INSTRUCTIONS FOR
EXCEPTION REQUEST AND RECORD OF JUSTIFICATION UNDER 42 CFR § 8.11(h)
(FORM SMA-168)

Purpose of Form: The SMA-168 form was created to facilitate the submission and review of patient exceptions under 42 CFR § 8.11(h). SAMHSA will use the information provided to review "patient exception requests" and determine whether they should be approved or denied. A "patient exception request" is a request signed by the physician for approval to change the patient care regimen from the requirements specified in Federal regulation (42 CFR, Part 8). The physician makes this request when he/she seeks SAMHSA approval to make a patient treatment decision that differs from regulatory requirements.

This is a flexible, multi-purpose form on which various patient exception requests may be documented and approved or denied, along with an explanation for the action taken. It is most frequently used to request exceptions to the regulation on the number of take-home doses permitted for unsupervised use, such as during a family or health emergency. The form is also frequently used to request a change in patient protocol or for an exception to the detoxification standards outlined in the regulation.

GENERAL INSTRUCTIONS

Please complete **ALL** items on the form. As appropriate, there is space to indicate if an item does not apply. If you complete this form by hand, **PLEASE PRINT LEGIBLY.** We will not be able to process illegible information.

The instructions below show the item from the form in **bold text**. In the column next to the bold text is a description of the information requested.

ITEM	INSTRUCTION
BACKGROUND INFORMATION ON PROGRAM AND PATIENT	
Program OTP No	Opioid Treatment Program (OTP) identification number-same as the old FDA number. Begins with 2 letters of your State abbreviation, followed by 5 numbers, then a letter. This number should fit into the format on the form.
Patient ID No	Confidential number you use to identify the patient. Please do not use the patient's name or other identifying information. Number of digits does **NOT** have to match number of boxes on the form.
Program Name	Name of opioid treatment program, clinic or hospital in which patient enrolled.
Telephone	Voice telephone number. **PLEASE INCLUDE YOUR AREA CODE.**
Fax	Facsimile (FAX) number. **PLEASE INCLUDE YOUR AREA CODE.**
Email	Indicate electronic mail (e-mail) address of the CONTACT person.
Name & Title of Requestor	Name and title of physician or staff member authorized to submit this request.
Patient's Admission Date	Date patient enrolled at this facility.
Patient's current dosage level	Dosage patient receives **NOW.** Please indicate the dosage in milligrams (mg).
Methadone/LAAM/Other	Place an "X" on the line next to the medication the patient takes. If you check "Other," write in the name of the medication in the space provided.
Patient's program attendance schedule per week	Place an "X" on the line to the left of each day per week the patient **NOW** reports to the clinic for medication.
***If current attendance is less than once per week, please enter the schedule**	If patient **NOW** reports to the clinic **LESS** that once a week, please indicate how often he/she reports.
Patient status	Place an "X" on the line to the left of the item that best describes the patient's **CURRENT** status. If the patient's status does not appear on the list on the form, please place an "X" on the line next to "Other" and write in the patient's **CURRENT** status.
REQUEST FOR CHANGE	
Nature of request	Please place an "X" on the line to the left of the description that **BEST** describes this request. If your request is not listed in this item on the form, place an "X" on the line to the left of "Other" and describe your request.
Decrease regular attendance to	Place an "X" on the line to the left of each day per week that the patient is to report for medication.
Beginning date	Enter the date that the exception is scheduled to begin.

***If new attendance is less than once per week, please enter the schedule**	If you are asking to reduce the patient's attendance schedule to **LESS THAN** once per week, please indicate the schedule on the line provided.
Dates of Exception	Please indicate the dates that the exception will be effective.
# of doses needed	Indicate how many doses will be dispensed during the exception period.
Justification	Please place an "X" on the line to the left of the best description of the reason for this request. If the reason is not listed in this item, place an "X" on the line next to "Other" and write in the justification.
REQUIREMENTS	
Regulation Requirements	There are certain guidelines that programs must follow regarding take-home medication and detoxification admissions. Next to each of the 3 statements listed in this item, please indicate whether the OTP followed the stipulated requirements. For each statement that does not apply , place an "X" on the line to the left of "N/A" (not applicable).
Submitted by:	
Printed Name of Physician	Please **PRINT** the name of the physician making the request.
Signature of Physician	Once ALL the items above have been completed, the physician should SIGN here.
Date	Date the form is signed.
APPROVAL-This section will be completed by the appropriate authorities.	
State response to request	If this form must be reviewed or approved by your State, be sure that you forward this form to the proper authority, who will indicate approval or denial of your request in the space provided.
Federal response to request	This is the place on the form where CSAT will indicate whether the request is accurate and approved. The form will be faxed or e-mailed back to you.
Please submit to CSAT/OPAT- Fax: (240) 276-2710 or Email: otp@samhsa.hhs.gov	When you have completed the form, either fax or email it to CSAT at the numbers provided here.

