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| DEPARTMENT OF HEALTH AND HUMAN SERVICES  SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION  CENTER FOR SUBSTANCE ABUSE TREATMENT | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Form Approved: OMB Number 0930-0206  Expiration Date: xx/xx/xxxx  See OMB Statement on Reverse | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 provided at http://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs/submit-exception-request. PLEASE** complete **ALL** applicable items on this form and submit online\* for a prompt reply. Thank you. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Program OTP No:** (e.g., AL-10001-M)  BACKGROUND INFORMATION | | | | |  | |  | | | **–** | | | |  | |  | | |  | |  | | |  | | | | **–** | | |  | **Patient ID No:** | | | | | | | | | | | | | | |  | | |  | |  | |  |  | |  | | |  |  | | | |  | |  | |  |  | |  |  | | |
| Program Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Telephone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **E-mail:** | | | | | | | | | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name & Title of Requestor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Patient’s Admission Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Patient’s applicable drug(s) and dosage (check all that apply):  \_\_\_ Methadone \_\_\_ Buprenorphine \_\_\_ Other  \_\_\_ mg \_\_\_ mg \_\_\_mg | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Most recent urinalysis result (check all that apply):  \_\_\_ Methadone \_\_\_ Buprenorphine \_\_\_Other   positive  negative  positive  negative  positive  negative | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 curren**t** attendance is less than once per week, please enter the schedule **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Patient status: | | | | | | | | \_\_\_ | | | | Employed | | | | | | | | | | | | | | | | | | **\_\_\_** Caregiver **\_\_\_** | | | | | | | | | | | | | | | | | | | Student | | | | | | | | | | **\_\_\_** | | | | | | | Disabled | | | | | | | | |
|  | | | | | | | | **\_\_\_** | | | | Other: | | | | | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Nature of Request:  REQUEST FOR CHANGE | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | **\_\_\_** | Temporary take-home medication | | | | | | | | | **\_\_\_** | | | | Temporary change  in protocol **\_\_\_** Medically Supervised Withdrawal 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 | | | | | | | | | | | | | |  | | | Weather Crisis | | | | | | | | | | \_\_ | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | \_\_ | | Other: | | | | | | | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Regulation Requirements:  REQUIREMENTS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. For take-home medication: Has the patient been informed of the dangers of children ingesting methadone? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **\_\_\_** Yes | | | | | **\_\_\_** No | | | **\_\_\_** N/A | | | | |
| 2. For take-home medication: Has the program practitioner considered factors that indicate the therapeutic benefits of unsupervised doses outweigh the risks to determine whether the patient is suitable for dispensed methadone or buprenorphine as outlined in 42 CFR § 8.12(i)(2)(i)-(vi)? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **\_\_\_** Yes | | | | | **\_\_\_** No | | | **\_\_\_** N/A | | | | |
| **Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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

**FORM SMA-168** (revised 2024) (FRONT)

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| State response to request: | | |  | | \_\_ Approved | | |  | | \_\_ Denied | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | | |  | |  | | | | | | | State Opioid Treatment Authority | Date |
|  | | | **\_\_** | | Decision not required | | | | | | |  |  |
| Explanation: | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | |
| Federal response to request: | | | |  | | | \_\_ Approved | | **\_** | | Denied | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | | | | | | | | | | | | Public Health Advisor,  Center for Substance Abuse Treatment | Date |
|  | | | | **\_\_** | | Decision not required | | | | | |  |  |
| Explanation: | | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | |
| *\*The preferred method for submitting this form to CSAT/DPT is online at the SAMHSA OTP Extranet Web site,* <http://otp-extranet.samhsa.gov>*.  For instructions or technical support, contact the OTP Extranet Information Center at 1-866-348-5741 or* OTP-Help@jbsinternational.com*.*  APPROVAL | | | | | | | | | | | | | |
| *This exception is contingent upon approval by your State Opioid Treatment 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.

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| **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); 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** (revised 2024) (BACK)