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1. PURPOSE

The Risk Management Plan is designed to support the mission and vision of Children's Medical Services (CMS) as it pertains to clinical and patient safety. The purpose of the program is to provide a systematic process of identifying, evaluating and reducing losses associated with care and safety of enrollees as well as injuries of employees, visitors, property loss or damages that could be a source of potential legal liability for the CMS.

2. GUIDING PRINCIPLES

The Risk Management Plan is an overarching, conceptual framework that guides the development of a program for risk management and patient safety initiatives and activities. The Risk Management Plan is operationalized through a formal, written risk management program. Risk management activities are carried out through the Quality and Practice Management Unit (QI/UM/RM Community Nursing Consultant). The Risk Management Program encompasses review of the areas of actual or potential sources or risk and/or liability. An incident reporting system is utilized to collect and trend undesirable or adverse occurrences in all areas throughout the organization.

The Risk Management Program supports CMS's philosophy that patient safety and risk management is everyone’s responsibility. Teamwork and participation among management, providers, volunteers and staff are essential for an efficient and effective Risk Management Program. The program is implemented through the coordination of multiple organizational functions and activities of multiple departments and contracted entities. The Risk Management Program applies a consistent application throughout CMS that includes our area offices and all departments in the program.

CMS supports the establishment of a just culture that emphasizes implementing evidence-based best practices, learning from error analysis and providing constructive feedback, rather than blame and punishment. In a just culture, unsafe conditions and hazards are readily and proactively identified, medical or patient care errors are reported and analyzed, mistakes are openly discussed and suggestions for systemic improvements are welcomed. Individuals are still held accountable for compliance with patient safety and risk management practices. As such, if evaluation and investigation
of an error or event reveals reckless behavior or willful violation of policies, disciplinary actions will be taken.

CMS’s Risk Management Plan is used to stimulate the development, review and revision of the organization’s practices and protocols in light of identified risks and chosen loss prevention and reduction strategies. Principles of the Risk Management Plan provide the foundation for developing key policies and procedures for day-to-day risk management activities and are evaluated on an on-going basis. Principles include:

- Claims management
- Complaint and grievance resolution
- Confidentiality and release of information
- Event investigation, root-cause analysis and follow-up
- Failure mode and effects analysis
- Provider and staff education, competency validation and credentialing requirements
- Reporting and management of adverse events and near misses
- Trend analysis of events, near misses and claims
- Analysis of enrollee and provider satisfaction surveys
- Reports from Fraud, Waste and Abuse Coordinator

CMS identifies potential improvements in processes or systems that would tend to decrease the likelihood of incidents in the future, or determines, after analysis, that no such improvement opportunities exist.

2.1 Governing Body Leadership

The success of the CMS Risk Management Program requires top-level commitment and support. The governing body authorizes the formal program and adoption of this Plan through a resolution documented in meeting minutes of the body. The governing body reviews and approves the Risk Management Program annually including review of enrollee and provider satisfaction surveys.

The governing body is committed to promoting the safety of all patients and individuals involved in the organization’s operations. The Risk Management Program is designed to reduce system-related errors and potentially unsafe conditions by implementing continuous improvement strategies to support an organizational culture of safety. The governing body empowers the organization’s leadership and management teams with the responsibility of implementing performance improvement and risk management strategies.
3. DEFINITIONS

- **Adverse event or incident**: Critical events that negatively impact the health, safety or welfare of patients. Adverse incidents may include events involving abuse, neglect, exploitation, major illness or injury, involvement with law enforcement, elopement/missing or major medication incidents. An adverse event or incident is an undesired outcome or occurrence, not expected within the normal course of care of treatment, disease process, condition of the patient or delivery of services. It is an unexpected occurrence during a health care encounter involving member death or serious physical or psychological injury or illness including loss of limb or function, not related to the natural course of the member’s illness or underlying condition. An adverse event or incident includes any process variation for which a recurrence carries a significant chance of a serious adverse outcome. It also includes events such as actual breaches in medical care, administrative procedures or other occurrences resulting in an outcome that is not associated with the standard of care or acceptable risks associated with the provision of care and service for an enrollee including reactions to drugs and materials. Circumstances or events that could have resulted in an adverse event (“near miss”) are included in this definition.

