

October 22, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, ME 20857

Re: Docket No. 98N-0617

Dear Sir/Madam:

On behalf of the Region VI state methadone authorities, I am submitting these written comments to the proposed rules to repeal the current regulations about narcotic drugs in maintenance and detoxification treatment of narcotic dependence, and the proposed new regulations. This group is comprised of Mr. Larry Raper, Director, Office of Program Compliance, Arkansas Department of Health; Ms. Sandy Record, Director of Treatment, Office of Alcohol and Drug Abuse, Louisiana Department of Health and Human Services; Ms. Susan Bosarge, Treatment Program Manager, New Mexico Department of Health; Dr. Johanna Clevenger, Director of Behavioral Services, Oklahoma Department of Mental Health and Substance Abuse Services; and Ms. Karen Tannert, Senior Pharmacist, Drugs and Medical Devices Division, Texas Department of Health.

The Region VI state methadone authorities are in agreement concerning the following language of certain sections of the proposed rules. These comments represent a regional concern and should be considered separate from any comments the state authorities choose to submit individually.

Proposed Title 42, Code of Federal Regulations (CFR), §8.11(a)(2) states the criteria for certification with Substance Abuse and Mental Health Services Administration (SAMHSA) by Opioid Treatment Programs (OTP). In this section, no reference is made to requiring the OTP to obtain a license or permit from the state in which they are located. Section 8.11(c) stipulates that SAMHSA will consult with an appropriate state authority regarding qualifications of an applicant prior to certification. Once again, a license or permit from the state is not expressly required. Section 8.11(h) provides for exemptions from regulatory requirements. SAMHSA "may consult" with the state authority, but they are not required to obtain concurrent approval of the state for any exemptions granted. Our concern is twofold. First, SAMHSA may certify an OTP in a state where no methadone authority exists or state regulation is lacking or nonexistent. Secondly, certification could occur feasibly without any state approval. Section 8.11(f) appears to address this by stating that OTPs shall comply with all pertinent state laws and regulations; however, SAMSHA certification is still not dependent upon concurrent state approval. We suggest that criteria for certification include a requirement that the OTP must obtain a license or permit from the state in which the program is located.

42CFR 8.12(d) describes staff credentials. We would like to see an interpretation of "sufficient education, training, and experience" included in the regulations. This section stipulates that licensed

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professionals must comply with the credentialing standards of their professions, but no requirements are listed for unlicensed individuals (ie: counselor interns). This section also does not stipulate that licensed professionals must be licensed in the state in which the OTP is located. We suggest that this section is amended to include this requirement.

Sincerely,

A handwritten signature in black ink, appearing to read 'Karen Tannert', written over a horizontal line.

Karen Tannert
Senior Pharmacist
Drugs and Medical Devices Division
Bureau of Food and Drug Safety
Texas Department of Health

cc: Mr. Larry Raper, Arkansas Department of Health
Ms. Sandy Record, Louisiana Office of Alcohol and Drug Abuse
Ms. Susan Bosarge, New Mexico Department of Health
Dr. Johanna Clevenger, Oklahoma Department of of Mental Health and Substance Abuse
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FIRST CLASS

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