520.0 Medication Error/Incident Reporting and Adverse Drug Reactions

520.1 Policy Approval Clearance Record

☐ Rural Services Policy ☒ Rural Clinics Policy ☐ Rural Regional Center Policy	This policy supersedes:	Number of pages in Policy: 11
Review by Representative from the Office of the Attorney General: n/a	Date: n/a	Date Policy Effective: 08/31/2012
Rural Services Director Approval Signature: *Barbara Legier*	Date: 08/31/2012	Policy Lead: Sally Mitchell, DON; Kathryn Baughman, CPM II

520.2 Statement of Purpose

520.2.1 **Policy Statement:** Rural Clinics will employ sound reporting procedures relating to medication errors/incidents and adverse drug reactions in order to promote health and safety of the consumers served.

520.2.2 **Purpose:** To establish procedures essential for accurate identifying, reporting, recording, and routing reports of medication errors/incidents and adverse drug reactions to the appropriate authority. In addition, this policy will allow the Quality Assurance Unit to trend and review for systemic errors, identify the need for staff training, and develop a plan of improvement.

520.3 Authority

NRS 449.0175; 454; 632.30; 639
NAC 454; 639
MHDS Policy SP-3.2

520.4 Unique Definitions and Acronyms

520.4.1 **Refer to the Standard Definitions Policy 000**

520.4.2 **Error/incident:** An act that through ignorance, deficiency, or accident departs from or fails to achieve what should be done, and may apply to an event without intent, volition, or plan.

An error/incident involving medication that is not in accordance with State laws, Division and Rural Clinics policies and procedure includes, but is not limited to incidents involving:

A. Medical provider written orders. Orders written by MD/APN in his/her own hand, or, entered into an electronic record by his/her own hand.

B. Misinterpreted medical provider telephone orders. Orders received from an MD/APN over a phone which are not heard correctly, not interpreted correctly, or not entered into the electronic or physical record correctly.

C. Transcription errors: To make an inaccurate copy of dictated or recorded matter in longhand or on a computer through ignorance, deficiency, or accident**.**

D. Medications dispensed:

1. Incorrect consumer: A person with a different name and ID than the medication is written on the order and medication bottle.

2. Incorrect route: Administration of medication via a method other than the MD/APN order; for example, giving a consumer a medication ordered by mouth, which is administered by injection.

3. Incorrect time: Medication ordered by MD/APN to be administered at a specific date and time is given at a time other than the order specifies.
4. Incorrect dose: Medication ordered by the MD/APN at a specific quantity of a medication to be taken at one time and which is administered at a quantity of medication other than specifically ordered.
5. Medication not ordered: Medication administered to a consumer not ordered by an MD or APN for that consumer.
6. Incorrect medication: The wrong medication is dispensed to a consumer.

E. Omission of medications. Medications ordered by an MD/APN which are not administered to the consumer through ignorance, deficiency, or accident.

F. Medication storage errors, such as:

1. Missing medication.
2. Storage area contains incorrect medication.
3. Mislabeled medication.
4. Mishandling of medications- medication not kept refrigerated, refrigerator temperature not maintained, and/or refrigerator malfunction not reported.
5. Outdated medication

520.4.3 **Adverse Drug Events (ADE):** Refers to an injury resulting from the administration of a drug, including errors in administration.

520.4.4 **Adverse Drug Reactions (ADRs):** 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.

520.4.5 **Medwatch, The FDA Medical Products Reporting Program:** An initiative designed both to educate all health professionals about the critical importance of being aware of, monitoring for, and reporting adverse drug events and problems to the FDA, and /or the manufacturers and~~,~~ to ensure that new safety information is rapidly communicated to the medical community thereby improving consumer care.

520.4.6 **Predictable ADRs:** Side effects, which are often unavoidable pharmacologic actions of the medications at the usual prescribed dosages and drug interactions.

520.4.7 **Serious Adverse Event:** Any adverse drug reaction that results in death, life threatening event, inpatient hospitalization, or prolongation, persistent or significant disability/incapacity or congenital defects.

