Office of the Registrar of Regulations,
Legislative Council,
State of Delaware

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF DEVELOPMENTAL DISABILITIES SERVICES

Statutory Authority: 29 Delaware Code, Section 7909A(e) (29 **Del.C.** §7909A(e))

PROPOSED

PUBLIC NOTICE

2103 Reportable Incident Management and Corrective Measures

In compliance with the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the Delaware Code), 42 CFR §447.205, and under the authority of Title 31 of the Delaware Code, Chapter 5, Section 512, Delaware Health and Social Services (DHSS)/Division of Developmental Disabilities Service (DDDS) is proposing to implement oversight and monitoring of reportable incidents pursuant to DHSS Policy Memorandum 46.

Any person who wishes to make written suggestions, compilations of data, testimony, briefs or other written materials concerning the proposed new regulations must submit same to James Dickinson, Division of Developmental Disabilities, Service Integrity and Enhancement, 1056 South Governor's Avenue, Suite 101, Dover DE 19947, E-Mail: james.dickinson@delaware.gov by October 1, 2019.

The action concerning the determination of whether to adopt the proposed regulation will be based upon the results of Department and Division staff analysis and the consideration of the comments and written materials filed by other interested persons.

SUMMARY OF PROPOSAL

The proposal creates regulations to ensure the health and safety of persons served in Home and Community-Based Services (HCBS) by the Division of Developmental Disabilities Services (DDDS) under its contracts with providers, consistent with Policy Memorandum 46 (PM46) of the Department of Health and Social Services (DHSS).

Under this policy, DDDS is responsible for oversight and monitoring of the prevention, discovery, investigation, and correction of Reportable Incidents and all other threats to the safety and health of DDDS service recipients.

Statutory Authority

Title 16 of the **Delaware Code**, Chapter 55, Subchapter 1, Section 5506
DHSS PM46
29 **Del.C.** §7909A(e)

Background

PM46 was updated August 2016 and requires DDDS to establish rules, standards and processes for prevention, discovery, investigation and mitigation of Reportable Incidents: abuse, financial exploitation, medication diversion, mistreatment, neglect, unanticipated death, and significant injury.

The original version of this proposed regulation was published in the June 1, 2019 *Register of Regulations* on page 989 (**22 DE Reg. 989**) for public comment through July 1, 2019. In response to public comment, substantial changes have been made to the proposed regulation. In light of this, DDDS is reposting the revised document for public comment. Due to the amount of revision and in the interest of readability, DDDS is reposting as a new proposed regulation.

Summary of Proposal

The purpose of this regulation is to ensure the health and safety of persons served in Home and Community-Based Services (HCBS) by the Division of Developmental Disabilities Services (DDDS) under its contracts with providers, consistent with Policy Memorandum 46 (PM46) of the Department of Health and Social Services (DHSS).

This regulation specifies incidents that must be reported to DDDS, the manner and timeliness within which they must be reported, and the actions DDDS and providers of DDDS services shall take regarding reportable incidents, including corrective measures that can be assessed for incidents caused by dereliction of duty by providers.

These regulations apply to DDDS and provider staff that provide direct HCBS services to DDDS service recipients, excluding; durable medical equipment suppliers; assistive technology providers; and home and vehicle modification services.

Fiscal Impact Statement

This proposed regulation is being implemented to clarify current DDDS practices and there is no projected fiscal impact.

2103 Reportable Incident Management and Corrective Measures

1.0 Purpose and Scope

1.1 The purpose of this regulation is for Division of Developmental Disabilities Services (DDDS) to ensure the health and safety of service recipients of Home and Community-Based Services (HCBS) in DDDS's role as operating and oversight agency for several Medicaid authorities and under its contracts with providers, consistent with Policy Memorandum #46 (PM 46) of the Department of Health and Social Services (DHSS).

1.2 Under this PM 46, DDDS is responsible for oversight and monitoring of the prevention, discovery, investigation, and correction of reportable incidents and all other threats to the safety and health of DDDS service recipients.

1.3 This regulation specifies the incidents that designated entities must report to DDDS, the manner and timeliness within which the incidents must be reported, and the actions DDDS and providers of DDDS services must take regarding reportable incidents. These actions may include corrective measures that DDDS may assess for incidents caused by dereliction of duty by providers.

1.4 These regulations apply to providers of HCBS services and their staff related to the provision of direct HCBS services to DDDS service recipients, excluding; durable medical equipment suppliers; assistive technology providers; and home and vehicle modification services.

1.5 Nothing in this regulation shall supplant the requirements for mandatory reporting of abuse, neglect, mistreatment, financial exploitation and significant injury per Delaware law.

2.0 Authority and Applicability

The Division is authorized by 29 **Del.C.** §7909A(e) to promulgate rules and regulations to ensure the health and safety of HCBS service recipients. This regulation shall apply to all DDDS providers of direct HCBS, as defined in this regulation.

3.0 Definitions

The following words and terms, when used in this regulation, have the meaning ascribed to them unless the context clearly indicates otherwise:

"**Abuse**" means any of the following:

"**Emotional Abuse**" means the use of oral, written, or gestured language that includes disparaging and derogatory terms to or within the hearing distance of service recipients, residents or their families, regardless of their age, ability to comprehend, or disability. "Emotional abuse" includes the violation of resident rights and privacy through the posting of inappropriate materials on social media. "Emotional abuse" includes all of the following: ridiculing, demeaning, humiliating, bullying, or cursing at a patient or resident; punishment or deprivation; or threatening a patient or resident with physical harm.

"**Physical Abuse**" means the infliction of pain or injury to a service recipient. This includes, but is not limited to, hitting, kicking, punching, slapping or pulling hair. When any act constituting physical abuse has been proven, the infliction of pain is presumed. These actions may be taken by staff to service recipient; service recipient to service recipient (sometimes referred to as resident to resident); or other to service recipient.

"**Sexual Abuse**" means but is not limited to: a) any sexual contact, sexual penetration, or sexual intercourse by an employee or contractor with a service recipient, as defined in §761 of Title 11. It shall be no defense that the sexual contact, sexual penetration, or sexual intercourse was consensual; b) non-consensual service recipient to service recipient; or c) non-consensual other to service recipient.

"**Adverse Outcome**" means a substantial and undesirable effect resulting from 1) administration of the wrong medication; administration of the wrong dose of a medication; failure to administer medication as prescribed; or 2) failure to deliver non-medical services as indicated in the person-centered-plan. Adverse outcomes may be physical, mental, emotional or behavioral. A licensed and qualified medical provider shall determine if an adverse outcome has occurred related to medication and can reasonably be attributed to a medication treatment error. Non-medication related adverse outcomes may be determined by DDDS subject matter experts.

