

# STATE OF COLORADO

COLORADO DEPARTMENT OF HUMAN SERVICES

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November 15, 1999

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

RE: Docket No. 98N-0617

Dear Ladies and Gentlemen:

On behalf of the Alcohol and Drug Abuse Division, (ADAD), Department of Human Services of the State of Colorado, this letter is being submitted in response to the proposed rule change pertaining to Narcotic Drugs in Maintenance and Detoxification Treatment of Narcotic Addiction.

Currently over 1,800 patients receive opioid maintenance treatment in eight programs in the state of Colorado. Of these programs, four are publicly funded and the other four are privately owned and operated. ADAD, through the state methadone authority, has developed and sustains an excellent rapport with the opioid treatment programs and meets quarterly with all program directors to discuss relevant issues and concerns. The state methadone authority and the programs work collaboratively considering and preparing for the future of opioid treatment in the state.

In principle ADAD is in agreement with the justification for the proposed rule change and supports the shift from process oriented regulations towards quality assurance and improvement systems and implementation of proven clinical guidelines. Ultimately success in treatment comes in assisting patients to achieve stability and productivity, which can be better measured using these tools. The time has come to transfer federal authority to SAMSHA as our understanding of treatment for opioid addiction has expanded.

We currently have three programs participating in the pilot accreditation project with CARF. We are frankly puzzled by the determination of the secretary to move forward with this proposed rule change before any data has been analyzed from the pilot project. Crucial information regarding performance of the accrediting bodies and implementation of accreditation standards in opioid treatment programs will be lost if this rule change goes into effect before the pilot project can even collect data. Additionally, a more comprehensive analysis of the possible financial burden to programs to come into compliance can be made if acceptance and implementation of the proposed rule change can be deferred until data from the pilot project can be evaluated.

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*Building Partnerships to Improve Opportunities for Safety, Self-Sufficiency, and Dignity for the People of Colorado*

Review of the proposed rule change has lead us to several specific points for clarification as well as concerns with regard to maintaining the integrity of programs and oversight. Following please **find a** section by section **discussion**.

### **Subpart A - Accreditation**

1.) Our understanding is that private not for profit organizations, states or political subdivisions of states may apply **to** become **accrediting** agencies as long **as** they meet the requirements set out by SAMSHA. We encourage the Secretary to consider several points: a.) the conflict of interest this may create where the state *or* local government is both the accrediting body and the funding agency; b.) that as more accrediting bodies are approved market competition **will** naturally lead to decreased accreditation **costs** and; c.) the **possibility** that as greater numbers of accrediting bodies are approved the more difficult it will become to maintain consistent treatment standards nationwide.

2.) **Specific** feedback is solicited with regard to the issue of modification of the rule to accommodate physician, office based treatment and whether a separate set of federal opioid treatment standards should be included in this rule to address an office based treatment option. We would not welcome the development of a separate set of federal standards to address physician based opioid treatment. Should physicians be allowed **to** offer **office** based opioid treatment they should be held to the same standard as opioid treatment programs in order to maintain a standard of care regardless of where treatment is accessed, We **believe** it is a more reasonable proposal to consider utilization of physician based opioid treatment by long term, stabilized **opioid** maintenance patients in order to open up program access to new patients, In such a case, the physician offering **office** based **opioid** treatment can be considered as a "medication unit" of the "hub" opioid treatment program. The physician and the program would require **two** way communication on all shared patients, and the physician would have access to program resources and referrals for all shared patients. Any indication that a **patient** accessing office based treatment is becoming unstable would necessitate return to **the referring** opioid treatment program. We would encourage you to consider the burden that oversight of physician **based** opioid treatment would place on state and federal agencies the sustain and monitor controlled substance licensing.

3.) Use of the term "craving " in defining opioid addiction may be somewhat ambiguous, We suggest incorporating language into this definition that refers to accepted medical criteria for addiction such as those listed in the DSM IV.

### **Subpart B - Certification and Treatment Standards**

1.) This section does not preclude states from regulating the use of opioid drugs for treatment, or from developing standards for licensing opioid treatment. It also requires programs **to** comply with all **requests** **for** program inspection and **review** by states, as well as SAMSHA, **DEA** and accreditation bodies. Failure to comply with any of these **requests** is grounds for denial, suspension or revocation of **certification**. In the proposal, federal **certification** of opioid treatment programs, however, **does** not **require** state approval or licensure. We support more substantive acknowledgment of state involvement in opioid treatment. We intend to continue active state involvement in this treatment modality.

2.) Exemption from the regulatory requirements is allowed in the proposed rule change. The illustration provided for exemption describes a case in **which** a private practitioner may seek to provide treatment for a limited number of patients in a remote geographic area in which access to certified/accredited programs is difficult or impossible. We cautiously support this. The example provided is typical for frontier **states** like Colorado It is not unusual for patients currently **residing** in remote areas to travel two or more hours to access **treatment**. We believe that certification **exemptions** should be granted judiciously, only in limited circumstances **as defined** by SAMSHA.

