

CENTER FOR ADDICTIVE PROBLEMS

609 NORTH WELLS • CHICAGO, ILLINOIS 60610 • 312-266-0404 • FAX: 312-266-8169

September 29, 1999

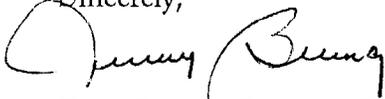
Mr. Raymond D. Hylton, RN, MSN, MPH
Project Officer/Public Health Advisor
Center for Substance Abuse Treatment
Office of Pharmacologic & Alternative Therapies
5600 Fishers Lane
Rockwall II Building, Suite 740
Rockville, MD 20857

Dear Ray,

I got the impression you endorse the humane practice of treating opioid dependent patients which is consistent with our philosophy. I hope my response to these proposed FDA regulations will be heard. I work with Marc Shinderman, MD at the Center For Addictive Problems and CAP of Downers Grove. We collectively treat over 1500 patients. We have patients which travel as far as Detroit Michigan, Wisconsin and Iowa for their care at our programs.

Although I am impressed with the vigor CSAT is attempting to find solutions in upgrading the treatment programs across the country I am afraid many of the providers that maintain moralistic attitudes and promote questionable procedures will find a way to become accredited. Good intentions do not always translate to good outcomes! Has anyone at CSAT thought about going to the patients or actively using heroin addicts themselves? They are the current/future consumers who will benefit by your agency's direction. You can find them on the NAMA website. I enjoyed our brief conversations and look forward to seeing you at future events. I have asked Mike Bacon to submit my response to these FDA proposed rules which accompanies this letter in the public record.

Sincerely,



Terry Bering, Program Director

cc: Mike Bacon, MS Project Officer CSAT
Sharon Dow, MS Project Director JCAHO
Richard Weisskopf, Manager, Methadone treatment Services IDHS
Cynthia Hope Bolger, RPH Consultant Pharmacist

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To: Notice of Proposed Rule Making

Fr: Terry Bering, Program Director

Re: Proposed Food and Drugs Administration, F.D.A. Regulations
Reviewing Agency: Substance Abuse and Mental Health Services Administration,
SAMHSA

Overview:

Upon reviewing the FDA regulations it is clear that there are a number of issues that all individual programs, associations, physicians and program administrators can comment on which relate to the proposed FDA rules and accreditation. The proposed rules from SAMHSA and their implementation seems to hinge on the fact that an accreditation model (overseen by Joint Commission Association on Accreditation of Healthcare Organizations (JCAHO) or Commission on Accreditation of Rehabilitation Facilities (CARF)), will be a reality sometime within the next three years for all currently licensed programs. The proposal discusses the estimated costs for each clinic and the cost differential between FDA licensing and projected accreditation fees. Costs for even a small clinic could run as high as \$3-5000.00 per site visit. Site visits are scheduled to occur once during a three year cycle. This cost does not include the probationary approval for one year during the initial accreditation phase. The annual cost differential between FDA licensing, (\$3.9 million) vs some form of accreditation (\$8.3 million annually) is significant for the government or the combined treatment providers who must assume these costs. Regardless of whether a licensing or an accreditation body is involved, each Methadone Treatment Provider (MTP) must be thoughtful of their individual budgets. Secondly, the proposal suggests that using an accreditation model will upgrade the quality of services for MTP's. Their own conclusion of the current methadone treatment community reads "Improvements in outcomes after methadone treatment are almost always equal to or greater than improvements seen in treatments for other chronic relapsing disorders. Studies of methadone maintenance programs routinely show reductions of 80 % or more in heroin use in several months with even greater reductions for patients who remain in treatment for one year".

Accreditation:

Some credit must be given to methadone itself, on its own pharmacological benefits, versus a program's stance that patients return to the program for the vocational or talking therapies. We should question the logic of Center For Substance Abuse Treatment, CSAT, mandating accreditation for each program. Will accreditation for MTP's result in better outcomes? How better to measure outcomes than by the reduction or cessation of heroin usage and the retention of patients in treatment.

There are programs that discourage adequate dosage levels and carry medication privileges for their patients. An effort should be undertaken to investigate what funding arms are in place from the regulatory bodies which encourage such practices in lieu of the decades of methadone treatment research.

