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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(617)279-1675 FAX: (617)279-1742

WARNING LETTER

September 4, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NWE-13-97

Warren M. Davis, President and CEO
Center for Health and Human Services, Inc.
370 Faunce Corner Road
North Dartmouth, MA 02741

Dear Mr. Davis:

During an inspection of your narcotic treatment program located at 88-90 Gifford Street, New Bedford, MA, conducted during the period from June 19 through July 16, 1997, our investigators documented violations of the Narcotic Treatment Program Standards as set forth under Title 21, Code of Federal Regulations (21 CFR) Part 291.505, Conditions for the Use of Narcotic Drugs.

Your narcotic treatment program is not operating in compliance with all regulations governing the use of narcotic drugs in the treatment of narcotic addiction. You failed to inform individuals who provide services of these regulations, and failed to monitor their activities to assure compliance with provisions required by 21 CFR 291.505(c)(2)(i).

The specific violations are as follows:

1. You failed, as sponsor, to ensure that the program physician was responsible for the amount of narcotic drug administered (21 CFR 291.505(d)(6)(i)). For example, patient 105004 was administered an unauthorized and unrecorded double dose of methadone on March 29, 1995.
2. You failed, as sponsor, to ensure that the program physician was responsible for changes in the dosage schedules for patients 104596, 4546, 106357, 106502, 106030, 107537, and 107098 (21 CFR 291.505(d)(6)(i)).
3. You failed, as sponsor, to ensure that the program physician reviewed and concurred with the findings of medical evaluations conducted by the nurse practitioner (21 CFR 291.505(d)(3)(ii)). For example, the program physician failed to date his countersignature documenting his review of and concurrence with admission evaluations in eleven patient records.
4. You failed, as sponsor, to ensure that the program physician documented a one year history of addiction in six patient records (21 CFR 291.505(d)(i)(C)).
5. You failed, as sponsor, to ensure that the program physician requested or received a summary of the treatment outcome for four patients and offspring from the physician or hospital to which the patients were referred (21 CFR 291.505(d)(1)(iii)(B)(3)).
6. You failed, as sponsor, to ensure that Forms FDA 2635, Consent to Treatment with an Approved Narcotic Drug, were adequately witnessed (21 CFR 291.505(d)(1)(ii)).
7. You failed, as sponsor, to meet minimum standards for long-term detoxification treatment. For example, the program physician (1) failed to document that short-term detoxification was not a sufficiently long enough treatment course prior to beginning long term detoxification, and (2) failed to ensure that periodic treatment plans were conducted monthly for four patients admitted to long-term detoxification (21 CFR 291.505(d)(9)(i)(C)and(F)).

In addition, there was no assurance that the dispensing pump delivers accurate doses. For example, daily accuracy tests on the pump were not documented and the [REDACTED] software, revision [REDACTED], was not validated to verify installation, operation, and performance.

It is your responsibility, as sponsor, to ensure that the medical director is responsible for the administration of all medical services performed by your narcotic treatment program. The purpose of the federal narcotic treatment program regulation, as described by the statute, is to develop "appropriate methods of professional practice in the medical

treatment of narcotic addiction..." (Section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L 91-513). Although a nurse practitioner may perform medical evaluations and write methadone orders, the medical director "assumes responsibility for administering all medical services performed by the program" (21 CFR 291.505(d)(4)(ii)). The regulation does not provide for delegation of this responsibility, and the physician's countersignature assures us of his responsibility for providing such services.

This letter is not intended to be all-inclusive. A list of Inspectional Observations (Form FDA 483) was issued to you at the conclusion of the inspection. It is your responsibility to assure that the operation of your narcotic treatment program is in compliance with all applicable federal and state laws and regulations. You should take prompt action to correct these violations. Failure to do so may result in enforcement action without further notice.

We acknowledge your July 22, 1997 response, which addresses the observations issued at the close of the inspection. It is currently under review. Corrective actions presented in that response may be referenced, as appropriate, in your reply to this letter, which should include any available supporting documentation.

Please respond in writing within 15 days of the receipt of this letter, setting forth the steps taken or being taken to correct these violations. If full corrective action has not been taken at the time of your response, please specify when it will be and explain the reason for any delay. Your reply should be directed to the attention of Mark Lookabaugh, Compliance Officer, Food and Drug Administration, One Montvale Avenue, Fourth Floor, Stoneham, MA 02180.

Sincerely,



John R. Marzilli
Director
New England District

cc: Drug Enforcement Agency