



This document is scheduled to be published in the Federal Register on 05/16/2013 and available online at <http://federalregister.gov/a/2013-11637>, and on [FDsys.gov](http://FDsys.gov)

**Billing Code 4162-20-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Substance Abuse and Mental Health Services Administration**

#### **Request for Comment on the Federal Guidelines for Opioid Treatment**

**AGENCY:** Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

**ACTION:** Request for Comment.

**SUMMARY:** This document is a request for comment on the revised draft of the Federal Guidelines for Opioid Treatment. These guidelines elaborate upon the Federal opioid treatment standards set forth under [42 CFR part 8](#).

**DATES:** *Comment Close Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 60 calendar days from the date of publication in the Federal Register.

**ADDRESSES:** The draft guideline may be obtained directly from <http://www.dpt.samhsa.gov> or by contacting the Division of Pharmacologic Therapies. You may submit comments in one of four ways (please choose only one of the ways listed):

•*Electronically.* You may submit electronic comments to [DPT@samhsa.hhs.gov](mailto:DPT@samhsa.hhs.gov).

•*By regular mail.* You may mail written comments to the following address ONLY: Substance Abuse and Mental Health Services Administration, Attention: DPT Federal Register Representative, Division of Pharmacologic Therapies, 1 Choke Cherry Road, Room 7-1044, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

•*By express or overnight mail.* You may send written comments to the following address ONLY: Substance Abuse and Mental Health Services Administration, Attention: DPT Federal Register Representative, Division of Pharmacologic Therapies, 1 Choke Cherry Road, Room 7-1044, Rockville, MD 20850.

•*By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following address prior to the close of the comment period:

•For delivery in Rockville, MD: Substance Abuse and Mental Health Services Administration, Attention: DPT Federal Register Representative, Division of Pharmacologic Therapies, 1 Choke Cherry Road, Room 7-1044, Rockville, MD 20850. To deliver your comments to the Rockville address, call telephone number (240) 276-2700 in advance to schedule your delivery with one of our staff members.

**FOR FURTHER INFORMATION CONTACT:** Nichole Smith, Division of Pharmacologic Therapies, CSAT, SAMHSA, 1 Choke Cherry Road, Room 7-1044, Rockville, Maryland 20857, (240) 276-2700 (phone) or e-mail at [nichole.smith@samhsa.hhs.gov](mailto:nichole.smith@samhsa.hhs.gov).

**SUPPLEMENTARY INFORMATION:** *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. Comments received by the deadline will be available for public inspection at the Substance Abuse and Mental Health Services Administration, Division of Pharmacologic Therapies, 1 Choke Cherry Road, Rockville, MD 20850, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone (240) 276-2700.

**Background:** Federal Regulations codified under 42 CFR part 8 set forth requirements for opioid treatment programs (“OTPs”), also known as methadone treatment programs. The regulations, which were the subject of a Final Rule published in the **Federal Register** on January 17, 2001, (“Final Rule” 66 FR 4075–4102, January 17, 2001) include standards for opioid treatment. OTPs are required to provide treatment in accordance with these standards as a basis for CSAT certification. These standards address patient admission requirements, medical and counseling services, drug testing, and other requirements. The final rule also established an accreditation requirement. Each OTP is required to obtain and maintain accreditation from an accreditation organization approved by SAMHSA under 42 CFR Part 8. Accreditation organizations that provide OTP accreditation under the final rule are required to apply for and obtain SAMHSA approval. Under 42 CFR 8.3(a)(3), each accreditation organization must develop a set of accreditation elements or standards together with a detailed discussion of how these elements will assure that each OTP surveyed by the accreditation organization is meeting each of the Federal opioid treatment standards. The Federal Guidelines for Opioid Treatment are

intended to guide accreditation organizations in preparing their accreditation standards. In addition, the Guidelines provide useful elaborations on the regulatory standards set forth under 42 CFR Part 8.

As such, the updated guidelines will assist both accreditation organizations and OTPs in complying with regulatory requirements. Prepared initially in 1997, the Federal Opioid Treatment Guidelines, originally titled *Guidelines for the Accreditation of Opioid Treatment Programs*, are being updated to reflect new information and research in the field of opioid assisted treatment. CSAT convened an expert panel to provide the draft guideline now being circulated for comment. CSAT is soliciting comments on the guideline from the public, and expects comments from OTPs, accreditation organizations, patients, the medical community and other interested parties. All comments submitted no later than 60 calendar days from the date of publication in the Federal Register will be considered.

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Summer King  
Statistician

[FR Doc. 2013-11637 Filed 05/15/2013 at 8:45 am; Publication Date: 05/16/2013]