Part 524 Amendments

Summary of Regulatory Changes

- Updated language throughout to conform with changes in naming conventions, including:
  - replacing gendered pronouns with gender neutral pronouns,
  - updating state agency names.
- 14 NYCRR Part 524.4 General Definitions.
  - Added a definition for human trafficking to mean a crime that involves compelling or coercing a person to provide labor or services, or to engage in commercial sex acts. Such coercion can be subtle or overt, physical, or psychological. Clarifies that exploitation of a minor for commercial sex is human trafficking, regardless of whether any form of force, fraud, or coercion was used.
- Section 524.5. Incident category definitions
  - Provides a definition for choking: to mean an event where a patient is unable to breathe as a result of ingestion of food or other foreign object, requiring a physical intervention (i.e. Heimlich Maneuver) resulting in serious injury or harm or admission to a hospital, or where there is a written directive for such patient concerning risk of choking in place at the time of the event.
  - Provides a definition for Inappropriate use of Restraint or Seclusion to include the use of restraint, as defined in Part 526.4, that is inappropriate because it was implemented without a valid physician's order or in a manner that was otherwise not compliant with applicable state or federal regulations, but which does not rise to the level of physical abuse, as defined in this section or the use of seclusion, as defined in Part 526.4, that was unauthorized because it was implemented without a valid physician's order or in a manner that was otherwise not compliant with applicable state or federal regulations.
  - Provides a definition for Human trafficking to include a patient of an inpatient or residential youth program, while on authorized leave or pass from the program.
  - Removes definition of mistreatment.

- Defines overdose to mean when a patient consumes an amount of a substance (e.g., prescription, over-the-counter, legal, or illegal) which is not intended to cause their own death, but results in serious injury or harm.
- Defines Reasonable Cause to Suspect to mean that based on all the evidence, facts, and circumstances known or readily available, it is rational to think a Reportable Incident may have occurred. Reasonable cause to suspect is a judgment about a statement, not about the condition, competency, or credibility of a patient.
- Redefines sexual assault to include nonconsensual sexual contact including the deliberate touching of a patient's intimate body parts, or clothing covering those body parts, or using force to cause self-touching by another patient of intimate body parts, or contact, that results in vaginal, anal, or oral penetration; any sexual contact between a person who is 18 years old or more and a person who is less than 15 years old, or between a person who is 21 years of age or older and a person who is less than 17 years old; or any sexual contact which involves a patient who is deemed incapable of consent.
- Clarifies that Sexual contact between children means vaginal, anal, or oral penetration by patients under age 18.
- Amends Wrongful Conduct to include activity of a sexual nature involving a patient and a custodian; or activity of a sexual nature involving a patient that is encouraged by a custodian to include social media. Adds the removal of a patient from regular programming and isolate them in an area for the convenience of a custodian or as a substitute for programming; and any intentional administration to a patient of a prescription drug or over-the-counter medication which is not in substantial compliance with a physician's, dentist's, physician's assistant's, specialist's assistant's, or nurse practitioner's prescription.

- Section 524.6. Incident management program
  - Is amended to provide that at a minimum, incident management programs shall consist of a written incident management plan which shall include the identification, review and documentation of incident patterns and trends.
- Section 524.7. Incident reporting requirements
  - Adds choking and inappropriate use of restraint of seclusion to the list of significant incidents when they occur on program premises.
  - Add OMH *Only Reportable Incidents* which must be reported to the Office in accordance with the provisions of Part 524.10 to include: Crimes in the Community; Missing Subject of AOT order; Off-site Suicide Attempt; Death of an individual receiving outpatient mental health services; or human trafficking.
- Section 524.8. Incident reporting procedures

  - Clarifies that incident management programs shall include procedures for promptly reporting incidents including OMH Reportable Incidents and that providers are responsible for immediately notifying OMH within 24 hours of discovery of such incident.
  - Clarifies that policies will be developed to address where patients have a demonstrated pattern of frequently reporting allegations of abuse or neglect and there is no reasonable cause to suspect that an incident occurred.
  - Clarifies that providers must establish a dedicated electronic mailbox to receive incident notifications to act on issues, including requests from the Office, in a timely manner.
- Section 524.9. Incident investigation, corrective action, and records maintenance
  - Clarifies that as soon as a provider of services is made aware that an allegation of abuse or neglect has been reported to the Justice Center, or a patient death has occurred, such provider is responsible for immediately conducting any assessment or review that may be necessary, provided, that witness statements, interviews, interrogations and written statements shall not be taken by anyone other than the designated investigating entity.
  - Clarifies that death reports must be submitted to the Justice Center and the Office within 5 business days of incident or discovery of incident and may be reopened and updated upon receipt of an autopsy report.
- Section 524.10. Additional incidents reportable to the Office of Mental Health
  - Clarifies that State operated or licensed mental health providers must immediately notify the Office, of OMH-Only reportable incidents when they occur off the premises of the facility or program or when the patient was not under the intended or actual supervision of a custodian.
- Section 524.11. Patient death reporting
  - Clarifies that the Justice Center Medical Review Board must be notified through the VPCR Death Reporting Unit, of the death of a patient of a State operated or licensed mental health provider who was enrolled in or receiving services from a CPEP, Inpatient, or Residential program at the time of the death, or whose death occurred within 30 days of discharge from such programs.
  - Clarifies that death reports from an Outpatient program must be made in accordance with Part 524.10.
- Section 524.12. Other required notifications
  - Updates provider procedures to assure notification to patients, family, or personal representatives occurs.

