PART 815
PATIENT RIGHTS

(Statutory Authority: Mental Hygiene Law, §§ 19.07(c) and (e), 19.09(b), 19.20, 19.20-a, 19.21(b), 22.03, 22.07, 32.01, 32.07(a), 32.05; Social Services Law § 492; Protection of People with Special Needs Act (Chapter 501 of the Laws of 2012; Article 15 of the Executive Law))

Sec.

Section 815.1 Background and intent.

This Part sets forth minimum standards to protect patient rights. For purposes of this Part, a patient is a person receiving services from a provider certified, funded or otherwise authorized by the Office. The term “patient” as used in this Part includes, but is not limited to, terms such as “client”, “resident”, “consumer”, “customer”, “participant” or such other term which applies to a current or former service recipient. All services shall be provided in a manner that is strength-based, person centered and trauma informed.

815.2 Legal base.

(a) Section 19.07(c) of the Mental Hygiene Law (“MHL”) charges the Commissioner with the responsibility of ensuring that the personal and civil rights of persons receiving care, treatment and rehabilitation are adequately protected.

(b) Section 19.07(e) of the MHL authorizes the Commissioner to adopt standards including necessary rules and regulations pertaining to addiction services.

(c) Section 19.09(b) of the MHL authorizes the Commissioner to adopt regulations necessary and proper to implement any matter under their jurisdiction.

(d) Section 19.20 of the MHL authorizes the Office to receive and review criminal history information from the Justice Center related to employees or volunteers of treatment facilities certified, licensed, funded or operated by the Office.

(e) Section 19.20-a of the MHL authorizes the Office to receive and review criminal history information from the Justice Center related to persons seeking to be credentialed by the Office or applicants for an operating certificate issued by the Office.

(f) Section 19.21(b) of the MHL authorizes the Commissioner to adopt regulations concerning the licensing, certification, inspection, and treatment standards of all facilities that provide addiction services.

(g) Section 22.03 of the MHL requires the director of any addiction services program to establish, communicate and post patient rights, to include information about how to communicate with the Office and the Commissioner.

(h) Section 22.07(c) of the MHL authorizes the Commissioner to adopt rules and regulations and take any other necessary action to ensure that the rights of individuals who have received or are receiving addiction services are protected.

(i) Section 32.01 of the MHL authorizes the Commissioner to adopt any regulation reasonably necessary to implement and effectively exercise the powers and perform the duties conferred by article 32 of the MHL.

(j) Section 32.07(a) of the MHL authorizes the Commissioner to adopt regulations to effectuate the provisions and purposes of Article 32 of the MHL.

(k) Section 32.05 of the MHL indicates that no provider of services shall engage in the provision of addiction services without an operating certificate issued by the Commissioner.

(l) Section 492 of the Social Services Law established the Vulnerable Persons' Central Register.

(m) The Protection of People with Special Needs Act (chapter 501 of the Laws of 2012) established the Justice Center for the Protection of People with Special Needs.

(n) Section 32.06 of the MHL prohibits the offering or acceptance of a payment, benefit or consideration in any form, in exchange for the referral of any person as a potential patient for substance use disorder services.

(o) Article 15 of the Executive Law enacts the Human Rights Law prohibiting discrimination against protected classes of New Yorkers including on the basis of sexual orientation and gender identity or expression.

815.3 Applicability.

This Part applies to any provider currently certified, funded or otherwise authorized by OASAS to provide addiction services.

815.4 Provider requirements.

(a) The facility or provider agency as program governing authority shall establish policies and procedures to protect patient rights. Such policies and procedures shall be consistent with the requirements of the program's operating certificate, including, but not limited to:

(1) standards governing staff conduct to ensure the protection of patient rights and to ensure the communication of such standards, rights and responsibilities to patients. When communicating, providers shall make every effort to accommodate patient differences in language and language abilities in accordance with applicable law.