- **Claims management**: Activities undertaken by the Risk Manager to exert control over potential or filed claims against the organization and/or its providers. This includes investigating adverse events or incidents.

- **Failure mode and effects analysis**: A proactive method for evaluating a process to identify where and how it might fail and for assessing the relative impact of different failures in order to identify the parts of the process that are most in need of improvement.

- **Loss control/loss reduction**: The minimization of the severity of losses through methods such as claims investigation and administration, early identification and management of events, and minimization of potential loss of reputation.

- **Loss prevention**: The minimization of the likelihood (probability) of a loss through proactive methods such as risk assessment and identification; staff and volunteer education, credentialing and development; policy and procedure implementation, review and revision; quality review and improvement; root-cause analysis; and others.

- **Near miss**: An event or situation that could have resulted in an accident, injury, or illness but did not, either by chance or through timely intervention. Near misses are opportunities for learning and afford the chance to develop preventive strategies and actions. Near misses receive the same level of scrutiny as adverse events that result in actual injury.
- **Risk analysis:** Determination of the causes, potential probability and potential harm of an identified risk and alternatives for dealing with the risk. Examples of risk analysis techniques include failure mode and effects analysis, systems analysis, root-cause analysis, and tracking and trending of adverse events and near misses, among others.

- **Risk assessment:** Activities undertaken in order to identify potential risks and unsafe conditions inherent in the organization or within targeted systems or processes.

- **Risk avoidance:** Avoidance of engaging in practices or hazards that expose the organization to liability.

- **Risk control:** Treatment of risk using methods aimed at eliminating or lowering the probability of an adverse event (i.e., loss prevention) and eliminating, reducing, or minimizing harm to individuals and the financial severity of losses when they occur (i.e., loss reduction).

- **Risk identification:** The process used to identify situations, policies or practices that could result in risk of patient harm and/or financial loss. Sources of information include proactive surveys, medical records, clinic and risk management research, walk-through inspections, safety and quality improvement committee reports, insurance company claim reports, risk analysis methods such as failure mode and effects analysis and systems analysis and informal communication with health care providers if needed.

- **Risk management:** Clinical and administrative activities undertaken to identify, evaluate, prevent and control the risk of injury to patients, staff, visitors, volunteers and others and to reduce the risk of loss to CMS itself. Activities include the process of making and carrying out decisions that will prevent or minimize clinical, business and operational risks.

- **Root-cause analysis:** A process for identifying the basic or causal factor(s) that underlie the occurrence or possible occurrence of an adverse event.

- **Sentinel event:** Defined by the Joint Commission as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes the loss of limb or function. The phrase “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse event.

- **Unsafe and/or hazardous condition:** Any set of circumstances (exclusive of a patient’s own disease process or condition) that significantly increases the likelihood of a serious adverse outcome for a patient or of a loss due to an accident or injury to a visitor, employee, volunteer or other individual.

- **Agency for Health Care Administration (AHCA):** State of Florida agency responsible for oversight and administration of the Medicaid Program.
4. PROGRAM GOALS AND OBJECTIVES

The Risk Management Program goals and objectives are to:

- Continuously improve patient safety and minimize and/or prevent the occurrence of errors, events and system breakdowns leading to harm to patients, staff, volunteers, visitors and others through proactive risk management activities.
- Ensure coordination of risk management activities with the CMS Quality Improvement Program.
- Minimize adverse effects of errors, events and system breakdowns when they do occur.
- Minimize losses to CMS overall by proactively identifying, analyzing, preventing and controlling potential clinical, business and operational risks.
- Facilitate compliance with regulatory, legal and accrediting agency requirements.
- Protect human and intangible resources (e.g., reputation).

5. SCOPE AND FUNCTIONS OF THE PROGRAM

The CMS Risk Management Program interfaces with many operational departments and services throughout the organization. The Risk Management Program consistently applies the program throughout the entire organization including all departments and all area offices.

