

## **SUMMARY OF EXPRESS TERMS**

The Proposed Rule relates to standards applicable to programs licensed or certified by the Department of Health (DOH; Public Health Law Article 28), Office of Mental Health (OMH; Mental Hygiene Law Articles 31 and 33) or Office of Alcoholism and Substance Abuse Services (OASAS; Mental Hygiene Law Articles 19 and 32) which desire to add to existing programs services provided under the licensure or certification of one or both of the other agencies.

§ 404.1 Background and Intent. This section speaks to the background and intent of the Proposed Rule as applicable to all three agencies (DOH, OMH, and OASAS). The purpose of the Rule is to promote increased access to physical and behavioral health services at a single site and to foster the delivery of integrated services based on recognition that behavioral and physical health are not distinct conditions.

§ 404.2 Legal Base. This section provides the Legal Base applicable to all three agencies for the promulgation of this Proposed Rule.

§ 404.3 Applicability. This section identifies providers of outpatient services or programs to which the standards outlined in the Proposed Rule would apply (e.g., providers certified or licensed, or in the process of pursuing licensure or certification, by at least two of the participating state agencies). Such providers would continue to maintain regulatory standards applicable to the host program's license or certification.

§ 404.4 Definitions. This section provides definitions as used in the Proposed Rule which would be applicable to any program licensed or certified by any of the three participating state agencies and identified as the host (program requesting the addition of services). Definitions specific to a host program's licensing agency are found in regulations of that agency. Among other things, the section defines an "integrated services provider" as a provider holding multiple operating certificates or licenses to provide outpatient services, who has also been authorized by a commissioner of a state licensing agency to deliver identified integrated care services at a specific site in accordance with the provisions of this Part.

§ 404.5 Integrated Care Models. This section describes three (3) models for host programs: (a) Primary Care Host Model with compliance monitoring by DOH; (b) the Mental Health Behavioral Care Host Model with compliance monitoring by OMH; and (c) the Substance Use Disorder Behavioral Care Host Model with compliance monitoring by OASAS.

§ 404.6 Organization and Administration. This section requires any integrated services provider to be certified by the appropriate state agency and to revise any practices, policies and procedures as necessary to ensure regulatory compliance.

§ 404.7 Treatment Planning. This section requires treatment planning for any patient receiving behavioral health services (OMH and/or OASAS) from an integrated service

provider and articulates the scope, standards and documentation requirements for such treatment plans including requirements of managed care plans where applicable.

§ 404.8 Policies and procedures. This section identifies minimum required policies and procedures for any integrated service provider.

§ 404.9 Integrated Care Services. This section identifies the minimum services required of any integrated services provider providing any of the three care models. The section also identifies services for each model which may be provided at an integrated services provider's option.

§ 404.10 Environment. This section outlines minimum physical plant requirements necessary for certifying existing facilities which want to provide integrated care services. The section requires programs seeking certification after the effective date of this Rule or who anticipate new construction or significant renovations to comply with requirements of 10 NYCRR Parts 711 (General Standards of Construction) and 715 (Standards of Construction for Freestanding Ambulatory Care Facilities).

§ 404.11 Quality Assurance, Utilization Review and Incident Reporting. This section outlines the requirements and obligations of an integrated service provider relative to QA/UR and Incident Reporting and are detailed by the type of model as the host program.

§ 404.12 Staffing. This section outlines staffing requirements by type of model as the host program and identifies specific requirements which may be unique to the primary care host model such as subspecialty credentials of a medical director.

§ 404.13 Recordkeeping. This section requires that a record be maintained for every individual admitted to and treated by an integrated services provider. Additional requirements include designated recordkeeping staff, record retention, and minimum content fields specific to each model. Confidentiality of records is assured via patient consents and disclosures compliant with state and federal law.

§ 404.14 Application and Approval. This section outlines the process whereby a provider seeking to become an integrated service provider may submit an application for review and approval. Applications are standardized for use by all three licensing agencies but shall be reviewed by both the agency that regulates the services to be added and the agency with authority for the host clinic. The section identifies minimum standards for approval.

§ 404.15 Inspection. This section requires the state licensing agency with authority to monitor the host clinic to have ongoing inspection responsibility pursuant to standards outlined in this Proposed Rule. The adjunct state licensing agency will not duplicate inspections for license renewal or compliance but shall be consulted about any deficiencies relative to the added services. The section identifies specific areas of review

and requires one unannounced inspection prior to renewal of an Operating Certificate or License.

A copy of the full text of the regulatory proposal is available on the DOH website at:

[http://www.health.ny.gov/regulations/proposed\\_rulemaking](http://www.health.ny.gov/regulations/proposed_rulemaking).

Pursuant to the authority vested in the Public Health and Health Planning Council, subject to the approval of the Commissioner of Health, pursuant to section 2803 of the Public Health Law, the Official Compilation of Title 10 of the Codes, Rules and Regulations of the State of New York (“NYCRR”) is amended to add a new Part 404, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

A new Part 404 is added to Subchapter A of Chapter V of 10 NYCRR, to read as follows:

## PART 404

### INTEGRATED OUTPATIENT SERVICES

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#### **§ 404.1 Background and Intent**

(a) Physical and behavioral health conditions (i.e., mental illness and/or substance use disorders) often occur at the same time. Persons with behavioral disorders frequently experience chronic illnesses such as hypertension, diabetes, obesity, and cardiovascular disease. These illnesses can be prevented and are treatable. However, barriers to primary care, as well as the difficulty in navigating complex health care systems, are a major obstacle to individuals with behavioral health disorders seeking treatment for their physical conditions.

(b) Primary care settings have, at the same time, become a gateway to the behavioral health system, as people seek care for mild to moderate behavioral health needs (e.g., anxiety, depression, or substance use) in primary health care settings. Health care providers have long recognized that many patients have both physical and behavioral health care needs, yet physical and behavioral health care services have traditionally been provided and paid for separately. Even behavioral health services have traditionally been treated in a bifurcated system (e.g., substance use disorder treatment is treated separately from mental health treatment).

(c) The term “integrated care” describes the systematic coordination of primary and behavioral health care services. The growing awareness of the prevalence and cost of

comorbid physical and behavioral health conditions, and the increased recognition that integrated care can improve outcomes and achieve savings, has led to increasing acceptance of delivery models that integrate physical and behavioral health care. Moreover, most patients prefer to have their physical and behavioral health care delivered in one place, by the same team of clinicians.

(d) Accordingly, these regulations will prescribe standards for the integration of physical and behavioral health care services in certain outpatient programs licensed by the Department of Health, the Office of Mental Health, and/or the Office of Alcoholism and Substance Abuse Services.

#### **§ 404.2 Legal Base**

(a) Office of Mental Health.

(1) Section 7.09 of the Mental Hygiene Law (MHL) grants the commissioner of Mental Health the power and responsibility to adopt regulations that are necessary and proper to implement matters under his or her jurisdiction.

(2) Section 7.15 of the MHL charges the commissioner of Mental Health with the responsibility for planning, promoting, establishing, developing, coordinating, evaluating and conducting programs and services of prevention, diagnosis, examination, care, treatment, rehabilitation, training, and research for the benefit of persons with mental illness. Such law further authorizes the commissioner to take all actions that are necessary, desirable, or proper to carry out the statutory purposes and objectives of the Office of Mental Health, including undertaking activities in



cooperation and agreement with other offices within the Department of Mental Hygiene, as well as with other departments or agencies of state government.

(3) Section 31.04 of the MHL authorizes the commissioner of Mental Health to set standards of quality and adequacy of facilities, equipment, personnel, services, records and programs for the rendition of services for adults diagnosed with mental illness or children diagnosed with emotional disturbance, pursuant to an operating certificate.

(4) Sections 31.07, 31.09, 31.13, and 31.19 of the MHL authorize the commissioner of Mental Health or his or her representatives to examine and inspect such programs to determine their suitability and proper operation. Section 31.16 authorizes such commissioner to suspend, revoke or limit any operating certificate, under certain circumstances.

(5) Section 31.11 of the MHL requires every holder of an operating certificate to assist the Office of Mental Health in carrying out its regulatory functions by cooperating with the commissioner of Mental Health in any inspection or investigation, permitting such commissioner to inspect its facility, books and records, including recipients' records, and making such reports, uniform and otherwise, as are required by such commissioner.

(6) Article 33 of the MHL establishing basic rights of persons diagnosed with mental illness.

(7) Sections 364 and 364-a of the Social Services Law give the Office of Mental Health responsibility for establishing and maintaining standards for medical care and

services in facilities under its jurisdiction, in accordance with cooperative arrangements with the Department of Health.

