

§ 122C-35. (Effective once contingency met – see note) Licensure of opioid treatment program medication units and opioid treatment program mobile units.

(a) Any licensed opioid treatment program facility that intends to establish, maintain, or operate an opioid treatment program medication unit or opioid treatment program mobile unit shall apply to the Division of Health Service Regulation on forms prescribed by the Department for certified services provided from an opioid treatment program medication unit or opioid treatment program mobile unit to be added to its license. The Commission shall adopt rules establishing the requirements for obtaining such licensure, which shall include a requirement that each opioid treatment program medication unit and each opioid treatment program mobile unit seeking to operate in this State must demonstrate satisfactory proof to the Secretary that it has (i) obtained approval from the State Opioid Treatment Authority and (ii) registered with the Department's Drug Control Unit and the federal Drug Enforcement Agency.

(b) An opioid treatment program facility shall not submit a license application to the Division of Health Service Regulation to provide certified services at an opioid treatment program facility medication unit or opioid treatment program mobile unit prior to receiving approval from the State Opioid Treatment Authority or prior to receiving confirmation of registration with the Department's Drug Control Unit and the federal Drug Enforcement Agency.

(c) The Department may issue a license to an opioid treatment program facility to provide certified services at an opioid treatment program medication unit or an opioid treatment program mobile unit if the Secretary finds that the program is in compliance with all rules adopted by the Commission regarding opioid treatment programs. The Secretary may approve or deny an application for a license to provide certified services based upon consideration of all of the following criteria:

- (1) The applicant's capacity, qualifications, and experience with regard to providing treatment and operating an opioid treatment program medication unit in compliance with applicable federal and State laws, regulations, and accepted clinical standards of practice.
- (2) Any history of adverse regulatory actions involving the applicant in North Carolina or another state.
- (3) Any history of suspension or revocation of, or other adverse regulatory action against, any professional licenses or narcotic licenses of persons proposed to be employed in the opioid treatment program medication unit or opioid treatment program mobile unit, in North Carolina or in another state, or any adverse regulatory action against the license of the opioid treatment program facility within the 12-month period preceding the application for licensure.
- (4) Any additional criteria or standards established in rules adopted by the Commission regarding opioid treatment programs.

(d) An opioid treatment program facility shall not establish, maintain, or operate an opioid treatment program medication unit or opioid treatment program mobile unit without a current license from the Secretary that includes and covers that specific medication unit or mobile unit and without first obtaining certification from the Substance Abuse and Mental Health Services Administration.

(e) An opioid treatment program mobile unit or opioid treatment program medication unit added to an opioid treatment program facility license shall be deemed part of the opioid treatment program facility license and may be subject to inspections the Department deems necessary to validate compliance with the requirements set forth in this section, applicable rules adopted by the Commission, and all applicable federal laws and regulations, including, without limitation, Substance Abuse and Mental Health Services Administration regulations in Parts 8 and 21 of Title 42 of the Code of Federal Regulations governing opioid treatment programs, and federal Drug Enforcement Agency regulations in Parts 1300, 1301, and 1304 of Title 21 of the

Code of Federal Regulations, including 21 C.F.R. § 1301.13(e), governing controlled substances, dispensers of controlled substances, mobile narcotic treatment programs, and federal Drug Enforcement Agency restraints. Substantial failure to comply with the requirements of this section, applicable rules adopted by the Commission, and applicable federal laws and regulations may result in an adverse action on a license under G.S. 122C-24 and administrative penalties under G.S. 122C-24.1. Any required services not provided in an opioid treatment program mobile unit or opioid treatment program medication unit must be conducted at the opioid treatment program facility, including medical, counseling, vocational, educational, and other assessment and treatment services.

(f) Each license issued under this section to an opioid treatment program facility to provide certified services at an opioid treatment program mobile unit or an opioid treatment program medication unit shall expire on December 31 of the year for which it was issued and shall be renewed annually by filing with the Division of Health Service Regulation on or after December 1 an application for license renewal on forms prescribed by the Department, accompanied by the required fee. License renewal shall be contingent upon (i) the applicant providing all information required by the Secretary for renewal and (ii) continued compliance with this Article and any applicable rules adopted by the Commission regarding opioid treatment programs. The Department shall charge an opioid treatment program facility a nonrefundable annual license fee plus a nonrefundable annual per-unit fee of two hundred sixty-five dollars (\$265.00) for each opioid treatment program medication unit or opioid treatment program mobile unit.

(g) The opioid treatment program facility is responsible for ensuring that opioid treatment program medication units and opioid treatment program mobile medication units adhere to all State and federal requirements for opioid treatment programs.

(h) Notwithstanding G.S. 122C-25(a), an opioid treatment program facility with no previous violations of State or federal requirements for opioid treatment programs may be subject to inspection once every other year, excluding any complaint investigation. An opioid treatment program facility with either an opioid treatment program medication unit or an opioid treatment program mobile unit may be subject to annual inspections.

(i) The Commission shall adopt emergency, temporary, or permanent rules for the licensure, inspection, and operation of opioid treatment program medication units and opioid treatment program mobile units, including rules concerning any of the following:

- (1) Compliance with all applicable Substance Abuse and Mental Health Services Administration and federal Drug Enforcement Agency regulations governing opioid treatment program mobile units and opioid treatment program medication units.
- (2) Identification of the location of opioid treatment program medication units and opioid treatment program mobile units.
- (3) Schedules for the days and hours of operation to meet client needs.
- (4) Maintenance and location of records.
- (5) Requisite clinical staff and staffing ratios to meet immediate client needs at each opioid treatment program medication unit or opioid treatment program mobile unit, including client needs for nursing, counseling, and medical care.
- (6) Emergency staffing requirements to ensure service delivery.
- (7) Criteria for policies and procedures for a clinical and individualized assessment of individuals to receive services at an opioid treatment medication unit or opioid treatment mobile unit that consider medical and clinical appropriateness and accessibility to individuals served.
- (8) Number of clients allowed per opioid treatment program medication unit and opioid treatment program mobile unit, based on staffing ratios.

- (9) Criteria to ensure the opioid treatment program facility is providing the required counseling to individuals receiving services at an opioid treatment program medication unit or opioid treatment program mobile unit.
- (10) Criteria for the opioid treatment program facility to ensure that individuals receiving services at an opioid treatment program medication unit or opioid treatment program mobile unit receive medical interventions when necessary. (2023-65, s. 10.2.)