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Methadone for Treatment of Opioid Use Disorder in an Opioid Treatment Program (OTP): Recommendations for Management in the Fentanyl Era

Scope: The San Francisco Health Network's Behavioral Health Services has previously published the Medications for Opioid Use Disorder Guideline in 2022. This document assists the clinician for opioid use disorder (OUD) management in the ambulatory setting. Methadone, as one of our two mortality-reducing medications for OUD, is provided through specialized opioid treatment programs (OTPs). Within these OTPs, the medical provider exercises their clinical judgment to determine dosing of the methadone, titration of the dose for absences, and whether the patient can access take-home (TH) bottles of methadone, while abiding by state and federal law.

This document aids providers on the following **core topic areas** for people enrolled in an OTP and receiving methadone:

1) Induction dosing of methadone,
2) Titration of methadone for clinic absences,
3) Approach to take home bottles of methadone,
4) EKG monitoring,
5) Dosing of methadone in pregnant patients, and
6) Methadone to Buprenorphine Transition

The appendix includes information about the current status of regulations. This guide does not replace clinical judgment, and individualized management decisions are best made by the clinician expert.

Introduction: San Francisco has been disproportionately affected by the national opioid overdose epidemic, with a 25% increase in overdose deaths between 2022 and 2023. There were 813 unintentional fatal overdoses in SF in 2023, the highest number of overdose deaths to date (San Francisco Office of the Chief Medical Examiner). Data also suggests that the number of patients enrolled in methadone maintenance has declined from 2020 to 2023. Given the life-saving benefits of methadone for opioid use disorder, the San Francisco Department of Public Health wants to ensure that patients can access timely, low-barrier, evidence-based, and cutting-edge methadone care. Recently, there have been recent changes to the federal statute that guides provision of methadone in OTPs, also known as 42 CFR (Code of Federal Regulations) Part 8. SAMHSA (Substance Abuse and Mental Health Services Administration) has disseminated guidance to providers about the change in federal regulations. There is also state

legislation – Title 9 of the Health and Safety Code – that informs the management of patients within an OTP. The medical provider in an OTP must abide by both federal and state statutes while providing care to their patient.

Existing guidelines for the management of patients receiving methadone and enrolled in an OTP include:

1) The Substance Abuse and Mental Health Services Administration (SAMHSA) published TIP 63: Medications for Opioid Use Disorder (2021);
2) The California Society of Addiction Medicine (CSAM): Guidelines for Physicians Working in California Opioid Treatment Programs (2019); and
3) The American Society of Addiction Medicine (ASAM) National Practice Guideline for the Treatment of Opioid Use Disorder (2020).

While comprehensive, these guidelines have not been updated to address the change in both the illicit drug supply – from a heroin to a fentanyl market – and the changing regulations. This guidance document is intended for reference for the OTP provider practicing in San Francisco, caring for people who are primarily using fentanyl.

Topic Area 1: Initiation Dosing of Methadone for People Using Fentanyl

Fentanyl is the predominant drug in the current illicit opioid market in San Francisco. Fentanyl is 50-100 times stronger than morphine. Fentanyl is used predominantly by the inhalational route in San Francisco at the time of this writing.[1] Studies of inhaled, aerosolized fentanyl show similar pharmacokinetic and pharmacodynamic profiles compared to an IV injection of the same dose, helping to explain the predominance of inhalational use. Fentanyl is highly lipophilic, has a small molecular weight, and can quickly cross the blood-brain barrier to produce euphoria. Fentanyl has a large volume of distribution, which means that after usage, fentanyl is rapidly distributed to well-perfused tissues (brain, lungs, heart), and then later distributed to less-perfused tissues (skeletal muscle, fat), which may be associated with a multiple peaking phenomenon and prolonged clearance.

In human drug administration studies, after IV administration of fentanyl, subjective effects of the drug are noted in 30-90 seconds, and the anesthetic effects lasted 40 minutes in total. Fentanyl is eliminated from the body as metabolites in the urine. Fentanyl terminal elimination half-life estimates vary from 3.6 to 14 hours. Fentanyl elimination occurs by CYP P450 metabolism: fentanyl is primarily N-dealkylated to norfentanyl by CYP3A enzymes. Norfentanyl is not considered an active metabolite. There are other minor metabolites of unclear clinical significance.[2] In studies of people with OUD, chronically using fentanyl suggest that clearance can be prolonged with the mean time for fentanyl and norfentanyl clearance being 7.3 (4.9) and

[1] Ciccarone D, Holm N, Ondocsin J, Schlosser A, Fessel J, Cowan A, et al. (2024) Innovation and adaptation: The rise of a fentanyl smoking culture in San Francisco. PLoS ONE 19(5): e0303403. https://doi.org/10.1371/journal.pone.0303403

[2] Bird H, Huhn A, and Dunn K. (2023) Fentanyl Absorption, Distribution, Metabolism, and Excretion: Narrative Review and Clinical Significance Related to Illicitly Manufactured Fentanyl. J Addict Med 17(5):503-508.

13.3 (6.9) days, respectively.[3] Individual differences – including age, genetics, renal and hepatic function – contribute to the pharmacokinetics of fentanyl. Additionally, it should be noted that real-world illicit fentanyl is not pure; it can be a mixture of different fentanyl analogs, or highly potent synthetic opioids (HPSOs),[4],[5] plus other sedatives (e.g., xylazine), each of which will have different pharmacokinetic traits, making it even more difficult to understand what a person's tolerance and withdrawal syndromes will be like.

The pharmacokinetics and impurity of fentanyl partially explain our clinical observations:

1) people with OUD using fentanyl have high physical dependence with rapid onset of severe withdrawal symptoms, which may not be readily apparent through COWS because of drug re-distribution (or multiple peaking phenomenon);
2) a person may have a pattern of very frequent inhalational use, or depending on the person's metabolism and body fat composition, a pattern of more intermittent use;
3) a person may have difficulty inducing onto buprenorphine because of the prolonged clearance of fentanyl and possible precipitated withdrawal.

Methadone provides a helpful alternative for the patient with opioid use disorder and using fentanyl that are seeking treatment. Methadone is a full agonist at the mu opioid receptor. It has a long half-life (20-60 hours) that makes it amenable to daily dosing through an OTP. The long half-life impacts the titration, as methadone levels will continue to rise in the absence of a dosage change while reaching steady-state plasma levels. The U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) developed their methadone treatment guidelines prior to the introduction of fentanyl into the drug supply and suggest a starting dose of methadone of no more than 30 mg, with increases of 5–10 mg every 3–5 days (SAMHSA, 2021). This is echoed in practice guidelines from the American Society of Addiction Medicine (ASAM).[6] Using this schedule, it would take weeks to months to achieve a nominally sufficient dose of 60-120mg daily.

Leaders in Addiction Medicine have called for modernization of dosing guidelines[7] given the risk conferred to patients from ongoing fentanyl use. In February 2024, SAHMSA updated

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[3] Huhn A, Hobelmann J, Oyler G, Strain E. Protracted renal clearance of fentanyl in persons with opioid use disorder. Drug Alcohol Dependence. 2020;214: 108147. Doi: 10.1016/j.drugalcdep.2020.108147

[4] Valdez, C. A. (2021). Gas Chromatography-Mass Spectrometry Analysis of Synthetic Opioids Belonging to the Fentanyl Class: A Review. *Critical Reviews in Analytical Chemistry*, *52*(8), 1938–1968. https://doi.org/10.1080/10408347.2021.1927668

[5] Galust, H., Seltzer, J.A., Hardin, J.R. *et al.* Adulterants present in the San Diego county fentanyl supply: a laboratory analysis of seized law enforcement samples. *BMC Public Health* **24**, 923 (2024). https://doi.org/10.1186/s12889-024-18459-

[6] National Practice Guidelines For the Treatment of Opioid Use Disorder (2020). American Society of Addiction Medicine (ASAM). Available at: https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline

[7] Megan Buresh, Shadi Nahvi, Scott Steiger, Zoe M. Weinstein. Adapting methadone inductions to the fentanyl era. Journal of Substance Abuse Treatment, 2022 Vol 141. https://doi.org/10.1016/j.jsat.2022.108832.

regulations to allow a day 1 dosage of methadone up to 50mg.[8] Locally in San Francisco, the Opiate Treatment Outpatient Program (OTOP) has modified their initiation dosing schedule and observed high short-term retention with no safety events.[9] A large private OTP network has released their own preliminary data showing high retention and low safety risk with "rapid" methadone starts. A compilation of available data on safety and efficacy of rapid induction dosing is available in Table 1.

Table 1: Studies on Rapid Initiation of Methadone in People with OUD

Author	Setting	Design	Intervention	Results	Comment
Casey et al.[10]	Hospitalized patients	Observational case series	76.8mg in average of 5.6 days	● 3.5% had safety event "probably or definitely" related to methadone ● 76% of patients connected to an OTP prior to discharge	Unknown prevalence of fentanyl use.
Steiger et al. [7]	OTP	Observational case series (n=93)	Day 1 40mg, Day 2 60mg, day 3-5 80mg, and day 6 100mg for OUD pt with daily fentanyl use	● In the rapid protocol, 79/83 (85%) retained at 30 days ● No OD fatalities, no reports of excess sedation ● Use of MA meant less likely to complete rapid protocol	High touch clinic with ample staffing.
Nicholas Van Dyke, PhD (Baymark™)	OTPs	Observational case series	80-120mg within 10 days	● 77% retention at 3 mos. (7% higher than overall avg)	Unknown prevalence of fentanyl use.

[8]

[9] Steiger S, McCuistian C, Suen L, Shapiro B, Tompkins A, Bazazi A. Induction to Methadone 80mg in the First Week of Treatment of Patients Who Use Fentanyl: A Case Series From an Outpatient Opioid Treatment Program. J of Addiction Medicine, 2024 Aug 16. doi: 10.1097/ADM.0000000000001362.