(b) Department of Health. Section 2803 of the Public Health Law (PHL) authorizes the Public Health and Health Planning Council to adopt and amend rules and regulations, subject to the approval of the commissioner, to implement the provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

(c) Office of Alcoholism and Substance Abuse Services.

(1) Section 19.07(c) of the MHL charges the commissioner of the Office of Alcoholism and Substance Abuse Services with the responsibility to ensure that persons who abuse or are dependent on alcohol and/or substances and their families are provided with care and treatment that is effective and of high quality.

(2) Section 19.07(e) of the MHL authorizes the commissioner of the Office of Alcoholism and Substance Abuse Services to adopt standards including necessary rules and regulations pertaining to substance use disorder treatment services.

(3) Section 19.09(b) of the MHL authorizes the commissioner of the Office of Alcoholism and Substance Abuse Services to adopt regulations necessary and proper to implement any matter under his/her jurisdiction.

(4) Section 19.21(b) of the MHL requires the commissioner of the Office of Alcoholism and Substance Abuse Services to establish and enforce regulations concerning the licensing, certification, and inspection of substance use disorder treatment services.

(5) Section 19.21(d) of the MHL requires the Office of Alcoholism and Substance Abuse Services to establish reasonable performance standards for providers of services certified by the Office.

(6) Section 19.40 of the MHL authorizes the commissioner of the Office of Alcoholism and Substance Abuse Services to issue operating certificates for the provision of substance use disorder treatment services.

(7) Section 32.01 of the MHL authorizes the commissioner of the Office of Alcoholism and Substance Abuse Services to adopt any regulation reasonably necessary to implement and effectively exercise the powers and perform the duties conferred by Article 32 of the MHL.

(8) Section 32.07(a) of the MHL authorizes the commissioner of the Office of Alcoholism and Substance Abuse Services to adopt regulations to effectuate the provisions and purposes of Article 32 of the MHL.

(9) Section 32.05(b) of the MHL provides that a controlled substance designated by the commissioner of health as appropriate for such use may be used by a physician to treat a chemically dependent individual pursuant to section 32.09(b) of the MHL.

(10) Section 32.09(b) of the MHL provides that the commissioner of the Office of Alcoholism and Substance Abuse Services may, once a controlled substance is approved by the commissioner of health as appropriate for such use, authorize the use of such controlled substance in treating a chemically dependent individual.

(d) Pursuant to section 365-l(7) of the Social Services Law and Part L of Chapter 56 of the Laws of 2012, the commissioners of the Office of Mental Health, Office of Alcoholism and Substance Abuse Services and Department of Health are jointly

authorized to establish operating, reporting and construction requirements, as well as joint survey requirements and procedures for entities operating under the auspices of one or more such agencies in order to integrate the delivery of health and behavioral health services in an efficient and effective manner.

### **§ 404.3 Applicability**

(a) The provisions of this Part shall apply to providers seeking approval to provide integrated care services at a single outpatient site (host site). This includes: (i) locations licensed under Article 28 of the Public Health Law as diagnostic and treatment centers, extension clinics as defined in paragraph (g) of section 401.1 of Title 10 and general hospital outpatient programs as defined by this Part, (ii) substance use disorder outpatient services certified under MHL Article 32, and (iii) clinic treatment programs licensed under MHL Article 31.

(b) The standards apply to providers certified or licensed by at least two of the said participating agencies or in the process of pursuing licensure or certification by the Department of Health, the Office of Mental Health, or the Office of Alcoholism and Substance Abuse Services.

(c) The requirements of this Part shall be in addition to the requirements of the state agency that licensed or certified the proposed host site.

(d) An integrated services provider shall continue to ensure documentation as required per 18 NYCRR sections 504.3, 517.3(b), 518.1(c), and 518.3(b).

(e) Integrated services providers of mental health services shall continue to ensure compliance with 14 NYCRR Part 599.

(f) Integrated services providers of substance use disorder services shall continue to ensure compliance with 18 NYCRR section 505.27.

(g) With respect to billing for medical assistance, an integrated services provider shall continue to ensure compliance with 18 NYCRR sections 540.6(a) and 540.6(e).

#### **§ 404.4 Definitions**

For the purposes of this Part:

(a) “Behavioral health care” means care and treatment of mental illness and/or substance use disorders.

(b) “Diagnostic and treatment center” means a medical facility as defined in 10 NYCRR section 751.1 or an extension clinic as defined in 10 NYCRR 401.1(g).

(c) “Governing authority” means the entity that substantially controls the operator or provider of services to which a state licensing agency has issued an operating certificate. The governing authority is the body possessing the right to appoint and remove directors or officers, to approve bylaws or other organizational documents, to approve strategic or financial plans for a provider of services, or to approve operating or capital budgets for a provider of services.

(d) “General hospital outpatient program” means a distinct part or unit within a general hospital as defined by section 2801(10) of the Public Health Law through which outpatient services, other than hospital-based ambulatory surgery services, are provided.

(e) “Host site” means a single outpatient site at which a provider who is licensed or certified by the Department of Health, the Office of Mental Health or the Office of

Alcoholism and Substance Abuse Services is approved to provide integrated care services pursuant to this Part.

(f) “Integrated care services” means the systematic coordination of evidence-based physical and behavioral health care in clinics licensed by one or more state licensing agencies in order to promote health and better outcomes, particularly for populations at risk.

(g) “Integrated services provider” means a provider holding multiple operating certificates or licenses to provide outpatient services, who has also been authorized by a commissioner of a state licensing agency to deliver identified integrated care services at a specific site in accordance with the provisions of this Part.

(h) “Medical director” is a physician who is responsible for the medical services provided by the integrated services provider, for the overall direction of the medical procedures provided and the direct supervision of medical staff in the performance of medical services.

(i) “Outpatient services” means clinic services provided by a diagnostic and treatment center or general hospital outpatient program pursuant to PHL Article 28, a mental health clinic licensed pursuant to MHL Article 31, or a substance use disorder clinic certified pursuant to MHL Article 32.

(j) “Primary care services” means services provided by a physician, nurse practitioner, or midwife acting within his or her lawful scope of practice under Title VIII of the Education Law and who is practicing primary care.

(k) "State licensing agency" means the state agency with statutory authority to license or certify a provider of outpatient services and designated in accordance with the

provisions of this Part with responsibility to monitor compliance by an integrated services provider with the provisions of this Part. State licensing agency is limited to the Department of Health, the Office of Mental Health, or the Office of Alcoholism and Substance Abuse Services, as applicable.

#### **§ 404.5 Integrated Care Models**

Integrated services providers will be approved by the appropriate state licensing agency and designated to deliver integrated care services as one of the following models:

(a) Primary Care Host Model: Given the recognition that the general health care system can serve as a gateway to the behavioral health care system, treatment for substance use disorder and/or mental illness is integrated into a single outpatient physical health setting. In this model, a diagnostic and treatment center or a general hospital outpatient program shall be the host site and the department shall be responsible for monitoring compliance of an integrated services provider with the provisions of this Part.

(b) Mental Health Behavioral Care Host Model: Given that persons with mental health disorders frequently have a co-occurring substance use disorder and/or also experience chronic illnesses, treatment for substance use disorder and/or physical health is integrated into a single outpatient mental health setting. In this model, an Article 31 clinic treatment program shall be the host site and the Office of Mental Health shall be responsible for monitoring compliance of an integrated services provider with the provisions of this Part.

(c) Substance Use Disorder Behavioral Care Host Model: Given that persons with substance use disorders frequently have a co-occurring mental health disorder and/or also

experience chronic illnesses, treatment for mental illness and/or physical health is integrated into a single outpatient substance use disorder treatment setting. In this model, an Article 32 substance use disorder outpatient treatment clinic shall be the host site and the Office of Alcoholism and Substance Abuse Services shall be responsible for monitoring compliance of an integrated services provider with the provisions of this Part.

#### **§ 404.6 Organization and Administration**

(a) A provider may promote itself as an integrated services provider if the provider has been properly certified by an appropriate state licensing agency, pursuant to this Part.

(b) Governing Authority

(1) The established governing authority shall be legally responsible for the quality of patient care services, for the conduct and obligations of the integrated services provider and for ensuring compliance with all Federal, State and local laws, including the New York State Public Health Law, Mental Hygiene Law, and the Education Law.

(2) In order to achieve and maintain generally accepted standards of professional practice and patient care services, the governing authority shall establish, cause to implement, maintain and, as necessary, revise its practices, policies and procedures for the ongoing evaluation of the services operated or delivered by the integrated services providers and for the identification, assessment and resolution of problems that may develop in the conduct of the program.