520.4.8 **Unpredictable ADRs:** Side effects related to intolerance, idiosyncratic effects, or the consumer's immunologic responses (allergy).

520.5 Procedures

520.5.1 Medication Errors/Incidents

A. All medication errors/incidents identified by the Registered Nurse or designated staff will be recorded on the "Rural Clinics Medication Error/ Incident Report" (Attachment RC520A) and submitted to the Center Director or designee immediately upon discovery.

B. The Center Director or designee will review the report, sign it, and forward it to the Director of Nurses (DON) or designee within one (1) working day.

C. The prescribing medical provider will be notified of the error immediately by the designated RN to determine appropriate action. Medical provider orders will be

followed regarding an error/incident involving a consumer and a progress note entered into the electronic record within one (1) working day.

D. DON or designee will review and complete Attachment RC520A. DON will forward to other management members on the form.

E. The completed Attachment RC520A is then emailed or faxed to the NNAMHS Pharmacist by the DON or designee within five (5) working days.

520.5.2 Adverse Drug Reactions

A. The prescribing medical provider will be notified immediately by the designated RN, and all actions taken will be noted under the Treatment/Action section of the Rural Clinics Adverse Drug Reaction form (Attachment RC520B). The designated RN will enter a progress note into the electronic medical record within one (1) working day.

B. All suspected adverse drug reactions will be recorded on Attachment RC520B. The RN must complete Section I of Attachment RC520BB and submit it to the DON within one (1) working day.

C. An entry regarding the adverse drug reaction will be noted in the consumer's electronic chart by the medical provide~~r~~ within one (1) working day.

D. The DON or designee will review the form to determine the need for corrective action and route the form to the NNAMHS Pharmacy within two (2) working days.

E. The Pharmacy and Therapeutics Committee will review all ADRs, provide recommendations to the Agency, and ensure ongoing surveillance of ADRs, thereby promoting awareness and education to the staff.

520.5.3 Life Threatening Reactions – If the consumer experiences a life-threatening reaction to a medication while at the Mental Health Center, emergency medical intervention is the first priority. Call 911 immediately and explain the reaction, provide the name of the drug, and stay on the phone to answer further questions in case information is requested.

520.5.4 Timelines

Requirement	Deadline	Starting Date	Responsible Party	Actions to be Taken
520.5.1	Immediately	Discovery of medication error or incident	RN	Notify medical provider and seek follow up orders
	Immediately	Discovery of medication error or incident	RN	Record medication error/incident on the Error/Incident form (Attachment A) and notify the Center Director
	Within one (1) working day.	Discovery of error/incident	RN	Make a progress note in electronic record.
	Within one (1) working day.	Notification of error/incident	Medical Provider	Record medication error/incident on Attachment A form and make a progress note in the electronic record.
	Within one (1) working day	Receipt of Attachment A	Center Director or designee	The Center Director reviews and forwards Attachment A to the DON
	Within five(5) working days	Receipt of Attachment A	DON or designee	DON reviews, completes Attachment A. and routes to other managers on Attachment A. Attachment A is emailed or faxed to NNAMHS Pharmacist.

Requirement	Deadline	Starting Date	Responsible Party	Actions to be Taken
520.5.2	Within one (1) working day	Adverse Drug Reaction Report	RN	RN completes Attachment B and forwards to the DON\
	Immediately	Adverse Drug Reaction Report	RN	RN notifies medical provider for further orders
	Within one (1) working day	Adverse Drug Reaction Report	RN	RN enters a progress note
	Within one (1) working day	Adverse Drug Reaction Report	Medical Provider	Medical provider enters a progress note
	Within two (2) working days	Receipt of ADR (Attachment B)	DON	Complete ADR and fax or email to NNAMHS Pharmacist
520.5.3	Immediately	Life threatening Medication reaction	RN or designee	Emergency medical intervention and 911

520.5.5 Documentation

A. Electronic Documentation:

Applicable Screen	Data Required
Progress Note	Medication Error/Incident and follow-up
Progress Note	Adverse Reaction and follow-up

520.5.6 Supervisory Responsibilities: Supervisors will provide in-service training to ensure all staff understands the requirements of this policy and its procedures. Supervisors will revisit this policy periodically, but no less than annually to identify recommendations for improvement.

