



Food and Drug Administration  
Denver District Office  
Building 20 - Denver Federal Center  
P. O. Box 25087  
Denver, Colorado 80225  
TELEPHONE: 303-236-3000

March 11, 1998

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Rick L. Robinson, Executive Director  
Cheyenne Community Drug Abuse Treatment Council  
121 West Carlson Street, Suite 3  
Cheyenne, WY 82009

**URGENT**

Ref. # - DEN-98-07

Dear Mr. Robinson:

On November 6 - 7, 1997, Consumer Safety Officer Anthony E. Keller, R.Ph., inspected your methadone maintenance and detoxification center located at 121 West Carlson Street, Suite 3, Cheyenne, Wyoming, 82009.

Our review and evaluation of Mr. Keller's report from that inspection revealed the following significant violations of the Narcotic Treatment Program Standards, Title 21, Code of Federal Regulations, Part 291.505 (21 CFR 291.505), Conditions for the Use of Narcotic Drugs:

1. Failure to maintain adequate records for each patient showing accurate dispensing of methadone, as required by 21 CFR 291.505(d)(13)(ii & iii). For example, several patient Methadone Treatment Records reviewed indicated erroneous dates with respect to dispensing doses, or indicated that the patient had reported to the clinic when they had, in fact, received take-home doses. Several records reviewed failed to document whether the patient was observed at the clinic taking the dose or whether the patient took the dose home.
2. Failure to document the rationale for the decision to reduce the frequency of a patient's clinical visits in their clinical record as required by 21 CFR 291.505(d)(6)(iv)(A).
3. Failure of the program physician to increase the frequency of the patient's clinic attendance following two unexcused absences as required by 21 CFR 291.505(d)(6)(v)(B)(1).

4. Failure of the program physician to review, countersign and date patient records documenting the rationale for exceptions to take-home requirements, as required by 21 CFR 291.505(d)(6)(vi)(B).
5. Failure to maintain adequate security over drug stocks as required by 21 CFR 291.505(d)(14). For example, the "Master Methadone Dispensing Record" is not dated and is not complete in that it indicates a greater number of doses dispensed than were actually dispensed.
6. Failure to document the authorization to decrease the frequency of attendance at the clinic for observation of patient # [redacted], as per 21 CFR 291.505(d)(6)(iv)(A).
7. Failure to document the tuberculin skin tests and serological tests for syphilis were performed as part of the admission physical examination for two of four patients whose records were reviewed, as required under 21 CFR 291.505(d)(3)(ii).
8. Failure to note use of a narcotic drug when considering a patient for take-home medication as per 21 CFR 291.505(d)(6)(iv)(A). Patient # [redacted] take-out privileges were increased although prior urinalysis disclosed the presence of narcotics. In the "Rationale for Take-Out Privileges," it was noted that this patient has given "clean" urines since admission to the program on 6/5/95.
9. Failure of the Medical Director to ensure that the periodic treatment plan of patients [redacted] and [redacted] were dated, reviewed and countersigned as required by 21 CFR 291.505(d)(3)(v)(C).
10. Failure to provide educational, vocational rehabilitation and employment requirements and medical, psychosocial, economic, legal or other support services needed for the initial treatment plan for patient # [redacted], as required by 21 CFR 291.505(d)(3)(iv)(A)(1).

At the conclusion of this inspection, Consumer Safety Officer Keller issued a written report of observations (FDA-483) to you. A copy of that report is enclosed for your reference.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. As Executive Director, it is your responsibility to assure adherence with all requirements of the Food, Drug and Cosmetic Act and the Narcotic Treatment Program Standards.

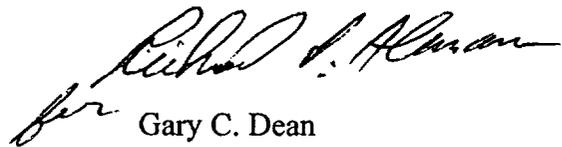
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice. Federal agencies are advised of the issuance of all warning letters so that they may take this information into account when considering the award of contracts.

We acknowledge that we have not received any formal or written response to Mr. Keller's inspectional observations.

**URGENT**

Please advise this office in writing, within fifteen (15) working days after receipt of this letter, of the specific actions you have taken to correct the violations. Your response should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the corrective action is not completed within the response time and (4) any documentation necessary to indicate correction has been achieved. Your response should be directed to Ms. Regina A. Barrell, Compliance Officer, at the address above.

Sincerely,

  
for Gary C. Dean  
District Director

Enclosures  
As Stated in Letter

**PURGED**