#### **§ 404.7 Treatment Planning**



(a) Behavioral health treatment planning is an ongoing process of assessing the behavioral health status and needs of the patient, establishing his or her treatment and rehabilitative goals, and determining what services may be provided by the program to assist the patient in accomplishing these goals. An integrated services provider offering behavioral health services shall provide patient-centered treatment planning for each patient as set forth in this section. The treatment planning process is a means of reviewing and adjusting the services necessary to assist the patient in reaching the point where he or she can pursue life goals, without impediment resulting from his or her illness. The treatment planning process includes, where appropriate, a means for determining when the patient's goals have been met to the extent possible in the context of the programs offered by the integrated services provider, and planning for the appropriate discharge of the patient from the program.

(b) Patient participation in treatment planning shall be documented by the signature of the patient or the signature of the person who has legal authority to consent to care on behalf of the patient or, in the case of a child, the signature of a parent, guardian, or other person who has legal authority to consent to health care on behalf of the child, as well as the child, where appropriate, provided, however, that the lack of such signature shall not constitute noncompliance with this requirement if the reasons for non-participation by the patient are documented in the treatment plan. The patient's family and/or collaterals (i.e., significant others) may participate as appropriate in the development of the treatment plan and shall be specifically identified in the treatment plan.

(c) Each patient must have a written patient-centered treatment plan developed by the responsible clinical staff member and patient. Standards for developing a treatment plan include, but are not limited to:

(1) For mental health or substance use disorder behavioral care host models, treatment plans shall be completed no later than 30 days after admission. For primary care host models, treatment plans shall be completed no later than 30 days after the decision to begin any mental health and/or substance use disorder services beyond pre-admission services.

(2) Notwithstanding other provisions of this section, services provided to a recipient enrolled in a managed care plan which is certified by the commissioner or a commercial insurance plan which is certified or approved by the Superintendent of Financial Services, treatment plans shall be prepared pursuant to the requirements of the managed care plan or commercial insurance plan.

(3) If the patient is a minor, the treatment plan must also be developed in consultation with his/her parent or guardian unless the minor is being treated without parental consent as authorized by MHL section 22.11 or 33.21, as applicable.

(4) For patients moving directly from one program offered by an integrated services provider to another program offered by the same provider, whether or not it is a program approved to provide integrated services, the existing treatment plan may be used if there is documentation that it has been reviewed and, if necessary, updated within 14 days of transfer.

(d) The treatment plan shall include physical health, behavioral health, and social services needs. In addition, specific consideration of the need for health home care coordination should be noted when appropriate.

(e) The treatment plan shall include identification and documentation of the following:

- (1) patient-identified problem areas specified in the admission assessment;
- (2) treatment goals for these problem areas (unless deferred);
- (3) objectives that will be used to measure progress toward attainment of treatment goals and target dates for achieving completion of treatment goals;
- (4) methods and treatment approaches that will be utilized to achieve the goals developed by the patient and primary counselor;
- (5) schedules of individual and group counseling;
- (6) each diagnosis for which the patient is being treated at the program;
- (7) descriptions of any additional services (e.g., vocational, educational, employment) or off-site services needed by the patient, as well as a plan for meeting those needs; and
- (8) the signature of the qualified health professional, or other licensed individual within his/her scope of practice, involved in the treatment and responsible for review of the treatment plan.

(f) All treatment plans shall be reviewed and updated as clinically necessary based upon the patient's progress, changes in circumstances, the effectiveness of services, and/or other appropriate considerations. Such reviews shall occur no less frequently than every 90 days or by the next occasion when a service is to be provided to the patient,

whichever shall be later. For services provided to a recipient enrolled in a managed care plan which is certified by the commissioner or a commercial insurance plan which is certified or approved by the Superintendent of Financial Services, treatment plans may be reviewed pursuant to such other plan requirements as shall apply.

(g) Treatment plan reviews shall include the input of relevant staff, as well as the recipient, family members and collaterals, as appropriate. The periodic review of the treatment plan shall include the following:

- (1) assessment of the progress of the patient in regard to the mutually agreed upon goals in the treatment plan;
- (2) adjustment of goals and treatment objectives, time periods for achievement, intervention strategies or initiation of discharge planning, as appropriate;
- (3) an evaluation of physical health status; and
- (4) the signature of the qualified health professional, or other licensed individual within his/her scope of practice, involved in the treatment and responsible for review of the treatment plan.

#### **§ 404.8 Policies and Procedures**

An integrated services provider shall have written policies, procedures, and methods governing the provision of services to patients, including a description of each service provided. These policies, procedures, and methods shall be reviewed annually and revised as necessary. They shall address, at a minimum, the following:

- (a) admission criteria;
- (b) evaluations and treatment plans;

- (c) screening for substance use disorder, mental health, and/or physical health issues;
- (d) the provision of medical services, including screening and referral for associated physical or behavioral health conditions;
- (e) how to ensure prompt follow-up action on patients with abnormal test results or physical findings;
- (f) identification of specific support and ancillary providers, where appropriate, and methods for coordinating such service delivery;
- (g) appropriate transfer and referral procedures to and from other services;
- (h) discharge criteria;
- (i) procedures for handling patient emergencies and identification of available off-hour emergency services seven days per week, 24 hours per day, including, but not limited to, detoxification, withdrawal and acute psychiatric services;
- (j) how to ensure that staff are prepared to care for emergencies in accordance with the services provided at the host site, and necessary emergency equipment is maintained in working order;
- (k) the continuity of care, including regular participation of all integrated care services staff in case conferences, in-service training and staff meetings;
- (l) the prescription and administration of medication which shall be consistent with applicable Federal and State laws and regulations;
- (m) for providers providing primary care, policies and procedures for investigating, controlling and preventing infections in the host site. The policies and procedures shall include those for:

(1) isolating patients with communicable or infectious diseases or patients suspected of having such diseases;

(2) training all personnel rendering care to such patients in the employment of standard infection control techniques;

(3) obtaining periodic reports of health care associated infections (health care associated infections shall include an increased incidence or outbreak of disease due to biological, chemical or radioactive agents or their toxic products occurring in patients or persons working in the host site); and

(4) reporting immediately to the department, in a manner specified by the commissioner, the presence of health care associated infections; and to the city, county or district health officer where the host site is located, the presence of any communicable disease as defined in section 2.1 of Title 10 NYCRR (State Sanitary Code);

(n) public health education and screening with regard to tuberculosis, sexually transmitted diseases, hepatitis, and HIV/AIDS prevention and harm reduction; and

(o) the requirement of the mandatory offer of HIV testing in accordance with section 2781-a of Article 27-F of the Public Health Law.

#### **§ 404.9 Integrated Care Services**

##### **(a) Primary Care Services**

(1) *General Principles.* Integrated services providers of primary care services shall effectively meet patient physical health needs by:

- (i) providing patient care in a continuous manner by the same health care practitioner, whenever possible;
- (ii) appropriately referring to other health care facilities or health care practitioners for services not available;
- (iii) identifying, assessing, reporting and referring cases of suspected or confirmed child abuse or maltreatment;
- (iv) identifying, assessing, reporting and referring cases of suspected or confirmed domestic violence;
- (v) ensuring that all staff receive education in the identification, assessment, reporting and referral of cases of suspected child abuse or maltreatment or domestic violence; and
- (vi) developing a written plan of treatment which shall be periodically revised, as necessary, in consultation with other health care professionals.

*(2) Provision of Primary Care Services*

- (i) All primary care services shall be provided in a manner that safely and effectively meets the needs of the patients served in the integrated care services program.
- (ii) Integrated care services programs delivering primary care services must have sufficient staff and appropriate equipment to deliver primary care services.
- (iii) Integrated services providers delivering primary care services shall conduct periodic reviews of its integration of primary care services with behavioral health services as part of its overall quality assurance program.

(iv) Integrated services providers delivering primary care services shall assign a medical director to be responsible for the primary care services.

(v) Primary care services provided within the specialty of OB/GYN are limited to routine gynecologic care and family planning provided pursuant to 10 NYCRR Part 753.

(vi) Primary care services shall not include prenatal care, dental services or ambulatory surgery which includes any procedure that requires more than minimal sedation or local anesthesia, unless specifically authorized by the Department of Health.