- Provides that upon admission patients and qualified persons shall be informed in writing of their rights to receive information pursuant to Mental Hygiene Law Sections 33.23 and 33.25.
- Clarifies that where an incident affects a patient's health or safety, or a reportable incident occurs involving an Allegation of Abuse or Neglect, Wrongful Conduct, Missing Patient, or Death, the agency must provide telephone notice to a qualified person, as defined in paragraph six of subdivision (a) of section 33.16 of the Mental Hygiene Law, within 24 hours of the initial reporting of an incident. Notice must not be provided where: the qualified person is the alleged abuser, there is written advice from the qualified person that they object to receiving such notification and the person receiving services is a capable adult who objects to such notification being made.
- A qualified person may request a copy of the written incident report, provided that the names and other personally identifiable information of patients and employees are redacted unless patients and employees authorize such disclosure; an opportunity to meet to discuss the incident; and receive within 10 days a written report on the actions taken to address the incident.
- Qualified persons may request in writing, records and documents related to reportable incidents including the results of the investigation within 21 days of either the conclusion of the investigation or the written request, whichever is later with appropriate redactions.
- Clarifies that incidents or allegations reported to the Justice Center, are not deemed to be serving a quality assurance function as defined by Social Services Law section 490(b).
- Clarifies that providers must maintain documentation including telephone notice and responses received, including the identity and position of the person providing the notice, the name of the person receiving the notice, the time of the original call or attempted call, the time of subsequent attempted calls if the initial call was not successful and the time of follow up calls if the notice occurred in more than one call; any requests for a meeting or the initial incident/occurrence report; meetings held in response to the request, and those present; a copy of the report on actions taken and any initial incident/occurrence report (with redaction) that was given to the qualified person; and advice that a particular qualified person does not want to receive notifications or that the capable adult receiving services objects to notice or objects to the provision of documents/information.
- Provides for an administrative appeal process for qualified persons who are denied access to records.

- Section 524.13. Analysis, review, and monitoring of incidents
  - Clarifies the Incident Review Committee to permit a state oversight agency to allow a facility or provider agency's incident review committee: to be shared with

another facility or provider agency or performed by another facility or provider agency on its behalf where a facility or provider agency is co-located within another organization or agency, or is part of a larger organization or agency, or has a larger "parent" or "umbrella" organization or agency

  - Provides that the composition of an Incident Review Committee must be such that a free and open exchange of information is ensured, in order to facilitate full and complete investigations. Requires committee membership to include: members of the governing body of the mental health provider; persons identified by the director of such provider, including direct support staff, licensed health care practitioners; service recipients; and representatives of family, consumer, or advocacy organizations.
  - Clarifies the Incident Review Committee must include a licensed health care practitioner (e.g. physician, physician assistant, nurse practitioner, or registered nurse), on a regular membership or ad hoc basis to participate in review of all medically related incidents.
  - Provides that the scheduling of Incident Review Committee meetings shall in no way preclude the prompt and thorough review of each incident and requires meetings within 45 days of acceptance of the report by the Justice Center and/or the Office, or sooner, should the circumstances so warrant, but no less frequently than on a quarterly basis.

- Section 524.14. Special investigations
  - Adds to the list of incidents, where the mental health provider shall ensure that a special investigation is completed to include Inappropriate use of Restraint or Seclusion; and Financial Exploitation.
- Section 524.15. Employee code of conduct and training
  - Clarifies that Directors of mental health providers shall ensure that all employees who are Mandated Reporters shall receive training in the following areas upon hire and at least on an annual basis: abuse prevention, identification, reporting, and processing of allegations of abuse and neglect; laws, regulations and policies/procedures governing protection from allegations of abuse and neglect; and incident reporting and processing.

14 NYCRR Part 524 is amended to read as follows:

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Section 524.4. General definitions

As used in this Part:

(a) **Custodian** means:

(1) a director, operator, employee, security personnel, or volunteer of a mental health provider; or

(2) a contractor that performs services pursuant to a contract that permits regular and substantial contact with patients of a mental health provider.

(b) **Discovery** means at the time a Mandated Reporter witnesses an activity which appears to be a [R]reportable [I]incident or when any other person comes before the Mandated Reporter in [~~his or her~~] their professional or official capacity and provides information that gives the Mandated Reporter reasonable cause to suspect that a [R]reportable [I]incident has occurred.

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(n) **Qualified person** means any person who may request access to a patient's clinical record in accordance with section 33.16 of the Mental Hygiene Law.

(o) **Reportable Incident** means Significant Incidents including death, and allegations of Abuse and Neglect that must be reported to the Justice Center for the Protection of Persons with Special Needs and the Office.

(p) **Restraint** means the use of any manual, pharmacological or mechanical measure or device to immobilize or limit the ability of a person receiving services to freely move [~~his or her~~] their arms, legs, head or body.

