Carolina Health Centers

Risk Management Plan

Reviewed and Approved by the Board of Directors
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Overview

I. Purpose

Risk management is a systematic process of identifying, evaluating and reducing losses associated with patient, employee or visitor injuries, property loss or damages and other sources of potential legal liability. The Risk Management Plan is designed to support the mission and vision Carolina Health Centers as it pertains to clinical risk and patient safety as well as visitor, third party, volunteer, and employee safety and potential business, operational, and property risks.

II. Responsibility

The Board of Directors is entrusted with the responsibility for the oversight of the Risk Management Program at Carolina Health Centers and its satellite facilities. This responsibility is delegated to the Chief Executive Officer (CEO) and the Carolina Health Centers staff.

III. Scope

The Risk Management Program encompasses review of the areas of actual or potential sources of risk and/or liability involving patients, visitors, staff and property. This program is utilized to collect and trend undesirable or adverse occurrences in all areas throughout the facilities. The Quality Improvement Committee may assist with the data collection in the Risk Management areas through Medical Staff and Clinical Staff monitoring and evaluating specific data information. To accomplish this function, the Risk Manager or the CEO's designee is responsible for developing and maintaining a Risk Management Program that meets the basic operational needs of Carolina Health Centers. Among the programs required to meet that end is an insurance program for both commercial and medical malpractice coverage and the development of new programs designed to train staff in minimizing or eliminating risks or safety concerns on a corporate-wide basis.

The Risk Manager or the CEO appoints a designee to handle this function and make regular reports to the CEO or his/her designee on a monthly basis, or more frequently, if necessary. The Risk Manager will review risk exposure on a regular basis and make specific recommendations to the CEO when changes in the Risk Management Program are needed. An example of this would be the increase of coverage for buildings and automobiles, malpractice and general liability policies or the need for new safety or staff training programs in specific areas.

The following is an outline of insurance needs and training programs that would address areas of risk exposure. While the list is not all inclusive, it will assist in the development of a successful Risk Management Program:

COMMERCIAL INSURANCE

1. Property & Casualty
2. Auto
3. Business Interruption
4. General Liability
5. Directors' and Officers' Coverage
6. Errors and Omissions
7. Inland Marine (i.e., accounts receivable, valuable papers, electronic data processing)
8. Crime (i.e., employee dishonesty, Welfare and Pension Plan, ERISA Compliance)
9. Worker's Compensation
10. Benefits (i.e., health insurance, disability, group life, employment practices)

TRAINING PROGRAMS

1. Safety Programs (Safety Committee: fire drills, disaster planning, workforce safety, building safety inspections, workplace violence)
2. OSHA Training Compliance (exposure to blood borne pathogens, needle sticks, hazardous waste disposal, employee injuries, ergonomic design)
3. Security Programs (employee patient safety issues)
4. Confidentiality Programs (patient and staff confidential information)
5. Provider-Patient Care Issues (i.e., patient complaints of improper medical treatment or dealing with difficult patients
6. Specialty-Specific Clinical Training (e.g., annual training for staff serving in clinical roles related to prenatal care and postpartum care).

IV. Risk Management Strategies

In order to approach the process of Risk Management systematically, Carolina Health Centers utilizes the following four-step model for Risk Management:

- The identification of risks
- The analysis of the risk identified
- The treatment of risks
- The evaluation of risk treatment strategies

This model assists in setting priorities for Risk Management activities and ensures a comprehensive Risk Management effort.

Risk Identification

Risk Identification is the process through which the center staff become aware of risks in the health care environment that constitute potential loss exposures for Carolina Health Centers

The staff will utilize the following information services to identify potential risks:

- Identification of trends through the incident reporting system

- Patient, visitor, staff and provider complaint reports
- Performance improvement functions
- Peer review activities
- Informal discussions with management and staff members

Risk Analysis

Risk Analysis is the process of determining the potential severity of the loss associated with an identified risk and the probability that such a loss will occur. These factors establish the seriousness of a risk and will guide management in the selection of an appropriate risk treatment strategy. Retroactive analysis is the primary tool used to investigate and evaluate specific occurred events in the lens of risk management. The typical analysis would include event investigation, root-cause analysis, and follow-up. Prospective analysis is performed as well, with a modified failure mode and effect method being the primary tool for this process.

