MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
OFFICE OF DRUG CONTROL POLICY

TREATMENT POLICY 04

SUBJECT: Off-Site Dosing Requirements for Medication Assisted Treatment

ISSUED: September 1, 2004, revised March 1, 2006, revised November 13, 2006

EFFECTIVE: December 1, 2006

PURPOSE:

The purpose of this policy is to clarify the rules and procedures pertaining to off-site dosing of opioid treatment medication by clients in Opioid Treatment Programs (OTP).

SCOPE:

This policy pertains to off-site dosing for all clients who are receiving medication-assisted treatment as an adjunct in an OTP in Michigan, regardless of the funding source. Due to the complexities of off-site usage and the variety of rules and regulations involved, in situations where there is a conflict between state and federal rules not otherwise addressed in this policy, the most stringent rule applies. Off-site dosing is a privilege, not an entitlement, nor a right.

BACKGROUND:

The use of methadone and buprenorphine, through an OTP, as adjunct therapies in substance abuse treatment, is highly regulated. Clients must attend the OTP daily for on-site supervised dispensing of their medication until they have met certain specified criteria for the privilege of reduced attendance and dosing off site. Safety is the driving force behind the strict regulations for off site dosing with the goal of preventing diversion of the medication to the general public and the accidental ingestion of the medication by children.

Off-site dosing can be used on a temporary basis in cases when the clinic is closed for business, such as Sundays and holidays. On an individual basis, off-site dosing may be temporary or permanent. As specified in this policy, some off-site dosing may need approval from the Michigan Department of Community Health/Office of Drug Control Policy (MDCH/ODCP) and/or the Center for Substance Abuse Treatment/Division of Pharmacologic Therapies (CSAT/DPT).

REQUIREMENTS:

OTP program physicians and other designated OTP staff must ensure that clients are responsible for managing off-site dosing prior to granting the privilege. The amount of time in treatment, progress towards meeting the treatment goals, as well as exceptional circumstances or physical/medical issues are used to determine the number of doses of methadone allowed off site.

Exceptions to these rules are allowed with approval from the State Methadone Authority (SMA) at MDCH/ODCP and, where federal law requires, CSAT/DPT approval.

On-Site OTP Clinic Attendance Requirements

A client in maintenance treatment must ingest the medication under observation, at the OTP clinic, for not less than six days a week for a minimum of the first 90 days in treatment (R 325.14417 Part 417[1]). If a client discontinues treatment and later returns, the time in treatment is restarted as if the client was newly admitted to treatment, unless there are extenuating circumstances.

When a client transfers from another OTP, the cumulative time in treatment must be used in calculating the client's time if the gap in treatment time is less than 90 days (R 325.14417 Part 417[4]).

After 90 days of treatment, a client may be allowed to reduce on-site dosing to three times weekly while receiving no more than two doses at one time for off-site dosing (R 325.14417 Part 417[2]).

After two years in treatment, a client may be allowed to reduce the on-site dosing to two times weekly while receiving no more than three doses at one time for off-site dosing (R 325.14417 Part 417[3]).

The inability of the client to qualify for off-site dosing or to maintain an off-site dosing schedule must be addressed as part of the client's individualized treatment plan. Dosage adjustments, establishment of compliance contracts, additional counseling sessions, specialized treatment groups, or assessment for another level of care must be considered. OTPs must coordinate sanctions with the prior authorization source such as an Access Management System (AMS) agency for funded clients or other involved third party as appropriate.

Off-Site Dosing Requirements

Rules that Apply to All Off-Site Dosing:

All clients who are dispensed medication for off-site dosing must be deemed responsible for handling the medication. This includes when the program is closed for business, such as Sundays and holiday observances as well as other qualified times. If the client is deemed not to be responsible for any of these times, other arrangements must be made for the client to be dosed on site at their current OTP or at another OTP. If a client needs to go to another program to be dosed, coordination between both programs is required to ensure the client is only dosing at one OTP for days when the client's OTP of record is closed.

Client Criteria:

Medication for off-site dosing may only be given to a client who, in the reasonable clinical judgment of the program physician, is responsible in the handling of opioid substitution medication. Before reducing the frequency of on-site dosing, the rationale for this decision must be documented in the client's treatment record by a program physician or a designated staff. If a designated staff member records the rationale for the decision, a program physician must review, countersign, and date the client's record (R 325.14416 Part 416[1] and 42 CFR Part 8.12[I][3]). The client's off-site dosing schedule is to be reviewed every sixty days while the client receives doses for off-site use.