(2) Copies of a statement of the rights and responsibilities of patients shall be posted prominently and conspicuously throughout the provider's facility. This statement, at a minimum, shall include the requirements of sections 815.5 and 815.6 of this Part. Such postings shall also include contact information for the toll-free hotline to the Vulnerable Persons' Central Register, the provider's director, the Commissioner, the Office patient advocate, and the Office toll-free telephone number.

(3) The postings shall include the policy and procedures for addressing patient concerns or grievances with the provider and/or the Office. Such policy shall include, at a minimum, the following rights:

(i) to question a policy, voice a concern or grievance with the provider or the Office;

(ii) to receive a timely response and/or resolution;

(iii) to not suffer adverse consequences or retaliation as a result; and

(iv) to communicate with the provider's director, medical director, board of directors, other responsible staff and the Commissioner.

(4) A copy of this Part, and any other Part of Title 14 that is applicable to the provider, shall be provided to a patient upon request.

(5) The provider shall develop policies and procedures to help patients follow their treatment/recovery plan. Such policies and procedures shall specify standards and expectations for patient conduct, including conduct that may result in discharge, achievement of goals consistent with the plan, and procedures for reevaluating and revising the treatment plan when goals are not met.

(6) Provider policies and procedures shall, at a minimum, address patient conduct with timely incremental interventions that are strength-based, person-centered and trauma-informed and designed to assist patients in responding positively to treatment. Such incremental interventions shall be incorporated and delivered consistent with the patient's treatment/recovery plan; be time-limited, and documented in the patient's record.

When a patient poses an imminent threat to others, immediate discharge may be warranted consistent with other provisions of this Part.

(7) The provider shall establish a policy and procedure for implementing quality improvements with respect to patient concerns and complaints, changes in regulatory requirements, or other factors, and shall review such policies no less frequently than once every two years. Documentation shall be kept of all such reviews.

(b) Upon admission, each patient shall be given a written copy of provider services, including onsite and referral service, and the policy relating to the rights and responsibilities of the patient and the provider, and other provider rules and requirements. The patient shall acknowledge in writing the provision and understanding of these documents, and such attestation shall be kept in the patient's record. Patients shall be informed that if they wish to express a concern or grievance, they will be provided documents to initiate such grievance and resolution process upon request.

(c) The provider shall make every effort to accommodate patient differences in language and language abilities and ensure effective communication in accordance with applicable law.

(d) A patient's rights as a citizen of the United States or as a resident of the State of New York shall not be forfeited or abridged because of such patient's participation in addiction services as defined in Part 800 of this Title.

(e) The provider shall comply with the federal confidentiality regulations at 42 Code of Federal Regulations (CFR) Part 2, the Health Insurance Portability and Accountability Act ("HIPAA"), the Public Health Law, and all other applicable law. At the time of admission, the provider shall inform each patient that federal and state law protects the confidentiality of all records of identity, diagnosis, prognosis, or treatment in connection with a person's attendance, participation, or receipt of addiction services. Such information shall be released only in accordance with applicable provisions of federal and state law.

(f) The provider shall establish a policy and procedure for patient discharge pursuant to section 815.7 of this Part. Discharge decisions and appeal results shall be recorded, reviewed and incorporated into the provider's quality review and improvement process.

(g) Participation in addiction services is voluntary and no provider shall force or coerce any person to enter or remain in any service. All patients shall be informed prior to admission that their participation is voluntary and that they are entitled to terminate their participation at any time. Providers may make mutual help or support-group services available to patients but shall not compel attendance. A patient's inability to complete treatment required by a judicial or child welfare mandate may have legal consequences to the patient under the terms of such mandate but, nevertheless, treatment remains voluntary.

(h) The delivery and receipt of emergency substance use disorder services for incapacitated persons shall be governed by Mental Hygiene Law section 22.09.

(i) When admitting a patient to a facility or provider agency, the provider shall not add admission criteria not required by regulation, including, but not limited to, residency, specific identification requirements and/or citizenship status. Applicants not admitted to the program shall be given information concerning other service providers which can more appropriately meet the needs of the patient and, if clinically necessary, a referral and connection shall be made on the patient's behalf.

