This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rulemaking prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE
Drug Enforcement Administration
[21 CFR Parts 1301, 1304, 1305, 1306] NARCOTIC TREATMENT PROGRAMS

Proposed Regulatory Controls Relating to Registration, Security, and Recordkeeping


Section 2 of the Act adds two definitions to Section 102 of the Controlled Substances Act. “Maintenance treatment” is defined as the dispensing, for a period not exceeding twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs. “Detoxification treatment” is defined as the dispensing of a narcotic drug to an individual in decreasing doses, for a period not exceeding twenty-one days, for the purpose of alleviating adverse psychological or physiological effects incident to withdrawal from the continuous or sustained use of a narcotic drug in order to bring the individual to a narcotic-free state. The definition of detoxification inherently requires the use of decreasing doses in order to reach a drug-free state.

Section 3 of the Act amends section 303 of the Controlled Substances Act containing registration requirements by adding a new subsection (g). This subsection provides that all practitioners who dispense narcotic drugs to individuals for maintenance or detoxification treatment shall annually obtain a separate registration for that purpose. The Administrator of the Drug Enforcement Administration (Administration) is directed to register an applicant to dispense narcotic drugs for maintenance or detoxification treatment if:

1. The applicant is a practitioner who is determined by the Secretary of Health, Education, and Welfare, under standards established by the Secretary, to be qualified to engage in the type of treatment for which registration is sought;
2. The Administrator determines that the applicant will meet the standards established by the Administrator with respect to security of stocks of narcotic drugs used in such treatment, and maintenance of records on such drugs; and
3. The Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Administrator) respecting the quantity of narcotic drugs which may be provided for unsupervised use by those in maintenance or detoxification programs.

This section preserves the distinctions found in the Controlled Substances Act between the functions of the Attorney General and the Secretary of Health, Education, and Welfare. All decisions of a medical nature are to be made by the Secretary of Health, Education, and Welfare. Law enforcement decisions respecting the security of stocks of narcotic drugs and the maintenance of records on such drugs are to be made by the Administrator.

The Congress recognized that the registration of narcotic drugs to individuals for their unsupervised use, principally a medical judgment, may have some law enforcement ramifications. Therefore, before the Secretary establishes standards respecting the quantities of narcotic drugs which may be provided for such use, he is to consult with the Administrator.

The registration required under this section is separate and distinct from regular registration under the Controlled Substances Act. However, the amount of paper work required of practitioners by this section will be minimal. This Act is not intended to impose a heavy new burden on practitioners, and every effort will be made to use registration forms which are brief, simple, and similar to other forms already in use.

Section 4(a) of the Act amends section 303(c) of the Controlled Substances Act to provide that failure to comply with a standard referred to in section 303(g) may be revoked or suspended by the Administrator upon finding that the registrant has failed to comply with any of the standards required in section 303(g).

Section 4(b) amends section 304(d) of the Controlled Substances Act to provide that failure to comply with a standard referred to in section 303(g) may be treated as grounds for immediate suspension of a registration granted under that section.

Under current law, the registration of a practitioner can only be revoked if he does not have a State license, has been convicted of a felony, or has fraudulently applied for registration. This new subsection provides that in such instances, the Administrator may immediately revoke or suspend the narcotic treatment registration of any practitioner who does not meet the standards set forth in section 303(g).

The suspension or revocation of a registration issued under section 303(g) does not in any manner affect a practitioner’s basic registration under the Controlled Substances Act. A practitioner who has lost his registration under section 303(c) would not lose his basic registration unless another provision of Section 304(a) is met.

Section 5 of the Act amends section 307(e)(1) of the Controlled Substances Act so as to extend the recordkeeping requirements of section 307 to the prescribing or administering of a controlled substance by a practitioner in the course of maintenance or detoxification treatment of an individual.

These new recordkeeping requirements are not intended to change or add to the existing requirements of practitioners who do not engage in either detoxification or maintenance treatment.

The proposed regulations are intended in no way to restrict the authority that the Food and Drug Administration already exercises in this area with regard to methadone treatment programs. The standards established by the Secretary of Health, Education, and Welfare (his designee, the Commissioner of the Food and Drug Administration) for methadone treatment are published in § 310.505 (formerly § 130.44) of this title. Any additional standards promulgated under this Act will be published in the Federal Register.

Therefore, under the authority vested in the Attorney General by 21 U.S.C. 821 and 823(p), and delegated to the Administrator of the Drug Enforcement Administration by 28 C.F.R. 0.100, if it is proposed that Parts 1301, 1304, 1305, and 1306 of Title 21 of the Code of Federal Regulations be amended 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 (f); paragraph (g) as paragraph (h); paragraph (h) as paragraph (i); and paragraph (i) as paragraph (m) and by adding four new paragraphs as follows:

§ 1301.02 Definitions.