Risk Treatment

Risk Treatment refers to the range of choices available to management in handling a given risk. Risk Treatment strategies include the following:

A. Risk acceptance involves assuming the potential loss associated with a given risk and making plans to cover any financial consequence of such losses.
B. Risk avoidance is a strategy utilized when a given risk poses a particularly serious threat that cannot be effectively reduced, and the conduct or service giving rise to the risk may perhaps be avoided.
C. Risk reduction or minimization involves various loss control strategies aimed at limiting the potential consequences or frequency of a given risk without totally accepting or avoiding the risk. Strategies may include staff education, policy and procedure revision and other interventions aimed at controlling adverse occurrences without completely eliminating risk activities.

Any single strategy or combination of the above Risk Management strategies may be employed to best manage a given situation.

Risk Management Evaluation

The final step in the Risk Management process is risk management evaluation, whereby the effectiveness of the techniques employed to identify, analyze and treat risks are assessed and further action taken when warranted. If improvement and/or resolution of the risk is evident, additional follow-up will be done at predetermined intervals to evaluate continued improvement.

V. Risk Management Plan Elements

The Carolina Health Centers Risk Management Program is concerned with a variety of issues and situations that hold the potential for liability or losses for the center. It addresses the following categories of risk:

Patient-Related Risks

- Confidentiality and appropriate release of patient medical information
- The securing of appropriate informed patient consent for medical treatment
- Nondiscriminatory treatment of patients, regardless of race, religion, national origin or payment status
- Protections of patient valuables from loss or damage

Medical Staff-Related Risks

- Medical Staff peer review and quality/performance improvement activities
- Confidentiality and protection of the data obtained
- Medical Staff credentialing, appointment and privileging processes

Employee-Related Risks

- Maintaining a safe work environment
- Reduction of the risk of occupational illnesses and injury
- Provision for the treatment and compensation of workers who suffer on-the-job injuries and work-related illnesses
- Ensuring nondiscrimination in recruitment, hiring and promotion of employees

Other Risks

- Ensuring mechanisms to prevent and reduce the risk of losses associated with fire, flood, severe weather and utilities malfunction
- Ensuring the development and implementation of emergency preparedness plans
- Ensuring that appropriate protocols are in place for hazardous materials/waste management
- Maintaining a safe environment for patients and visitors
- Assisting Quality/Performances Improvement efforts to identify those areas which represent an opportunity to improve patient care and reduce risk

VI. Annual Appraisal

As part of the Risk Management Program, the scope, organization and effectiveness of Risk Management activities will be reviewed annually. Program revisions will be recommended, approved and implemented as necessary.

Corporate Risk Management Program

1. Authority

The Board of Directors and CEO of Carolina Health Centers strive to provide a safe environment for customers, visitors and employees by requiring and supporting the establishment of an effective Risk Management Program.

2. Duties And Responsibilities

1. A Risk Manager appointed by the CEO and qualified by experience and/or education shall be responsible for the development, implementation and monitoring of a Corporate Risk Management Program including the creation and maintenance of any committee deemed necessary.
2. The Risk Manager shall chair the Risk Management Committee, which will include key staff members from clinical, finance, operations, corporate compliance, facilities, and information technology and pharmacy departments.
3. The Risk Management Committee shall be responsible for coordinating the investigation of significant incidents including, but not limited to, review of the medical record, interviews of any knowledgeable personnel, review of pertinent policies and/or procedures, and referral of the occurrence as necessary to the appropriate department head or committee(s).
4. The Corporate Risk Management Program shall be based on the monitoring and evaluation of the following:
    i. Customer care occurrences and other center events
    ii. center experience
    iii. applicable laws as indicated
    iv. applicable regulations as indicated
    v. acceptable medical practice as indicated
5. Through the monitoring of the above, Risk Management shall attempt to identify, evaluate and reduce the risk of injury or loss to customers, visitors and employees of Carolina Health Centers.
6. Risk Management Reports shall be presented to the Quality Improvement Committee and that committee shall present a report to the Board of Directors.
7. The Risk Management Committee shall report to the Quality Improvement Committee and with any other departments or committees as needed to exchange information to support the efforts of the Risk Management Program.
8. Risk Management shall be represented on the Quality Improvement Committee and Emergency Preparedness Committee, as well as any other committees established to ensure continuity of patient care.
9. Risk Management and/or any committee formed under this policy may recommend policy, procedure and protocol changes designed to reduce risks. The recommendation shall be become effective as policy, procedure or protocol unless the Department Director, Chief Medical Officer or CEO overrules the recommendation in writing.

