NORTH CAROLINA
INCIDENT RESPONSE IMPROVEMENT SYSTEM

Department of Health and Human Services
Division of Mental Health, Developmental Disabilities, and Substance Abuse Services

Incident Response and Reporting Manual

February 2011

NORTH CAROLINA DIVISION OF MH/DD/SAS

325 N. Salisbury Street
3003 Mail Service Center
Raleigh, NC 27699-3003

Phone: 919-733-0696

THIS PAGE IS INTENTIONALLY LEFT BLANK

TABLE OF CONTENTS

Incident Reporting and Improvement System (IRIS)

I. GENERAL INSTRUCTIONS

A. Purpose

The purpose of the Department of Health and Human Services (DHHS) and Division of Mental Health/ Developmental Disabilities/Substance Abuse Service (DMH/DD/SAS) Incident Reporting System is to ensure that serious adverse events involving persons receiving publicly-funded mental health, developmental disabilities, and/or substance abuse (mh/dd/sa) services are addressed quickly and analyze trends to prevent future occurrences and improve the service system.

B. Who must submit incident reports?

Providers of publicly funded services licensed under NC General Statutes 122C (Category A providers), except hospitals, and providers of publicly funded non-licensed periodic or community-based mental health, developmental disabilities and/or substance abuse services (Category B providers) are required to report incidents involving consumers receiving mental health, developmental disabilities and/or substance abuse services. Failure to do so, as required by North Carolina Administrative Code 10A NCAC 27G .0600, may result in DHHS taking administrative action against the provider's license or authorization to provide services. Hospitals and providers of services licensed under G.S. 131D or G.S. 131E (Category C providers) and individuals certified or licensed in North Carolina to provide only outpatient or day services (Category D providers) are not required to submit incident reports in IRIS.

Note: All Opioid Treatment Providers are required to submit incident reports regarding Level III incidents to the Division of MH/DD/SAS. These agencies are also required to submit Level II reports of medication errors as well as suspensions and expulsions from services.

Note: Residential Level II-Family Type (TFC) agencies are G.S. 131-D, Category C providers, licensed by the Division of Social Services (DSS); therefore, the TFC provider must follow the DSS incident reporting requirements. However, when there is a service being provided to a child receiving therapeutic foster care by a MH/DD/SAS provider*, the MH/DD/SAS provider must follow DHHS incident reporting requirements. In order to prevent multiple agencies going into TFC agencies to investigate incidents, DSS alone is responsible for investigations.

*This is not limited to reporting incidents that occur only when the MH/DD/SAS provider is providing a MH/DD/SAS service to the consumer. When the MH/DD/SAS provider observes or otherwise learns of the incident they should begin the incident reporting process.

Providers should also notify all other appropriate agencies (such as any accrediting or regulatory agencies) as required by all governing rules or statues, including federal requirements.

C. What is an Incident?

An "incident," as defined in 10A NCAC 27G .0103(b)(32), is " any happening which is not consistent with the routine operation of a facility or service or the routine care of a consumer and that is likely to lead to adverse effects upon a consumer." Therefore, Category A and B providers are required to report any adverse event that is not consistent with the routine operation of a facility or service or the routine care of a consumer.

There are three levels of response to incidents, based on the potential or actual severity of the event. Appendix A at the end of this document defines incidents at each level in detail and describes the reporting responsibilities for each level of incident. Appendix B defines the criteria for determining these levels and Appendix C defines the reporting requirements and timeframes.

D. Confidentiality

All incident reports are confidential quality assurance documents, protected by G.S. 122C-30, G.S. 122C-31, G.S. 122C-191, and G.S. 122C-192. Do not file incident reports in the individual's service record. Use this incident reporting process according to confidentiality requirements in NC General Statutes and Administrative Code and in the Code of Federal Regulations:

- NC General Statutes 122C-52 through 56 and Administrative Code 10A NCAC 26B
- Federal regulations 42 CFR Part 2 and 45 CFR Parts 160 and 164. Approved use of this form is permitted under the audit or evaluation exception of 42 CFR Part 2.53, which allows disclosure of information without the individual's consent. Re-disclosure of information is explicitly prohibited except as provided in 42 CFR Part 2.

E. When to File?

(Table 1. Reporting Timelines) *

Type of Incident	Report to Host LME	Report to Home LME	Report to DMH/ DD/SAS *(all providers)*	Report to DHSR Complaint Intake Unit *(122C-Licensed providers only)*
Level II incident (including death from natural causes or terminal illness)	IRIS report within 72 hours	If required by contract	No report except for Opioid providers	No report
Level III incident (other than death)	Verbal report immediately IRIS report within 72 hours	Verbal report immediately IRIS report within 72 hours	IRIS report within 72 hours	No report
Death from suicide, accident, homicide, other violence	Verbal report immediately IRIS report within 72 hours	Verbal report immediately IRIS report within 72 hours	IRIS report within 72 hours	IRIS report within 72 hours
Death from unknown cause	Verbal report immediately IRIS report within 72 hours	Verbal report immediately IRIS report within 72 hours	IRIS report within 72 hours	No report
Death within 7 days of seclusion or restraint	IRIS report immediately	IRIS report immediately	IRIS report immediately	IRIS report immediately

* **Reports to DHSR Health Care Personnel Registry regarding an allegation against an unlicensed staff in a licensed or unlicensed facility should be submitted within 24 hours of the agency becoming aware of the incident.**

F. How to Submit?

DHHS and DMH/DD/SAS developed the Incident Reporting and Improvement System (IRIS) as a web based incident reporting system for reporting and documenting response to Level II and III incidents. The purpose of IRIS is to provide a consistent process for all providers, LMEs and DHHS staff to report incidents in a timely manner, and to use data and data analysis to prevent future incidents and improve the service system. The IRIS web-based reporting system replaces the DHHS Incident and Death Report (DMH/DD/SAS Form QM02).