(d) The term "compounder" means any person engaging in maintenance 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 the course of maintenance or detoxification treatment, where the activities of mixing, preparing, packaging or changing the dosage forms are carried out.
(c) 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 adverse physiological or psychological effects incident to withdrawal from the continuos 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.

(b) 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 drugs.

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

2. Section 1301.31 is amended by adding a new, paragraph (a) (1) as follows:

§ 1301.11 Fee amounts.

(f) For each registration or re-registration to engage in a narcotic treatment program, including a compounding of 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.

(g) Conducting a narcotic treatment program using any narcotic drug listed in Schedules II, III, IV or V. Each entity located away from the principal location at which place narcotic drugs are stored or dispensed must be separately registered.

II. A compounding as defined by § 1301.05 (d).

4. Section 1301.29 is added to read as follows:

§ 1301.29 Provisional registration of narcotic treatment programs; compounding.

(a) All persons currently approved by the Food and Drug Administration under § 310.505 (formerly § 310.44) 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 § 1301.45-1301.57 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.

5. Section 1301.32 (a) is amended by adding new paragraphs (a) (9) and (b) (9) as follows:

§ 1301.32 Application forms, contents, signature.

(a) (9) To conduct a narcotic treatment program, including a compounding shall apply on DEA Form 362.

(b) (9) To continue to conduct a narcotic treatment program, including a compounding shall apply on DEA Form 363.

6. Section 1301.72 is amended by revising the title to read as follows:

§ 1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

7. Section 1301.73 is amended by revising the title and first paragraph to read as follows:

§ 1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.

All manufacturing activities; including processing, packaging and labeling involving controlled substances listed in any schedule and all activities of compounders shall be conducted in accordance with the following:

8. Section 1301.74 is amended by revising the title and by adding paragraphs (g), (h), (i), (j) and (k) to read as follows:

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(g) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individual designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(h) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse or other authorized individual designated in writing, shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

9. Section 1301.04 is amended by revising paragraphs (a) (9) and (a) (10) to read as follows:

§ 1301.04 Maintenance of records and inventories.

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

10. Section 1301.28 is added to read as follows:

§ 1301.28 Records for maintenance treatment programs and detoxification treatment programs.

(a) Each person registered or authorized (by § 1301.23 of this chapter) to maintain and/or detoxify controlled substance users in a narcotic treatment program shall maintain records with the following information for each narcotic controlled substance:

(1) Name of substance;

(2) Strength of substance;

(3) dosage form;

(4) adequate identification of patient (to the extent required by law);

(5) amount consumed;

(6) amount and dosage form taken home by patient; and

(7) Dispenser's initials.

(b) The records required by paragraph (a) of this section will be maintained in a dispensing log at the narcotic treatment program site. All sites which compound or dispense a bulk narcotic solution from bulk narcotic powder to liquid for on-site use must keep a separate batch record of the compounding.

(1) Records of Identification, diagnosis, prognosis, or treatment of any patients which are maintained in connection with the performance of a narcotic treatment program shall be confidential, except that such records may be disclosed for purposes and under the circumstances authorized by Part 310 and Part 1401 of this title.
11. Section 1304.29 is added to read as follows:

§ 1304.29 Records for treatment programs which compound narcotics for treatment programs and other locations.

Each person registered or authorized by Section 1301.22 of this chapter to compound narcotic drugs for off-site use in a narcotic treatment program shall maintain records which include the following information for each narcotic drug:

(a) For each narcotic controlled substance in bulk form to be used in, or capable of use in, or being used in, the compounding of the same or other non-controlled substances in finished form:

(1) The name of the substance;

(2) The quantity compounded in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch compounded;

(3) The quantity received from other persons, including the date and quantity of each receipt and the name, address and registration number of the other person from whom the substance was received;

(4) The quantity imported directly by the registrant (under a registration as an importer) for use in compounding by him, including the date, quantity and import permit or declaration number of each importation;

(5) The quantity used to compounding the same substance in finished form, including:

(i) The date and batch or other identifying number of each compounding;

(ii) The quantity used in the compound;

(iii) The finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter);

(iv) The number of finished form compounded;

(v) The quantity used in quality control;

(vi) The quantity lost during compounding and the causes therefore, if known;

(vii) The total quantity of the substance contained in the finished form;

(viii) The theoretical and actual yields; and

(ix) Such other information as is necessary to account for all controlled substances used in the compounding process;

(b) The quantity used to manufacture other controlled and non-controlled substances; including the name of each substance manufactured and the information required in subparagraph (5) of this paragraph;

(c) The quantity distributed in bulk form to other programs, including the date and quantity of each distribution and the name, address and registration number of each program to whom a distribution was made;

(d) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation; and

(e) The quantity disposed of by destruction, including the reason, date and manner of destruction.