[10] Casey S, Regan S, Gale E, Adams ZM, Lambert E, Omede FO, Wakeman SE. Rapid Methadone Induction in a General Hospital Setting: A Retrospective, Observational Analysis. Subst Abus. 2023 Jul;44(3):177-183. doi: 10.1177/08897077231185655

				● 60% retention at 5 mos. ● Improved utox: 52% (rapid titration) v 80% with unfavorable utox	Not peer reviewed.
Hemmons et al.[11]	Hospital	Case Report	70mg within 48h of admission	● No safety risk	
Klaire et al.	Hospital	Observational Case Series (n=135)	30-40mg + 10mg q3h up to max 70mg (d1) (max 3 prn doses per day). Dose increases q3-5 days	● Mean doses (d1 = 40mg, d2 = 49mg, d3 = 50mg, d7 =65mg) ● Serious safety event in 1.2% (n=2) – 1 use of naloxone, 1 ICU transfer. Mild sedation (requiring holding or modifying dose) in 8.9%	80% with IDU, 92% methadone-experienced
Bromley et al.[12]	--	Consensus Guidelines	Start: 30mg; increase 10-15mg every 3-5 days if not risk of methadone toxicity until reaching 75-80mg, then increase 10mg every 5-7 days	--	Ontario

[11] P. Hemmons, P. Bach, K. Colizza, S. Nolan. Initiation and rapid titration of methadone in an acute care setting for the treatment of opioid use disorder: A case report. Journal of Addiction Medicine, 13 (5) (2019), pp. 408-411, 10.1097/adm.0000000000000507

[12] L. Bromley, M. Kahan, L. Regenstreif, A. Srivastava, J. Wyman
Methadone treatment for people who use fentanyl: Recommendations.

Stone et al.[13]	OTP, Rhode Island	Observational Case Series (n=154)	30mg (d1), 40mg (d2), 50mg (d3), then increase up to 20mg per week.	● 53% of fentanyl-using patients retained at 1 year	No difference in retention for fentanyl users versus not.
Taylor et al.[14]	Bridge Clinic	Observational Case Series (n=139)	40mg (d1), 50mg (d2), and 60mg (d3)	● 87% patients linked to the OTP	85% of patients using fentanyl.

Given the existing published data and our local experience in San Francisco, this rapid initiation guide is offered as a resource for the OTP clinician making dosage decisions for the patient using fentanyl (Figure 1). This algorithm does not replace clinical judgment, and it is expected that the OTP provider will consider numerous factors while making a dosage decision. Most OTP providers have experienced the frustration of seeing a patient new to treatment who cannot yet stop their illicit drug because they are waiting to get to a therapeutic dose. The change in federal guidelines allows practitioners to get to a target dose more quickly, thus allowing cessation of illicit drug use. There are important caveats about the data listed in table 1: first, they are primarily case series publications, which are considered lower quality in the evidence hierarchy; second, each case series is not sufficiently powered to detect a rare safety event, such as an overdose; and third, there is significant heterogeneity between OTPs (e.g., staffing robustness, clinical norms for frequency of visits, etc) making it difficult to guarantee the same outcomes in a different setting.

The rapid initiation algorithm starts with a clinical assessment by the provider at intake. There are various factors that can influence the decision to use a rapid induction. Foremost, a patient is considered for rapid induction if they use fentanyl (aka, “fetty,” “iso,” “clean”) daily and have high opioid tolerance. Clinical factors that suggest that patient is **not** a good candidate for rapid induction include:

- Low opioid tolerance (e.g. prescription opioid use disorder, intra-nasal use of opioids, recent period of abstinence such as from incarceration or inpatient treatment)
- History of sedation with methadone
- Medical comorbidities:
    - Severe pulmonary disease (e.g. baseline hypoxemia or O2 saturation <95%)

[13] Stone A, Carroll J, Rich J, Green T. One year of methadone maintenance treatment in a fentanyl endemic area: Safety, repeated exposure, retention, and remission. JSAT 2020;115:108031.

[14] Taylor JL, Laks J, Christine PJ, Kehoe J, Evans J, Kim TW, Farrell NM, White CS, Weinstein ZM, Walley AY. Bridge clinic implementation of "72-hour rule" methadone for opioid withdrawal management: Impact on opioid treatment program linkage and retention in care. Drug Alcohol Depend. 2022 Jul 1;236:109497. doi: 10.1016/j.drugalcdep.2022.109497. Epub 2022 May 14. PMID: 35607834.

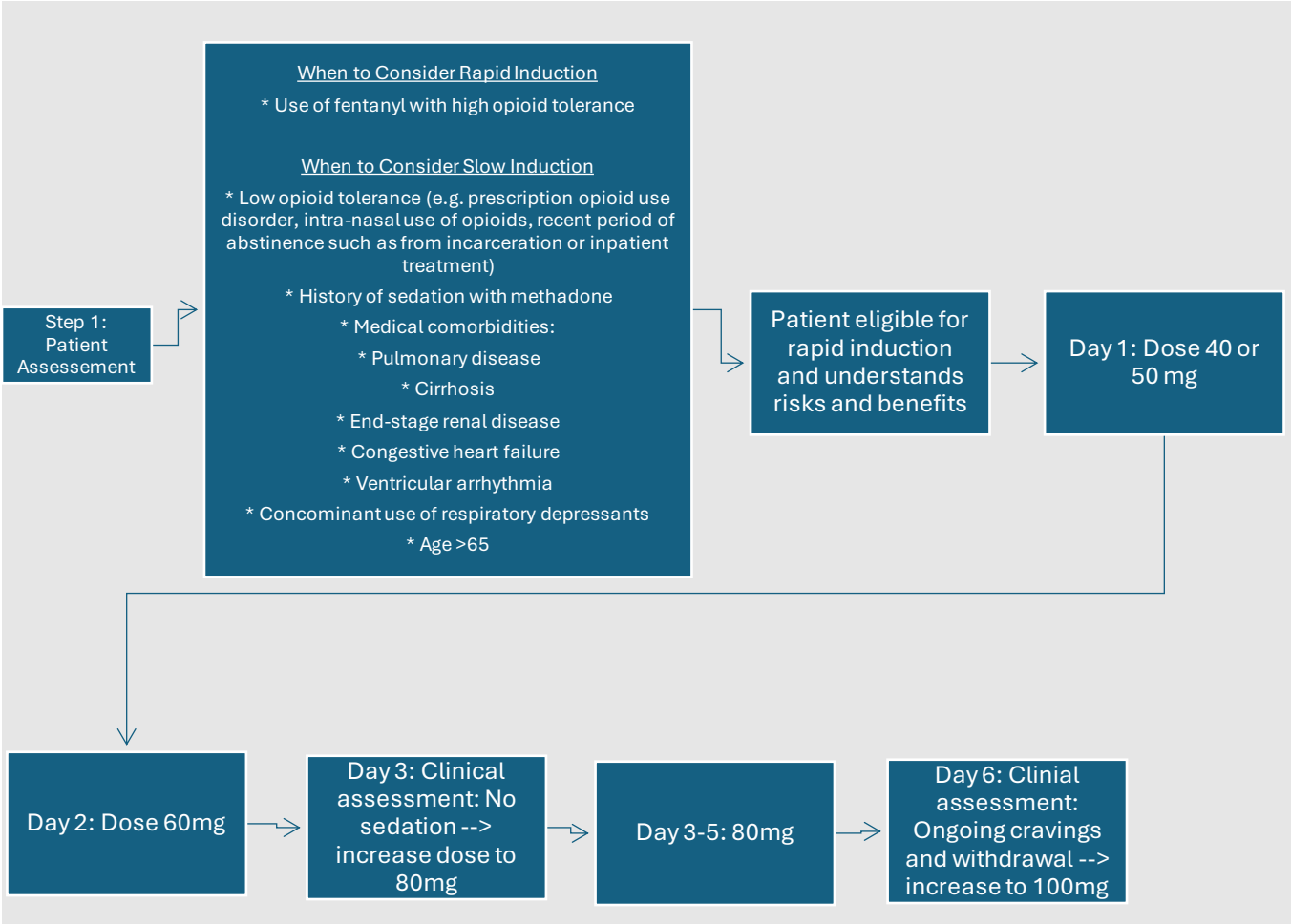
    - Cirrhosis
    - End-stage renal disease
    - Congestive heart failure
    - Ventricular arrhythmia
- Concominant use of respiratory depressants
- Age >65

The potential benefits of a rapid initiation should be described to the patient, including: alleviation of withdrawal symptoms, decreased illicit opioid use, faster time to a "blocking dose" (dose of methadone at which the pleasurable effects of an opioid can no longer be felt), and decreased behaviors associated with drug use. The potential harms or risks of a rapid induction should also be described, including the risk of sedation and overdose, particularly if methadone is combined with illicit opioids or other sedatives (e.g., alcohol, benzodiazepines, or barbituates). Risk of overdose is highest in the first two to four weeks of methadone treatment,[15],[16] likely due to ongoing use of illicit opioids in concert with rising methadone levels. The adage "start low, go slow" dominated the methadone treatment world in the pre-fentanyl era. Now, as we witness the tragic loss of life to fentanyl, and waning enrollment in methadone treatment, methadone management is modernizing to meet patients' needs.

[15] Degenhardt L, Randall D, Hall W et al. Mortality among clients of a state-wide opioid pharmacotherapy program over 20 years: Risk factors and lives saved. Drug and Alc Dep 2009;105 (1-2):9-15.

[16] Baxter LE Sr, Campbell A, Deshields M, Levounis P, Martin JA, McNicholas L, Payte JT, Salsitz EA, Taylor T, Wilford BB. Safe methadone induction and stabilization: report of an expert panel. J Addict Med. 2013 Nov-Dec;7(6):377-86. doi: 10.1097/01.ADM.0000435321.39251.d7. PMID: 24189172.

Figure 1: Rapid Initiation Algorithm



Topic Area 2: Titration of Methadone for Missed Doses

Patients enrolled in an OTP frequently have absences from treatment, likely due to the requirement to present daily to the clinic for dosing. Clinics vary in terms of their response to absent days. Typically, for missed days, a patient will have their dose decreased and then titrated back up to their baseline or target dose over successive days. The percentage of the dose that is decreased for the number of days missed is not clearly outlined in available guidelines. If a patient repeatedly fails to show up, and their dose is decreased, that dosage may not sufficiently address their withdrawal symptoms, and they may be discouraged from continuing their treatment and never return for additional methadone treatment. If a person does not present to clinic for 14 or more days, without notice of the reason for their absence, then they were to be discharged according to regulations.

In order to improve retention in care, more rapid titration to the baseline dose after an absence is important. The guide below offers a framework for dosage adjustments for missed days of methadone. Notably, this table does not replace clinical judgment. There are many factors that

a provider may consider when titrating a person back to their baseline dose, including: pattern and frequency of absences, baseline dose, other substance use, and medical co-morbidities, so this table is only offered as a reference.