(q) **Serious injury or harm** means:

(1) physical harm requiring medical treatment or intervention beyond first aid, including the use of an opioid antagonist(i.e. Narcan/Naloxone)when used to counter the effects of a suspected opioid overdose (excluding routine diagnostic tests such as laboratory work, X-rays, or scans if no medical treatment is [~~provided~~]indicated);

(2) psychological harm evidenced by negative changes in affect, behavior, cognition, or which necessitate a significant change in psychotropic or psychotherapeutic intervention; or

(3) a risk for life threatening physical injury or for psychiatric emergency or trauma

(r) Human trafficking, also known as trafficking in persons, means a crime under the penal law that involves compelling or coercing a person to provide labor or services, or to engage in commercial sex acts. The coercion can be subtle or overt, physical, or psychological. Exploitation of a minor for commercial sex is human trafficking, regardless of whether any form of force, fraud, or coercion was used.

([r]s) Significant [i]Incident means a Reportable Incident, other than an incident of abuse or neglect, that because of its severity or the sensitivity of the situation may result in, or has the reasonably foreseeable potential to result in, harm to the health, safety or welfare of a patient.

([s]t) Vulnerable Persons' Central Register means the statewide Vulnerable Persons' Central Register of the Justice Center established pursuant to Section 492 of the Social Services Law.

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Section 524.5. Incident category definitions

For purposes of reporting incidents pursuant to Section 524.7 of this Part, the following terms are defined; provided, however, nothing contained herein shall be construed as restricting the discretion of the Justice Center in categorizing incident reports:

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(c) **Choking**: an event where a patient is unable to breathe as a result of ingestion of food or other foreign object which requires a physical intervention (i.e. Heimlich Maneuver): (1) that results in serious injury or harm or admission to a hospital, or (2) where there is a written directive for such patient concerning risk of choking in place at the time of the event.

([c]d) **Crime:** an event which is or appears to be a crime under New York State or Federal law, which occurs on program premises or when a patient is under the actual or intended supervision of a custodian, and which involves a patient as a victim, or which affects or has the potential to affect the health or safety of one or more patients of the program or has the potential to have a significant adverse impact on the property or operation of the program. For the purposes of this Part, crimes shall include acts committed by persons less than [16] 18 years of age which, if committed by an adult, would constitute a crime.

([d]e) **Crimes in the Community:** an event which is, or appears to be, a crime under New York State or Federal law, and which is perceived to be a significant danger to the community, or which involves a patient whose behavior poses an imminent concern to the community.

([e]f) **Falls by patients:** events where patients trip, slip, or otherwise fall while in an inpatient or residential setting, resulting in serious injury or harm.

([f]g) **Fight:** a physical altercation between two or more patients, in which there is no clear aggressor and no clear victim, resulting in serious injury or harm.

([g]h) **Financial exploitation**: use, appropriation, or misappropriation by a custodian of a patient's resources, including but not limited to funds, assets, or property, by deception, intimidation, or similar means, with the intent to deprive the patient of those resources. Examples include the deliberate misplacement, theft, or wrongful, temporary, or permanent use of a patient's belongings or money.

([h]i) **Fire setting:** action by a patient of a mental health provider, either deliberate or accidental, that results in fire on program premises.

(j) **Inappropriate use of Restraint or Seclusion**.

(1) use of restraint, as defined in section 526.4 of this Title, that is inappropriate because it was implemented without a valid physician's order or in a manner that was otherwise not compliant with applicable state or federal regulations, but which does not rise to the level of physical abuse, as defined in this section or

(2) use of seclusion, as defined in section 526.4 of this Title, that was unauthorized because it was implemented without a valid physician's order or in a manner that was otherwise not compliant with applicable state or federal regulations.

([I]k) **Injury of unknown origin:** an injury to a patient for which a cause cannot be immediately determined because:

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(l) **Human trafficking – Off Site:** A patient of an inpatient or residential youth program, while on authorized leave or pass from the program, is the victim of human trafficking.

([j]m) **Medication error:** an error in prescribing, dispensing, or administering a drug which results in serious injury or harm.

([k]n) **Missing patient.**

(1) a patient of an inpatient or residential program:

(i) who has not been accounted for when expected to be present (in accordance with facility or program practice or policies) and who has not been found on the facility grounds or other expected location, or

(ii) who is known to have left the facility grounds without the permission of an employee, when such permission is otherwise required and who is considered dangerous to others or unable to care for themselves [~~him/herself~~]; or

(iii) who has not been accounted for when expected to be present and while missing was a victim of human trafficking.

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([l]o) **Missing subject of AOT Order**: A person subject to an Assisted Outpatient Treatment (AOT) order who fails to keep a scheduled appointment and[~~/or~~] who cannot be located within a 24-hour period, or who cannot be located within a 24-hour period.

[~~(m)~~ ~~**Mistreatment**~~.

> (~~1) use of restraint, as defined in section 526.4 of this Title, that is inappropriate because it was implemented without a valid physician's order or in a manner that was otherwise not compliant with applicable state or federal regulations, but which does not rise to the level of physical abuse, as defined in this section;~~
>
> ~~(2) use of seclusion, as defined in section 526.4 of this Title, that was unauthorized because it was implemented without a valid physician's order or in a manner that was otherwise not compliant with applicable state or federal regulations;~~
>
> ~~(3) removal of a patient from regular programming and isolate him/her in an area for the convenience of a custodian or as a substitute for programming; or~~
>
> ~~(4) any intentional administration to a patient of a prescription drug or over-the-counter medication which is not in substantial compliance with a physician's, dentist's, physician's assistant's, specialist's assistant's, or nurse practitioner's prescription.~~]

([n]p) **Neglect:** any action, inaction or lack of attention that breaches a custodian's duty and that results in or is likely to result in physical injury or serious or protracted impairment of the physical, mental or emotional condition of a patient. Neglect shall include, but is not limited to:

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([o]q) **Other Incident:** An event, other than one identified in this section, which has or creates a risk of serious injury or harm [,~~a serious adverse effect on the life, health, or safety of a patient~~]

(r) **Overdose:** When a patient consumes an amount of a substance (e.g., prescription, over-the-counter, legal, or illegal) which is not intended to cause their own death, but results in serious injury or harm.