(j) Office funded service providers must use a sliding scale when evaluating a self-pay patient that considers the patient's ability to pay. Admission to an Office funded provider agency may not be conditioned upon a patient's ability or inability to pay.

(k) Providers shall adhere strictly to the Confidentiality requirements of 42 CFR Part 2, and shall make each release form signed by a patient as specific as possible so as to ensure that clients are fully aware of who is receiving the information. Additionally, providers shall have a policy that ensures an end date to all release of confidential information forms. Copies of records shall be given to a patient or former patient upon request, in accordance with applicable law, regulations, and the program's procedures, within fifteen (15) calendar days of a request.

(l) The provider shall admit and treat minors in accordance with the requirements of Mental Hygiene Law section 22.11.

(m) The provider shall establish guidelines to ensure that patients at inpatient and residential facilities may correspond, have reasonable access to telephones, and have regularly scheduled opportunities to meet with visitors consistent with treatment needs. Patient correspondence addressed to, or from, the Office, public officials, attorneys, and clergy shall be unrestricted and shall be forwarded promptly without being opened or read by provider staff.

(n) The provider director or their designee may take temporary custody of a patient's personal property with the patient's written permission. Personal property retained by the provider shall, at the patient's direction, be returned to the patient when the patient leaves the service, sent to an address designated by the patient at the patient's expense, or donated to the provider. All property left by a patient will be disposed of as abandoned property within thirty (30) days, or in accordance with applicable law. Any interest on money received and held for a patient shall be the property of the individual patient and shall not accrue for the benefit of the provider or for the general welfare of all patients in a facility. A provider who serves as a representative payee for a patient pursuant to designation by a governmental entity or assumes management responsibility over the funds of a patient shall maintain such funds in a fiduciary capacity to the patient.

(o) The provider may submit reports or information to criminal justice entities regarding any patient only after receiving a request and executing a proper consent. Such reports shall be limited to only treatment or clinical information about the patient that is sufficient to satisfy the request, consistent with applicable law, and shall not contain any recommendation or suggestion of any legal action or consequence, such as: court intervention; remand; custody; violation; or incarceration.

(p) Providers shall not offer or accept payment, benefit, or other consideration in any form, in exchange for the referral of any person as a potential patient for substance use disorder service**s** and shall not advertise, or otherwise solicit patients, in false, deceptive or misleading ways.

(q) Providers shall develop and implement policies and procedures consistent with the requirements for hiring and training all custodians, as such term is defined in Part 836 of this Title. Such procedures shall include, but not be limited to, receipt of signed attestations that such custodian has been notified of, and understands, their obligations pursuant to chapter 501 of the Laws of 2012 and Justice Center regulations and that such custodian shall abide by the Code of Conduct for custodians as established by the Justice Center for the Protection of People with Special Needs; and provider's obligation to cooperate with any investigation of a custodian regarding a reportable or significant incident by the Justice Center as an agent of the Office.

(r) Providers shall develop and implement policies and procedures to ensure the provision of culturally appropriate and affirming services for patients, including but not limited to, sexual orientation and gender identity or expression.

(s) Providers shall develop and implement policies and procedures to ensure access to approved medications for substance use disorder treatment as follows and in accordance with guidance issued by the Office:

(1) Medication for Addiction Treatment (MAT) for Substance Use Disorder:

(i) Providers shall maintain a patient with substance use disorder on approved medication, including those federal Food and Drug Administration (FDA) approved medications to treat substance use disorder, if deemed clinically appropriate and in collaboration with the patient’s existing provider, and with the patient’s consent, in accordance with federal and state rules and guidance issued by the Office. Such contact with the existing program or practitioner prescribing such medications shall be documented in the patient record.

