



Developmental Disabilities Administration
HEALTH & WELFARE PROCESS REVIEW for
CRITICAL AND RESTRAINT RELATED INCIDENTS
Standard Operating Procedure

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AUDIENCE

- Liberty Healthcare staff
- Developmental Disabilities Administration (DDA) staff
- Office of Health Care Quality (OHCQ)
- Coordination of Community Services Agencies (CCS)
- Maryland licensed and certified service providers

PURPOSE

This guidance outlines the oversight responsibilities of Liberty Healthcare Corporation on behalf of the Maryland Department of Health Developmental Disabilities Administration (DDA) to provide Health and Welfare reviews related to quality assurance of critical incident investigation and restraint related incident procedures. Ultimately, the purpose of the Health and Welfare process reviews are to verify that critical incidents are effectively investigated and resolved according to waiver and state requirements, that restraint procedures are followed based on state requirements and that the health and welfare of participants in services is preserved and protected.

Liberty Healthcare's Clinical Specialist will conduct the following as part of the Health and Welfare reviews:

- Review of the critical incident process that includes reviewing the completeness, timeliness, and results of each step in the process (provider reporting, OHCQ investigation and provider corrective actions).
- Review of critical incidents in correlation to Health Risk Screening Tool assessments of participants
- Review of the process for restraint related incidents

DEFINITIONS

- A. "Clinical Specialist" is the Liberty reviewer that will conduct all Health and Welfare reviews on behalf of the Developmental Disabilities Administration (DDA).
- B. "Coordinator of Community Services" or "CCS" is an individual who provides Coordination of Community Services. They can be either an employee or contractor of a DDA approved Provider of Coordination of Community Services.

- C. “Coordination of Community Services” are targeted case management services to help people receiving and/or requesting services funded by the DDA. Targeted case management services are provided in accordance with [COMAR 10.09.48](#)
- D. “Critical Incidents” for the purposes of the Health and Welfare Reviews are categorized as Type I incidents (which include Abuse, Neglect, Exploitation or Death) in PORII that are prioritized for investigation by OHCQ as Priority Level A – Immediate Jeopardy or Priority Level B – High Priority.
- E. “Findings Report” is a report generated by Liberty Healthcare Corporation that summarizes the outcome of each indicator question included in the review. This report includes recommendations for improvement or suggested remediation actions to address Unmet standards related to each indicator question.
- F. “Health Risk Screening Tool (HRST)” is a screening tool utilized by teams to determine health and safety risks for a person.
- G. “High Priority” is defined in PORII under OHCQ Incident Prioritization and Guidelines for Investigation as an incident where the participant is not in imminent danger, but the incident presents a situation where a serious threat exists to the participant’s health and/or safety or harm that could significantly compromise a participant’s physical and/or mental health.
- H. “Immediate Jeopardy” is defined in PORII under OHCQ Incident Prioritization and Guidelines for Investigation as an incident that presents an immediate and serious threat of injury, harm, impairment or death of a participant.
- I. “LibertyTraks” is the name of the technical platform that supports the administration and quality evaluation of critical incident review evaluations. The platform supports the data generated from critical incident review evaluations.
- J. “[LTSSMaryland](#)” is the state’s data management system, developed and supported by the Department. It is used by the DDA, the Coordinator of Community Service, and DDA Providers to create, review, and maintain records about:
 - a. A person’s eligibility status for DDA-funded services; and
 - b. The person’s Person-Centered Plan, services, and funding authorized by the DDA.