10. The Risk Management Committee may present and/or participate in ongoing educational programs.
11. The Risk Manager and/or Corporate Compliance Officer may provide advice and consultation on emergent issues.
12. All Center departments shall comply with the incident reporting policies established by the Risk Management Program and shall cooperate fully in the investigation of incidents.

Risk Management Committee

I. Authority

The Risk Management Committee is a corporate committee approved by the Board of Directors through the CEO.

II. Purpose

To provide a timely review of significant incident reports and other risk management data sources, a means of following significant issues and trends, and a means of determining and recommending the most appropriate correction for problems with no obvious solution.

III. Organization

1. The Risk Management Committee is chaired by the Risk Manager or designee(s) appointed by the Chief Medical Officer and Chief Executive Officer.
2. The Risk Management Committee shall be comprised of representatives from the following groups:
    a. Corporate Compliance
    b. Medical Staff
    c. Quality Improvement
    d. Facilities and Safety
    e. Finance
    f. Clinical Staff
    g. Information Technology
    h. Operations
    i. Pharmacy
3. If an appointed member is unable to attend, a proxy may represent the member at any and all meetings.

IV. Functions

1. The Committee shall meet on a scheduled bi-monthly basis and maintain minutes. It is most important to reflect in the minutes the action taken to correct or prevent future occurrence of a particular type of incident or problem. The Committee will monitor the recommendations or actions taken until final resolution occurs. The minutes are to be maintained on file in the Risk Manager's office or other designated location.
2. The Risk Management Committee shall review the Policies and Procedures Manual as well as appropriate federal and state regulations to ensure continued compliance.
3. Functions of the Risk Management Committee also include:
    a. Establishing and implementing risk identification, evaluation, treatment and monitoring subsystems
    b. Identifying data resources
    c. Developing lines of communication

   d. Evaluating problems to determine corrective action
   e. Implementing corrective actions
   f. Monitoring effectiveness of actions implemented
   g. Advising CEO on matters of policies and procedures
   h. Reviewing claim activity
   i. Developing educational programs aimed at the reduction of liability claims
   j. Participating in the investigation of potentially compensable events
   k. Conducting periodic audits of departments and services for risk exposure
4. It is the Risk Management Committee's responsibility to review and investigate patient incident reports and recommend new or additional programs and procedures to prevent future occurrence of the same or related types of patient incidents.
5. The Risk Management Committee may call upon employees and other personnel who have specific knowledge of incidents under review.
6. The Risk Management Committee may request medical records and other documents specific to incidents under review.
7. The Risk Management Committee may make recommendations to the pertinent clinical departments and/or the Center administration to improve customer care, organization, procedure or policy.
8. The Risk Management Committee shall take all steps necessary to maintain the confidentiality of its review, investigations and other activities.

Risk Control

I. General

In an effort to minimize losses, Carolina Health Centers has established this manual to provide a systematic program designed to reduce or eliminate preventable injuries and accidents to employees, patients and visitors. The ultimate goal of these control measures is to minimize the financial severity of claims arising out of such injuries.

The specific objectives of Carolina Health Centers Risk Management Program are to:

1. Identify the causes of injuries or losses to patients, visitors and employees.
    a. Seek out situations that could produce occurrences resulting in financial loss.
    b. Use the Incident Report as a source of data to be reviewed as described herein.
    c. Contact the person involved in the incident as soon as possible. If the person is involved is a patient or visitor, contact should be made prior to the person leaving the premises. If the person has a grievance, attempts should be made to deal with the complaint immediately with notification to the appropriate manager in the situation.
2. Eliminate dangerous procedures that provide an element of risk in the practice of medicine.
3. Produce a mechanism, other than the courts, to handle claims, i.e.,
    a. Transfer of liability. The center is liable only for that which is its own doing.
    b. Promote good visitor and patient relations.
4. Each department manager or his/her designee has the overall responsibility to do the following:
    a. Provide training programs for all members of the health care team to preclude people failures, errors and other deviations from normal operating procedures that lead to financial loss.
    b. Identify, evaluate and eliminate high risk variances and supportive data.
    c. Recognize high risk areas and make recommendations to eliminate or at least minimize them.
    d. Establish a communication system between providers, clinical staff and other health personnel to ensure quality patient care through careful scrutiny of all areas for potential legal liability.
    e. Improve claims coordination by consultation with legal counsel and outside insurance carriers to improve future conditions and correct errors.

II. Worker's Compensation: Employee Injuries

Carolina Health Centers has established procedures to review injuries to employees while they are on the job. If an employee is injured while in the course of employment, the center may be responsible for the employee's medical expenses, and must, through the state worker's compensation system, provide weekly compensation until the employee returns to work. Benefits are paid in accordance with the compensation laws specific to each state.

1. REQUIRED ACTION

    a. If an injury to an employee occurs, it is Carolina Health Centers' responsibility to take charge of the situation. Employees should be instructed on their responsibilities in handling situations that arise.
    b. Immediate medical assistance will be provided to the injured staff member as soon as possible. Visit the injured employee to determine the circumstances and cause of the accident. If the employee is unable to provide this information at the time of the accident, obtain it as soon as practical thereafter, but continue to obtain statements from eyewitness to the accident.

2. HOW TO REPORT

    a. The "First Report of Injury" must be completed immediately after the accident. All Worker's Compensation losses require completion of this form. The original and one copy should be forwarded to the local claims office.
    b. If the injury is severe or assistance is needed in the completion of the form, contact the Risk Manager at Carolina Health Centers.
    c. The accurate completion of the form is vital as most states require all compensation claims to be filed within 72 hours. By sending the form to the insurance company as outlined in statement a. above, the insurance company will handle filing of the injury report with the State.
    d. It is vital that the report be filed, as no benefits can be paid to the injured employee until the insurance carrier is in receipt of this report. Failure to properly complete the form can cause needless delay in the filing and payment of benefits to an injured staff member.

    There will be times when the injury to an employee is not immediately known. However, when you have first been made aware of the situation, follow the appropriate procedures for the filing of Worker's Compensation Claim. Telephone notification of a loss is not adequate for the reporting of a Worker's Compensation Claim since State laws require the completion of the "First Report Injury" Form on all Worker's Compensation Claims.

3. FILING INSTRUCTIONS

    A file copy of the "First Report Injury" is to be placed in the employee's personnel file for permanent record. As part of Carolina Health Centers' Risk Management Program, an incident report is also to be completed on all employee injuries. The purpose of this report is to serve as an in-house prevention mechanism in order to minimize and eliminate future similar occurrences. This may best be reviewed through the Risk Management Committee. In conjunction with the evaluation of injuries, the center needs to establish an active educational, safety and security program designed to reduce the risk of financial loss due to injury and accidents.

Reporting of Incidents

I. Authority

Employees, medical staff and specified professional staff of Carolina Health Centers will complete an Incident Report when any incident, variance or occurrence transpires with any patient, visitor and/or other non-employee. A report must be completed even if there is no injury.

II. Definition of Incident, Variance or Occurrence

1. An incident, variance or occurrence (hereinafter "incident") is any event which is not consistent with the desired operation of the facility or care of the patient or any event causing patient, visitor and other non-employee dissatisfaction.
2. Examples of incidents include, but are not limited to:
   a. Physical harm to patient, staff or third parties (visitors, students, etc.)
   b. Unauthorized leaves by patients
   c. Accidents in which patients, staff or third parties are injured or die
   d. Drug or alcohol use or traffic of these substances from the outside
   e. Damage to or loss of property
   f. Medication errors
   g. Poor results from treatment of procedures
   h. Injuries
   i. Patient dissatisfaction
   j. Retained foreign bodies
   k. Accidental burns
   l. Neurological deficits
   m. Mistaken identity
   n. Patient and visitor falls
   o. Unexpected transfers to any hospital
   p. Complaints or serious threats of lawsuits by the patient or the family
   q. Patient leaving the center against medical advice
   r. Severe drug reactions
   s. Unexpected deaths
   t. Incidents from the use of equipment and medical devices.