(s) **Reasonable Cause to Suspect:** Based on all the evidence, facts, and circumstances known or readily available, it is rational to think a Reportable Incident may have occurred. Reasonable cause to suspect is a judgment about a statement, not about the condition, competency, or credibility of a patient.

([p]t) **Self-abuse:** self-inflicted injury not intended to result in death that results in serious injury or harm.

([q]u) **Severe adverse drug reaction:** an unintended, unexpected, or excessive response of a patient to a medication that occurs at doses normally used in patients for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function and which:

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[~~(r)~~ ~~**Sexual assault:**~~ ~~a sexual attack including but not limited to those that result in vaginal, anal, or oral penetration, i.e., rape or attempted rape and sodomy or attempted sodomy; and/or any sexual contact between a person who is 18 years old or more and a person who is less than 15 years old, or between a person who is 21 years of age or older and a person who is less than 17 years old, or which involves a patient who is deemed incapable of consent~~.]

(v) **Sexual assault:**

(i) nonconsensual sexual conduct including the deliberate touching of a patient's intimate body parts, or clothing covering those body parts, or using force to cause self-touching by another patient of intimate body parts, or contact, that results in vaginal, anal, or oral penetration, i.e., rape or attempted rape and sodomy or attempted sodomy; or

(ii) any sexual conduct between a person who is 18 years old or more and a person who is less than 15 years old, or between a person who is 21 years of age or older and a person who is less than 17 years old; or

(iii) any sexual conduct which involves a patient who is deemed incapable of consent.

([s]w) **Sexual contact between children:** vaginal, anal, or oral penetration by patients under age 18 [~~that occurs in a setting where the patient receives around-the-clock care or on the premises of an outpatient program~~].

([t]x) **Suicide attempt:** an act committed by a patient of a mental health provider in an effort to cause [~~his or her~~] their own death that occurs on program premises or when the patient was under the actual or intended supervision of a custodian.

([u]y) **Suicide attempt, Off Site**: an act committed by a patient of a mental health provider in an effort to cause [~~his or her~~] their own death that occurs off program premises, when the patient was not under the actual or intended supervision of a custodian.

([v]z) **Verbal Aggression by Patients:** a sustained, repetitive action or pattern by a patient or patients of ridiculing, bullying, demeaning, making derogatory remarks, verbally harassing, or threatening to inflict physical or emotional harm on another patient or patients, which causes serious injury or harm.

([w]aa) **Wrongful Conduct**: Actions or inactions on the part of a custodian that are contrary to sound judgment or training, and which are related to the provision of services, the safeguarding of patient health, safety, or welfare, or patient rights, but which do not meet the definition of abuse or neglect, including but not limited to:

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(3) activity of a sexual nature (physical or non-physical) involving a patient and a custodian; or activity of a sexual nature involving a patient that is encouraged by a

custodian. Examples include inappropriate touching or physical contact, sending sexually explicit materials through electronic means (including but not limited to mobile phones, electronic mail, and social media[etc.]), voyeurism, or sexual exploitation; [or]

(4) conduct that falls below the standards of behavior established in regulations or facility policies and procedures for the protection of patients against unreasonable risk of harm [(e.g., sleeping while on duty).];

(5) removal of a patient from regular programming and isolate them in an area for the convenience of a custodian or as a substitute for programming; or

(6) any intentional administration to a patient of a prescription drug or over-the-counter medication which is not in substantial compliance with a physician's, dentist's, physician's assistant's, specialist's assistant's, or nurse practitioner's prescription.

Section 524.6. Incident management program

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(b) At a minimum, incident management programs shall consist of the following components:

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(2) Incident management plan. Mental health providers shall develop and implement a written incident management plan, which shall include the following:

(i) the goals and objectives of the incident management program; and

(ii) the policies and procedures for the operation of the incident management program which address, at a minimum, the following:

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(*d*) identification, [and] review and documentation of incident patterns and trends; and

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Section 524.7. Incident reporting requirements

§524.7 Incident reporting requirements.
The following incidents are considered [R]reportable [I]incidents which must be reported to the Justice Center and/or the Office in accordance with the provisions of Section 524.8 of this Part:

(a) *Allegations of Abuse or Neglect*
(1) Physical abuse;
(2) Psychological abuse;

(3) Sexual abuse;
(4) Deliberate Inappropriate Use of Restraint;
(5) Obstruction of reports of [R]reportable [I]incidents;
(6) Unlawful use or administration of controlled substance;
(7) Use of Aversive Conditioning; or
(8) Neglect.

