5122-40-01  Definitions and applicability.

(A) In addition to the definitions listed in rule 5122-24-01 of the Administrative code, the following definitions apply to Chapter 5122-40 of the Administrative Code.

(1) "Administration" means the direct application of methadone medication assisted treatment to a client.

(2) “Department” mean the Ohio department of mental health and addiction services.

(3) "Detoxification" means the administering of any methadone medication in decreasing doses to an individual to alleviate adverse physiological or psychological effects of withdrawal from the continuous use of a narcotic drug and as a method of bringing the individual to an opiate drug-free state.

(4) "Dispense", means the final association of any Methadone medication for take home doses with a particular patient pursuant to the prescription, drug order or other lawful order of the prescriber and the professional judgment of and responsibility for: interpreting, preparing, compounding, labeling and packaging of any methadone medication used for medication assisted treatment.

(5) “Good standing” means that the program, program owner, program sponsor, medical director, program administrator, or principal shall not have been denied a license, certificate, or similar approval to operate a methadone program by an appropriate issuing body of any state or jurisdiction; or been the subject of the following by any appropriate issuing body of any state or jurisdiction:

(a) An action that resulted in the suspension, proposed revocation, or revocation of the program or person’s license or registration; or

(b) A disciplinary action that was based, in whole or in part, on the program or person’s inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(6) "Interim maintenance" means maintenance provided in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance.

(7) "Long-term detoxification" means the administering of Methadone medication assisted treatment for detoxification of a patient for a period of more than thirty days but not in excess of one hundred eighty days.
(7) "Medication-assisted treatment" has the same meaning as in section 340.01 of the Revised Code."

(8) "Medical director" is a physician, licensed to practice medicine in Ohio by the state of Ohio medical board, who assumes the responsibility for the administration delivery of all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and qualified healthcare professionals functioning under the medical director's direct supervision.

(9) "Medication unit" means any center for substance abuse treatment (CSAT) approved facility established as part of, but geographically separate from, an opioid treatment program from which medication assisted treatment is administered or dispensed. A unit established by a methadone medication maintenance program solely to dispense methadone medication for observed ingestion.

(10) "Methadone medication maintenance" means the administering or dispensing of methadone medication assisted treatment at stable dosage levels for a period in excess of twenty-one days in the treatment of a patient for opioid addiction.

(11) "Methadone Opioid treatment program" or "program" means a community addiction services provider engaged in the treatment of individuals with opioid dependence through on-site administration or dispensing of an opioid treatment medication in the form of methadone medication that engages in supervised assessment and treatment, using any form of medication assisted treatment for individuals who have opioid use disorders. Services include medically supervised withdrawal and/or maintenance treatment, along with various levels of medical, psychiatric, psychosocial, and other types of supportive care.

(12) "Partial opioid agonist" means buprenorphine products or combination products approved by the federal food and drug administration for maintenance or detoxification of opioid dependence, or any other partial agonists federally approved, controlled substances used for the purpose of narcotic opioid replacement treatment. These medications are used as an alternative to opioid agonists in the treatment of opioid addiction. At certain dosages, a partial agonist can both activate and block the effects of opioid medications or receptors, thereby assisting in control of opioid addiction. Partial agonists bind to the receptors and activate them, but not to the same degree as full agonists.

(13) “Permanent patient transfer” means the transfer of a patient from one opioid treatment program to another opioid treatment program.
"Physician extender" means a qualified medical staff person other than a physician, functioning within his or her scope of practice to provide medical services to patients admitted to opioid treatment programs.

"Principal" means a person who has controlling authority or is in a leading position, e.g., executive director, chief financial officer, chief clinical officer, chief operating officer.

“Program administrator” is a person who is responsible for the day-to-day operation of the methadone opioid treatment program in a manner consistent with the laws and regulations of the United States department of health and human services, United States drug enforcement administration, and the laws and rules of the state of Ohio.

"Program sponsor" is a person or representative of the program, who is responsible for the operation of the methadone medication program opioid treatment program and who assumes responsibility for all of its employees, including any practitioners, agents or other persons providing medical, rehabilitative or counseling services at the program.

"SAMHSA" means the federal substance abuse and mental health services administration.

"Short-term detoxification" means the administering of a methadone medication assisted treatment for detoxification of a patient for a period not to exceed thirty days.

"State authority" or "state opioid treatment authority" (SOTA) means the agency or individual designated by the Ohio department of mental health and addiction services to exercise the responsibility and authority of the state for governing the treatment of opiate addiction with medication assisted treatment by an opioid treatment program. The state authority shall act as the state’s coordinator for the development and monitoring of opioid treatment programs and shall serve as a liaison with the appropriate federal, state and local agencies.

"State oversight agency" means the agency or office of state government identified by the governor to provide regulatory oversight of opioid treatment programs on behalf of the state of Ohio. The designated state oversight agency is responsible for licensing, monitoring and investigating complaints or grievances regarding opioid treatment programs. The Ohio department of mental health and addiction services is the agency designated by the governor to provide regulatory oversight on behalf of the state of Ohio.
(B) This Chapter is applicable to any community addiction services provider subject to methadone medication licensure as an opioid treatment program in accordance with section 5119.391 of the Revised Code through June 29, 2019 and section 5119.37 of the Revised Code after June 29, 2019, which includes any opioid treatment program requiring certification, as certification is defined in 42 C.F.R. 8.2, program that employs methadone medication treatment; or prescribes, dispenses, or administers methadone for the treatment of opioid addiction.

(C) Programs licensed as methadone medication, an opioid treatment program at the time of the effective date of this rule shall remain licensed until the expiration of their current licensure. If a program wants to continue to operate as a licensed methadone medication, opioid treatment program, then it is required to apply to the department for licensure in accordance with this Chapter.

(D) A methadone, an opioid treatment program directly operated by the department of veterans affairs, the Indian health service or any other department or agency of the United States is not required to obtain a state license.
Effective: 1/1/2019

Five Year Review (FYR) Dates: 6/1/2022

CERTIFIED ELECTRONICALLY

Certification

11/05/2018

Date

Promulgated Under: 119.03
Statutory Authority: 5119.391
Rule Amplifies: 5119.391
Prior Effective Dates: 07/01/2001, 10/01/2003, 06/01/2017