520.6 Policy Cross Reference

520.6.1 Rural Clinics 1109, Mental Health Services Medication Policy

520.6.2 MHDS Policy 3.2008, Medication Procedures

520.7 Attachments

520.7.1 RC520A Rural Clinics Medication Error/Incident Report Form

520.7.2 RC520B Rural Clinics Adverse Drug Reaction Form

520.7.1
RC520A
Rural Clinics Medication Error/Incident Form

RURAL CLINICS ADULT MENTAL HEALTH SERVICES

MEDICATION ERROR/INCIDENT REPORT

Please Indicate

Error/Incident Occurred Time ☐ ☐ ☐ ☐

Error/Incident Discovered Time ☐ ☐ ☐ ☐

Consumer Name I.D. # Attending Prescriber

Medication

Type of Error/incident (Check all appropriate)

☐ Wrong Dose ☐ Wrong Time ☐ Wrong Medication ☐ No Pharmacy Review Prior to Administration ☐ Missed Medication

☐ Wrong Consumer ☐ Omitted Dose ☐ Wrong Route ☐ Script Miss-fill ☐ Delay-no Fax/Scan to Pharmacy ☐ Other

Reason for Error/incident (Check all appropriate)

☐ Incomplete Order ☐ Miscalculated/Measured Dosage ☐ Transcription ☐ Delay-no Fax/Scan to Pharmacy

☐ Misread MAR/Order ☐ Misread Medication Label ☐ Outdated Order ☐ Labeled Incorrectly

☐ Failure to Administer ☐ Consumer off unit w/o arrangement ☐ Failed to check Consumer ID

Number of doses affected by error: __1_____

Description of error/incident (if necessary, use additional sheet of paper)

Name of person originating report Date Time

Name of Supervisor Notified Date Time

Name of Prescriber Notified Date Time

Consumer Notified of error by: _____RN/MD Progress Notes

Action taken for or with consumer:

Results of Action Taken:

Supervisor Signature_____ Date Report Signed_____

Date rec'd in PI _____

(Date revised: _____)

Attending Physician/Presciber's Comments: ☐ **Action required** ☐ **No Action Required**

_____

_____

_____

_____Signature

_____Date_____

☐ **Action required** ☐ **No Action Required**

Approved by MARS: 08/31/12

Director of Nursing or Designee Comments:

_____
_____
_____
_____**Signature**
_____**Date**_____

Director of Pharmacy Comments: ☐ **Action required** ☐ **No Action Required**

_____
_____
_____
_____**Signature**
_____**Date**_____

Pharmacy and Therapeutics Committee's Comments: ☐ **Action required** ☐ **No Action Required**

_____
_____
_____
_____**Signature**
_____**Date**_____

Agency Director's Comments: ☐ **Action required** ☐ **No Action Required**

_____
_____
_____
_____**Signature**
_____**Date**_____

Quality Improvement Coordinator's Comments: ☐ **Action required** ☐ **No Action Required**

_____
_____
_____
_____**Signature**
_____**Date**_____

Medical Director's Comments: ☐ **Action required** ☐ **No Action Required**

_____
_____
_____
_____
Signature_____**Date**_____

520.7.2
RC520B
Rural Clinics
Adverse Drug Reactions Form

RURAL MENTAL HEALTH CENTERS
ADVERSE DRUG REACTION FORM

Section I: (Witness of reaction/initiator)
DEFINITION: An adverse drug reaction (ADR) is any response to a drug that is unexpected, unintended, undesired or excessive and occurs at doses used in human prophylaxis, diagnosis, therapy or modification of psychological function.