Table 2: Methadone Dose Titration After Missed Days (No-Shows)

Days Absent	Dosage Titration	Clinician Visit
2	Resume full dose	As needed
3	Resume full dose	As needed
4	80% of baseline dose, then resume full dose	As needed
5	70% of baseline dose (d1), then 90% of baseline dose (d2), then resume full dose (d3)	As needed
6	60% of baseline dose (d1), then 70% of baseline dose (d2), then 80% of baseline dose (d3), then resume full dose (d4)	As needed
7	Individualized	Recommended

Topic Area 3: Approach to Take-Home (TH) Bottles of Methadone

As part of the changes to 42 CFR, part 8, the federal government modified the criteria for consideration of take-home doses of methadone (see table 3). Importantly, regulations in California are not yet aligned with the changes in 42 CFR, part 8, but the opiate treatment programs in San Francisco all have a blanket exception (see Appendix) that allows them to operate in accordance with federal rules.

The change in take-home rules was largely influenced by scientific literature showing the safety and benefits of THs born from the COVID19 pandemic. The Lancet article[17] has a nice summary of publications that influenced the federal rule changes, but there continues to be strong evidence showing that liberalized take-home policies are associated with:

[17] Krawczyk N, Rivera BD, Levin E, Dooling BCE. Synthesising evidence of the effects of COVID-19 regulatory changes on methadone treatment for opioid use disorder: implications for policy. Lancet Public Health. 2023 Mar;8(3):e238-e246. doi: 10.1016/S2468-2667(23)00023-3. PMID: 36841564; PMCID: PMC9949855.

1) Low rates of diversion[18],[19]
2) Improved retention[20],[21],[22]
3) No increase in mortality[23],[24],[25],[26]

[18] Figgatt MC, Salazar Z, Day E, Vincent L, Dasgupta N. Take-home dosing experiences among persons receiving methadone maintenance treatment during COVID-19. J Subst Abuse Treat. 2021 Apr;123:108276. doi: 10.1016/j.jsat.2021.108276.

[19] Amram O, Amiri S, Panwala V, Lutz R, Joudrey PJ, Socias E. The impact of relaxation of methadone take-home protocols on treatment outcomes in the COVID-19 era. Am J Drug Alcohol Abuse. 2021 Nov 2;47(6):722-729. doi: 10.1080/00952990.2021.1979991.

[20] Kawasaki SS, Zimmerman R, Shen C, Zgierska AE. COVID-19-related flexibility in methadone take-home doses associated with decreased attrition: Report from an opioid treatment program in central Pennsylvania. J Subst Use Addict Treat. 2023 Dec;155:209164. doi: 10.1016/j.josat.2023.209164. Epub 2023 Sep 18. PMID: 37730014.

[21] Hoffman KA, Foot C, Levander XA, Cook R, Terashima JP, McIlveen JW, Korthuis PT, McCarty D. Treatment retention, return to use, and recovery support following COVID-19 relaxation of methadone take-home dosing in two rural opioid treatment programs: A mixed methods analysis. J Subst Abuse Treat. 2022 Oct;141:108801. doi: 10.1016/j.jsat.2022.108801. Epub 2022 May 8. PMID: 35589443; PMCID: PMC9080674.

[22] Kathiresan P, Patel V, Jangra J, Chattopadhyay A, Abdus S, Jadhav M, Rao R, Arya A, Bansal PD, Chinggouman C, Bhad R, Ambekar A, Agrawal A, Chatterjee B, Yadav D. Experience of patients on methadone maintenance treatment receiving take-home methadone doses during COVID-19 pandemic: A multi-site study from India. Asian J Psychiatr. 2024 May;95:103979. doi: 10.1016/j.ajp.2024.103979. Epub 2024 Feb 24. PMID: 38442535.

[23] Kawasaki SS, Zimmerman R, Shen C, Zgierska AE. COVID-19-related flexibility in methadone take-home doses associated with decreased attrition: Report from an opioid treatment program in central Pennsylvania. J Subst Use Addict Treat. 2023 Dec;155:209164. doi: 10.1016/j.josat.2023.209164. Epub 2023 Sep 18. PMID: 37730014.

[24] Harris RA. Methadone Take-Home Policies and Associated Mortality: Permitting versus Non-Permitting States. Subst Use. 2024 Aug 16;18:29768357241272379. doi: 10.1177/29768357241272379. PMID: 39161774; PMCID: PMC11331457.

[25] Brothers S, Viera A, Heimer R. Changes in methadone program practices and fatal methadone overdose rates in Connecticut during COVID-19. J Subst Abuse Treat. 2021 Dec;131:108449. doi: 10.1016/j.jsat.2021.108449. Epub 2021 Apr 29. PMID: 34098303; PMCID: PMC9758251.

[26] Levander XA, Pytell JD, Stoller KB, Korthuis PT, Chander G. COVID-19-related policy changes for methadone take-home dosing: A multistate survey of opioid treatment program leadership. Subst Abus. 2022;43(1):633-639. doi: 10.1080/08897077.2021.1986768. Epub 2021 Oct 19. PMID: 34666636; PMCID: PMC8810732.

In studies of providers' opinions about changes in the regulations, increased flexibilities were regarded as broadly positive, despite initial safety concerns[27]. Despite the existing evidence that has accumulated, implementation of regulatory changes has been variable.[28]

Implementation of take-home rule changes will vary by clinic, and may be influenced by institutional policies and procedure, and provider discretion. Based on the observational data showing improved retention in care with no increase in mortality, plus evidence that there are racial inequities in take-home provision,[29] **providers and clinics should consider a near-universal approach to take-homes** to give patients access to this evidence-based intervention. This approach is outlined in figure 2 below. In the appendix of this document are sample policies and procedures for a new system of take-home methadone. This change impacts all staff. It is crucial to have collective understanding about any new take-home rules, so that patients receive consistent information.

[27] Adams A, Blawatt S, MacDonald S, Finnick R, Lajeunesse J, Harrison S, Byres D, Schechter MT, Oviedo-Joekes E. Provider experiences with relaxing restrictions on take-home medications for opioid use disorder during the COVID-19 pandemic: A qualitative systematic review. Int J Drug Policy. 2023 Jul;117:104058. doi: 10.1016/j.drugpo.2023.104058. Epub 2023 May 8. PMID: 37182352; PMCID: PMC10165059.

[28] Levander XA, Pytell JD, Stoller KB, Korthuis PT, Chander G. COVID-19-related policy changes for methadone take-home dosing: A multistate survey of opioid treatment program leadership. Subst Abus. 2022;43(1):633-639. doi: 10.1080/08897077.2021.1986768. Epub 2021 Oct 19. PMID: 34666636; PMCID: PMC8810732.

[29] Choi S, Zhang Y, Unruh MA, McGinty EE, Jung HY. Racial and Ethnic Disparities in Take-Home Methadone Use for Medicare Beneficiaries With Opioid Use Disorder. JAMA Netw Open. 2024 Aug 1;7(8):e2431620. doi: 10.1001/jamanetworkopen.2024.31620. PMID: 39212993; PMCID: PMC11364990.

Table 3: Revised Federal Regulations for Take-Home Methadone

Take-Home Methadone: Updated Federal Regulations (42 CFR, Part 8)		
Tenure in MMT	No. of TH Doses	***Criteria to Consider While Considering Whether the Therapeutic Benefits of Unsupervised Doses Outweigh the Risks (5 Point Criteria)***
0-14 d	Up to 7 TH doses	(a) Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely; (b) Regularity of attendance for supervised medication administration; (c) Absence of serious behavioral problems that endanger the patient, the public or others; (d) Absence of known recent diversion activity; and (e) Whether take home medication can be safely transported and stored; and (f) Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.
15-30 d	Up to 14 TH doses	
>31 d	Up to 28 TH doses	

Figure 2: Universal Access to Take-Home Methadone for People with Opioid Use Disorder

Clinic Modifies **Take-Home Policy** to Support Universal Access & Equitable Approach to Change in TH Status

- Consider all patients eligibile for 2-4 TH (2 at a time max) per week within the first 2 weeks of treatment (once dose relatively stable) regardless of substance use or housing status.
  - Exceptions: prior mishandling of methadone, psychiatric instability, drug screen neagtive methadone, dementia, or patient preference not to have THs
  - Example: Client on stable dose --> Enter order for 4THs (dosing days M/W/Fr, or T/Th/Sat) --> Client returns every other day to dose in person and return bottle from previous day --> If urine toxicology non-reactive for opioids and engaged in treatment --> Increase from 4TH to 6TH
    - TH Order in Methasoft: Give -- TH to facilitate daily dosing and retention in care. Risks of diversion are outweighed by therapeutic benefit to patient.
- See appendix for example documents

Clinic Develops a **Take-Home Agreement** for Client to Sign

- See appendix for example documents
- Client sign agreement at intake, or if established patient, signs agreement with counselor

Clinic Develops a Risk Mitigation Policy such as **Take-Home Bottle Return Policy**

Topic Area 4: EKG Monitoring

EKG monitoring in outlined in TIP 63 from SAMHSA and the ASAM Guidelines for Treatment of Opioid Use Disorder. The recommendations from ASAM – most recently updated - state: "While there is not clear data on the threshold dose of methadone that confers risk for QT prolongation, the consensus of the committee is that ECG should be considered for patients receiving over 120mg per day. However, there is no research on the use of ECG data for improving patient outcomes."

In 2015 in Ontario, Canada, in response to the fentanyl crisis, they expanded their addiction treatment centers through the RAAM initiative – rapid access addiction medicine – with creation of seven new clinical centers to treat addiction. Publicly-sponsored educational resources were developed to support the providers working in these settings, including guidance on methadone dosing and monitoring. They recommend screening for the following groups: patients on doses above 150mg, patients at risk of arrhythmias (e.g., current endocarditis, history of cardiac surgery, previous ventricular arrhythmia, or other significant cardiac disease); and patients taking medications that could prolong the QT interval. They also including in their summary recommendations that "Methadone dose increases should not be

delayed due to the absence of an ECG." They note that "the benefit of opioid agonist treatment for a patient at high risk of overdose or morbidity and mortality outweigh the risks of a prolonged QTc interval."[30] The RAAM network has been evaluated through an observational study of patients with problematic opioid use, comparing those getting RAAM care to those propensity-matched controls not receiving RAAM care, and they showed that RAAM care decreased your odds of the composite outcome (all-cause ED visit, hospitalization, or mortality) by 32% (OR 0.68). Similarly, for the outcome of opioid-related events (e.g., ED visit or hospitalization related to an opioid, or death related to an opioid), RAAM patients had a 53% lower odds of this outcome.[31]

Locally, in San Francisco, the Opiate Treatment Outpatient Program (OTOP), who has no on-site ECG services, follows a practice of ECG monitoring for patients without risk factors starting at a dose of 200mg daily. For patients that do have risk factors, clinician judgment is used to determine the timing and frequency of ECG monitoring.