- K. Office of Health Care Quality or “OHCQ” is the state entity that investigates critical incidents and monitors corrective action plans associated with those incidents.
- L. “Participant” is a person who receives DDA-funded services.
- M. “Person-centered plan” is a written plan that is developed through a collaborative planning process driven by the person with a developmental disability to:
 1. Identify the goals and preferences Identify services to support the them in pursuing defined outcomes in the most integrated community setting
 2. Direct the delivery of services that reflect their personal preferences and choice and
 3. Identify their specific needs that must be addressed to ensure the their health and welfare.
- N. “Plan of Correction” is a plan developed by a provider organization after being issued a State of Deficiency (SOD) by OHCQ.
- O. [“Provider Consumer Information System \(PCIS2\)”](#) means DDA’s legacy Management Information System. The system tracks licensed statewide information on the following areas: Provider Demographics, Consumer Demographics, Rates, Contracts, Payments, Community Services Budget, Incidents, Waiting List and Federal Fund Participation.
- P. [“Policy on Reportable Incidents and Investigations \(PORII\)”](#) is policy, as required by [COMAR 10.22.02.01](#), to ensure the health, safety and welfare of people receiving DDA – funded services by formalizing a process to identify, report, investigate, and resolve incidents in a timely manner.
- Q. “Restraint” means any physical, chemical or mechanical intervention used to impede an participant’s physical mobility or limit free access to the environment and /or to control acute, episodic behavior including those that are approved as part of the Person-Centered Plan or those used on an emergency basis.
 - a. "Chemical restraint" means the use of an injectable medication as an intervention in a behavioral emergency;
 - b. "Mechanical restraint" means a mechanical device which restricts the free movement of an individual, such as a safety coat or posey mittens;

- c. "Physical restraint" means a manual method used to restrict the free movement of an individual, such as therapeutic hold.
- R. "Statement of Deficiency (SOD)" is the OHCQ State form used to report regulatory(COMAR) citations from an investigation that is issued to a provider
- S. "Unauthorized/Inappropriate Use of Restraints" means the use of mechanical devices or physical interventions to restrain a person without having a behavior plan which has been reviewed and approved by the standing committee or use of a restraint without documentation of a mechanical support plan. -The use of physical interventions that are not part of the DDA approved curriculum – Behavioral Principles and Strategies. -The use of mechanical devices, physical interventions or psychotropic medication to restrict the movement of a person for the convenience of staff, as a substitute for programming or for disciplinary/punishment purposes.

OVERVIEW

To protect the rights of individuals with developmental disabilities, community provider agencies that are licensed by the Developmental Disabilities Administration (DDA); and support brokers are required to identify, report, investigate, review, correct and monitor situations and events that threaten the health, safety or well-being of people receiving services. The purpose of these activities is to protect participants from harm and enhance the quality of services provided to them.

Accurate and complete documentation and conducting a thorough investigation of all incidents are necessary to assure that the appropriate agencies receive information that can be used for system improvements. DDA-licensed and operated providers must report and collaborate with state agencies such as DDA, the Office of Health Care Quality (OHCQ), and the State Medicaid Agency (SMA) to ensure that corrective measures are immediately taken to protect the individual and all others who may be affected and to prevent recurrence. Uniform reporting of incidents assists in identifying trends across the service delivery system. This information can be used to develop preventive and quality improvement strategies. (State of Maryland DDA Policy on Reportable Incidents and Investigations; [DEVELOPMENTAL DISABILITIES ADMINISTRATION \(maryland.gov\)](http://www.dda.health.maryland.gov))

As part of the Health and Welfare Reviews, The Liberty Clinical Specialist will review the submitted Critical Incident Report in PCIS2, the Agency Investigation Report (AIR), and the OHCQ Investigation Report/Notes, Statement of Deficiency(SOD) sent to the provider and related Plan of Correction(POC). During the review process, the Clinical Specialist will also review any submitted incident reports for the person that occurred ninety(90) days prior to the current incident, HRST forms, and other case related documents.

Unauthorized Restraint Incidents will also be reviewed. The Clinical Specialist will review the Restraint Incident Report, AIR, restraint incidents in the prior 90 days from the incident, and any applicable corrective action plans.

The Clinical Specialist will complete reviews using the Health and Welfare tools built in LibertyTraks for both Critical Incidents and Restraint Related Incidents. LibertyTraks will then create a Findings Report that outlines if the provider was compliant with the PORII policy and process

APPLICABILITY

This guidance applies to the Developmental Disabilities Administration (DDA) Policy on Reportable Incidents and Investigations.

HEALTH AND WELFARE SAMPLE SELECTION PROCESS

1. Health and Welfare Incident Report Sample-

Critical Incident Review: Includes review of a statistically valid sample of:

- Type 1 incidents of Abuse, Neglect, Exploitation and Unexplained Deaths **and**
- Incidents and complaints investigated by the Office of Health Care Quality (OHCQ).