(b) *Significant Incidents:* The following incidents are Significant Incidents when they occur on program premises or, with the exception of paragraph ([3]4), when the patient was under the actual or intended supervision of a custodian when the event occurred:

(1) Assault;
(2) Choking;
([2]3) Crime;
([3]4) Falls by patients while in an inpatient or residential setting;
([4]5) Fights;
([5]6) Financial exploitation;
([6]7) Firesetting;
([7]8) Injury of unknown origin;
([8]9) Medication errors;
([9]10) Missing patient;
([10]11) [~~Mistreatment;~~]Inappropriate use of Restraint or Seclusion;
([11]12) Other Incident;
(13) Overdose;
([12]14) Self abuse;
([13]15) Severe adverse drug reaction;
([14]16) Sexual contact between children;
([15]17) Sexual assault;
([16]18) Suicide attempt;
([17]19) Verbal aggression by Patients;
([18]20) Wrongful conduct.

(c) *OMH-Only Reportable Incidents:* The following incidents are considered reportable incidents which must be reported to the Office in accordance with the provisions of Section 524.10 of this Part:

(1) Crimes in the Community;
(2) Missing Subject of AOT order;
(3) Suicide Attempt, Off-Site;
(4) Death of an individual receiving outpatient mental health services; or
(5) A patient of an inpatient or residential youth program, while on authorized leave or pass from the program, is the victim of human trafficking.

Section 524.8. Incident reporting procedures

Incident management programs shall include procedures for promptly reporting incidents consistent with the following:

(a) Reportable [I]incidents identified in section 524.7(a), [and] (b), and (c) of this Part that must be reported to the Justice Center and/or the Office must be made in accordance with the following, provided, however, that nothing in this Section shall

be deemed to prohibit a Mandated Reporter from contacting or reporting to law enforcement or emergency services before or after making a report to the Vulnerable Persons' Central Register.

(1) Justice Center. Employees of mental health providers who are Mandated Reporters, must immediately make a report of a Reportable Incident to the Justice Center's Vulnerable Persons' Central Register, upon discovery of what appears to be a Reportable Incident.

(i) The report to the Register shall include the name, title, and contact information of every person known to the Mandated Reporter to have the same information as the Mandated Reporter concerning the incident.

(ii) If the reportable incident is a death for which there is any reason to believe that abuse or neglect may be involved, the Mandated Reporter must immediately contact the Justice Cnter's Vulnerable Persons' Central Register 24/7 Hotline and provide all information requested by the Justice Center, to the best of [~~his/her~~] their ability.

(iii) The Mandated Reporter must immediately notify the director of the mental health provider, or [~~his/her~~] their designee, that a report has been made.

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(2) Office of Mental Health. Mental health providers are responsible for immediately notifying the Office of Reportable Incidents within 24 hours of [~~occurrence or~~ discovery[~~, whichever occurs first~~].

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(e) In cases where multiple mandated reporters have direct knowledge of the same reportable incident or have reasonable cause to suspect such incident has occurred, each mandated reporter is required to report such incident, unless they know [~~he or she knows~~] that the report has already been made by another mandated reporter and that this person [~~he or she~~] has been named in that report as a person with knowledge of such incident. Providers shall establish written protocols to ensure reports involving multiple mandated reporters are properly made and documented.

(f) The Office shall develop protocols in consultation with the Justice Center to assist providers in appropriately and therapeutically responding in circumstances where patients have a demonstrated pattern of frequently reporting allegations of abuse or neglect where there is no reasonable cause to suspect that an incident occurred. [~~that are not reasonably reliable (i.e., there is no possibility that an allegation is true).~~]

(g) In circumstances where a patient reports an allegation of abuse or neglect to a provider which appears to be impossible or incredible, such provider shall promptly review the matter and must determine, within 24 hours of such report, whether there is reasonable cause to suspect that [~~believe~~] a reportable incident has occurred. Discovery of the incident shall be deemed to be when the provider determined that such reasonable cause exists. If it is determined that reasonable cause does not exist and a report is not made to the Justice Center, such decision shall be documented.

(h) [~~The Office shall identify a standard process to be used by providers by which incident reporting and management notifications, alerts, and any other correspondence necessary for the timely follow up of reportable events are received and organized~~.] Providers must establish a dedicated electronic mailbox to receive incident notifications in order to act on issues, including requests from the Office, in a timely manner.

Section 524.9. Incident investigation, corrective action, and records maintenance

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(c) Investigation Process. Investigations conducted by the Office and mental health providers shall be governed by the provisions of this subdivision.

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(3) Restrictions.

(i) No one may conduct the investigation of any [R]reportable [I]incident in which [~~he or she was~~] they were directly involved, or in which [~~his~~] their testimony has been incorporated, or in which a spouse, domestic partner, or immediate family member was directly involved.

(ii) No party in the line of supervision of staff who were directly involved in a [R]reportable [I]incident may conduct the investigation, provided, however, the director of the mental health provider may conduct the investigation if [~~he or she is~~] they are not an immediate supervisor of any staff who were directly involved in such incident.

(4) Commencing the investigation. As soon as a provider of services is made aware that an allegation of abuse or neglect has been reported to the Justice Center, or a patient death has occurred, such provider is responsible for immediately conducting any assessment or review that may be necessary, provided, however, that witness statements, interviews and interrogations are not conducted and written statements shall not be taken by anyone other than the investigating entity designated in accordance with paragraph (2) of this subdivision. If the Justice Center or the Office subsequently assumes responsibility for the investigation, the provider must identify the initial investigatory steps that have been taken and supply any and all preliminary information it has obtained.

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(d) Final Reports.