Effective July 1, 2010, all incident reports must be reported via the IRIS system. IRIS will be used for reporting incidents pursuant to rules for 10A NCAC 27G .0600- .0610, and the Report of Death to DHHS Form (rev. 8/10/00) for reporting deaths to DHHS, pursuant to G.S. 122C-31.

All incidents are to be submitted electronically through IRIS at the following website: https://iris.dhhs.state.nc.us/

(Download or Print a copy of each incident report you submit for your records. Keep a copy of the incident report number in case you need to view the report later. Keep the incident report number in a secure location.)

Note: If IRIS is unavailable at any time, providers still must meet the required timeframes for submission of an incident. Incident reporting forms in paper format are available on the N.C. Division of Mental Health/ Developmental Disabilities/ Substance Abuse Services website at: http://www.ncdhhs.gov/mhddsas/statspublications/manualsforms/index.htm

Providers should download the appropriate form (based on the type of incident that has occurred) and fax the incident report to the appropriate agencies. The provider must enter the data into IRIS as soon as possible once the IRIS system is available.

Once an incident report is submitted, IRIS automatically notifies all appropriate agencies of the submission and the report is made available to each of these agencies.

Paper forms are not accepted except in an extreme situation. Paper forms should then be should be submitted to the proper agencies as applicable, such as DSS, Host LME, Home LME, DMH/DD/SAS, DHSR Complaint Intake Unit and/ or DHSR Health Care Personnel Registry (HCPR). **Forms may be submitted to DMH/DD/SAS Quality Management Team via fax at (919) 508-0986 and to the NC Division of Health Services Regulation (DHSR), Complaint Intake Unit, 2711 Mail Service Center, Raleigh, NC 27699-2711, Fax: (919) 715-7724, Voice: (800) 624-3004**.

Note: If the cause of death is initially unknown and later determined to be a result of suicide, accident, homicide or other violence or occurs within 7 days of seclusion or restraint, the provider must update the original incident/death report with the additional information or changes regarding the cause of death by the end of the next business day after the provider learns of the new information.

II. REPORTING GUIDELINES

A. Documentation of All Incidents:

All incidents should be documented and analyzed as part of the provider's quality assurance and improvement processes.

- Level I incidents are to be documented on the provider agency's internal form and should not be submitted in IRIS.
- Level II and III incidents must be documented in IRIS. All incident reports are protected quality assurance documents and should not be filed in the individual's service record.

Complete all required sections for Level II and III incidents. Give as much information as is known about an incident even if the incident occurred when the individual was not under your active care.

B. Under Your Care

- The definition for "a consumer under the care of a provider" refers to a consumer who has received any service in the 90 days prior to the incident.
- Reporting of Incidents is required for purposes of communication and timely response.

Individuals receiving Residential or Assertive Community Treatment Team (ACTT) services are considered under the provider's care 24 hours a day. Individuals receiving day services or periodic services are considered under the provider's care while a staff person is providing services or if the consumer received any services from the provider in the 90 days prior to the incident.

Note: Providers of crisis, day, and periodic services should report all deaths and errors in self-administration of medications upon learning of the incident, even if it did not happen while under the provider's care.

Crisis Service Exceptions:

- All crisis providers are expected to report incidents that occur during the provision of crisis services.
- For mobile crisis providers, this includes incidents that occur between the time they receive the request for crisis services and during their face-to-face contact with the consumer.
- For facility-based crisis providers, this includes incidents that occur when a consumer is on their premises or in their care.

C. Incident Categories

Note: Illness of a Consumer: Medical illness is not reportable unless it results in injury or death, or is believed to be caused by abuse/ neglect or medication error.

1. Consumer Deaths

Report all consumer deaths whenever you become aware of the death, even if the death occurred while the individual was not under your care. The purpose is to ensure that all local and state agencies are aware of consumer deaths and work to eliminate deaths.

Note: Cause of death by Natural Cause or Terminal illness should be documented by a physician, Medical Examiner or Death Certificate

- **Requirements Regarding a Consumer's Death by Suicide, Homicide/Violence, Accident, or Unknown Cause (All Level III's).**

  In an effort to obtain accurate data regarding the cause of death of a consumer, providers should obtain a copy of the Medical examiner's (ME) report and /or the autopsy report. If the Medical Examiner's report or autopsy report is not available, the provider may request a copy of the death certificate. Providers should request this information and submit updated information based on 10A NCAC 26C .0303 (f) (3).

Note: The web address for requesting a free copy of the Medical Examiner's Report, Autopsy Report or Toxicology Report is http://www.ocme.unc.edu/docrequest.shtml.

Providers must update the incident report based upon this information even if the cause of death does not change the level of the incident. Updated information should be entered into IRIS and the specific reason for the update should be explained by the supervisor of the provider agency in the Supervisor's Action section of IRIS. Attach a copy of the aforementioned documents and resubmit the incident report with a comment briefly describing the change.

- For Level III incidents that occurred while the consumer was receiving a service or was on the provider's premises, the provider must complete an Internal Team Review. For Level III incidents that did not occur while the consumer was receiving a service or was on the provider's premises, the responsible LMEs may continue to request detailed information regarding services if this information is not already provided in the incident report.

