and promptly filed his request for appeal.

(d) The individual was actively-seeking evidence in support of his claim and he was unaware that such evidence could be submitted afterwards; or

(e) Unusual or unavoidable circumstances, the nature of which demonstrate that the individual could not reasonably be expected to have been aware of the need to file timely, or such circumstances prevented him from filing timely.

[FED. REG. 74-28556 Filed 10-24-74; 7:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C—DRUGS

PART 125C—NEW ANIMAL DRUGS IN ORAL DOSAGE FORMS

Cam bendazo Suspension, Veterinary Correction

In FED. REG. 74-23836 appearing on page 36113 in the issue for Tuesday, October 8, 1974 make the following corrections:

1. In the fourth line of the second paragraph change 360(b)(1) to read "360(b)(1)."

2. In 125C.136 change paragraph (c) to read as follows:

(c) Conditions of use. (1) It is used in horses for the control of large strongyles (Strongylus vulgaris, S. edentatus, S. equinus); small strongyles (Trichostrongylus foetidus, Cylicobothrus, Craterostomum, Oesophagostomum); roundworms (Parascaris); pinworms (Oxyures); and threadworms (Strongyloides).

(2) It is administered by stomach tube or as a drench at a dose of 0.9 gram of cam bendazo per 100 pounds of body weight (30 milligrams per kilogram).

(3) For animals maintained on premises where reinfestation is likely to occur, re-treatment may be necessary. For most effective results, re-treat in 6 to 8 weeks.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares or to stallions at stud.

(6) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

NARCOTIC TREATMENT PROGRAMS

Regulatory Controls Relating to Registration, Security, and Recordkeeping

A notice was published in the Federal Register of July 19, 1974 (39 FR 26529), proposing regulatory controls relating to registration, security and recordkeeping which reflect amendments to the Controlled Substances Act made by the Narcotic Addict Treatment Act of 1974.

Comments on the proposal. Written comments on the proposed amendments to the regulations were received from the American Society of Hospital Pharmacists; the New York State Bureau of Drug Abuse; the Oregon Methadone Treatment Program; the State of New York's Drug Abuse Control Commission and Department of Health; the City of New York's Department of Health; the State of Wisconsin's Controlled Substances Board; the National Social Psychology, Inc.; Corpus Christi Drug Abuse Council; Charles Spray, M.D.; M. J. Short, M.D.; the Department of Public Health of Portsmouth, Va.; University of Wisconsin Hospitals; Narcotic Drug Treatment Center, Inc. (Anchorage, Alaska) ; and the Department of Health, Prince George's County, Maryland.

American Society of Hospital Pharmacists (ASHP) and the Department of Health of the State of New York questioned the new definition in § 1301.02(d). ASHP suggested amending two other sections to avoid the term "compound," Section 1301.02(d) has been modified in an effort to avoid confusion.

The Oregon Methadone Treatment Program requested that the definition in § 1301.02(d) be clarified and raise questions of ambiguity in § 1301.22(a)(6). Section 1301.02(d) is in its general definition of the term "narcotic treatment program." Section 1301.22(a)(6) has been modified in an effort to remove confusion caused by the term "entity.

ASHP expressed approval of § 1301.74(g) because it would include unregistered individuals employed in the shipping and receiving department of hospitals who would not generally know whether a package contained controlled substances for treatment programs. The Ohio Bureau of Drug Abuse criticized § 1301.74(g) and suggested new language providing that the acceptance of delivery of narcotic substances be made only by a licensed practitioner or other licensed personnel at his direction. The New York City Health Department questioned use of the word "involves" in this section. Section 1301.74(h) has been re-delineated as § 1301.74(h), and the text has been modified to provide for more efficient control.

The Ohio Bureau of Drug Abuse also criticized § 1301.74(h) (5), and proposed that this language be eliminated. Joining in this criticism, the New York State Drug Abuse Control commission speculated that § 1301.74(h) (5) might sanction activity which is probably unlawful in most states. Section 1301.74(h) has been re-delineated as § 1301.74(1), and subsection (5) has been deleted to respond to these concerns for the prevention of diversion of controlled substances and for the improvement of accountability and dispensing records.

ASHP is joined by the New York City Health Department in questioning the requirements of what is described as "the narcotic dispensing area" in § 1301.74(1). The language has been modified to clarify any ambiguities, and the section has been re-designated as § 1301.74(1).

The Oregon Methadone Treatment Program commended the language of § 1301.74(3), noting that requirements for treatment programs and associated medication units to have to adhere to restrictions designed to encompass the range of programs also would be counterproductive to stated goals of Federal agencies. This section has been re-designated as § 1301.74(3).

