

Instructions for the use of SAMHSA/CSAT Opioid Treatment Program

Extranet

For Submission of Form SMA-168
Exception Request and Record of
Justification under 42 CFR § 8.11(h)

Welcome!

The CT Department of Mental Health and Addiction Services (DMHAS) has developed both an informational and training slide presentation for the SAMHSA/CSAT Opioid Treatment Program Extranet for exception requests. The slides also provide instruction for the Exception Request and Record of Justification under 42 CFR § 8.11(h), form SMA-168.

Anyone who accesses the slide presentation for the first time is encouraged to review the entire presentation. Each slide will manually proceed forward by left clicking your mouse.

It is expected that the information provided will assist you in completing the SMA-168 form and answer any questions you may have regarding the process.

Thank you,

Lauren Siembab, M.S., LADC, Director
Community Services Division, DMHAS
CT State Opiate Treatment Authority (SOTA)



What is an
Exception Request and Record of Justification?

Exception Request and Record of Justification

Section 8.12 of Federal Regulation 42 CFR sets forth Federal standards for the administration and management of opioid treatment.

Included in the standards are a schedule of maximum allowable unsupervised use (i.e., take-home medications) and standards for the provision of detoxification treatment.

Exception Request and Record of Justification (continued)

On occasion, patients may need exceptions from the Federal opioid treatment standards due transportation hardships, employment, vacation, medical disabilities, etc.

In these instances, the physician must submit an exception request to SAMHSA (federal Substance Abuse and Mental Health Services Administration) and DMHAS (State Opioid Authority) to obtain approval to change the patient care regimen from the requirements specified in the regulations.

What are the most common reasons for submitting exception requests?

- Temporary increase in the number of take-home doses permitted for unsupervised use.
- An exception to the detoxification standards outlined in the regulations.
- Temporary delivery of individually prepared methadone doses to medical facilities or residential treatment programs.

Temporary Increase in Take Home Doses

In the next slide, Table 1 displays the allowable schedule defined in Regulation 42 CFR Section 8.12 for the provision of take-home medications.

To be eligible for take-home medications according to this schedule a patient must meet the following eight conditions (unchanged from the previous rule):

- no recent drug use,
- attends clinic regularly,
- no serious behavioral problems,
- no criminal activity,
- stable home environment and good social relationships,
- length of time in treatment (see table),
- assurance that take-home medication will be safely stored, and
- judgment that the rehabilitative benefit to the patient will outweigh the risk of diversion: 42 CFR Part 8.12.(c) i (2).

Schedule of Maximal Take-Home Medications

Patient Time in Treatment	Maximum Take-Home Medication Permissible (not automatic)
1-90 days	1 take-home a week, and 1 take-home for program closure for State and Federal holidays, and 1 take-home if the program is closed for business on Sundays.
91-180 days	2 take-homes a week, and 1 take-home for program closure for State and Federal holidays, and 1 take-home if the program is closed for business on Sundays.
181-270 days	3 take-homes a week, and 1 take-home for program closure for State and Federal holidays, and 1 take-home if the program is closed for business on Sundays.
271-365 days	6 take-homes a week (reporting once a week).
After 1 year	Up to 14 days take-homes (reporting up to twice a month). DMHAS must be contacted after 14 days for an exception request.
After 2 years	Up to 31 days take-homes. DMHAS must be contacted for an exception request.

Exception Request for Variation from Detoxification Standards

Section 8.12(e)(4) of Federal Regulation 42 CFR specifies that a program may not admit a patient for more than two detoxification treatment episodes in one year.

Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. An example is Methadone Maintenance.

Exception Request for Variation from Detoxification Standards

(continued)

If, after the physician's assessment, the physician believes it would be in the best interest of an individual patient to receive a third (or greater) detoxification treatment episodes in one year, approval of an SMA-168 exception request by SAMHSA and DMHAS the State Opioid Treatment Authority is required.

On the submission, the physician must justify the reason for requesting more than two detoxification episodes per year and attest that the patient has been assessed for other forms of treatment.

Exception Request for Other Reasons

Programs should submit an exception request for approval of any other treatment that differs from the Federal opioid treatment standards set forth under 42 CFR Section 8.12(i)(3).

When should an exception request be submitted?

