

12 VAC 35-105 Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services

PART VI.
ADDITIONAL REQUIREMENTS FOR SELECTED SERVICES.

Article 1.
Opioid Treatment Services.

12 VAC 35-105-925. Standards for the Evaluation of the Need for New Licenses for Providers of Services to Persons With Opioid Addiction

A. Applicants requesting an initial license to provide a new service for the treatment of opioid addiction through the use of Methadone or any other controlled substance shall supply information to demonstrate the need for, and appropriateness of, the proposed service in accordance with this section.

B. Applicants shall demonstrate that the geographic and demographic parameters of the service area are reasonable and the proposed service is expected to serve a sufficient number of individuals to justify the service, as documented in subsection D of this section. For purposes of demonstrating need, applicants shall define a service area that is located entirely in Virginia and does not extend more than 100 miles from the proposed location of the service. Applicants also shall identify the number of individuals it seeks to be licensed to serve.

C. Applicants shall submit admission policies which give priority to individuals residing in the service area for admission and placement on waiting lists.

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D. Applicants shall demonstrate that there are persons residing in its service area who have an opioid addiction who would benefit from the proposed service. The following information may be used by the applicant to document that individuals in the service area are known or reasonably expected to need the proposed service:

1. Numbers of persons on waiting lists for admission to any existing opioid addiction or other public substance abuse treatment program in the service area for the most recent available 12-month period;
2. Numbers of opioid use disorder cases (e.g. overdoses) originating from the proposed service area that have been treated in hospital emergency rooms for the most recent available 12 month period;
3. Projections of the number of persons in the service area who are likely to obtain services for opioid addiction, based on drug-use forecasting data;
4. Data reported on suicidal and accidental deaths related to opioid use in the proposed service area for the most recent available 12-month period;
5. Data regarding arrests from local law enforcement officials in the proposed service area related to illicit opioid activities;
6. Data on communicable diseases for the proposed service area related to injection drug abuse (e.g. HIV, AIDS, TB, and Hepatitis B and C);
7. Data on the availability of any evidence-based alternative service or services that have been proven effective in the treatment of opioid addiction, and that are accessible to persons within the proposed service area, including services provided by physicians' offices; and

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8. Letters of support from citizens, governmental officials, or health care providers, which indicate that there are conditions or problems associated with substance abuse in the community that demonstrate a need for opioid treatment services in the service area.

E. The Department shall determine whether a need exists for the proposed service based on the documentation provided in accordance with subsection D, and the consideration of the following standards:

1. Whether there are a sufficient number of persons in the proposed service area who are likely to need the specific opioid treatment service that the applicant intends to provide;

2. Whether the data indicate that evidence-based service capacity in the service area is not responsive to or sufficient enough to meet the needs of individuals with opioid addiction; and

3. Whether there is documentation of support to confirm the need for the proposed service in the proposed service area.

F. The proposed site of the service shall comply with Virginia Code § 37.2-406 and, with the exception of services that are proposed to be located in Planning District 8, shall not be located within one-half mile of a public or private licensed day care center or a public or private K-12 school.

G. In jurisdictions without zoning ordinances, the department shall request that the local governing body advise it as to whether the proposed site is suitable for and compatible with use as an office and the delivery of health care services. The department

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shall make this request when it notifies the local governing body of a pending application.

H. Applicants shall demonstrate that the building or space to be used to provide the proposed service is suitable for the treatment of opioid addiction by submitting documentation of the following:

1. The proposed site complies with the requirements of the local building regulatory entity;

2. The proposed site complies with local zoning laws or ordinances, including any required business licenses;

3. In the absence of local zoning ordinances, the proposed site is suitable for and compatible with use as offices and the delivery of health care services;

4. In jurisdictions where there are no parking ordinances, the proposed site has sufficient off-street parking to accommodate the needs of the individuals being served and prevent the disruption of traffic flow;

5. The proposed site can accommodate individuals during periods of inclement weather;

6. The proposed site complies with the Virginia Statewide Fire Prevention Code; and

7. The applicant has a written plan to ensure security for storage of methadone at the site, which complies with regulations of the Drug Enforcement Agency (DEA), and the Virginia Board of Pharmacy.

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- I. Applicants shall submit information to demonstrate that there are sufficient personnel available to meet the following staffing requirements and qualifications:
 - 1. The program director shall be licensed or certified by the applicable Virginia health regulatory board or by a nationally recognized certification board, or eligible for this license or certification with relevant training, experience, or both, in the treatment of persons with opioid addiction;
 - 2. The medical director shall be a board certified addictionologist or have successfully completed or will complete within one year, a course of study in opiate addiction that is approved by the department;
 - 3. A minimum of one pharmacist;
 - 4. Nurses;
 - 5. Counselors shall be licensed or certified by the applicable Virginia health regulatory board or by a nationally recognized certification board, or eligible for this license or certification; and
 - 6. Personnel to provide support services.
- J. Applicants shall submit a description for the proposed service that includes:
 - 1. Proposed mission, philosophy, and goals of the provider;
 - 2. Care, treatment, and services to be provided, including a comprehensive discussion of levels of care provided and alternative treatment strategies offered;
 - 3. Proposed hours and days of operation;
 - 4. Plans for on-site security; and

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5. A diversion control plan for dispensed medications, including policies for use of drug screens.

K. Applicants shall, in addition to the requirements of 12 VAC 35-105-580 C 2, provide documentation of their capability to provide the following services and support directly or by arrangement with other specified providers when such services and supports are (i) requested by an individual being served; or (ii) identified as an individual need, based on the assessment conducted in accordance with 12 VAC 35-105-60 B and included in the individualized services plan:

1. Psychological services;
2. Social services;
3. Vocational services;
4. Educational services; and
5. Employment services.

L. Applicants shall submit documentation of contact with community services boards or behavioral health authorities in their service areas to discuss its plans for operating in the area and to develop joint agreements, as appropriate.

M. Applicants shall provide policies and procedures that require every six months, each individual served to be assessed by the treatment team to determine if that individual is appropriate for safe and voluntary medically supervised withdrawal, alternative therapies including other medication assisted treatments, or continued federally approved pharmacotherapy treatment for opioid addiction.

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N. Applicants shall submit policies and procedures describing services it will provide to individuals who wish to discontinue opioid treatment services.

O. Applicants shall provide assurances that the service will have a community liaison responsible for developing and maintaining cooperative relationships with community organizations, other service providers, local law enforcement, local government officials, and the community at large.

P. The department, including the Office of Licensing, Office of Human Rights, or Office of Substance Abuse Services, shall conduct announced and unannounced reviews and complaint investigations, in collaboration with the state methadone authority, Board of Pharmacy, and DEA to determine compliance with the regulations.