(ii) To facilitate access to full opioid agonist medication for patients who are maintained on such medication at the time of admission or who choose to start such medication during admission, providers

shall develop a formal agreement with at least one Opioid Treatment Program (OTP) certified by the Office to facilitate patient access to full opioid agonist medication, if clinically appropriate. Such agreements shall address the program and the OTPs responsibilities to facilitate patient access to such medication in accordance with guidance issued by the Office.

(iii) Providers shall provide FDA approved medications to treat substance use disorder to an existing patient or prospective patient seeking admission to an Office certified program in accordance with all federal and state rules and guidance issued by the Office.

(iv) Providers shall provide education to an existing patient or prospective patient with substance use disorder about FDA approved medications for the treatment of substance use disorder if the patient is not already taking such medications, including the benefits and risks. The program shall document such discussion and the outcome of such discussion, including a patient's preference for or refusal of medication, in the patients record.

(v) Providers shall ensure that the patient's discharge plan includes an appointment with a treatment provider or program that can continue the medication post-discharge.

(2) Overdose Prevention Education.

(i) Providers shall offer overdose prevention education and naloxone education and training to a patient, prospective patient, and/or their significant other(s), in accordance with guidance issued by the Office.

(ii) Providers shall offer a naloxone kit or prescription to patients, prospective patients, and/or their significant other(s), in accordance with guidance issued by the Office.

(t) Providers shall document all formal agreements with Opioid Treatment Programs to facilitate patient access to opioid full agonist medication, where appropriate, and consistent with state and federal rules and guidance issued by the Office.

815.5 Patient rights.

(a) Each patient has the following rights:

(1) to receive services responsive to individual needs in accordance with an individualized treatment/recovery plan, which the patient helps develop and periodically update;

(2) to receive services from provider staff who are competent, respectful of patient dignity and personal integrity, and in sufficient numbers to deliver needed services consistent with the requirements of the provider's operating certificate;

(3) to receive services in a therapeutic environment that is safe, sanitary, and free from the presence of addictive substances;

(4) to know the name, position, and function of any person providing treatment to the patient, and to communicate with the provider director, medical director, board of directors, other responsible staff or the Commissioner;

(5) to receive information concerning treatment, such as diagnosis, condition or prognosis in understandable terms, and to receive services requiring a medical order only after such order is executed by a medical provider working within their scope of practice;

(6) to receive information about provider services available on site or through referral, and how to access such services;

(7) to receive a prompt and reasonable response to requests for provider services, or a stated future time to receive such services in accordance with an individual treatment/recovery plan;

(8) to be informed of and to understand the standards that apply to their conduct, to receive timely warnings for conduct that could lead to discharge and to receive incremental interventions that are strength-based, person centered and trauma-informed for conduct contrary to program rules;

(9) to receive in writing the reasons for a recommendation of discharge and to be informed of the process to appeal such discharge recommendation;

(10) to voice a grievance, file a complaint, or recommend a change in procedure or service to provider staff and/or the Office, free from intimidation, reprisal or threat;

(11) to examine, obtain a receipt, and receive an explanation of provider bills, charges, and payments, regardless of payment source;

(12) to receive a copy of the patient's records for a reasonable fee;

(13) to be free from physical, verbal or psychological abuse;

(14) to be treated by provider staff who are not under the influence of substances that would impair their ability to perform the duties stated in their job description;

(15) to be free from any staff or patient coercion, undue influence, intimate relationships and personal financial transactions;

(16) to be free from performing labor or personal services solely for provider or staff benefit, that are not consistent with treatment goals, and to receive compensation for any labor or employment services in accordance with applicable state and federal law; and

(17) the following rights apply to patients who reside in an inpatient/residential setting:

(i) to practice religion in a reasonable manner not inconsistent with treatment/recovery plans or goals and/or have access to spiritual counseling if available;

(ii) to communicate with outside persons in accordance with the individualized treatment/recovery plan;

(iii) to communicate freely with the Office, public officials, clergy, attorneys and other persons identified by the patient;

(iv) to receive visitors at reasonable times in relative privacy in accordance with the individualized treatment/recovery plan;

(v) to be free from restraint or seclusion;

(vi) to have a reasonable degree of privacy in living quarters and a reasonable amount of safe personal storage space;

(vii) to retain ownership of personal belongings, to the extent such belongings are not contrary to program rules; and

(viii) to have a balanced and nutritious diet.