DDA will provide Liberty the universe of incidents described above each review quarter using the following chart.

Quarter Incidents Occurred	Time Period Incidents Occurred	Report Due to Liberty	Liberty Review Period
1 st Quarter	July through September	November 15th	January - March
2 nd Quarter	October through December	February 15th	April - June
3 rd Quarter	January through March	May 15th	July - September
4 th Quarter	April through June	August 15th	October - December

Liberty will select a statistically valid random sample of incidents to review from the universe of incidents provided by DDA each quarter.

- The sample size will be calculated proportionate to Waiver/Program (CSW, CPW, FSW, state funded, and complaints for which program is unknown). Proportions to participant’s region, if known, also will be maintained in selection of records.
- A sampling methodology of 95% confidence interval (+/- 5% error margin), using the following automatic sampler, will be used to determine the final sample size (Raosoft software, <http://www.raosoft.com/samplesize.html>). The sample size calculator will generate the total number of incidents that must be randomly selected quarterly.

Example of sample selection:

Regions	CP	CS	FS	State Funded	Grand Total
Central	130	1	0	18	149
Eastern	20	0	2	5	27
Southern	59	1	0	15	75
Western	34	0	1	0	35
Grand Total	243	2	3	38	286
Quarterly Sample Size	149	1	1	35	186
Estimated Annual Sample Size	600	4	5	140	744

2. Unauthorized Restraints Sample-

Sample size calculated from:

- 100% of incidents with the category of “Restraint Related” incidents and categorized as **Unauthorized Restraints** for participants in each program (CSW, CPW, FSW, and State Funded).

The universe of incidents is defined by the following participant population:

- All Active DDA Participants (Waiver and State Funded)
- All Ages
- Not Deceased
- Category = Restraint Related and categorized by DDA regional staff as “Unauthorized Restraints”

HEALTH AND WELFARE REVIEW PROCESS

The Health and Welfare Review process is outlined below for the two (2) types of Health and Welfare Reviews.

REVIEW ACTIVITIES FOR CRITICAL INCIDENT REPORTING:

Step 1: Samples uploaded into LibertyTraks and assigned to the Clinical Specialist

(Critical Incidents Reporting): To complete Health and Welfare Critical Incident Report Reviews, Liberty will draw the required sample of incidents and assign those to the Clinical Specialist.

Step 2: The Clinical Specialist will contact the OHCQ point of contact at the beginning of the review period and request copies of the OHCQ investigation, statements of deficiency report, provider plans of correction and complaint investigation if applicable, related to the incidents/complaints in the sample. OHCQ will send requested documentation in weekly batches by incident to the Liberty reviewer over a four-week period at the beginning of the review quarter.

Step 3: While waiting for documentation from OHCQ, the Clinical Specialist will build the record in LibertyTraks by completing the following four steps for each incident: (1) capture additional information from LTSSMaryland records needed for the review (i.e., HRST); (2) upload required documentation into LibertyTraks (as applicable); (3) capture all necessary information from PCIS 2; and (4) review available information in preparation for completing the review.

Step 4: Once OHCQ documentation is received it will be uploaded into LibertyTraks within 3 business days. The Clinical Specialist will then complete the review of the incident by using a detailed instructional guide (see Appendix A. Health and Welfare Review Indicator Questions Guide) and will enter findings, evidence for each finding and applicable recommendations and/or remediation actions into LibertyTraks. The clinical specialist will complete reviews within three (3) business days of initiating the review and all reviews will be completed by the end of the review quarter.

Step 5: Supervisors of the Clinical Specialist will conduct quality control checks on at least 10% of reviews to ensure each step of the review was conducted as outlined in the instructional guide. Assignment of cases for quality control checks will be randomly selected at the time the sample is loaded into LibertyTraks. Follow-up coaching and re-training will be provided to reviewers not meeting an 85% or higher accuracy threshold. Findings will be adjusted accordingly to accurately reflect the correct finding and evidence.

Step 6: A Summary Findings report will be generated at the end of the review period and sent to the applicable DDA Regional Director, the DDA QIO Contract Monitor and the OHCQ point of contact. The summary will include findings for each indicator question for all incidents reviewed during the quarterly review period.