"**Bullying**" means any written, digital, electronic, verbal, or physical action that is intended to elicit fear or cause harm, directly or indirectly through inciting others to act, to a service recipient's emotional, psychological, or physical wellbeing. The actions may be taken by staff to service recipient; service recipient to service recipient; or others to service recipient.

"**Chief Executive Officer**" or "**CEO**" means a provider's highest-ranking administrator.

"**Corrective Measures**" means actions that include a series of required activities or limitations of activities developed in collaboration with a provider for systemic failures to comply with federal/ state/ DMMA/ DDDS regulations, standards, policies, rules and mandates. Such measures include Enhanced Monitoring, Mandatory Technical Assistance, Enrollment Moratorium, Management Transfer, and Termination of Provider

Agreement. Some examples of situations requiring imposition of corrective measures include but are not limited to: obstruction of a DDDS investigation; revocation or suspension of a site license, or issue of a provisional license by The Division of Health Care Quality (DHCQ); or failure to maintain minimum training requirements, as defined in the DDDS training policy, for direct service staff.

"**Corrective Measures Committee**" means an internal DDDS body chaired by the DDDS Director of Service Integrity and Enhancement and composed of, but not limited to: DDDS Service Integrity and Enhancement staff; DDDS Program Evaluators; Chief of Office of Business Support Services (or designee); the DDDS Director of Community Services (or designee); a DDDS Regional Program Director designated by the DDDS Director of Community Services; and the DDDS Deputy Director. The committee may call on subject matter experts as need to assess the specifics of each corrective measures review. The committee is tasked with reviewing relevant data and making recommendations to the chair regarding applying or not applying corrective measures to a provider. The Corrective Measures Committee meetings are closed, as they deal with HIPAA protected information and confidential information about investigations.

"**Corrective Measures Plan**" or "**CMP**" means a plan created to address one or more systemic issues as part of the corrective measures process as presented in Sections 15.0 and 16.0. The CMP must address the common root causes found among the incident-level quality improvement plans (QIPs) generated to address individual substantiated incidents within a site, program or provider.

"**Critical Incidents**" means a subset of reportable incidents that has resulted in actual physical, financial, mental or emotional harm to (adverse outcome); or presents a significant and immediate threat to the health and safety of a service recipient. This includes, but is not limited to: physical/emotional/sexual abuse; neglect; mistreatment; financial exploitation; errors in medication administration of a prescription medication resulting in an adverse outcome, medication diversion; missed medical appointments required for maintenance of serious health conditions; and significant injury to a service recipient.

"**DDDS**" means the Division of Developmental Disabilities Services a division within the Department of Health and Social Services established under 29 **Del.C.** §7909A.

"**DDDS Director**" means the Director of the Division of Developmental Disabilities Services.

"**DDDS Investigator**" means an employee of the Division of Developmental Disabilities Services who has completed a DDDS-approved training on the investigation of reportable incidents.

"**Delay of Treatment**" means when a service recipient, due to provider's failure to seek treatment, does not receive a planned or emergency medical service (lab test, physical therapy treatment or any kind of significant treatment) that had been ordered for them in the timeframe in which it was supposed to be delivered; or a delay in seeking assessment and treatment for injuries or conditions that are a threat to the service recipient's physical or mental health.

"**Deputy Director**" means the Deputy Director of the Division of Developmental Disabilities Services.

"**DHCQ**" means the Delaware Division of Health Care Quality.

"**DHSS Policy Memorandum 46**" or "**PM 46**" means the approved, published document describing the Department of Health and Social Services' response to reportable incidents/allegations of abuse, neglect, mistreatment, significant injury and financial exploitation of HCBS service recipients.

"**Direct Support Professional**" or "**DSP**" means a person who is employed or contracted by a provider to assist a HCBS service recipient to lead a self-determined life and contribute to the community; assist with activities of daily living, if needed; and encourage attitudes and behaviors that enhance community inclusion.

"**DMMA**" means the Delaware Division of Medicaid and Medical Assistance.

"**Elopement**" means when the whereabouts of the service recipient was unknown and was in contradiction with the level of support specified in the service recipient's person-centered plan, with any of the following circumstances:

1. Whereabouts of the service recipient was unknown, but the service recipient was not harmed before being located;
2. Whereabouts of the service recipient was unknown and the service recipient was harmed before being located;
3. Whereabouts of the service recipient was unknown, law enforcement was involved in locating the service recipient, but no harm occurred before s/he was located;
4. Whereabouts of the service recipient was unknown, law enforcement was involved in locating the service recipient, and harm occurred before the service recipient was located.

"**Enhanced Collaboration**" means the process by which Service Integrity and Enhancement (SIE) works with providers that are at risk for corrective measures due to the number and types of incidents that they are reporting, which may indicate a need for technical assistance. Enhanced Collaboration is voluntary, is initiated by request of DDDS or providers, and is implemented by mutual agreement. The objective of enhanced

collaboration is to provide sufficient technical assistance to improve quality of services provided and avoid the need to officially impose corrective measures.

"**Enhanced Monitoring**" means a corrective measure of service quality checks that augments standard DDDS monitoring of service provisions and may include, but is not limited to: increased routine site visits, unannounced site visits, record review, billing review and observation of service delivery.

"**Enrollment Moratorium**" means a corrective measure that prohibits a provider from accepting new referrals of service recipients into DDDS services at individual provider service sites, other provider service locations, or provider type of service or across the entire provider's line of businesses covered under the DDDS HCBS contract.

"**Financial Exploitation**" means the illegal or improper use, control over, or withholding of a service recipient's property, income, resources, or financial rights by another person, whether through intent to exploit or through benign neglect of financial management laws, regulations, policies or procedures. Financial Exploitation includes, but is not limited to, use of deception, intimidation or undue influence by a person or entity in a position of trust and confidence with a service recipient to obtain or use the service recipient's resources in a manner not in the best interest of the service recipient.

"**Home and Community Based Services**" or "**HCBS**" means services offered to prevent institutionalization and in lieu of institutional care that focus on integration of those with developmental disabilities into the wider community, to facilitate their 'best lives' through inclusive person-centered-planning. HCBS services include, but are not limited to Medicaid authorized services under sections 1915(c),(i),(j) or (k) of the Social Security Act and State Plan Day Services under the Rehabilitative Services Option approved by the Centers for Medicare and Medicaid Services (CMS) and administered by DDDS.

"**Incident-Level Quality Improvement Plan**" or "**QIP**" means a description of quality improvement action steps recommended by the provider, and approved by DDDS designed to remediate a substantiated critical incident or a pattern of non-critical incidents. The Quality Improvement Plan documents the steps that shall be taken to address the root causes of the incident and clearly indicates the criteria for the successful completion of the QIP.

"**Incident Management System**" means the software system designated by DDDS to record and manage incident reporting, investigation processes, and incident remediation efforts related to reportable incidents.

