BACKGROUND INFORMATION

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: 11/30/2024
See OMB Statement on Reverse

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Exception Request and Record of Justification Under 42 CFR § 8.11(h)	DATE OF SUBMISSION: 12/15/2021										
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) X X X - 1 2 3 4 5 - M	Patient ID No:	A L	L	S	Т	АВ	L	Е	PT		
Program Name:Example OTP											
Telephone:(333) 333-3333											
Name & Title of Requestor: John Smith, MD											
Patient's Admission Date:N/A Most recent urinalysis result (check all that apply):											
Patient's applicable drug(s) and dosage (check all that apply): X_ Methadone Buprenorphine											
Methadone Buprenorphine Other Other mg mg mg											
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:											
Nature of Request:											
X Temporary take- Temporary change in protocol Deta	exification exception	Oth	er:								
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 sched	ule:										
Dates of 12/23/2021 12/25/2021 Exception: From to # of doses needed:1 dose per day for 500 pts											
Justification: Family Emergency Incarceration		Vacati				•	-		tion Hardship		
Step/Level Change Employment	Medical	_	Term	Care		_	Ot	ner Resi eatment	•		
Homebound Split Dose	Weather Crisis		,			_	-				
Other: Christmas Holiday [The Federal holiday is observed on Christmas Eve (12/24) and we are seeking blanket exceptions for 12/23 and 12/25].											
Regulation Requirements:											
1. For take-home medication: Has the patient been informed of the dangers of children ingesting methadone?X_YesNoN/A											
2. For take-home medication: Has the program physician considered the 8-point evaluation criteria to determine whether the patient is suitable for dispensed methadone or buprenorphine as outlined in 42 CFR § 8.12(i)(2)(i)-(viii)? X Yes No N/A											
3. 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 NoX N/A											
Comments:The clinic will be open 12/23 – 12/25 for abbreviated hours for unstable pts (pt# AB3, AB5, AB10, CD40); 500 patients will receive unsupervised doses											
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Submitted by: John Smith, MD	<u>John Smith, MD</u>	<u>12/15/2021</u>		
Printed Name of Physician	Signature of Physician	_ Date		

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	Center for Substance Abuse Treatment	
Explanation:			
		SAMHSA OTP Extranet Web site, http://otp-extranet.samhsa48-5741 or OTP-Help@jbsinternational.com .	.gov. For instructions
This exception is contingent upon a approval.	approval by your State Opioid Treatment	Authority (as applicable) and may not be implemented until	you receive such

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); 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 2021) (BACK)