An exception request must be submitted for approval by DMHAS and SAMHSA whenever a physician wishes to vary from the opioid treatment standards set forth in Federal Regulation 42 CFR 8.12 in the treatment of an individual patient.

What if I don't submit an exception request when one is required?

Failure to submit an exception request and obtain approval from SAMHSA and DMHAS the State Opioid Treatment Authority prior to providing care that deviates from the Federal opioid treatment standards constitutes a **serious regulatory violation** which may threaten a program's Federal and state compliance, accreditation and certification.

When is an exception request NOT required?

Programs do **not** need to submit exception requests for the provision of care that is in compliance with the treatment standards set forth in Regulation 42 CFR Part 8.

For example, a common misconception is that a program must obtain approval from SAMHSA when treating a patient with methadone at doses greater than 100mg.

- 42 CFR Part 8 places no such limit on the maximal allowed dose of methadone for a patient in treatment.
- Thus no exception request is required by SAMHSA in this case.

When in doubt, submit!

There are no penalties for submitting an exception request when one is NOT required.

If a program has consulted the text of the Federal opioid treatment standards in 42 CFR Part 8 and is unsure if the care it intends to provide for a patient is in compliance with the standards, then the program should submit an SMA-168 exception request.

Remember, failure to submit and obtain approval from SAMHSA and DMHAS prior to providing care that deviates from the Federal opioid treatment standards, constitutes a serious regulatory violation.

How to Submit an Exception Request and Record of Justification under 42 CFR § 8.11(h)

Form SMA-168

Purpose of Form SMA-168

Form SMA-168 Exception Request and Record of Justification Exception was created to facilitate the submission and review of patient exceptions under 42 CFR § 8.11(h).

SAMHSA uses the information provided to review "patient exception requests" and determine whether they should be approved or denied.

Purpose of Form SMA-168

(continued)

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.

Form SMA-168 is Flexible

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.

How do I submit Form SMA-168 ?

SMA-168 Exception Request forms must be submitted ON-LINE at the SAMHSA OTP Extranet Exception Request Web Site

otp-extranet@opioid.samhsa.gov

Why was the extranet created?

SAMHSA decided that an electronic request system was necessary to ensure compliance with Federal regulations and to maintain accurate records of requests.

SAMHSA's decision for on-line exception requests is typically viewable by the submitting OTP within one hour of submission.

How do I access the Extranet?

For help getting started with on-line exception requests, and to request a physician account on the OTP Exception Request Web site,

Call the SAMHSA OTP Exception Request Information Center

1-866-OTP-CSAT (1-866-687-2728)