In summary, it is recommended that the OTP practitioner do individualized risk assessment for need for ECG, weighing their medical history, other medications, current dosage, and whether ECG will be a barrier to ongoing methadone treatment. Some clinics are able to do on-site EKG monitoring, while others lack that capacity. Use of dose holds, dose reductions, or involuntary discharge for failure to do an ECG is discouraged as it risks the person de-stabilizing with their OUD treatment. Large treatment programs in San Francisco and Canada start ECG monitoring for low-risk patients when their dose exceeds 150-200mg daily.

Topic Area 5: Caring for Patients that are Pregnant and on Methadone

Individuals with opioid use disorder and pregnancy require outstanding, multi-disciplinary care. For many individuals, pregnancy can be a tremendous catalyst for change. Opioid agonist maintenance (with either methadone or buprenorphine) is the standard of care for pregnant people who use drugs, and recommended by by the American College of Obstetrics and Gynecology (ACOG).[32] There are well-documented benefits of MAT for both the pregnant person and their fetus.[33] Benefits for the pregnant person include 70% reduction in overdose

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[30] Bromley L, Kahan, M, Regenstreif L, Srivastave A, Wyman J. Methadone treatment for people who use fentanyl: Recommendations. META PHI (Mentoring, Education, and Clinical Tools for Addiction. Partners in Health Integration). Available at: https://www.metaphi.ca/wp-content/uploads/Guide_MethadoneForFentanyl.pdf

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[32] ACOG Committee Opinion, Number 711, August 2017. Available at: Opioid Use and Opioid Use Disorder in Pregnancy | ACOG

[33] Klaman SL, Isaacs K, Leopold A, Perpich J, Hayashi S, Vender J, Campopiano M, Jones HE. Treating Women Who Are Pregnant and Parenting for Opioid Use Disorder and the Concurrent Care of Their

related deaths, decreased risk of HIV, HBV, HCV, and increased engagement in prenatal care and recovery treatment. Fetal benefits include reduced fetal stress, decreased intrauterine fetal demise, decreased rates of intrauterine growth restriction, and decreased preterm delivery. Of note, rates or duration of neonatal abstinence syndrome do not differ based on parental methadone dose, so there is no indication to attempt to minimize dose for this reason.[34]

The update in 42 CFR, Part 8, now recommends split dosing for pregnant people.[35] Pregnant patients benefit from this because the more rapid metabolism of methadone in pregnancy results in faster clearance of the medication. The half-life of methadone in a pregnant person is much shorter than non-pregnant individuals – 8.1 hours, instead of 22-24 hours.[36] For the same reason, **patients often need higher methadone doses during pregnancy** than they do when not pregnant**.** As in non-pregnant patients, methadone should be titrated until a clinically effective dose is reached. Table 4 offers a dosing schedule that may be utilized for care of the pregnant patient using fentanyl.

San Franciso is highly-resourced to take care of this group, but it hinges on collaborative care. **Any pregnant patient on methadone should be able to receive OUD care at the opiate treatment program of their choosing.** The Pregnancy Discrimination Act of 1978, which amended Title VII of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000e *et seq*., prohibits discrimination on the basis of pregnancy, childbirth, or related medical conditions. The Department of Health Care Services (DHCS) also follows a non-discrimination policy.

California code of regulations for OTPs, also known as title 9,[37] has multiple requirements for the care of pregnant patients, which are listed below. For clinics embarking on the care of pregnant patients, clinics must adhere to these regulations and have that reflected in their clinical charting. Following that list is information about care coordination for this group of individuals. There are programs in place to assist these patients, and each OTP should feel like they can capably make a referral to meet state and federal requirements. Note also for the patient in stable recovery on methadone, not using substances, an exception request can be placed to eliminate the requirement of weekly urine toxicology screens.

Infants and Children: Literature Review to Support National Guidance. J Addict Med. 2017 May/Jun;11(3):178-190. doi: 10.1097/ADM.0000000000000308. PMID: 28406856; PMCID: PMC5457836.

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[36] Albright B, de la Torre L, Skipper B, et al. Changes in methadone maintenance therapy during and after pregnancy. J of Substance Abuse Treatment. 2011;41(4):347-353.

[37] California Code of Regulations, Title 9, Section 10360 – Additional Requirements for Pregnant Patients. Available at: Cal. Code Regs. Tit. 9, § 10360 - Additional Requirements for Pregnant Patients | State Regulations | US Law | LII / Legal Information Institute (cornell.edu)

1) Within 14 days of awareness of the pregnancy, the medical director shall review, sign and date a confirmation of pregnancy. The medical director shall also document:
    a. Acceptance of medical responsibility for the patient's prenatal care, or
    b. Verification that the patient is under the care of a provider for the pregnancy
2) Within 14 days of awareness of the pregnancy, the counselor will update the treatment plan in accordance with section 10305, including:
    a. Monthly visits with the medical director of physician extender designated by the medical director
    b. Collection of body specimens at least weekly
    c. Prenatal instructions
3) The medical director or licensed health personnel designated by the medical director must document that they have educated the patient on the following:
    a. Risk to the patient and unborn child from continued use of both illicit and legal drugs, including premature birth.
    b. Benefits of replacement narcotic therapy and risks of abrupt withdrawal from opioids, including premature birth.
    c. Importance of attending all prenatal care visits.
    d. Need for evaluation for the opioid addiction-related care of both the patient and the newborn following the birth.
    e. Signs and symptoms of opioid withdrawal in the newborn child and warning that the patient not share take-home medication with the newborn child who appears to be in withdrawal.
    f. Current understanding related to the risks and benefits of breast-feeding while on medications used in replacement narcotic therapy.
    g. Phenomenon of postpartum depression.
    h. Family planning and contraception.
    i. Basic prenatal care for those patients not referred to another health care provider, which shall include instruction on at least the following:
        i. Nutrition and prenatal vitamins.
        ii. Child pediatric care, immunization, handling, health, and safety.
    j. Evidence-based practices for managing neonatal abstinence syndrome.
4) If the patient repeatedly refuses referrals offered by the program for prenatal care or refused prenatal services, the medical director shall document the refusals and have the patient acknowledge in writing that they refused treatment.
5) Within 14 days of delivery and/or termination, the medial director shall document:
    a. The hospital or attending physician's summary of the delivery and treatment outcome for the patient and baby; or
    b. Evidence that a request for information was made, but no response was received.
6) Within 14 days of delivery and/or termination, the counselor shall update the patient's treatment plan in accordance with Section 10305.

Table 4: Dosing Guidance For the Pregnant Patient Using Fentanyl

	Split Dosing • **2nd or 3rd trimester** • **Early wear-off (e.g., withdrawal) of methadone (may occur in 1st trimester)**		**Daily Dosing**	**Provider Assessment**
	AM dose	PM dose	Single Dose	
Day 1	40mg	None	40mg	Patient assessed
Day 2	60mg	None	60mg	
Day 3	80mg	None	80mg	
Day 4	40mg	40mg	80mg	
Day 5	50mg	50mg	100mg	Reassess patient before dose increase
Day 6	50mg	50mg	100mg	
Day 7	50mg	50mg	100mg	
Day 8	60mg	60mg	120mg	Reassess patient before dose increase
Day 9	60mg	60mg	120mg	
Day 10	60mg	60mg	120mg	

Care Coordination for Pregnant Patients

1) The city of San Francisco has public health nurses (PHNs) that are an invaluable resource to pregnant patients with substance use disorders – PHNs can directly connect patients to prenatal care and many other resources. You can directly contact Dana Lazarovitz (lead PHN) at 415-920-3543 or Dana.Lazarovitz@sfdph.org. For care coordination, it is tremendously helpful to collect demographic/location information and to ask the patient permission for a public health nurse to reach out to them to help connect them to resources.
2) Provide information about the Team Lily Programs at SFGH. These are low-barrier, walk-in clinics for pregnant people with mental illness, substance use disorders, and/or unstable housing. The public health nurses work closely with these clinics.
    a. Prenatal program, housed in the OB/GYN department at SFGH: Team Lily Program. Refer by contacting social worker Rebecca Schwartz at 415-802-7615.
    b. Postpartum program (also provides family, pediatric care), housed in the Family Health Center at SFGH (995 Potrero Avenue, Building 80, 1st Floor). Refer by contacting social worker Sandra Torres at 415-370-0810.
3) Provide education to your patient about engaging in OUD treatment during pregnancy, including: 1) safety of methadone during pregnancy; 2) methadone treatment does not

preclude having custody of your child; 3) collaboration between community partners exists to help the pregnant patient and future child.

4) Sign release of information (ROI) for: SFGH, Team Lily Team at SFGH, Public Health Nurse
5) If a pregnant patient is struggling with outpatient methadone initiation, they can often be admitted to the antepartum service at SFGH for inpatient methadone initiation. Please reach out to public health nurse Dana Lazarovitz (see above) for coordination.

Topic Area 6: Methadone to Buprenorphine Transition

People with opioid use disorder should be aware of the different life-saving medications available for OUD, including buprenorphine. People may seek transition from methadone to buprenorphine for a variety of reasons – for example, more flexibility, side effects, or limited effectiveness. As opiate treatment program providers, we should be equipped to discuss the pros and cons of approved medications, and to navigate the transition between them. This section will focus on how the OTP can assist the patient to switch from methadone to buprenorphine.

Previous guidance recommended a decrease in the methadone dose to 30-40mg prior to transition to buprenorphine, but for many patients, this dose reduction risks their clinical stability. Increasingly, we understand that patients continue the same methadone dose, while doing a gradual induction onto buprenorphine (e.g., the Bernese method). Once the patient has reached a certain dosage of buprenorphine, the methadone dose can be tapered off. This process is best done in the OTP where the provider can adjust the methadone and buprenorphine dosages. Alternatively, the OTP can partner with the primary care addiction doctor to do the transition, if so desired. Key to this process is giving the patient small doses of buprenorphine, which is best done at the outset with transdermal buprenorphine patches (trademarked as Butrans, and FDA approved for pain dosed one patch applied to skin q week). This can be prescribed for the patient if they also have a chronic pain diagnosis. Given the challenging nature of the transition, it is recommended to counsel and discuss with the patient on repeat visits, and have the counselor discuss with the patient, to ensure they are ready. This includes informing them of the risks of: precipitated withdrawal, destabilization of their OUD, and possible side effects from the dual medications. The provider can seek assistance from the Substance Use Warmline, or National Clinical Consultation Center, #855-300-3595. Below are a series of transition steps, and then dosing recommendations for providers working in the OTP.

