



Are CA Funds used for media campaigns?	Y	N
Are any services subcontracted?	Y	N
If yes, is there documentation available that the CA has given permission to the Provider to subcontract services?	Y	N N/A
Are clients aware of publication rights?	Y	N
Are clients aware of continuation of publication rights?	Y	N
<b>Does the Vendor's Plan include cultural competency?</b>	<b>Y</b>	<b>N</b>

***Emergency Situations:***

Opioid Treatment Programs (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 methadone and client records will be maintained.

<b>Is a copy of the Program's Emergency Procedure/Protocol readily available (attach a copy if possible)?</b>	<b>Y</b>	<b>N</b>
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<b>Upon review of the Emergency Procedure/Protocol, does it appear that the situations and security issues listed above have been adequately addressed?</b>	<b>Y</b>	<b>N</b>
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***Product preparation:***

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

<b>Is the methadone dispensed only the oral form?</b>	<b>Y</b>	<b>N</b>
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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 methadone twice daily (split dosing), two separate childproof containers must be utilized. These efforts will help minimize the likelihood of accidental ingestion by children.

<b>Are the doses packaged in childproof containers?</b>	<b>Y</b>	<b>N</b>
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<b>For split dosing, are two containers packaged for each day?</b>	<b>Y</b>	<b>N</b>
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**Labeling:**

Is medication labeled as follows:

The name of the medication;

*Dosage;*

*Date dispensed;*

*Treatment Center's name, address, and phone number;*

The OTP's name, address, and phone number;

Client's name or code number;

Medical Director's name;

Directions for use;

Date to be used;

A cautionary statement that the medication should be kept out of the reach of children; *and*

*The cautionary statement: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."*

**Is the medication properly labeled per the above? Y N**  
**Include a sample label if possible.**

**CLIENT FILE:**

*Has the client provided a complete list of all prescribed medication? Y N*

*Is a step down process evidenced in the client file? Y N*

**In the client file is there evidence that the client attended the Opioid Treatment Program (OTP) daily for on-site supervised dispensing of their methadone until they met certain specified criteria for the privilege of reduced attendance and dosing off site? Y N**

**Has the client received proof of eligibility for self-dosing that could be presented when requested by the OTP, AMS, or CA? Y N**

**Is there evidence that the client's self dosing schedule is reviewed every sixty days while the client receives doses for off-site use? Y N**

**Is there a checklist or some other form of documentation that the physician utilizes in determining whether or not a client is responsible to handle the opioid medication off-site? Y N**

Does this checklist include the following and have these items been noted?

**Background and history of the client including (where applicable):  
employment, disability, has the client appropriately handled self-dosing in  
the past such as on Sundays and Holidays or other off-site situations.**

**Y N**

**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 methadone).** Y N

**The absence of current and/or recent abuse (within 90 days) of drugs, including alcohol on the basis of toxicology screen(s) which must include opioids, methadone metabolites, amphetamines, cocaine, cannabinoids, and benzodiazepines. Other drugs, as indicated in Administrative rules must be included unless a waiver has been granted.** Y N

**Regularity of clinic attendance.** Y N

**Absence of serious behavioral problems in the clinic.** Y N

**Stability of the client's home environment and social relationships.** Y N

**Absence of recent known criminal activity.** Y N

**Length of time in opioid substance abuse treatment with methadone as an adjunct.** Y N

**Assurance that methadone can be safely stored off-site, particularly with respect to prevention of accidental ingestion by children.** Y N

**The rehabilitative benefit to the client derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.** Y N

**Has the client received 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.** Y N **Attach rules if possible.**

**Has the above been adequately addressed?** Y N

***Security:***

The client is expected to secure the methadone in a locked box. The box must be stored in a manner that prevents the key or combination from being readily available to children and others who could be harmed from accidental use and to prevent diversion by third parties. Empty and unused bottles are to be returned to the ORP in the locked box for proper disposal.

**Is a locked box provided to the client by the Vendor?** Y N

**Is the "home storage" procedure on the directions to the client?** Y N

**Has it been made clear to the client to return both the empty and unused bottles to the ORP in the lock box for proper disposal?** Y N

-Has the Vendor determined that client can take out drugs? Y N

-Has client signed a form allowing them to take out drugs (self dose)? Y N

-Has client signed form agreeing to random Bottle Checks during regular business hours (The form will have the program's expectations regarding the bottle check explained to the client. Also possible consequences regarding the non-compliance to the Bottle Check will appear on the form. A copy of the form will be given to the client with the original placed in the client file. If a client does not consent to the Bottle Check, then the client will not be a candidate for the Take Out Medication/Self Dosing mode of methadone substance abuse treatment)? Y N

-Has the client signed a form for release of information allowing the dissemination of information from the designate to the Vendor. This form must be signed and the original retained by LSTC. Y N

-Obtain possible dates, times, and locations from designate (from the list of individuals remitted to the Vendor by the CA) for Bottle Checks Y N

-Determine date, time, and location for the client to commence with the Bottle Check and inform the client of the Bottle Check Y N

-Confirm the Bottle Check date, time, and location with the designate Y N

Has the individual conducting the Bottle check:

-Ensured that the Bottle Check is in a secure, private location Y N

-Taken a count of the opened vials Y N

-Taken a count of the un-opened vials Y N

-Ensured that all un-opened vials have not been tampered with Y N

-Completed the form provided by LSTC Y N

-Remitted/submitted the form to LSTC (either electronically, or by mail) ensuring that the original is properly retained/filed in a client file per the instructions by LSTC? Y N

In the event of a no-show situation (client does not show within one hour of the appointed time), has the designate informed LSTC as soon as possible? Y N NA

-Has LSTC attempted to reschedule the Bottle Check as soon as possible and inform the CA that the client failed to show for a Bottle Check? Y N NA

If the client fails to show up for two consecutive Bottle Checks, has LSTC made a determination regarding the mode of treatment for the client ensuring to inform the CA of each action taken. Y N NA

In the event of inclement weather situation (called in by either the client or designate):

-LSTC informed the CA regarding the rescheduling of the Bottle Check? Y N NA

-LSTC attempted to reschedule the Bottle Check as soon as possible utilizing the protocol initially established regarding the contact of the client and the designate? Y N NA

The Vendor has:

-Compared the data submitted/remitted by the designate to ensure that the self dosing was conducted according to expectations. Y N

-Validated proper self-dosing and all unused bottles appeared to have not been tampered with, and informed the customer and the CA of the compliant results Y N

-If there are any discrepancies, then the Vendor will contact the client and the CA with the questioned results Y N NA

-The client, staff, and program director will meet to determine if the patient will continue to qualify for the Take Home Methadone Program. LSTC will inform the Agency of any action(s) taken with the client regarding the mode of treatment. Y N NA

**FILES/REPORTING/SERVICES:**

Does the Vendor provide services as contracted? Y N

Has the Vendor submitted monthly Financial Statement Report or invoices for services as agreed to by both parties? Y N

Has the Vendor submitted an Individual Treatment Admission Form for each client? Y N

Has the Vendor submitted an Individual Discharge Form for each client served? Y N NA

When applicable, is there an ability to document a Central Diagnostic Referral Assessment/Screening? Y N

Are client files stored in a secure location? Y N

Does the Vendor operate under client confidentiality regulations? (42 C.F.R. 2.53(b)(2)). Y N

\_\_\_\_\_  
Program Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Agency Representative

\_\_\_\_\_  
Date