



Notice of Proposed Rulemaking

14 NYCRR Part 810

Establishment, Incorporation and Certification of Providers of Addiction Services

Section:

- 810.1 Background and Intent
- 810.2 Legal base
- 810.3 Applicability
- 810.4 Definitions
- 810.5 Applications requiring full review
- 810.6 Applications requiring administrative review
- 810.7 Standards for approval of an application requiring full or administrative review
- 810.8 Full review process
- 810.9 Administrative Review Process
- 810.10 Actions requiring prior approval
- [810.11 Coordination with the health department]
- 810.[12] 11 Criteria and procedures for approval of management contracts
- 810.[13] 12 Certification
- 810.[14] 13 Inspection and reviews
- 810.[15] 14 Suspension, revocation or limitation of operating certificates
- 810.[16] 15 Voluntary termination of authorized services
- 810.[17] 16 Ownership of operating certificates
- 810.[18] 17 Severability

Section 810.1 Background and intent.

An existing or prospective provider of addiction services is required to obtain the prior approval of the commissioner (commissioner) of the New York State Office of Addiction Services and Supports (Office or OASAS) before establishing, incorporating and/or constructing a facility or offering a service. This Part prescribes the criteria and procedures applicable for obtaining such prior approval, as well as the procedural requirements for obtaining the required authorization to provide one or more services by either a prospective or existing provider.

Section 810.2 Legal base.

- (a) Section 19.07(c) of the Mental Hygiene Law (MHL) charges the Office with the responsibility for ensuring that persons in need of addiction services, care and treatment receive services of high quality and effectiveness and that the personal and civil rights of persons seeking and receiving such services are adequately protected.
- (b) Section 19.07(e) of the MHL authorizes the [Commissioner] commissioner to adopt standards including necessary rules and regulations pertaining to addiction treatment services.
- (c) Section 19.09(b) of the MHL authorizes the [Commissioner] commissioner to adopt regulations necessary and proper to implement any matter under their jurisdiction.
- (d) Section 19.20 of the MHL requires review of criminal history information review concerning certain prospective employees and volunteers of providers of services certified, operated or otherwise authorized by the office.
- (e) Section 19.20 -a of the MHL authorizes the Office to receive criminal history information from the Division of Criminal Justice Services related to persons seeking to be credentialed or applicants for an operating certificate issued by the office that will have regular and substantial unsupervised or unrestricted contact with patients/clients.
- (f) Section 19.21(b) of the MHL requires the [Commissioner] commissioner to establish and enforce regulations concerning the licensing, certification, inspection and treatment standards of addiction treatment services.
- (g) Section 19.21(d) of the MHL requires the office to establish reasonable performance standards for providers of services certified by the Office.
- (h) Section 19.40 of the MHL authorizes the [Commissioner] commissioner to issue operating certificates for the provision of addiction treatment services, including the authority to waiver regulatory requirements.
- (i) Section 32.01 of the [Mental Hygiene Law] MHL authorizes the [Commissioner] commissioner to adopt any regulation reasonably necessary to implement and effectively exercise the powers and perform the duties conferred by Article 32 of the [Mental Hygiene Law] MHL.
- (j) Section 32.05 of the MHL provides that no substance use disorder services may be established without an Operating Certificate issued by the commissioner.
- (k) Section 32.07(a) of the MHL authorizes the [Commissioner] commissioner to adopt regulations to effectuate the provisions and purposes of article 32 of the MHL.
- (l) Section 32.09 of the MHL contains criteria that the [Commissioner] commissioner must consider when issuing an operating certificate.
- (m) Section 32.21 of the MHL provides the [Commissioner] commissioner with the authority to suspend, revoke or limit operating certificates and imposition of fines.
- (n) Section 32.29 of the MHL authorizes the [Commissioner] commissioner to approve the construction of a facility for which an operating certificate will be issued.
- (o) Section 32.31 of the MHL provides the process for the establishment or incorporation of facilities for addiction services.
- (p) Section 406 of the Business Corporation Law requires any corporation which intends to establish or operate a program of services for addiction services to obtain the approval of the [Commissioner] commissioner as to the proposed filing of its certificate of incorporation.
- (q) Section 404(u) of the Not-For-Profit Corporation Law gives the [Commissioner] commissioner the responsibility of approving the certificate of incorporation of any corporation which intends to establish or operate an addiction program Certified by the Office.
- (r) The Protection of People with Special Needs Act (Chapter 501 of the Laws of 2012) establishes the Justice Center for the Protection of People with Special Needs (Justice Center) and requires criminal information history reviews of all applicants for authorization to operate a program of services for addiction; and of all employees, contractors, or volunteers of such certified program who will have the potential for, or may be

permitted, regular and substantial unsupervised or unrestricted physical contact with the patients or clients of such programs.

810.3 Applicability.

This Part applies to any existing or prospective provider of services which is required to obtain an operating certificate from the [Commissioner] commissioner in accordance with Articles 19 and 32 of the [Mental Hygiene Law] MHL and which is proposing the establishment, incorporation, and/or construction of a facility to provide addiction services.

810.4 Definitions.

For purposes of this Part:

(a) *Acquisition* means obtaining real property by purchase, lease, donation, condemnation, inheritance or bequest.