(18) participants referred to a faith-based provider have the right to be given a referral to a non-faith based provider.

(19) Patients have the right to placement in gender segregated settings based on their gender identity or expression.

(20) Patients have the right to culturally appropriate and affirming care and to be free from harassment and/or discrimination in accordance with the factors outlined in paragraph (21) of this subdivision.

(21) Prohibition against discrimination in admission. No individual that meets level of care criteria for admission shall be denied admission to any program based solely on the following factors, including but not limited to:

(i) prior treatment history;

(ii) referral source;

(iii) pregnancy;

(iv) history of contact with the criminal justice system;

(v) HIV status;

(vi) physical or mental disability;

(vii) lack of cooperation by significant others in the treatment process;

(viii) toxicology test results;

(ix) use of any substance, including but not limited to, benzodiazepines; or

(x) use of medications for substance use disorder prescribed and monitored by an appropriate practitioner;

(xi) actual or perceived gender or gender identity;

(xii) national origin;

(xiii) race or ethnicity;

(xiv) actual or perceived sexual orientation;

(xv) marital status;

(xvi) military status;

(xvii) familial status; ~~or~~

(xviii) religion; or

(xix) age.

(22) Patients have the following rights with regard to access to medication for addiction treatment:

(1) Medication for Addiction Treatment (MAT) for Substance Use Disorder.

(i) Patients have the right to be offered or maintained on all forms of approved medication for substance use disorder treatment when admitted or seeking admission to any Office certified program, in accordance with guidance issued by the Office.

(ii) Patients have the right to be educated about all forms of FDA approved medications for the treatment of substance use disorders, including the benefits, risks and alternatives.

(23) Overdose Prevention Education. (i) Patients have the right to receive overdose prevention education and naloxone education and training, and a naloxone kit or prescription, in accordance with guidance issued by the Office.

815.6 Patient responsibilities.

(a) Participation in treatment for an addiction disorder presumes a patient's continuing desire to acquire healthy habits and requires each patient to act responsibly and cooperatively with provider staff, in accordance with an individual treatment/recovery plan and reasonable provider procedures. Therefore, each patient is expected to:

(1) work toward the goal of recovery, as defined by the patient;

(2) treat staff and other patients with courtesy and respect;

(3) respect other patients' right to confidentiality;

(4) participate in developing and following a treatment/recovery plan;

(5) become involved in productive activities according to ability;

(6) pay for services on a timely basis according to financial means;

(7) participate in individual counseling and/or group and/or family counseling sessions as appropriate;

(8) inform medical staff if receiving other medical or psychiatric services;

(9) address all personal issues adversely affecting treatment; and

(10) act responsibly and observe all provider rules, regulations and policies.

(b) Addressing patient non-adherence. (1) Provider policies and procedures to address patient non-adherence shall be strength-based, person-centered, trauma-informed and designed to support a patient's positive response to treatment. Such policies and procedures must specify standards and expectations for patient conduct, and any consequences of non-adherence, including conduct which may result in treatment termination.

(2) Providers shall address patient non- adherence with timely and appropriate incremental interventions that are strength-based, person centered, trauma-informed, and designed to assist patients in responding positively to treatment. Such incremental interventions shall be incorporated in the patient's treatment/recovery plan, be time-limited, and be documented in the patient's record.

(3) No treatment intervention or action can include delay or denial of any clinical, medical, or other required services vital to the health or recovery of the patient.

(4) Providers shall first warn patients of any conduct that could result in a recommendation of discharge with continued non- adherence, and must document such warning(s) in the patient's record.