III. Procedure

1. Provide immediate appropriate care and follow-up for the patient, visitor or other non-employee if he/she is injured.
2. When there is a serious injury or the subject of an incident (or the family) is angry or upset about the incident, Risk Management should be notified immediately, along with taking other requisite actions, to resolve the issue/matter.
3. Complete an Incident Report Form to:

a. Provide a record of the event, document the facts of the incident, identify witnesses and preserve any other evidence at the scene
b. Provide a base from which the corporation can further determine, investigate, and evaluate deviations from the standard of care, policies, procedures, protocol, etc.
c. Provide a means of refreshing the memory of those having direct knowledge of the event.
d. Alert Risk Management of the possibility of a claim or lawsuit to allow for complete investigation and documentation and
e. Comply with state and federal regulatory requirements.

4. The Incident Report Form should be completed by the person having the best knowledge of the incident occurs or is discovered. The need for immediate reporting cannot be overemphasized.
5. The following information must be included:
    a. the name of the patients, visitor or other non-employee
    b. the address of the person
    c. a patient's medical record number
    d. the facts surrounding the incident or occurrence
    e. any follow-up action taken
    f. any injury (physical, emotional or otherwise) to the person
    g. the reaction of the person the family to the incident
    h. the identity and location of any medical device or equipment that caused and/or contributed to the incident
6. The person completing the Incident Report Form shall sign it, print his or her name underneath the signature and indicate the extension where he or she can be reached for additional information.
7. The examining provider should not sign the Incident Report Form. However, his or her name should be printed on the form.
8. Should additional space be necessary, attachments to the form are appropriate but should be marked with the identifying information and indicated to be a continuation of the Incident Report Form. The attachment must be stapled securely to the form.
9. The manager or supervisor of the area should review and sign the Incident Report Form and take any appropriate follow-up action necessary (counsel employee, documentation, report to superiors, etc.).
10. All copies of the Incident Report Form must be forwarded to the Compliance Officer within 48 hours following the occurrence or discovery of the incident.
11. The supervisor of the area should complete the Risk Management Follow-up and forward it to Risk Management when follow-up has been completed. If follow-up is completed immediately after review of the Incident Report Form, staple it to the Incident Report Form.

IV. Medical Records

1. The facts of the events should be documented in the medical record when the incident involves a patient. However, no reference should be made to the Incident Report Form in the medical record or the fact than an Incident Report was completed.
2. The Incident Report Form is never placed in the medical record.
3. The following guidelines should be used in the medical record documentation of the event:
    a. be objective and accurate
    b. write a brief narrative of the events surrounding the incident/occurrence, the follow-up action taken, and the status of the patient
    c. do not use any of the following terms:
        1. "incident report" or "accident"
        2. "negligent" or "negligently"
        3. "inadvertent" or "inadvertently"
        4. "in error"
        5. "by mistake" or "mistakenly"

V. Equipment Related Incidents

1. If a piece of medical equipment (examples are an x-ray machine, a nebulizer) or a medical device (examples are a syringe, a catheter, a tube) is involved in an incident, the name of the equipment or device, the manufacturer, the manufacturer's lot number, if available, and other related identification should be documented on the incident report. If there is a malfunction, the incident report should relate the facts that indicated malfunction
2. It is of primary importance in cases of suspected malfunctions that the equipment be removed from service for later testing. The suspected malfunctioning equipment should be labeled as such and sent to the Chief Medical Officer and duly noted on the Incident Report Form.
3. Under no circumstance should the medical device or equipment be discarded. It must be preserved for further investigation. If the device or equipment is contaminated, contact the Chief Medical Officer for instructions regarding its proper preservation.