(b) For each narcotic controlled substance in finished form:

1. The name of the substance;

2. Each finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume or finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

3. The number of containers of each such commercial finished form compounded from bulk form by the registrant, including the information required pursuant to subparagraph (5) of paragraph (a) of this section;

4. The number of units of finished forms and/or commercial containers received from other persons, including the date and number of units of each receipt and the name, address and registration number of the person from whom the units were received;

5. The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import) including the date of the importation and the number of units of each importation;

6. The number of units and/or commercial containers compounded by the registrant from units in finished form received from others or imported, including:

(i) The date and batch or other identifying number of each compounding;

(ii) The operation performed (e.g., re-packaging or relabeling);

(iii) The number of units of finished form used in the compound, the number compounded and the loss of material during compounding, with the causes for such losses, if known;

(iv) Such other information as is necessary to account for all controlled substances used in the compounding process;

(b) The number of containers distributed to other programs, including the date of a number of containers in each distribution and the name, address and registration number of the program to whom the containers were distributed;

(c) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(d) The number of units of finished forms and/or commercial containers destroyed in any manner by the registrant, including the reason, the date and manner of destruction.

PART 1305—ORDER FORMS

12. Section 1305.08 is amended by adding a new paragraph (e) to read as follows:

§ 1305.08 Persons entitled to fill order forms.

(e) A person registered as a compounder of narcotic substances for use at off-site locations in conjunction with a narcotic treatment program at the compounder’s location who is authorized to handle Schedule II narcotics, is authorized to fill order forms for distribution of narcotic drugs to off-site narcotic treatment programs only.

PART 1306—PRESCRIPTIONS

13. Section 1306.04 is amended by revising paragraph (a) to read as follows:

§ 1306.04 Purpose of issue of prescription.

(a) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for "detoxification treatment" or "maintenance treatment" as defined in section 102 of the Act (21 U.S.C. 802).

14. Section 1306.07 is amended to read as follows:

§ 1306.07 Administering or dispensing narcotic drugs.

(a) The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug dependent person for "detoxification treatment" or "maintenance treatment" as defined in section 102 of the Act (21 U.S.C. 802) shall be deemed to be within the meaning of the term "in the course of his professional practice or research" in section 303(e)(2) and section 102(20) of the Act (21 U.S.C. 828)(e): Provided, That the practitioner is separately registered with the Attorney General as required by section 303(c) of the Act (21 U.S.C. 828(c)) and thereafter complies with the regulatory standards imposed relative to treatment qualification, security, records and unsupervised use of drugs pursuant to such Act.

(b) Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day’s medication may be administered to the person or for the person’s use at one time. Such emergency treatment may be carried out for no more than three days and may not be renewed or extended.

(c) This section is not intended to impose any limitations on a physician to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incident to medical or surgical treatment of conditions other than addiction, or to administer or dis-
All interested persons are invited to submit their comments and objections, in writing, regarding this proposal. Comments and objections should be submitted in quintuplicate to the Office of Chief Counsel, Drug Enforcement Administration, Department of Justice, Room 1203, 1405 Eye Street, NW, Washington, D.C. 20537, and should be received on or before September 3, 1974.

DATED: July 12, 1974.

JOHN R. BARTELIS, JR.,
Administrator,
Drug Enforcement Administration,
[PE Doc.74-16352 Filed 7-18-74; 8:45 am]

DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service
[50 CFR Part 16]

INJURIOUS WILDLIFE
Notice of Hearing

Correction
In FR Doc. 74-14311 appearing in the first column on page 22247, in the issue of July 24, 1974, the address now reading "1130 NW, 27th Ave.", should read "11000 NW, 27th Ave."

DATED: July 15, 1974.