"**Incident Record**" means a set of data with all details of an incident, documenting the history of the incident from occurrence to resolution, including original report, investigation, conclusions, remediation, verification of completion of remediation, and assessment of the resilience of improvements achieved. Contents of the incident record shall contain only information permitted by state law or DHSS/DDDS policies.

"**Inconclusive**" shall mean that there is no conclusion that can reasonably be made based on the available evidence and for which lack of documentation is typically the primary factor.

"**Infestation**" means the presence of lice, bed bugs or other pests sufficient to cause harm or medical symptoms in service recipients. Infestation is a reportable incident.

"**Investigation Summary Report**" means a standardized report used by DDDS to document and summarize the comprehensive investigation: process, evidence, and conclusions. This report is also sometimes known as the "Report of Findings" and is sent to providers by Office of Incident Resolution at the conclusion of an investigation.

"**Knowingly**" means having actual knowledge of, or acting with deliberate ignorance, or reckless disregard for the laws, regulations, standards, or contract provisions governing service provision and environmental safety.

"**Limited Lay Administration of Medications**" or "**LLAM**" means a set of rules and regulation devised by the Delaware Board of Nursing defining criteria and requirements for administration of medications by unlicensed care givers in specified service settings, authorized by 24 **DE Admin. Code** 1900 – Section 5.0.

"**Management Transfer of a Service Site**" means a corrective measure that requires the mandatory transfer of provider services and service sites to another provider at the direction of DDDS. Every attempt shall be made to honor the wishes of the service recipient, in balance with documented health and safety issues. A Management Transfer of the site shall not occur if the site is owned by the provider unless the provider supports the Management Transfer. The provider shall retain all other rights regarding the disposition of its physical property, if a management transfer is ordered. Management transfer is a last resort corrective measure, under the conditions described in subsection 15.1.4.

"**Mandatory Technical Assistance**" means a corrective measure in which technical assistance (TA) is required by DDDS to assist the provider to address and correct persistent, specific, localized or systemic compliance challenges. TA may include, but is not limited to: facilitation of root cause analysis and other discovery processes; quality improvement planning sessions and plan development; review of agency policies and policy implementation practices and assistance with necessary revisions to ensure compliance; training; on-site

observation of services; development of formal quality Improvement plans. Technical assistance may be provided by DDDS (or one of its delegates), or by consultant chosen, contracted and paid by the provider.

"**Medical Intervention**" means any action that requires involvement of a health care professional in response to an event requiring medical treatment beyond first aid.

"**Medication Administration Error**" means a deviation from the prescriber's medication order in administration of a prescription medication. See definition of "prescription medication" for purposes of this regulation.

"**Medication Diversion**" means the knowing or intentional interruption, obstruction, or alteration of the delivery, or administration of a prescription drug to a service recipient, if both of the following apply:

1. The prescription drug was prescribed or ordered by a licensed independent prescriber for the service recipient.
2. The interruption, obstruction, or alteration occurred without a change in the prescription or order of a licensed independent practitioner.

"**Mistreatment**" means the inappropriate application on a service recipient of medications, isolation, or physical or chemical restraints as negative reinforcements, punishment, or retaliation for behaviors.

"**Neglect**" means any of the following:

1. Lack of attention to the physical needs of a service recipient to include but not be limited to toileting, bathing, nutrition and safety;
2. Failure to report problems or changes in health problems or health condition to an immediate supervisor or nurse;
3. Failure to carry out a service recipient's person centered plan that resulted in an adverse outcome;
4. A knowing failure to provide adequate staffing which results in an adverse outcome to a service recipient.

"**Non-Critical Incident**" means a reportable incident that has not resulted in observable physical, mental, or emotional harm to a service recipient (adverse outcome); and does not present a significant or immediate threat to the health and safety of DDDS service recipients or are correctable issues not likely to cause immediate or significant harm or injury. This includes all incidents not classified as a critical incident such as: minor physical injuries, errors administering medications not identified as critical by the prescriber, service recipients not receiving preferred choice of foods, and other correctable issues not likely to cause immediate or significant harm or injury.

"**Nuisance Complaint**" means a service-related complaint that is likely to be part of a documented pattern of reporting not related to potential abuse, neglect or exploitation of a service recipient.

"**Obstruction of Investigation**" means hindering incident investigations. This includes withholding of documentation; preventing or discouraging staff from being available to investigators; failure to respond to requests for information in a timely manner; intimidation of witnesses; and any other actions intentionally taken to interfere with an investigation.

"**Office of Incident Resolution**" or "**OIR**" means a unit within the DDDS Service Integrity and Enhancement Unit that is responsible for the investigation of all reportable incidents, directly or through delegates.

"**Office of Incident Resolution Administrator**" means the DDDS administrator responsible for overseeing OIR.

"**Office of Service Enhancement**" or "**OSE**" means a unit within the DDDS Service Integrity and Enhancement Unit responsible for monitoring provider performance and providing technical assistance to address quality improvement issues both within DDDS and with DDDS providers.

"**Person-Centered Plan**" means a document that identifies how services and supports will enhance the participant's life. This assessment data, including information about services the participant receives through other state and federal programs is coordinated by the case manager.

"**Preliminary Investigation**" means the initial assessment by the Office of Incident Resolution Administrator of an allegation to determine if: 1) sufficient detail about the reported incident exists or can be quickly gathered to guide further investigation; 2) the alleged incident is critical or non-critical; and 3) the investigation will be assigned to a DDDS or provider investigator.

"**Prescription Medication**" means a medication required by federal or state law or regulation to be dispensed only by a prescription, which means a lawful written or verbal order of a practitioner for a drug, including finished dosage forms and active ingredients, subject to §503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §353(b)). For the purpose of this regulation, this does not include medications that may have been prescribed, but can be typically bought over-the-counter.

"**Primary Provider Contact**" means the person designated by the CEO of a provider that shall receive DDDS notifications, shall work directly with DDDS on incident investigations and the Quality Improvement Plans that may be required for incidents, and shall be responsible for ensuring that all provider incident remediation processes included in this regulation are executed.

"**Provider**" means an entity that has been authorized to provide one or more DDDS HCBS services to meet the specialized needs of DDDS service recipients.

"**Provider Investigator**" means an employee of the provider who has completed DDDS-approved training on the investigation of reportable incidents.

"**Reportable Incident**" means an event that is witnessed by a mandated reporter, that has been reported to a mandated reporter, or that the mandated reporter has reason to suspect has occurred, including the following]: abuse (physical/ sexual/ emotional); bullying; criminal offense; delay of treatment; service recipient to service recipient incidents; elopement; financial exploitation; infestation; medication diversion; medication error; missed medical appointments; mistreatment; neglect; significant injury; unanticipated death; property damage caused by the service recipient; abuse of substances; aggression of service recipient toward the general public; or use of restraints not permitted in the person-centered plan or as specified in DDDS policy. An incident may be comprised of multiple component incidents or attributed to a combination of multiple causes and, therefore, may be substantiated with a combination of the sub-classifications listed below. For instance, a medication scheduling error that affects four service recipients shall be recorded as four individual reportable incidents; multiple errors affecting a single service recipient shall be recorded as multiple reportable incidents; a medication error may be attributed to a combination of lack of training, lack of supervision, and lack of properly documented procedures.