VI. Multi-Department/Area Incidents

1. When two or more departments or areas are involved in an incident, one of the following should be done:
    a. Each department or area should complete separate forms.
    b. The supervisors of the involved departments should collaborate to complete one set of forms.
2. Each department/area will be responsible for following through on all steps of reporting, regardless of the method of reporting chosen

VII. Risk Management Investigation

1. Risk Management will review the Incident Report Form.
2. Risk Management may investigate any and all incidents and perform any or all of the following during that investigation:
    a. review the medical record
    b. interview knowledgeable personnel identified in the report
    c. review any pertinent policies and/or procedures which may be applicable to the incident
    d. request the assistance of other in-house personnel in the review of the incident
    e. refer to the incident to the appropriate department head for action
    f. take or request any additional follow-up action that is indicated
    g. take any other action deemed necessary by the Risk Management Committee to respond to the incident

VIII. Availability of Risk Management Data

Risk Management logs document certain information into an information system and some statistical analysis is performed on this data. Non-specific information from this database and non-specific information from investigations is available to nursing and other staff who can justify a need for this information (quarterly and annual reports, etc.) However, specific information will not be released unless authorized by the CEO.

Carolina Health Centers Inc.

Incident Report

THIS IS NOT A REPORT OF CLAIM
NOT PART OF THE MEDICAL RECORD

Site:

Name and address of person Involved Give Medical Chart Number (if patient)	Event Date / / Mo Day Year Time of Event AM/PM Report Date / / Mo Day Year	Name and title of person preparing report Supervisor's Signature

Type of Event		Location of Event	Nature of Injury
Fall Medication Error Vaccine Error Needle Stick Test/Proc/Tx Personal Property Loss Equipment Related Adverse drug reaction Cardiac/respiratory arrest Pt/Fam/Staff complaint Patient disruption/disruptive behavior Other (Describe)	**Pt condition prior to event confused, alert….** **Pt condition after event**	Building Exterior Employee Bathroom Front Office Laboratory Corridor Nursing Area Patient Bathroom Patient Waiting Room Waiting Room Bathroom Procedure Room Pt Exam Room # Other (Describe)	Laceration/Cut Contusion/Abrasion Fracture/Dislocation Burn/Scald Sprain/Strain Retained Foreign Body Allergic Reaction Neurological Deficit No Apparent Injury Other (Describe)

Describe the Facts of the Event: (Name, treatment, device, etc.)

Please list all witnesses on the back of this form.

Provider notified if applicable (name only, no notes or sig):	Director of QI and Population Health Signature and date:
	Corporate Compliance Officer Signature and date:
Patient or Witness Comments:	Chief Medical Officer Signature and date:
	☐ Appropriate Action Taken
	Action taken, if any:

Adverse Drug Reaction

I. Policy

1. Definition: An adverse Drug Reaction is any response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. This excludes therapeutic failures and those reactions, which may normally be anticipated side effects.
2. Reporting: Adverse drug reactions are to be reported immediately according to procedure.
3. Documentation: Adverse Drug Reactions are to be documented in the Medical Record, and Adverse Drug Reaction (ADR) Assessment Form.
4. Review: The Chief Medical Officer and the Risk Management Committee are to review adverse drug reactions. Significant reactions are those reactions that are unexpected and will be reported to the FDA as determined by the Risk Management Committee.

II. Personnel Qualified to Perform Procedure

Registered Nurse, Licensed Practical Nurse, Pharmacist, Physicians, Nurse Practitioners, Physician Assistants and other personnel authorized to administer medications.

III. Equipment Needed

Medical Record, Adverse Drug Reaction Assessment Form

IV. Procedure

1. The clinical staff are to notify their supervisor and appropriate provider of known or suspected Adverse Drug Reaction.
2. Prescribed treatment is to be carried out promptly.
3. Document reactions in the patient medical record.
4. Initiate Adverse Drug Reaction (ADR) Assessment Report.
5. Completed reports are to be forwarded to the Chief Medical Officer.
6. The Chief Medical Officer is to evaluate and trend Adverse Drug Reactions identified through spontaneous reporting and retrospective review. The Chief Medical Officer is to review all reported adverse reactions.
7. Adverse Drug Reactions and summary reports are represented to the Risk Management Committee for review.
8. Adverse Drug Reactions are to be reported to the FDA as determined by the Risk Management Committee.