PATIENT INFORMATION

NAME: _____ UNIT/ LOCATION: _____

AGE: _____ GENDER: ☐ MALE ☐ FEMALE PREGNANT/NURSING (CIRCLE OPTION)

RACE: _____ DIAGNOSIS (including medical diagnosis):_____

_____

KNOWN ALLERGIES: _____

LIST ALL CURRENT MEDICATIONS (including medical, psychiatric, over-the-counter, and herbal medications): _____

_____

_____

DESCRIPTION OF REACTION:
DATE OF REACTION: _____, 20_____ TIME: _____ AM PM
DURATION OF REACTION: _____ (Hours and/or Days)
SUSPECTED MEDICATION(S): (date started, time given, dose, route)

_____

_____

TYPE OF REACTION: (check all that apply)

Allergy
- ☐ Anaphylaxis
- ☐ Fever
- ☐ Skin reaction (rash, itching, hives)
  - Type: _____
  - Location: _____

Gastrointestinal
- ☐ Diarrhea
- ☐ Constipation
- ☐ Bleeding
- ☐ Nausea/Vomiting

Psychiatric
- ☐ Confusion
- ☐ Delirium
- ☐ ↑ Psychosis

Other
- ☐ Paradoxical reaction
- ☐ Seratonin Syndrome
- ☐ NMS (Neuroleptic Malignant Syndrome)

Blood-Lab
- ☐ ↓ WBC, RBC, HCT, Platelets
- ☐ ↑ Creatinine
- ☐ ↑ Prolactin
- ☐ ↓ Sodium
- ☐ ↓ Potassium
- ☐ ↑ Potassium

Neurological
- ☐ Cog wheeling/ rigidity
- ☐ Restlessness
- ☐ Headache
- ☐ Dyskinesia/ Dystonia/ TD
- ☐ Tremor
- ☐ Seizure
- ☐ Sedation/ Lethargy
- ☐ Dizziness
- ☐ Anxiety
- ☐ Depression
- ☐ Altered mental status

Renal
- ☐ Anuria/ Oliguria
- ☐ Failure
- ☐ Urinary retention

ENT (Ear, Nose, Throat)
- ☐ Hearing Loss
- ☐ Stomatitis
- ☐ Tinnitus

Respiratory
- ☐ Wheezing
- ☐ ↑ Respiration
- ☐ ↓ Respiration

Liver
- ☐ LFTs (Liver function tests)

Cardiovascular
- ☐ Arrythmias
- ☐ Angina
- ☐ Hypertension
- ☐ Hypotension
- ☐ Bradycardia
- ☐ Tachycardia

OTHER: (Explain) _____

_____

_____

TREATMENT/ACTION: (check all that apply)
☐Drug Discontinued
☐Treatment given _____
☐Prescriber notified _____Date: _____ Time: _____AM/PM
☐Reaction noted in chart and electronic medical record
OUTCOME AFTER TREATMENT/ACTION:
_____

_____

Person Preparing Report: _____Date: _____ Time: _____ AM/PM
(Signature)
RETURN COMPLETED FORMS TO PHARMACY

Section II: (Pharmacy Department)

ADVERSE DRUG REACTION PROBABILITY/SEVERITY WORKSHEET

	YES	NO	UNKNOWN	SCORE
1. Are there any previous conclusive reports on this reaction?	+1	0	0	
2. Did the ADR appear after the suspected drug was administered?	+2	-1	0	
3. Did the ADR improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	
4. Did the ADR reappear when the drug was re-administered?	+2	-1	0	
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	
8. Did the patient have a similar type reaction to the same or similar drugs in any previous exposure?	+1	0	0	
9. Was the ADR confirmed by any objective evidence?	+1	0	0	
		TOTAL SCORE:		

Pharmacist Completing Report_____Date:_____

TOTAL SCORE	≥9	5-8	1-4	≤0
PROBABILITY	HIGHLY PROBABLE	PROBABLE	POSSIBLE	DOUBTFUL

SEVERITY:

A mild ADR requires no treatment and has an insignificant patient impact.
A moderate ADR requires treatment but is not life-threatening and not likely to result in permanent disability.
A severe ADR is potentially life threatening and could result in permanent disability or death.

ADR PROBABILITY RATING:___Highly probable ___Probable ___Possible ___Doubtful

ADR SEVERITY RATING :___Severe ___Moderate ___Mild

REPORT TO MEDWATCH ____YES ___NO

Section III (P&T review)

_____

_____

_____

Signature of P&T Chair: _____ Date:_____