Department of Alcohol and Drug Programs
Narcotic Treatment Programs
State and Federal Regulations Comparison on Key Issues

FEDERAL (42 CFR Part 8)	STATE (Health and Safety Code & Title 9 CCR)	Comments
DETOXIFICATION		
• Only allow two episodes of detox treatment per year. • After two in the same year, physicians must explore other treatment alternatives.	• HSC and Title 9 require seven days to elapse between episodes. • Parent consent is required for people under 18. • Patients must have two documented unsuccessful episodes before being eligible for other treatment.	"Delete the 7 days separation between modalities. This outdated rule forces patients in to relapse with potentially fatal consequences." "The seven days between treatment episodes is cruel. We should change the regs and the health and safety code as needed. " "State regs don't appear to be necessary. Obtaining consent on minors is standard practice. 7 day requirement plays little to no bearing as Federal regs only allow for two detox episodes per year anyways."
		"Allow NTP program physicians the full authority to treatment opioid addiction where the duration of methadone treatment is determined between patients and their doctor. "Detox" and "maintenance" are outdated terms and are inconsistent with current evidence based practices and care standards for chronically ill patients."
		"One problem is: State medical pays only for 21 day detox, which is outdated. Frequently a patient needs longer detox. Federal allows up to 180 days."

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MAINTENANCE		
• Requires one year documented history of addiction. • People under 18 must have had two failed detox episodes within a 12-month period.	• Requires two years documented history of addiction. • Patients must be 18 years old. • HSC and Title 9 require seven days to elapse between episodes. • Requires two failed attempts at detox treatment.	"Allow the NTP program physician to determine all methadone admissions based on medical justification and medical need. Methadone should no longer be a second-line treatment option. "
		"Federal regs do not say documented history of addiction. States "the person is currently addicted to an opioid drug, and that the person became addicted at least one year before admission for treatment." 42CFR 8.12(e)"
		"HSC and Title 9 require seven days to elapse between episodes. This only applies to Detox."
		"Requires two failed attempts at detox treatment—unless program has 2+2 Exception." "If you have the 2+2 waiver, it aligns with the feds." "2 year documentation history is a barrier to treatment. Medically Assisted Treatment (MAT) has proven to be the most successful modality for opiate addicts…. Why should an opiate addict have to wait two years before entering appropriate treatment? This regulation appears to make the patient draw out their addiction longer, with adverse events occurring to the patient along the way. Persons under the age of 18 should have access to MMP if detox hasn't been effective for the minor. "
		"State should come into line with Federal."

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EXAMINATION		
• Documented physical evaluation must be done within 14 days of admission to treatment. • Examination must include results of serology and other tests.	• Documented physical evaluation must be done before admission to treatment. • Requires laboratory test for determination of narcotic drug use, tuberculosis, and syphilis (unless medical director determines patient's subcutaneous veins are damaged to extent blood cannot be obtained). • Evaluation must consist of screening for other infectious diseases, co-occurring disorders, patterns of other drug use, criminal activity, etc.	"It is important that the physical be done on admission for proper patient care." "Patients should not be admitted unless examined for withdrawal and evidence of addiction. If addiction cannot be documented on physical, onsite drug tests should be used. Other physical examination and labs can wait 14 days, but the part of the physical that confirms opioid addiction is essential before treatment." "Agree with State regs on this issue and feel Federal regs are too liberal in this area." "State should align with Feds on this"

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DRUG TESTING		
• Requires adequate testing or analysis for drugs of abuse (does not specify forms of testing). • Requires at least eight random tests per year for maintenance patients. • Requires at least one initial test for patients in short-term detox. • Requires initial and monthly testing for patients in long-term detox.	• HSC requires urinalysis testing. • Title 9 allows patient body specimen testing. • Requires monthly testing for maintenance and long-term detox patients. • Requires test at admission and any other time deemed necessary for short-term detox patients. • Requires weekly drug testing for pregnant patients.	"Align more with feds with the minimum of 8 random tests per year." "Would like to see eight tests per year. Cost effective and harder for patients to determine when their tests are coming up. Weekly testing for pregnant patients is excessive and expensive and we are not reimbursed for that."
		"Continue weekly for pregnant patients. Otherwise, should come into line with federal requirements. Specially designated methadone testing labs should NOT be used. Drugs tested should those that are frequently abused in the community." "Our program would continue to test pregnant patients weekly regardless of a regulation change (i.e. only requiring monthly testing). We feel pregnant patients should be required to test weekly and all patients should test at least monthly."
		""Detox" and "maintenance" are outdated terms and are inconsistent with current evidence based practices and care standards for chronically ill patients. Delete referencing anything other than methadone treatment."