V. Documentation

1. The clinical staff and/or provider are to document Adverse Drug Reactions in the patient's medical record to include the suspected medication and the reaction observed.
2. An Adverse Drug Reaction (ADR) Assessment Report is to be prepared by the staff and routed to the Chief Medical Officer.

VI. Adverse Drug Reaction Recognition

Recognition of adverse reactions is essential to appropriate intervention to improve patient outcome. Adverse Drug Reactions include anticipated side effects as well as allergic reactions, extension of the therapeutic effect, and toxicities. Examples of indicators of adverse reactions include the following:

1. Physical systems, such as a rash.
2. Changes in mental status, such as lethargy in patients on sleeping aids.
3. Hypokalemia in patients on diuretic therapy.
4. Changes in serum creatinine in patients on aminoglycosides.
5. Toxic serum drug concentration levels, such as serum digoxin levels above 2.0.

Adverse Drug Reaction (ADR) Assessment Form

Definition

An Adverse Drug Reaction (ADR) is any unintended, undesirable, or unexpected response to a drug. It includes any reaction that results in the discontinuation of a drug, necessitates additional drug therapy, or causes a hospital admission, prolongation of hospital stay, permanent injury, or death

Patient: _____ Age: ____ Sex: ____

Diagnosis: _____

Date of Reaction____/_____/_____

Known Drug Allergies: _____

Current Medications: _____

_____

Medication Suspected (generic and trade name, route, dose, frequency, lot #):

_____

Reaction Description: _____

Relevant Lab Data (drug serum concentration, electrolytes, etc.)_____

_____

Provider Notified? ____ Yes ____ No Date: ____/____/____Time:_____

Name of Provider: _____

Name of Person Reporting Reaction: _____ Date: _____/_____/_____

Treatment: _____

Additional Comments: _____

Patient Outcome

_____ Slight morbidity-may/may not require change in drug therapy
_____ Moderate morbidity-drug therapy must be discontinued
_____ Severe morbidity-potential for life threatening or irreversible reaction
_____ Death

Classification

_____ Definite reaction appears after rechallenge
_____ Probable reaction disappears after drug discontinued, but without rechallenge
_____ Possible reaction fits known response pattern but may also be caused by other elements of the patient's disease.
_____ Unrelated reaction is unrelated to drug therapy (does not meet ADR definition)
_____ Unclear

Follow-up _____

_____

_____

_____

_____

Person Completing Follow-up_____ **Date**_____

Send reports of all suspected adverse drug reactions to the Chief Medical Officer for review.

Infection and Exposure Control

I. Policy

Safety of the employees of Carolina Health Centers is a top priority of the organization. A written infection control plan is in place and followed for the safety of employees and clients. (See Infection and Exposure Control Policy and Procedures Manual)

II. Procedure

1. Comprehensive infection and exposure control measures are defined in the Infection and Exposure Control Policy and Procedures Manual and will be strictly followed.
2. These measures include, but are not limited to, requirements for:
    a. Hand hygiene
    b. Bloodborne pathogen exposure prevention
    c. Universal precautions
    d. Personal protective equipment
    e. Housekeeping
    f. Engineering and work practice controls
    g. Post exposure procedures
    h. Exposure reporting procedures.
3. These policies are distributed and available to staff and new staff members and reviewed yearly as part of the organization's comprehensive safety program.

Handling Hazardous Waste

I. Policy

Hazardous waste will be packaged, transferred, and disposed of properly to protect both those handling the waste and the environment.

II. Procedure

1. Comprehensive safety measures defined in the Infection and Exposure Control Policy and Procedures Manual are strictly followed.
2. Portable OSHA approved sharps containers for disposal of used lancets and OSHA approved plastic bags for disposal of cotton balls, alcohol swabs and any other contaminated supplies are provided as applicable.
3. Center exam rooms have wall mounted OSHA approved sharps containers for Disposal of used needles and any other sharp object. Exam rooms have trash containers with OSHA approved plastic bags for disposal of any contaminated materials. (See also the Infection and Exposure Control Policy and Procedures Manual)

Accident, Injury or Illness Report

I. Policy

Employee accidents, injuries, illnesses or other events or incidents which would cause an accident, injury or illness will be reported to ensure proper treatment and/or implementation of measures to avoid future injury, accident or illness.

