

**Exception Request and Record of Justification  
Under 42 CFR § 8.11(h)**

DATE OF SUBMISSION: \_\_\_\_\_

**Note:** This form was created to assist in the interagency review of patient exceptions in opioid treatment programs (OTPs) under 42 CFR § 8.11(h).

**Detailed INSTRUCTIONS are on the cover page of this form. PLEASE complete ALL applicable items on this form. Your cooperation will result in a speedy reply. Thank you.**

**Program OTP No:** (e.g., AL-10001-M)   -      -

**Patient ID No:**

BACKGROUND INFORMATION

**Program Name:** \_\_\_\_\_

**Telephone:** \_\_\_\_\_ **Fax:** \_\_\_\_\_ **E-mail:** \_\_\_\_\_

**Name & Title of Requestor:** \_\_\_\_\_

**Patient's Admission Date:** \_\_\_\_\_ **Patient's current dosage level:** \_\_\_\_\_ mg \_\_\_\_\_ Other: \_\_\_\_\_  
\_\_\_\_\_ Methadone \_\_\_\_\_ LAAM \_\_\_\_\_ Buprenorphine

**Patient's program attendance schedule per week**  
(Place an "X" next to all days that the patient attends\*): \_\_\_\_\_ S \_\_\_\_\_ M \_\_\_\_\_ T \_\_\_\_\_ W \_\_\_\_\_ T \_\_\_\_\_ F \_\_\_\_\_ S

\*If **current** attendance is less than once per week, please enter the schedule: \_\_\_\_\_

**Patient status:** \_\_\_\_\_ Employed \_\_\_\_\_ Homemaker \_\_\_\_\_ Student \_\_\_\_\_ Disabled  
Other: \_\_\_\_\_

REQUEST FOR CHANGE

**Nature of Request:**  
Temporary take-home medication \_\_\_\_\_ Temporary change in protocol \_\_\_\_\_ Detoxification exception \_\_\_\_\_ Other: \_\_\_\_\_

**Decrease regular attendance to**  
(Place an "X" next to appropriate days\*): \_\_\_\_\_ S \_\_\_\_\_ M \_\_\_\_\_ T \_\_\_\_\_ W \_\_\_\_\_ T \_\_\_\_\_ F \_\_\_\_\_ S **Beginning date:** \_\_\_\_\_

\*If **new** attendance is less than once per week, please enter the schedule: \_\_\_\_\_

**Dates of Exception:** From \_\_\_\_\_ to \_\_\_\_\_ **# of doses needed:** \_\_\_\_\_

**Justification:** \_\_\_\_\_ Family Emergency \_\_\_\_\_ Incarceration \_\_\_\_\_ Funeral \_\_\_\_\_ Vacation \_\_\_\_\_ Transportation Hardship  
\_\_\_\_\_ Step/Level Change \_\_\_\_\_ Employment \_\_\_\_\_ Medical \_\_\_\_\_ Long-Term Care Facility \_\_\_\_\_ Other Residential Treatment  
\_\_\_\_\_ Homebound \_\_\_\_\_ Split Dose  
\_\_\_\_\_ Other: \_\_\_\_\_

REQUIREMENTS

**Regulation Requirements:**

- For take-home medication:** Has the patient been informed of the dangers of children ingesting methadone or LAAM? \_\_\_\_\_ Yes \_\_\_\_\_ No \_\_\_\_\_ N/A
- For take-home medication:** Has the program physician determined that the patient meets the 8-point evaluation criteria to determine whether the patient is responsible enough to handle methadone as outlined in 42 CFR § 8.12(i)(2)(i)-(viii)? \_\_\_\_\_ Yes \_\_\_\_\_ No \_\_\_\_\_ N/A
- For multiple detoxification admissions:** Did the physician justify more than 2 detoxification episodes per year and assess the patient for other forms of treatment (include dates of detoxification episodes) as required by 42 CFR § 8.12(e)(4)? \_\_\_\_\_ Yes \_\_\_\_\_ No \_\_\_\_\_ N/A

**Submitted by:** \_\_\_\_\_  
Printed Name of Physician Signature of Physician Date

APPROVAL

**State response to request:** \_\_\_\_\_ Approved \_\_\_\_\_ Denied  
State Methadone Authority Date

**Explanation:**

**Federal response to request:** \_\_\_\_\_ Approved \_\_\_\_\_ Denied  
Public Health Advisor, Center for Substance Abuse Treatment Date

**Explanation:**

Please fax to CSAT/DPT at (240) 276-1630 or e-mail: otp@samhsa.hhs.gov

*This exception is contingent upon approval by your State Methadone Authority (as applicable) and may not be implemented until you receive such approval.*

**Purpose of Form: This form was created to facilitate the submission and review of patient exceptions under 42 CFR § 8.11(h). This does not preclude other forms of notification.**

### **Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 25 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to SAMHSA Reports Clearance Officer; Paperwork Reduction Project (0930-0206); Suite 7-1043, 1 Choke Cherry Road, Rockville, MD 20857. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0206.

**FORM SMA-168 (revised January 2007) (BACK)**