(b) *Applicant* means a provider or prospective provider of services who submits an application for the commissioner's approval in accordance with this Part.

(c) *Criminal history information, criminal background, or criminal history record* means a record of pending criminal charges, criminal convictions which are not vacated or reversed, and certificates filed pursuant to subdivision (2) of section 705 of the Correction Law, and which the New York State Division of Criminal Justice Services is authorized to maintain pursuant to subdivision (6) of section 837 of the Executive Law. For purposes of this Part, criminal history information, criminal background, or criminal history record shall also include information from the Federal Bureau of Investigation as a result of a national criminal history record check.

(d) *Construction* means the erection, building, substantial acquisition, alteration, reconstruction, improvement, extension or modification of a facility, including, equipment, the inspection and supervision thereof, and the studies, surveys, designs, plans, working drawings, specifications, procedures and other actions necessary thereto.

(e) *Establishment* means planning, developing or organizing by a prospective or existing provider related to services or a facility to be used for providing addiction services.

(f) *Facility* means any place where addiction services certified by the office are provided.

(g) *Governing authority* [means the overall policy making authority, whether an individual or group, that exercises general direction over the affairs of a provider of services and establishes policies concerning its operation.] means the provider of service or an entity, such as a sponsor, that substantially controls or has the ability to substantially control the provider of service. For the purpose of this Part, factors used to determine whether there is substantial control shall include, but are not limited to, the following:

(1) the right to appoint and remove directors or officers;

(2) the right to approve bylaws or articles of incorporation;

(3) the right to approve strategic or financial plans for a provider of service; or

(4) the right to approve operating or capital budgets for a provider of service.

(h) *Incorporation* means the process of forming a corporation, including the filing of a certificate of incorporation under any statute to form a corporation, which shall also include certificates of amendment, merger or consolidation of other certificates filed by the corporation under any statute.

(i) *Local governmental unit* means a unit of local government or a local agency given authority in accordance with Articles 25 and/or 41 of the [Mental Hygiene Law] MHL and by the local government to be responsible for addiction services.

(j) *Operating certificate* means a written notice conveying to the public that the [Commissioner] commissioner has issued approval for the governing authority to operate authorized services at the location or locations specified thereon.

(k) *Project* means all information, documents, planning and development activities and all activities relating to establishment, incorporation or construction prior to any operation or change in operation of a facility or service.

(l) *Provider of services* means an individual, association, partnership, corporation, public or private agency, other than an agency or department of the State, which provides addiction services.

(m) *Specialized service* means services defined in Part 824 of this Title requiring an appropriate review and approval of a certification application pursuant to this Part.

810.5 Applications requiring full review.

(a) The following applications are subject to full review in accordance with the provisions of section 810.8 of this Part:

(1) establishment of any service by a prospective provider that has not been previously certified by the office to provide addiction services; or

(2) any transfer, assignment or other disposition of 10 percent or more of the stock or voting rights of a business corporation which is the operator of an authorized service, or any transfer, assignment or other disposition of the stock or voting rights thereunder of such business corporation which results in the ownership or control of more than 10 percent of the stock or voting rights thereunder of such business corporation; [or]

(3) any capital project proposed by a certified voluntary provider which requires a new or amended operating certificate[.]; or

(4) any new sponsor that is a governing authority over an existing provider.

(b) An applicant shall not separate or divide a project requiring full review into separate applications and apply for approval of the parts separately through the administrative review process. The Office may, as it deems appropriate, combine applications for separate projects in order to provide for full disclosure of the nature or scope of a project.

810.6 Applications requiring administrative review.

(a) The following applications are subject to administrative review in accordance with the provisions of section 810.9 of this Part:

(1) establishment or operation of a new service by an existing provider of certified services, including an additional location application submitted in accordance with section 810.13(c) of this Part; or

(2) an increase in the capacity of a service where capacity is identified on the operating certificate; or

(3) the relocation of any certified service; or

(4) any capital project proposed by a certified voluntary provider which proposes a funding source for such project, other than the mental health services facilities program (Dormitory Authority of the State of New York), directly or indirectly through a closely related entity[.]; or

(5) any merger between existing OASAS certified providers; or

(6) any addition of physical space to an existing OASAS certified site; or

(7) any transfer of ownership of existing certified treatment services to another existing OASAS certified provider of certified services.

810.7 Standards for approval of an application requiring full or administrative review.

(a) To approve a project requiring either full or administrative review, the Office must find the application meets all of the following:

- (1) that there is a public need for the services at the time and place and under the circumstances proposed;
- (2) that there are no facilities or services available which serve as alternatives or substitutes, for the services and facilities proposed;
- (3) that there are no substantiated negative findings as to the character, competence and standing in the community of the applicant;
- (4) that the available financial resources and the sources of future revenues are adequate to meet all necessary and proper capital and operating expenses;
- (5) that services will be provided in compliance with applicable laws and regulations, including, but not limited to, the regulatory requirements of this Title;
- (6) that ten percent of the owners or principals of the applicant have demonstrated, and can substantiate, prior substantial experience directly providing or managing substance use disorder treatment services, as determined by criteria established by the Office and will maintain such experience while [Certified] certified; and
- (7) that the owners or principals of the applicant have received a criminal history information review pursuant to the provisions of Part 805 of this Title, and the applicant has been subsequently approved by the office.