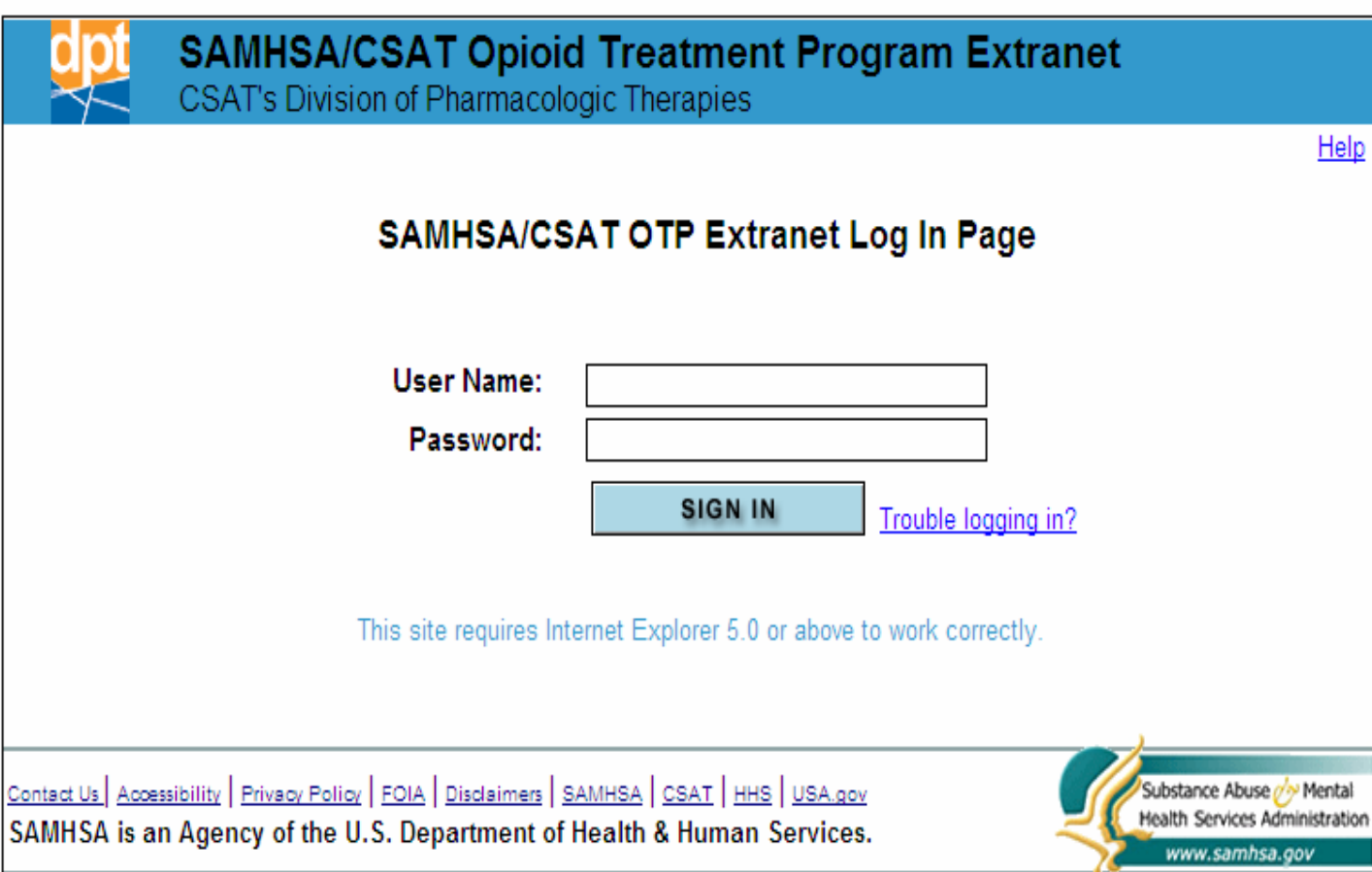
or email

otp-extranet@opioid.samhsa.gov

How do I access the Extranet?

(continued)

The log-in page for the SAMHSA OTP Extranet Web Site is <http://otp-extranet.samhsa.gov>



The screenshot shows the login page for the SAMHSA/CSAT Opioid Treatment Program Extranet. At the top left is the 'dpt' logo. The main header reads 'SAMHSA/CSAT Opioid Treatment Program Extranet' and 'CSAT's Division of Pharmacologic Therapies'. A 'Help' link is in the top right. The page title is 'SAMHSA/CSAT OTP Extranet Log In Page'. Below this are two input fields: 'User Name:' and 'Password:'. A 'SIGN IN' button is positioned below the password field, with a 'Trouble logging in?' link to its right. A note at the bottom states 'This site requires Internet Explorer 5.0 or above to work correctly.' The footer contains a row of links: 'Contact Us', 'Accessibility', 'Privacy Policy', 'FOIA', 'Disclaimers', 'SAMHSA', 'CSAT', 'HHS', and 'USA.gov'. Below these links is the text 'SAMHSA is an Agency of the U.S. Department of Health & Human Services.' On the right side of the footer is the SAMHSA logo and the text 'Substance Abuse & Mental Health Services Administration' and 'www.samhsa.gov'.

dpt SAMHSA/CSAT Opioid Treatment Program Extranet
CSAT's Division of Pharmacologic Therapies [Help](#)

SAMHSA/CSAT OTP Extranet Log In Page

User Name:

Password:

SIGN IN [Trouble logging in?](#)

This site requires Internet Explorer 5.0 or above to work correctly.

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SAMHSA is an Agency of the U.S. Department of Health & Human Services.

Substance Abuse & Mental Health Services Administration
www.samhsa.gov

General Instructions for Form SMA-168

Please complete ALL items on the form.

Accurate completion will result in a prompt response.

As appropriate, there is space to indicate if an item does not apply.