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(4) Submission of reports or investigative findings:

(i) Final reports and investigative findings for [R]reportable [I]incidents must be submitted in the manner, form, and format specified by the Justice Center and the Office.

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(iv) Death Reporting. Death reports must be submitted to the Justice Center and the Office within 5 business days of incident or discovery of incident. A Death Report shall be reopened and updated upon receipt of an autopsy report, where applicable.

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Section 524.10. Additional incidents reportable to the Office of Mental Health

(a) State operated or licensed mental health providers shall immediately notify the Office, in a form and format prescribed by the Office, of OMH-Only reportable incidents when they occur off the premises of the facility or program or when the patient was not under the intended or actual supervision of a custodian. [In addition to reportable incidents, pursuant to Mental Hygiene Law section 29.29, State operated or licensed mental health providers shall immediately notify the office, in a form and format prescribed by the office, of the following incidents when they occur off the premises of the facility or program or when the patient was not under the intended or actual supervision of a custodian.
(1) crimes in the community;
(2) missing subject of AOT order;
(3) suicide attempt, off-site.]

(b) These incidents shall not be reported to the Vulnerable Persons' Central Register, but must be reported and investigated consistent with guidelines of the Office.

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Section 524.11. Patient death reporting

(a) State operated or licensed mental health providers are responsible for reporting the death of a patient who was enrolled in or receiving services from the facility or program at the time of the death, or whose death was within 30 days of discharge from a mental health program.

(b) Reports of patient death must be made in accordance with the following:

(1) Justice Center Medical Review Board.

(i) The Justice Center Medical Review Board must be notified through the VPCR Death Reporting Unit, of the death of a patient of a State operated or licensed mental health provider who was enrolled in or receiving services from a CPEP, Inpatient, or Residential [patient who was enrolled in or receiving services from the program the facility or] program at the time of the death, or whose death occurred within 30 days of discharge from such [a mental health] programs.

(ii) Such notification must be made immediately upon discovery of the death, and in no event later than 24 hours thereafter in the form and format prescribed by the Justice Center, and shall include:

(*a*) the name and age of the deceased;

(*b*) the date, time, location and circumstances of the death;

(*c*) to the extent known, whether or not the death:

(*1*) was related to an accident;

(*2*) may have resulted from a suicide or homicide;

(*3*) may have resulted from a medication overdose, or the use of controlled substance or alcohol;

(*4*) occurred within 72 hours of the use of restraint or seclusion; or

(*5*) may be an unexplained death.

(iii) The director or [~~his/her~~] their designee shall submit any additional information requested by the Justice Center within five working days of such request, in the manner prescribed by the Justice Center.

(iv) In addition to the information submitted in accordance with subparagraph (iii) of this paragraph, a report of any autopsy performed on the decedent shall be submitted to the Justice Center within 60 working days of the report made to the Justice Center, provided, however, that the Justice Center may extend that timeframe for good cause shown.

(2) Coroner/medical examiner. The following shall be reported to the coroner/medical examiner:

(i) the death of a patient resulting from an apparent homicide, suicide, or unexplained or accidental cause;

(ii) the death of a patient which is unrelated to the natural course of illness or disease; or

(iii) the death of a patient which is related to the lack of treatment provided in accordance with generally accepted medical standards.

(c) Reports of patient death from an Outpatient program must be made in accordance with Part 524.10.

Section 524.12. Other required notifications

In addition to the reporting requirements identified in section 524.7 of this Part, mental health providers shall have procedures to assure that the following notifications occur:

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(b) Notification to patients, family, or personal representatives.

[(~~1) Patients may be notified of the outcome of incidents involving them, if and as clinically appropriate, and in accordance with applicable Federal and State laws and regulations.~~

~~(2) Next of kin/persons involved in care. Consistent with Federal and State confidentiality laws and regulations, the patient's next of kin or other persons identified in the patient's plan of care as a person involved in his or her care, shall be notified immediately of allegations of abuse or neglect, missing patients or incidents involving patient death or injury.~~

~~(3) Qualified persons. In accordance with the procedures identified in Mental Hygiene Law section 33.23, providers of mental health services subject to this Part must provide telephone notice to a qualified person of a patient of a reportable incident involving such patient and identified as injury, death, medication error, missing person, or allegation of abuse or neglect within 24 hours of the initial report of the incident~~.]

(1) Upon admission patients and qualified persons shall be informed in writing of their rights to receive information pursuant to Mental Hygiene Law Sections 33.23 and 33.25.

(i) When an incident affects a patient's health or safety, or a reportable incident occurs involving an Allegation of Abuse or Neglect, Wrongful Conduct, Missing Patient, or Death, the agency must provide telephone notice to a qualified person, as defined in paragraph six of subdivision (a) of section 33.16 of the Mental Hygiene Law, within 24 hours of the initial reporting of an incident.

(ii)The agency must not provide such notice to a qualified person in the following situations:

(*a*) if the qualified person is the alleged abuser;

(b) if there is written advice from the qualified person that they object to receiving such notification. The notice must then be provided to another qualified person if one exists; or

(*c*) if the person receiving services is a capable adult who objects to such notification being made.

(*1)* If the capable adult objects to notification of a qualified person, the capable adult must be provided the notice described in this subdivision.