5.1 Functional Interfaces

Functional interfaces with the Risk Management Program include the following:

- Area office oversight
- Care coordination
- Credentialing of providers (uses a risk management review process for re-credentialing and in the provider clinical record review by the ICSs)
- Disaster preparation and management
- Event/incident/accident reporting and investigation
- Information technology
- Legal
- Patient and family education
- Patient and provider satisfaction
- Pharmaceuticals and therapeutics
- Policy and procedures
- Quality Improvement and performance assessment
- Regulatory, legal and accrediting compliance
• Safety and security
• Staff education
• Utilization management
• Complaints and grievances
• Fraud, waste and abuse

All potential quality issues are reported to the Central Office QI committee.

5.2 Risk Management Program Functions

Risk Management functional responsibilities include:

a) Assisting in developing systems for overseeing the reporting of adverse events, near misses and potentially unsafe conditions, through established channels within CMS. This includes the development and implementation of event-reporting policies and procedures. Reporting responsibilities may include internal reporting as well as external reporting to regulatory, governmental or voluntary agencies. In addition to other required reports to AHCA, CMS will report a summary of adverse incident on a monthly basis. CMS will report suspected unlicensed assisted living facilities (ALF) and adult family care homes (AFCH) to AHCA and require its providers to do the same pursuant to section 408.812, Florida Statutes (F.S.).

b) Ensuring the collection and analysis for data to monitor the performance of processes that involve risk or that may result in serious adverse events. Proactive risk assessment can include the use of failure mode and effects analysis, system analysis and other tools. Proactive risk assessments will be used to identify potential improvements in processes or systems that would tend to decrease the likelihood of such incidents in the future or determines, after analysis that no such improvement opportunities exist.

c) Overseeing the organizational data collection and processing, information analysis and generation of statistical trend reports for the identification and monitoring of adverse events, claims and effectiveness of the Risk Management Program from the appropriate Integrated Care System (ICS). This includes the review of the frequency of occurrences, severity of outcomes and reportable events. A review that includes action plans that identify strategies that CMS may implement to reduce the risk of similar incidents occurring in the future and addresses responsibility for implementation, oversight, pilot testing as appropriate, timelines and strategies for measuring the effectiveness of the actions.
This system will utilize and include, but is not limited to, the following:

- Attorney requests for medical records
- Periodic review of all litigation involving CMS, CMS staff and health care professionals
- Committee reports and minutes
- Criteria-based outcome studies
- Event, incident or near miss reports
- Medical record reviews
- Monitoring systems based on objective criteria
- Nursing reports
- Patient complaints/grievances
- Physician and other medical professionals’ input
- Results of failure mode and effects analysis of high risk processes
- Root-cause analyses of sentinel events

d) Analyzing data collected thoroughly on adverse events, near misses and potentially unsafe conditions; providing feedback to providers and staff; and using this data to facilitate systems improvements to reduce the probability of occurrence of future related events. Root-cause analysis and systems analysis can be used to identify the basic or causal factors that underlie variation in performance and contributing factors in the occurrence of such events.

e) Assisting with ensuring compliance with data collection and reporting requirements of governmental, regulatory and accrediting agencies in accordance with law and regulation.

f) Reviewing provider participation in educational programs on patient safety and risk management from each ICS and assisting with ensuring staff participation in educational programs on patient safety and risk management and taking corrective action as needed to ensure all providers comply with adverse incident reporting.

g) Facilitating a culture of safety in the organization that embodies an atmosphere of mutual trust in which all providers and staff members can talk freely about safety problems and potential solutions without fear of retribution. This ordinarily involves performing safety culture surveys and assessments.

h) Proactively advising CMS on strategies to reduce unsafe situations and improve the overall environmental safety of patients, visitors, staff and volunteers.
i) Decreasing the likelihood of claims and lawsuits by reviewing patient and family communications and education plans. Conducts periodic reviews of all litigation involving CMS and its staff and health care professionals.

j) Supporting quality improvement programs throughout the organization.

k) Assisting in implementing programs that fulfill regulatory, legal and accreditation requirements.