ASHP suggested that § 1304.28(b) be deleted and, as an alternative, suggested that the approach should be to require that the records be maintained in accordance with § 1304.21. Section 1304.28(b) has been modified in the final regulation, requiring that the records will be maintained in compliance with § 1304.26. Additionally, a new subparagraph (4) has been added to § 1304.28(a).

The Corpus Christi Drug Abuse Council and Dr. Charles Spray opposed § 1305.04(e) on the grounds that this regulation would cause the demise of "out-patient" detoxification programs. The section is not designated to inhibit the "take-home" of medication dispensed at the site of the narcotic treatment program, the program may dispense to the patient (consumer) as much medication as is allowable under current FDA regulations. The section does prohibit the issuance by a physician of a prescription for narcotic detoxification or maintenance to be filled at a pharmacy. Moreover, hospitals that conduct in-patient detoxification treatment (not as an adjunct to treatment for illness other than addiction) are required to register separately as treatment programs. The Oregon Methadone Treatment Program asked whether § 1305.04(e) and § 1305.07(a) permit a program physician to issue a medication order for maintenance or detoxification purposes even though administration to the ultimate user might extend over a several week period, and therefore not be "immediate" within the language of § 1305.02(e). These sections permit the issuance of a medication order by a program physician only if the medication is to be dispensed to the patient under the order is to be dispensed at the same narcotic treatment program location at which the medication order was prescribed. The patient is required to return to the issuing program site or its medication unit, to have the medication dispensed, and may not have the order filled at another narcotic program location or at a conventional pharmacy.

The Oregon Methadone Treatment Program questioned whether, under § 1306.07(a), a physician who is detoxifying patients in a hospital as part of his medical practice and who is also associated with a narcotic treatment program will be required to have separate registration for the same activity at two locations. In that case, the physician will be able to dispense controlled substances at both the hospital's DEA registration number, and if the physician is a practitioner under § 1302(c)(2) of the Act, the physician will...
be able to dispense narcotic drugs at the site of the narcotic treatment program under the DEA registration number of that program. See §1301.32(a) (6) and §1301.24.

The Department of Health of the State of New York suggested that §1306.07(c) be expanded to designate the specific narcotic substances listed in Schedules II through V deemed appropriate for use in detoxification or maintenance treatment. Specific designation would be inappropriate in this instance, because the Act itself does not limit the narcotic drugs by its language. ASHP suggested that §1306.07(c) be amended to clarify the ability of an "institutional practitioner", as distinguished from a physician, to treat patients in accordance with this section. The final regulation has been modified to accommodate aspects of this suggestion.

Therefore, under the authority vested in the Attorney General by 21 U.S.C. 802 and 832(e) and delegated to him by 21 CFR 1.180, the Administrator of the Drug Enforcement Administration hereby promulgates regulations amending Parts 1301 and 1306 of Title 21 of the Code of Federal Regulations as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

1. Section 1301.02 is amended by redesignating paragraph (d) as paragraph (e); paragraph (e) as paragraph (g); paragraph (f) as paragraph (i); paragraph (g) as paragraph (k); paragraph (h) as paragraph (d); paragraph (i) as paragraph (l); and by adding four new paragraphs as follows:

§1301.02 Definitions.

(d) The term "compounder" means any person engaged in the manufacture or detoxification treatment who also mixes, prepares, packages or changes the dosage form of a narcotic drug listed in Schedules II, III, IV or V for use in maintenance or detoxification treatment by another narcotic treatment program.

(e) The term "detoxification treatment" means the dispensing for a period not in excess of twenty-one days, of a narcotic drug or narcotic drugs in decreasing doses to an individual in order to alleviate some physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period of time.

(f) The term "maintenance treatment" means the dispensing for a period in excess of twenty-one days, of a narcotic drug or narcotic drugs in the treatment of an individual for dependence upon heroin or other morphine-like drug.

(i) The term "narcotic treatment program" means a program engaged in maintenance and/or detoxification treatment with narcotic drugs.

(ii) Section 1301.11 is amended by adding a new paragraph (d) as follows:

§1301.11 Fee amounts.

(d) For each registration or reregISTRATION to engage in a narcotic treatment program, including a compounder, the registrant shall pay a fee of $5.00.

3. Section 1301.22(a) (6) is amended and a new paragraph (a) (11) is added to read as follows:

§1301.22 Separate registration for independent activities.