<u>Methadone to Buprenrophine Transition Steps</u>

1) Patient Assessment and Education:
    a. Reasons for Transition
    b. Assess for clinical stability (note: for transition of high-dose methadone to buprenorphine, local experience suggests that the chances of success are increased if that person is stable and no longer using extra-medical opioids)
    c. Risks and benefits of changing medicine

    d. Willingness to attend in-clinic visits for assessment and monitoring during transition
2) Collaboration with Counselling
    a. Solicit any feedback or concerns from maintenance counselor
3) Collaboration with Primary Care Provider (PCP)
    a. Signed ROI
    b. Determine if PCP will take over prescribing of buprenorphine after transition
4) Collaboration with Pharmacy
    a. Pharmacy may be able to deliver medication to assist with transition, or patient can bring in own medications
    b. Ensure insurance coverage and stock of medication
5) Collaboration with Dispensing and Nurses
    a. Orders in Methasoft may be novel and confusing to nursing team
6) During Transition
    a. Ensure staffing for patient check-ins and visits
    b. Comfort medications

Table 5: Methadone to Buprenorphine Transitions: Dosing Schedule

Day	Methadone Dose	Buprenorphine Dose	Assessment
1	Same dose	2 TD buprenorphine patches applied to skin (each is 20mcg/hr)	
2	Same dose	Place 2 additional TD buprenorphine patches (each is 20mcg/hr)	
3	Same dose	Continue patches	
4	Same dose	Continue patches	
5	Same dose	Continue patches	
6	Same dose	Buprenorphine 1mg SL x 1	Assess patient
7	Same dose	Buprenorphine 1mg SL BID (1 take-home buprenorphine)	
8	Same dose	Buprenorphine 1mg SL TID (2 TH buprenorphine)	Assess patient. Patches have expired and may be removed.
9	Same dose	Buprenorphine 1mg SL qid (3 TH buprenorphine)	

10	Same dose	Buprenorphine 2mg SL TID (2 TH buprenorphine)	
11	Same dose	Buprenorphine 2mg every 3 hours until total of 10mg taken (4 TH buprenorphine)	
12	Decrease methadone dose by 50%	Buprenorphine 4mg SL TID (2 TH buprenorphine)	Assess patient
13		Buprenorphine 4mg SL QID (3 TH buprenorphine)	Assess patient. If ongoing withdrawal symptoms, taper methadone off more slowly. If no withdrawal symptoms, may try to stop the methadone
14	No methadone or reduced dose	Buprenorphine 8mg SL BID (2 TH buprenorphine)	Assess patient. Determine whether patient may need a total of 24mg of buprenorphine to manage withdrawal symptoms

This transition can be particularly difficult for some patients. For that reason, it is important to do the "pre-work" with them to determine if this is the best thing for them. At various times in the cross-taper, a person may feel "a little sick" an hour after the buprenorphine, which may be an indication that the buprenorphine dose from that day was too high. It may also be that they feel unwell because the methadone dose dropped too quickly. The provider needs to see the patient frequently to understand their symptoms and how to adjust the medication. The schedule above is intended to provide guidance; it does not replace the provider's clinical decision making.

Appendix:

1. Regulation Updates
2. Approach to patient insurance problems

3. Take-Home Policy and Procedures from OTOP
4. DHCS Exception Request Letters

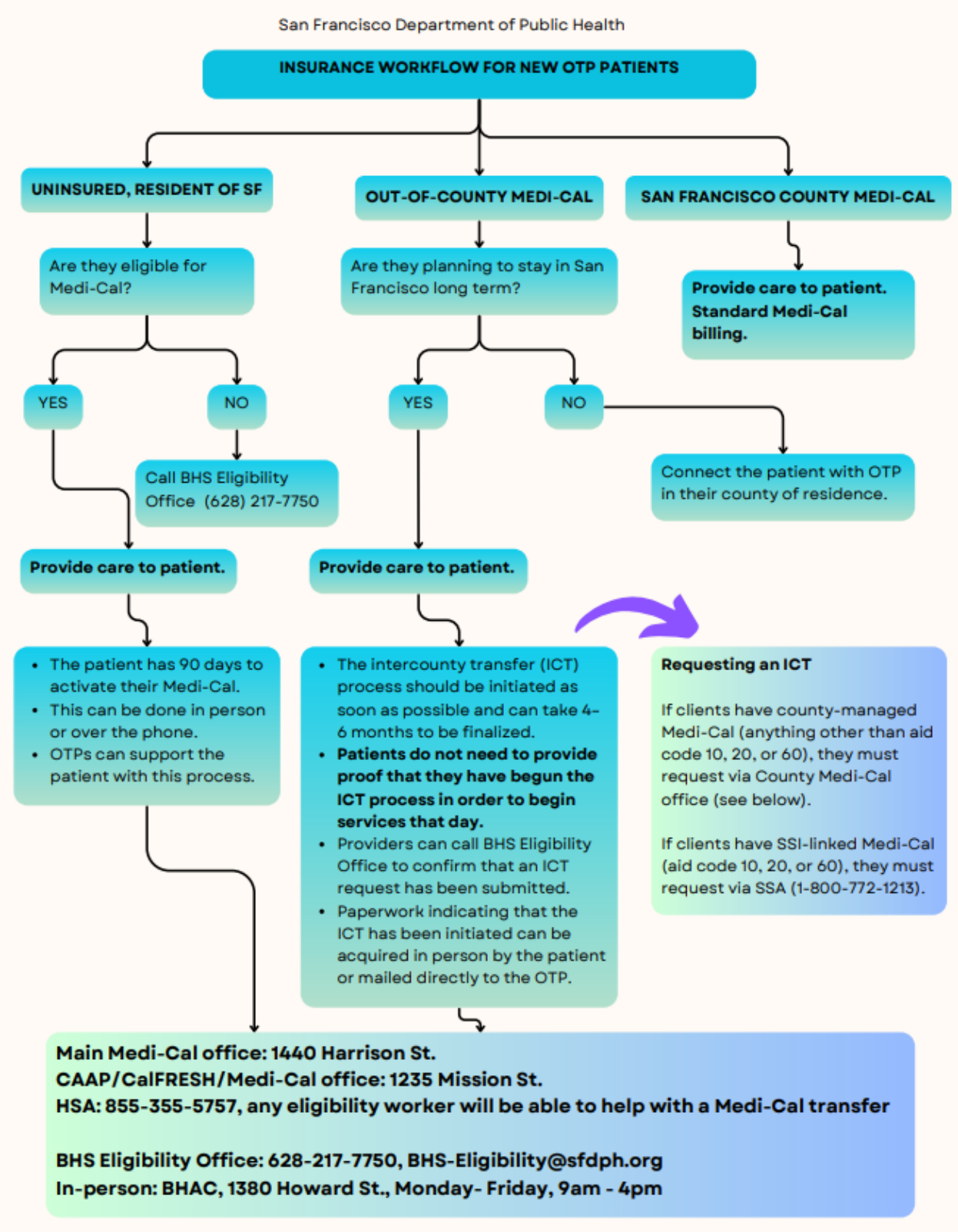
Regulation Updates

The San Francisco Department of Public Health has written to the Department of Health Care Services on behalf of our network of OTPs to request exception requests to several regulations in title 9 that are in conflict with new federal guidance. Below is a list of the exceptions that have been approved by the state. Each clinic should have received a letter from DHCS summarizing the approval of their exception requests. See the letter in the appendix of this document.

Table Summarizing Current Exception Requests in Place:

Old Regulation	New Exemption
Requires 1 year of documented opioid addiction	No required documentation of opioid addiction
Requires medical director to perform or approves medical examination prior to admittance	Allows non-OTP practitioners to complete the initial medical examination (example: emergency departments), and allows up to 14-days to complete the exam
Requires physical examination to be conducted in-person	Allows for physical examinations to be conducted via audio-visual telehealth
Requires patient discharge after 14 days of absence	Requires patient discharge after 30 days of absence
Restricts first dose to 40 milligrams	Allows for patients to start dosing at 50 milligrams on day 1 of treatment
Requires 90-days in continuous treatment to receive take-home doses and restrictions of take-homes based on toxicology testing	Allows for take-homes starting on day 1 of treatment and does not require restrictions based on toxicology testing

Flow Chart for Patient Insurance Problems



Take-Home Policy and Procedures from OTOP

OTOP
OPIATE TREATMENT OUTPATIENT PROGRAM
1001 Potrero Avenue • Ward 93 • San Francisco, CA 94110 • p: 628.206.8412 • f: 628.206.4153
METHADONE MAINTENANCE | OFFICE-BASED OPIATE TREATMENT (OBOT) | MOBILE METHADONE MAINTENANCE | METHADONE DETOX

Subject: Take-Homes, Standard

Policy:
It is the policy of OTOP to implement a consistent take-home medication policy that falls within the constraints of the regulations that govern Opioid Treatment Programs. Take-home doses of methadone may be permitted in certain situations within the limits of State and Federal regulations. SAMHSA published a "final rule" effective 4/2/24 that asks medical directors of OTPs to use their clinical judgment to determine number of take-home doses suitable for individual patients after considering certain criteria. OTOP received a blanket exception from the state to follow this rule.

The aim of the OTOP Take Home Policy is to balance patient autonomy and recovery with the intention of protecting the patient and the general public from adverse events. All Take Homes doses are placed in childproof bottles and contain the name, address and phone number of the clinic.

There are two major areas to consider in determining eligibility for regular, scheduled take-homes:

1. Does the patient have enough time in methadone maintenance treatment*?
*Federal and State regulations do not include this criterion for patients on buprenorphine

The following are the Federal minimum time in treatment for step level schedules

Take-home doses:	Time in treatment:	Weekly Clinic attendance:
0-6 plus holiday	1-14 days	1-7 days
13 plus holiday	15-30 days	1 day every other week
27 plus holiday	31+	1 day every four weeks

2. Consider the Federal "5 point Criteria?"

CRITERIA FOR CONSIDERATION: EARNED TAKE-HOME MEDICATION PRIVILEGES:
These are general guidelines to consider. They neither requirements for nor guarantee of take homes
(i) Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely;
(ii) Regularity of attendance for supervised medication administration;
(iii) Absence of serious behavioral problems that endanger the patient, the public or others;
(iv) Absence of known recent diversion activity;
(v) Whether take-home medication can be safely transported and stored;

Most patients at OTOP are considered to be eligible for 4 TH per week no more than 2 TH at a time (see chart at bottom of this policy). To qualify for 6+ TH (see exception bellow) patients generally must demonstrate safe handling of 4 TH per week, abstinence from opioids, non-prescribed benzodiazepines, non-prescribed barbiturates, and have no problematic alcohol use. To qualify for 13 TH per week, patients must additionally demonstrate safe handling of 6 TH for a month and be responsive to random callbacks while on 13 TH. To qualify for 27 TH, patients generally must demonstrate abstinence from stimulants and be responsive to random callbacks while on 13 and 27 TH.