l) Establishing an ongoing Risk Management Committee that is part of the Quality Improvement Committee and is composed of representatives from clinical and administrative departments and services. The Risk Management Committee ensures the development of action plans that identify strategies that are intended to reduce the risk of similar incidents occurring in the future and addresses responsibility for implementation, oversight, pilot testing as appropriate, timeliness and strategies for measuring the effectiveness of these actions. Enrollee quality of care issues are reported and coordinated with the QI nursing consultant.

m) Monitoring the effectiveness and performance of risk management and patient safety actions. Performance monitoring data may include:

- Culture of safety surveys
- Event trending data
- Ongoing risk assessment information
- Patient’s and/or family’s perceptions of how well CMS meets their needs and expectations
- Quality improvement data
- Monitoring effective handoff processes for continuity of patient care
- Review of patient complaints/grievances

n) Participating and direct service providers are required to report adverse incidents to CMS with forty-eight (48) hours of the incident. The following participating and direct services providers are not required to submit adverse incidents to the plan due to the requirement that licensed settings shall report in accordance with the facility’s licensure requirements:

- Health Maintenance Organizations and Health Care Clinics
- Ambulatory Surgical Centers and Hospitals
- Assisted Living Facilities
- Nursing Facilities
• Crisis Stabilization Units, Residential Treatment Centers for Children and Adolescents, and other Residential Treatment Centers

o) Reporting immediately to the Department of Children and Families (DCF) Central Abuse Hotline any suspected cases of abuse, neglect or exploitation of enrollees as required by law. CMS will maintain documentation related to the reporting of such events, in a confidential file, separate from the enrollee’s case file. Such file will be made available to the AHCA upon request.

6. ADMINISTRATIVE AND COMMITTEE STRUCTURE AND MECHANISM FOR COORDINATION

The Risk Management Program is administered through the Risk Manager designee who reports to the Director of the Quality and Practice Management Unit and who has access to the Directors of Plan Administration and Operations and the Managed Care Plan Director. The Risk Manager is appointed by the Managed Care Plan Director, through the direction of the governing body and is qualified by experience and/or education. The Risk Manager interfaces with administration, staff and other professionals. Risk management may at times cross operational lines in order to meet the goals of the program. The Risk Manager is also the Quality Improvement Committee co-chairperson. The Risk Manager is responsible for developing, implementing and monitoring a Risk Management Program that meets the needs of CMS as well as compliance with accrediting agencies. The Risk Manager works with the contract managers for each ICS and AHCA in meeting contractual requirements. A designated employee is trained to act as a back-up should the appointed Risk Manager be unavailable. The Risk Management Committee is part of the Quality Improvement Committee and meets quarterly, or more often if needed, and includes representatives from key clinical and administrative services. The composition of the Risk Management Committee is designed to facilitate the sharing of risk management knowledge and practices across multiple disciplines and to optimize the use of key findings from risk management activities in making recommendations to reduce the overall likelihood of adverse events and improve patient safety. The committee is an integral part of the quality improvement evaluation system. The Risk Manager receives information and regular reports from each ICS regarding risk management activities.

Documentation of the designation of the Risk Manager is contained in the Risk Management Plan. The Risk Manager is responsible for overseeing day-to-day monitoring of patient safety and risk management activities and for investigating and reporting to the appropriate administrative and management staff actual or potential clinical and operational issues. The Risk Manager, with the ICS contract managers,
oversees the reporting of events to external organizations per regulations and contracts and communicates analysis and feedback of reported risk management and safety information to CMS for action.

Each ICS has established a program for documentation of risk management coverage after normal working hours for CMS.

7. **MONITORING AND CONTINUOUS IMPROVEMENT**

The Risk Management Committee, through the Quality Improvement Committee, reviews risk management activities regularly. CMS ensures coordination of its risk management activities with the CMS QI program. Enrollee quality of care issues will be reported to the Quality Improvement Committee and the governing body. The Risk Manager reports activities and outcomes (e.g., risk and safety assessment results, event report summaries and trends) regularly to the governing body. These reports inform the governing body of efforts made to identify and reduce risks and the success of these activities and communicates outstanding issues that need input and/or support for action or resolution. Data reporting may include event trends, claims analysis, frequency and severity data, credentialing activity, relevant provider and staff education and risk management activities. In accordance with CMS’s governing body policies and procedures, recommendations from the Risk Management Committee are submitted at least quarterly to the governing body for action or non-action. Performance improvement goals are developed to remain consistent with the stated risk management goals and objectives.