(vii) For integrated services providers providing primary care, practitioners, or their delegate, shall provide their patient complete and current information concerning his or her diagnosis, treatment and prognosis in terms the patient can be reasonably expected to understand, and necessary for the patient to give informed consent prior to the start of any nonemergency procedure or treatment or both. An informed consent shall include, at a minimum, the provision of information concerning the specific procedure or treatment or both, the reasonably foreseeable risks involved, and alternatives for care or treatment, if any, as a reasonable medical practitioner under similar circumstances would disclose in a manner permitting the patient to make a knowledgeable decision. A patient also may refuse treatment to the extent permitted by law, and if so, shall be fully informed of the medical consequences of his/her action.

(b) Mental Health Services



(1) *General principles.*

(a) For adult patients, integrated services providers of mental health care shall effectively meet patient mental health care needs by diagnosing and treating an individual's mental illness, working with the individual in developing a plan of care designed to minimize symptoms and adverse effects of illness, maximize wellness, and promote recovery toward the achievement of life goals such as, but not limited to, education and employment.

(b) For integrated services providers of mental health care that serve children, effective care includes early assessment and identification of childhood emotional disturbances, and engagement of the child and family in the development of a plan of care designed to minimize the symptoms and adverse effects of illness, maximize wellness, assist the child in developing a resilient and hopeful approach to school, family, and community, and maintain the child in his or her natural environment.

(2) *Provision of Mental Health Services*

Integrated services providers of mental health care shall offer each of the following mental health services, to be provided consistent with patients' conditions and needs, and which include:

(i) Outreach;

(ii) Crisis Intervention:

(a) mental health crisis intervention services must be available 24 hours a day/7 days per week.

(b) after hours coverage may be provided directly by the integrated services provider or pursuant to a clinical services contract, as defined

in 14 NYCRR § 599(f), which must require, at a minimum, that in the event of a crisis, the nature of the crisis and any measures taken to address such crisis are communicated to the primary care clinician or other designated clinician involved in the individual's treatment in the primary care component of the integrated services provider on the next business day.

(iii) Psychotropic medication treatment, including injectable psychotropic medication administration for adult patients;

(iv) Psychotherapy services, including but not limited to:

(a) Individual psychotherapy;

(b) Family/Collateral psychotherapy;

(c) Group psychotherapy; and

(d) Complex Care Management.

(3) The following optional services may be offered:

(i) Developmental testing (for children and adolescents);

(ii) Psychological testing;

(iii) Psychiatric consultation; or

(iv) Injectable Psychotropic medication administration for patients who are minors.

(4) Integrated services providers delivering mental health services shall conduct periodic reviews of the integration of primary care and/or substance use disorder services as part of its overall quality assurance program.

(c) Substance Use Disorder Services

*(1) General Principles.*

Integrated services providers of substance use disorder treatment shall effectively meet patient substance use disorders needs by diagnosing and treating an individual's substance use disorders, working with the individual in developing a plan of care to achieve goals identified in the individual's treatment plan and promote recovery.

*(2) Provision of Substance Use Disorder Services.*

For purposes of this subdivision, the term "clinical staff" shall mean staff who provide services directly to patients as prescribed in the treatment plan; including licensed medical staff, credentialed or licensed staff, non-credentialed staff, non-licensed staff and student interns.

(3) Integrated services providers of substance use disorder services shall offer, at a minimum, each of the following services, to be provided consistent with patients' conditions and needs:

(i) Assessments;

(ii) Counseling, which can be delivered via two distinct methods:

(a) Individual counseling, which is a face-to-face service between a clinical staff member and a patient focused on the needs of the patient to be delivered consistent with the treatment/recovery plan, its development, or emergent issues. Individual counseling must be provided with a frequency and intensity consistent with the individual needs of each unique patient, as prescribed by the responsible clinical staff member; and

(b) Group counseling, which is a face-to-face service between one or more clinical staff member and multiple patients at the same time, to be delivered consistent with patient treatment/recovery plans, their development, or emergent issues. Group counseling must contain no more than 15 patients in each group counseling session.

(iii) Education about, orientation to, and the opportunity for participation in, available and relevant peer support and mutual assistance groups; and

(iv) Chemical abuse and dependence awareness and relapse prevention.

(4) An integrated services provider of substance use disorder services shall:

(i) promote the achievement and maintenance of recovery from substance use disorder and abuse;

(ii) improve functioning and development of necessary recovery management skills so the patient can be treated in the least intensive environment; and

(iii) develop individualized treatment/recovery plans to support the achievement and maintenance of recovery from substance use disorder and abuse, the attainment of economic self-sufficiency (including, where appropriate, the ability to sustain long-term productive employment), and improvement of the patient's quality of life.

(5) Integrated services providers of substance use disorder services may offer:

(i) Collateral services;

(ii) Complex care coordination;

(iii) Medication administration and management;

(iv) Outreach; and

(v) Peer support services.

(6) Integrated services providers delivering substance use disorder services shall conduct periodic reviews of the integration of primary care and/or mental services as part of its overall quality assurance program.

#### **§ 404.10 Environment**

(a) The minimum physical plant requirements necessary for certification for existing facilities to provide integrated care services are described herein. Providers licensed or certified by a state licensing agency after the effective date of this Part that wish to provide integrated care services or anticipate new construction or significant renovations shall comply with the requirements under Part 710 (Approval of Medical Facility Construction), Part 711 (General Standards of Construction) and Part 715 (Standards of Construction for Freestanding Ambulatory Care Facilities) of Title 10 of New York Codes, Rules and Regulations.

(b) Outpatient clinic sites proposing to integrate services pursuant to these standards must currently be in compliance with the applicable state licensing agency's environmental standards currently governing the site.

(c) Standards for Integrated Care Services Clinics. In addition to being in compliance with the applicable state licensing agency's environmental standards currently governing the site as required under subdivision (b) of this section, integrated services providers shall meet the following requirements:

(1) General Facility Requirements

(i) A current and accurate floor plan, specifying room locations, dimensions and functions will be provided to each applicable state licensing agency. Program space, except medical examination and treatment rooms, may be shared between certified outpatient services pursuant to an approved schedule. Individual and group rooms shall not be utilized for multiple services simultaneously.

(ii) An adequately furnished waiting area shall be available to those waiting for services and shall be supervised to control access to the facility. There shall be sufficient separation and supervision of various treatment groups (e.g. children) to ensure safety.

(iii) Accessibility for person with disabilities, including availability of accessible bathroom facilities.

(iv) Sufficient space for individual and group sessions consistent with the number of people served and the service offered shall be available. Space shall afford visual and acoustical privacy for both individuals served and staff.

(v) Sufficient and appropriate furnishings and program related equipment and materials for the population served.

(vi) Areas for the proper storage, preparation and use or dispensing of medications and medical supplies and equipment shall be made available. Sharps containers shall be provided and secured, syringes and other supplies should be securely stored, and provisions for holding medical waste are required.

(vii) Controlled access to and maintenance of records and confidentiality of all patient information.

(viii) Annual inspection and testing of the existing fire alarm system, including battery operated smoke detectors, fire extinguishers, emergency lighting systems, illuminated exit signs and environmental controls and heating/cooling systems shall be conducted.

(ix) Facilities shall be maintained in a clean and responsible manner which protects the health and safety of all occupants.

(2) Specific Facility Requirements for Integrating Primary Care Services

(i) Notwithstanding Part 710 (Approval of Medical Facility Construction), Part 711 (General Standards of Construction) and Part 715 (Standards of Construction for Freestanding Ambulatory Care Facilities) of Title 10 NYCRR, physical plant standards under this sub-clause apply to a behavioral health clinic provider authorized to integrate primary care services with no more than 3 proposed examination rooms for physical health services.

(a) Clean Storage. A separate room or closet for storing clean and sterile supplies shall be provided. This storage shall be in addition to that of cabinets and shelves within the examination rooms or patient treatment areas.

(b) An integrated services provider shall dispose of soiled linens and trash appropriately, either through specially-designated receptacles or separate holding room depending upon the volume of soiled materials generated.

(c) If utilizing a receptacle for soiled linens and trash, such receptacle shall not exceed 32 gallons in capacity, except as set forth in clause

(d), and shall meet the following:

(1) The average density of the container capacity in a room or space shall not exceed 0.5 gal/ft sq.

(2) A receptacle with a capacity of 32 gallon shall not exceed any 64 ft sq. area.

(3) Mobile soiled linen or trash collection receptacles greater than 32 gallons shall be located in a room protected as a hazardous area when not attended.

(d) If utilizing a receptacle for soiled linens and trash exceeding 32 gallons in capacity at any given time, the integrated services provider shall maintain a soiled holding room.

(1) Soiled holding is for separate collection, storage, and disposal of soiled materials.