2. **Injury:**

Complete this section whenever a consumer is injured and requires more than first aid. First aid given by a licensed health professional should be considered a Level I incident and does not need to be reported outside of the provider agency. Use the federal Occupational Safety and Health Administration's guidelines [29 CFR 1904.7(b)(5)(ii)] in Appendix D to distinguish between injuries requiring first aid and those requiring treatment by a health professional.

A visit to an emergency room (in and of itself) is not considered an incident. Do not submit incident reports for visits to a hospital emergency room, if the person received no treatment. An X-ray, CAT Scan, drawing of blood or any other diagnostic assessment is not considered treatment. (Example: Bob thinks his arm is broken and goes to the E.R. An x-ray is performed and his arm is not broken. This is not an incident. If the x-ray showed his arm to be broken and the doctor applied a cast, the application of the cast is treatment. Putting a sprained arm in a cast, stitches, cleaning a wound, all of these are treatment. Shots and prescription medication are treatment.

3. **Allegations of Abuse, Neglect or Exploitation**

Report all suspected or alleged cases of abuse, neglect or exploitation of a child (age 17 or under) or disabled adult to the local DSS, pursuant to G.S. 108A Article 6, G.S. 7B Article 3 and 10A NCAC 27G .0610.

Note: Level I incidents of suspected or alleged cases of abuse, neglect or exploitation of a child (age 17 or under) or disabled adult must still be reported pursuant to G.S. 108A Article 6, G.S. 7B Article 3 and 10A NCAC 27G .0610.

(a) To the county Department of Social Services in which the suspected activity occurred, if the activity involves a parent, guardian, or caretaker,

(b) To the DHSR Healthcare Personnel Registry, if the activity involves healthcare personnel,

(c) To the host LME using IRIS, and, if required by contract or memorandum of understanding, to the individual's home LME, **and**

(d) If a Level III incident is involved, to the home LME and to the DMH/DD/SAS Quality Management Team.

Note: IRIS cannot submit report to Department of Social Services (DSS). The provider is responsible for contacting DSS.

4. Restrictive Interventions

Report any restrictive intervention that is:

(a) used in an unplanned, emergency situation (i.e., not part of the individual's service plan and approved according to 10A NCAC 27E .0104);

(b) planned, but administered improperly or without proper authorization, by staff without proper training, or for longer than the authorized time; or

(c) planned, but resulting in discomfort, complaint, death or injury requiring treatment by a licensed health professional.

Note: The Restrictive Intervention Details Report should be filed in the individual's service record as documentation of the use of the intervention. However, do not file the DHHS Incident and Death Report in the individual's record, as this is a quality assurance document.

5. Incidents of Concern for Community

If an incident is perceived to be a significant danger to the community or involves a consumer whose behavior poses an eminent concern to the community, the provider is to verbally report the incident to the Host LME and the DMH/DD/SAS Customer Service and Community Rights Team (919-715-3197) immediately upon learning of the incident.

6. Medication Errors

In the case of any medication error, the consumer's physician or pharmacist, should be notified immediately of any medication error, as required by 10A NCAC 27G .0209(h).. **The physician pharmacist, physician's assistant or a nurse practitioner should determine the level of threat to the consumer's health and determine the treatment required, if any.**

If the physician or pharmacist indicates that the medication error does not threaten the consumer's health or safety, document the error as a Level I incident. The Level I documentation should indicate the type of error, name of the physician or pharmacist consulted, their statement about the error, the date and time of the contact, and the name of the person making the contact.

Note: If after the medication error the consumer shows any side effects or distress (coughing, pain, confusion, vomiting, unusual sleepiness, etc., seek immediate medical attention.

Note: Report Level II or III errors in self-administration of medications within 72 hours of learning of the incident, even if it did not happen while actively engaged in providing services.

Report the following errors as necessary:

(a) **Missed dose** – Any dosage of a medication not given to a consumer. This does not include a refusal.

(b) **Wrong dosage** – Any dosage of a medication that does not follow the prescribed order

(c) **Dose preparation error** – Medication is not mixed properly.

(d) **Wrong time** – Any dosage of a medication not given within one hour before or after the prescribed dosing time

(e) **Wrong administrative technique** – Medication is give improperly, such as orally instead of via rubbed into the skin.

(f) **Dose given to wrong consumer** – Someone's medication given to someone else.

(g) **Wrong medication** – Any incorrect or expired prescription medication administered to a consumer

(h) **Loss or spillage of medication** - Pills are dropped and lost, liquid medication spilled

(i) **Refusal** - Missed dosages due to the individual's refusal to take the medication

(j) **Other**

7. Consumer Behavior:

Report any sexual, aggressive, or destructive behavior that involves a report to law enforcement, a complaint to an oversight agency, including any LME, DSS, DHSR or DMH/DD/SAS, or a potentially serious threat to the health or safety of self or others.

Note to providers of day and periodic services: Report to the LME any consumer acts that are reported to law enforcement in any of the following situations:

- if the incident occurs when you are actively engaged in providing services, or
- if the incident is related to the reason the individual is in treatment, or
- when you learn of the legal involvement of the individual.

Consumer sexual behavior between two competent, consenting adults is considered a Level II incident only if it occurs in an inappropriate setting (for example, a public area).

A Consumer absence is any absence over the time specified in the individual's service plan or any absence that may or may not require police contact is an incident. The level of the incident is determined by the number of hours that a person is absent and whether police contact is required. If an Amber or Silver Alert has been issued, it is a Level III incident and providers should alert appropriate agencies as soon as possible.

8. Suspension or Expulsion from Services

Complete this section whenever a consumer is suspended or expelled from services. For suspensions of an individual from services, check the box and also enter the length of the suspension.