Documentation is in the format of quarterly risk management reports to the governing body on risk management activities and outcomes.

8. **CONFIDENTIALITY**

Any and all documents and records that are part of the risk management process shall be privileged and confidential to the extent provided by state and federal law. Confidentiality protections can include attorney client privilege, attorney work product and peer review protections.

9. **RISK MANAGEMENT EDUCATION**

Risk management education is provided to all new staff within 30 days of employment. Risk Management training is also provided to staff annually thereafter (and more frequently as may be needed). CMS will take corrective action with staff as needed to ensure employees comply with training requirements. Each ICS is responsible for its staff education regarding risk management activities associated with CMS. The Risk
Management Program is provided to the provider network on the CMS Managed Care Plan Website. Information regarding critical incidents can be found in the CMS MMA Title XIX Provider Manual.

10. METHOD FOR DISMISSAL FROM CARE

There are only six (6) approved reasons for Medicaid involuntary disenrollment from the CMS Plan. With proper written documentation, the CMS Plan may submit involuntary disenrollment requests to AHCA or its enrollment broker through the CMS Central Office in a manner prescribed by AHCA. The following are acceptable reasons which the plan may submit involuntary disenrollment requests:

- Fraudulent use of the enrollee’s identification card. In such cases the Area Office must notify the fraud, waste and abuse section at the appropriate ICS. Each ICS will notify Medicaid Program Integrity (MPI).
- Falsification of prescriptions by an enrollee. In such cases the Area Office must notify the fraud, waste and abuse section at the appropriate ICS. Each ICS Office will notify MPI.
- Enrollee’s behavior is disruptive, unruly, abusive or uncooperative to the extent that enrollment in CMS seriously impairs the organization’s ability to furnish services to either the enrollee or other enrollees. All involuntary request related to enrollee behavior must meet requirements as listed in the AHCA contract Section III, C.3. (3)(b).
- Enrollee will not relocate from an Assisted Living Facility or Adult Family Care Home that does not, and will not conform to Home and Community-Based (HCB) characteristics required by AHCA contract FP031, Department of Health (DOH) CMS.
- Enrollee is no longer clinically eligible to participate in CMS as determined pursuant to the approved screening tool.
- Enrollee no longer meets the age qualifications (under age 21) to participate in CMS.

Please refer to the Care Coordination Operational Plan and the policy entitled “CMSN Medicaid Client Disenrollment, Closure and Transfer,” (HCMSP 145-302) for detailed procedures on involuntary disenrollment.

11. CMS AREA OFFICE CRITICAL AND ADVERSE REPORTING

CMS area office employees are required to complete the DOH Incident Report (DH 1152) for all critical/adverse incidents that involve DOH employees, occur at a DOH
facility, or involve alleged abuse/neglect. The DOH incident report can be found on the DOH Website or at the link below:

http://dohiws.doh.state.fl.us/Divisions/Insp_General/IncidentReports.htm

CMS employees will refer to the CMS policy entitled “CMS Incident/Adverse Event Reporting,” (HCMSP 145-014) for detailed information regarding reporting. Area office CMS employees are required to report all critical/adverse incidents to the appropriate ICS and the Central Office ICS contract manager even if a DOH incident report is not needed. CMS employees will refer to the CMS policy entitled “ICS/AHCA Critical Incident Reporting,” (HCMS 145-031) for detailed information regarding reporting to the ICS. For reporting purposes, the ICS for each area is responsible for maintaining a log of adverse/critical incidents. The ICS submits monthly reports and ad hoc reports to CMS Central Office regarding adverse/critical incidents. These reports are submitted to the appropriate CMS committees for review and analysis.

CMS will report a summary of adverse incidents in a report to AHCA as specified in Section XIII, Reporting Requirements, in the Managed Care Plan Report Guide. The report will be in the manner and format determined by AHCA.