"**Root Cause Analysis**" means a class of problem solving methods aimed at identifying the root causes of problems or events. The practice of root cause analysis is predicated on the belief that problems are best solved by attempting to correct or eliminate root causes, as opposed to merely addressing the immediately obvious symptoms.

"**Service Integrity and Enhancement Unit**" or "**SIE**" is the unit within DDDS that is responsible for evaluating DDDS and provider performance; measuring compliance with all applicable regulations, standards, policies, rules, and mandates; providing technical assistance to providers to help correct persistent performance or compliance challenges; recognizing providers who exhibit superior performance; and sharing best practices by providers, as they are observed. SIE is the umbrella unit for the Office of Service Integrity, Office of Incident Resolution, Office of Service Enhancement, and Office of Constituent Relations.

"**Service Recipient**" is any person eligible for and receiving DDDS services.

"**Service Recipient to Service Recipient Incident**" means any reportable incident that is between or among service recipients who receive DDDS services that results in injury or significant potential for harm.

"**Significant Injury**" means:

1. Injury from an incident of unknown source in which the initial investigation or evaluation supports the conclusion that the injury is suspicious. Circumstances which may cause an injury to be suspicious are: the extent of the injury, the location of the injury (e.g. the injury is located in an area not generally vulnerable to trauma), the number of injuries observed at one time; or the incidence of injuries over time;
2. Injury which results in transfer to an acute care facility for treatment or evaluation or which requires periodic neurological reassessment of the service recipient's clinical status by professional staff for up to 24 hours:
3. Areas of contusions or bruises caused by staff to a service recipient during ambulation, transport, transfer, bathing, or other activity in the course of providing services;
4. Significant error or omission in medication/treatment, including medication diversion, which causes the resident discomfort, jeopardizes the service recipient's health and safety or requires periodic monitoring for up to 48 hours;
5. A burn greater than first degree occurs;
6. Any serious, unusual, or life-threatening injury.

"**Substantiated**" means when a reasonable person weighing the facts and circumstances has concluded that the incident did occur and enough information is available to reasonably assign fault or determine no-fault for the incident. The following are the sub-classifications of substantiated incidents:

1. **Dereliction of Duty**
   a. "**Administrative**" means a type of incident in which a likely contributing factor is a failure of provider administration, including but not limited to: failure to communicate new standards, regulations, or policies affecting the health or safety of service recipients to employees or failure to assure staff training; failure to staff facilities at levels that are needed to meet the needs of service recipients; failure to repair or ensure repair of facility infrastructure, that results in significant injury or risk of such injury to service recipients (such as a broken window).
   b. "**DSP / Employee**" means a type of incident in which a DSP or another staff member employed or contracted by a provider, having been documented to have completed all necessary training, failed

to follow established policy, protocol or training that put a service recipient at risk, including but not limited to: sleeping on the job; failure to document or report incidents properly; and failure to provide medications as scheduled.

c. "**Supervisory**" means a type of incident in which a likely contributing factor is lack of proper supervision including but not limited to: supervisory staff employed by a provider directly observed DSPs failing to follow policy, protocols, or procedures without providing correction to the DSPs; failure to properly schedule coverage, putting service recipients at risk; and failure to communicate vulnerability risks to their direct reports.

2. "**Criminal Offense**" means a type of incident that included alleged criminal activities, whether or not the police were called or the service recipient (victim) pressed charges, including but not limited to: drug use on premises; assault/abuse; sexual abuse/assault; or theft of the property/assets of a service recipient.

3. "**Inadequate Training**" means a type of incident in which a likely contributing factor is a lack of proper training including, but not limited to: DSPs administering medications without proper LLAM training; DSPs not following safety / vulnerability protocols, such as monitoring of food intake for service recipients with swallowing difficulties; or the inability of staff to recognize a reportable incident.

4. "**No Fault / Accidental**" means a type of incident that was verified to have occurred, but is deemed to have been the result of an accident without a breach in policy, protocol, or standard of care.

"**Termination of Provider Contract**" means the termination or non-renewal of a contract between DDDS and a provider for the provision of a DDDS HCBS service. This level of corrective measure requires the approval of the Division Director prior to imposition.

"**Unanticipated Death**" means death of a service recipient that could not have been anticipated based on the circumstances of the service recipient. These cases are referred to the Division of Forensic Science, Department of Safety and Homeland Security.

"**Unsubstantiated**" means when a reasonable person weighing the facts and circumstances has concluded that the incident did not occur. In some cases, DDDS may require a quality improvement plan to address conditions discovered as part of an investigation, in accord with subsection 11.1.2 of this regulation.

"**Witness/Victim Intimidation**" means any situation in which a victim or witness of a reportable incident is coached, threatened, or otherwise pressured in a way intended to prevent or retaliate for reporting of a reportable incident or testifying in an investigation.

4.0 General Requirements

4.1 The Director or designee is the official DHSS designee under the State Mandatory Patient Abuse Reporting Law and as it applies to DHSS PM 46.

4.2 DDDS shall maintain data on the type and frequency of investigated reportable incidents, the victim or victims and location, and any Quality Improvement Plans (QIP) and Corrective Measures Plans (CMP) that have been required.

4.3 All persons covered by the scope of this regulation shall protect the confidentiality of records and information related to the investigation as well as the identity of persons involved in the case as required under Delaware law.

4.4 Information about investigations shall be shared only as allowed under state law.

4.5 Providers must develop specific policies and procedures that include the requirements set forth in this regulation and explicitly document how the requirements shall be accomplished in all service settings in which they deliver HCBS, including specific staff assigned to the responsibilities. Provider-specific reportable incidents policies must be consistent with this regulation and DHSS PM 46.

4.5.1 Providers must document that all staff have received an initial orientation to and annual reviews of this regulation and the provider-specific policies.

4.5.2 Provider-specific policy and procedures shall be available to all staff at all service sites. Non-facility based sites shall maintain the policy and procedures at their administrative offices.

4.5.3 Providers shall document employee orientation and annual reviews about laws prohibiting intimidation of witnesses and victims (11 **Del.C.** §§3531-3534).

4.6 Providers shall have at least one person on staff or contracted at all times that is trained in a DDDS-approved investigation curricula.

4.7 DDDS will send written notifications to the provider concerning any part of the investigation or remediation process via letter or e-mail to both the primary provider contact and the Chief Executive Officer.