(b) In determining whether the requirements of subdivision (a) of this section are met, the office shall consider the extent to which:

- (1) the services and facilities conform to local and statewide plans, including but not limited to plans for Medicaid managed care;
- (2) existing similar services are able to meet or exceed regulatory compliance; and
- (3) there exist any other matters determined to be in the public interest.

(c) The Office must find that an application demonstrates the following standards for approval:

- (1) A management level staff person is identified to be responsible for coordinating all requirements relating to diversity, equity, and inclusion, consistent with all rules and regulations issued by the Office;
- (2) the services and facilities will meet the particular needs of the community to be served, based on a needs assessment of the catchment area to be serviced, including the identification of unserved and underserved marginalized communities, uninsured and underinsured persons, and is reflective of the cultural and linguistic needs of the community; and
- (3) the provider of services is affirmatively addressing opportunities to overcome systemic barriers to accessing care for the communities and persons identified as part of the needs assessment.

(d) If an application involves construction, the office may require the applicant to demonstrate, through the submission of detailed architectural schematic drawings, that the following requirements are met:

- (1) that the proposed construction ensures patient confidentiality including gender neutral restroom facilities;
- (2) that there is no more efficient architectural solution to the proposed construction, except that providers may include creation of gender neutral restroom facilities;
- (3) that the proposed construction will not adversely affect the costs of providing services;

(4) that the proposed construction conforms to applicable Federal, State and local laws and regulations; and

(5) that the proposed construction ensures patient confidentiality.

(e) Criteria and procedures for approval of leases.

(1) If an applicant proposes to lease a facility in which all or part of the proposed services are to be provided, the lease agreement shall include, but is not limited to, the following language: "The landlord acknowledges that the rights of reentry into the premises as set forth in this lease do not confer on the landlord the authority to operate an addiction services program. The landlord agrees to give the New York State Office of Addiction Services and Supports at least thirty (30) day's notice by certified mail of the intent to re-enter the premises or to initiate dispossession proceedings and at least sixty (60) days notice of expiration of the lease."

(2) Lease terms must be for a term sufficient to ensure program continuity with an option to renew for an additional term of years. Longer terms may be required if financial support is provided for a capital project by the office. Month-to-month lease terms shall not be deemed sufficient.

(f) Amendment of an application.

Any amendment to an application, other than technical or minor amendment, that changes the application during the process of review to such an extent that it requires, in the opinion of the commissioner, a re-initiation of a full or administrative review in accordance with this Part must include a written explanation as to the reason for such amendments.

(g) Failure to notify of changes. Failure to provide the office with information about changes in an application or to obtain prior approval when required by this section may constitute grounds for the denial of authorization to provide services and revocation, limitation or amendment of any operating certificate previously granted for that application.

(h) Withdrawal of an application by the applicant. An application made to the office in accordance with this Part may be voluntarily withdrawn by written notice from the applicant at any time prior to the decision of the Commissioner.

(i) Criteria and procedures for approval of certificates of incorporation.

(1) Not-for-profit corporations. An entity incorporated or proposed to be incorporated under the Not-for-Profit Corporation Law shall provide the commissioner with a proposed certificate of incorporation or certificate of amendment that conforms with the requirements of the Not-for-Profit Corporation Law and the [Mental Hygiene Law] MHL. The board of directors of a not-for-profit corporation shall:

(i) include qualified members, broadly representing the community, who have sufficient independence from senior management of such corporations and who will provide the board with expertise to oversee the agency's programmatic and fiscal operations, and any other criteria determined by the office;

(ii) the board shall include members from the community in which the services are to be provided;

(iii) board members shall avoid conflicts of interest, including but not limited to self dealings;

(iv) Reimbursement to board members shall be documented and shall be limited to their reasonable costs and expenses in a manner which ensures that the integrity of the not-for-profit corporation will not be compromised;

(v) no compensated employee or consultant of the corporation shall be a corporate director of such board; however, such employee or consultant of the corporation may be an ex officio corporate member without the right to vote;

(vi) family members of senior management of the not-for-profit corporation shall be prohibited from serving on the board unless it can be sufficiently demonstrated to the office that the independence of the board will not be compromised by such appointment;

(vii) board members shall review on a regular basis the not-for-profit's operation, including but not limited to the performance and compensation of senior executives, the financial operations of the provider of services and implementation of corrective actions to ensure compliance with applicable rules and regulations governing such provider; and

(viii) There shall be members of the board that can demonstrate and substantiate prior substantial experience directly providing or managing addiction services and maintain such experience going forward, unless the corporation is an Article 28 facility co-licensed by the New York State Department of Health and defined in Article 28 of the Public Health Law.

(2) Business corporations. For purposes of this paragraph, the term business entity shall mean any entity incorporated or proposed to be incorporated or organized under the Business Corporation Law or the Limited Liability Company Law.

(i) If the business entity is an individual practitioner, partnership of practitioners, a professional service limited liability company, or a professional service corporation of practitioners licensed and currently registered by the New York State Education Department in one of the health professions which is authorized to provide addiction services, it is exempt from the requirement of needing an operating certificate from the office so long as all the following conditions are met:

(a) the business entity employs only persons licensed by the New York State Education Department in the same profession to provide professional services;

(b) the business entity practices under a name that does not indicate an intent, ability or willingness to operate an addiction program; and

(c) a professional service corporation, limited liability company and any stockholder or member thereof has obtained all required approvals from the New York State Education Department and the Department of State.