3.) The proposed rule change indicates that approval from the chief public health officer in the **state must** be granted to provide **interim** maintenance treatment. We do not currently have a need to offer **interim** maintenance treatment in Colorado, however, in the event that this **possibility** exists in the future, we **feel** obliged to note that the chief public health officer does not have jurisdiction over drug and alcohol treatment in all **states** and suggest that it may be more appropriate to refer to "the proper or presiding state official(s)."

4.) Opioid treatment programs, under the proposed change, will be required to maintain a current "Diversion Control Plan" as part of **their** quality **assurance** programs. We support **this** measure and suggest that the rule **specify** with some greater detail what is **to** be contained in such a plan. We believe that methods used to minimize diversion **should** be based on research and experience in the field, in order to truly reduce the risk of diversion in opioid treatment programs.

5.) We support reducing the wait between **detoxification** admissions from **seven** days **to** two in light of the patients increased vulnerability to **using** drugs resulting in an increased likelihood of **exposure to** communicable diseases and/or related illnesses.

6.) The **proposed** rule **change** indicates that an initial medical examination must be conducted within **thirty days of** admission. **It is** our belief that this period of time is too long, allowing for the **possibility** that patients may switch programs before actually **being** medically evaluated, in order to avoid this exam. These medical examinations are crucial in determining the physiological well **being** of the patient, their history of illness, **assessing** for reportable communicable disease and establishing positive patient rapport with the program. We recommend that these **examinations** should occur within 48 hours of patient admission.

7.) We support changing the federal proposal for drug abuse testing services from eight random drug abuse tests per year, per patient **to** twelve random drug abuse **tests** per year, per patient. Consultation with opioid treatment program directors in Colorado indicates that eight may be too few **tests** to adequately determine whether or **not** a patient is using **illicit** substances. We **suggest twelve** as a minimal standard, knowing that programs will use their **discretion** in deciding if more than twelve will be needed on a case by case basis,

8.) We cautiously support take home use of **LAAM**. Speaking from the experience of a state that has recently had **LAAM** diverted which fell into the hands of a four year old child, we are painfully aware of the negative, possibly **terminal** effect of improper ingestion of **LAAM**. The lethality of **LAAM** is greater than that of methadone. If ingested improperly, **particularly** if it is ingested by **children**. We would only support take home use of **LAAM** for approved travel, whether in an emergency or for vacations, by patients who are clean, stable and would otherwise qualify for take homes under a methadone take home structure. We understand that **LAAM** is **less** available when developing a plan for **courtesy** dosing for patients who need or want to travel and believe that this limited plan would allow for greater **flexibility** for these patients without substantially increasing the risk of improper or inappropriate use.

9.) We **do not** support any of the proposed changes in **the** take home schedule for methadone. We counter propose the following:

Phase	Time in Treatment	Take Home Status
1	0 - 60 days	One take home per week
2	60 - 90 days	Two take <b>homes</b> per week
3	3 months - 9 months	Go to clinic 3 x week, 2 take homes max
4	9 months - 18 months	Go to clinic 2x week, 3 take homes max
5	18 months - 24 months	Go to clinic 1x week, 6 take homes max
6	2 years - 3 years	Go to clinic 1x every other wk, 14 take homes max
7	3 years and beyond	Go to clinic 1x month, 30 take homes max

Failure to abide by federal take home criteria and/or program rules and regulations and/or state standards for treatment by a patient with take home status would of course result in a **reduction** or elimination of that patient's take *home* status, and would require a process by which they could earn that status back.

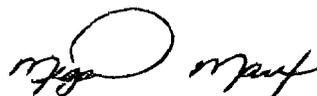
10.) The proposed rule change does not attest to **state's roles** in deliberating accreditation and/or **certification** suspensions or revocations. We support, at minimum, **notification** to the state authority when such suspensions or revocations occur. We prefer that states be **involved** in these **proceedings**. Additionally, states should be **notified** when approval of an accrediting body has been removed and when new accrediting bodies have been approved.

Upon *review* of the proposal we are also concerned about the costs that will be shouldered by the programs to **come** into compliance with the proposed rule change. Based on input from Colorado programs we anticipate that it will be a financial hardship for them **to adhere to** the conditions of this proposal. We urge you to consider the availability of federal Funds and support; **services to assist** programs **to** make the required changes if ultimately the goal of this proposed change is **to** increase access to and **availability of opioid treatment**. We also reiterate **the importance of deferring** final approval **of** this **proposed** rule change until data from the pilot project can better inform us of the **financial implications** for **opioid** treatment programs to come into compliance.

Your time and **effort** in reviewing this **response** is **appreciated**.



Janet Wood  
Director



Megan Marx  
Controlled Substance Administrator