The area office will conduct a thorough analysis when an adverse incident occurs, in order to identify the basic or causal factors (root cause analysis) that underlie variation in performance, including the occurrence or possible occurrence of other adverse incidents. This will be reported on the DOH Incident Report (DH 1152), pages 3 and 4 (Incident Review), if applicable. The investigation will include, but is not limited to, review of medical records, interviews of any knowledgeable personnel and the review of pertinent policies and procedures.

12. HANDLING OF IMPAIRED HEALTH CARE PROFESSIONALS

Employees are expected to adhere to the state’s standards of conduct concerning the possession and/or use of drugs or alcohol while on duty or while in or on state property. Violations of this policy will result in referral to the Employee Assistance Program and/or disciplinary action, up to and including dismissal (section 112.0455, F.S.). Handling of impaired health care professionals is addressed in the following DOH policies:

- Florida Department of Health Employee Handbook
- Drug-Free Workplace (DOHP 60-9)
- Employee Assistance Program (DOHP 60-11)
13. PREVENTION OF UNAUTHORIZED PRESCRIBING

The security and safety of prescription pads in our CMS clinics and area offices is of paramount importance. It is the responsibility of the health care professional in charge of the clinic to ensure the security of prescription pads at all times. Prescription pads and the recording book for serial numbers must be stored securely when not in use. Storage rooms for prescription pads must not be accessible to patients. All CMS clinical staff are responsible and accountable for the safe and secure storage and management of prescription pads when used within their department. Refer to the CMS policy entitled “Prevention of Unauthorized Prescribing,” (HCMSP 145-032) for detailed information.

14. CLINICAL RECORDS AUDITS

CMS subcontracts with two (2) ICSs. Each ICS contracts with all network providers and the ICSs are responsible for provider training on standard documentation requirements for the clinical record and the process for provider on-site clinical record reviews. Each ICS has a dedicated staff to perform clinical record audits. If a provider does not meet compliance standards, the ICS will conduct interventions with the provider. Each ICS will inform CMS of providers who do not meet clinical record review standards. CMS will use the findings in the recredentialing process. Provider clinical record reviews are reported to the Governing Body. Refer to the CMS policies entitled “ICS Provider Network Medical Records,” (HCSMP 145-704) and “Provider Credentialing Process,” (HCMSP 145-707) for detailed information.
15. PROGRAM APPROVAL

Areas of responsibility include the Director, Office of the CMS Managed Care Plan, Director of CMS Managed Care Plan Administration, Director of CMS Managed Care Plan Operations. Signatures below indicate the Risk Management Program and the appendices have been approved for implementation as CMS policies and procedures.

Melissa Vergeson
Director, Office of Children's Medical Services Plan Administration

Kelli Stannard, RN, BSN
Director, Office of Children's Medical Services Plan Operations & Specialty Programs

16. GOVERNING BODY APPROVAL

Cheryl Young
CEO Children's Medical Services
Managed Care Plan
Governing Body Representative

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Critical Incident Occurs with Title 19, 21 or Safety Net

- Complete DOH Incident Report
- If Title 19 or Title 21, also complete the spreadsheet and send to the appropriate ICS and Central Office Contract Manager and Contract Management Unit Supervisor.
- Central Office sends AHCA report and Director of CMS Managed Care Plan Attestation to AHCA
- DOH Electronic incident report sent to Central Office within 24 hours of the event or of notification of the event.
- ICS completes AHCA report for Title 19 and sends back to Central Office
- Monthly Reports received regarding all critical incidents reported to ICS
- Central Office completes data for any critical incidents for safety net clients
- Reported quarterly to Central Office QI Committee that oversees Risk Management activities

- DOH incident report not needed if the incident did not occur at our facility, did not involve one of our licensees or did not involve alleged abuse/neglect.
- The spreadsheet for the ICS and central office must be completed for any deaths or baker acts regardless of the facility or location even though a DOH incident report is not necessary.
- Copies of the DOH Incident Report are not to be sent to anyone but CMS Central Office.
- This approach allows for activities to be prioritized and ensures consistency of the Risk Management effort throughout CMS.