5.0 Safety of the Service Recipient

5.1 The provider is required to immediately assure and secure the safety of all service recipients that are affected by a threat to health and safety during an incident.

5.2 For any incident resulting in harm to a service recipient that requires acute care, the provider shall immediately inform any legal and documented guardian or designated emergency contact for the service recipient of the incident and of any immediate steps taken to assure safety and wellbeing of the service recipient. In the event that the legal and documented guardian or designated emergency contact cannot be located or contacted, the provider must document all efforts to do so.

5.3 If the incident involves a sexual assault, as soon as is possible after knowledge of the assault, the provider staff shall recommend that an examination by a Sexual Assault Nurse Examiner (SANE) be performed at the hospital and shall contact law enforcement to report the alleged crime. The provider staff will assist the Sexual Assault Nurse Examiner in obtaining the consent of the service recipient. In cases where the service recipient is not able to give consent, the provider shall aid the hospital to identify and locate the legal and documented guardian or designated emergency contact that can provide consent for the SANE exam for the service recipient.

5.4 Incidents that involve conduct that a reasonable person would suspect also constitute a criminal offense under local, state, or Federal law shall be reported to the appropriate law enforcement agency as soon as possible after discovery of the incident. Incidents resulting in serious bodily injury must be reported to law enforcement within two (2) hours. All actions taken to assure safety and health of service recipients, directly or indirectly affected by an incident must be documented in the DDDS-required Electronic Case Record System and the Incident Management System within 24 hours of becoming aware of the incident.

5.5 Incidents requiring immediate action to secure the health and safety of service recipients must be reported immediately to a DDDS Regional Program Director. If the incident occurs after DDDS business hours, a phone call must be made to the identified DDDS off-hours on-call DDDS Community Services staff person, as specified in DDDS Emergency Contact System policy to affirm that the health and safety of service recipients has been secured or to request DDDS staff assistance in securing the health and safety of service recipients.

6.0 Reporting of Incidents

6.1 Any employee or volunteer of DDDS or of a DDDS service provider or any other person who provides services to a DDDS service recipient on a regular or intermittent basis who has reasonable cause to believe that a service recipient has been abused, mistreated, neglected, or financially exploited shall report such abuse, mistreatment, neglect, or financial exploitation to DDDS via the DDDS web-based reporting form or oral communication, in-person or by phone, as soon possible after the health and safety of the service recipient has been assured.

6.1.1 DDDS shall provide educational materials to service recipients or their guardians that explains incident reporting, the investigation process and risk mediation processes. The materials shall be available via the DDDS website and distributed at person-centered planning sessions beginning December 1, 2019.

6.2 A written report shall be filed for all reportable incidents via the web-based incident reporting form component of the DDDS Incident Management System by the employee or person providing services to a service recipient within 24 hours after the employee or person providing services to a service recipient first gains knowledge of the abuse, mistreatment, neglect or financial exploitation. If the reporter is a provider, a summary of actions taken to secure the safety and health of the service recipients affected must be provided. The link to the incident reporting form, available to service providers, service recipients/guardians and the general public 24-hours a day, shall be displayed on the DDDS website home page.

6.3 If the reportable incident occurs in a setting that is licensed by the Division of Health Care Quality (DHCQ), the DDDS Office of Incident Resolution shall inform DHCQ via the web reporting form within 48 hours of the incident report.

6.4 In the case of service recipient-to-service recipient incidents in a setting that is licensed by DHCQ, the provider will, within 48 hours of the incident, report the incident via the DHCQ web reporting form. This notification is in addition to notification of DDDS OIR.

7.0 Who to Notify that an Investigation Has Been Opened or Completed

7.1 DDDS shall contact the service recipient and guardian by phone or written communication (as most appropriate of the abilities of the person contacted) within one business day of a critical incident to inform them that an incident has occurred. This notification shall only contain information permitted by state law or DHSS/ DDDS policies.

7.2 DDDS shall mail a written notification that a Critical or Non-Critical incident has occurred and is being investigated to the service recipient or guardian within two (2) business days of the assignment of the investigator. The notification shall contain only information permitted by state law or DHSS/DDDS policies.

7.3 Information may not be shared with family members or any other persons who are not documented as the legal guardians of the service recipient without a specific release of information from the service recipient or guardian.

7.4 The Office of Incident Resolution (OIR) shall notify, as appropriate, the provider, the case manager as designated by DDDS and other DDDS staff, as appropriate, related to the service recipient's care. OIR shall also notify, as appropriate, DHSS, DHCQ, or DOJ/Law Enforcement that an incident had occurred and the incident will be investigated.

7.5 DDDS shall mail a written notification, within five (5) business days of the OIR Administrator's approval of the Investigation Summary Report, to the service recipient and guardian and, as necessary, to other entities listed in subsection 7.4, that an investigation has been concluded and of the outcome of the investigation. The notification shall contain only information permitted by state law or DHSS/DDDS policies.

8.0 Determination of Investigative Method

8.1 The DDDS Office of Incident Resolution (OIR) Administrator shall, within two (2) business days of the incident report, conduct a preliminary investigation and assessment of all reported incidents to determine the level of subsequent investigation required, and assign the investigation to a DDDS or service provider investigator, as appropriate.

8.2 Assignment to Investigator

8.2.1 The OIR Administrator will assign a provider or DDDS investigator, as appropriate.

8.2.2 Critical incidents must be assigned to and investigated by DDDS.

8.2.3 Non-Critical incidents may be assigned by OIR to and investigated by DDDS or provider investigators as appropriate or expedient.

8.2.4 The assigned investigator shall be alerted to the assigned investigation through the DDDS Incident Management System.

8.2.5 The identified provider primary contact and CEO will be informed via email regarding the assignment of an investigator within two (2) business days of the assignment. The assignment of an investigator may be included in the notice of investigation referenced in subsection 7.4.

8.3 If DDDS assigns DDDS staff to conduct the investigation, the provider may not conduct an internal investigation beyond what is immediately needed to assure the health and safety of the service recipient, until such time as the DDDS investigation is completed.

8.4 The Office of Incident Resolution (OIR) will inform the provider primary contact and CEO via letter or email within five (5) business days of the conclusion of a preliminary investigation, if a decision is made that further investigation of an incident will not be required.

9.0 Conduct of Investigations

9.1 Investigations shall be conducted in accord with DDDS-approved investigator training and should minimally include:

9.1.1 Direct interview with the service recipient;

9.1.2 Interview with the reporter of the investigation, when possible;

9.1.3 Interview with all potential witnesses and service recipients whom may have pertinent information;

9.1.4 Written statements from employees/contractors and from any other people interviewed;

9.1.5 Documents and physical evidence that relate to the investigation.

9.2 Primary fact finding for critical incident investigations assigned to DDDS investigators shall be completed in no more than five (5) business-days from the day of the assignment of the investigator. Extensions may be approved by the OIR Administrator, if key witnesses, alleged perpetrators, or victims are not available for interview within the five (5) business days.

