

Proposed Rules

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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 rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Proposal To Place Carfentanil Into Schedule II

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Administrator of the Drug Enforcement Administration (DEA) proposes that carfentanil, a narcotic substance, be placed into Schedule II of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). This action has been initiated following DEA's receipt of a letter from the Assistant Secretary for Health, Department of Health and Human Services (DHHS), recommending that DEA initiate the scheduling of carfentanil while review of the new animal drug application for carfentanil is nearing completion. The scheduling of carfentanil in Schedule II will not be finalized until carfentanil is approved for marketing by the Food and Drug Administration (FDA). If finalized, this proposed rule would impose the regulatory controls and criminal sanctions of a Schedule II narcotic substance under the CSA to the manufacture, distribution, importation and exportation of carfentanil.

DATE: Written comments and objections must be received on or before February 11, 1988.

ADDRESS: Send comments to DEA Federal Register Representative, Office of Chief Counsel, Drug Enforcement Administration, Washington, DC 20537.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 633-1366.

SUPPLEMENTARY INFORMATION: On

November 12, 1987, the Assistant Secretary for Health, on behalf of the Secretary, DHHS, sent to the Administrator of DEA a letter recommending that the scheduling process be initiated for placement of carfentanil into Schedule II of the CSA. Enclosed with the letter was a document prepared by the FDA entitled "Basis for the Recommended To Control Carfentanil Into Schedule II of the Controlled Substances Act." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)) and the summarized recommendations regarding the scheduling of carfentanil.

The factors considered by the Assistant Secretary for Health with respect to carfentanil were:

- (1) Its actual or relative potential for abuse;
- (2) Scientific evidence of its pharmacological effects, if known;
- (3) The state of current scientific knowledge regarding the drug (or other substance);
- (4) Its history and current pattern of abuse;
- (5) The scope, duration and significance of abuse;
- (6) What, if any, risk there is to the public health;
- (7) Its psychic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under this title.

Carfentanil is a rapidly acting and extremely potent synthetic compound that is an analog of fentanyl. Its pharmacological profile appears to be highly similar to that of fentanyl and related compounds. The pharmacological effects of carfentanil in experimental animals are readily reversed by administration of narcotic antagonists. The main therapeutic use of carfentanil will be its use in veterinary medicine to immobilize certain species of larger deer.

Based on the scientific and medical evaluation and the recommendation contained in the November 12, 1987 letter from the Assistant Secretary for Health, DHHS, the Administrator of DEA, pursuant to the provisions of 21 U.S.C. 811(a) and 811(b), finds that:

(1) Based on all available information, carfentanil has a high potential for abuse;

(2) Carfentanil, upon final approval of a new animal drug application by the FDA, will have a currently accepted medical use in treatment in the United States; and

(3) Abuse of carfentanil may lead to severe psychological or physical dependence.

The above findings are consistent with the proposed placement of carfentanil into Schedule II of the CSA. The Administrator further contends that carfentanil is an opiate as defined in 21 U.S.C. 802(18) since it has an addiction-forming and addiction-sustaining liability similar to morphine. Consequently, carfentanil is a narcotic since the definition of narcotic, as stated in 21 U.S.C. 802(17)(A), includes: "Opium, opiates, derivatives of opium and opiates."

Interested persons are invited to submit their comments or objections in writing regarding this proposal. If a person believes that one or more issues raised by him warrant a hearing, he should so state and summarize the reasons for his belief. In the event that comments, objections or requests for a hearing received in response to this proposal raise one or more issues which warrant a hearing, the Administrator will publish in the **Federal Register** an order for a public hearing which will summarize the issues to be heard and set the time for the hearing that will not be less than 30 days after the date of the order. If no objections presenting grounds for a hearing on this proposal are received within the time limitation or if interested parties waive or are deemed to have waived their opportunity for a hearing or to participate in a hearing, the Administrator, after giving consideration to written comments and objections, will issue a final order pursuant to 21 CFR 1308.48 without a hearing. DEA's final decision concerning the scheduling of carfentanil will take into account the Assistant Secretary's recommendation, its own review, and any information received in response to this proposal.

Pursuant to Title 5, United States Code, Section 605(b), the Administrator

certifies that the scheduling of carfentanil will not have a significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). These proposed drug control actions relate to the initial control of a substance that is not yet marketed in the United States. Commercial products which contain carfentanil will be used in veterinary clinics specializing in big game control and treatment. This rule, if finalized, will cause such establishments to handle carfentanil in a manner identical to that in place for other Schedule II products.