The program physician must utilize all of the following information in determining whether or not a client is responsible to handle opioid medication off site:

- Background and history of the client: the client is employed, actively seeking employment as evidenced by a sign-off sheet from potential employers, or disabled and unable to work as evidenced by a Social Security Income or Social Security Income Disability or Workmen's Compensation checks; and the client has appropriately handled off-site dosing in the past such as on Sundays and holidays or other off-site situations.

- General and specific characteristics of the client and the community in which the client resides (the client is working toward or maintaining treatment goals; the client has taken measures to ensure that third parties do not have access to the medication).

- An absence of current and/or recent abuse (within 90 days) of drugs, including alcohol on the basis of toxicology screens that must include opioids, methadone metabolites, barbiturates, amphetamines, cocaine, cannabinoids, benzodiazepines and any other drugs as appropriate for individual clients. Alcohol testing must be conducted by the use of a Breathalyzer or other standard testing means if alcohol is suspected at the time of dosing. (Clients who appear to be under the influence of any drug or alcohol will not be dosed until safe to do so. Clients should not be allowed to drive under this condition.) Any evidence of alcohol abuse in the client's chart within the past 90 days will be considered as positive for alcohol, as will any legal charges related to alcohol consumption. The need to verify toxicology tests or the need for more frequent toxicology tests must be components of the clinic rules. Legally prescribed drugs, including controlled substances, will not be considered as illicit substances, provided the OTP has verification the drug(s) were prescribed for the client. Such documentation must be included in the client's chart. Prescription documentation for all prescribed medication must be updated at least every 60 days until discontinued. Prescription medication documentation must be updated in the client's chart at the first opportunity – preferably at the next clinic visit – when the client is prescribed a medication or a medication is renewed. A copy of the prescription label, a printout from the pharmacy, or the information recorded in the chart from viewing

the patient's prescription bottle shall constitute documentation. All medications are to be considered within the context of coordinating care with other prescribing healthcare providers, and the safety considerations of granting off-site dosing privileges.

- Regularity of clinic attendance.
- Absence of serious behavioral problems in the clinic.
- Stability of the client's home environment and social relationships.
- Absence of recent known criminal activity.
- Length of time in opioid substance abuse treatment with medication as an adjunct.
- Assurance that medication can be safely stored off site, particularly with respect to prevention of accidental ingestion by children.
- The rehabilitative benefit to the client derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

R 325.14416 Part 416[3] and 42CFR Part 8.12 [I][2][i-viii]

Clients must receive a copy of the clinic's rules pertaining to responsible handling of off-site doses and the reasons for revoking them. Clinic rules must include a list of graduated sanctions such as decreasing and rescinding of all off-site dosing. A form signed by the client acknowledging receipt of this information must be included in the client file.

Product Preparation:

Methadone for off-site dosing must be dispensed in a liquid, oral form and formulated in such a way to minimize use by injection. The methadone must contain a preservative so refrigeration is not required.

Methadone must be dispensed in disposable, single use bottles, and must be packaged in childproof containers pursuant to section 3 of the Poison Prevention Packaging Act, 15 USC Part 1472. (R 325.14415 Part 415) In cases when clients take medication twice daily (split dosing), two separate childproof containers must be utilized. These efforts will help minimize the likelihood of accidental ingestion by children.

Buprenorphine/naloxone must be packaged in childproof containers and labeled similar to methadone. However, because buprenorphine/naloxone is in tablet form, a maximum of 30-days supply can be contained in the same bottle. The dose(s) dispensed for unsupervised off-site use must adhere to 42 CFR Part 8 unless an exception request has been approved. (MCL 333.17745)

Labeling:

Medication for off-site administration must be labeled as follows:

- The name of the medication
- The strength of the medication
- The quantity dispensed
- The OTP's name, address, and phone number
- Client's name or code number
- Medical director's/prescriber's name
- Directions for use
- The date dispensed and the date to be used
- A cautionary statement that the medication should be kept out of the reach of children
- Statement that this medication is only intended for the person to whom it was prescribed

R 325.14415 Part 415(2)
MCL 333.17745(7)(a-h)

Security:

The client is expected to secure all take home medication in a locked box prior to leaving the OTP. It is expected that the client store this box in a manner that will prevent the key or combination from being readily available to children and/or others who could be harmed from accidental use and to prevent diversion to or by third parties. Clients should be able to explain the process that will be used to secure the medications that are taken home when asked by an OTP staff member. This process should be recorded in the client's record and updated when the client's take home status is reviewed every 60 days. Empty and unused bottles are to be returned to the OTP in the locked box for proper disposal. Failure to do so could result in revocation of take home privileges.