9.3 DDDS will notify providers via email within 24 hours of DDDS' completion of the primary fact finding for critical incidents so that providers may begin internal investigation, as needed.

9.4 The immediate focus of the investigation shall be to verify that the provider has effectively secured the health and safety of any service recipients involved.

9.5 In investigations involving law enforcement, DDDS shall investigate as possible through existing electronic case records and any other source of information that is possible to access without direct interaction with

victims, witnesses, or alleged perpetrators. DDDS may interview victims, witnesses, or alleged perpetrators, if necessary, after law enforcement informs DDDS that law enforcement has concluded collection of statements/ interviews, and after appropriate consent by the service recipient or legal guardian is obtained. DDDS will assist law enforcement to provide access to or referral to subject matter experts, if needed for the interviewing of service recipients.

9.6 Criminal investigations by law enforcement are excluded from the five (5) day completion requirement.

9.7 Within ten (10) business days of completion of DDDS investigation of critical incidents, a summary of findings that provides determination of substantiation and additional information as permitted by state law or by DHSS/ DDDS policy shall be provided to the provider.

9.8 Non-critical incident investigations assigned to provider investigators shall be completed in no more than ten (10) business days from the date of the assignment to the investigator. Any request for an extension of these deadlines must be submitted in writing with justification for the extension. The extension shall be granted or denied by the Office of Incident Resolution Administrator.

9.8.1 The DDDS or provider investigator, as applicable, shall enter and investigation report into the DDDS Incident Tracking System for review and approval of the DDDS Administrator of the Office of Incident Resolution. The Administrator may request additional investigation and documentation be completed before approval of the final investigation report.

10.0 Post-Investigation Analyses and Follow-up

10.1 The OIR Administrator shall make determination of whether an incident has been substantiated or unsubstantiated, based on an analysis of the evidence submitted by the DDDS investigator or provider investigator. This determination shall be made within 10 business days from the submission of the completed investigation to the OIR Administrator. If a determination cannot be made within ten (10) business days from the submission of the completed investigation, the provider shall receive notification from the OIR Administrator including a proposed date by which a determination may be issued.

10.2 If insufficient evidence has been collected or the investigation lacks thoroughness, the OIR Administrator may require the investigator to continue the investigation to answer outstanding questions.

10.3 DDDS shall send a notification of completion of investigation to the service recipient and guardian within five (5) business days after the final determination of substantiation. The notification shall only contain information permitted by state law or by DHSS/DDDS policies.

11.0 Quality Improvement Plans (QIPs)

11.1 The OIR Administrator has discretion to request or waive a QIP for any incident substantiated or unsubstantiated.

11.1.1 If an incident investigation outcome is Inconclusive (see Definitions) or a lack of mandatory documentation is identified during any investigation, a QIP may be required to identify the root-causes of the poor documentation and to implement fixes to ensure proper documentation of services.

11.1.2 DDDS may request the provider complete and implement a QIP for incidents ultimately determined to be unsubstantiated if, in the course of the investigation, conditions are discovered that, if not corrected, present a significant potential serious risk to future health and safety of service recipients.

11.1.3 If required by the OIR, the provider shall submit a QIP within fifteen (15) business days of receipt of notification.

11.2 The identified provider primary contact and CEO shall hold primary responsibility for ensuring the agency submits QIPs and associated documentation in accord with this regulation.

11.3 A quality improvement plan must include:

11.3.1 A root-cause analysis that identifies the specific casual factors leading to the failures that resulted in the incident or incidents;

11.3.2 Specific, measurable, attainable, relevant, and time-limited (SMART) goals and objectives: short, medium and long term;

11.3.3 Specific and relevant actions to prevent recurrence of the same or similar events that shall be taken by provider staff to achieve the SMART goals and objectives and identify the specific persons responsible for implementing those actions.

11.3.4 Specific and relevant criteria and process by which the implementation of the actions shall be monitored and evaluated; and

11.3.5 Specific and relevant criteria and process by which the outcomes of the completed implementation shall be assessed.

11.4 Provider may submit a request for an extension for producing a QIP. The request must be submitted in writing and include justification for the extension. The OIR Administrator has discretion to grant or deny the extension in writing within five (5) business days.

11.5 DDDS shall review and approve or reject the QIP within five (5) business days of receipt.

11.6 If the QIP is rejected:

11.6.1 DDDS shall provide specific feedback to the primary contact and CEO of the provider via e-mail and certified mail requesting a revision of the QIP.

11.6.2 The provider must resubmit a corrected QIP within five (5) business days of the receipt of the communication in subsection 11.6.1.

11.6.3 The provider may submit a request for an extension for producing a revised QIP to the OIR Administrator. The request must be submitted in writing and include justification for the extension. The OIR Administrator shall grant or deny the extension in writing within five (5) business days.

11.7 After two (2) revised QIP's are not accepted by DDDS, the provider shall be required to accept technical assistance from the DDDS Office of Service Enhancement (or its delegates) to produce an acceptable QIP and the primary contact and CEO shall be informed via e-mail and certified mail.

12.0 DDDS Verification of QIP Implementation

12.1 The provider will submit to DDDS OIR, as specific tasks in the QIP are completed or at the end of the QIP implementation, a summary report detailing implementation of goals and objectives. Types of documentation may include but are not limited to: documentation of attendance of staff at implemented training; documentation of any pre/post testing; skills acquisition testing or verification; policy/procedure changes made; solutions to any challenges encountered while implementing the QIP; documentation of progress achieved in attaining the service recipient's goals in the person-centered plan; and remaining plans to assess long-term efficacy of the implemented QIP interventions.

12.2 DDDS will review and approve or disapprove the submitted verification documentation within ten (10) business days of receipt of the summary report.

12.3 If the report is disapproved, a meeting between DDDS and the provider will be scheduled within 5 business days of the disapproval to provide specific feedback to the provider CEO and primary contact regarding additional information needed.

12.4 The provider will resubmit the revised summary report within ten (10) business days of the meeting noted in subsection 12.3.

12.5 Upon approval of the QIP Summary Report, DDDS will close out the QIP in the Incident Management System.

13.0 Criteria for Corrective Measures Committee (CMC) Review

13.1 SIE will refer incidents to the CMC for review based on the determination that a pattern of substantiated critical or non-critical incidents exists demonstrating a provider is not able to consistently provide care to service recipients meeting DDDS service standards.

13.2 SIE shall prepare for the CMC a written summary report that identifies the provider's incident patterns by service sites or programs, and includes:

13.2.1 A minimum of six (6) month history of all substantiated incidents that includes the specific types of incidents, including specifics of medication types if medication related, and the investigation conclusion.