(iii) At the qualified person’s request, the following must be completed:

(*a*) provide the qualified person with a copy of the written incident report, provided that the names and other personally identifiable information of patients and employees are redacted unless patients and employees authorize such disclosure;

(*b*) meet with the qualified person to discuss the incident; and

(*c*) within 10 days send the qualified person a written report on the actions taken to address the incident (Actions Taken Report).

(iv) In accordance with Mental Hygiene Law 33.25, upon written request to the provider, qualified persons may obtain records and documents related to reportable incidents including the results of the investigation within 21 days of either the conclusion of the investigation or the written request, whichever is later, provided that the names and other personally identifiable information of patients and employees are redacted unless patients and employees authorize such disclosure.

(v) In accordance with Mental Hygiene Law section 33.25, incidents or allegations reported to the Justice Center, shall not be deemed to be serving a quality assurance function as defined pursuant to Social Services Law section 490(b). As such, the only information that may be redacted are names and other personally identifying information of other patients and employees unless such patients and employees authorize disclosure.

(2) The following documentation must be maintained by the provider:

(i) the telephone notice and responses received, including the identity and position of the person providing the notice, the name of the person receiving the notice, the time of the original call or attempted call, the time of subsequent attempted calls if the initial call was not successful and the time of follow up calls if the notice occurred in more than one call;

(ii) any requests for a meeting or the initial incident/occurrence report;

(iii) meetings held in response to the request, and those present;

(iv) a copy of the report on actions taken and any initial incident/occurrence report (with redaction) that was given to the qualified person; and

(v) advice that a particular qualified person does not want to receive notifications or that the capable adult receiving services objects to notice or objects to the provision of documents/information.

(vi) a copy of the full investigative report with identifying names of employees.

(3) Administrative appeal process—denial of requested records/documents.

(i) A qualified person denied access to the records and documents requested pursuant to this section may appeal such denial, in writing, [such denial]to the Office of Mental Health’s Office of Quality Improvement.

(ii) Upon receipt of the appeal, the agency issuing the denial will be notified of the appeal and given an opportunity to submit relevant information to the Office of Quality Improvement, including the reasons for denial, within 10 business days of the receipt of such appeal. The Office of Quality Improvement may also request

additional information from the qualified person as may be necessary to resolve the appeal.

(iii) Within 10 business days of the receipt of complete information, the Office of Quality Improvement will make a determination about whether the requested records and/or documents should be released. The Office of Quality Improvement will issue their determination with an explanation of the reasons for the determination to the qualified person and the agency. If so, directed by the Office of Quality Improvement, the agency must provide the requested records and/or documents to the requestor.

(iv) Note that records maintained by the agency may also be available under section 496 of the Social Services Law to *other persons named in the report* as defined in section 488 of the Social Services Law.

Section 524.13. Analysis, review, and monitoring of incidents

(a) Mental health providers are responsible for compiling and analyzing incident data for [R]reportable [I]incidents, incidents reported to the Office pursuant to section 524.10 of this Part, and patient death, for the purpose of identifying possible patterns and trends and to determine the timeliness, thoroughness, and appropriateness of the provider's responses.

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(2) Reviews shall not be considered to be complete until all relevant information, (including final investigation reports and relevant systems analyses), has been gathered, opportunities for improvement have been identified, and, if deemed necessary, plans of correction/prevention have been developed, implemented, and monitored for efficacy.

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(b) Incident Review Committees. Each mental health provider shall appoint a standing Incident Review Committee to assure that all [R]reportable [I]incidents, incidents reported to the Office pursuant to section 524.10 of this Part, and patient death, are reviewed and monitored, that all reportable incidents that may adversely affect the care and safety of patients are appropriately addressed, and that preventive and corrective measures are identified, as appropriate.

(1) Incident Review Committees may be organized on a provider-wide, multi-program or program-specific basis, and may have responsibilities other than those related to incident management. [~~The composition of an Incident Review Committee must be such that a free and open exchange of information is ensured, in order to facilitate full and complete investigations. Providers shall maintain current documentation attesting that committee membership at least includes:~~

~~(i) members of the governing body of the mental health provider;~~

~~(ii) persons identified by the director of such provider, including some members of the following:~~

~~(*a*) direct support staff, which shall mean staff who are involved in the provision of direct care services;~~

~~(*b*) licensed health care practitioners;~~

~~(*c*) service recipients; and~~

~~(*d*) representatives of family, consumer, or advocacy organizations.~~]

(i) A state oversight agency may allow a facility or provider agency's incident review committee:

(a) to be shared with another facility or provider agency or

(b) performed by another facility or provider agency on its behalf where a facility or provider agency is co-located within another organization or agency, or is part of a larger organization or agency, or has a larger "parent" or "umbrella" organization or agency

(ii) The composition of an Incident Review Committee must be such that a free and open exchange of information is ensured, in order to facilitate full and complete investigations. Providers shall maintain current documentation attesting that committee membership at least includes:

(i) members of the governing body of the mental health provider;

(ii) persons identified by the director of such provider, including some members of the following:

(*a*) direct support staff, which shall mean staff who are involved in the provision of direct care services;

(*b*) licensed health care practitioners;

(*c*) service recipients; and

(*d*) representatives of family, consumer, or advocacy organizations.

(2) The director of the mental health provider shall not be a member of the Incident Review Committee. For purposes of this Section, "director" shall mean:

(i) the Executive Director of a State operated facility; or

(ii) the Chief Executive Director of a licensed provider of mental health services, as designated by the signatory (or [~~his/her~~]their successor) of the Prior Approval Review form Part A Acknowledgment submitted in accordance with Part 551 of this title.