Form SMA-168

Background Information Section

(Instructions follow)

DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION CENTER FOR SUBSTANCE ABUSE TREATMENT	Form Approved: OMB Number 0930-0208 Expiration Date: 03/31/2013 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 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)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>
	Patient ID No: <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
Program Name: _____	
Telephone: _____	Fax: _____
	E-mail: _____
Name & Title of Requestor: _____	
Patient's Admission Date: _____	Patient's current dosage level: _____ mg
	<input type="checkbox"/> Methadone <input type="checkbox"/> Buprenorphine
	<input type="checkbox"/> Other: _____
Patient's program attendance schedule per week (Place an "X" next to all days that the patient attends*):	
	<input type="checkbox"/> S <input type="checkbox"/> M <input type="checkbox"/> T <input type="checkbox"/> W <input type="checkbox"/> T <input type="checkbox"/> F <input type="checkbox"/> S
*If current attendance is less than once per week, please enter the schedule: _____	
Patient status:	<input type="checkbox"/> Employed <input type="checkbox"/> Homemaker <input type="checkbox"/> Student <input type="checkbox"/> Disabled
	<input type="checkbox"/> Other: _____

BACKGROUND INFORMATION

Background Information

Instructions

Program OTP Number

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 Number

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.

Background Information

(Instructions continued)

Program Name

Name of opioid treatment program, clinic or hospital in which patient enrolled.

Telephone Number

Please include your area code and EXTENSION number.

Facsimile Number (FAX)

Please include your area code with your fax number.

Email

Indicate electronic mail (e-mail) address of the CONTACT person.

Background Information

(Instructions continued)

Name & Title of Requestor

Name and title of physician or staff member authorized to submit this request.

Patient's admission date

Enter the date patient enrolled at this facility. If the patient was transferred from another opioid treatment program ***with no interruption in treatment***, enter the ***original date admitted to opioid treatment.***

Patient's current dosage level

Dosage patient receives NOW. Please indicate the dosage in milligrams (mg).

Background Information

(Instructions continued)

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" in the box to the right 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.

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.

Form SMA-168

Request For Change Section

(Instructions follow)

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: _____

Request For Change

Instructions

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.

Justification

If the Request involves the client traveling, enter the travel destination, mode of travel and travel companions, if any. Include the dates and results of the last four urinalysis results for drug screens.

Example: Patient is traveling to Seattle, Washington on a family vacation. Patient's urine drug screens for 2/3, 3/4, 4/1, 5/8/2010 have been positive for methadone only.

For requests involving a client's admission to an extended care facility, include medical diagnosis and any other pertinent medical information. "CHAIN OF CUSTODY" protocol must be followed and documented as such.

OTHER: Define "other" circumstances.

Form SMA-168

Requirements Section

(Instructions follow)

REQUIREMENTS

Regulation 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 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)? 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

Comments: _____

Submitted by: _____

Printed Name of Physician

Signature of Physician

Date

Requirements

Instructions

Regulation Requirements

There are certain guidelines that programs must follow regarding take-home medication and detoxification admissions. Next to each item, 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).

Comments:

Briefly, provide additional information on patient's status. Furnish last three urinalysis results for drug testing with dates and any other information to support request.

Submitted By:

Name of person submitting request.

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 form is signed.

Form SMA-168

Approval Section

(Instructions follow)

APPROVAL	State response to request:	<input type="checkbox"/> Approved	<input type="checkbox"/> Denied	_____	_____
				State Methadone Authority	Date
		<input type="checkbox"/> Decision not required			
	Explanation:	_____			
	Federal response to request:	<input type="checkbox"/> Approved	<input type="checkbox"/> Denied	_____	_____
				Public Health Advisor, Center for Substance Abuse Treatment	Date
		<input type="checkbox"/> Decision not required			
	Explanation:	_____			

Requirements

Instructions

APPROVAL - This section will be completed by the appropriate authorities.

State response to request

This form must be reviewed or approved by DMHAS. Be sure that you forward this form to DMHAS, 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.
**FEDERAL APPROVAL IS CONTINGENT UPON
STATE APPROVAL.**

The form will be faxed or e-mailed back to you.

To send, click on **SUBMIT**



This concludes the DMHAS presentation on the SAMHSA/CSAT Opioid Treatment Program Extranet.

If you have any questions or suggestions,
we would like to hear from you.
Please contact the following DMHAS staff:

Mary L. Costa
Behavioral Health Specialist
860-418-6859

Julie Higgins
Behavioral Health Specialist
860-418-6917

Thank you