13.2.2 The QIPs implemented: root cause analysis, implemented interventions, and outcome analysis.

13.2.3 Any data that does/does not support the efficacy of the QIP outcomes.

14.0 Corrective Measures Committee Review and Enhanced Collaboration

14.1 The Corrective Measures Committee shall meet on a monthly basis to review data regarding the status of investigations, QIPs, and other available data relative to service providers or service sites recommended for review by SIE or other units within DDDS to determine the need for corrective measures.

14.2 If the CMC has completed a review without making a recommendation for either enhanced collaboration or corrective measures, DDDS will schedule a meeting within ten (10) business days of the completion of the CMC review to inform the provider of the issues that led to the review, recommend remediation efforts to avoid future review and possible corrective measures, and offer enhanced collaboration to assist achieving early remediation.

14.3 If review of the data suggests a pattern of ongoing quality of service issues that, if not corrected, could lead to significant on-going harm to service recipients, the CMC will recommend that the provider engage in a period of enhanced collaboration. The goal of referring the provider for enhanced collaboration is to aid the provider to

remediate service issues and to ensure that the provider understands the rules that govern the provision of service in order to avoid the need to apply corrective measures.

14.4 If justification exists to apply a corrective measure, based on the extent to which service recipients were harmed by the substantiated incidents and likelihood of future incidents, the Corrective Measures Committee may recommend bypassing enhanced collaboration or some levels of corrective measures in order to apply a more restrictive measure.

14.5 Within five (5) business days after the CMC completes its review and recommends enhanced collaboration or corrective measures, DDDS shall notify the primary contact and CEO of the provider via both e-mail and certified mail of the recommendations of the CMC and the specific data considered in making the recommendation.

14.6 Within ten (10) business days of the notice to the provider outlined in subsection 14.4, DDDS will hold a meeting with the provider to ensure the provider understands the CMC's basis for recommendations for enhanced collaboration or corrective measures and the process the provider must follow after application of corrective measures.

14.6.1 At the meeting referred to in subsection 14.6, the provider may present evidence to dispute the investigation findings for any incident presented in the letter referenced in subsection 14.5 relative to application of corrective measures.

14.6.2 The Director of SIE shall have ten (10) business days after the meeting in subsection 14.6, regardless of whether the provider disputes the findings, to issue a letter of final ruling on imposition of CMC recommendations.

14.7 Enhanced Collaboration

14.7.1 Enhanced Collaboration shall be coordinated by the Service Enhancement Unit and will include but not be limited to the provider, SIE staff, Community Services Administration, Regional Program Directors, and Support Coordinators, as may be appropriate, to address the specific quality issues that are discovered through the root cause analyses and the efforts being made by the provider to correct them.

14.7.2 Enhanced collaboration may be initiated a period up to ninety (90) calendar days at the end of which time, the CMC will review the provider's remediation efforts and results.

14.7.2.1 If the provider has made significant progress in remediating service issues but requires more time under enhanced collaboration, the CMC may recommend extending enhanced collaboration for a period of up to (sixty) 60 calendar days.

14.7.2.2 If the provider fails to significantly remediate service issues, the CMC may recommend application of corrective measures.

14.7.2.3 If, after enhanced collaboration, the provider demonstrates 1) a knowing disregard of standards of care or 2) a lack of capacity to remediate the service quality issues that if not corrected could likely result in imminent threat to the health and safety of the service recipient, the CMC may recommend application of a more restrictive corrective measure that bypasses one or more levels of the corrective measures presented in Section 16.0.

15.0 Corrective Measures

15.1 The following corrective measures are to be applied in a proportional manner, from least restrictive to most restrictive, based on the recommendations of the Corrective Measures Committee. If justification exists to apply a more restrictive corrective measure, based on the extent to which service recipients were harmed by the substantiated incidents, the Corrective Measures Committee may bypass one or more levels of the corrective measures to impose a more restrictive measure.

15.1.1 Enhanced Monitoring for up to 90 calendar days, during which SIE staff, Community Services staff, and OBSS staff, may conduct a combination of site visits, increase monitoring of electronic medical records, and document findings. Enhanced monitoring may operate in conjunction with Mandatory Technical Assistance, as deemed appropriate by DDDS.

15.1.2 Mandatory Technical Assistance to address the issues that were identified, including supervisory training, human resources, programmatic methods, etc., for up to 90 calendar days. Technical Assistance may be provided by DDDS (or one of its delegates), or by consultancy chosen, contracted and paid by the provider. If this corrective measure is applied, enhanced monitoring may operate concurrently to help monitor the efficacy of the technical assistance and associated corrective measures plan.

15.1.3 An Enrollment Moratorium, during which the provider shall not be allowed to accept new referrals for service recipients to its programs or to specified services or settings for up to 90 calendar days.

15.1.4 Management Transfer of programs or sites to another provider, if after 180 calendar days of attempts to correct deficiencies, the provider remains unable to provide a safe and healthy environment or positive outcomes for the service recipients; or immediately, if the provider is knowingly disregarding standards of care, that if not corrected, could likely result in imminent threat to the health and safety of service recipients residing at the site. This measure is considered a last resort in addressing deficiencies at a service site.

15.1.5 Termination of the DDDS Provider Contract for the complete failure of the provider to provide a safe and healthy environment for service recipients at any of its program sites.

15.1.6 DDDS may also apply corrective measures for obstruction of a DDDS investigation.

15.1.7 DDDS may apply corrective measures to providers as a result of an open investigation with the State of Delaware Department of Justice Medicaid Fraud Control Unit or DMMA Surveillance and Utilization Review.

15.2 The Director of Service Integrity and Enhancement shall have authority to impose and lift corrective measures recommended by the Corrective Measures Committee. Management Transfer and the Termination of Provider Agreement require the approval of the Division Director.

15.2.1 Imposition of corrective measures shall be documented in a letter (see subsection 14.6.2) sent via certified mail.

15.2.2 The provider shall submit a corrective measures plan within fifteen (15) business days of receipt of the letter imposing corrective measures and summarizing the issues identified as the basis for the application of corrective measures.

15.2.3 The basic content requirements of CMPs and processes are the same as those listed in subsection 11.3, but the CMP is based on a meta-analysis of all related QIPs considered in the application of corrective measures. A corrective measures plan must include:

15.2.3.1 A root-cause analysis that identifies the specific casual factors leading to the failures that resulted in the incidents and that reflect analysis of all previous QIP attempts to correct the performance issue.

15.2.3.2 Specific, measurable, attainable, relevant, and time limited (SMART) goals and objectives: short, medium and long term.

15.2.3.3 Specific and relevant actions that shall be taken to achieve the SMART goals and objectives and persons responsible for implementing those actions.

15.2.3.4 Specific and relevant criteria and process by which the implementation of the actions shall be monitored and evaluated.

