Section 2 Guidance for Monitoring the Reporting of Complaints and Incidents

The Policy

Oversight of the health and welfare of Health Home members through care coordination and linkage to services and programs is an essential element within the provision of care and services of the Health Home program.

Health Homes (HH) must establish a procedure to identify and investigate complaints and incidents that occur or those received from Health Home members/designee (e.g., family, guardian, etc.), staff or other relevant parties, and work toward resolution. The result of the investigation should ease the impact of the situation for the member, and prevent reoccurrence of similar or future events whenever possible.

HHs must ensure that care management agencies (CMA) have policies and procedures in place which provide guidance regarding how to manage and report complaints and incidents, and maintain supporting documentation related to the receipt and resolution of complaints and incidents (e.g., steps taken toward resolution, member satisfaction, etc.).

HHs must have policies and procedures in place to identify problematic trends in agencies within their partner networks and provide appropriate interventions when corrective actions are needed. Actions must be taken to minimize the probability of recurrence. Such actions must be documented and available for review by the New York State Department of Health (NYSDOH).

HHs must have policies and procedures in place to assure that members are informed of their right to file a complaint, incident, and/or request a State fair hearing as per 42 CFR § 438.100, § 438.10 and 42 CFR §§ 438.400 - 438.424 (for Managed Care members), Title 18 of the New York Codes, Rules and Regulations (NYCRR), Sub Part 358 (for fee-for-service members) and Sub Part 360-10.8 (for Managed Care Enrollees), and other applicable State law and regulations. This information must be written in a reading level easily understood by HH members.

During outreach and engagement, potential HH members must be provided with a Letter of Introduction that includes contact information for the HH, CMA, and the Medicaid Help Line should the potential member have any concerns related to this process. In addition, HHs must provide enrolled members with clearly written instructions on how to file a complaint, incident, and/or request a State fair hearing including all appropriate contacts, (e.g., CMA, HH, NYSDOH, Office of Temporary
Health Home Monitoring: Policies and Procedures
Revised: October 2015

Disability Assistance (OTDA), Managed Care Organizations (MCO), etc.). This information shall be contained in the Member Rights and Responsibilities document which is reviewed and signed by the CMA/HH and member at the time of enrollment annually and as otherwise necessary. The signed document is maintained in the member’s record with a copy provided to the member upon signing. Additionally, HHs will inform members that assistance and support to file a complaint, incident and/or fair hearing will be provided by the HH or CMA, e.g., written/verbal notification, language interpretation, hearing and vision assistance, etc.

NOTE: HHs are required to work with State agencies such as NYSDOH, Office of Mental Health (OMH), Office of Alcoholism and Substance Abuse Services (OASAS), Aids Institute (AI), and the Bureau of Managed Care Certification and Surveillance (MCO), and with managed care plans (MCP) who become involved in an investigation of a complaint or incident. HHs must comply with requests from these agencies to provide documentation including but not limited to case records of the Health Home member. It is critical that HHs and these entities work collaboratively to ensure a thorough investigation is conducted without duplicating efforts.

Purpose:
To monitor the reporting of complaints and incidents, this policy identifies three reporting Levels as follows:

Level 1 Complaints that are managed by the CMA;
Level 2 Incidents that are managed jointly between the HH and CMA and do not require notification to the NYSDOH; and,
Level 3 Incidents that are managed jointly between the HH and CMA and must be reported to the NYSDOH.

This policy provides guidance to HHs regarding the Reporting, Documentation and Notification requirements, Timeframes for Resolution, and Tracking for all three levels.

Section 2A: Level 1 Complaints

Definition
A Level 1 Complaint is defined as any dissatisfaction expressed verbally or in writing by the member or member’s designee related to the provision of Health Home care management services or other services identified in the member’s plan of care.

Level 1 Complaints do not:
• require psychiatric treatment and are resolved with reassurance and support;
Health Home Monitoring: Policies and Procedures

- affect the health and welfare of the member (e.g., do not result in physical or psychological harm);

Some examples of Level 1 Complaints may include, but are not limited to:
- Customer service issues or dissatisfaction with services;
- CM did not coordinate the member’s plan of care to his/her satisfaction;
- CM failed to set up needed transportation resulting in the member’s late arrival at an appointment;
- Member informs CM of a long wait time in doctor’s office;
- CM repeatedly didn’t return phone calls;
- CMA did not respond to member’s request to change CMs;

Reporting Requirements

HHs must have policies and procedures in place for how CMAs handle complaints from/on behalf of members.

Level 1 Complaint investigations are managed solely by the CMA regardless of whether the agency is part of the lead HH or one of the HHs contracted downstream CMAs.

Policies must include how CMAs will self-monitor for trends.