(a) * * *

(d) Conducting a narcotic treatment program using any narcotic drug listed in Schedules II, III, IV or V, however, pursuant to §1301.24, employees, agents, or affiliated practitioners, in programs, need not register separately. Each program site located away from the principal location and at which place narcotic drugs are stored or dispensed must be separately registered and obtain narcotic drugs by use of order forms pursuant to §1305.03.

(i) A compounder as defined by §1301.02(d)

4. Section 1301.29 is added to read as follows:

§1301.29 Provisional registration of narcotic treatment programs; compounders.

(a) All persons currently approved by the Food and Drug Administration under §310.505 (formerly §130.44) of this title to conduct a methadone treatment program and who are registered by the Drug Enforcement Administration under this section will be granted a Provisional Narcotic Treatment Program Registration.

(b) The provisions of §1301.45-1301.47 relating to revocation and suspension of registration, shall apply to a provisional registration.

(c) Unless sooner revoked or suspended under paragraph (b) of this section, a provisional registration shall remain in effect until (1) the date on which such person has registered under this section or has had his registration denied, or (2) such date as may be prescribed by written notification to the person from the Drug Enforcement Administration for the person to become registered to conduct a narcotic treatment program, whichever occurs first.

§1301.32 Application forms, contents, signature.

(a) * * *

(g) To conduct a narcotic treatment program, including a compounder, shall apply on DEA Form 363.

(b) * * *
RULES AND REGULATIONS

(1) DEA may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

9. Section 1304.04 is amended by revising paragraph (b) to read as follows:

§ 1304.04 Maintenance of records and inventories.

(a) Each registered manufacturer, distributor, importer, narcotic treatment program and compounding pharmacist for narcotic treatment programs shall maintain inventories and records of controlled substances as follows:

(i) Each record of controlled substances shall be made in a legible form and shall be maintained for at least 5 years following the end of the recordkeeping period or for 5 years from the date of destruction, whichever is later.

(ii) Each record shall be maintained in a secure manner and shall be readily accessible to authorized persons.

(iii) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the location of any controlled substance.

(iv) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the quantity of any controlled substance.

(v) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the date of destruction of any controlled substance.

(vi) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the manner of destruction of any controlled substance.

(vii) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the number of containers of any controlled substance.

(viii) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the number of bottles or vials of any controlled substance.

(b) Each register mark on each bottle or vial shall be legible and shall include:

(i) The name of the substance.

(ii) The amount of the substance.

(iii) The date of destruction.

(iv) The manner of destruction.

(v) The number of containers.

(vi) The number of bottles or vials.

10. Section 1304.28 is added to read as follows:

§ 1304.28 Records for maintenance treatment programs and detoxification treatment programs.

(a) Each person registered or authorized to maintain a dispensing list at a narcotic treatment program site and shall maintain an inventory of controlled substances as follows:

(i) Each record of controlled substances shall be made in a legible form and shall be maintained for at least 5 years following the end of the recordkeeping period or for 5 years from the date of destruction, whichever is later.

(ii) Each record shall be maintained in a secure manner and shall be readily accessible to authorized persons.

(iii) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the location of any controlled substance.

(iv) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the quantity of any controlled substance.

(v) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the date of destruction of any controlled substance.

(vi) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the manner of destruction of any controlled substance.

(vii) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the number of containers of any controlled substance.

(viii) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the number of bottles or vials of any controlled substance.

(b) Dispenser's initials, date dispensed, amount consumed, the name of the substance, the amount and dosage form taken home by the patient and the number of containers.

(c) The records required by paragraph (a) of this section shall be maintained in a secure manner and shall be readily accessible to authorized persons.

(d) Each record of controlled substances shall be made in a legible form and shall be maintained for at least 5 years following the end of the recordkeeping period or for 5 years from the date of destruction, whichever is later.

(e) Each record shall be maintained in a secure manner and shall be readily accessible to authorized persons.

(f) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the location of any controlled substance.

(g) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the quantity of any controlled substance.

(h) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the date of destruction of any controlled substance.

(i) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the manner of destruction of any controlled substance.

(j) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the number of containers of any controlled substance.

(k) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the number of bottles or vials of any controlled substance.

11. Section 1304.29 is added to read as follows:

§ 1304.29 Records for treatment programs which compound narcotics for use at off-site locations.

(a) Each person registered or authorized to compound narcotics for use at off-site locations shall maintain records as follows:

(i) Each record of controlled substances shall be made in a legible form and shall be maintained for at least 5 years following the end of the recordkeeping period or for 5 years from the date of destruction, whichever is later.

(ii) Each record shall be maintained in a secure manner and shall be readily accessible to authorized persons.

(iii) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the location of any controlled substance.