The proposal discussed the current burden of paperwork now associated with FDA licensing requirements. Accreditation, according to the FDA proposal, would eliminate paperwork by one third over a three year cycle. What paperwork are they reducing? Treatment plan reviews and FDA exceptions will not reduce paperwork by one third. Again, state regulatory agencies must relinquish regulatory control to the assigned accreditation organizations if SAMSHA's assessment of reduced paperwork can be realized.

Mandated detox schedules:

The patient Admission Criteria is still ambiguous in the proposal.

1) They require a patient to be opioid dependent for one year. This rule should be discretionary based upon the M.D's evaluation. Addiction is a metabolic disease. Patients deserve access to methadone maintenance treatment for this medical condition. Providing time restrictions for addicts to become eligible for methadone maintenance reflects naivete from those experts who have proposed the rule. Patients admitted to treatment with less than a one year history of dependence need to be stabilized on a methadone dosage which will extinguish the compulsion to use illicit drugs. These patients rarely have an opportunity to stabilize during a six month detox schedule. There is no time for a 30 day detox patient to stabilize. These patients are at a higher risk for infectious diseases. They are younger, immature addicts who feel impervious to Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV) disease. Younger addicts, like their elder counterparts, respond favorably to adequate dosages of methadone regardless of their participation in other program services.

2) The proposal recommends a two day versus seven day wait before failed detox patients can be readmitted for a second detox schedule. We recommend the FDA abandon the short term detox schedule entirely for out-patient methadone treatment. This detox schedule is medically unsound and places the patient at risk for infectious diseases and impulsive drug seeking behavior not only during the two day waiting period but throughout the entire detox schedule. During this withdrawal period patients have never demonstrated the ability to stabilize on the medication or make meaningful changes in their lives that support an illicit drug free lifestyle. Conversely, patients drop out after realizing they will never be able to normalize during this crucial period of

their treatment and life. This rule is clearly outdated and serves only to expose patients to recidivism, infectious diseases, criminality and an absence of medically available support from programs mandated to reduce their medication.

Recording Medication dosages above 100 mg: in the Patient's Medical Chart:

3) The proposal still requires an MD explanation in the patient's medical file justifying doses above 100 mg. Early research from Dole and Nyswander revealed that for most patients doses of 80 mg - 120 mg would be required to eliminate the addict's craving for narcotics. Subsequent to this research, the MTP's have routinely worked with patients who need higher dosages than this range. MTP's have been a gateway for patients with HIV disease, Hepatitis C and pain management problems to receive higher dosages which have historically provided a therapeutic benefit for many dual diagnosis patients. The overall grade of heroin on the street is at a much higher quality over the past few years as well.

Requiring programs to justify a patient's dose in the medical chart is a simple review process for knowledgeable programs; however, it acts as a barrier for less sophisticated programs. As a result physicians may second guess their medical judgement and deny patients an adequate dose of medication. 100 mg is an arbitrary number at best. The proposed rule reflects a disregard of the summation of medical research in this field for the past three decades. We support the elimination of this rule.

Carry Medication privileges:

The proposal's review of the three options concerning take home medications is hopeful. Option I is the same as our current rules and seems to be supported by the DEA. Option III is cumbersome; it describes setting maximum amounts of methadone and LAAM (in grams?).

Far and away, Option II will give programs the best opportunity to provide carry medication privileges based on the patient's progress in treatment.

This rule may need modification related to the manner in which patients earn eligibility for carry medication privileges. Experience assessing patients for reduced clinic visits dictates gradually reducing visits over a period of time, which again should be discretionary based upon the program's evaluation process. Option II does not mention the method of moving patients from a one time per week pick up schedule to a monthly pick up schedule. We have found this schedule, one time per week pick up schedule, to be particularly helpful for many eligible patients. One time weekly clinic visits serve as a necessary step for patients who demonstrate responsibility with carry medication to reduce clinic visits further.

A) 1 month - 1 carry bottle permitted

B) In the 2nd month- 2 carry doses each visit (this would mean a 3 x weekly p/u for our patients unless we begin full service on Sundays).