Reviewed 8/8/18; Revised 9/21/21, 10/4/2022, 7/31/2024

EXCEPTION TO ALLOW 6 TH: Is the patient participating in gainful vocational or educational activity or have a serious medical condition which is documented in the patient's record?

Typical examples include a job, school; caring for children or elders; or a chronic medical illness causing ambulatory difficulty. In these select cases, patients may be considered for more than 4 TH per week at the discretion of the medical director. Their schedule will be returned to 4 TH per week if they demonstrate unsafe handling, but they will not be reduced for evidence of ongoing substance use unless problematic.

CALL BACKS:

To prevent mishandling of Methadone all patients with 13 or more take-homes will have a minimum of two random call backs a year. Anyone with take-homes may be required to bring in all remaining doses of medication & give a urine specimen for drug screen (call back) to ensure take-home methadone is being handled responsibly.

OTHER EXCEPTIONS FOR TAKE-HOME DOSES:

Federal and state regulations allow for take-home doses to be dispensed to patients around holidays. See the policy "Take Homes, Holiday" for details.

Reviewed 8/8/18; Revised 9/21/21, 10/4/2022, 7/31/2024

CA/FED Step Level	# of take-homes	Days/wk in clinic	Reasons to reduce to this level
0	0	7	• Patient prefers not to have take home medication • Psychiatric instability that increases the risk of methadone misuse, mishandling or diversion (Requires MD review and approval) • Recent lost or stolen take homes at 4 TH (restore per Medical Director or Designee) • Drug screen negative methadone or buprenorphine on drug screen not explained by absence or dose (Requires MD review and approval) • No show for 7 or more consecutive days • Other Reasons as approved by Medical Director, Program Director or Designee

CA/FED Step Level	# of take-homes	Days/wk in clinic	Reason to reduce to this level	Reason to increase to this level
4	4 (2 at a time max)	3 (NOT SEQ UEN TIAL)	• Unstable housing • Breathalyzer positive while at higher step level (immediate) • Refused/altered UA while at higher step level (immediate) • Incarceration (immediate) • Drug screen positive for non-prescribed opioid, benzodiazepines, or alcohol while at 6 TH • Unexcused absence while at 6 TH • Return early while at 6 TH • Failure to meet counseling requirement at 6 TH	• Patient back to baseline dose after no show of 7+ days • 2 weeks since TH lost or stolen, plan for safe storage • 1 mo since negative methadone or buprenorphine and subsequent testing is positive • Resolution of Other Reasons identified by Medical Director, Program Director or Designee
4	6	1	• Urine drug screen positive for non-prescribed opioid, benzodiazepines, or alcohol while at 13 TH • Unexcused absence while at 13 TH, including no response to call back • Return early while at 13 TH • Failure to meet counseling requirement while at 13 TH	• Stable housing • No evidence non-prescribed opioid, benzodiazepines, and alcohol at 4 TH • Adherent to counseling at 4 TH • <4 absences in last 4 weeks
5	13	1 every other week	• Urine drug screen positive for non-prescribed opioid, benzodiazepines, alcohol, *or stimulants* while at 27 TH • Unexcused absence while at 27 TH, including no response to call back • Return early while at 27 TH • Failure to meet counseling requirement at 27 TH	• No evidence non-prescribed opioid, benzodiazepines, and alcohol at 6 TH • Adherent to counseling at 6 TH
6	27	1 every 28 days	Not applicable	• Stable on 13 TH for 1 month with no evidence non-prescribed substance use

Patients needing take homes that they do not qualify for (for emergency or other valid reasons) may be considered for takehomes doses on a one-time basis, for personal reasons in accordance with State laws & Federal regulations. Because a state or federal exception to regulations may be required, staff must submit a request for take-homes at least 48-hours in advance (although the 48-hour notice may be waived in the case of exceptional circumstances such as personal or family crisis). If the patient must travel out of the program area, the counselor should attempt to arrange courtesy dosing at another methadone program before requesting takehome doses. The patients should be instructed that before finalizing travel plans (buying airline tickets, etc.); the counselor

should be consulted about dosing options. If courtesy dosing is desired the patient should give the counselor 7-days' notice because accepting clinic often requires significant advance notice.

REVOKING TAKE-HOME PRIVILEGES:

If at any time the medical director or designee determines that it would not be safe for a patient to get take-homes, the take-homes will be revoked. Counselors have a requirement to report any concerns or concerning information about patients with take-home medication privileges to the Charge Nurse, Program Director or Medical Director. Take-home doses can be reduced by one step or more or totally revoked for any violation of program rules or failure to meet any take-home requirement.

When patients have a positive urine drug screen, the assumption is that they have relapsed & need a reduction in take home medication or no take-home medications at all. Occasionally, a patient may have had a "slip" & be able to continue to manage some take homes safely, but this will require evaluation & supportive documentation from the counselor.

Reviewed 8/8/18; Revised 9/21/21, 10/4/2022, 7/31/2024

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OTOP Treatment & Take Home Agreement

1. **Treatment with medications for opioid use disorder (MOUD) including methadone or buprenorphine is voluntary.** The use of these medications in conjunction with counseling, care coordination and referral services is part of comprehensive treatment.

2. **I will meet with my counselor as required in accordance with program guidelines.** Development of treatment plan goals is a collaborative process between my counselor and myself aimed at identifying my strengths I can use to accomplish my goals.

3. **Clinic Hours:** Weekdays: 6:45 am – 11:00 am and 12:30 pm – 2:00 pm
   Weekends and Holidays: 7:30 am - 11:00 am and 12:30 pm – 2:00 pm
   Unfortunately, exceptions to these dosing hours are not possible. I understand I need to arrive at least 30 minutes before clinic closing if I need to meet with medical or counseling staff.

4. **I understand I will be discharged from the program due to lack of attendance if I miss more than 14 consecutive days**.

5. **State & Federal guidelines require obtaining random urine specimens for drug screening.** Failure to submit a urine specimen on the day it is requested may result in termination of treatment. Female urine analyses taken at intake will include testing for pregnancy.

6. **A physician or nurse practitioner will evaluate me at the initiation of treatment and periodically, as needed throughout treatment.** The Department of Justice of the State of California maintains a database for all prescriptions for controlled substances filled by pharmacies in California called CURES. Licensed OTOP medical staff check this database as part of the initial assessment and at other times during treatment in accordance with State & Federal guidelines.

7. **Patients are assessed for sedation and signs of drug or alcohol use prior to dosing.** If a mental status assessment and/or a breathalyzer test is required, I understand that I must cooperate, or I may not receive a methadone/buprenorphine dose for that day. Doses may be adjusted based on assessment.

8. Annual medical screenings including RPR and TB testing are required for continuation in the program.

9. **I will inform my counselor if I am taking any prescription medications and provide current prescription information to maintain Take-Home eligibility if applicable.** If for any reason, I must bring prescription medications to the clinic, I will keep them in my custody.

10. **Acts or threats of violence, carrying a weapon, and/or use of abusive derogatory language in the clinic or on the hospital grounds may result in immediate termination of treatment.**

11. **The use, purchase or sale of drugs (including alcohol) in the clinic or on the hospital grounds will result in immediate termination of treatment.** Any exchange of money, goods or drugs (prescribed or illicit) will be treated as a sale and may result in immediate termination of treatment. Please conduct any business or personal transactions off hospital grounds.

12. Fair hearing procedures in the event of involuntary termination are available on request.

13. **I understand that privacy of all patients in the program must be respected.** Information concerning any patient or their presence is confidential and should not be shared with anyone outside the clinic.

14. **I cannot concurrently receive medication from more than one Opiate Treatment Program.** Enrollment in two such programs will result in immediate discharge from treatment.

15. **I understand I may be offered take-home doses as part of my care at OTOP.** I have received a copy of the Guidelines for Take-Home Doses in the OTOP Patient Handbook. OTOP Staff will determine whether a take-home is appropriate on a case-by-case basis based on OTOP Policy and State & Federal Regulations.
    a. **I agree to take only the dose of methadone or buprenorphine prescribed to me each day**.

    b. **I agree to store my methadone or buprenorphine in a safe place, out of reach of children.** I realize that methadone can be fatal to children or other individuals for whom it is not prescribed.

    c. **I will not sell, share or trade my methadone or buprenorphine.** (Transfer, distribution, or sale of methadone is prohibited by state and federal law and may result in criminal prosecution.)

    d. **I understand methadone can be dangerous when taken with other drugs or alcohol**.

    e. **BUPRENORPHINE:** I agree to dispose of my empty container of buprenorphine in a responsible manner by removing my name from the container. (Patients are not required to return buprenorphine bottles.)

    f. **METHADONE:**
        i. **1-12 Take-Home Doses:** I agree to return my empty bottle(s) of methadone to the dosing nurse at my next clinic visit. (The dosing nurse must be able to read my name and the date on the label.)

        ii. **13-27 Take-Home Doses:** I agree to provide OTOP staff with a working phone number with voice mail set up. I agree to complete at least two "call-backs" each year. A "call-back" is when OTOP staff tells me by phone or voicemail that I have 24 hours to bring my take-home medication back to clinic for staff to count. I understand it is my responsibility to check and respond to missed calls.

        iii. **I understand I may need to return to dosing daily at the clinic and I may be discharged from OTOP if I break this agreement or any other OTOP Program requirements.**

16. **I have received a copy of the Patient Handbook** including Take-home Dose Guidelines, Dispensary Dosing Rules, Patient Bill of Rights, Patient Behavior Policy, Notice of Privacy Practices & Emergency Provisions.

17. **My initials above and signature below indicate I understand the content of these documents as explained to me by a staff member and I agree to MOUD treatment at OTOP.**

_____ _____

Signature of Client **Date**

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Subject: Take Home Bottle Return

Policy: As part of the general OTOP policy on Diversion Control, patients who manage their own take home methadone and receive less than a 2 week supply of medication are required to return the empty bottles on their next day in clinic. Patients will be informed of the policy on admission and at annual treatment planning.