(2) A soiled holding room shall be provided, if a dedicated space cannot be provided in the storage area.

(3) All contaminated materials shall be located and placed in a secured and sealed container and disposed of properly in accordance with all applicable laws and regulations. This shall be in the dedicated storage space that is secured and access is only by the integrated care services clinic staff.



(4) The containers used solely for recycling clean waste or for patient records awaiting destruction outside a hazardous storage area shall be a maximum capacity of 96 gallons. Containers used solely for recycling clean waste or for patient records awaiting destruction outside of a hazardous storage area may exceed 96 gallons, but only if the provider/supplier is in compliance with National Fire Protection Association (NFPA) 101 Life Safety Code, 2012 edition, sections 18/19.7.5.7.2,.

(e) Toilet Rooms

- (1) A toilet room containing a hand-washing station shall be accessible from all examination and treatment rooms.
- (2) Public Toilet. Toilet(s) for public use shall be immediately accessible to the waiting area. In smaller units (less than four employees), the toilet may be unisex.
- (3) Where a facility contains no more than three examination and/or treatment rooms, the patient toilet shall be permitted to serve waiting areas.
- (4) Staff toilet and lounge shall be provided in addition to and separate from public and patient facilities.
- (5) Centralized staff facilities are not required in small centers. In small centers, staff may utilize shared toilet facilities. Small centers less than four employees.

(6) Floors shall have a smooth, hard, non-absorbent surface that extends upward onto the walls at least 6 inches (152 mm).

Vinyl composition tile (VCT) shall not be used in toilet rooms.

*(f)* Examination and Treatment Rooms

(1) No more than 3 examination rooms shall be provided.

(2) At least one examination room shall be available for each provider who may be on duty at any one time.

(3) Provision shall be made to preserve patient privacy from observation from outside an examination/treatment room through an open door.

(4) A counter or shelf space for completing documentation shall be provided.

*(g)* Space Requirements

(1) Each examination/observation room shall have a minimum clear floor area of 80 square feet.

(2) The examination room can be a minimum of 72 square feet in size. If other examination rooms meet the Americans with Disabilities Act (ADA) standards for accessible design set forth in Parts 35 and 36 of Title 28 of the Code of Federal Regulations (ADA accessibility standards), assistance can be provided by an individual accompanying the patient or a staff member who escorts the patient in and out of the examination room.

- (3) If three examination rooms are provided, two shall meet the ADA accessibility standards.
- (4) Room arrangement shall permit a minimum clear dimension of 2 feet 8 inches (81.28 centimeters) at each side and at the foot of the examination table, recliner, or chair.
- (5) Each room shall be designed so that the dimensions of the room are proportional to the square footage to avoid configurations that might hinder the functionality of the program space.

*(h) Hand-Washing Stations*

- (1) A hand-washing station shall be provided in each room where hands-on patient care is provided.
- (2) Hand sanitation dispensers shall be provided in addition to hand-washing stations.
- (3) Hand-washing basins/countertops shall be made of porcelain, stainless steel, or solid surface materials. Basins shall be permitted to be set into plastic laminate countertops if, at a minimum, the substrate is marine-grade plywood (or equivalent) with an impervious seal.
- (4) Sinks shall have well-fitted and sealed basins to prevent water leaks onto or into cabinetry and wall spaces.
- (5) The water pressure at the fixture shall be regulated.

(6) Design of sinks shall not permit storage beneath the sink basin, and should accommodate ADA accessibility standards for clearance under the sink basin.

*(i) Waiting Area*

- (1) The waiting area for patients and any individuals that accompanies patients shall be under staff control.
- (2) The seating shall contain no fewer than two spaces for each consultation room and no fewer than 1.5 spaces for the combined projected capacity at one time of the group rooms.
- (3) Where the psychiatric outpatient unit has a formal pediatrics service, a separate, controlled area for pediatric patients shall be provided.
- (4) The waiting area shall accommodate wheelchairs.
- (5) Provisions for drinking water shall be available for waiting patients. In shared facilities, provisions for drinking water may be outside the outpatient area if convenient for use.

*(j) Corridor Allowed to be Used as a Waiting Area*

- (1) Fixed furniture in egress corridor. The furniture must be securely attached to the floor or wall and can be on only one side of the corridor. Each grouping of furniture cannot exceed 50 square feet and must be at least 10 feet from other groupings.

- (2) Furniture shall be located so as to not obstruct access to building service and fire protection equipment, such as fire extinguishers, manual fire alarm boxes, shutoff valves, and similar equipment
  - (3) Corridors throughout the smoke compartment shall be protected by an electrically supervised automatic smoke detection system, or the fixed furniture spaces shall be arranged and located to allow direct supervision by the facility staff from a nurses' station or similar space
  - (4) The smoke compartment shall be protected throughout by an approved, supervised automatic sprinkler system.
- (k) Combustible Decorations in Egress Corridors and Rooms
- (1) Combustible decorations shall be flame-retardant or are treated with approved fire-retardant coating that is listed and labeled for application to the material to which it is applied.
  - (2) The decorations shall meet the requirements of NFPA 701, Standard Methods of Fire Tests for Flame Propagation of Textiles and Films.
  - (3) The decorations exhibit a heat release rate not exceeding 100 KW when tested in accordance with NFPA 289, Standard Method of Fire Test for Individual Fuel Packages, using the 20 KW ignition source.

(4) The decorations, such as photographs, paintings, and other art, are attached directly to walls, ceiling, and non-fire rated doors in accordance with the following:

- i. Decorations on non-fire rated doors shall not interfere with the operation or any required latching of the door.
- ii. Decorations shall not exceed 20 percent of the wall, ceiling, or door areas inside any room or space of a smoke compartment that is not protected throughout by an approved automatic sprinkler system.
- iii. Decorations shall not exceed 30 percent of the wall, ceiling, and door areas inside any room or space of a smoke compartment that is protected throughout by an approved supervised automatic sprinkler system.

(l) Existing openings in exit enclosures to mechanical equipment spaces that are protected by fire-rated door assemblies. These mechanical equipment spaces must be used only for non-fuel-fired mechanical equipment, must contain no storage of combustible materials, and must be located in sprinklered buildings. This waiver allowance will be permitted only if the provider/supplier is in compliance with all other applicable NFPA 101 Life Safety Code, 2000 edition, exit provisions, as well as with section 7.1.3.2.1(9)(c) of the NFPA 101 Life Safety Code, 2012 edition.

(ii) Behavioral health clinic providers authorized to integrate physical health services with more than 3 proposed examination rooms shall comply with the requirements under Part 710 (Approval of Medical Facility Construction), Part 711 (General Standards of Construction) and Part 715 (Standards of Construction for Freestanding Ambulatory Care Facilities) of Title 10 NYCRR.

(d) Building Code Requirements

- (1) All services and facilities are required to adhere to applicable building codes as well as all local occupancy, use, building and zoning laws.
- (2) A valid Certificate of Occupancy is required.
- (3) NFPA 101 Life Safety Code, 2000 edition, for Chapter 20 New Ambulatory Health Care, Chapter 21 Existing Ambulatory Health Care, Chapter 38 New Business, and Chapter 39 Existing Business occupancies.
- (4) New York State Sanitary Code.
- (5) All occupied areas shall be ventilated by natural and/or mechanical means.
- (6) Air-handling duct systems shall meet the requirements of NFPA 90A.

**§ 404.11 Quality Assurance, Utilization Review and Incident Reporting**

(a) Quality Assurance

(1) Primary Care Services.

(i) Integrated services providers which provide primary care shall ensure the development and implementation of a written quality assurance program that includes a planned and systematic process for monitoring and assessing

the quality and appropriateness of patient care and clinical performance on an ongoing basis. The integrated care services program shall resolve identified problems and pursue opportunities to improve patient care.

(ii) The integrated care services program shall be supervised by the medical director. This responsibility may not be delegated.

(iii) There shall be a written plan for the quality assurance program which describes the program's objectives, organization, responsibilities of all participants, scope of the program and procedures for overseeing the effectiveness of monitoring, assessing and problem-solving activities.

(iv) The quality assurance plan shall define methods for the identification and selection of clinical and administrative problems to be reviewed.

The plan shall include but not be limited to:

(a) the establishment of review criteria developed in accordance with current standards of professional practice for monitoring and assessing patient care and clinical performance;

(b) regularly scheduled reviews of medical charts, patient complaints and suggestions, reported incidents and other documents pertinent to problem identification;

(c) documentation of all quality assurance activities, including but not limited to the findings, recommendations and actions taken to resolve identified problems; and

(d) the timely implementation of corrective actions and periodic assessments of the results of such actions.