C) In the 3rd month- 2 x weekly p/u

D) In the remainder of the 1st year (After 90 days) - 3 carry doses each visit (same as B)

There are two versions of Option II pertaining to carry medication privileges after one and two

Proposed Simultaneous Enrollment in two Programs:

Regarding the proposed FDA regulations that relate to a patient's enrollment in two programs at one time: The proposal states in one section that programs must ensure that patients are not enrolled in two programs at any one given time. In another section of the proposal it states that a patient can be enrolled in two programs at one time under exceptional circumstances justifying this dual enrollment. The proposal suggesting that a patient be allowed to enroll in two programs under exceptional circumstances is not sound. Having a patient simultaneously enrolled in two programs complicates the patient's care for everyone involved. The patient would be subjected to the redundancy of each program's rules. Additionally, the patient would be occupying two slots in a modality in which the opioid dependent population are already grossly under-served. Patients with exceptional circumstances would be better served by adequate dosages of methadone and the reduction of cumbersome regulations.

Medication:

MTP's may be the only out-patient modality that prepares a patient's daily dose of medication scheduled to be ingested later in the week, in a formulation not consistent with the manner in which it was manufactured.

The proposal does not address wet or dry forms of medication. The packaging of dry medication would allow patients to take the medication under conditions which are best suited to maintain accurate potency over an extended time period. Allowing programs to dispense medication diskettes and pills in dry form would allow patients to manage their medication in the same consistent manner as they manage all other prescribed medicines in their daily life. Pre-packaging dry forms of medication would also provide some relief from the program's labor associated with preparing each patient's take home dosage of methadone.

Allowing programs to dispense dry medication, pills and diskettes, will present a challenge for drug manufacturers to provide safeguards, with child-proof barriers. We support the use of dispensing medication in its manufactured formulation.

LAAM:

Regarding LAAM: The prohibition of LAAM carry doses has always been based on fear. As we know, LAAM has a lower potential of abuse than other narcotic agonists. Patients often experience unpleasant side effects during the induction phase. Given a choice, most patients do not embrace this medication to treat their opioid dependence. There is no evidence to suggest the controls of this drug (no carry bottles with LAAM) was ever medically justified. Indeed, the DEA exercised its law enforcement authority to severely restrict the utility of this drug.

In the past the DEA was concerned about the overdose potential of this drug. Physicians could use a combination of short (Narcan) and long acting narcotic antagonists (naltrexone hydrochloride or buprenorphine) to counter the longer acting effects of the LAAM in the event of an emergency room admission for overdose.

We support the ability for patients to receive LAAM carry medication. Some patients do not choose LAAM as their medication based on the regulatory restrictions associated with this drug. In the future other opiate agonists or combination agonist/antagonist drugs may be introduced to

the milieu. Clinics will not get a clear picture of the efficacy of the new opiate substitute drugs if restrictions are unevenly imposed in the dispensing for the drug.

Diversions

There is a great deal of emphasis on medication diversion with the proposed rules. The DEA stated 'that to relax controls in clearly identified areas which contribute to the illicit trafficking would not enhance treatment, but instead would further erode public confidence in treatment and expand traffic and abuse of methadone.' This belief is prejudicial and is not supported by over 30 years of methadone maintenance experience.

The DEA cited in their 1995 Methadone Diversion report examples where armed robberies of methadone delivery trucks occurred. Armed robberies of pharmacies and delivery trucks do occur. Everyone abhors these criminal actions. Should the DEA mandate a reduction of pharmacies which serve the public in order to reduce the number of targets for criminals?

Regarding carry medication diversion by individual patients, program staff should be prepared to discuss methadone diversion openly with their patients, have forms for them to sign and have consequences corresponding to any improper action with carry medication. Clinics should have a firm community policy that discourages diversion. Community issues, including issues of diversion prevention, should be discussed in staff meetings and subcommittees.

All programs need to address the diversion issue because it ultimately impacts the community of each program. The issue of diversion was prominently mentioned in this proposal. From a historical perspective, reducing or eliminating methadone diversion has always played a prominent role in the rules. The fear of methadone diversion has promoted an environment of excessive restrictions for our patients and brought a uniqueness to the manner in which we are required to dispense methadone. Programs are generally able to recognize diversion and address this problem when it presents itself. The attention this issue receives overshadows the complex medical and psychiatric problems programs must respond to each day in order to work effectively with its patients.

The concept of providing wet or liquid medication to discourage diversion is wishful thinking. An individual who is a criminal will act like a criminal, regardless of whether methadone is in wet or dry form. Addiction is a disease, not a criminal behavior. Patients given sufficient dosages of methadone will act responsibly with carry medication, regardless of its form.