DOUGLAS P. WHEELER,
Deputy Assistant Secretary for Fish
and Wildlife and Parks,

[FR Doc.74-16484 Filed 7-18-74; 8:45 am]

DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service
[7 CFR Parts 29, 1464]

TOBACCO
Allocation of Tobacco Inspection Service; Eligibility for Price Support

Notice is hereby given that the Department is considering the further amendment of its regulations (published at 39 FR 17783) relating to tobacco inspection and price support services with regard to flue-cured tobacco by amending Subpart B of the Pan (7 CFR Part 1464) and Subpart G--Policy Statement and Regulations Governing Availability of Tobacco Inspection and Price Support Services to Flue-Cured Tobacco on Designated Markets (7 CFR Part 29). The proposed amendments would establish separate sales schedules for designated and undesignated tobacco, restrict the warehouseman's ability to sell undesignated tobacco during the period allocated for designated sales, restrict the amount of tobacco, beyond his authorized sales quota, which a warehouseman could sell in any one day, and establish a procedure for the industry to nominate members for the Secretary's appointment to the Flue-Cured Tobacco Advisory Committee. The proposed policy statement and regulations are statements of agency policy and rules and regulations issued pursuant to the authority of the Tobacco Inspection Act (49 Stat. 731, (7 U.S.C. 511, et seq.),) and the Agricultural Act of 1949, as amended (63 Stat. 1051, (7 U.S.C. 1421, et seq.)); and the Commodity Credit Corporation Charter Act (63 Stat. 1079), as amended (15 U.S.C. 714 et seq.).

STATEMENT OF CONSIDERATION
At its June 21, 1974 meeting, which reconvened on July 25, 1974, the Flue-Cured Tobacco Advisory Committee recommended that the Secretary consider further amending the amendments to Title II, Code of Federal Regulations, Part 29 which were published in the Federal Register of May 20, 1974 (39 FR 77753). The Committee recommended sales schedules which would provide separate selling time for sales of designated tobacco and for undesignated tobacco. The inspection of flue-cured tobacco would be in accordance with the two schedules. Warehousemen would be allowed to sell designated tobacco during the sales time authorized for undesignated tobacco but undesignated tobacco could only be sold during time allotted for sales of undesignated tobacco. The Committee felt that, inasmuch as producers could designate up to 100 percent of their quota but in fact would only allow an average of approximately 95 percent of their warehousemen in certain geographical areas would have excess selling time allotted to them. Such excess selling time cannot be determined definitely enough to eliminate it from the selling schedule. An incentive is thereby provided warehousemen to utilize such excess selling time by attempting to attract tobacco from other marketing areas by encouraging growers to cancel their designations and sell at the distant market. If this were done, it would tend to negate the intent and purpose of the marketing system which the May 20, 1974 amendments to Part 29 sought to establish. The incidence of this type of activity would be curtailed substantially by the selling schedules prescribing separate selling times for designated and undesignated tobacco. The information available to the Committee also indicated that, of the tobacco which is actually marketed, a relatively small amount was not designated by the growers. Allowing warehousemen to sell designated tobacco during time allotted for undesignated tobacco sales would enable warehousemen with the flexibility to speed up the sale of designated tobacco and further discourage the incentive to encourage growers in other areas to cancel their designations to provide tobacco for undesignated tobacco sales time.

The Committee further recommended that no warehouseman be allowed to exceed the authorized sales volume for any given sales day by more than 2500 pounds for designated tobacco or 500 pounds for undesignated tobacco. Under the regulations as currently constituted, a warehouseman could sell three times his daily tobacco volume in any one sales day and still come into compliance on the third day. The Committee did not believe that this was an intent of Congress in enacting the amendment and, therefore, requested the correction. They further recommended that a warehouse which was within 100 pounds in adjusting its excess sales to the selling schedules would be considered in compliance with such rules.

PART 29—TOBACCO INSPECTION
The proposed amendments to Subpart G, Part 29, are as follows:

1. Revise §29.9403 as set forth below:

§29.9403 Flue-Cured Tobacco Advisory Committee.

(a) To assist the Secretary in making the appointment and assignment of inspectors, a Flue-Cured Tobacco Advisory Committee, appointed in accordance with the Federal Advisory Committee Act (5 U.S.C. App. C.,) shall advise and recommend to the Secretary marketing area opening dates and selling schedules for both designated and undesignated flue-cured tobacco to be sold in each marketing area and in each warehouse within each marketing area.

(b) The Committee shall consist of 35 representatives of the flue-cured tobacco industry: 20 producers, 7 warehousemen and 8 buyers.

(c) Recommendations to the Secretary for producer membership on the Committee will be received from the following organizations: one each from the Florida Farm Bureau and the South Carolina Grange, two each from the Georgia Farm Bureau, the South Carolina Farm Bureau and the Virginia Farm Bureau, four from the North Carolina Grange, and eight from the North Carolina Farm Bureau.

(d) Recommendations for the seven warehouse representatives shall be received from the various bulk warehouse associations.

(e) Recommendations for the eight buyer representatives shall be received: five from the Tobacco Association of the United States and two each from Philip Morris, Inc., P Lorillard Co. and R. J. Reynolds Tobacco Co.

2. Amend §29.9404 as follows:

FEDERAL REGISTER, Vol. 39, No. 140—FRIDAY, JULY 19, 1974