For providers connected to incidents in the sample, a similar summary report of incidents reviewed specific to the provider will be generated and sent to the provider point of contact in LibertyTraks within 15 business days after the end of the quarterly review.

Step 7: Corrective Action Plan

- When communicating findings from the review to the Contract Monitor, Liberty will highlight any findings that warrant further actions to determine what steps should be taken to correct.
- If quarterly trends analyses indicate possible systemic issues either at the OHCC investigation level or the provider incident reporting level, Liberty will request remediation strategies be submitted through a Corrective Action Plan.
- Liberty will utilize the threshold of individual indicator questions having >15% “unmet” standards present for requesting a Corrective Action Plan.
- If a CAP is required, the appropriate agency will be notified within fifteen (15) business days of receiving the quarterly summary report from Liberty Healthcare.
- The appropriate agency will then submit the CAP to Liberty Healthcare for approval within thirty (30) business days and will have thirty (30) business days from approval to submit evidence the CAP was implemented.
- Within five (5) business days, Liberty Healthcare will review the finalized CAP and will send a letter to the appropriate agency, the Regional Director and the DDA Contract Monitor verifying the finalized CAP.

Review Activities for Restraint Incidents

Step 1: Samples uploaded into LibertyTraks and assigned to the Clinical Specialist

(Restraints Reporting): To complete Health and Welfare Unauthorized Restraint Incident Reports, Liberty will draw the required sample of incidents and assign reviewers to a proportionate number of cases in Liberty’s web-based data collection and tracking system (LibertyTraks).

Step 2: The Clinical Specialist will then continue to build the record by completing the following four steps: (1) capture additional information from LTSSMaryland records needed for the review; (2) upload required documentation into LibertyTraks (as applicable); (3) capture all necessary information from PCIS 2: and (4) review available information in preparation for completing the review.

Step 3: The Clinical Specialist will then complete the reviews using a detailed instructional guide (see Appendix B. Indicator Questions Guide-Restraint Incidents)

and will enter findings, evidence for each finding and applicable recommendations and/or remediation actions into LibertyTraks. Reviewers will complete reviews within three (3) business days of initiating the review.

Step 4: Supervisors of the Clinical Specialists will conduct quality control checks on at least 10% of reviews to ensure each step of the review was conducted as outlined in the instructional guide. Assignment of cases for quality control checks will be randomly selected at the time the sample is loaded into LibertyTraks. Follow-up coaching and re-training will be provided to reviewers not meeting an 85% or higher accuracy threshold. Findings will be adjusted accordingly to accurately reflect the correct finding and evidence.

Step 5: Findings reports will be generated at the end of the review period and sent to the applicable DDA Regional Director, the DDA QIO Contract Monitor and applicable provider.

Step 6: Corrective Action Plan

- When communicating findings from the review to the Contract Monitor, Liberty will highlight any findings that warrant further actions to determine what steps should be taken to correct.
- If quarterly trends analyses for an agency indicate possible systemic issues for one or more indicator questions, Liberty will request remediation strategies be submitted through a Corrective Action Plan.
- Liberty will utilize the threshold of individual indicator questions having >15% “unmet” standards present for requesting a Corrective Action Plan.
- If a CAP is required, the applicable agency will be notified within fifteen (15) business days of receiving the quarterly summary report and individual review reports from Liberty Healthcare.
- The agency will submit the CAP to Liberty Healthcare for approval within thirty (30) business days and will have thirty (30) business days from approval to submit evidence the CAP was implemented.
- Within five (5) business days, Liberty Healthcare will review the finalized CAP and will send a letter to the Agency, the Regional Director and the DDA Contract Monitor verifying the finalized CAP.

FINDINGS REPORT

Summary Findings Reports will be created based on Critical Incident and Unrized Restraint reviews conducted by the Liberty Clinical Specialist. For each compliance indicator question of the review, a findings category will be selected, evidence related to the findings category selected will be documented and an appropriate remediation action (if applicable) or quality improvement recommendation (if applicable) will be noted in LibertyTraks. Any indicator questions that address future standards, not yet in effect, will also include a findings determination, evidence and recommended actions in order to meet standards by the effective date.