The fear of methadone diversion has never been realized by those entities that support layers of regulations which limit a patient's carry medication and ultimately their freedom. Isolated examples of carry medication diversion have occurred within the addicted community itself. Methadone carry bottle diversion is directly related to inadequate methadone dosages for those patients in treatment. Another contributing factor related to methadone diversion is insufficient treatment opportunities for those individuals unable to access treatment. Additionally, there is a subculture of addicts who know how to access treatment but who choose to remain in the periphery of methadone treatment. These opiate dependent individuals are the source of methadone diversion, if and when diversion exists. Addicts may not be able to afford private treatment or they may be unable to tolerate months of waiting lists associated with many

underfunded clinics.

Urinalysis:

The proposal for urinalysis screening is inconsistent. Eight mandatory urine screens is a sufficient number of tests for patients new in treatment who are unstable during the induction stage. These patients need increased urine monitoring as their drug usage is still an issue and they have not reached an adequate dosage level.

The utility of urinalysis testing diminishes over time for adequately dosed patients with longer treatment histories. Patients become anxious to provide urine specimens in a timely manner so as not to adversely affect their once weekly carry schedules. More importantly, the value of clinical relationships with the professional staff increases for these patients, making mandatory urinalysis testing less necessary. For those adequately dosed patients who are stable on their dosages, quarterly urinalysis testing is sufficient, regardless of the number of clinic visits each month.

Initial and periodic assessment services:

The proposal eliminates the process for utilizing a physician's involvement in non medically related services. Treatment plans can be reviewed periodically based on the program's policy, by credentialed staff and later reviewed by the clinic's supervising personnel.

Elimination of Forms FDA 2633 & 2635

The elimination of the responsibility statement for use of narcotic drugs in a treatment program and the consent to methadone form is long overdue. The use of these forms has been an exercise for a program's compliance to the rules with little attention to the meaning of each form itself. Physicians recognize their responsibilities to the patient and information stated in the methadone consent has yielded a limited insight into methadone for patients who are being prescribed methadone for the first or 101st time.

Interim treatment:

There is no evidence of any state in the country allowing interim methadone maintenance. In the past, our state methadone association has prohibited interim maintenance based on the recommendations of the American Methadone Treatment Association. Programs should be free from these restrictions and be allowed to provide interim maintenance to addicts awaiting treatment slots in funded programs. This may be an unpopular action considering that funded programs usually have waiting lists, and money for these Interim maintenance slots would be considerably less than dollars targeted for traditional methadone maintenance treatment patients..

The rules for interim maintenance are: 120 day limit to care.

- no assigned counselor / no clinic services
- initial u/a + 2 u/a's within 120 days
- no carry bottles (Sundays?)

State and FDA regulatory authority:

It is our understanding that each state must decide whether to continue its monitoring responsibilities with methadone programs or relinquish control to the accreditation bodies, JACHO or CARF. Regardless of the competence or understanding of each program's state monitoring agency, the MTP will always be affected by the politics of its community. State agencies have the authority to develop layers of rules which are more stringent than the FDA regulations. Rules are unique to that state and may have no compelling rationale as to why they exist. State rules do not reflect the work of rigorous clinical trials over a period of time.

In the event programs must be accredited and the FDA and state agency regulations remain the same, it will provide more redundancy in regulations than what currently exists for methadone programs. Additionally, the programs must assume the costs of accreditation.

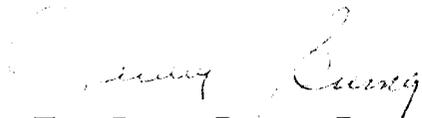
Finally, after attending JACHO training this past week-end in Oak Brook, Il, which was presented by very competent trainers, it is questionable whether the accreditation process will solve the real problem that exists in many treatment settings. This includes poor dosing practices by frightened or moralistic physicians. This is usually accompanied by mandated counseling and punitive attitudes by staff brow beating the patients into accepting lower dosages. Many of these patients are dual diagnosis and/or medically compromised. They require humane treatment and adequate dosages from program staff and understanding when it comes to receiving carry medication privileges.

Many of our current patients come from accredited programs which embrace doses limitations, punitive consequences when the patient relapses due to methadone dosage restrictions, and rigorous urine monitoring techniques which dehumanizes the patient. Of course these patients do not have carry medication privileges due to positive heroin urine results.

They apparently demonstrate good patient outcomes, however.

This concludes my response to the FDA proposed rules.

Sincerely,



Terry Bering, Program Director
Center for Addictive Problems
CAP of Downers Grove