

**WAC 246-341-1025 Opioid treatment programs (OTP)—Medication management.** An agency providing substance use disorder opioid treatment program services must ensure the medication management requirements in this section are met.

(1) An agency must use only those opioid treatment medications that are approved by the Food and Drug Administration under section 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid use disorder.

(2) An agency providing an opioid treatment program that is fully compliant with the procedures of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the federal Food, Drug, and Cosmetic Act for investigational use in the treatment of opioid addiction. The following opioid treatment medications are approved by the Food and Drug Administration for use in the treatment of opioid use disorder:

- (a) Methadone; and
- (b) Buprenorphine.

(3) An agency providing opioid treatment program services must ensure that initial dosing requirements are met as follows:

(a) Methadone must be administered or dispensed only in oral form and is formulated in such a way as to reduce its potential for parenteral abuse;

(b) The initial dose of methadone must not exceed thirty milligrams and the total dose for the first day must not exceed forty milligrams, unless the program physician documents in the individual's record that forty milligrams did not suppress opioid abstinence symptoms; and

- (c) The establishment of the initial dose must consider:
- (i) Signs and symptoms of withdrawal;
  - (ii) Individual comfort; and
  - (iii) Side effects from over medication.

(4) An agency providing an opioid treatment program services must ensure that:

(a) Each opioid treatment medication used by the program is administered and dispensed in accordance with its approved product labeling;

- (b) All dosing and administration decisions are made by a:
- (i) Program physician; or
  - (ii) Medical practitioner under supervision of a program physician familiar with the most up-to-date product labeling.

(c) Any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the individual's record.

(5) An agency providing opioid treatment program services must ensure that all take-home medications are:

(a) Consistent with 42 C.F.R. Part 8.12 (i)(1) through (5) and are authorized only to stable individuals who:

(i) Have received opioid treatment medication for a minimum of ninety days; and

(ii) Have not had any positive drug screens in the last sixty days.

(b) Assessed and authorized, as appropriate, for a Sunday or legal holiday as identified in RCW 1.16.050;

(c) Assessed and authorized, as appropriate, when travel to the facility presents a safety risk for an individual or staff member due to inclement weather; and

(d) Not allowed in short-term withdrawal management or interim maintenance treatment.

(6) All exceptions to take-home requirements must be submitted and approved by the state opioid treatment authority and Substance Abuse and Mental Health Services Administration (SAMHSA).

[Statutory Authority: 2018 c 201 and 2018 c 291. WSR 19-09-062, § 246-341-1025, filed 4/16/19, effective 5/17/19.]