- (v) The scope of clinical and administrative problems selected to be reviewed for the purpose of quality assurance shall reflect the scope of services provided and the populations served at the center.
- (vi) The outcomes of quality assurance reviews shall be used for the revision or development of policies and in granting or renewing staff privileges, as appropriate.
- (vii) There shall be participation in the quality assurance program by administrative staff and health-care professionals representing each professional service provided.
- (viii) There shall be joint participation in the quality assurance program by representatives from the behavioral health components of an integrated care services program; such participation shall include, but is not limited to, specific identification of quality improvement opportunities with respect to patient concerns and complaints, changes in regulatory requirements, or other factors, no less frequently than once every two years. Documentation shall be kept of all such reviews.
- (ix) The findings, conclusions, recommendations and actions taken as a part of the quality assurance program shall be reported to the operator by the medical director. An annual report shall be submitted to the governing authority, which documents the effectiveness and efficacy of the integrated care services program in relation to its goals and quality assurance plan and indicate any recommendations and plans

for improvement in its services to patients, as well as recommend changes in its policies and procedures.

(2) Behavioral Health Services

(i) Integrated services providers which provide mental health and/or substance use disorder services shall comply with all requirements of 14 NYCRR Part 599 or 822, as applicable, relating to quality assurance.

(ii) Integrated services providers of mental health and/or substance use disorder services shall prepare an annual report and submit it to its governing authority. This report must document the effectiveness and efficiency of the ambulatory care program in relation to its goals and quality assurance plan and indicate any recommendations and plans for improvement in its services to patients, as well as recommended changes in its policies and procedures.

(iii) Utilization review.

(a) Integrated services providers of mental health and/or substance use disorder services shall establish and implement a utilization review plan. The utilization review plan must include participation by all primary care and behavioral health components of the integrated services provider, as applicable.

(b) Integrated services providers of mental health and/or substance use disorder services may use a utilization review process developed by

the state licensing agency or may develop its own utilization review process that is subject to approval by the state licensing agency.

(c) Integrated services providers of mental health and/or substance use disorder services may perform its utilization review process internally; or it may enter into an agreement with another organization, competent to perform utilization review, to complete its utilization review process.

(d) Utilization review must be conducted by at least one clinical staff member. No member shall participate in utilization review decisions relative to any patient he or she is treating directly.

(e) The utilization review plan must include procedures for ensuring that retention criteria are met and services are appropriate. The utilization review plan must consider the needs of a representative sample of patients for continued treatment, the extent of the behavioral health problem, and the continued effectiveness of, and progress in, treatment. At a minimum, utilization review must include separate random samples based upon a patient's length of stay, with larger samples for patients with longer lengths of stay. Utilization review must also be conducted for all active cases within the twelfth month after admission and every 90 days thereafter.

(f) Documentation of utilization review must be maintained providing evidence that the deliberations:

- (1) were based on current progress in treatment relative to the applicable functional areas identified in the patient's comprehensive treatment/recovery plan;
- (2) determined the appropriateness of continued stay at the outpatient level of care and intensity of services, as well as whether co-occurring disorder(s) require referral to outside services;
- (3) determined the reasonable expectation of progress towards the accomplishment of the goals and objectives articulated in the patient's treatment/recovery plan, based on continued treatment at this level of care and intensity of services; and
- (4) resulted in a recommendation regarding continuing stay, intensity of care and/or referral of this case.

(b) Incident Reporting

(1) Mental health behavioral care host providers shall report incidents involving patients receiving mental health services in accordance with the provisions of 14 NYCRR Part 524.

(2) Substance use disorder behavioral care host providers shall report incidents involving patients receiving substance use disorder services in accordance with the provisions of 14 NYCRR Part 836.

(3) Primary care host providers shall report incidents in accordance with the provisions of 10 NYCRR section 405.8 or 10 NYCRR section 751.10, as applicable.

## § 404.12 Staffing

(a) Personnel. The governing authority shall ensure the employment of personnel without regard to age, race, color, sexual orientation, religion, sex or national origin. A personnel file shall be maintained for each employee.

(b) Integrated services programs that are providing primary care services shall ensure that:

(1) the health status of each employee is examined prior to the beginning of employment, which is sufficient in scope to ensure that the employee is free from a health impairment which is of potential risk to patients or which may interfere with the performance of his/her duties;

(2) a record of the following tests, procedures and examinations is maintained for all employees:

(i) a certificate of immunization against rubella which means:

(a) a document prepared by a physician, physician's assistant, specialist's assistant, nurse practitioner, licensed midwife or a laboratory possessing a laboratory permit issued pursuant to Part 58 of Title 10 of the New York Codes of Rules and Regulations, demonstrating serologic evidence of rubella antibodies;

(b) a document indicating one dose of live virus rubella vaccine was administered on or after the age of 12 months, showing the product administered and the date of administration, and prepared by the health practitioner who administered the immunization; or

(c) a copy of a document described in clause (a) or (b) of this subparagraph which comes from a previous employer or the school which the employee attended as a student; and

(ii) a certificate of immunization against measles, for all personnel born on or after January 1, 1957, which means:

(a) a document prepared by a physician, physician's assistant, specialist's assistant, nurse practitioner, licensed midwife or a laboratory possessing a laboratory permit issued pursuant to Part 58 of Title 10 of the New York Codes of Rules and Regulations, demonstrating serologic evidence of measles antibodies; or

(b) a document indicating two doses of live virus measles vaccine were administered with the first dose administered on or after the age of 12 months and the second dose administered more than 30 days after the first dose but after 15 months of age showing the product administered and the date of administration, and prepared by the health practitioner who administered the immunization; or

(c) a document, indicating a diagnosis of the employee as having had measles disease, prepared by the physician, physician's assistant/specialist's assistant, licensed midwife or nurse practitioner who diagnosed the employee's measles; or

(d) a copy of a document described in clause (a), (b) or (c) of this subparagraph which comes from a previous employer or the school which the employee attended as a student;

(iii) if any licensed physician, physician's assistant/specialist's assistant, licensed midwife or nurse practitioner certifies that immunization with measles or rubella vaccine may be detrimental to the employee's health, the requirements of subparagraph (i) and/or (ii) of this paragraph relating to measles and/or rubella immunization shall be inapplicable until such immunization is found no longer to be detrimental to such employee's health. The nature and duration of the medical exemption must be stated in the employee's employment medical record and must be in accordance with generally accepted medical standards, (see, for example, the recommendations of the American Academy of Pediatrics and the Immunization Practices Advisory Committee of the U.S. Department of Health and Human Services); and

(iv) for all personnel prior to employment or affiliation, except for personnel with no clinical or patient contact responsibilities who are located in a building or site with no patient care services, either tuberculin skin test or Food and Drug Administration (FDA) approved blood assay for the detection of latent tuberculosis infection, prior to employment or affiliation and no less than every year thereafter for negative findings. Positive findings shall require appropriate clinical follow-up but no repeat tuberculin skin test or blood assay. The medical staff shall develop and implement policies regarding positive outcomes;

(v) an annual, or more frequent if necessary, health status reassessment to assure freedom from a health impairment which is a potential risk to the patients or might interfere with the performance of duties; and

(vi) documentation of vaccination against influenza, or wearing of a surgical or procedure mask during the influenza season, for personnel who have not received the influenza vaccine for the current influenza season, pursuant to section 2.59 of Title 10 of the New York Codes of Rules and Regulations.

(3) each person delivering health care services wears identification indicating his/her name and title.

(c) Medical Director.

(1) Integrated services providers providing primary care services shall have a medical director. The governing authority shall be responsible for appointing a medical director who:

(i) is qualified by training, experience, and administrative ability;

(ii) is a physician licensed by and currently registered with the New York State Education Department;

(iii) develops and recommends to the governing authority policies and procedures governing patient care, medical staff and clinical privileges; and

(iv) is responsible for the supervision of the quality assurance program and reporting to the governing authority.



(2) Integrated services providers providing substance use disorder services, shall have a medical director who, unless such medical director was in place on July 1, 2011:

(i) holds at least one of the following certifications:

(a) a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties;

(b) an addiction certification from the American Society of Addiction Medicine; or

(c) a certification by the American Board of Addiction Medicine (ABAM); or

(d) a subspecialty board certification in Addiction Medicine from the American Osteopathic Association; and

(ii) possesses a Federal DATA 2000 waiver (buprenorphine-certified).