Temporary Off-Site Dosing:

Special circumstances such as a client's physical/medical needs or other exceptional circumstances, situations in which a program is closed such as Sundays and Holidays, or emergency situations may result in cases when the client is allowed to dose off site for a temporary time period.

Physical/Medical Necessity:

If a client's physician provides written documentation that reduced attendance at the clinic is necessary due to physical/medical necessity of the client and the OTP physician concurs, off-site dosing of up to 13 doses within a 14-day time frame is allowed without prior MDCH/ODCP approval unless the request exceeds the

CSAT/DPT amounts allowed. (See Section entitled "CSAT/DPT Approval Required.")

The written documentation from the client's physician must include a medical diagnosis and whether the condition is permanent or temporary. If the condition is temporary, the date the client can return to his/her usual clinic attendance must be indicated. Whenever possible, the client's personal physician and the OTP physician should coordinate care including the prescribing of medication that interacts with methadone.

Temporary exceptions need to be reviewed and reissued if the exception is needed beyond the initial time frame. All exceptions must be reviewed during the usual 60-day OTP physician's review. All documentation must be maintained in the client's chart (R 325.14417 Part 417(5)). Requirements for counseling sessions and toxicology screens must be coordinated with CAs if the client is funded.

Exceptional Circumstances:

Medication for off-site dosing may only be given to a client who has an exceptional circumstance as indicated in this section and who, in the reasonable clinical judgment of the program physician, is responsible in the handling of opioid substitution medication. The exceptional circumstance must be clearly documented and any supportive documentation should be included in the client's chart.

Clients who have been in OTP treatment for at least 6 months and who are eligible for a 3-times a week schedule may be permitted up to three consecutive off-site doses within a specific 7-day period, depending on the situation, without prior approval from MDCH/ODCP, for the following exceptional circumstances:

- Employment schedule conflicts
- Educational training schedule conflicts
- Medical or mental health appointment conflicts
- Appointments with other agencies relative to the client's treatment goals

Clients who have been in OTP treatment for at least nine months may be permitted up to six off-site doses within a 7-day time period without prior approval from MDCH/ODCP for the following exceptional circumstance:

- Travel hardship (at least 60 miles or 60 minutes one way from an OTP). The actual mileage must be documented in the client's chart with the city of origin listed.

Vacations are a special type of exceptional circumstance and shall be limited to six days within a 7-day period for clients who have been in treatment for at least nine months and 13 days within a 14-day period for clients who have been in treatment for one year or more without prior MDCH/ODCP approval. Sunday and holiday doses must be included in the specified off-site amounts (R 325.14416 Part 417[6]).

Documentation must be included in the chart verifying the client did travel to the planned destination(s) as indicated on the exception request.

Allowable Program Closures:

Medication for off-site dosing due to program closure may only be given to a client who, in the reasonable clinical judgment of the program physician, is responsible in the handling of opioid substitution medication.

Sunday Dosing

OTPs may be closed on Sundays without prior approval from MDCH/ODCP.

Holiday Observances

- OTPs may be closed for the following holidays without prior MDCH/ODCP approval:

New Year's Day	Labor Day
Martin Luther King, Jr. Birthday	Veterans' Day
Presidents' Day	Thanksgiving Day
Memorial Day	Christmas Day
Independence Day – July 4	

- Should the holiday fall on a Sunday, OTPs may be closed the following Monday without prior MDCH/ODCP approval.

- A day in which the OTP has abbreviated hours in which methadone will be dispensed will not be considered as a program closure.

- If the OTP wishes to close for more than two consecutive days (including Sundays and holidays), the SMA at MDCH/ODCP and CSAT/DPT must approve a plan. The plan must meet the following criteria:

  - The request must be for each circumstance. OTPs may request all holidays for the entire year at once. No approvals will be automatically approved from year to year.

  - The request must be submitted for each individual OTP.

  - The plan must be submitted to the SMA at MDCH/ODCP at least 10 working days prior to the first day the program wishes to close. MDCH/ODCP is not obligated to approve any plans submitted that do not meet the 10 day criteria. Fax the request to the current number for MDCH/ODCP – (517) 335-2121.

  - Be written on OTP letterhead.

- Be signed by the OTP sponsor or administrator.
- Name holidays to be closed.
- List dates to be closed including the holiday as well as a Sunday, if applicable.
- Describe how clients who lack 90 days in treatment and those clients who do not meet the criteria for unsupervised dosing will be dosed face-to-face.