(ii) If the business entity is not an exempt entity under subparagraph (i) of this paragraph, then it shall provide the [Commissioner] commissioner with a proposed certificate of incorporation or certificate of amendment that conforms to the requirements of the Business Corporation Law and the [Mental Hygiene Law] MHL.

(iii) Board of directors requirements. For all business entities not exempt under subparagraph (i) of this paragraph, the board of directors shall include members with a diversity of experience sufficient to ensure competent direction and control; and

(a) if any such board member is or has been an incorporator, board member, partner or stockholder in an entity which has operated a hospital, or any other type of residential facility certified by the State Department of Health or a residential facility for the developmentally disabled within the last 10 years, the name of each such facility and any interest such individual held or currently holds therein shall be reported to the commissioner;

(b) all stock or ownership certificates of a corporation shall contain a statement that no person shall own 10 percent or more of the stock of the corporation unless such person has been approved for ownership by the Commissioner. The stock or ownership certificate shall also contain a statement that any transfer, assignment or other disposition of 10 percent or more of the stock or of 10 percent or more of the voting rights there under must receive the prior approval of the [Commissioner] commissioner; and

(c) no stock in such a corporation may be owned in its entirety or in part by another corporation.

810.8 Full review process.

(a) Forms.

An application for approval of a project that meets the criteria in section 810.5 of this Part for full review shall be submitted on forms provided by the office, together with such additional information required to address the standards and criteria for approval set forth herein including, but not limited to, instructions on compliance with any required criminal history information review pursuant to Part 805 of this Title.

(b) Signatures.

(1) If the applicant is a corporation, individual, association or agency, the application shall be signed by the chief executive officer or other duly authorized officer.

(2) If the applicant is a partnership, the application shall be signed by a general partner of such partnership.

(3) If the applicant is a local governmental unit, the application shall be signed by the director of community services.

(4) If the applicant is a municipal government other than the local governmental unit, the application shall be signed by the head of the department of the municipal government under which the proposed service is to be operated.

(5) If the applicant is a State or Federal department or agency, the application shall be signed by the head of such department or agency.

(c) Office reviews.

(1) Threshold review. Upon receipt of any application indicated by the applicant as being complete, the office will verify that no components of the application are missing. If any components are missing, the application shall be deemed incomplete and returned to the applicant. Applicants may resubmit when the required documentation is provided.

(2) Completeness review.

(i) The Office shall review the content of each application which has passed the threshold review pursuant to paragraph (1) of this subdivision for completeness and if necessary, notify the applicant within a reasonable time (defined as fourteen (14) days from date of receipt for purposes of this Section) from the Office's receipt of such application, of any lack or insufficiency of information and the need to submit such additional information within a reasonable time (defined as no later than thirty (30) days from date of receipt for purposes of this Section) from the date of such notification.

(ii) If the applicant does not provide the additional information within a reasonable time from the date of notification, or within any additional time as may have been approved by the office, the application shall be deemed abandoned and withdrawn and no further action shall be taken thereon.

(iii) The office shall provide notice of status to any applicant requiring criminal history information reviews pursuant to Part 805 of this Title; no application shall be considered complete until such history review, if required, has been concluded.

(iv) The office may at its discretion, based upon review of required criminal history information, decline to consider an application any further.

(d) Local governmental unit review.

If the office determines that the application is eligible for full review:

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(1) The Office shall provide copies of the completed application and accompanying documents to each local governmental unit in the area of the proposed project. However, when an application is submitted by a local governmental unit, the application shall not require local governmental unit review.

(2) The local governmental unit shall have a reasonable time to review the application, commencing with its receipt of the application, and submit its recommendations to the office.

(e) Behavioral Health Services Advisory Council.

Upon completion of the office's review, a summary of the application with the recommendation of each responding reviewer shall be submitted to the Behavioral Health Services Advisory Council (Advisory Council) for review and recommendation to the [Commissioner] commissioner.

(1) The [Commissioner] commissioner shall make a decision on the application within a reasonable time (defined as no later than fifteen (15) days from date of receipt, purposes of this Section) after their receipt of the recommendations of the Advisory Council.

(2) If the [Commissioner] commissioner proposes to act on the application in a manner contrary to the recommendation of the Advisory Council, the [Commissioner] commissioner shall first appear before the Advisory Council and explain the reasons for the action, unless the Advisory Council waives such appearance.

(f) When a decision on the application is reached, the [Commissioner] commissioner shall notify the applicant and advise of any additional procedures to be followed for obtaining an operating certificate as applicable. If the applicant does not follow the additional procedures as requested within a reasonable period of time (defined as 180 days from date of receipt for purposes of this Section), the application shall be deemed abandoned and withdrawn, and no further action shall be taken thereon.

(g) An initial operating certificate authorizing the provision of new services shall be issued for a period of no longer than one year and may be subsequently renewed in accordance with the term of renewal established by section 810.[14] 13 of this Part.

(h) No applicant approved in accordance with this section shall provide the approved services until the effective date indicated on the operating certificate issued by the [Commissioner] commissioner.

(i) Administrative appeals.