II. Procedure

1. Serious injury or illness posing a life-threatening situation will be reported immediately to local emergency response medical services (Call 911)
2. Injuries and illnesses will be reported by the injured employee to his or her supervisor in person or by phone as soon as possible after any life-threatening situation has been addressed. If the injured employee is unable to report immediately, then the incident should be reported as soon as possible.
3. Non-emergency injury or illness will be triaged by available clinical staff.
4. A decision may be made to direct employee to their personal provider or a Carolina Health Centers designated provider.
5. Upon notification of an occupational injury or illness, the supervisor will notify Human Resources and then prepare the necessary record keeping forms (Incident Report Form).
6. Employee will confer with Human Resources regarding Workman's Compensation rules and regulations as required.

Patient's Rights

I. Policy

Patients of Carolina Health Centers will be treated with respect and fairness.

II. Procedure

1. Patient's rights as defined by the Patient's Bill of Rights and Responsibilities, in the Corporate Policy Manual, will be observed by all staff members.
2. Patient's Bill of Rights and Responsibilities is posted in a visible place in the clinical area.

Customer Grievance

A customer grievance procedure evolves from expressed customer dissatisfaction with one or more aspects of the program or its attendant services. Dissatisfaction may stem from an administrative decision or procedure, provided (or unprovided) medical care, or with the customer's ability to access medical care.

All customers have an opportunity to file a complaint or grievance and to receive a reasonable and workable resolution to the complaint. Grievances may be initiated as a result of either a notice of adverse action directed toward a customer or as a result of a customer's dissatisfaction with the Carolina Health Centers program itself.

All customers are informed of the grievance procedure at the time of registration. In addition, written information will be available at each primary care site.

I. The Grievance Process

Grievances may be initiated orally (by telephone or in person) or in writing. Most grievances will originate with an oral complaint.

II. Oral Grievance Procedure

The highest-level appropriate Carolina Health Centers employee available at the time of the grievance (typically the office manager) will strive to ascertain the true nature of the complaint and resolve it as directly and as quickly as possible. If the situation presented evolved from a misunderstanding or lack of information, the individual will act to ensure that the customer is advised of the correct information. If the information provided alleviates the customer's concerns, the grievance process need not be documented and is ended. However, if after a discussion has taken place, the customer still has one or more unresolved complaints, the process must proceed to the more formal written grievance procedure.

III. Written Grievance Procedure

Written grievances may be initiated either as a result of an unresolved oral complaint or without any prior contact. A patient may request a Patient Complaint Form from any employee of Carolina Health Centers. The patient, any other involved individual, or a designated employee shall indicate on the form the facts resulting in the patient's complaints as well as any attempts made previously to resolve the situation (e.g., a verbal conference). Patient complaints should be resolved to the patient's satisfaction as quickly as possible. Threats of litigation must be reported immediately to the Compliance Officer. The provider, the director of the department or the Chief Medical Officer will address all complaints involving the perceived quality of care, and of any complaints that have not been resolved to the patient's satisfaction. The Director of Quality, or a designee, will track and trend the types of patient complaints. This information will be presented to the Quality Improvement Committee and will be presented to the Risk Management Committee if deemed necessary by the Risk Manager and/or Director of Quality. Relevant issues, trends, and outcomes of

these complaints will be provided to the board of directors as part of the general Quality Improvement and/or Risk Management reporting to the board.

Patient Complaint Form

(All patient, family, or external customer concerns/complaints are confidential. This report and any attached documents are part of the Quality Improvement program.)

Date of Report: _____

Name of Patient (or others involved) and MRN if applicable:

_____

Describe the nature of the concern. Use quotations when possible. Suggest the patient (or other) write his/her concern in his/her own words if possible. Attach patient letters, surveys or any document that details the concern.

Name of person recording information: _____

Investigation, follow-up, and resolution: (use back of paper or additional pages if needed)

For QI purposes, check one:

☐ Medical care ☐ Nursing care ☐ Reception/Front office ☐ Billing ☐ Access to care

☐ Telephone problem ☐ Medical records ☐ Lab ☐ Radiology

☐ Other: _____

All completed forms should be sent to the Director of Quality Improvement.

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