MDCH/ODCP will approve and forward the request to CSAT/DPT for their approval. Should MDCH/ODCP not approve the plan, the OTP will be notified. This notification will include the reason(s) for the denial.

Emergency Situations

OTPs must have written plans and procedures which include how dosing clients on-site, as well as dispensing doses for off-site use, will be accomplished in emergency situations. Emergency situations include power failures, natural disasters, and other situations in which the OTP cannot operate as usual. This plan must also include how the security of the medication and client records will be maintained.

PROCEDURE:

MDCH/ODCP Approval Required:

MDCH/ODCP approval for off-site dosing is needed for clients who do not meet the criteria for approval at the OTP level and for all those cases where federal approval is needed. In addition, any client taking medication out of the country must have MDCH/ODCP approval. Note: medication transported out of the country is subject to that country's jurisdiction.

CSAT/DPT Approval Required:

CSAT/DPT approval is needed for clients not meeting the following federal off-site criteria for length of time in treatment:

- Less than 90 days in treatment - 1 dose plus the Sunday dose
- 90 to 180 days in treatment - 2 doses plus the Sunday dose
- 180 to 270 days in treatment - 3 doses plus the Sunday dose

- 270 to 360 days in treatment - 6 doses (includes the Sunday dose)
- One year in continuous treatment - 14 doses (includes the Sunday dose)

Submission Of Exception Requests:

As the CSAT/DPT Extranet system is in place and functioning well, the hard copy and fax method may only be used when the Extranet system is temporarily unavailable. The Extranet system is more efficient and allows for faster responses by MDCH/ODCP and CSAT/DPT and provides better confidentiality and eliminates the chance of not being able to read a hand written request due to fax quality and/or legibility. Programs must not submit both hard copy and Extranet-based forms for the same exception request. Programs may request a short-term waiver from the use of the Extranet from the SMA at MDCH/ODCP. Each request will be considered on a case-by-case basis.

Extranet System:

The CSAT/DPT Extranet System was designed to facilitate the processing of Exception and Record of Justification Forms nationwide. Instructions for using this system are the responsibility of CSAT/DPT. The Extranet form will be available as directed by CSAT/DPT on a Website designated by SAMHSA. OTPs must submit all exception requests using this method, even those that only require MDCH/ODCP approval. In those cases, CSAT/DPT will indicate, "Decision not required."

MDCH/ODCP requires that all exception requests be submitted by using the Extranet system. Faxed forms will only be accepted if the system is down or in special, pre-approved situations.

Extranet Downtime Procedure for Hard Copy Forms and Faxing:

All downtime exceptions to the rules for off-site dosing must be submitted to MDCH/ODCP on the "MDCH/ODCP Methadone Exception Request and Record of Justification" form (Attachment A). **This is the only form that will be accepted by MDCH/ODCP.** In urgent situations, such as funerals, illness, immediate work and travel hardships, this form can be used but the OTP should call the SMA so this exception can be obtained quickly. The SMA reserves the right to determine if the situation is urgent enough to warrant not using the Extranet and may request it is made in that manner.

MDCH/ODCP will identify those exception requests that also need CSAT/DPT approval by marking the appropriate box on the form when it is sent back. It is the responsibility of the OTPs to complete the SMA-168 "Exception Request and Record of Justification" (Attachment D) – **this is not the same form that is sent to MDCH/ODCP** – and fax it to CSAT/DPT at their current fax number for exceptions. As indicated on this form, the current fax number is (240) 276-1630. A copy of the approved MDCH/ODCP Exception Request and Record of Justification Form must be submitted along with this form. Attachment D was included in this policy as a convenience to the OTPs. However, OTPs

are responsible for using the most current CSAT/DPT form and fax number. This information can be located on the SAMHSA Website, www.dpt.samhsa.gov.

Delivery of Methadone to a Client by a Third Party or to Another Facility

Delivery of Methadone to a Client by a Third Party:

Documentation must be kept in the client's file that the client meets the criteria for off-site dosing as indicated in R 325.14416 (3) (a)-(k) and 42CFR Part 8.12 (i)(2)(i-viii). In addition, a "MDCH/ODCP Delivery to a Client by a Third Party" form (Attachment B) must be completed and maintained at the program. A copy of the form signed by the person receiving the methadone must be returned to the program so that the chain of custody can be documented before another supply is issued. A maximum of 7 doses may be delivered to a client for self-administration. The methadone must be secured in a locked box before leaving the OTP. Empty and unused bottles must be returned to the OTP.