In lieu of employing a medical director meeting these requirements, the integrated services provider providing substance use disorder services may have a consultation agreement with a full- or part-time physician who meets the requirements of this paragraph.

#### **§ 404.13 Recordkeeping**

(a) An integrated services provider shall maintain a record of all integrated care services provided to an individual who is admitted to and treated by such provider, and this may be accomplished via a single integrated record for the individual.

(b) Regardless of form or format, each integrated care services program shall establish a recordkeeping system which is maintained in accordance with recognized and accepted principles of recordkeeping.

(c) Each integrated care services program shall designate a staff member who has overall supervisory responsibility for the recordkeeping system. The recordkeeping supervisor shall ensure that:

(1) the integrated care record for each patient contains and centralizes all physical and behavioral health information which identifies the patient, justifies the treatment and documents the results of such treatment;

(2) entries in the integrated care record are current, legible to individuals other than the author, are authenticated with a signature of the person making the entry, date, and time;

(3) handwritten entries must be made in permanent, non-erasable blue or black ink or typed;

(4) information contained in the integrated care record is securely maintained, kept confidential, safeguarded from environmental damage, and made available only to authorized persons who have a need to know the information; and

(5) when a patient is treated by an outside provider, and that treatment is relevant to the patient's care, a clinical summary or other pertinent documents are obtained to promote continuity of care; if documents cannot be obtained, the reason must be noted in the integrated care record.

(d) The integrated care record format shall facilitate the ability to record the following information for each patient, as relevant:

- (1) patient basic demographic information;
- (2) patient physical health and behavioral health history:
  - (i) Physical health information
    - (a) physical examination reports;
    - (b) diagnosis or medical impression;
    - (c) diagnostic procedures/tests reports;
    - (d) medical orders and anesthesia record;
    - (e) immunization and drug history; and
    - (f) notation of allergic or adverse reactions to medications;
  - (ii) Mental health information
    - (a) diagnosis or diagnostic impression;
    - (b) psychosocial assessment; and
    - (c) mental health treatment history;
  - (iii) Substance use information
    - (a) diagnosis or diagnostic impression;
    - (b) substance use disorder assessment, including the use of tobacco;
    - (c) the impact of the use of substances, on self and significant others; and
    - (d) substance use disorder treatment history including prior periods of sustained recovery and how such recovery was supported;
- (3) admission note;
- (4) assessment of the patient's goals regarding basic treatment goals and needs;
- (5) treatment plan and applicable reviews;
- (6) dated progress notes that relate to goals and objectives of treatment;

- (7) discharge plan;
- (8) documentation of the services provided and any referrals made;
- (9) discharge summary;
- (10) dated and signed records of all medications prescribed by the clinic and other prescription medications being used by the patient, if applicable;
- (11) consent forms, if applicable; and
- (12) record of contacts with collaterals if applicable.

(e) Patient case records must be retained for a minimum period of six (6) years from the date of the last service provided to a patient or, in the case of a minor, for at least six years after the last date of service or three years after he/she reaches majority whichever time period is longer.

(f) Confidentiality

(1) Notwithstanding any other New York State regulation, in cases where component providers of an integrated care services program are governed by different state or federal laws and regulations protecting clinical records and information, the integrated care record shall be governed by the state and federal privacy rules and regulations that give the most protection to the record, unless it is possible to redact provisions of the record with more protection without compromising the purpose for which the record is being disclosed.

(2) An integrated care services program providing substance use disorder services must obtain patient consent prior to making any disclosures from the integrated care record, unless the disclosure is authorized as an exception pursuant to federal regulations.

(3) AIDS and HIV information shall only be disclosed in accordance with Article 27-F of the Public Health Law.

**§ 404.14 Application and Approval**

(a) Application and Approval Process.

(1) Providers that possess at least two licenses/certificates from at least two separate state licensing agencies and are seeking approval to integrate services for which they are licensed or certified may submit an application to the state licensing agency of the host site.

(2) Applications shall be submitted in a format prescribed for all applicants and reviewed by the state licensing agency that regulates the services to be added, in conjunction with the state licensing agency with authority for the host clinic, as appropriate.

(3) Applications shall include information needed to demonstrate that the provider is:

(a) licensed or certified by the relevant state licensing agencies to provide services for which the provider is seeking to integrate;

(b) in compliance with all applicable requirements of the relevant state licensing agencies.

(c) in good standing at the time of application approval. A provider is in good standing if each clinic site for which the provider is licensed or certified to offer services:

(i) is licensed by the Office of Mental Health and has a 1 year or greater time frame on operating certificate (Tier 3 providers are not eligible to participate); and/or

(ii) is certified by the Office of Alcoholism and Substance Abuse Services and all of its programs have an operating certificate with partial or substantial compliance (2 or 3 years); and/or

(iii) has an operating certificate from the Department of Health and not currently under any enforcement actions;

(d) in compliance with the physical plant requirements under this Part; and

(e) a member of a health home designated by the commissioner pursuant to section 365-1 of the Social Services Law.

(4) Applications may include but not be limited to requests for information regarding services to be added and the plan for implementation, staffing, operating expenses and revenues, and utilization of services as they relate to integrated care services as described in this Part.

(5) The applicant shall supply any additional documentation or information requested by the state licensing agency of the host site, in conjunction with the other state licensing agencies as appropriate, within a stated timeframe of such request, unless an extension is obtained. The granting of a request for an extension shall be at the discretion of such state licensing agency of the host site. Failure to provide the additional documentation or information within the time prescribed shall constitute an abandonment or withdrawal of the application without any further action from the state licensing agency.

(6) The affected state licensing agency shall approve or disapprove an application in writing.

(7) Applicants may appeal the denial of an application in accordance with the rules and regulations of the affected state licensed agency.

#### **§ 404.15 Inspection**

(a) The state licensing agency with authority for the host clinic shall have ongoing inspection responsibility for the integrated services clinic, pursuant to this Part. The purpose of the inspection is to ensure compliance with all applicable laws, rules, and regulations, as well as to determine the renewal term of the operating certificate or license, as applicable. Inspection activities shall not be duplicated.

(b) The host state licensing agency shall consult with the adjunct state licensing agency on matters specific to the provision of such add-on services, as may be necessary to assure patient health and safety. Any significant deficiencies will immediately be referred for enforcement to the responsible state licensing agency. If at any point during the inspection, findings are identified that suggest imminent risk of serious harm or injury to patients, the inspector(s) will immediately contact their supervisor, who will consult with the adjunct state licensing agency, as applicable.

(c) Inspections shall be conducted utilizing a joint-licensing instrument, developed collaboratively by the three state licensing agencies. This standardized procedure will ensure consistency of the inspection process throughout the State and provide standardized reviews of the operations and services at each integrated services clinic. All

deficiencies and/or corrective action will be overseen by the monitoring state licensing agency with notice to the adjunct state licensing agency or agencies, as applicable.

(d) Each integrated services provider shall undergo an unannounced inspection which will occur prior to renewal of the Operating Certificate or License.

(1) At the start of the inspection, the inspector(s) will meet with integrated services clinic administrative staff to explain the purpose and scope of the inspection and request any documentation (e.g., policies; staffing information; etc.) that may be needed to facilitate the review.

(2) The inspection will include, but not be limited to, the following areas of review:

- (a) on-site inspection of clinic appearance, conditions and general safety;
- (b) evaluation of the sponsor, its management systems, and procedures;
- (c) patient case record review;
- (d) interviews of staff and patients;
- (e) examination of staffing patterns and staff qualifications;
- (f) analysis of statistical information contained in reports required to be submitted by the clinic;
- (g) compliance with the reporting requirements;
- (h) verification of staff credentials, as applicable;
- (i) incident reporting requirements; and
- (j) such other operating areas of activities as may be necessary or appropriate to determine compliance with applicable laws and regulations.



(3) At the conclusion of the inspection, the inspector(s) will meet with the integrated services clinic administrative staff to discuss all deficiencies identified during the inspection.

(e) Upon completion of the inspection, a written report will be provided to the integrated services clinic which describes the results of the inspection, including each regulatory deficiency identified, if any. The provider of services shall take all actions necessary to correct all deficiencies reported. The provider of services shall submit a plan of correction to the state licensing agency with authority for the host clinic within 30 days, which states the specific actions taken or planned to achieve compliance with identified requirements. Any planned actions described in the plan of correction must be accompanied with a timetable for their implementation.

(f) 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 of the state licensing agency with authority for the host clinic may revoke, suspend or limit the operating certificate or license or levy a civil fine for such failures, in accordance with applicable regulations.