Timeframes for Resolution of a Complaint by CMA

The HH must have policies in place for how CMA will resolve Level 1 Complaints and expected timeframes for completing Level 1 Complaint investigations.

The CMA must work with the member to resolve Level 1 complaints and assist the member by advocating on his/her behalf.

Policies must include how the CMA will respond to the member depending on whether Complaint is submitted by the member verbally or in writing.

If a Level 1 Complaint cannot be immediately resolved to the member’s satisfaction, the CMA must strive to resolve it within a reasonable time frame as per agreement between the HH and CMA. This additional time required must be documented by the CMA.

The HH must have policies and procedures in place to assure that a hierarchical system for notifying the HH is used when:
Health Home Monitoring: Policies and Procedures

Revised: October 2015

1. the member is not satisfied with the outcome after attempts were made by the CMA to resolve the complaint; and,
2. the CMA determines that the Level 1 complaint is actually a Level 2 or 3 incident.

This hierarchical system must include time frames for notifying the HH when either of these situations occur per agreement between the HH and CMA. In addition, the policy must also include the process for upgrading a Level 1 complaint to a Level 2 or Level 3 incident, when indicated.

Documentation Requirements

Level 1 complaints must be maintained separately from the member’s case record.

HHs must have policies in place to assure that CMAs document all Level 1 complaints including all attempts made to resolve the complaint, timeframe for completion, and member satisfaction.

Additionally, if the Level 1 complaint was brought to the HHs attention by the CMA due to inability to resolve or being identified as a Level 2 or 3 incident, the CMA must document measures taken to notify the HH and outcomes of those actions.

Section 2B: Level 2 Incidents
Section 2C: Level 3 Incidents

Investigation of Level 2 and Level 3 Incidents by HHs and CMAs are required when a HH member is involved. If a HH or CMA is aware of a Level 2 or Level 3 incident that occurs in a licensed agency or facility, or involves the actions of a licensed agency or facility, or of an individual in its employ, it is the responsibility of that licensed agency or facility to investigation and report the incident per its established protocols.

The HH and CMA should have policies to document when this occurs, and assist and support the member as necessary. The State has established the New York Justice Center (NYJC) to serve as a central reporting point for allegations of fraud and abuse against persons with special needs by entities licensed by OMH, OASAS, State Educations Department (SED), and Office for People with Developmental Disabilities (OPWDD). HHs and CMAs may report any such allegations to the NYJC as required and maintain documentation of the report. Information on reporting to the NYJC can be found at: http://www.justicecenter.ny.gov/incident-reporting/report-abuse.
Health Home Monitoring: Policies and Procedures

Revised: October 2015

NOTE: HHs are required to work collaboratively with State agencies such as NYSDOH, OMH, OASAS, AI, MCO, and with managed care plans (MCP) any time during the investigation. HHs must comply with requests from these agencies to provide documentation including but not limited to case records of the Health Home member. It is critical that HHs and these entities work collaboratively to ensure a thorough investigation is conducted without duplicating efforts.

Section 2B: Level 2 Incidents

Definition

A Level 2 Incident is defined as an urgent issue, event, or action either perceived or an actual threat that could have potential ill effect on the member’s health and welfare, and can include an action taken by or against the member or, by another individual(s). The member may experience or subject another person to a level of physical and/or psychological harm, sustain or cause injury resulting in medical intervention and treatment, pose serious physical injury or life threatening harm, or require emergency life-saving procedures. Some Level 2 events may be a crime under New York State or Federal Law.

Examples of Level 2 incidents may include but are not limited to:

1) Abuse (physical, verbal, etc.);
2) Neglect;
3) Suicide attempt;
4) Violation of Civil Rights;
5) Missing Person;
6) Sexual Assault (rape or attempted rape);
7) Domestic violence;
8) Any voluntary or involuntary sexual contact involving a member and CMA staff;
9) Illegal sale or possession of narcotics;
10) Robbery;
11) Motor vehicle accident;
12) Possession of a deadly weapon;
13) DWI/DUI;
14) Verbal or physical aggression toward the member, or by the member toward another person without life threatening injury;
15) Death of a HH member (While it is understood that some causes of death may be anticipated (e.g.,
someone who is terminally ill and receiving end-of-life care), it is important to evaluate all deaths involving Health Home members to determine whether there was a lapse or failure in care management that negatively impacted the member and potentially contributed to the occurrence of death. In cases where this has been determined, an investigation must be conducted).

**NOTE:** Member death is categorized into two incident levels (Level 2 and Level 3). Please refer to Section 2C - Level 3 Incidents to assure compliance with managing member deaths at the appropriate Level.

### Reporting Requirements

HHs must have policies in place for how Level 2 incidents are investigated.

All Level 2 incidents must be reported to the HH. The HH and CMA work jointly to assure the Incident is investigated.

