

Addiction Research and Treatment Services  
Outpatient Clinic

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School of Medicine

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November 11, 1999

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

**RE: Written comments on proposed rule:**

**Food and Drug Administration, 21 CFR Part 291  
Public Health Service, 42 CFR Part 8  
[Docket No. 98N-0617]**

To Whom it May Concern,

We are writing in **response** to the Federal Register **Notice of** July 22, 1999, describing the proposed rule governing narcotic treatment programs. The proposed rule has been carefully reviewed by the Colorado Association of Opioid Treatment **Programs**. Directors, or their designees, from **all 8 of the** existing narcotic treatment programs in Colorado are represented via signature at the close of this **letter**.

We are in agreement that the proposed rule represents a positive step and that an accreditation model would be superior to the **current** FDA regulatory model. We feel **that** data from the CSAT pilot project should **not** be overlooked in the adoption of any new rule. We have comments on specific aspects of the proposed rule as **detailed below**:

**Definitions**

Any definition of opioid addiction or dependence in the rule should refer to "accepted medical criteria such as those listed in DSM-IV, or later versions of the Diagnostic and *Statistical* Manual of Mental Disorders". Definitions should not be based **solely** on the term "craving",

**Take-home doses (methadone)**

We feel that none of the 4 options described in the proposed rule are ideal, We **propose** an alternative, which closely **resembles** "Option 2", but which makes more sense based on our collective clinical experience and expertise, **and** which would do a better job of guarding

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The University of Colorado Health Sciences Center is committed to equal opportunity and affirmative action

against possible diversion early in treatment. It also removes **some** of the ambiguity inherent in “Option 2”. Our **proposed “Step Level” or “Phase” take-home dose system is as follows:**

1. **Phase 1:** For the first two months of treatment, the maximum take-home supply is limited to a Sunday take-home only, or one other day per week **should a** clinic **be** routinely closed on **a day** other **than** Sunday.
2. **Phase 2:** In the third month of treatment (days **61-90**), the **maximum** take-home supply is limited to two days per week either **two** consecutive days (**e.g. weekend**), **or any** other two **days of the** week.
3. **Phase 3:** From day 91 (after three **full** months in **treatment**) **until the end** of the **9<sup>th</sup>** month, the maximum **take-home** supply **is limited** to 4 doses per week (**observed** ingestion 3 times per week), with no more than two consecutive take-home doses to be given at any one time.
4. **Phase 4:** **After** nine **full** months **of** treatment and through the **end of** 18 months, the maximum take-home **supply is 5 doses** per week (observed **ingestion** two days), with no more than 3 three consecutive **doses to be given** at any one time.
5. **Phase 5:** From the end of 18 months through the end of two years, the maximum **take-home** supply is limited to 6 **doses per** week.
6. **Phase 6:** From the end of two years to the end of three years, the maximum take-home **supply** is limited to 15 doses at a time, such that the patient would be required to ingest their dose under observation **twice per month**.
7. **Phase 7:** From the end of three years and on, the maximum **take-home** supply is limited to 30 doses at a time, such that the patient would be required to ingest their dose under observation once per month.

### **Take-home doses (LAAM)**

We recommend that take-home dose for **LAAM** be allowed only in cases of travel (emergency or vacation) for **clean**, stable patients, who would otherwise qualify for take-homes under **the methadone take-home structure. We have not yet seen data supporting the** safety of regular, on-going **LAAM** take-homes.

### **Cost**

We believe the costs associated with implementing the proposed rule are **substantial**, and we agree with the **recommendation of** the **American** Methadone Treatment Association that the federal government establish a multiyear, **multipurpose** fund to **assist with this effort**. A prime intent of the proposed rule, that is, to increase treatment **access and** availability, could be seriously undermined if programs are forced to close because they **cannot** bear the substantial costs of accreditation.

**Miscellaneous**

- The **waiting** period **between detox** admissions should be reduced **from 7 days to two days**. Unacceptable risks are present for **opioid** addicts who have to wait 7 days between detox admissions.
- The initial **full** medical examination **by** the program physician, primary care physician, or authorized health care **professional** under **the** supervision of the program physician **should take** place **within the first 48 hours**.

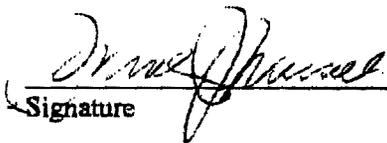
Thanks you for considering our comments.

Sincerely,

  
Signature

Eric Ennis, LCSW  
Printed Name

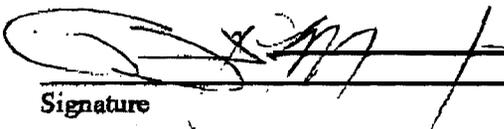
Addiction Research and Treatment Services  
University of Colorado School of Medicine

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CACH, MEd, RFD, MEd, PA, LMC Pamela J. Higgins  
Printed Name

Comprehensive Addiction Treatment Services

 Signature  
RN, MS NANCY E Higgins  
Printed Name

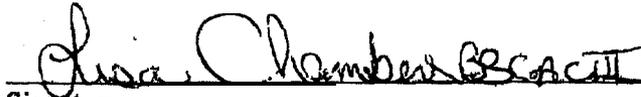
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