IREDELL HEALTH SYSTEM

Adverse Drug Event Reporting	
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Risk Management/Safety Committee P&T Committee	Date: 06/2021 Date: 08/2021

Purpose: Iredell Health System strives to prevent adverse patient outcomes related to medication use. The goal is to prevent medication errors, reduce the severity of adverse drug reactions (ADRs), analyze the data present related to adverse drug events (ADEs), and implement plans to prevent or mitigate the occurrence of ADEs.

Standards:

- All adverse drug events (with the exceptions noted below) should be reported in MIDAS (the incident reporting system) in a timely manner and investigated as soon as possible to facilitate patient safety and risk management.
- All adverse drug events that result in a severe patient outcome (Category G,H,I) should be investigated immediately by the appropriate personnel.
- The treating provider should be notified as soon as possible of ADEs in categories D-I. The treating provider is responsible for notifying the attending provider.

Definitions:

- Medication Process: the process by which medications are selected, procured, prescribed, prepared, labeled, dispensed, and administered to a patient.
- Adverse Drug Events (ADEs): A deviation in the medication process is a medication error and ADE, with or without an undesirable outcome. Any adverse drug reaction is considered an ADE. This may or may not be the result of a medication error, and includes medication side effects both unknown and predicted.

  Categories of Adverse Drug Events: the severity of each ADE is determined by pharmacy and nursing administration through the selected review of nursing documentation, physician comments, pharmacy records and monitoring notes, objective lab data, medical record audits, and Midas reports. Events are grouped into one of nine categories as defined by The United States Pharmacopeia. These categories are utilized by nursing and pharmacy leadership to determine appropriate actions during investigations of events. For purposes of clarification, these categories may be referred to in this policy as follows:

  - **Category A:** Circumstances or events that have the potential to cause harm (i.e., any ADE that does not fall into another category).
  - **Category B:** An event occurred but the medication did not reach the patient (e.g. dispensing errors corrected by nursing)

- **Category C:** An event occurred that reached the patient but did not cause any cognitive and/or physical deterioration or impairment, disability, life threatening event, death or congenital anomalies.
- **Category D:** An event occurred that resulted in the need for increased patient monitoring but did not cause any cognitive and/or physical deterioration or impairment, disability, life threatening event, death or congenital anomalies.
- **Category E:** An event occurred that resulted in the need for treatment or intervention because of cognitive and/or physical deterioration or impairment.
- **Category F:** An event occurred that resulted in initial or prolonged hospitalization because of cognitive and/or physical deterioration or impairment.
- **Category G:** An event occurred that resulted in permanent disability.
- **Category H:** An event occurred that resulted in a near-death event (e.g., anaphylaxis or cardiac arrest) or is life-threatening.
- **Category I:** An event occurred that resulted in patient death or results in congenital anomalies.

- Severe ADE (or Harm): An ADR that is categorized as Category G, H or I.
- Non-reportable ADE: An ADR that is a well-known, published reaction or common side effect of a medication described in the medication's package insert will NOT be considered reportable in MIDAS in category E or below. Anything in a higher category (F and above) should be entered into MIDAS in a timely manner to be further evaluated by pharmacy and nursing.
- Medication Error: any deviation in the medication process.
- Drug incompatibilities: (also drug interactions) Pharmacists with assistance from a drug interaction screening data-base, will concurrently monitor all new orders for potential drug interactions, and notify the provider of any potential problems. These interaction interventions are documented by the pharmacist, and would only be considered an ADE if any of the above criteria are met.
- Types of Errors: (examples)
  - Deteriorated product
  - Drug prepared incorrectly
  - Expired product
  - Extra dose
  - Improper dose / quantity
  - Mislabeling
  - Omission
  - Prescribing
  - Unauthorized / Wrong drug
  - Wrong administration technique
  - Wrong dosage form
  - Wrong patient
  - Wrong route
  - Wrong time

Policy:

- The treating provider should be notified as soon as possible of any adverse drug event in categories D-I. In the event of a severe adverse drug event (G-I) the immediate supervisor should also be informed, with timely notification of the Director, or Administrative Nursing Supervisor in the absence of the director. The decision will be made to contact the Administrator on Duty if an event investigation is required.
- The course of any investigation will be determined by Administration, Risk Management and/or the Department Directors of the involved/affected units upon review of the incident and discussion with parties involved.
- For any suspected ADE (excluding those defined above as non-reportable), a report should be completed in MIDAS for the purpose of future statistical analysis and review of the medication process. Documentation should be made in the patient's medical record regarding relevant assessment or treatment. Notation should be made if the physician was notified. There should **not** be a notation in the medical record that a MIDAS report was completed. Follow-up and investigation of MIDAS reporting should be conducted by the appropriate Department Director(s) in a timely manner. Findings, conclusions and necessary action are reported in MIDAS.
- All adverse drug event reports are reviewed by Pharmacy Administration.
- A summary of medication error reports and any trends and issues affecting the organization are presented to the Risk Management/Safety Committee and the Pharmacy and Therapeutics Committee.
- Adverse Drug reporting is monitored by Pharmacy and other department directors/staff as appropriate. Pharmacy reports results of this monitoring to the Pharmacy & Therapeutics Committee on a quarterly basis.
- Events resulting in a patient death should be reported to the NC Board of Pharmacy. The NC Board of Nursing may also be notified dependent on the results of the investigation.

INITIAL EFFECTIVE DATE: (go-live date or Board approval date)
DATES REVISIONS EFFECTIVE: 08/2013, 03/2016, 06/2021
DATES REVIEWED (no changes):