9. Fire

Complete this section whenever there is an injury, a consumer faces a threat to health or safety or the fire has an impact on public confidence.

III. QUARTERLY REPORTING OF LEVEL I INCIDENTS

Providers are required to report aggregate information on Level I incidents involving restrictive interventions, medication errors, and searches and seizures to the host LME quarterly, using a form provided by the DHHS. The Quarterly Provider Incident Report is available on the DMH/DD/SAS website at http://www.ncdhhs.gov/mhddsas/statspublications/manualsforms/index.htm#incident.

A. When to Report

The quarterly reports must be submitted by the 10th of the month following the end of the quarter.

Information on Incidents In:	Is Due:
First quarter (July-September)	October 10th
Second quarter (October-December)	January 10th
Third quarter (January-March)	April 10th
Fourth quarter (April-June)	July 10th

B. What / Where to Report

Submit aggregate information on Level I restrictive interventions, medication errors, and searches/seizures should be collected and reported to the host LME. For each type of incident, report:

(1) the total number of incidents,

(2) the unduplicated count number of consumers who were involved,

(3) the highest number of incidents for any one consumer,

(4) a brief narrative summarizing any patterns and/or trends you have found in your internal QI process has identified in its analysis of incidents that may indicate an opportunity to make improvements, and

(5) a brief narrative summarizing the quality assurance/improvement efforts being undertaken to address any opportunities for improvement that have been identified.

IV. UPDATING INFORMATION OF REPORTS

A provider must submit an initial incident report within 72 hours of learning about an incident, even if the provider does not have all of the facts about an incident. This report should contain all of the information that the provider knows at the time of submission. When provider obtains or is informed about new or additional information related to the incident, the provider must update the original report and submit the update information by the end of the next business day after becoming aware of the information. **If the cause of death is initially unknown and later determined to be a result of suicide, accident, homicide or other violence or occurs within 7 days of seclusion or restraint, file a Level III incident/death report within 72 hours of receiving the additional information on the cause of death.**

The provider must submit the updated report even if the new information does not change the level of the incident. Providers are further required to submit, "upon request by the by the LME, other information obtained regarding the incident, including:

- hospital records including confidential information;
- reports by other authorities; and
- the provider's response to the incident."

When updating an incident report, the supervisor of a provider agency needs to provide information regarding the reason for the resubmission of incident report in the boxes on the Supervisor Action section of the incident Report.

V. INTERNAL REVIEW TEAM (formerly "Peer Review") FOR LEVEL III INCIDENTS

All Category A and B providers except ICF-MR's are required to conduct an internal team (formerly "peer review") review of Level III incidents when a consumer was receiving a service at the time the incident occurred or if the incident occurred on the provider's premises. **(ICF-MRs are required to abide by federal regulations to ensure client protection, investigate incidents and take appropriate corrective action. CFR 483.420)**

For Level III incidents that did not occur while the consumer was receiving a service or was on the provider's premises, an internal review team is not needed but the responsible LMEs may request additional information regarding services if this information is not already provided in the incident report if the information is necessary for complete review of the incident by the responsible LME.

VI. Clarification of Internal Review (formerly "Peer Review") Team Requirements

(10A NCAC 27G .0603) **(Highlighted area indicates clarification of the rule)**

(A). Categories A and B providers shall develop and implement written policies governing their response to level I, II or III incidents. The policies shall require the provider to respond by:

(1) attending to the health and safety needs of individuals involved in the incident;
(2) determining the cause of the incident;
(3) developing and implementing corrective measures according to provider specified timeframes not to exceed 45 days;
(4) developing and implementing measures to prevent similar incidents according to provider specified timeframes not to exceed 45 days ;
(5) assigning person(s) to be responsible for implementation of the corrections and preventive measures;
(6) adhering to confidentiality requirements set forth in G.S. 75, Article 2A **(**Identity Theft Protection Act), 10A NCAC 26B (MH/DD/SA Confidentiality Rules**)**, 42 CFR Parts 2 and 3 (Federal confidentiality regulations) and 45 CFR Parts 160 and 164 (Health Information Portability and Accountability Act {HIPAA} Privacy Rule) ; and
(7) maintaining documentation regarding Subparagraphs (a)(1) through (a)(6) of this Rule.

(B). In addition to the requirements set forth in Paragraph (a) of this Rule, ICF/MR providers shall address incidents as required by the federal regulations in 42 CFR Part 483 Subpart I.

(C). In addition to the requirements set forth in Paragraph (a) of this Rule, Categories A and B providers excluding ICF/MR providers, shall develop and implement written policies governing their response to a level III incident that occurs while the provider is delivering a billable service or while the client is on the provider's premises. The policies shall require the provider to respond by:

(1) immediately securing the client record by:

(a) obtaining the client record;
(b) making a photocopy ***of the entire record* (or at least 12 months if consumer has received services for more than 1 year prior to the incident, including notes about the incident)***
****Return original record to where it is normally kept so that it continues to be available for use;***
(c) certifying the copy's completeness ***with a written statement attached to the copy and signed by an administrator;*** and
(d) transferring the copy to an internal review team;

(2) convening a meeting of an internal review team within 24 hours of the incident. The internal review team shall consist of individuals who were not involved in the incident and who were not responsible for the client's direct care or with direct professional oversight of the client's services at the time of the incident. The internal review team shall complete all of the activities as follows:

(a) review the copy of the client record to determine the facts and causes of the incident and make recommendations for minimizing the occurrence of future incidents;
(b) gather other information needed;
(c) issue written preliminary findings of fact within five working days of the incident. The preliminary findings of fact shall be sent to the LME in whose catchment area the provider is located and to the LME where the client resides, if different; and
(d) issue a final written report signed by the owner within three months of the incident. The final report shall be sent to the LME in whose catchment area the provider is located and to the LME where the client resides, if different. The final written report shall address the issues identified by the internal review team, shall include all public documents pertinent to the incident, and shall make recommendations for minimizing the occurrence of future incidents. If all documents needed for the report are not available within three months of the incident, the LME may give the provider an extension of up to three months to submit the final report; and

(3) immediately notifying the following:
- (a) the LME responsible for the catchment area where the services are provided pursuant to Rule .0604;
- (b) the LME where the client resides, if different;
- (c) the provider agency with responsibility for maintaining and updating the client's treatment plan, if different from the reporting provider;
- (d) the Department;
- (e) the client's legal guardian, as applicable; and
- (f) any other authorities required by law ***(DSS, Medical Examiner, law enforcement, DHSR Complaint Unit, DHSR Health Care Personnel Registry, DMH Advocacy).***

VII. DISCLOSURE OF INFORMATION

The LME is responsible for monitoring the provider's response to the incident to ensure that the necessary steps have been taken to protect the individuals involved in the incident and to minimize the occurrence of future incidents. **If the LME is unsatisfied with the provider's response to the incident or has concerns of potential licensure, personnel, or liability issues, the LME may choose to monitor the provider, investigate the incident, or refer the incident to DHHS for investigation. If needed, the LME may request additional information, including confidential information,** as authorized by **NCGS 122C-25, 122C-112.1, and 143B-139.1** to assist in determining that:

- provider policies, protocols, and procedures are adequately developed and followed in accordance with state requirements,
- steps are taken to determine the cause of the incident;
- appropriate corrective and preventive measures are implemented and sustained; and
- the incident is addressed in the provider's quality improvement processes.

A level III incident triggers an internal team review process by the provider, in addition to the LME's review of the provider's response. The internal team review process is intended to be a review by the provider of its internal processes that may contribute to incidents. It is not an internal investigation to determine responsibility for any particular incident. **Other than the report issued to the LME, documents produced by the internal team review team, such as minutes or interview notes, are considered part of the provider's internal quality management activities. As such, they are protected from disclosure under NCGS 122C-30, 122C-191, and 122C-192.** These documents do not need to be included in the report to the LME and cannot be requested by the LME during an investigation.

However, the protected status of the internal team **review process is not a means of avoiding other reporting requirements.** The report from the provider's review team to the LME is to assist the LME in its monitoring responsibilities. It must include details of the incident, a summary of the activities undertaken by the provider to respond to the incident, and any corrective or preventive measures that are being put in place.

Incident reports are considered quality assurance documents and are protected from disclosure, except for purposes of meeting the requirements set forth in statute and rule and discussed above. A consumer involved in an incident has a right to receive a summary report of an investigation, as set forth in 10A NCAC 27G.7003(12), but a copy of the incident report and identifying information on other consumers must not be included in the report.

Direct any questions to:

The Host LME for your county or the DMH/DD/SAS Quality Management Team –

Phone: (919) 733-0696 FAX: (919) 508-0986

or

ContactDMHQuality@ncmail.net

VIII: APPENDIX A: GLOSSARY

Incident: An "incident," as defined in 10A NCAC 27G .0103(b)(32), is " any happening which is not consistent with the routine operation of a facility or service or the routine care of a consumer and that is likely to lead to adverse effects upon a consumer." Some variation in reporting requirements occurs due to differences in the types of services being provided to or sought by the individual. There are three levels of response to incidents, based on the potential or actual severity of the event. The criteria for determining these levels is outlined in Appendix B

- ***Level I*** includes any incident, as defined above, which does not meet the definition of a Level II or III incident. Level I incidents are events that, in isolated numbers, do not significantly threaten the health or safety of an individual, but could indicate systematic problems if they occur frequently. Level I incidents ***may signal a need for the provider to review its clinical care and practices,*** including supervision and training. These incidents require communication among the provider's staff, documentation of the incident, and report to other authorities as required by law. In addition, aggregate information on Level I incidents involving restrictive interventions, medication errors, and searches/seizures must be reported to the host LME, according to guidelines provided by DHHS.

- ***Level II*** includes any incident, as defined in 10A NCAC 27G .0602, which involves a consumer death due to natural causes or terminal illness, or results in a threat to a consumer's health or safety or a threat to the health or safety of others due to consumer behavior. Level II incidents ***may signal a need for the LME to review the provider's clinical care and practices and the LME's service management processes***, including service coordination, service oversight, and technical assistance for providers. These incidents require communication between the provider and LME, documentation of the incident, and report to the LME and other authorities as required by law.

- ***Level III*** includes any incident, as defined in 10A NCAC 27G .0602, that results in (1) a death, sexual assault or permanent physical or psychological impairment to a consumer, (2) a substantial risk of death, or permanent physical or psychological impairment to a consumer, (3) a death, sexual assault or permanent physical or psychological impairment caused by a consumer, (4) a substantial risk of death or permanent physical or psychological impairment caused by a consumer or (5) a threat caused by a consumer to a person's safety. Level III incidents ***signal a need for the DHHS and LME to review the local and state service provision and management system***, including coordination, technical assistance and oversight. These incidents require communication among the provider, LME and DHHS, documentation of the incident, and report to the LME, DHHS and other authorities as required by law. Level III incidents that occur while the consumer was receiving a service or on the provider's premises also require a formal internal team review process to be initiated by the provider within 24 hours of the incident, according to guidelines provided by DHHS.

