, Jr., M.D.; St. Clairsville - 03/14/97.

Richard Leonard Weitzel, M.D.; Youngstown - 02/14/97.

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