1. **PURPOSE**

The facility recognizes that adverse drug reactions and medication administration errors place patients at considerable risk. For safe, quality care, the facility acknowledges it must have systems in place to respond to and monitor a patient in the event of an adverse drug reaction or medication error. The purpose of this Adverse Drug Reactions and Drug Administration Errors Policy (“Policy”) is:

1. To establish written standards and reporting systems that are consistent with applicable State law for monitoring, reporting, and analyzing real or potential adverse drug reactions and drug administration errors.
2. To facilitate effective internal facility reporting that can be used to assess vulnerabilities in the medication process and implement corrective actions to reduce or prevent reoccurrences.
3. To establish leadership and responsibility for the implementation and development of this Policy.
4. To fulfill Critical Access Hospital conditions of participation in the Medicare program and Joint Commission accreditation standards.
5. **POLICY / SCOPE**
6. The facility is responsible for ensuring that this Policy and its associated systems exist and operate to provide quality health care in a safe environment.
7. The Policy Advisers shall be responsible for advising the facility on developing the adverse drug reactions and medication administration errors policy, and for review of this Policy.
8. The staff shall be responsible for reporting all necessary patient care and Quality Assessment and Performance Improvement program adverse drug reactions and medication administration errors.
9. The standards captured in this Policy shall apply to all departments that involve the ordering, dispensing, prescribing, administration, treatment, and monitoring of patients using medication, including but not limited to the Pharmacy Services department, all clinical and nonclinical staff, independent contractors, medical staff members, and any other person who works in the facility or comes into the facility.
10. **DEFINITIONS**
11. ***“Adverse drug reaction”*** means any unexpected, unintended, undesired, or excessive response to a drug that: (1) requires discontinuing the drug (therapeutic or diagnostic); (2) requires changing the drug therapy; (3) requires modifying the dose (except for minor dosage adjustments); (4) necessitates admission to a hospital; (5) prolongs stay in a health care facility; (6) necessitates supportive treatment; (7) significantly complicates diagnosis; (8) negatively affects prognosis, or (9) results in temporary or permanent harm, disability, or death.
12. ***“Drug (medication) administration error”*** means any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. A medication administration error is one that occurs in the phase of the medication process where the drug actually enters the patient by one of various possible routes, e.g., orally, intravenously, etc.
13. ***“Policy Advisers”*** means the members of the facility’s professional healthcare staff, including one or more physicians and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff, who provide advice in developing the adverse drug reactions and drug administration errors policy.
14. “***QAPI***” means Quality Assurance and Performance Improvement.
15. **PROCEDURES**
16. Facility Responsibilities. The facility, through its designee, must:
    1. *Written Policies*. Develop and maintain written policies and procedures for reporting and responding to adverse drug reactions and drug administration errors.
    2. *Stakeholder Input*. Obtain the advice of members of its professional healthcare staff, including one or more physicians and one or more physician assistants, nurse practitioners, or clinical nurse specialists in developing the policies.
       1. [PLACEHOLDER – include organization-specific processes and protocols related to this requirement]
    3. *Reporting Systems*. Establish system(s) for staff to report and identify adverse drug reactions and drug administration errors for patient care purposes and QAPI purposes.
       1. The reporting systems will indicate the timeframe in which reports should be made.
       2. The reporting system will identify the persons that staff should notify when an adverse drug reactions and medication error occurs.
       3. The report will be documented in the patient’s medical record.
       4. [PLACEHOLDER – include organization-specific processes and protocols related to this requirement]
       5. Reporting may also be made to FDA MedWatch Reporting Program and the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program if applicable.
    4. *Education*. Educate staff, including nursing, pharmacy, and medical staff, on medication administration errors and adverse drug reactions, including the criteria for those errors and adverse drug reactions that are to be reported for quality assurance / improvement purposes, and how, to whom, and when they should be reported.
       1. The facility should maintain documentation of the education/training that it required of its staff regarding reporting standards.
       2. [PLACEHOLDER – include organization-specific processes and protocols related to this requirement]
    5. *Guidance on Response*. Provide clinical staff with expected guidance on how to respond to various adverse drug reactions and drug administration errors situations that may arise.
       1. [PLACEHOLDER – include organization-specific processes and protocols related to this requirement]
    6. *Remediation*. Take effective action to address problems or errors that are identified, if appropriate.
       1. [PLACEHOLDER – include organization-specific processes and protocols related to this requirement]
    7. *Data Collection*. Collect data on the following:
       1. Significant medication errors;
       2. Significant adverse drug reactions; and
       3. Adverse events related to using moderate or deep sedation or anesthesia.
       4. [PLACEHOLDER – If relevant to implementation of this procedure, provide organization-specific details here]
    8. *Additional Methods of Identification*. In addition to staff-generated incident reporting, the facility has implemented the following methods to help identify medication administration errors and adverse drug reactions that may otherwise go unnoticed:
       1. Observation of medication passes
       2. Concurrent and retrospective review of patient’s clinical records
       3. Implementation of medication usage evaluations for high-alert drugs
       4. Identification of indicator drugs that, when ordered, automatically generate a drug regimen review for a potential adverse drug event
       5. [PLACEHOLDER – Please confirm, remove, or add to this list, and provide any other organization-specific details here regarding methods used by the facility]
    9. *Assessment of Effectiveness*. The facility shall assess the effectiveness of its internal reporting system to determine whether or not it is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by the facility.
       1. The facility should refer to established benchmarks or studies on error or adverse drug reaction rates published in peer-review journals in making such assessments.