- **Reports to law enforcement:** For the purposes of the DHHS incident system, this includes reports to police, sheriff departments, and magistrates of destructive, aggressive, absences/missing person or potentially dangerous acts by consumers, including self-endangerment. Do not include reports related to a consumer's violation of a probation judgment.

Searches & seizures: Searches include both body checks (for bruises or other marks) and searches of an individual's possessions and personal space. All searches and seizures are considered as Level I incidents and must be documented in accordance with the provider's policies and procedures, as required by the Client Rights Rules in 10A NCAC 27D .0103.

Under the care of: Individuals are generally considered under the care and control of a provider when actively engaged in a service or has received any services in the 90 days prior to the incident. Refer to the **"Exceptions"** in Appendix B and **"Notes to Crisis, Day, and Periodic Service Providers"** in the instructions for additional guidance on responsibilities for incident response when not actively engaged in service provision

IX. APPENDIX B: CRITERIA FOR DETERMINING LEVEL OF RESPONSE TO INCIDENTS

	INCIDENT	LEVEL I	LEVEL II	LEVEL III	Guidelines
CONSUMER DEATH	**Consumer Death**	**NONE**	**Due to:** - Terminal illness or other natural cause	**Due to:** - Suicide - Violence / homicide - Accident - Unknown cause - Death occurring within 7 days of seclusion or restraint	• Providers should report Level II deaths to the Host LME as soon as they learn of the death. • Providers should report Level III deaths as soon as they learn of the death. Report all Level II and III deaths that occur within 90 days of the last service provision. • Level III internal reviews are required only if the incident occurred when a consumer was receiving a billable service or the incident occurred on provider premises.
RESTRICTIVE INTERVENTION	**Seclusion** **Isolated time-out** **Restraint**	Any planned use administered appropriately and without discomfort, complaint, or injury	1. Any emergency or unplanned use **OR** 2. Any planned use that exceeds authorized limits, is administered by an unauthorized person, results in discomfort or complaint, or requires treatment by a licensed health professional	Any restrictive intervention that results in permanent physical or psychological impairment or if the incident is perceived to be a significant danger to or concern of the community.	Providers will submit aggregate numbers of Level I restrictive interventions to the host LME each quarter.
CONSUMER INJURY	**Due to:** **Accident** **Aggressive behavior** **Self-harm** **Trip or fall** **Auto accident** **Other** **Unknown cause**	Any injury that requires first aid only, as defined by OSHA guidelines in manual *(regardless of who provides the treatment)*	Any injury that requires treatment* by a licensed health professional *(such as MD, RN, or LPN)* beyond first aid, as defined by OSHA guidelines in manual. *Treatment does not include diagnostic tests such as blood work, x-ray, MRI, EKG, etc.	Any injury that results in permanent physical or psychological impairment; or if the is perceived to be a significant danger to or concern of the community.	Level III internal reviews are required only if the incident occurred when a consumer was receiving a billable service or the incident occurred on provider premises.

	INCIDENT	LEVEL I	LEVEL II	LEVEL III	Guidelines
ABUSE/ NEGLECT/ EXPLOITATION	**Physical abuse:** Any form of physical harm including but not limited to sexual abuse, hitting, groping, pushing, or any physical punishment, or allowing or encouraging someone else to harm the consumer. **Mental abuse:** Scare, berate, belittle, threaten yell at, curse, make fun of, taunt, name calling, etc. **Verbal abuse:** Scaring, berating, belittling threatening, yelling, cursing, , making fun of, taunting, name calling, etc. **Neglect:** Failure to: provide or assist with any daily care or training activity; provide food/liquids/nourishment; warmth/cooling. Failure to provide prescribed medications. Failure to get someone out of bed as needed/wanted or reposition them as needed. Failure to supervise or protect. Failure to report abuse, neglect or exploitation. **Exploitation:** Using a person or their belongings for another person's gain or benefit.	**NOTE:** If a child *(anyone 17 or younger)* or disabled adult makes a disclosure of an alleged incident of sexual abuse or assault or other abuse or neglect or exploitation that occurred prior to the consumer's receiving services from the current agency, treat and document these disclosed incidents as level I incidents. The incidents are to be reported to the DSS in the county where the incident occurred.	Any allegation of abuse, neglect or exploitation by anyone, including a caretaker, friend, relative, staff or stranger. This includes domestic violence. **NOTE:** Any sexual activity perpetrated by a staff/caretaker or other adult (or by an older or bigger child) upon a child (17 or younger) or an incompetent adult is illegal. These acts are **Level III incidents.** Sex between any consumer and any staff or between a minor consumer and an older or bigger child, is illegal. *This includes but is not limited to unwanted touching/kissing, coercing someone to perform sexual behaviors they would not ordinarily do, etc.). These acts are* **Level III incidents.**	Any allegation of abuse, neglect or exploitation that results in permanent physical or psychological impairment. Or if the incident is perceived to be a significant danger to or concern of the community. **NOTE** Any sexual activity perpetrated by a staff/caretaker or other adult (or by an older or bigger child) upon a child (under 17) or an incompetent adult, is illegal. *This includes but is not limited to unwanted touching/kissing, coercing someone to perform sexual behaviors they would not ordinarily do, etc.)* Sexual intercourse with a child (17 or younger) or an incompetent adult is considered rape. Any such incident is required by law to be reported to DSS and the appropriate law enforcement agency.	Level III internal review within 24 hours needed only if incident occurred when a consumer was receiving a billable service or the incident occurred on provider premises.