Delivery of Methadone to Another Facility Form:

A "MDCH/ODCP Delivery of Methadone to Another Facility Form" (Attachment C) must be completed and maintained at the program. A copy of the form signed by the person receiving the methadone must be returned to the program so that the chain of custody can be documented before another supply is issued. A staff member of the facility in which the client is housed may obtain a maximum of 14 doses. The facility will transport, secure, and administer the methadone, as well as dispose of empty and unused bottles, according to that facility's protocols for the use of medications that are controlled substances.

Exception Verification for Coordinating Agencies:

Funded OTPs must submit a copy of approved MDCH/ODCP Methadone Exception and Record of Justification Form to their respective CAs when requested to do so.

Monitoring For Compliance:

Site visits to OTPs by MDCH/ODCP will include a review of documentation verifying that clients meet the criteria for off-site dosing. Probation or rescinding of off-site dosing privileges, when the client has not followed the rules for off-site usage, will also be reviewed. This document must include the coordination of sanctions and any changes to the treatment plan or services authorized by the CA or AMS for funded clients. OTPs must have a system to readily identify those clients issued doses for off-site use.

REFERENCES:

American Society of Addiction Medicine (for Buprenorphine information). http://www.asam.org/

Certification of Opioid Treatment Programs: United States Code of Federal Regulations, Title 42, Part 8, Washington, D.C. (s003) http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=%2Findex.tpl

Division of Pharmacologic Therapies. (2002). *Patient Exceptions SMA-168-Exception Request and Record of Justification under 42 CFR § 8.12.* Retrieved from the Substance Abuse and Mental Health Services Administration website at http://dpt.samhsa.gov/webintro.htm

Drug Addiction Treatment Act of 2000: Public Law 106-310, Section 3502, United States House, 106th Congress, Washinigton, DC. (October 17, 2000).

Labeling and Dispensing of Prescription Medication. *Public Health Code:* 1978 Public Act 369, as amended, Article 6. MCL 333.17745, Michigan Legislature, 1977-78 Legislative Session, Lansing, Michigan. (September 30, 1978). http://www.legislature.mi.gov/mileg.aspx?page=getObject&objectName=mcl-333-17745

Methadone Treatment and Other Chemotherapy: Michigan Administrative Code, Rules 325.14401-325.14423, State Office of Administrative Hearings and Rules. Lansing, Michigan. (September 10, 1971). http://www.michigan.gov/documents/cis_bhs_fhs_sa_part4_37163_7.pdf

Poison Prevention Packaging At of 1970: Public Law 91-601, 84 Stat. 1670, as amended, 90th Congress, Washington, DC. (December 30, 1970). http://www.cpsc.gov/businfo/pppatext.html

Public Health Code: 1978 Public Act 368, as amended, MCL 333.1100-333.25211, Michigan Legislature, 1977-1978 Legislative Session, Lansing, Michigan. (September 30, 1978). http://www.legislature.mi.gov/mileg.aspx?page=getobject&objectname=mcl-act-368-of-1978

APPROVED BY: _____
Donald L. Allen, Jr., Director
Office of Drug Control Policy

ATTACHMENT A

MDCH/ODCP METHADONE EXCEPTION REQUEST AND RECORD OF JUSTIFICATION FORM

DIRECTIONS FOR COMPLETING THE FORM:

NOTE: This form is only to be used during Extranet downtime and may be used in rare urgent situations at the SMAs discretion.

Program ID: Type the I-SATS Number.

City: Fill in the location of the program.

Client ID: Fill in the client's ID number.

Program Telephone: Type the program's phone number.

E-mail Address: Type the program's e-mail address if available.

Name and Title of Requestor: Type name and title of requestor.

Client's admission date: Fill in the patient's admission date to the program.

If transfer from another program-original date: If the client transferred from another OTP, use that program's admission date in addition to the admission date to your program if the gap between services is less than 90 days. If there has been a 90-day or more gap in treatment, leave this blank.

Client's dosage level: Fill in the patient's dosage level.

Client's program attendance schedule per week: Circle appropriate days.

Client is: employed, unemployed, student, other (specify): Circle appropriate category. If other, explain.

Client is disabled (specify): Specify and provide an explanation of the disability.

Permanent Decrease in Attendance to: Circle days.

Temporary Change in Attendance: Temporary Change in Attendance (please explain). Fill in the explanation.

Justification for request: Describe the justification for request. Be as specific as possible without providing any patient identifying information. Travel hardships must include the city and the roundtrip mileage. If visiting another city, indicate city and state and why guest dosing is not being done. Any criterion that is not in compliance must be explained. A positive toxicology screen for drugs other than methadone metabolites must be documented as having a prescription for that time period. Toxicology screens must be positive for methadone or methadone metabolites.