Policy must include specific timelines for reporting allegations of Level 2 incidents to the HH by the CMA. An example may be: within three (3) days of learning that an incident occurred the CMA must notify the HH.

Policy must include the HHs involvement in the investigation process including discussion of the focus of the investigation with the CMA, documentation review, determining outcomes, etc.

HHs and CMAs must take necessary steps to assure the member’s safety is secured upon receiving notification that the incident occurred.

HHs must also assure incidents are reported to the appropriate reporting agency, e.g., Adult Protective Services (APS), Child Protective Services (CPS), legal aid, law enforcement, etc., as per usual protocol.

### Timeframes for Resolution of Level 2 Incidents by Health Homes

Policy must include timelines for completing a Level 2 investigation and determining the outcome. This includes timeframes for investigation by the CMA, reporting findings to the HH, and the HH’s assessment. CMAs must make every effort to investigate and provide an outcome of the incident to the HH. HHs must monitor for timely response from CMAs and address any inconsistencies in this process.
Health Home Monitoring: Policies and Procedures

Revised: October 2015

Documentation Requirements

Level 2 incidents must be maintained separately from the member’s case record.

HHs must assure that information shared between the HH and CMA is done so in a secure manner.

HHs must have policies and procedures in place to assure that all incidents are tracked by the HH and CMA.

HHs are responsible for assessing network providers, identifying trends, and for taking corrective action related to incidents.

Notification Requirements

Policy must include a mechanism for CMAs to notify HHs when investigations require additional time for completion due to the nature of the allegation and investigation process. HHs must work with the CMA to determine a reasonable period of time to obtain a satisfactory resolution. Extension of time must be documented by the HH and CMA.

Once all information is obtained and reviewed by the HH, the HH must document findings including substantiation of the allegation, negative outcomes, and need for corrective action. Final outcome must be provided to the CMA by the HH in writing.

The HH must have policies and procedures in place to assure that a hierarchical system is used when satisfactory resolution of a Level 2 Incident cannot be obtained. Examples of this may be but are not limited to:

1. The member is not satisfied with the outcome after attempts were made by the HH and CMA to resolve the incident and the HH feels that guidance from NYSDOH is warranted;
2. The HH cannot determine appropriate findings after thorough investigation has been completed and feels that guidance from NYSDOH is warranted;
3. The investigation reveals that the Level 2 Incident is actually a Level 3 Incident;
4. The HH determines that there are negative findings related to activities or inactivity of the CMA or HH that contributed to the incident;
5. The HH determines a negative trend that impacts the member(s) or its overall network.
Health Home Monitoring: Policies and Procedures

Revised: October 2015

Upon any of these occurrences, the HH must notify NYSDOH within **24-business hours** of making this determination (refer to Section 2C - Level 3 Incidents).

**Section 2C: Level 3 Incidents**

**Definition**

Level 3 incidents require involvement by NYSDOH when any of the following occurs:

1. Homicide committed against or by the member;
2. The HH identifies trends in its network that has impacted or has the potential to impact members;
3. The HH cannot conclude its findings, or member satisfaction cannot be reached during Level 2 investigations that warrants guidance from NYSDOH;
4. The HH determines that the actions/inactivity of the CMA or HH negatively impacted the member and contributed to the allegation of Level 2 incidents;
5. Any Level 1 complaint or Level 2 incident investigation that is determined to be a Level 3.

**Reporting Requirements**

HHs must have policies in place for how Level 3 Incidents will be investigated.

All Level 3 Incidents must be reported by the HH to the NYSDOH who will provide guidance regarding the focus of the investigation.

NYSDOH will determine whether notification to another State agency (e.g., OASAS, AI, OMH, the Bureau of Managed Care Certification and Surveillance) or other entity is warranted.

**Timeframes for Resolution of Level 3 Incident by Health Homes**

HHs must have policies and procedures in place for notifying NYSDOH upon identifying that a Level 3 Incident has occurred.

Within **twenty-four (24) hours** of learning that a Level 3 incident has occurred, the CMA and HH must communicate. The HH will discuss the focus of the investigation with the CMA, including the need to involve other State agencies in the investigation process.
Health Home Monitoring: Policies and Procedures

The Health Home must in turn, contact NYSDOH via the Health Home Provider Line within twenty four (24) hours of identifying that a Level 3 incident has occurred.

The HH and CMA will continue to work together to obtain information related to the incident to fully understand what has occurred.

A timeline for completion of the investigation will be provided to the HH by the NYSDOH (generally this is 10 business days but is subject to change depending on the nature and severity of the Level 3 Incident). The HH will review all information obtained during the investigation and document findings, including any negative outcomes identified, and potential corrective actions. The HH must provide this information to the NYSDOH by the due date specified by NYSDOH.