If the commissioner proposes to deny or limit the approval of an application, the commissioner shall notify the applicant and the local governmental unit and provide the reasons for the decision and shall afford the applicant an opportunity for an administrative appeal in accordance with Part 831 of this Title.

810.9 Administrative review process.

(a) An application for approval of a project that meets the criteria for administrative review in section 810.6 of this Part shall be made in accordance with the provisions of section 810.8(a)-(c) of this Part and the additional provisions of this section.

(b) Local governmental unit review.

If the office determines that the application is eligible for administrative review:

(1) the office shall provide copies of the completed application and accompanying documents to each local governmental unit in the area of the proposed project. However, when an application is submitted by a local governmental unit, the application shall not require local governmental unit review;

(2) the local governmental unit shall have a reasonable time (defined as thirty (30) [fourteen (14)] days from date of receipt for purpose of this Section) from its receipt of the application, to review the application and provide its recommendations to the office.

(c) If there has been an adverse recommendation of the local governmental unit, the Office shall render a decision on the application. If the applicant objects to the Office's decision the applicant may request an administrative appeal in accordance with Part 831 of this Title.

(d) When a decision on an administrative review is reached, the [Commissioner] commissioner shall notify the applicant and inform them of any additional procedures to be followed for obtaining approval of construction and/or for obtaining an operating certificate based upon the specifics of the project being reviewed. If the applicant does not address the additional procedures within a reasonable period of time as specified by the Office, the application will be deemed abandoned and withdrawn and no other action shall be taken thereon.

(e) An initial operating certificate authorizing the provision of requested services shall be issued for a period of no longer than one year and may be subsequently renewed in accordance with the terms for renewal established in section 810.[14] 13 of this Part.

(f) If the services proposed in an approved application require amendment of an existing operating certificate, the services may not be rendered until the effective date indicated on the amended operating certificate issued by the Commissioner.

810.10 Actions requiring prior approval.

(a) The following changes and actions require prior approval by the commissioner:

(1) the proposed incorporation of a new corporation under the Business Corporation Law or the Not-for-Profit Corporation Law by an individual association or partnership, previously certified by the Office, which involves no additional owners or holders of stock or voting rights of 10 percent or more, other than those approved for the unincorporated entity; or

(2) the change in the name by which a certified provider of services is generally known; or

(3) a decrease in the capacity of a service where capacity is identified on the operating certificate; or

(4) a reduction in the majority of owners or principals with prior addition services experience; or

(5) any change in ownership that would result in non-compliance with Section 810.7(a)(6) of this Part.

(b) Upon receipt of written notification by a provider of services requesting prior approval of the proposed actions listed under subdivision (a) of this section, the office shall, within a reasonable time (defined as fourteen (14) days for purpose of this Section) of its receipt of such notification, advise the applicant whether:

(1) the proposed action is acceptable; or

(2) the proposed action is acceptable, provided that certain identified additional actions are followed in implementing the approved change or action; or

(3) additional information must be submitted to the Office in order to make a determination; or

(4) the proposed action is not approved with a statement of the reasons therefore and, as appropriate, identifying acceptable alternatives to the proposed change or action.

[810.11 Coordination with the Department of Health.

In order to avoid duplication of administrative effort, those proposed actions which require a review by both the Office and the Department of Health shall be subject to a single review coordinated by the Office.]

810.[12] 11 Criteria and procedures for approval of management contracts.

(a) When a governing authority initially contracts, or renews a contract, with a separate organization to manage or operate some or all of the Office certified services, including the management of clinical services or the employment of managerial or clinical staff, the following requirements shall be met:

(1) The governing authority shall show that a proposed management contractor is a New York State corporation incorporated under the Business Corporation Law or the Not-for-Profit Corporation Law as applicable, and approved as a provider of addiction services by the Office.

(2) The governing authority shall show:

(i) the necessity for the contract;

(ii) the absence of feasible alternatives to the contract; and

(iii) that the proposed contractor has successfully performed similar services in the past.

(3) Each proposed contract shall be submitted to the Office and shall not be effective until the Office has approved it in writing. Each contract shall:

(i) be dated and signed by the authorized representatives of the governing authority and the contractor;

(ii) specify each party's responsibilities, objectives, functions, financial arrangements and charges;

(iii) require compliance with all provisions of law governing such contracts, including this Title and the provisions of part 2 of title 42 of the Code of Federal Regulations;

(iv) specify the powers delegated to the contractor by the governing authority consistent with budgetary limitations set by the governing authority;

(v) specify that powers not specifically provided to the contractor remain with the governing authority;

(vi) specify the term of the contract, the provisions governing renewal, and the provisions governing termination prior to expiration;

(vii) require the contractor to provide all information required by the Office and to cooperate with the Office in carrying out inspections and investigations;

(viii) include the following language: "Notwithstanding any other provision in this contract, the governing authority remains responsible for ensuring that any service provided pursuant to this contract complies with all pertinent provisions of Federal, State and local statutes, rules and regulations";

(ix) retain in the governing authority the authority to remove any person working in the facility or unit regardless of employer or regardless of change in employment status;

(x) state the terms by which the contractor may hire and discharge persons working in the facility or unit; such terms to include, but not be limited to compliance with the provisions of Part 805 of this Title; and

(xi) require the principal administrators of the management contractor, and any employees of such contractor who will have the potential for, or may be permitted, regular and substantial unsupervised or unrestricted physical contact with the clients in the program, to complete a criminal history information review pursuant to Part 805 of this Title.