DO NOT SUBMIT DOCUMENTATION TO MDCH/ODCP OR CSAT/DPT UNLESS IT IS SPECIFICALLY REQUESTED. ENSURE THAT ALL CLIENT IDENTIFYING INFORMATION IS REMOVED FROM THE DOCUMENTS.

Dates of Exception: Fill in the date of the first and last off-site doses.

Number of doses to be dispensed: Fill in number of doses to be dispensed.

Has the client been informed of the dangers of children ingesting methadone: Circle the correct response.

Does the client meet the criteria used to determine if the patient is responsible in handling methadone as outlined in MDCH/ODCP Policy-04, Administrative Rules of Substance Abuse Treatment Programs in Michigan – R 325.14416 Part 416(3)(a-k) and 42 CFR Part 8.12(i) (2) (i-viii):
Circle the correct response. If no, the explanation must be included under the justification.

Name of Concurring Physician: Type the name of the concurring physician and MD or DO.

Signature of Physician: Signature by physician along with MD or DO.

DO NOT WRITE BELOW THIS LINE: Leave Blank.

MDCH/ODCP will approve or deny the Exception Request. Denials will be explained.

This Exception Request Also Requires Federal Approval. MDCH/ODCP will identify those Exception Requests that also need CSAT/DPT approval. IT IS THE RESPONSIBILITY OF THE OTP TO COMPLETE FEDERAL FORM SMA-168 EXCEPTION REQUEST AND RECORD OF JUSTIFICATION AND FAX IT TO CSAT/DPT AT 240-276-1630 ALONG WITH A COPY OF THE SIGNED MDCH/ODCP FORM. SUBMIT ONLY THOSE REQUESTS THAT NEED CSAT/DPT APPROVAL.

TO: State Methadone Authority, MDCH/ODCP **Fax: 517-335-2121** **DATE**_____

FROM: Program Name_____ **FAX** _____

MDCH/ODCP EXCEPTION REQUEST AND RECORD OF JUSTIFICATION

NOTE: This form is only to be used during Extranet downtime and may be used in rare urgent situations at the SMAs discretion.

Program ID: _____City: _____ Client ID: _____

Program Telephone: _____ E-Mail Address_____

Name & Title of requestor _____

Client's admission date _____ If transfer, original admission date _____ Client's dosage level_____

Client's program attendance schedule per week S M T W T F S (circle days)

Client is: Employed Unemployed Student Other (Circle) (specify)_____

Client has a disability (please explain)_____

Permanent Decrease in Attendance to S M T W T F S (circle days)

Temporary Change in Attendance (please explain)_____

Justification for request:_____

Dates of Exception ___/___/___ to ___/___/___ Number of doses to be dispensed _____

Has the client been informed of the dangers of children ingesting methadone? Yes No (circle)

Does the client meet the criteria used to determine if the client is responsible in handling methadone as outlined in MDCH/ODCP Policy-04, Administrative Rules of Substance Abuse Treatment Programs in Michigan – R 325.14416 part 416(3)(a-k) and 42 CFR § 8.12(i) (2) (i-viii)? Yes No (circle)

_____ _____

Print Name of Concurring Physician Signature of Physician

STATE USE ONLY

Approved Denied Date ___/___/___ _____

State Methadone Authority or Designee
ODCP (517) 373-4700

Explain:_____

_____

☐**This Exception Request Also Needs Federal Approval.** Complete Form SMA-168 for federal approval and fax Form SMA-168 and this state approved request to CSAT per Form SMA-168 instructions.

State Comments:_____

_____

Confidentiality Notice: "The documents contain information from the Michigan Department of Community Health/Office of Drug Control Policy (ODCP) which is confidential in nature. The information is for the sole use of the intended recipient(s) named on the coversheet. If you are not the intended recipient, you are hereby notified that any disclosure, distribution or copying, or the taking of any action in regard to the contents of this information is strictly prohibited. If you have received this fax in error, please telephone us immediately so that we can correct the error and arrange for destruction or return of the faxed document."

ATTACHMENT B

DIRECTIONS FOR COMPLETING MDCH/ODCP DELIVERY TO A CLIENT BY A THIRD PARTY FORM

Date: Fill in date methadone dispensed.

Client#: Fill in client's number.