(5) Patients have the ability to consent or refuse treatment recommendations from the program. Providers may not discharge a patient solely for their refusal to participate in a recommended service.

815.7 Procedure at discharge.

(a) The director of a facility or service provider shall be responsible for any recommendation to discharge a patient against the patient's wishes. The director or their designee shall implement such recommendations only after the director:

(1) reviews the recommendation to discharge to ensure that the reason(s) is fair, not arbitrary or capricious, and is serious enough to warrant discharge;

(2) reviews and evaluates the patient's total response to treatment, in light of the recommendation to discharge;

(3) confers with staff at a multidisciplinary meeting to discuss the patient's response to treatment and the recommendation to discharge;

(4) confirms that, within reasonable clinical judgment, all incremental strength-based and trauma-informed interventions have been tried but without success, including consideration of transfer to another provider;

(5) provides a written notice to the patient that indicates the reason(s) for the recommended discharge as well as required information on how to appeal;

(6) if the patient appeals, meets with the patient to conduct the appeal no sooner than twenty-four (24) hours after provision of the notice, to allow the patient time to seek the advice of others, if desired, and discusses with the patient the reasons to implement or rescind the recommendation to discharge; and

(7) informs the patient in writing of the decision to implement or rescind the recommendation to discharge no later than seventy-two (72) hours after the appeal is made;

(i) if discharge is decided after the appeal, assures that the patient receives information about treatment and referral options, and connections to such referrals if desired;

(ii) if rescission of the discharge is decided after the appeal, assure the patient full opportunity to continue treatment.

(b) For providers of opioid full agonist medications, no dose taper shall begin until after completion of the aforesaid process and all efforts to transfer the patient to another provider of opioid full agonist medications have been exhausted.

(c) For inpatient and residential providers, no patient shall be forced to leave the program until after completion of the aforesaid process. No patient shall be forced to leave the program between 6:00 P.M. and 8:00 A.M. unless appropriate arrangements have been made. Safe and appropriate transportation, travel arrangements, and travel costs shall be provided or arranged as needed.

(d) The patient, and their family/significant other(s) shall be offered overdose prevention education, naloxone education and training and a naloxone kit or prescription.

(e) None of the foregoing shall apply to an emergency discharge where the patient is determined reasonably to be a danger to others. A provider may make an emergency discharge immediately upon making such a determination, subject to the patient's right to appeal after the patient is discharged.

(f) A discharge pursuant to a patient's refusal to consent to a proper request to screen in accordance with section 815.10 of this Part may be made immediately upon the refusal but incremental strength-based and trauma informed interventions should be employed before a patient is discharged for the refusal, subject to the patient's right to appeal after the patient is discharged.

(g) All of the foregoing must be documented in the patient's record.

815.8 Toxicology testing.

(a) The provider may administer toxicology tests to a patient to ascertain the use and/or presence of alcohol and/or other substances, in accordance with program policies for screening, applicable regulations, clinical judgment, guidance issued by the Office and mindful of patient dignity. The provider shall inform a patient of each result and document all results in the patient's record. Supervised collection of a urine toxicology screen may only be conducted by persons of the same gender, or gender identity, as the patient, based on patient preference. Toxicology testing may not be used by a provider as a punitive tool.

(b) The provider must conduct such tests with reliable testing devices and administer such tests in accordance with manufacturer instructions and in compliance with all Department of Health requirements.

815.9 Patient use of prescription medicine.

(a) Patients have the right to use lawfully prescribed and properly monitored medication, including controlled substances, from a duly-authorized medical practitioner(s). For all such patients:

(1) The provider shall document the medication name, purpose, and administration frequency as well as the prescribing practitioner's name, phone number and, if applicable, affiliation;

(2) The provider shall seek to obtain a proper consent from the patient, in accord with 42 CFR Part 2, so that the provider practitioner may consult with the prescribing practitioner and discuss:

(i) the patient's medical condition**(s)**;

(ii) the prescribed medication(s), and available alternatives;

(iii) the best plan of services to be rendered by each practitioner, given the patient's concurrent treatment.