(g) Concurrently, each integrated services clinic shall undergo a fiscal viability review which will 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 state licensing agency with authority for the host clinic, for compliance with minimum standards established by the state licensing agency, in order to determine the provider's fiscal capability to effectively support the authorized services.

(h) Providers of services that fail to meet the minimum standards of the state licensing agency with authority for the host clinic shall be required to submit a corrective action plan setting forth the specific actions to be taken to meet the minimum standards within a reasonable time frame.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

These proposed regulations concerning integrated outpatient services are being issued by the Department of Health (DOH) and were developed with the Office of Mental Health (OMH), and the Office of Alcoholism and Substance Abuse Services (OASAS). For DOH, the regulations will appear in a new Part 404 of Title 10 of the New York Codes, Rules and Regulations. OMH and OASAS each will issue an identical set of regulations which will appear in Part 14 of the New York Codes, Rules and Regulations (NYCRR).

These regulations are issued pursuant to: (1) Social Services Law (SSL) sections 365-a(2)(c) and 365-l(7) and Part L of Chapter 56 of the Laws of 2012, which authorize the Commissioners of DOH, OMH and OASAS, with the approval of the Director of the Budget, to promulgate regulations to facilitate integrated service delivery by providers; and (2) Public Health Law (PHL) § 2803, which authorizes the Public Health and Health Planning Council to adopt rules and regulations, subject to the approval of the Commissioner of Health, to effectuate the purposes of PHL Article 28. OMH and OASAS will reflect their statutory authorities in their regulatory impact statements.

### **Legislative Objectives:**

Pursuant to SSL sections 365-a(2)(c) and 365-l(7) and Part L of Chapter 56 of the Laws of 2012, the Commissioners of the Office of Mental Health (OMH), Office of Alcoholism and Substance Abuse Services (OASAS) and the Department of Health

(DOH) are authorized, with the approval of the Director of the Budget, to promulgate regulations to facilitate integrated service delivery by providers.

Since 2012, OASAS, OMH and DOH have pursued an Integrated Licensure Pilot Project pursuant to this authority. The goals of that project have been to streamline the approval and oversight process for clinics interested in providing services under the licensure of more than one agency (OMH, DOH, OASAS) at one or more location(s), thereby:

- Providing an efficient approval process to add new services to a site that is not licensed for those services.
- Establishing a single set of administrative standards and survey processes under which providers will operate and be monitored.
- Providing single state agency oversight of compliance with administrative standards for providers offering multiple services at a single site.

In addition, the project sought to improve the quality and coordination of care provided to people with multiple needs, by:

- Promoting integrated treatments records that comply with applicable Federal and State confidentiality requirements.
- Making optimal use of clinical resources jointly developed by OASAS and OMH that support evidence-based approaches to integrated dual disorders treatment.
- Ensuring that optimal clinical care, and not revenue, drive the program model.
- Providing an opportunity for optimal clinical care in a single setting creating cost efficiencies and increasing quality.

Highlights of the Project have included the formation of an interagency workgroup (OMH, DOH, OASAS) to develop a single set of administrative standards and a single application for licensure or certification. Though a provider may have multiple licenses, they are overseen by a single State agency utilizing a single review instrument.

It was from the Project that development of this regulatory proposal was conceived, to be used by all three State oversight agencies to promote consistency in the provision of integrated services. This regulatory proposal is therefore crafted utilizing the principles of the Integrated Licensure Project (the “Project”) as its basis:

- to allow a single outpatient clinic provider to deliver the desired range of cross-agency (DOH, OMH, OASAS) clinic services under a single license.
- the clinic provider would need to possess licenses from at least 2 of the 3 participating State agencies within their network.
- the current license of the clinic site would serve as the “host”, allowing that State agency to assume all surveillance activities relative to the site.
- the desired “add-on” services would be requested via the State agency currently with primary oversight responsibility for such services.

**Needs and Benefits:**

Physical and behavioral health conditions (i.e., mental illness and/or substance use disorders) often occur at the same time. Persons with behavioral disorders frequently experience chronic illnesses such as hypertension, diabetes, obesity, and cardiovascular

disease. These illnesses can be prevented and are treatable. However, the difficulty in navigating complex health care systems calls for the implementation of regulatory changes to facilitate the ability of individuals with behavioral health disorders to seek integrated treatment for their physical conditions.

Primary care settings have, at the same time, become a gateway to the behavioral health system, as people seek care for mild to moderate behavioral health needs (e.g., anxiety, depression, or substance use) in primary health care settings. Health care providers have long recognized that many patients have both physical and behavioral health care needs, yet physical and behavioral health care services have traditionally been provided and paid for separately. Even behavioral health services have traditionally been treated in a bifurcated system (e.g., substance use disorder treatment is treated separately from mental health treatment).

The term “integrated care” describes the systematic coordination of primary and behavioral health care services. The growing awareness of the prevalence and cost of comorbid physical and behavioral health conditions, and the increased recognition that integrated care can improve outcomes and achieve savings, has led to increasing acceptance of delivery models that integrate physical and behavioral health care. Moreover, most patients prefer to have their physical and behavioral health care delivered in one place, by the same team of clinicians. Accordingly, these regulations will prescribe standards for the integration of physical and behavioral health care services in certain outpatient programs licensed by DOH, OMH, and/or OASAS.

## **Costs**

### **Costs to Private Regulated Parties:**

There are no additional costs to participating providers for this initiative. Integrated service sites will likely benefit from administrative process improvements related to facility licensure and recertification, which will be coordinated by a single host agency pursuant to this rule. Absent the process set forth in the regulations, providers would have to obtain the approval of another agency to provide such services and would be subject to the oversight of the other agency. Accordingly, the proposed regulations may reduce the administrative costs that would otherwise be incurred as a result of adding services. In addition, the ability of providers to integrate primary care and behavioral health services will improve the overall quality of care for individuals with multiple health conditions and will reduce overall health and behavioral health care costs.

### **Costs to Local Government:**

The proposed regulations will not impose any additional costs on local governments. To the extent that a local government operates a provider that will be able to integrate services under the expedited process established by the regulations, it will benefit from the administrative efficiencies created by the regulations. In addition, as previously noted, the ability of providers to integrate primary care and behavioral health services will improve the overall quality of care for individuals with multiple health conditions and will reduce overall health and behavioral health care costs, which could have a beneficial impact on the local government.

**Costs to the Department of Health:**

Approving and overseeing the addition of integrated services as set forth in the proposed regulations would not add any administrative burdens or costs to DOH, since it otherwise would have to approve and oversee the addition of primary care services. OMH and OASAS will approve and oversee the addition of behavioral health services.

**Costs to Other State Agencies:**

Approving and overseeing the addition of integrated services as set forth in the proposed regulations would not add any administrative burdens or costs to OMH or OASAS, since they otherwise would have to approve and oversee the addition of behavioral health services. DOH will approve and oversee the addition of primary care services.

**Local Government Mandates:**

This regulatory proposal will not result in any additional imposition of duties or responsibilities upon county, city, town, village, school or fire districts.

**Paperwork:**

Providers will be required to submit an application to deliver integrated services. The application has been significantly streamlined from a standard certification or licensing application, and providers will not be required to maintain any more documentation than already required under the regulations of their oversight agency. Under the regulations, integrated services providers will be able to use a single integrated record for patients



receiving services, instead of maintaining two or three separate records currently required for patients receiving services at multiple sites.

**Duplication:**

This is a new initiative intended to streamline the administrative licensure and recertification processes for providers that qualify under this rule and hold multiple licenses or certifications. Without the proposed regulations, providers with multiple licenses would be subject to all the rules and site survey requirements imposed by each agency through which they are licensed.

**Alternatives:**

“Integrated licensure” is one model for providers to integrate physical and behavioral health services in a single location. Alternative models continue to be pursued (e.g., ambulatory services thresholds in clinics, the Collaborative Care Demonstration, the Delivery System Reform Incentive Payment (DSRIP) Program, the Patient Centered Medical Home and the Geriatric Services Demonstration). Such alternative models have not been rejected by the State oversight agencies. Rather, the barriers to the expansion of each alternative model continue to be examined for possible adoption on broader scales.

**Federal Standards:**

The regulatory amendment does not exceed any minimum standards of the federal government for the same or similar subject areas.

**Compliance Schedule:**

The regulatory amendment would be effective immediately upon adoption.

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**STATEMENT IN LIEU OF  
REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

## **STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS**

No rural area flexibility analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

## **STATEMENT IN LIEU OF JOB IMPACT STATEMENT**

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. The proposed amendments will not have a substantial adverse impact on jobs and employment opportunities.