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TAKE-HOME/SELF-ADMINISTERED MEDICATION		
• Take-home schedule is as follows: o One dose per week after first 90 days of treatment. o Two doses per week after second 90 days. o Three doses per week after third 90 days. o Six doses per week in remaining months of first year in treatment. o 14 doses at a time after one year of continuous treatment. o 30 doses at a time after two years of continuous treatment (but patient must make monthly visits to the clinic).	• HSC requires take-home doses be provided only when daily attendance at clinic is incompatible with gainful employment, education, or responsible homemaking. • Methadone shall be diluted in liquid (no pill form). • Methadone must be available seven days a week. • Take-home schedule in Title 9 is as follows: o Step Level I: one take-home per week after three months continuous treatment o Step Level II: two take-homes per week after six months continuous treatment. o Step Level III: two take-homes per week after nine months continuous treatment. o Step Level IV: two take-homes after one year continuous treatment. o Step Level V: three take-homes after two years continuous treatment. o Step Level VI: six take-homes after three years continuous treatment.***** *******ADP issued a bulletin allowing for a 30-day take-home supply after three years of continuous treatment and Step Level VI to conform to Federal allowance.*	"No recommended changes • Hardship exceptions—Up to a one-week supply • Medical exceptions—Up to a two-week supply (9CCR 10385 a & b)" "Seven days a week requirement should stay. Otherwise come into line with Federal regs." "State regs are too stringent and provide barriers to new patients that don't have established treatment history. There shouldn't be specific criteria for take home eligibility (i.e. gainful employment, etc.).… Seems discriminatory." "Everyone that is compliant with treatment should be eligible for take homes. We have quite a few disabled persons and people who have transportation issues. I would like to see the take home schedule match the feds except for the 14 day and 30 day take homes. I think 14 take homes after the first year is too much and I have never agreed with the 30 day take homes. I don't have anyone on 30 day take homes. I did write a 30 day protocol because the state forced me to."

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PREGNANT PATIENTS		
Some key requirements are shared by feds and state. Next column identifies additional requirements from the state.	• Requires aftercare for women and infants, service access, and coordination of ancillary services. • Title 9 requires weekly drug testing for pregnant patients.	"No recommended changes" "Agree with State regs."
		"Some patients are non compliant as far as the aftercare goes, and bringing us proper documentation. If we don't have the documentation, we are subject to deficiencies from the state."
		"Continue weekly testing for pregnant women; otherwise come into line with Federal."
		"We are not reimbursed for any of this and it takes a lot of time and expense to meet these requirements. "
ONE-DAY/SUNDAY CLOSURE		
• Allows one take-home, for patients in maintenance, for a day that the clinic is closed for business, including Sundays and State and Federal holidays.	• Title 9 requires methadone to be available seven days a week.	"No recommended changes" "At any given time we will always have patients that will not be eligible for even a one day take home so we will have to remain open 7 days a week anyway." "Keep seven days per week; allow holidays only if patient is deemed stable. Allow all Federal holidays."
		"Neutral"

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COUNSELING REQUIREMENTS		
• Requires "adequate" substance abuse counseling as clinically necessary.	• Requires patient treatment plans to specify type and frequency of counseling. • Requires minimum of 50 minutes per calendar month (but allows medical director to adjust or waive at any time by medical order).	"Align with feds on this as the State's minimum 50 minutes/month is unproductive for long-term patients on Step 6 or 27 who have demonstrated sustained functionality for over 5 years." "Come into line with Federal. Please note: drug medi-cal pays according to 10 minute increments of counseling. This change would require a change in fiscal policies." "It is very difficult to ensure what you put on a treatment plan actually occurs in regards to frequency. Life happens and patients have to miss a session now and then for a variety of reasons. We agree with the state minimum 50min. counseling requirement. " "Requiring treatment plans to specify type and amount of counseling assures us and the patient that he /she is getting good treatment. Frequencies do not help a patient; it is a tool used by the state for punitive action. You cannot make this population comply month after month with the frequencies nor can you continually change the treatment plans when patients don't comply. I think counseling is just as important as the medication. I would like to see the punitive side of this regulation taken away. Most deficiencies stem from the treatment plan and patients not meeting the required frequencies or minutes. So much of that is out of our control, we deal with a tough population, yet we are penalized for trying to make sure they comply. The treatment plans, minutes and frequencies should be a tool used by the providers to give good care, not by the state for punitive action."

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ANNUAL UPDATE/TWO-YEAR JUSTIFICATION		
• Requires assessment initially after admission and periodically thereafter to determine the most appropriate combination of services and treatment.	• Requires medical director or program physician to discontinue a patient's maintenance treatment within two continuous years after treatment unless: o He/she evaluates patient's progress and determines discontinuing would cause patient to relapse. • Patient's status shall be re-evaluated every year after two-year evaluation, and medical director or program physician must document in patient's record. • Each program must include in protocol a plan for scheduled termination of maintenance treatment indicating average period for maintenance.	"Come into line with federal." "Agree with federal regs." "Align with the feds on this issue. Allow length of treatment to be determined by patient and doctor as with any other chronic illness. A diabetic or people with asthma for example, don't have to engage in the discussion of discontinuing treatment when they have achieved stabilization. Why should methadone treatment for opioid addiction be any different from other chronic health conditions? As with other illnesses, the status of the patient is monitored constantly and reviewed for continued sustained improvements." "Over time, statistics have shown the effectiveness of long term narcotic treatment. Continuing treatment is a medical decision and a patient decision. Discontinuing ANY patient's treatment would cause that patient to relapse. I don't feel like a piece of paper justifying continued treatment just to satisfy a regulation is needed. Again, I feel that the current regulation for Annual Justification is just another tool used by the state for punitive reasons. If this regulation remains, it would be helpful to all NTP's if it could be aligned with CalOMS annual. As it stands now, we are required to do annuals for both on different dates."