Program Treatment Name: Fill in Treatment Programs Name

Program ID: Fill in Program's I-SATS Number

Program Telephone: Fill in Program's Phone Number

Fax: Fill in Program's Fax Number

E-Mail: Fill in Program's E-Mail Address

Name of Dispensing Nurse: Fill in Name of Dispensing Nurse

Licensing Number of Dispensing Nurse: Fill in Licensing Number

Signature of Dispensing Nurse: Dispensing Nurse's Signature

Justification for why client is unable to pick up the methadone at the clinic: Explain the reason, such as a disability; specify. A note from the client's physician or similar documentation from the OTP physician must be placed in the client's chart.

Methadone is being transported to: Fill in client at residence, relative's residence, not the specific address.

Medication provided from _____to _____: List dates

Number of Doses Dispensed at One Time_____: List number of doses dispensed. Not to exceed 7 doses without MDCH/ODCP written permission.

Person Delivering the Methadone: List person's name that is delivering the methadone.

Relationship to Client: Indicate relationship to client, such as spouse, roommate, etc.

Liability Statement: Person delivering methadone should read and sign on the signature line.

Signature of Person Delivering Methadone: Deliverer signs.

Witness: Witness to the Deliverer's signature.

Signature of Person Receiving Medication: Signature of client who receives the methadone.

THE FORM, SIGNED BY THE CLIENT, IS TO BE RETURNED TO THE CLINIC WITH THE EMPTY AND UNUSED BOTTLES.

Both the delivery person and the client agree to all terms stated on this form as well as to additional requirements the OTP may have pertaining to off-site dosing. By signing this form, both parties will not hold the OTP or MDCH/ODCP liable for any unauthorized use of the methadone.

Distribution

Original Copy to OTP: The original of the form is retained at the OTP.
Copy to Client: A copy of the form is to made and given to the client.

MDCH/ODCP DELIVERY TO A CLIENT BY A THIRD PARTY FORM

DATE:_____ Client #:_____

Program Treatment Name:_____ Program ID:_____

Program Telephone:_____Fax:_____E-Mail:_____

Name Of Dispensing Nurse:_____License#:_____

Signature of Dispensing Nurse:_____

Justification for why client is unable to pick up the methadone at the clinic:

_____

_____

(Documentation from the client's physician or OTP physician must be included in the client's chart)

Methadone is being Delivered to: _____

Methadone provided from: _____to _____ Number of Doses Dispensed at One Time:_____
(Date) (Date) (Not to exceed 7 doses)

Person Delivering Methadone :_____Relationship to Client:_____

Due to the above named client's temporary inability to pick-up his/her methadone, the above named Opioid Treatment Program has permission from MDCH/ODCP to allow delivery of the methadone to the client. I understand that this arrangement is for a specific period of time only, and that when this time ends, I will either no longer be picking up the medication, or will have to complete another MDCH/ODCP DELIVERY TO A CLIENT BY A THIRD PARTY FORM. I further understand that methadone is a narcotic, to be ingested by the client only, and that harm, including death could come to anyone else ingesting it. When I pick-up this medication, I must present current government issued pictured identification (Driver's License, State Identification Card, Military Identification Card). I mus t also present any necessary documentation from the treating physician, so that the clinic is kept up-to-date on the current status of the client's medical condition. I am aware that the methadone must be transported in a locked box and kept in this manner. Empty and unused bottles must be returned in the locked box. I have been made aware that loitering within a one-block radius of the clinic is prohibited. Both the delivery person and the client agree to all terms stated on this form as well as to additional requirements the OTP may have pertaining to off-site dosing. By signing this form, both parties will not hold the OTP or MDCH/ODCP liable for any unauthorized use of the methadone.

_____ _____
Signature of Person Delivering the Methadone Signature of Person Receiving Methadone

_____
Witness

THE FORM, SIGNED BY THE BOTH THE PERSON DELIVERING AND THE PERSON RECEIVING THE METHADONE, IS TO BE RETURNED TO THE CLINIC WITH THE USED BOTTLES.

DISTRIBUTION: Original to OTP
Copy to Client

ATTACHMENT C

DIRECTIONS FOR COMPLETING MDCH/ODCP DELIVERY OF METHADONE TO ANOTHER FACILITY FORM

Date: Fill in date methadone dispensed.

Client#: Fill in client's number.

Program Treatment Name: Fill in Treatment Programs Name

Program ID: Fill in Program's I-SATS Number

Program Telephone: Fill in Program's Phone Number

Fax: Fill in Program's Fax Number

E-Mail: Fill in Program's E-Mail Address

Methadone Delivered to: Facility Name, Phone Number: Fill in name of facility and phone number.