<table>
<tr><th></th><th>INCIDENT</th><th>LEVEL I</th><th>LEVEL II</th><th>LEVEL III</th><th>Guidelines</th></tr>
<tr><td rowspan="2">MEDICATION ERROR</td><td>Refusal
Missed dose
Wrong dose
Wrong medication
Wrong time (more than 1 hr. before or after prescribed time)
Dose given to wrong person
Dose taken by wrong person
Dose preparation error
Loss or spillage of medication
Other</td><td>Any error that does not threaten the individual's health or safety (as determined by the physician or pharmacist notified of the error)</td><td>Any error that threatens the individual's health or safety (as determined by the physician or pharmacist notified of the error)</td><td>Any error that is likely to result in permanent physical or psychological impairment or if the is perceived to be a significant danger to or concern of the community.</td><td rowspan="2">• Providers of periodic services should report errors for individuals who self-administer medications as soon as they learn of the incident.
• Internal incident review for a Level III within 24 hours required only if incident occurred when a consumer was receiving a billable service or the incident occurred on provider premises.
• All providers will submit aggregate numbers of Level I medication errors to the host LME each quarter</td></tr>
<tr><td colspan="3">NOTE: Report all drug administration errors and all adverse drug reactions to the consumer's physician or pharmacist immediately*, as required by 10A NCAC 27G .0209(h).

*However, if the consumer requires immediate medical attention, do not hesitate to give or get the medical attention.</td></tr>
<tr><td>CONSUMER BEHAVIOR</td><td>Suicidal behavior</td><td>Any suicidal threat or verbalization that indicates new or different behaviors or an increase in the number of these behaviors.</td><td>Any suicidal behavior that does not result in death or permanent physical or psychological impairment</td><td>Any suicidal behavior that results in permanent physical or psychological impairment, or if the incident is perceived to be a significant danger to or concern of the community.</td><td></td></tr>
</table>

	INCIDENT	LEVEL I	LEVEL II	LEVEL III	Guidelines
	Sexual behavior **(exhibited by the consumer)**	Inappropriate sexual behavior that is not a potentially serious threat to the health or safety of self or others and does not involve a report to law enforcement or complaint to an oversight agency. EXAMPLES: Masturbation, consensual sex. Inappropriate but consensual touching/kissing, etc. *that occurs in an inappropriate setting.*	Any sexual behavior that involves a potentially serious threat to the health or safety of self or others or involves a report to law enforcement, complaint to an oversight agency, including DSS. EXAMPLES: Unwanted touching/kissing, physically injurious masturbation,	Any sexual behavior that results in death, permanent physical or psychological impairment caused by the consumer; or if the incident is perceived to be a significant danger to or concern of the community. EXAMPLES: Rape, sexual assault including unwanted touching/kissing, physically injurious masturbation, coercing someone to perform sexual behaviors they would not ordinarily do, etc.	
	Consumer act	Any aggressive or destructive act that does not involve a report to law enforcement or complaint to an oversight agency *EXAMPLES: Throw a chair, smash a window, theft, start a fire, push someone, self injurious behavior, etc.*	Any aggressive or destructive act or illegal behavior that involves a report to law enforcement, complaint to an oversight agency, or a potentially serious threat to the health or safety of self or others. *EXAMPLES: Hit someone, destroy public or private property other than his own, steal (including diverting/ stealing drugs) shoot or otherwise injure someone, take illegal drugs or drugs not prescribed for himself, start a fire, etc.*	Any consumer act that results in death, permanent physical or psychological impairment caused by the consumer; or if the incident is perceived to be a significant danger to or concern of the community.	
	Consumer absence	Any absence of 0 to 3 hours over the time specified in the service plan, if police contact is not required	Any absence greater than 3 hours over the time specified in the individual's service plan or any absence that requires police contact	**Amber Alerts** **Silver Alerts**	Report all amber and silver alerts .

	INCIDENT	LEVEL I	LEVEL II	LEVEL III	Guidelines
SUSPENSION	**Suspension from services**	Any provider withdrawal of services for less than one day due to consumer misconduct	Any provider withdrawal of services for one day or more due to consumer misconduct	**NONE**	Includes suspension and expulsion from any provider. Includes suspension for not following agency rules: specify rule when reporting. Report only if a mh/dd/sa service provider was on-site and providing a direct service at the time of the cause of the incident. This includes public school if a mh, dd and/or sa service was being provided at the time of the incident.
EXPULSION	**Expulsion from services**	**NONE**	Any permanent provider withdrawal of services due to consumer misconduct	**NONE**	Includes expulsion for not following agency rules. Specify rule when reporting.
FIRE	**Fire**	Any fire that poses no threat to the health or safety of consumers or others	Any fire that threatens the health or safety of consumers or others	Any fire that results in permanent physical or psychological impairment or if the incident is perceived to be a significant danger to or concern of the community.	

	INCIDENT	LEVEL I	LEVEL II	LEVEL III	Guidelines
	Search and seizure	The search of the consumer or his living area. The seizure of the consumer's property or property in the possession of the consumer. This does not apply to searches and seizures that are an approved part of the consumer's treatment plan.	**NONE**	**NONE**	All providers will submit aggregate numbers of searches and seizures to the host LME each quarter.
	Confidentiality breach	Any breach of consumer's confidentiality	**NONE**	**NONE**	

Note: Illness of a Consumer: Medical illness is not reportable unless it results in injury or death, or is believed to be caused by abuse/ neglect or medication error.

X. Appendix C: INCIDENT RESPONSE OVERVIEW

Note: All incidents at each level must be reviewed as part of the reporting and receiving agencies' quality assurance process to ensure adequate and timely response and to minimize the likelihood of future incidents of a similar nature. Aggregate information on all incidents at each level must analyzed to identify trends and patterns and potential improvements, as part of the reporting and receiving agencies' quality improvement process.