Procedures:

A) Upon admission to OTOP, each patient receives and signs a Take Home Agreement, which outlines instructions and expectations for safe handling of take home medication. As part of this agreement, patients are advised that they are required to return their empty take home bottles on their return to clinic.

B) When patients who received one to six take home bottles of methadone at their last visit to clinic present to the dispensing window, dispensing nurse will ask the patient to present their bottles. Nurse will confirm that the bottles are the patient's and count them to confirm appropriate number is returned.

C) If appropriate, nurse will discard the bottles in a bin designated for materials containing protected health information (PHI) and proceed with dispensing today's dose and any new take homes according to usual procedure.

D) If inappropriate, nurse will not provide any TH.
   a. On that day, they will reduce the number of T/O days to 0 (zero). They will enter a "Dose Comment" that details which bottle(s) were missing. They will enter new Flag, clicking to display on "Dosing" screen with "Next Flag Date" as the next day. It should be a Stop Dose flag. Pick Flag should read "Patient missing TH bottles." They will discard any bottles that they do receive in a bin designated for materials containing protected health information (PHI) and proceed with dispensing today's dose according to usual procedure. They will remind the patient that they must return the missing bottle(s) the next day that the patient presents to dose, or else their step level will be reduced (see below in E).
   b. The next time that the patient presents to dose, the stop dose flag will prompt the nurse to ask the patient to present the missing bottle(s). If appropriate, nurse will discard the bottles in a bin designated for materials containing protected health information (PHI) and proceed with dispensing today's dose and any new take homes according to usual procedure. If bottle return is inappropriate for a second time, the nurse will call medical provider for order to reduce the number of take homes (see below in E). In either case, the nurse will delete the stop flag before proceeding with dosing per usual procedure.

E) The maximum number of take homes provided to patients whose bottle return is inappropriate is listed below

Current # take homes	Max # take homes if error in bottle return
6	4

Revised 1/23/24 SS
T:\WARD93\Policy and Procedures\bottle return

5	4
1, 2, 3, or 4	0

Notes:

1) the second column lists the MAXIMUM number. In some circumstances clinic staff may find it appropriate to reduce more.

2) patients who are on a split dose will initially have the number of take-home days reduced. Patients on a split who come every day will have their dose consolidated to once daily dosing.

F) Patients will remain at the lower number of take-home doses for at least 4 weeks (except for Note 1 above). They should work with their counselor to change their behaviors around safe handling of their methadone before being returned to previous number of take home doses.

The following patients are excluded from this requirement:

1) Patients who receive take home bottles with chain of custody protocol will not be expected to return the empty bottles, as requiring bottle return would put undue burden on programs handling the take home medication, and there are already diversion control procedures in place.
2) Patients who are on buprenorphine. Generally, these patients receive several days of medication in a single bottle, so a bottle return policy would not have the intended effect.

Patients with 13 or more Take Homes

3) All patients with 13 and 27 take-homes are not required to bring take home bottles back, instead, they will have a minimum of two random call backs a year. Patients are required to bring in all remaining doses of medication & give a urine specimen for drug screen (call back) to ensure take-home methadone is being handled responsibly. See Call Back policy for further details.

OTOP
OPIATE TREATMENT OUTPATIENT PROGRAM
1001 Potrero Avenue • Ward 93 • San Francisco, CA 94110 • p:628.206.8412 • f:628.206.4153
METHADONE MAINTENANCE | OFFICE-BASED OPIATE TREATMENT (OBOT) | MOBILE METHADONE MAINTENANCE | METHADONE DETOX

OTOP TAKE-HOME AGREEMENT

I _____ understand I may be offered take-home doses as part of my care at OTOP. **I have received a copy of the Guidelines for Take-Home Doses in the OTOP Patient Handbook.** OTOP Staff will determine whether a take-home is appropriate on a case-by-case basis based on OTOP Policy and State & Federal Regulations.

- I agree to take only the dose of methadone or buprenorphine prescribed to me each day.
- **I agree to store my methadone or buprenorphine in a safe place, out of reach of children.** I realize that methadone can be fatal to children or other individuals for whom it is not prescribed.
- **I will not sell, share or trade my methadone or buprenorphine.** (Transfer, distribution, or sale of methadone is prohibited by state and federal law.)
- I understand methadone can be dangerous when taken with other drugs or alcohol.
- **BUPRENORPHINE:** I agree to dispose of my empty container of buprenorphine in a responsible manner by removing my name from the container. (Patients are not required to return buprenorphine bottles.)
- **METHADONE:**
    - **1-12 Take-Home Doses:** I agree to return my empty bottle(s) of methadone to the dosing nurse at my next clinic visit. (The dosing nurse must be able to read my name and the date on the label.)
    - **13-27 Take-Home Doses:** I agree to provide OTOP staff with a working phone number with voice mail set up. I agree to complete at least two "call-backs" each year. A "call-back" is when OTOP staff tells me by phone or voicemail that I have 24 hours to bring my take-home medication back to clinic for staff to count. I understand it is my responsibility to check and respond to missed calls.
- **I understand I may need to return to dosing daily at the clinic and I may be discharged from OTOP if I break this agreement or any other OTOP Program requirements.**

_____ _____

Patient Signature **Date**

Take Home Assessment Tools from the Behavioral Health Network, Springfield, MA (Developed by Carissa Cutler, LCSW and Ari Kriegsman, MD)[38]

Protective Factor Question	Client Quotes / Response
Let's talk about how you're doing overall – how has your methadone treatment improved your life or reduce your substance use?	
In what ways does having THB help support your recovery?	
Can you tell me about something that's going well right now or that you're proud of with your recovery?	

When did you (recently) start using? How much were you using at that time, and how much are you using now? …. (if they report an increase) Is there a reason you have started to use more? (look for indication of tolerance)	Criteria 1 Criteria 10
Have you recently tried to stop using ___? (Describe)/ "How did that go?"	Criteria 2
Have you noticed any withdrawal symptoms if you haven't used in a while?	Criteria 11
Are you having any physical or mental issues or concerns? When did these begin? Have you seen a doctor? Do you see ways in which your use impacts your mental health? Does it put your physical health at risk?	Criteria 9
How often are thoughts about using ____ crossing your mind?	Criteria 4
How do you get your supply? (look for how much time they are spending) do you spend a lot of time working to get the money that you need to buy drugs?	Criteria 3
Where are you using and with who? Have you ever felt unsafe?	Criteria 8
What times of the day or week are you using? Has it ever effected your ability to work or get things accomplished at home?	Criteria 5/3
(hopefully you have some knowledge of this client's typical activities and you can ask them how they are going, how often they are engaging in them) (if no knowledge of typical activities, inquire) Tell me about your hobbies or things you like to do… How often are you able to participate in these things? Has there ever been a time recently that you missed these activities because you had an opportunity to use ____ instead? Have you recently missed an activity because you were busy purchasing _____?	Criteria 7
Has anyone asked you recently if you were using or suspected you were using ____? i. What do you think made them ask? Has anyone recently asked you to stop using? Do you feel like your relationships are affected by using ____?	Criteria 6

[38] "Is Your Methadone Clinic Helping or Hurting in the Era of Fentanyl?" Ruth Potee MD, Laura Kehoe MD, Zoe Weinstein MD. Presented at 55th ASAM Annual Conference, Dallas, TX, April 2024. Available at: https://c36a7b585371cb8e876b-385db121fa2b55910fed97d2d3aaf4f8.ssl.cf1.rackcdn.com//2622581-910154-002.pdf

Criteria	Description	Client Quotes / Response	Criteria Met? Y/N
1	Substance is taken in larger amounts over longer period than was intended		
2	Persistent desire, or unsuccessful efforts to reduce or control use		
3	A great deal of time spent in activities necessary to obtain, use, and recover		
4	Craving, strong urges to use		
5	Failure to fulfill obligations (work, school, home) as result of substance use		
6	Continued use despite experiencing social/interpersonal problems caused by or increased by the effects of substance use		
7	Important social, occupational, or recreational activities are given up or reduced because of substance use		
8	Recurrent substance use in situations in which it is physically hazardous		
9	Substance use is continued despite knowledge of having a persistent physical or psych problem that is likely to have been caused or increased by the substance use		
10	Tolerance (a need for increased amounts to achieve desired effect OR reduced effect from using same amounts)		
11	Withdrawal		

Potential Risk Factors:
(any YES response will warrant a comment)

Y/N Active Substance Use Disorder (see above assessment)
Y/N Concern for inconsistent dosing attendance
Y/N Serious behavioral problems that endanger the patient, the public, or others
Y/N Known recent diversion activity
Y/N Concern for client ability to safely transport and store Take Home Medication
Y/N Other : _____

Determination :
(select one)

Client's THB privileges will be reduced at this time due to clinical concern for risk factors.
Client's THB privileges will remain intact at this time due to therapeutic benefits of THB outweigh the risks.
Client's THB privileges will be sent up to Multidisciplinary Team Meeting (MDT) for review at this time. Please see MDT note for determination.

PLAN:

_____
_____

DHCS Blanket Exception Request Letter:

DHCS
CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES
Michelle Baass | Director

August 6, 2024

THIS LETTER SENT BY EMAIL

Gillian Otway
Program Sponsor
San Francisco County Department of Public Health
DBA: Opiate Treatment Outpatient Program
1001 Potrero Avenue, Ward 93 / Ward 95
San Francisco, CA 94110

Re: Temporary Exception to:

- **Prohibition Against Multiple Registration, CCR, Title 9, § 10205(b)**
- **Criteria for Patient Selection, California Code of Regulations, (CCR), Title 9 §10270(a), 10270(a)(1), 10270(a)(2), 10270(a)(3), 10270(d)(1)**
- **Patient Attendance Requirements, CCR, Title 9, § 10295(b)**
- **Patient Absence, CCR, Title 9, § 10300(b)(1)**
- **Procedures for Collection of Patient Body Specimens, CCR, Title 9, § 10310(e)**
- **Medication Dosage Levels, CCR, Title 9, § 10355(d)(1) and (2)**

Dear Mr. Otway:

The request for temporary exceptions to the regulations noted above were received by the Department of Health Care Services (DHCS) on April 16, 2024 by San Francisco Department of Public Health. DHCS approves the aforementioned exception requests to expand accessibility and timeliness of patient admissions to receive narcotic treatment program (NTP) services. The licensee(s) shall adhere to the following requirements:

1. A screening examination is required to ensure the patient meets criteria for admission and that there are no contraindications to treatment with medications for opioid use disorder (OUD). The screening examination may be conducted on "audio-visual or audio only" telehealth platforms for patients receiving buprenorphine treatment, or via "audio-visual" telehealth platforms for patients receiving methadone treatment in accordance with subparagraph (a) or (b) below. The screening may completed by a non-NTP provider, however the examination must be completed no more than seven days prior to NTP admission. If there are no contraindications, a patient may commence medications for opioid use disorder treatment after the screening examination is complete.