15.2.3.5 Specific and relevant criteria and process by which the outcomes of the completed implementation shall be assessed.

15.2.4 Provider may submit a request for an extension for producing a CMP. The request must be submitted in writing and include justification for the extension. The Director of SIE at his/her discretion, shall grant or deny the extension in writing within five (5) business days.

15.2.5 DDDS shall review and approve or reject the CMPs within ten (10) business days of receipt. If additional information is needed after the provider submits the CMP, DDDS may request a meeting to review the submission with the provider and request a revised CMP.

15.2.6 If the changes to the CMP are requested:

15.2.6.1 DDDS shall provide specific feedback to the primary contact and CEO of the provider via e-mail and certified mail requesting a revision of the CMP.

15.2.6.2 The provider must resubmit a corrected CMP within five (5) business days of the receipt of the communication in subsection 15.2.6.1.

15.2.6.3 Provider may submit a request for an extension for producing a revised CMP. The request must be submitted in writing and include justification for the extension. The Director of SIE shall grant or deny the extension in writing within five (5) business days.

15.2.7 If two (2) sequential revised CMP submissions are not accepted by DDDS, the provider shall be required to accept Mandatory Technical Assistance from DDDS Service Enhancement Unit (or its delegates) to produce the needed CMP.

16.0 On-going Review, Monitoring, and Conclusion of Corrective Measures

16.1 The Corrective Measures Committee shall review the provider's reported activities and outcomes, and any other relevant data gathered during the corrective measures period, at the soonest monthly meeting scheduled after the submission.

16.2 The provider may choose to submit monthly updates to the CMC (or its delegates) or submit a summary at any time within the 90 day period if the tasks of the CMP have been completed.

16.3 At minimum, the provider must, within five (5) business days after each corrective measure period, submit a summary report of the implementation components and outcomes of CMP goals and objectives.

16.4 At the next monthly meeting after submission of the summary report, the CMC will review the provider's summary report, and any other relevant data gathered during the corrective measures period, and make one of the following recommendations to the Director of SIE:

16.4.1 The provider shall submit additional information in order for the CMC to make a determination.

16.4.2 The provider shall be released from the corrective measure entirely, based on their diligence in completing all relevant CMPs.

16.4.3 The provider shall continue the current correct measures for another 90 calendar days or step up to the next level of corrective measures for a failure to complete all relevant CMPs.

16.4.4 The provider shall fall back to the previous level of corrective measures if the relevant CMPs were only partially completed.

16.5 The Director of SIE shall have up to five (5) business days after the meeting to send an e-mail and certified letter to the primary contact and CEO of the provider documenting any requests or decisions after the CMC reviews provider reports.

17.0 Appeals

17.1 Appeals, as described in subsection 17.2, are limited to corrective measures imposed (formerly referred to as "sanctions") after implementation of this regulation.

17.2 Appeals of Corrective Measures

17.2.1 The provider may appeal the imposition of corrective measures.

17.2.2 The first level appeal of the imposition of corrective measures shall be to the Corrective Measures Committee (CMC).

17.2.2.1 The application of corrective measures will be suspended during the first level appeal.

17.2.2.2 Within ten (10) business days of the receipt of the intent to appeal, an appeal meeting with the CMC shall be scheduled to discuss the dispute. The provider shall have an opportunity to present a written, data-based rebuttal of the findings that resulted in the application of corrective measures.

17.2.2.3 The CMC shall have up to ten (10) business days from the receipt of the written request for appeal to issue a decision to grant or deny the appeal.

17.2.2.4 DDDS shall notify the primary contact and CEO of the provider of the decision to grant or deny the appeal via e-mail and certified letter within five (5) business days of the decision.

17.2.2.5 If the appeal is denied, corrective measures will become effective upon issuance of the decision communication.

17.2.3 The second level of appeal of the imposition of corrective measures shall be to the Division Director.

17.2.3.1 The application of corrective measures by DDDS will not be suspended during this second level appeal.

17.2.3.2 Within ten (10) business days of the receipt of the notification of outcome of the first level of appeal, the provider must submit to the Division Director a written request for second level appeal, documenting the basis for the appeal and including all supporting data or evidence to be considered in the appeal. The request submission must identify supporting data or evidence that is new or different than what was presented in the first level of appeal. The request must identify the provider's primary contact and CEO to be notified of the appeal decision.

17.2.3.3 The Division Director shall have up to ten (10) business days from receipt of the written request for appeal to issue a decision to grant or deny the appeal.

17.2.3.4 DDDS shall notify the primary contact and CEO of the provider of the decision to grant or deny the appeal via e-mail and certified letter within five (5) business days of the decision.

17.2.4 The third level of appeal of imposition of corrective measures shall be with the Division of Health Care Quality Investigation Unit.

17.2.4.1 The application of corrective measures by DDDS will not be suspended during this third level appeal.

17.2.4.2 Within ten (10) business days of the receipt of the notification of outcome of the second level of appeal, the provider must submit to the Health Care Quality Hearing Officer and DDDS Division

Director a written request for third level appeal, documenting the basis for the appeal and including all supporting data or evidence to be considered in the appeal. The request submission must identify supporting data or evidence that is new or different than what was presented in the second level of appeal. The request must identify the provider's primary contact and CEO to be notified of the appeal decision.

17.2.4.3 Within ten (10) business days of the receipt of the request for third level appeal, DDDS shall submit to the DHCQ Hearing Officer the DDDS evidence and rationale for imposing corrective measures.

17.2.4.4 The DHCQ hearing officer shall have up to fifteen (15) business days from the receipt of the written request for appeal to issue a decision granting or denying the appeal.

17.2.4.5 DHCQ shall notify the primary contact, the CEO of the provider and the DDDS Director of the decision to grant or deny the appeal via e-mail and certified letter within five (5) business days of the decision.

17.2.5 The fourth and final level of appeal shall be with Division of Medicaid and Medical Assistance (DMMA) in accordance with The *Delaware Medical Assistance Program (DMAP), General policy Manual*, Section 6.0, Appendix A – Appeals Procedures. This level of appeal is available only for corrective measures that constitute an adverse action, as defined in the DMAP policy.

17.2.5.1 Per the DMAP Appeals Policy, a provider appeal filed in accordance with the DMAP appeal procedures does not stop the adverse action.

17.2.5.2 However, upon application by the provider, the DMMA Director may, in its sole discretion and as permitted by federal law, grant a stay of the adverse action pending the outcome of the hearing.

17.2.5.3 Prior to submitting an appeal to DMMA, providers must exhaust all avenues of appeal and resolution through the entity that imposed the adverse action.

18.0 Severability

Should any section, sentence, clause or phrase of these regulations be legally declared unconstitutional or invalid for any reason, the remainder of said regulations shall not be affected thereby.

23 DE Reg. 182 (09/01/19) (Prop.)