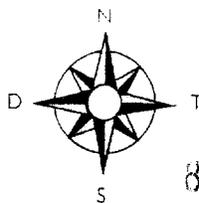


NEW DIRECTIONS Treatment Services



8565 '99 AUG 27 A10:28

August 24, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Dear Sir/Madam:

I'm writing to make comments on the proposal to delete certain FDA regulations concerning methadone under 21CFR, Part 291 and replace them with an accreditation system overseen by SAMHSA. I oversee an agency serving approximately 380 methadone patients. Coming into this field from a diversified public health background, I have found the regulatory environment to be extremely burdensome and unreasonable. I support the direction embodied by the proposed federal regulatory change. However, the primary problem in our experience is regulation at the state level, not the federal level. Even as I write this letter, Pennsylvania's Secretary of Health is considering his licensing staff's proposal for revamping the state's methadone regulations. Far from the spirit of moving in the direction of outcomes versus process criteria, Pennsylvania will be greatly expanding process criteria and will even be adopting large parts of the current FDA language as state regulation. Thus, the accreditation process here will, to a large extent, actually be layered on top of the existing FDA language in a place where regulatory oversight is already absurd in terms of its unrelentingly controlling nature.

I realize that the problem of inappropriate regulatory activity from the state level is in many ways a separate issue from the federal accreditation proposal. However, it is important to not see the federal effort as being in any way likely to solve the problem of burdensome regulation in the field of methadone treatment. The FDA was never the problem, at least in our experience. The problem has been and, unless other changes are made, will continue to be at the state level and these people show absolutely no inclination to change.

Sincerely,

Glen Cooper
Executive Director

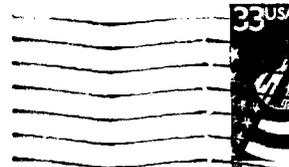
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NEW DIRECTIONS
Treatment Services

1810 Steelstone Road, Suite 101
Allentown, Pennsylvania 18103



Dockets Management Branch (HFA-305)
Food and Drug Administration
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