810.[13] 12 Certification.

(a) Standard certification.

An initial or amended operating certificate shall be issued by the office upon approval of an application through either a full or administrative review process, in accordance with section 810.8 or 810.9 of this Part, as applicable.

(b) Temporary certification.

(1) Emergency certification.

(i) Whenever deemed necessary, the commissioner may issue an emergency operating certificate to a certified provider to continue services in the event of a threat or imminent threat of a catastrophic or emergency loss of available services.

(ii) The provider of services must demonstrate to the office that it meets the requirements of paragraph (3) of this subdivision. The commissioner may require any additional information necessary to assure the safe and efficient operation of the facility.

(iii) An emergency operating certificate to provide services shall be effective upon issuance, for a period established by the commissioner, but not to exceed 120 days.

(iv) The commissioner may extend the emergency authorization to provide services for one additional period not to exceed 120 days.

(2) Conditional certification.

(i) Prior to the issuance or renewal of an operating certificate, a conditional operating certificate may be issued which requires the provider to meet specified conditions in order to maintain its authorization to provide services, and may carry with it a fine or penalty imposed by the office.

(ii) A conditional operating certificate to provide services shall be effective upon issuance, for a period established by the commissioner.

(3) Provisional certification.

(i) A provisional operating certificate will be issued upon approval of the application for authorization to provide services.

(ii) A provisional operating certificate to provide services shall be effective upon issuance, for a period established by the commissioner.

(4) Approval and issuance of temporary operating certificates. Prior to the issuance of any temporary operating certificate in accordance with this subdivision, the office may require that a provider demonstrate the following:

(i) that sufficient levels of staff are employed to effectively support the services to be provided;

(ii) that services will be provided in a safe and efficient manner;

(iii) that, upon inspection, the physical plant and space meets office regulations and standards;

(iv) that financial resources are available to meet operating expenses; and

(v) any other information necessary to assure the safe and efficient operation of the facility.

(5) The provider of services shall acknowledge that it understands the temporary nature of the emergency or conditional operating certificate to provide services and that such certification confers no right to an operating certificate.

(c) Additional locations.

(1) A certified provider of outpatient addiction services may operate at one or more additional locations with the approval of the commissioner.

(2) For purposes of this section, an additional location is a place open to the public for the provision of addiction outpatient services which is dependent upon and subordinate to the main location of the provider of services for operation, administration and supervisory activities.

(3) The provider of service shall apply for the additional location approval by completing an application prescribed by the commissioner, clearly indicating the characteristics of the space, the schedule of services,

the staffing, demonstrating an involvement or engagement with the community and other relevant information. Each such additional location shall be considered for approval by the commissioner where the provider of services shows a clear need for access to outpatient services at the site proposed as well as a financial and programmatic ability to provide the service.

(4) Each additional location shall have adequate space to allow for the type and volume of services planned at the location. Unless impractical, patient evaluation and medical services shall also be conducted by professional staff of the main location.

(5) There shall be sufficient staffing, including an appropriate number of qualified health professionals as defined in this title, to provide the proposed type and volume of services during the hours the location is open. Procedures shall be established to [insure] ensure that utilization review and case supervision shall be conducted by professional staff of the main location.

(6) Policies and procedures shall be developed which describe the subordinate relationship of the additional location to the main location, ensure that all operating regulations are met, and ensure that each person served primarily at an additional location has access to, as needed, the same character and quality of service available to persons served at any other location.

(7) The application shall be reviewed in accordance with section 810.9 of this Part.

(8) If the Office proposes to limit approval of an application for an additional location, or if there has been an adverse recommendation of the local governmental unit, the Office shall offer the applicant an opportunity to submit the application for full review in accordance with section 810.8 of this Part. If either the applicant or the local governmental unit objects to the Office's recommendation to either limit approval of the application, or submit the application for full review, either the applicant or the local governmental unit may request an administrative appeal in accordance with Part 831 of the Title.

(9) Opioid Treatment Programs. Medication units established as an additional location of an Opioid Treatment Program certified pursuant to Part 822 of this Title, whether mobile, stand alone or integrated within another certified program, shall be required to meet all applicable federal rules, regulations and any guidance issued by the Office.

810.[14] 13 Inspection and reviews.

(a) Certified providers of services shall be inspected at least two times per year, once without prior notice, for compliance with rules, regulations, policies, procedures and requirements of the office. In the sole discretion of the office, providers with established records of substantial compliance may be inspected only once per year, provided such inspection is without notice.

(b) Activities which shall constitute inspections for purposes of satisfying the requirements of subdivision (a) of this section include, but are not limited to:

(1) a recertification review, made pursuant to this section;

(2) an interim regulatory compliance review, made pursuant to [subdivision (f) of this section] Office policy;

(3) an interim or annual performance review, made pursuant to Office policy;

(4) a focused or targeted review, made pursuant to Office policy;

(5) a facilities evaluation, made pursuant to Office policy;

(6) a fiscal audit or fiscal viability review, made pursuant to Office policy;

(7) corrective action plan monitoring;

(8) a cursory on-site visit; [and]

(9) health and safety visit; and

[9] (10) an accreditation survey, completed by a nationally recognized accrediting organization.
(c) Prior to the expiration of an operating certificate, the office shall conduct a recertification review for purposes of assessing a provider's compliance with applicable laws, rules and regulations [and to determine the renewal term of the operating certificate].