          1. [PLACEHOLDER – If applicable, provide organization-specific details here and/or specific benchmarks, studies, and journals that should be referenced]
       2. The QAPI program’s responsible individual must be able to demonstrate how the facility determines if the number of errors and reactions reported is consistent with the facility’s size and scope of services provided.
       3. The QAPI program’s activities for medication administration errors and adverse drug reactions must demonstrate that, upon analyses of the reports, potential corrective actions were identified and implemented, if appropriate.
       4. [PLACEHOLDER – If relevant to implementation of this procedure, provide organization-specific details here]
17. Policy Advisers’ Responsibilities. The Policy Advisers must:
    1. Advise the facility on development of this Policy and related policies.
    2. Review this Policy and related policies and documentation, if applicable, at least every other year.
    3. [PLACEHOLDER – include any education, training, experience, or certification that your organization shall require for these advisers]
    4. [PLACEHOLDER – Populate with any organization-specific selection, appointment, or election procedures applicable]
    5. Review of this Policy otherwise follows [PLACEHOLDER – Reference the organization’s “Policy on policies” that addresses the organization’s general guidelines for review and drafting of policies] located at [PLACEHOLDER - Location of “Policy on policies”]
18. Staff Responsibilities.
    1. *Identification.* Staff will monitor and identify adverse drug reactions and medication errors.
       1. Staff shall monitor patients for side effects, including the patient’s perceived side effects, and the effectiveness of his or her medication(s), including sample medication(s).
       2. Staff shall monitor activities for medication errors
       3. [PLACEHOLDER – include organization-specific processes and protocols related to this requirement]
       4. [PLACEHOLDER – if applicable, refer to clinical guidelines specific to identification of certain adverse effects for specific medications, or documents detailing how staff can identify medication errors through black box warnings, etc. Include references to any specific documents in **SECTION VI. RELATED DOCUMENTATION AND FORMS** below]
    2. *Response*. Upon identification of an actual or potential adverse drug event, significant adverse drug reaction, and/or medication error, including those involving sample medications, staff should:
       1. Follow the written process for responding to the event. The written process can be found/is available [PLACEHOLDER - Location of written process for responding to event]
       2. [PLACEHOLDER – include organization-specific processes and protocols related to this requirement. Note that reporting processes can be tailored to the specific error or reaction at issue. ]
    3. *Reporting and Notification*. Staff must report medication administration errors and adverse drug reactions as follows:
       1. Staff must notify the prescriber when an adverse drug event, significant adverse drug reaction, or medication error has occurred.
       2. All adverse drug reactions and medication administration errors that are not caught before they reach the patient must be reported to a practitioner responsible for the care of the patient*:*
          1. The report must be made immediately after the staff identify the adverse reaction or (potentially) harmful error to enable a timely assessment and intervention.
          2. The report must be made directly in a manner that confirms a practitioner received the report.
          3. If the impact of the medication error that reached the patient is unknown, the error must be reported to the practitioner immediately.
          4. Examples of medication administration errors which have “reached” the patient include:
             1. Administration of a medication to the wrong patient
             2. Administration of a medication in the wrong dose
             3. Administration of a wrong medication
             4. Administration of a medication used the wrong route
             5. Administration of a medication was not timely
          5. [PLACEHOLDER – If relevant to this procedure, provide organization-specific details here]
       3. Medication administration errors that have reached the patient but result in no harm and do not have the potential to cause harm can be reported to a practitioner during usual working hours*:*
          1. [PLACEHOLDER – If relevant to this procedure, provide organization-specific details here]
       4. Medication administration errors that have occurred, but have not reached the patient, do not need to be reported to the responsible practitioner.
          1. If the wrong dose of a drug has been prepared for a patient but is caught prior to administering the drug to the patient, it is still a medication administration error subject to the other requirements of this Policy, but it does not need to be reported to the responsible practitioner.
          2. [PLACEHOLDER – If relevant to this procedure, provide organization-specific details here]
       5. For rehabilitation and psychiatric distinct part units in the facility, medication administration errors, adverse drug reactions, and medication incompatibilities (as defined by the facility) are immediately reported to the attending physician or clinical psychologist and as appropriate to the organization-wide QAPI program.
          1. [PLACEHOLDER – Include any QAPI specific reporting requirements; “medication incompatibilities” definition]
          2. [PLACEHOLDER – If relevant to implementation of this procedure, provide organization-specific details here]
       6. [PLACEHOLDER – include organization-specific processes and protocols related to this requirement. Note that reporting processes can be tailored to the specific error or reaction at issue.]
    4. *QAPI Reporting*. Staff must report all medication administration errors and all adverse drug reactions to the QAPI program for QAPI purposes.
       1. All identified medication administration errors must be reported for QAPI purposes, regardless of whether the medication “reached” the patient or not.
       2. [PLACEHOLDER – include organization-specific processes and protocols related to this requirement]
    5. *Medical Record Documentation*. The person who identifies the error and/or adverse reaction, or who notifies the practitioner, must promptly document the identification and/or notification in the patient’s medical record.
       1. [PLACEHOLDER – If relevant to implementation of this procedure, provide organization-specific details here, including any facility-specific medical record documentation standards and requirements]
19. Pharmacy Services Responsibilities. Pharmacy services should:
    1. Assess all adverse drug reactions and medication administration errors reports.
    2. Determine if problems or errors in pharmacy services caused or contributed to the adverse reaction or medication administration error.
    3. [PLACEHOLDER – Include any other processes the organization may have in place regarding Pharmacy services’ role in assessing and responding to reactions and errors]

