



October 10, 1997

WARNING LETTER  
CHI-1-98

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Gordon R. Lang, M.D.  
Sponsor/President  
Therapeutic Interventions, Inc.  
1545 Hicks Road  
Rolling Meadows, IL 60008

Dear Dr. Lang:

An inspection your firm, which does business as Medical Management and Detoxification (MMD), was conducted from June 9-13, 1997, by Investigator Richard E. Kingdon.

This inspection revealed your institution is operating in serious violation of the Narcotic Treatment Program Standards as defined in Title 21, Code of Federal Regulations (CFR), Section 291.505, Conditions for the Use of Narcotic Drugs. These deviations include the following:

1. The program fails to assure that the initial dose of methadone for new patients does not exceed 30 mg. The inspection revealed that [REDACTED] of [REDACTED] patient files for clients entering the program after November 1, 1996, showed that those patients received an initial dose of methadone that exceeded the 30 mg. limit. We note that this deviation was reported during the last inspection conducted of your firm from October 10-16, 1996, and reported to you in Warning Letter CHI-13-97 issued on January 29, 1997. Your written response to the Warning Letter, dated February 10, 1997, indicated that this deficiency had been corrected.
2. The program fails to assure that records for patients with 6-day take home privileges document the results of monthly drug screening tests. Of the files for [REDACTED] patients examined, [REDACTED] files failed to list the test results for each of the last five months.
3. Files for [REDACTED] of [REDACTED] patients examined failed to contain the results of the physician's annual review and the countersignature of the treatment plan. Quarterly and semi-annual review files were also missing.

4. The program fails to assure that patients which received more than 100 mg of methadone per daily dose are screened monthly for illicit drugs. For example, patient [REDACTED] (130mg) missed screening in February 1997, and patient [REDACTED] (125mg) missed screening in February and March 1997.
5. The program fails to assure that existing treatment plans in patient files contain all required elements. For example, the files for patients [REDACTED], [REDACTED] and [REDACTED] fail to contain:
  - a. Behavioral tasks for short term goals;
  - b. Patient requirements and assessments of their need for education, vocational rehabilitation, employment, medical, economic, psychosocial, legal or other supportive services;
  - c. Frequency at which services are to be provided.

The violations listed above and the inspectional observations, Form FDA 483, presented and discussed with Dr. Bageshwari S. Parihar, Executive Director, at the conclusion of the inspection, are not all-inclusive. It is your responsibility as sponsor to ensure your program operates in compliance with the narcotic treatment program standards. A copy of the Form FDA 483, which was issued to Dr. Parihar, was sent to you on June 24, 1997.

Failure to promptly correct these violations may result in administrative or enforcement actions, i.e., revocation of approval to receive methadone.

Please notify this office in writing within 15 days of receipt of this letter as to the steps you have taken, or intend to take, to correct these violations. Your response should be directed to the attention of George F. Bailey, Compliance Officer.

Sincerely,

*RS*

Raymond V. Mlecko  
District Director

cc: Bageshwari S. Parihar, Ph.D.  
Executive Director  
Therapeutic Interventions, Inc.,  
1645 Hicks Road, Suite C  
Rolling Meadows, IL 60008