

**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: (Same as FDA ID) | | | - | | | , | | | | - | | | | **Patient ID No:** | | | | | | | | | | | | | | | | | | | | | |

Program Name:

Telephone: | | | | | | | | | | | | | | | | | | | | | | **Fax:** | | | | | | | | | | | | | | | | | | | | | | **E-mail:** | | | | | | | | | | | | | | | | | | | | | |

Name & Title of Requestor:

Patient's Admission Date: | | | | | | | | | | | | | | | | | | | | | | **Patient's current dosage level:** mg **Methadone Other:** LAAM

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 Unemployed Homemaker Student Disabled
 Other: | | | | | | | | | | | | | | | | | | | | | |

BACKGROUND INFORMATION

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

REQUEST FOR CHANGE Homebound Split Dose Other: | | | | | | | | | | | | | | | | | | | | | |

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

State response to request: REQUIREMENTS

Approved Denied

State Methadone Authority

Date

Explanation:

Federal response to request:

Approved Denied

Public Health Advisor, Center for Substance Abuse Treatment

Date

Explanation: APPROVAL

Please fax to CSAT/OPAT, (301) 443-3994 or Email: otp@samhsa.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); Room 16-105, Parklawn Building; 5600 Fishers Lane, 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 (BACK)