In accordance with the provisions of section 201(a) of the CSA (21 U.S.C. 811(a)), this proposed scheduling action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, have been exempted from the consultation requirements of Executive Order 12291 (46 FR 13193).

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by Section 201(a) of the CSA (21 U.S.C. 811(a)) and delegated to the Administrator of DEA by regulations of the Department of Justice (28 CFR Part 0.100), the Administrator hereby proposes to amend 21 CFR Part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR Part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b).

2. Paragraph (c) of § 1308.12 is amended by redesignating the existing paragraphs (c)(6) through (c)(24) as (c)(7) through (c)(25) and adding a new paragraph (c)(6):

§ 1308.12 Schedule II.

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- (c) * * *
- (6) Carfentanil—9743
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Dated: January 5, 1988.

John C. Lawn,
Administrator, Drug Enforcement Administration.

[FR Doc. 88-417 Filed 1-11-88; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Care Financing Administration
42 CFR Parts 434 and 435

[BERC-306-P]

Medicaid Program; Waiver of Certain Membership Requirements for Certain Health Maintenance Organizations (HMOs), and State Option for Disenrollment Restrictions for Certain HMOs Under Medicaid

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposal would revise current Medicaid rules to expand the waiver authority of the Secretary to permit certain health maintenance organizations (HMOs) meeting certain requirements to exceed the composition of enrollment limit, to allow certain organizations to contract on a risk basis, to permit continuation of benefits to recipients enrolled in certain organizations after they have lost entitlement to Medicaid, and to give a State the option of restricting a Medicaid enrollee's right to disenroll from certain types of risk HMOs and other organizations. These regulations would conform our regulations with authority provided in section 2364 of Pub. L. 98-369, the Deficit Reduction Act of 1984, as amended by section 9517 of Pub. L. 99-272, the Consolidated Omnibus Budget Reconciliation Act of 1985. We are also proposing to make a technical correction concerning HMO and PHP contracts.

DATE: To assure consideration, comments must be received by March 14, 1988.

ADDRESSES: Address comments in writing to: Health Care Financing Administration, U.S. Department of Health and Human Services, Attention: BERC-306-P, P.O. Box 26676, Baltimore, Maryland 21207.

If comments concern information collection or recordkeeping requirements please address a copy of comments to: Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Allison Herron, Room 3208, New Executive Office Building, Washington, DC 20503, Attention: Desk Officer for HCFA

In commenting, please refer to file code BERC-306-P.

If you prefer, you may deliver your comments to Room 309-G Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, DC, or to Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

Comments will be available for public inspection as they are received, beginning approximately three weeks after publication, in Room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone, 202-245-7890).

FOR FURTHER INFORMATION CONTACT: Thomas Saltz, (301) 594-9374.

SUPPLEMENTARY INFORMATION:

I. Background

A. Program Description

Section 2178 of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97-35) was enacted to encourage and enable Medicaid agencies to make greater use of health maintenance organizations (HMOs) that provide cost-effective health care to Medicaid recipients. That section raised the maximum allowable proportion of Medicare and Medicaid enrollees an HMO delivering Medicaid services on a risk basis may have in order for a State to be eligible for Federal financial participation in its Medicaid expenditures to those entities. The amendment raised the limit on Medicare and Medicaid enrollees from fewer than 50 percent to fewer than 75 percent of the total enrollment. It did not alter the provision which authorizes a temporary waiver of that upper limit for new HMOs. (Section 1903(m)(2)(C) of the Social Security Act (the Act)). Waivers of the Medicare/Medicaid enrollee percentage limit are available during the first 3 years of a contract with a State, if the Secretary is satisfied that it has made an continues to make efforts to meet the enrollment limits as required in section 1903(m)(2)(C) of the Act. Additionally, the 1981 amendments provided for a waiver of indefinite duration to an HMO that is a public entity (i.e., owned or operated by a State, county, or municipal health department or hospital) if the Secretary determines the waiver can be justified and the public HMO is making reasonable efforts to meet the enrollment limit by enrolling persons not entitled to Medicare or Medicaid as permitted under section 1903(m)(2)(D) of the Act.

The Act also provided specific exceptions to certain organizations at section 1903(m)(2)(B). This section provides for a specific group of entities to be exempt altogether from the composition of enrollment requirement as well as other requirements in section 1903(m)(2)(A) pertaining to organizations contracting with the State