(1) Recertification reviews [shall be conducted on an unannounced basis and] may include, but not be limited to, the following areas of review, on an unannounced basis:

- (i) inspection of facility appearance, conditions and general safety;
- [(ii) evaluation of the governing authority;]
- (ii)[i]) interviews of staff and patients/clients;
- (iii)[v]) examination of staffing patterns, staff credentials and qualifications;
- (iv) compliance with the requirements of Part 836 of this Title, guidance issued by the Office and applicable rules and regulations of the Justice Center; and
- (v[i]) such other operating areas or activities as may be necessary to determine compliance with applicable laws, rules and regulations,

(2) Recertification reviews may include, but not be limited to, the following areas of review, on an announced basis:

- (i) Evaluation of the provider's governing authority and administrative processes, such as quality improvement and incident management; and
- (ii) Evaluation of provider operations, such as priority of admissions in compliance with federal substance abuse prevention and treatment (SAPT) block grant requirements, policy and procedures, and applicable clinical standards.

(3) Upon completion of a recertification review, the Office shall submit a written report to the provider describing the findings and results of such review. The provider shall take all actions necessary to correct any findings reported. If instructed, the provider shall submit a corrective action plan (CAP), which is deemed satisfactory by the Office, within a specified period of time, as directed by the Office. Such CAP must include:

- i. the steps and actions to correct the findings;
- ii. the planned timeline for correction of each finding;
- iii. the name and title of the official responsible for the corrective action; and
- iv. a plan to monitor corrective actions to ensure that the identified findings do not recur. Such monitoring plan should include the person or role responsible for monitoring corrective actions; how all corrective actions will be tracked, monitored and recorded; and what additional measures will be implemented if planned corrective actions are not effective at addressing the findings.

4) Upon acceptance of the CAP by the Office, the provider's operating certificate shall ordinarily be renewed for a term of three years for all certified services, subject to the commissioner's authority to issue a conditional operating certificate for a different time period under Part 810.12 of this Title. The Office will conduct CAP follow-up at specified intervals from the date of CAP acceptance. At such time as the Office determines that all findings have been resolved and satisfied, the CAP will be closed with no further action required until the next recertification review.

(5) Notwithstanding the acceptance of a CAP resulting in renewal of the operating certificate for a term of three years, if the provider fails to satisfactorily resolve any reported findings or otherwise to maintain satisfactory compliance with applicable laws, rules and regulations, the commissioner may revoke, suspend or limit the operating certificate or levy a civil fine for such failures, in accordance with section 810.13 of this Part.

(6) Fiscal viability reviews shall include an assessment of the financial information of the provider of services. Such information shall be submitted in intervals and in a form prescribed by the Office, for compliance with minimum standards established by the office, in order to determine the provider's fiscal capability to effectively support the authorized services.

[(3) The specific renewal term shall be based on the results of the recertification review and fiscal viability review, utilizing the lowest compliance rating achieved by the provider of services on either the recertification review or fiscal viability review, except as otherwise provided in subdivision (i) of this section.]

(d) For inspections enumerated in subdivision (b), other than recertification reviews, [T]the inspection process shall include appropriate reporting and corrective action follow-up[subsequent to the review], including the possibility of initiating an unannounced interim inspection [inspection which may encompass the areas of review listed under subdivision (e) of this section,]to assure attention to and correction of cited deficiencies.

(1) Upon completion of an inspection, office staff shall, within forty-five (45) days of such completion, submit a written report to the provider of services describing the results of such [review]inspection, including each regulatory deficiency identified, if any.

(2) The provider of services shall take all actions necessary to correct the deficiencies reported. If instructed the provider of services shall submit a [corrective action plan]CAP, which is deemed satisfactory by the Office, within a specified period of time, as directed by the Office, stating the specific actions taken or planned to achieve compliance with identified requirements. Any planned actions described in the [corrective action plan]CAP must be accompanied with a timetable for their implementation.

(3) If the provider of services fails, within the specified or an otherwise reasonable time, to correct any reported deficiencies, or fails to maintain satisfactory compliance with applicable laws, rules and regulations, the [Commissioner] commissioner may revoke, suspend or limit the operating certificate or levy a civil fine for such failures, in accordance with section 810.[15] 14 of this Part.

(e) The office shall not perform fiscal viability reviews of governmental agencies or hospitals authorized by the Office and/or the Department of Health.

(f) Any fines imposed by the [Commissioner] commissioner against the provider of services must be paid in full before an operating certificate may be renewed.

810.[15] 14 Suspension, revocation or limitation of operating certificates.

(a) Any operating certificate may, on written notice to the provider of services, be suspended, revoked or limited at any time for any of the following reasons:

(1) the provider of services, or anyone on its behalf, has procured any approval or certification through fraud or deceit;

(2) the Office, or any other State agency, has revoked any other approval, authorization or certificate issued to the provider;

(3) any principal of the provider of services has been convicted in a court of competent jurisdiction, either within or without the State, of a felony, or has been convicted of an act in another state that would be a felony in New York State;

(4) the provider of services has failed to report any important change in the information about a project as required by section 810.7(e) of this Part;

(5) the provider of services has failed to operate in accordance with the representations made in its application;

- (6) the provider of services has failed to comply with any terms and conditions established by the [Commissioner] commissioner on which any operating certificate was issued;
- (7) the provider of services has failed to operate in compliance with any applicable law, rule or regulation or any combination thereof; and/or
- (8) the provider ceases to provide, or fails to commence, the services that it is authorized to provide.