(3) The Incident Review Committee shall include a licensed health care practitioner (e.g. physician, physician assistant, nurse practitioner, or registered nurse) [physician], on a regular membership or ad hoc basis. These licensed health care practitioners [physician] shall participate in review of all medically related incidents.

(4) The scheduling of Incident Review Committee meetings shall in no way preclude the prompt and thorough review of each incident. Each Incident Review Committee shall meet within 45 days of [completion of any pending investigation,] acceptance of the report by the Justice Center and/or the Office, or sooner, should the circumstances so warrant, but no less frequently than on a quarterly basis, to allow for the timely review and closure of incidents.

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(7) Written minutes of all meetings shall be maintained.

(i) Minutes shall indicate when review of a particular incident has been completed. Review shall be deemed complete when all relevant information, including the final investigative report, has been gathered, opportunities for improvement have been identified, and plans of correction/prevention have been developed, [and] implemented, and monitored.

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Section 524.14. Special investigations

(a) For the following types of incidents, if the Justice Center is not conducting an investigation, the mental health provider shall ensure that a special investigation is completed.

(1) Inpatient homicides;

(2) Inpatient suicides;

(3) All inpatient deaths except natural deaths;

(4) Homicide and suicide attempts by inpatients;

(5) Allegations of abuse and neglect;

(6) Inpatient assaults resulting in serious injury to any person, including sexual assaults;

(7) Missing patients of inpatient programs; [and]

(8) Wrongful conduct[.];

(9) Inappropriate use of Restraint or Seclusion; and

(10) Financial Exploitation.

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Section 524.15. Employee code of conduct and training

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(b) Training.

(1) Directors of mental health providers shall ensure that all employees who are Mandated Reporters shall receive training in the following areas upon hire and at least on an annual basis:

(i) abuse prevention, identification, reporting, and processing of allegations of abuse and neglect;

(ii) laws, regulations and policies/procedures governing protection from allegations of abuse and neglect; and

(iii) incident reporting and processing.

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14 NYCRR Parts 524

Regulatory Impact Statement

1. Statutory Authority: Section 7.07 of the Mental Hygiene Law gives the Office of Mental Health the responsibility for seeing that persons with mental illness are provided with care and treatment. Sections 7.09 and 31.04 of the Mental Hygiene Law grant the Commissioner of Mental Health the authority and responsibility to adopt regulations that are necessary and proper to implement matters under his or her jurisdiction. Section 7.21 of the Mental Hygiene Law requires directors of facilities operated by the Office of Mental Health to investigate, or cause to be investigated, every reportable incident in accordance with Article 11 of the Social Services Law. Section 29.29 of the Mental Hygiene Law requires the establishment of uniform standards and procedures for the compilation and analysis of incident reports in facilities operated by the Office of Mental Health. Section 31.11 of the Mental Hygiene Law requires programs licensed by the Office of Mental Health to notify the district attorney or other law enforcement official and the Commissioner or his or her authorized representative if it appears that a crime may have been committed against a patient. Section 33.25 of the Mental Hygiene Law requires the release of records and documents pertaining to allegations and investigations of abuse or neglect to qualified persons. Section 556 of the Executive Law provides the Justice Center the authority to make recommendations of preventive and remedial actions to the Office of Mental Health in response to investigations of allegations of abuse or neglect involving patients. Sections 490, 491 and 492 of the Social Services Law requires the Office of Mental Health to promulgate regulations governing the development of incident management programs and require the reporting of allegations of abuse and neglect and significant incidents to the Vulnerable Persons' Central Register.

2. Legislative Objectives: Articles 7 and 31 of the Mental Hygiene Law reflect the Commissioner's authority to establish regulations regarding mental health programs.

3. Needs and Benefits: The purpose of this Part is to ensure that providers of mental health services develop and implement effective incident management programs in order to protect the health and safety of patients and enhance their quality of care. This was necessary due to an audit which indicated that providers we not incompliance with the requirements surrounding Mental Hygiene Law sections 33.23 and 33.25. Suggested amendments were developed based upon feedback from various providers of services, State oversight agencies and family input. Incident management programs include the components of effective abuse protection; the classification of incidents; tracking and trending of incidents; and implementing effective actions to protect individuals served from harm. Clarifies that providers review incident trends to identify areas for improvement through use of databases.

4. Costs:

(a) Cost to State government: There are no new costs to State or local government as a result of these amendments. Additional time will be required of providers to improve the documentation of their efforts to comply with Mental Hygiene Law sections 33.23 and 33.25.

5. Local government mandates:

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

6. Paperwork: There may be additional reporting requirements for some providers, but such reporting will be generated through provider accessible databases.

7. Duplication: These regulatory amendments do not duplicate existing State or federal requirements.

8. Alternatives: The only alternative considered to the proposed amendment was to leave Part 524 as is currently written. The proposed amendments conform the regulation to current statutory authority and provide additional clarification. Without such amendments, there would be conflict between the regulation as written and the enacting statute. Many of the changes suggested have been developed based upon feedback from various providers of services, State oversight agencies and family input. These changes aim to improve the reporting process and provide clarity to the requirements.

9. Federal standards: There are currently no federal standards specific to the provision of these services.

10. Compliance schedule: The amendments would be effective upon adoption.