(3) If the patient refuses to consent or if the practitioners cannot agree on concurrent treatment, the provider practitioner shall discuss with the patient the possible risks of continued concurrent treatment. If refusal to consent continues or if the patient opts to continue taking the prescribed medicine in light of the explained possible risks, the provider may consider a recommendation for referral and connection to a more appropriate program.

(b) Inpatient and residential providers shall develop policies and procedures governing the handling and storage of patients' medications, including controlled substances, in accordance with applicable law, regulations and guidance issued by the Office. For such providers to take custody of such medicines lawfully, the provider must register with the New York State Department of Health as an Institutional Dispenser in accordance with the requirements of 10 NYCRR Part 80 and follow all applicable rules relating to storage of such medication.

(c) The provider shall not offer or withhold medical or pharmacological services, including prescribed medicines, for any reason other than medical necessity. The provider shall not delay, postpone, or withhold any prescribed medicine for a patient's non-adherence with a program rule, policy, or procedure. Only duly-authorized medical staff may deliver medical services and/or administer prescribed medicines.

815.10 Patient screening.

(a) The purpose of screening is to ensure a safe and therapeutic environment for all patients. However, patients shall be free from screening except as authorized pursuant to this section.

(b) Subject to the following requirements, a provider may choose to screen patients by establishing written policies and procedures provided to each patient at admission. Such policies may include the following:

(1) Routine screens of patients at admission or when returning to the service are permitted. Routine screening does not involve any physical contact between patient and staff; it does not involve having the patient remove all clothing; and the patient must consent to routine screening by the program.

(2) Screening of a patient's room or a patient's belongings may be conducted at any time with reasonable cause; consent for room screening may be requested by a program and granted upon admission.

(c) When a provider suspects that a patient may have items that may create an unsafe environment in the program, in lieu of a search that requires the patient to remove all clothing, or a body cavity search which is not permissible under any circumstances, providers should arrange for and develop alternative policies in accordance with guidance issued by the Office.

(d) If a patient refuses to consent to program identified alternatives to a body cavity search, they may be discharged in accordance with this Part.

(e) All items that may create an unsafe environment in the program must be disposed of in accordance with the applicable law including but not limited to 10 NYCRR Part 80.51, and 21 CFR Part 1307.21.

815.11 Research subjects.

(a) A person may participate only in research which does not conflict with their individual treatment/recovery plan. Participation as a "subject at risk" in any research project or activity shall not deprive any patient of the rights, privileges, and protections provided to all patients by this Part. "Subject at risk" means any individual who may be exposed to the possibility of injury, including physical, psychological or social injury, as a consequence of participation as a subject in any research, development or related activity which departs from the application of those established and accepted methods necessary to meet their needs or which increases the risks of daily life. The research project or activity must be approved by an independent institutional review board and the approval kept on file.

(b) Participation in any research project or activity and informed written consent.

(1) The informed written consent of a patient who participates as a subject at risk in any human subjects' research project shall be obtained in accordance with 45 Code of Federal Regulations Part 46.

(2) Prior to seeking consent required above, approval of any research placing human subjects at risk must be secured in accordance with 45 Code of Federal Regulations Part 46.

(3) Research projects which involve placing patients admitted to or enrolled in an addiction service at risk must be reported to the Office prior to initiation of the project.

815.12 Staff and client relationships

(a) Sexual contact prohibited. All sexual contact between OASAS program staff and a client is sexual abuse.

(b) Sexual contact includes inappropriate touching, indecent exposure, sexual assault, taking or distributing sexually explicit pictures, voyeurism or other sexual exploitation.

(c) A client is incapable of consenting to sexual contact if they are admitted to a program funded, certified or otherwise authorized by the Office.

(d) All staff shall be trained, upon hire and annually thereafter, on, and be provided with supervision about, maintaining appropriate boundaries with clients.

815.13 Severability.

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