Name of Dispensing Nurse: Fill in Name of Dispensing Nurse

Licensing Number of Dispensing Nurse: Fill in Licensing Number

Signature of Dispensing Nurse: Dispensing Nurse's Signature

Justification for why client is unable to pick up the methadone at the clinic: Explain the reason such as incarceration, etc.

Methadone is being transported to: Facility's Name and Phone Number.

Medication provided from _____to _____: List dates

Number of Doses Dispensed at One Time_____: List number of doses dispensed. Not to exceed 14 doses without MDCH/ODCP written permission.

Liability Statement: Person delivering the methadone should read and then sign.

Person Delivering the Methadone: Print the facility staff person's name.

Witness: Witness to the transporters signature. Print name and Sign.

Name of Person Receiving the Methadone at the Facility: Printed Name and Signature of facility staff who accepts delivery of the methadone.
Both the delivery person and the facility agree to all terms stated on this form as well as to additional requirements the OTP may have pertaining to off-site dosing. By signing this form, both parties will not hold the OTP or MDCH/ODCP liable for any unauthorized use of the methadone.

Distribution: Original Copy to OTP: The original of the form is retained at the OTP.
Copy to Facility: A copy of the form is to made and given to the facility.

MDCH/ODCP DELIVERY OF METHADONE TO ANOTHER FACILITY FORM

DATE:_____ Client # _____

Program Treatment Name:_____ Program ID:_____

Program Telephone:_____Fax:_____E-Mail:_____

Methadone Delivered to: Facility Name_____Phone _____

Name Of Dispensing Nurse:_____License#:_____

Signature of Dispensing Nurse:_____

Justification for why client is unable to pick up the methadone at the clinic:

_____

_____

_____

Methadone provided from: _____to _____ Number of Doses Dispensed at One Time:_____
(Date) (Date) (Not to exceed 14 doses)

Due to the above named client's temporary inability to pick-up his/her methadone, the above named Opioid Treatment Program has permission from MDCH/ODCP to allow transportation of the methadone to the above named facility. I understand that this arrangement is for a specific period of time only, and that when this time ends, I will e ither no longer be picking up the methadone, or will have to complete another "MDCH/OD CP Delivery of Methadone to another Facility Form". I further understand that methadone is a narcotic, to be ingested by the client only, and that harm, including death could come to anyone else ingesting it. When I pick-up the methadone I must present current government issued pictured identification (Driver's License, State Identification Card, Military Identification Card). I must also present any necessary documentation from the treating physician, so that the clinic is kept up-to-date on the current status of the client's medical condition. I have been made aware that loitering within a one-block radius of the clinic is prohibited. I am aware that the methadone is a controlled substance and my institution's protocols will be observed. Both the delivery person and the client agree to all terms stated on this form as well as to additional requirements the OTP may have pertaining to off-site dosing. By signing this form, both parties will not hold the OTP or MDCH/ODCP liable for any unauthorized use of the methadone.

Person Transporting Methadone _____ Title_____
Print Print

_____
Signature

Facility Staff Receiving the Methadone_____
Print

_____
Signature Date

Witness_____ _____
Print Signature

DISTRIBUTION: Original to OTP
Copy to Client

ATTACHMENT D

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.

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.

ITEM	INSTRUCTION
	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 thi s item, please indicate whether the OTP followed the stipulated requirements. F or 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 S IGN 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 S tate, 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 CS AT 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: (301) 443-3994 or Email: otp@samhsa.gov	When you have completed the form, either f ax 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 an d 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); 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. Th e OMB control number for this project is 0930-xxxx).

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.

BACKGROUND INFORMATION

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.

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

REQUEST FOR CHANGE REGARDING PATIENT TREATMENT

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 (Place an "X" next to appropriate days*): S M T W T F S **Beginning 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.

REQUIREMENTS

REQUIREMENTS (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

APPROVAL

State 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: (301) 443-3994; 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION
CENTER FOR SUBSTANCE ABUSE TREATMENT

FORM SMA-168

Exception Request and Record of Justification
Under 42 CFR § 8.11 (h)

Form Approved: OMB Number 0930 -0206
Expiration Date: 09/30/2006
See OMB Statement on Reverse

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 ___ LAAM ___ Other: ___

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: ___

Request 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 ___

Regulation Requirements:

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

___ Approved ___ Denied

State Methadone Authority **Date**

Explanation: ___

Federal response to request:

___ Approved ___ Denied

C. Todd Rosendale, Public Health Advisor
Center for Substance Abuse Treatment **Date**

Explanation: ___

Please fax to CSAT/DPT, (240) 276-1630 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.