California Department of Health Care Services
Counselor & Medication Assisted Treatment Section,
Licensing and Certification Division
P.O. Box 997413 | Sacramento, CA | 95899-7413
MS Code 2603 | Phone (916) 322-6682 |
https://www.dhcs.ca.gov/provgovpart/Pages/Licensing_and_Certification_Division.aspx

State of California
Gavin Newsom, Governor

California Health and Human Services Agency

a. For methadone screening examinations via an "audio-visual" platform, the medical director must determine and document that an adequate evaluation of the patient has been, or can be accomplished via an audio-visual telehealth platform.

b. For methadone screening examinations, it is acceptable to use audio-only devices, but only when the patient is in the presence of a non-NTP licensed provider who is registered to prescribe (including dispense) controlled medications, such as the patient's primary care physician. The medical director shall review the examination results and order treatment medications as indicated.

2. A patient may be admitted to treatment regardless of the length of time a person has been addicted to opiates. In accordance with 42 CFR, §8.12(e)(1), the medical director shall determine that the patient meets diagnostic criteria for moderate to severe OUD; the individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose. Such decisions must be appropriately documented in the patient's file.

3. The physical and behavioral health assessments pursuant to 42 CFR 8.12(f)(4) shall be completed within 14 calendar days of admission and may be conducted via "audio-visual" telehealth platforms for patients receiving methadone treatment and "audio-visual or audio only" platforms patients receiving buprenorphine treatment.

4. The full physical examination shall be completed within 14 calendar days of admission and remain in person for patients receiving methadone and buprenorphine treatment.

5. The full physical exam may be completed by a non-NTP provider, if the exam is verified by a licensed NTP practitioner as being true and accurate and transmitted in accordance with applicable privacy laws.

6. Laboratory tests pursuant to CCR, Title 9, Chapter 4, § 10270 shall be completed within 14 calendar days of admission. Pursuant to 42 CFR §8.12(f)(2)(i)(B), a patient's refusal to undergo lab testing for co-occurring physical health conditions should not preclude them from access to treatment, provided such refusal does not have potential to negatively impact treatment with medications.

7. The medical director must verify and obtain the written results and narrative as well as lab testing results of examinations performed by non NTP providers. The examination documentation must be transmitted, consistent with applicable privacy laws, to the NTP.

8. For patients that are incarcerated, hospitalized, or admitted to a skilled nursing facility, the NTP shall conduct random tests for substances pursuant to CCR, Title 9, Chapter 4, § 10310(e) at a frequency that is in accordance with generally accepted clinical practice and as indicated by a patient's response to and stability in treatment, but no fewer than eight random drug tests per year patient in accordance with 42 CFR §8.12(f)(6). This requirement does not preclude distribution of legal harm reduction supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose.

9. The initial dose of methadone may exceed 30mg and 40mg as required by CCR Title 9, § 10355(d)(1) and (2), however, the initial dose shall be individually determined and shall include consideration of the type(s) of opioid(s) involved in the patient's opioid use disorder, other medications or substances being taken, medical history, and severity of opioid withdrawal. The total dose for the first day should not exceed 50 milligrams unless the NTP practitioner finds sufficient medical rationale, including but not limited to if the patient is transferring from another NTP on a higher dose that has been verified, and documents in the patient's record that a higher dose was clinically indicated.

10. Incarcerated patients may receive treatment for the duration of their incarceration without requiring a medication change order by the referring medical director or program physician permitting the patient to receive services on a temporary basis from another program every 30 days pursuant to CCR, Title 9, Chapter 4, §10295(b). The patient file must reflect the discharge date from incarceration.

11. A patient may be absent for 30-days before they are discharged from treatment rather than 14-days pursuant to CCR, Title 9, § 10300(b)(1). The medical director or program physician shall provide a new medication order before continuation of treatment in accordance with CCR, Title 9, § 10355(g).

The request for the aforementioned temporary exception is approved effective August 6, 2024 for the following locations:

OTP CA10, 098M
License No. 38-07
San Francisco County Department of Public Health
DBA: Opiate Treatment Outpatient Program
1001 Potrero Avenue, Ward 93 / Ward 95
San Francisco, CA 94110

OTP CA10, 098M
License No. 38-07M
San Francisco County Department of Public Health
d.b.a. Mobile Narcotic Treatment
1676 Newcomb Avenue
San Francisco, CA 94103

OTP CA10, 098M
License No. 38-07A
San Francisco County Department of Public Health
d.b.a Tom Waddell Health Center
230 Golden Gate Avenue
San Francisco, CA 94102

OTP CA10, 098M
License No. 38-07B
San Francisco County Department of Public Health
Potrero Hill Health Center
1050 Wisconsin Street
San Francisco, CA 94107

OTP CA10, 098M
License No. 38-07D
San Francisco County Department of Public Health
San Francisco General Hospital Pharmacy
1001 Potrero Avenue
San Francisco, CA 94110

OTP CA10, 098M
License No. 38-07F
San Francisco County Department of Public Health
Community Behavioral Health Services Pharmacy
1380 Howard Street, Room #130
San Francisco, CA 94103

OTP CA10, 098M
License No. 38-07G
San Francisco County Department of Public Health
Positive Health Program
1001 Potrero Avenue, Bldg. 80, 6th Floor
San Francisco, CA 94110

DHCS Exception Authority

DHCS will continue a temporary exception request in accordance with CCR, Title 9 §10425 for individual licensed locations. Under this section, DHCS may grant temporary exceptions to regulations that shall be subject to all of the following requirements:

1. Such exceptions shall be limited to program licensees operating in compliance with applicable laws and regulations;
2. Requests for exceptions shall be formally submitted in writing to the Department;
3. Exceptions shall be limited to a one-year period unless an extension is formally granted by the Department or the Department notifies the aforementioned licensed NTPs of the exception no longer being valid;
4. The program applicant shall comply with all Departmental requirements for maintaining appropriate records or otherwise documenting and reporting activity;
5. The formal approval of the Department shall contain an accurate description of the exception(s) granted and the terms and conditions to be observed by the licensee; and
6. Exception(s) shall be voided if the licensee fails to maintain compliance with this section or other applicable laws and regulations that govern NTPs.

If you have any questions, please contact the Counselor and Medication Assisted Treatment Section, at (916) 345-7482 or DHCSNTP@dhcs.ca.gov.

Sincerely,

Monique Garcia

Monique Garcia, Section Chief
Counselor & Medication Assisted Treatment Section
Licensing and Certification Division

cc:
Hasija Sisic, R.N. Program Director
Brad Shapiro, M.D., Medical Director
Hillary Kunins, MD, MPH, MS, San Francisco County BH Director

Exception Requests Denied by DHCS:

DHCS
CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES
Michelle Baass | Director

August 6, 2024

THIS LETTER SENT BY EMAIL

Gillian Otway
Program Sponsor
San Francisco County Department of Public Health
1001 Potrero Avenue, Ward 93 / Ward 95
San Francisco, CA 94110

Re: Temporary Exception to:

- **Patient Treatment Plans, CCR, Title 9, § 10305(f)**
- **Detection of Multiple Registration at Time of Application for Admission CCR, Title 9, § 10210(a)(5) and § 10210(c)(1)**

Dear Mr. Otway:

The request for temporary exceptions to CCR, Title 9, § 10210(a)(6) and CCR, Title 9, § 10305(f) were received by the Department of Health Care Services (DHCS) on April 16, 2024, by San Francisco Department of Public Health. In accordance with CCR, Title 9, § 10425, DHCS may grant temporary exceptions to CCR, Title 9, Chapter 4 if DHCS determines that such action is justified and would improve treatment services or afford greater protections to the health, safety or welfare of patients, the community, or the general public. No exception may be granted if it is contrary to or less stringent than the federal laws and regulations which govern narcotic treatment programs. DHCS denies the aforementioned exception requests as these requests do not meet the requirements for an exception in accordance with CCR, Title 9 § 10425.

CCR, Title 9, § 10210(a)(5)
DHCS denies the exception request to 9 CCR § 10210(a)(5). NTPs are required to obtain written consent from the patient to disclose the information required to determine if the patient is enrolled in multiple NTPs in accordance with 42 CFR § 2.34.

CCR, Title 9, § 10210 (c)(1)
DHCS denies the exception request to §10210(c)(1) to allow NTPs located in San Francisco to only contact other NTPs within San Francisco County. NTPs are required to contact each NTP within 50 miles to determine if the patient is simultaneously receiving replacement narcotic therapy at another program. (9 CCR § 10210(c)(1)). The detection of multiple registration is required to ensure NTP patients do not simultaneously receive medication from two different programs. This provision is also set in place to coordinate courtesy dosing, if necessary and requires the NTPs to

determine which NTP would assume responsibility of the patient if the multi registration detects that the patient is enrolled in another NTP. Currently there are an additional 15 licensed NTPs outside of the San Francisco County, but within a 50-mile radius.

CCR, Title 9, § 10305(f):
DHCS denies the exception request to 9 CCR §10305(f) to allow NTPs located in San Francisco County to update treatment plans at least once every twelve months, or more frequently as needed. The patient's primary counselor shall evaluate and update the patient's treatment/care plan whenever necessary, or at least every three months. (9 CCR § 10305(f)). A treatment/care plan is an individualized treatment and/or recovery plan that outlines attainable treatment goals and needs related to medical services, education, vocational training, employment, legal, housing, and other recovery support services that have been identified and agreed upon between the patient and the NTP clinical team. (42 CFR § 8.12(f); 9 CCR § 10305(f)). The treatment/care plan specifies the services to be provided and the proposed frequency and schedule for their provision. (42 CFR § 8.12(f)(4)(i)). The treatment plan frequency requirements specified in §10305(f) establish natural checkpoints for monitoring an individual's progress and goals.

If you have any questions, please contact the Counselor and Medication Assisted Treatment Section, at (916) 345-7482 or DHCSNTP@dhcs.ca.gov.

Sincerely,

Monique Garcia

Monique Garcia, Section Chief
Counselor & Medication Assisted Treatment Section
Licensing and Certification Division

cc:
Hasija Sisic, R.N. Program Director
Brad Shapiro, M.D., Medical Director
Hillary Kunins, MD, MPH, MS, San Francisco County BH Director