Effect: 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-xxxx); 1 Choke Cherry Road, Room 2-1075, 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-xxxx).

SMA-168 INSTRUCTIONS (BA

DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION CENTER FOR SUBSTANCE ABUSE TREATMENT **Exception Request and Record of Justification Under 42 CFR § 8.11 (h)**	Form Approved: OMB Number 0930-0206 Expiration Date: 09/30/2003 See OMB Statement on Reverse DATE OF SUBMISSION Date you submit form to CSAT.
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).	

BACKGROUND INFORMATION

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.

BACKGROUND INFORMATION ON PROGRAM AND PATIENT

Program OTP No: (Same as FDA No.)				-			,				-			**Patient ID No:**														

Program identification number-old FDA number. Begins with 2 letters of your State abbreviation, followed by 5 numbers, then a letter. Should fit into the format above.		Number you use to identify patient. Number of digits does **NOT** have to match number of boxes above. **DO NOT USE PATIENT'S NAME.**

Program Name:	Name used to identify opioid treatment program, clinic, or hospital in which patient enrolled.

Telephone:	Phone #, **including area code**.	**Fax:**	Fax #, **including area code**.	**E-mail:**	. . . of contact person.

Name & Title of Requestor:	Name and title of physician or staff member authorized to submit request.

Patient's Admission Date:	Date patient enrolled in this facility.		**Patient's current dosage level:**		mg			Methadone			LAAM
								Other:			

	Dosage patient receives **NOW**.	Place an "X" on the line next to the medication the patient takes. If you check "Other," write in the name of the medication.

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**	

Place an "X" on the line to the left of each day per week the patient **NOW** reports to the clinic for medication.

*If **current** attendance is less than once per week, please enter the schedule:	If patient **NOW** reports to the clinic **LESS** that once weekly, please indicate how often he/she reports.

Patient status:		Employed		Unemployed		Homemaker		Student		Disabled
		Other:								

Place an "X" on the line next to the item that best describes the patient's **CURRENT** status. If that status does not appear on this list, please place an "X" on the line next to "Other" and write in the patient's **CURRENT** status.

REQUEST FOR CHANGE REGARDING PATIENT TREATMENTREQUEST FOR CHANGE

Nature of request:	

	Temporary take-home medication		Temporary change in protocol		Detoxification exception		Other:

Please place an "X" on the line next to the item above that **BEST** describes what this request is about. If your request is not listed above, place an "X" on the line next to "Other" and describe your request.

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

Place an "X" on the line to the left of each day per week you want the patient to report for medication.		Date you want new attendance schedule to begin.

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

If you are asking to reduce the number of days per week the patient reports to the program to **LESS THAN** once per week, please indicate the schedule on the line above.

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

Please indicate the dates that the exception you are requesting will be effective.	Indicate how many doses will be dispensed during the exception period.

Justification:		Family Emergency		Incarceration		Funeral		Vacation		Transportation Hardship

		Step/Level Change		Employment		Medical		Long Term Care Facility		Other Residential Treatment

		Homebound		Split Dose		Other:

Please place an "X" on the line to the left of the item above that best describes the reason for this request. If the reason is not listed above, place an "X" on the line next to "Other" and write in the justification.

REQUIREMENTSREQUIREMENTS (GUIDELINES AND SIGNATURE)

Regulation Requirements:

1. **For take-home medication:** Has the patient been informed of the dangers of children ingesting methadone or LAAM?		Yes		No		N/A
2. **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
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		No		N/A

There are certain guidelines that programs must follow regarding take-home medication and detoxification admissions. Next to each item above, please indicate whether you followed the stipulated requirements. For each statement that does not apply to you, place an "X" on the line to the left of "N/A" (not applicable).

Submitted by:

Printed Name of Physician	Signature of Physician	Date
Please PRINT the name of the physician making the request.	Once ALL the items above have been completed, the physician should SIGN here.	Date form is signed.

APPROVAL OF AUTHORITIES

APPROVALState response to request:

	Approved	Denied		

	State Methadone Authority	Date

Explanation:	

If this form must be reviewed or approved by your State, be sure that you forward this form to the proper authority, who will indicate approval or denial of your request in the space above.

Federal response to request:

		Approved		Denied		

	Public Health Advisor, Center for Substance Abuse Treatment	**Date**

Explanation:	

CSAT will indicate whether the request is accurateand approved or denied in this space. The form will be faxed or emailed back to you.

Please submit to CSAT/OPAT-Fax: (240) 276-2710; Email: 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.

FORM SMA-168 (FRONT)

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

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FORM SMA-168 (BACK)