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1. **CROSS-REFERENCED POLICIES**

Related Adverse Drug Reactions and Drug Administration Errors Policies and Guidance: [PLACEHOLDER: Policy # - Cross-reference any relevant guidance and/or policies, procedures, or requirements that address how to respond to various adverse drug reactions and drug administration errors situations *if not addressed in related documents or clinical standards* captured in **Section VI. RELATED DOCUMENTS AND FORMS** below.]

Training and Education Policy and Procedures: [PLACEHOLDER: Policy # – If applicable, cross-reference any relevant policies, procedures, or requirements that address or overlap with the training, education, and competency requirements referenced in this policy]

Medical Staff / Nursing Services / Pharmacy Services [PLACEHOLDER: Policy # – If applicable to your organization, cross-reference any relevant policies, procedures, or requirements that address or overlap with standards in alignment with this policy]

Medical Records Policy and Procedures: [PLACEHOLDER: Policy # – If applicable, cross-reference any relevant policies, procedures, or requirements that address or overlap with the medical records documentation requirements referenced in this policy]

QAPI Policy and Procedures [PLACEHOLDER: Policy #]: Adverse drug reactions and drug administration errors identified must be reported to, reviewed, and addressed in coordination with the facility-wide QAPI program.

Drugs and Biologicals Policy: [PLACEHOLDER: Policy # – If applicable to your organization, cross-reference any relevant policies, procedures, or requirements that address or overlap with standards in alignment with this policy. Note that the Drugs and Biologicals Policy includes information about the Formulary, Hazardous Drugs, High-Alert Drugs, Sound-Alike Drugs, and Look-Alike Drugs that may be relevant to developing and implementing this policy. Ensure that these two policies work together accordingly.]

Pharmacy Services Policies and Procedures: [PLACEHOLDER: Policy # – If applicable to your organization, cross-reference or incorporate any relevant policies, procedures, or requirements that address or overlap with standards in alignment with this policy.]

1. **RELATED DOCUMENTATION AND FORMS**

Related Adverse Drug Reactions and Drug Administration Errors Documents: [Include specific adverse drug reactions and drug administration errors documentation, clinical guidelines, standards or forms that are specific to certain events, surgeries, diseases, populations, etc. *if not addressed in separate policies* captured in **Section V. CROSS-REFERENCED POLICIES** above. ]

Related Drugs and Biologicals Documents: [Include at least the following documents referenced in the Drugs and Biologicals Policy to the extent relevant to the development and implementation of this Policy:

1. Formulary
2. Hazardous Drugs List
3. High-Alert Drugs List
4. Sound-Alike and Look-Alike Drugs List]
5. **SOURCES**
6. 42 C.F.R. § 485.635(a)(3)(v) (2019).
7. The [State Operations Manual, Appendix W](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_w_cah.pdf) includes Survey Procedures and Interpretive Guidelines for this condition of participation, which are encompassed in this policy. In future reviews, update with any new procedures and guidelines.
8. The Joint Commission, Critical Access Hospital – Performance Improvement Chapter, PI.01.01.01 *et seq*.
9. The Joint Commission, Critical Access Hospital – Medication Management Chapter, MM.07.01.01 *et seq.*
10. The Joint Commission, Critical Access Hospital – Record of Care, Treatment, and Services Chapter, RC. 07.01.03 *et seq.*
11. [PLACEHOLDER – Include any clinical guidelines or best practice documents used to populate the clinical information above.]