If additional time if needed to complete the investigation and determine findings, the HH must notify NYSDOH of the extended time needed and self-monitor to assure this extended timeline is met.

Documentation Requirements

Level 3 Incidents must be well documented and maintained separately from the member’s case record.

Health Homes must assure that information shared between the CMA, HH and NYSDOH is done so in a secured manner.

Health Homes must assure that all Level 3 incidents are tracked by the HH and CMA, and monitored for trends to prevent reoccurrence.

Section 2D: Complaints and Incidents Reported During Outreach

If a Complaint is filed with the CMA, or an Incident is filed with the CMA or HH for an individual who is in Outreach, a determination must be made regarding the nature of the allegation and the extent to which the allegation needs to be investigated.

If a complaint or incident is reported by/on behalf of an individual who is in Outreach but not enrolled in the Health Home program, it is still important to look at the issue/allegation and determine whether the actions or inactivity of the HH or CMA could have potentially contributed to the occurrence of the complaint/incident.
Health Home Monitoring: Policies and Procedures

Revised: October 2015

Example: An individual was assigned to a HH who referred the individual to the CMA in two days. However, the CMA didn’t initiate outreach for two months, and attempts were minimal. In the interim something happened to the individual that appears to have been preventable if s/he had been connected to the HH program timely. An investigation of actions/inactivity during outreach would be warranted.

Section 2E: Personal Health Information (PHI) Breach

What is PHI?

The Office for Civil Rights enforces the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, which protects the privacy of individually identifiable health information; the HIPAA Security Rule, which sets national standards for the security of electronic protected health information; the HIPAA Breach Notification Rule, which requires covered entities and business associates to provide notification following a breach of unsecured protected health information; and the confidentiality provisions of the Patient Safety Rule, which protect identifiable information being used to analyze patient safety events and improve patient safety.

What to do in the event a Health Home or Care Management Agency identifies that a PHI breach has occurred

Health Homes are required by law to report any PHI breach as per the HIPAA Breach Notification Rule, 45 CFR §§ 164.400-414 which can be accessed on the US Department of Health and Human Services website at: http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/index.html

Additionally, as per the Data Exchange Application and Agreement (DEAA), Health Homes are required to report any PHI breach involving a Health Home member that occurs within the Health Home or its network providers to the NYSDOH Privacy Office at: caryl.shakshober@health.ny.gov

For information about the Breach Notification 45 CFR §§ 164.400-414, refer to the US Department of Health and Human Services website at: http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/index.html

For information related to HIPAA Privacy Rules, refer to The Office of Civil Rights at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html

Section 2F: Complaints and Incidents Initiated by NYSDOH
Health Home Monitoring: Policies and Procedures

NYSDOH may receive complaint/incident reports through other means, such as direct emails, HH Provider Line, New York Justice Center (NYJC), Executive Correspondence Unit (ECU), etc. These must be investigated using the same procedures outlined in this policy. Notification will come from NYSDOH to the HH where the member involved in the complaint or incident is enrolled.

Section 2G: Health Home and Care Management Agency Tracking Guidance for Complaints and Incidents

HHs must assure that policies and procedures include guidance for HHs and CMA(s) to track all complaints and incidents reported for trends, corrective action plans, and to prevent reoccurrence.

Options for tracking information may include but are not limited to:
- copy of original complaint or incident, if written;
- member or person reporting on member's behalf;
- allegation type(s);
- others involved in allegation
- date/time, location of alleged occurrence;
- date/time allegation received;
- date/time of initial contact between CMA and HH;
- notification to outside sources such as law enforcement, APS, CPS, legal aid, etc., as appropriate;
- notification to other entities, such as NYSDOH or other State agency, as appropriate;
- date/time/contact name of licensed facility/agency, if referred;
- timelines met for completing investigation;
- outcome of the investigation;
- Health Home findings;
- Corrective actions identified and completed;
- outcome of any additional investigation, as appropriate; and,
- notification to the member/complainant of outcome (general information may be provided but should not include specific examples such as the termination of an employee, etc.).

Section 2H: Health Home and Care Management Agency Quarterly Reporting Requirements
Health Home Monitoring: Policies and Procedures

Revised: October 2015

HHs must have policies and procedures in place to retain the following documentation regarding Level 1, 2 and 3 investigations. Documentation can be requested by the State for review at any time. A system will be developed for statistical reporting of numbers and types of complaints to NYSDOH. Documentation must include the following information:

- Level (1, 2 or 3);
- Allegation type;
- Reporting timelines met;
- Outcome of investigation;
- Whether complaint/incident rose to higher Level;
- Health Home’s findings;
- Member satisfaction;
- Corrective actions needed/taken;
- Notification required to NYSDOH;
- Notification to other State agency(s);
- Notification to Managed Care Plans; and,
- Notification to other entity/outside source.