Findings can be reported definitively as:

- **Met standards (Yes) or**
- **Unmet standards (No)**
- **If an indicator question is not applicable, the finding of Met standards will be selected**

APPENDIX A: INDICATOR QUESTIONS- CRITICAL INCIDENTS

Indicator Questions	Justification Categories
Was the AIR report with corrective actions submitted by the agency in the required timeframe?	<p>Met = AIR report with corrective action was submitted by the agency in the required timeframe.</p> <p>Unmet = AIR report with corrective action was not submitted by the agency in the required timeframe.</p>
Did the AIR contain a description of preventive measures implemented individually and/or globally or any recommendations made to reduce/eliminate risk of recurrence of the type of incident?	<p>Met=The AIR contains a description of preventive measures implemented individually and/or globally or any recommendations made to reduce/eliminate risk of recurrence of the type of incident?</p> <p>Unmet=The AIR does not contain a description of preventive measures implemented individually and/or globally or any recommendations made to reduce/eliminate risk of recurrence of the type of incident?</p>

<p>Did the AIR contain a corrective, remedial, or disciplinary action that has or will occur as a result of this incident for involved staff and/or systemically for the agency?</p>	<p>Met= The AIR contained a corrective, remedial, or disciplinary action that has or will occur as a result of this incident for involved staff and/or systemically for the agency?</p> <p>Unmet= The AIR did not contain a corrective, remedial, or disciplinary action that has or will occur as a result of this incident for involved staff and/or systemically for the agency?</p>
<p>Did the AIR contain the results of the internal investigation by the agency (explanation of findings and conclusion)?</p>	<p>Met= The AIR contained the results of the internal investigation by the agency (explanation of findings and conclusion)?</p> <p>Unmet= The AIR did not contain the results of the internal investigation by the agency (explanation of findings and conclusion)?</p>
<p>Was the HRST updated within 90 days of the current Person Centered Plan in place on the date of the incident?</p>	<p>Met= The HRST was updated within 90 days of the Person Centered Plan?</p> <p>Unmet= The HRST was not updated within 90 days of the Person Centered Plan?</p>
<p>Did the HRST rater follow IntellectAbility Standards?</p>	<p>Met= The HRST rater followed IntellectAbility Standards?</p> <p>Unmet= The HRST rater did not follow IntellectAbility Standards?</p>
<p>If a HCL 3 or higher did the HRST Reviewer complete a HRST review and within IntellectAbility Standards</p>	<p>Met= If a HCL 3 or higher the HRST Reviewer completed a HRST review within IntellectAbility Standards</p> <p>Unmet= If a HCL 3 or higher the HRST Reviewer did not complete a HRST review and/or not within IntellectAbility Standards</p>

<p>HRST Service and Training Considerations were followed at the time of the incident</p>	<p>Met= Documentation in the incident report in PCIS2 demonstrates the HRST Service and Training Considerations were followed at the time of the incident</p> <p>Unmet= Documentation in the incident report in PCIS2 does not demonstrate HRST Service and Training Considerations were followed at the time of the incident; Could Not Be Determined = insufficient documentation in the incident report in PCIS2 to determine if HRST Service and Training Considerations were followed at the time of the incident</p>
<p>Was the HRST updated within 30 days after the incident, if applicable (Incident report would not cause a change in the HRST)?</p>	<p>Met= The HRST was updated within 30 days after the incident if applicable?</p> <p>Unmet= The HRST was not updated within 30 days after the incident if applicable?</p>
<p>Were applicable preventable strategies included in the Risk section, Behavior Plan and or Nursing Care Plan of the active Person Centered Plan at the time of the incident?</p>	<p>Met= Applicable preventable strategies were included in the Risk section, Behavior Plan and or Nursing Care Plan of the active Person Centered Plan at the time of the incident.</p> <p>Unmet = Applicable preventable strategies were included in the Risk section, Behavior Plan and or Nursing Care Plan of the active Person Centered Plan at the time of the incident.</p>
<p>If an investigation was completed by OHCQ, was the OHCQ investigation initiated in the required time frame according to the assigned priority level?</p>	<p>Met = The OHCQ investigation was initiated in the required time frame according to the assigned priority level.</p> <p>Unmet= The OHCQ investigation was initiated in the required time frame according to the assigned priority level.</p>
<p>If an investigation was completed by OHCQ, the OHCQ investigation was completed in the required time frame.</p>	<p>Met= The OHCQ investigation was completed in the required timeframe.</p> <p>Unmet= The OHCQ investigation was not completed in the required time frame.</p>