Acronyms: DHSR = Division of Health Services Regulation, DSS = Division of Social Services, DRNC=Disability Rights NC, HCPR = Healthcare Personnel Registry, LME = Local Management Entity, QI = Quality Improvement

	Reporting Requirements	Reporting Timelines	Responsibilities of Provider	Responsibilities of Host LME	Responsibilities of DMH/DD/SAS
LEVEL I	*Provider reports to:* • Internal incident Mgmt staff • Other agencies as required by law, rule or statue (e.g. HCPR)	24 hours	Attend to safety & health needs of involved parties Analyze cause(s), correct problem, review in QI process to prevent similar incidents and document incident & response Report to required agencies & individuals within allowed timeframes Report quarterly to host LME aggregate information, trends and actions taken on medication errors, searches & seizures, and restrictive interventions	Review sample of documented responses as part of local monitoring, when determined necessary by the Frequency and Extent of Monitoring Tool (FEM). Analyze trends and patterns in Level I medication errors, searches & seizures, and restrictive interventions as part of QI and monitoring planning processes	None

	Reporting Requirements	Reporting Timelines	Responsibilities of Provider	Responsibilities of Host LME	Responsibilities of DMH/DD/SAS
LEVEL II	*Provider reports to:* • Internal incident Mgmt staff • Other agencies as required by law (e.g. law enforcement) • Host LME Incident Mgmt unit • Home LME (if required by LME contract)	Written report within 72 hours	Attend to safety & health needs of involved parties Analyze cause(s), correct problem, and review in QI process to prevent similar incidents Document incident and response on IRIS Report to required agencies & individuals within allowed timeframes	Review provider handling & ensure consumer safety Monitor and provide technical assistance as warranted to ensure that problems are corrected Analyze & respond to patterns of incidents as part of QI and monitoring processes Report aggregate information, trends, and actions taken to DMH/DD/SAS quarterly Determine if public scrutiny is an issue and ensure Level III report to DHHS as warranted	Analyze & respond to statewide patterns of incidents as part of QI and monitoring LME oversight of response processes Produce statewide quarterly incident trend reports

	Reporting Requirements	Reporting Timelines	Responsibilities of Provider	Responsibilities of Host LME	Responsibilities of DMH/DD/SAS
LEVEL III	*Provider reports to:* • Internal incident Mgmt staff • Other agencies as required by law (e.g. law enforcement) • Host LME Incident Mgmt unit • Home LME • Consumer's legal guardian, where applicable • DMH/DD/SAS Quality Management Team • DHSR Complaint Intake Unit (in cases of death, if service is licensed under G.S. 122-C) • DHSR Personnel Registry (in cases where staff is alleged perpetrator)	Verbal notification within 24 hours Written report within 72 hours <u>Exception</u>: Deaths within 7 days of restrictive intervention must be reported immediately	Attend to immediate health & safety needs of involved parties Convene an internal review committee within 24 hours for Level III incidents when a consumer was receiving a service at the time the incident occurred or if the incident occurred on the provider's premises. Analyze cause(s), correct problems and review in QI process to prevent similar incidents Document on reporting tools provided by the state	Review provider handling to ensure that consumers are safe, certified copy of record is secured, review committee meeting is convened, and appropriate agencies are informed Monitor and provide technical assistance as warranted to ensure that problems are corrected Analyze & respond to patterns of incidents as part of QI and monitoring processes Report aggregate information, trends, and actions taken to DMH/DD/SAS quarterly	Review LME oversight of providers and follow up as warranted to ensure problems are corrected Analyze & respond to statewide patterns of incidents as part of QI and monitoring processes Produce statewide quarterly incident trend reports

XI: APPENDIX D: INTERPRETIVE GUIDELINES FOR FIRST AID

Occupational Safety and Health Administration, 29 CFR 1904.7(b)(5)(ii)

1904.7(b)(5)(ii) **What is "first aid"?** For the purposes of Part 1904, "first aid" means the following:

(A) Using a non-prescription medication at nonprescription strength (for medications available in both prescription and non-prescription form, a recommendation by a physician or other licensed health care professional to use a non-prescription medication at prescription strength is considered medical treatment for record keeping purposes);

(B) Administering tetanus immunizations (other immunizations, such as Hepatitis B vaccine or rabies vaccine, are considered medical treatment);

(C) Cleaning, flushing or soaking wounds on the surface of the skin;

(D) Using wound coverings such as bandages, Band-Aids(tm), gauze pads, etc.; or using butterfly bandages or Steri-Strips(tm) (other wound closing devices such as sutures, staples, etc., are considered medical treatment);

(E) Using hot or cold therapy;

(F) Using any non-rigid means of support, such as elastic bandages, wraps, non-rigid back belts, etc. (devices with rigid stays or other systems designed to immobilize parts of the body are considered medical treatment for recordkeeping purposes);

(G) Using temporary immobilization devices while transporting an accident victim (e.g., splints, slings, neck collars, back boards, etc.).

(H) Using eye patches;

(I) Removing foreign bodies from the eye using only irrigation or a cotton swab;

(J) Removing splinters or foreign material from areas other than the eye by irrigation, tweezers, cotton swabs or other simple means;

(K) Using finger guards;

(L) Using massages (physical therapy or chiropractic treatment are considered medical treatment for record keeping purposes); or

(M) Drinking fluids for relief of heat stress.

1904.7(b)(5)(iii) **Are any other procedures included in first aid?** No, this is a complete list of all treatments considered first aid for Part 1904 purposes.