(b) If an inspection of the provider of services, made pursuant to section 810.[14] 13(b) of this Part, identifies that a provider of service is not in compliance with any of the rules, regulations, policies, procedures and requirements of the Office, a written notification of the deficiencies identified shall be delivered to the provider.

(1) The provider of services shall respond to the notification of deficiencies within stipulated time frames. The provider of services' response must include a plan for the correction of the noted deficiencies or an explanation, deemed satisfactory to the Office, of the reason for any deviations from the requirements of the Office.

(2) If the provider of services fails to correct deficiencies or fails to provide reasonable justification for its failure to take action, the [Commissioner] commissioner may impose sanctions on or require other corrective measures by the provider. Sanctions may include suspension, revocation, or limitation of the operating certificate, or the levying of a civil fine in accordance with the [Mental Hygiene Law] MHL.

(3) The imposition of any sanction shall be effected by the delivery of a notice, clearly stating the sanction imposed and the violation(s) for which the sanction is imposed, to the provider of services.

(c) If there are reasonable grounds to believe that continued operation presents an immediate danger to the health and welfare of the public or any person receiving services, the [Commissioner] commissioner may, upon written notice to a provider of services, immediately suspend an operating certificate or an emergency or conditional operating certificate for up to 30 days.

(d) A provider of services may request an opportunity for a hearing regarding any suspension, revocation or limitation, pursuant to Part 831 of this Title. If the time period for requesting a hearing has expired, or, after the hearing has been held based on the findings of such hearing, the commissioner may impose any of the following penalties:

- (1) revocation of the operating certificate;
- (2) suspension of the operating certificate, during which period of suspension the provider must discontinue operation of the addiction services; or
- (3) limitation of the operating certificate to temporarily or permanently prohibit the provider of services from operating certain identified programs or services, reducing the number of beds, restricting the number or types of patients served or other limitation determined appropriate by the [Commissioner] commissioner; and/or
- (4) in addition to or in lieu of any suspension, revocation or other terms and conditions imposed by the commissioner, imposition of a fine of up to \$1,000 for each separate incident of failure to comply with a requirement of law, rule, regulation or condition of certification: or, up to \$1,000 for each day of a continuing failure to comply with any such requirement.

(e) Appointment of a [Temporary Operator] temporary operator.

(1) The [Commissioner] commissioner may appoint a [Temporary Operator] temporary operator when:

(i) a program voluntarily requests the appointment of a [Temporary Operator] temporary operator;

(ii) the program is seeking extraordinary financial assistance;

(iii) the office collected data indicates that the program is experiencing serious financial instability issues;

(iv) the office collected data indicates that the program's board of directors or administration are unable or unwilling to ensure the proper operation of the program; or

(v) the office collected data indicates there are conditions that seriously endanger or jeopardize continued access to necessary addiction treatment services within the community.

(2) The appointment of a [Temporary Operator] temporary operator shall be effectuated pursuant to §32.20 of the [Mental Hygiene Law] MHL and for a [Mandatory Temporary Operator] mandatory temporary operator notice shall be given to the program via registered or certified mail and shall include a detailed description of the findings underlying the intention to appoint a Temporary Operator, along with the date and time of a required meeting with the [Commissioner] commissioner or their designee within ten (10) business days of the receipt of such notice. At such meeting, the established operator shall have the opportunity to review all relevant findings, and shall attempt to develop a mutually satisfactory plan of correction and schedule for implementation.

(3) In the event that the [Commissioner] commissioner and the program are unable to establish such plan of correction, or should the program fail to respond to the initial notification, there shall be an administrative hearing on the [Commissioner's] commissioner's determination to appoint a temporary operator to begin no later than thirty (30) days from the date of the notice to the program. If the decision to appoint a [Temporary Operator] temporary operator is upheld, the [Temporary Operator] temporary operator shall be appointed as soon as is practicable and shall operate the program pursuant to §32.20.

810.[16] 15 Voluntary termination of authorized services.

(a) A provider of services must provide the office with notice of any voluntary termination of any authorized service(s) and submit a termination plan at least six (6) months prior to the voluntary termination. Such termination plan shall be submitted in a format prescribed by the Office and shall include, at a minimum, a comprehensive description of clearly defined actions that will be taken to:

- (1) assure appropriate referral of patients;
- (2) preserve the confidentiality of patient records; and
- (3) ensure appropriate access to patient records, financial records and other accounts.

(b) Implementation of the termination process shall not commence until the termination plan has been approved by the Office.

810.[17] 16 Ownership of operating certificates.

All operating certificates shall remain the property of the Office, are non-transferable, and must be returned to the office upon revocation or voluntary termination.

810.[18] 17 Severability.

If any provision of this Part of the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of this Part which can be given effect without the invalid provisions or applications, and to this end the provisions of this Part are declared to be severable.