If applicable, was a Plan of Correction submitted within the timeframe to OHCQ from the Provider agency	Met= A Plan of Correction was submitted within the timeframe to OHCQ from the Provider agency. Unmet= A Plan of Correction was not submitted within the timeframe to OHCQ from the Provider agency
If applicable, did the provider show evidence that the Plan of Correction was completed?	Met= The provider showed evidence that the Plan of Correction was completed? Unmet= The provider did not show evidence that the Plan of Correction was completed?
If applicable, how many incidents of the same category for the provider agency were found in PCIS2 in the year leading up to the incident?	Number
If applicable, how many incidents of the same category for the provider agency were found in PCIS2 within three months following the incident.	Number

APPENDIX B: INDICATOR QUESTIONS-RESTRAINT INCIDENTS

Indicator Questions	Justification Categories
Was the AIR report about the restraint incident submitted with corrective actions (if applicable) by the agency in the required timeframe?	Met = The AIR report about the restraint incident was submitted with corrective actions (if applicable) by the agency in the required timeframe. Unmet = The AIR report about the restraint incident was not submitted with corrective actions (if applicable) by the agency in the required timeframe?
Did the AIR contain a description of the reason for use of restraint that specified the individual was a danger to self or presented a danger of serious bodily harm to others?	Met= The AIR contained a description of the reason for use of restraint that specified the individual was a danger to self or presented a danger of serious bodily harm to others? Unmet= The AIR did not contain a description of the reason for use of restraint that specified the individual was a danger to

	self or presented a danger of serious bodily harm to others?
The description of the reason for use of restraint in the AIR correctly indicated the restraint was not used as a punishment, for coercion, or for staff convenience.	Met= The description of the reason for use of restraint in the AIR correctly indicated the restraint was not used as a punishment, for coercion, or for staff convenience. Unmet= The description of the reason for use of restraint in the AIR did not correctly indicate that the restraint was not used as a punishment, for coercion, or for staff convenience.
Did the AIR determine that the staff performing the restraint had been properly trained to do so?	Met= The AIR determined that the staff performing the restraint had been properly trained to do so. Unmet= The AIR determined that the staff performing the restraint had not been properly trained to do so.
Did the AIR indicate that a team meeting was held within 5 days of the restraint incident?	Met= The AIR indicated that a team meeting was held within 5 days of the restraint incident. Unmet= The AIR did not indicate that a team meeting was held within 5 days of the restraint incident.
Did the AIR describe any seclusion associated with the restraint.	Met= The AIR did not describe any seclusion associated with the restraint. Unmet= The AIR described seclusion associated with the restraint.
Did the AIR correctly indicate the restraint did not result in any serious injury.	Met= The AIR correctly indicated the restraint did not result in any serious injury. Unmet= The AIR did not correctly indicate that the restraint did not result in any serious injury.

<p>Did the AIR indicate the Behavior Plan, Person Centered Plan and/or authorization from a healthcare provider has documented reasons for use of the restraint, the duration of use authorized and the frequency authorized.</p>	<p>Met= the AIR indicates Behavior Plan, PCP or authorization from a healthcare provider has documented reasons for use of restraint, the duration of use authorized and the frequency authorized.</p> <p>Unmet= the AIR does not indicate that the Behavior Plan, PCP and/or authorization from a healthcare provider has documented reasons for use of restraint, the duration of use authorized and the frequency authorized.</p>
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RELEVANT DOCUMENTATION:

State of Maryland DDA Policy on Reportable Incidents and Investigations; [DEVELOPMENTAL DISABILITIES ADMINISTRATION \(maryland.gov\)](#)

REFERENCE MATERIALS

COMAR Title 10 Subtitle 22 Developmental Disabilities