(iv) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the quantity of any controlled substance.

(v) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the date of destruction of any controlled substance.

(vi) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the manner of destruction of any controlled substance.

(vii) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the number of containers of any controlled substance.

(b) Each record of controlled substances shall be made in a legible form and shall be maintained for at least 5 years following the end of the recordkeeping period or for 5 years from the date of destruction, whichever is later.

(c) Each record shall be maintained in a secure manner and shall be readily accessible to authorized persons.

(d) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the location of any controlled substance.

(e) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the quantity of any controlled substance.

(f) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the date of destruction of any controlled substance.

(g) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the manner of destruction of any controlled substance.

(h) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the number of containers of any controlled substance.

(i) Each record shall be maintained in a manner that facilitates the prompt and accurate determination of the number of bottles or vials of any controlled substance.

FEDERAL REGISTER, VOL. 39, NO. 209—FRIDAY, OCTOBER 25, 1974

RULES AND REGULATIONS

Title 38—Pensions, Bonuses, and Veterans’ Relief
CHAPTER I—VETERANS ADMINISTRATION
PART 21—VOCATIONAL REHABILITATION AND EDUCATION
Subpart D—Administration of Educational Benefits; 38 U.S.C. Chapters 34, 35 and 36

CLARIFICATION OF COUNSELING REQUIREMENTS

On page 30058 of the Federal Register of August 20, 1974, there was published a notice of proposed regulatory development to amend §§21.4102 and 21.4106 to clarify the circumstances in which counseling shall be required if a veteran or eligible person requests a change of program pursuant to section 1791, title 38, United States Code. In addition minor editorial changes have been made to §21.4106(a) designed to reflect policy to avoid an appearance of seeming to preclude benefits for female veterans. Interested persons were given 30 days in which to submit comments, suggestions, or objections regarding the proposed regulations.

Pursuant to such notice, written comments were received from three interested parties. Two were favorable and one of these requested a change of law. The other comment was directed to changing the law. The proposed regulations are hereby adopted without change and are set forth below.

Effective date. Sections 21.4102 and 21.4106(a) are effective October 21, 1974.

Approved: October 21, 1974.

R. L. ROVERISAN,
Administrator.

1. Section 21.4102 is revised to read as follows:
(a) Child. Counseling is required for an eligible child before approval of an initial course except when the child has been accepted for, or is pursuing, courses leading to a 2-year or 4-year college degree at an approved institution. Counseling is required for all eligible children for reenrollment after discontinuation because of unsatisfactory conduct or progress. Counseling will be required before a change of program is approved as provided in §21.4106(a)(2). The counselor will assist in preparing an educational plan if requested by the eligible person, his or her parent or guardian (38 U.S.C. 1720).

(b) Wife, husband, widow or widower. Counseling is not required for a wife, husband, widow or widower for approval of an initial course or for a change from such course unless the earlier course was discontinued because of unsatisfactory conduct or progress. Counseling may be required before a second or subsequent change of program as provided in §21.4106(a)(3).

2. Section 21.4106 is revised to read as follows:
§ 21.4106 Counseling; change or reenrollment.
(a) When required. Counseling, or additional counseling, will be required under the following circumstances unless it is found by the counselor that the change requested is from a program that was not considered suitable in the initial counseling to a program which is supported by the counseling data, and need for additional counseling is not shown.
(1) 38 U.S.C. Chapter 34. For any change of program if the program was interrupted or discontinued due to the veteran’s own misconduct, neglect, or lack of application; or for resumption of a course of education which had been discontinued because of unsatisfactory conduct or progress under §21.4277; or for a second or subsequent change unless a counseling psychologist finds on the basis of evidence submitted by the veteran and/or the evidence of record that the change requested is to a program suitable to the veteran’s aptitudes, interests, and abilities.
(2) 38 U.S.C. Chapter 35. For any change of program if the program was interrupted or discontinued due to the eligible person’s own misconduct, neglect, or lack of application; or for resumption of a course of education which had been discontinued because of unsatisfactory conduct or progress under §21.4277.
(3) 38 U.S.C. Chapter 35; wife, husband, widow or widower. For any change of program if the program was interrupted or discontinued due to the eligible person’s own misconduct, neglect, or lack of application; or for resumption of a course of education which had been discontinued because of unsatisfactory conduct or progress under §21.4277.

Effective date: November 15, 1974.

Dated: October 21, 1974.

JOHN R. BARTLES, JR.,
Administrator,
Drug Enforcement Administration.

[FR Doc.74-2497 Filed 10-24-74; 9:46 am]