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Applicability:	DDSN Regional Centers, DDSN Service Providers of: Residential Habilitation, Day Activity, Career Prep, Community Services, Employment and Support Center Services

IMPLEMENTATION OF THIS REVISED DIRECTIVE MUST BE COMPLETED BY JANUARY 1, 2018

Purpose

This procedural directive establishes a standardized definition and reporting system for medication errors/events in order to improve the health and safety of individuals receiving supports from DDSN or a contracted provider. Medication errors/events may occur in DDSN Regional Centers or when the following services are being provided to DDSN individuals - Residential Habilitation, Day Activity, Career Preparation, Community Services, Employment and Support Center Services.

General

The South Carolina Department of Disabilities and Special Needs (DDSN) recognizes that medication errors represent one of the largest categories of treatment-caused risks to individuals. As a result of this, organizations that administer medications to individuals who are receiving

supports should have a medication error/incident reporting, analyzing, and follow up capability, as part of their overall risk management program.

The safe administration of medication is an important part of the overall health care program provided by DDSN and its network of service providers. Safe medication administration requires training, experience, and concentration on the part of the individual administrating the medication. For this reason, medication administration should occur in an orderly environment and at a time when those administrating medications are not distracted with other tasks. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) has urged agencies, institutions, and researchers to utilize this standard definition of medication errors. DDSN has adopted this definition. (For more information on NCC MERP, see www.nccmerp.org.)

"A medication error is 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."

Types of Medication Errors/Events

According to the above definition, there are some kinds of medication errors that are outside the control of DDSN and its network of service providers (e.g., naming, compounding, packaging etc.). If a board/provider's staff discovers errors of this type, the pharmacist should be notified immediately in order for corrective action to occur. The types of medication errors/events that are within the direct control of DDSN and its network of service providers can be divided into three (3) categories:

1) Bona fide or "true" medication errors;
2) Transcription and documentation/charting errors, and
3) "Red flag" events.

1) MEDICATION ERROR TYPES

- Wrong individual given a medication
- Wrong medication given
- Wrong dosage given
- Wrong route of administration
- Wrong time
- Omission: Medication not given by staff
- Other: Medication given without a prescriber's order
- Other: Order Expired
- Other: Pharmacy errors directly involving individuals

2) TRANSCRIPTION AND DOCUMENTED/CHARTING ERRORS

- Transcription error (i.e., from prescriber's order to label, or from label to the Medication Administration Record (MAR):
    - Transcription - Wrong Individual
    - Transcription - Wrong Medication
    - Transcription - Wrong Dose
    - Transcription - Wrong Route
    - Transcription - Wrong Time
    - Transcription - Omission
- Charting Error: Medication administration documented was not completed by the end of the shift.
    - Other: Prescribed Medical Observation/Pre-Treatment Requirements is not completed. The omission is related to documentation of a specific observation/pre-treatment prescribed for collecting data to monitor medication effect
    - Other: Prescribed Follow-up after Medication Administration is not documented

3) RED FLAG EVENTS

- Individual refuses medication (this event should prompt the board/provider to make every effort to determine why the individual refused the medication. Specific action taken should be documented. Each board/provider must develop a reporting system for these events)
- "Near Misses" (i.e., medication error almost occurred)
- Unsafe circumstances (i.e., that may lead to a medication error in the future)
- Medication found unsecured (i.e., on the floor, bureau, etc. Internal investigation must be conducted to determine the intended use of the discarded medication to insure this event would not lead to a medication error)
- Pharmacy event that indirectly involves individuals
- The texture of the medication is not consistent with orders for food and fluid intake
- The individual is not in the correct position to receive medication

Data Collection

DDSN Service Providers will be required to complete Medication Error Reporting documentation in Therap. This will assist each provider agency with developing its own data collection system to track, monitor and analyze medication errors/events. This includes the process of medication delivery and all components of the MAR.

As the Medication Error is recorded in Therap, the cause may be designated as follows:

- Forgot to Send to Program
- Forgot to Take on Activity
- Medication Refused
- Medication not Available
- Omission Unavoidable
- Pharmacy Error
- Staff Action/Inaction
- Other

Medication error rates and their corresponding data must be made available to DHEC and/or the Contract Compliance Review and Licensing Review contractors and DDSN staff upon request.

Reporting Procedure

The first individual finding the medication error/event is responsible to report the error or event in the GER Module and follow the provider agency's procedures for notifying supervisory/administrative staff, such as the employee's supervisor, program director, nurse in charge or Executive Director/DDSN Regional Facility Administrator. The date the error is discovered is the date of discovery. The immediacy of the error reporting is dependent on the severity of the incident or the board's/provider's internal policy. Depending on the type of error/event, the supervisor/administrative staff shall use professional judgment regarding whether a call to the prescriber is indicated. The supervisor/administrator may also determine that a "911" call is needed.

1) If the prescriber is contacted, the supervisor/administrator will follow the prescriber's orders, if given, and ensure the orders are well documented, including the name of the prescriber consulted. Only a nurse can take a verbal or telephone order from a prescriber, and the new order should be written on the medical/telephone orders sheet with supporting documentation in the Health Record in Therap.

2) The individual should be observed and monitored for any adverse reactions. These may include changes in behavior, levels of alertness, changes in vital signs, or other physiological responses.

3) Document findings in the Health Record and follow up with the prescriber as needed.

4) Medication errors/events that are the result of pharmacy errors should be reported to the pharmacist for immediate corrective action.

As soon as possible, the individual finding the error or identifying the event completes the GER entry on Therap to report the medication error.

The following fields must be completed as a part of the Medication Error Report, as applicable, when outside Medical Attention or Intervention is required:

- Consult with Nurse
- Consult with Physician
- Consult with Emergency Room
- Consult with Poison Control Center
- Immediate Physician Visit
- Immediate Emergency Room Visit
- Observe and Report Only

5) Upon notification of the GER entry/medication error report, the supervisor/administrative staff reviews it for accuracy, additional actions needed, and approves the entry. Provider agencies may designate other individuals to review medication errors according to their own policies.

6) A medication error/event resulting in serious adverse reactions must be reported as a Critical Incident on the DDSN Incident Management System (DDSN Directive: 100-09-DD-Critical Incident Reporting) in addition to the GER entry. The GER may be referenced in the Critical Incident Report in order to reduce duplication.

Severity Level 1

A medication error occurs when one of the following takes place: an individual receives the wrong drug, the wrong dose, a drug by the wrong route, a drug in the wrong form, or at the wrong time. A missed dose or a dose administered more than one (1) hour before or more than one (1) hour after the scheduled time constitutes a medication error. If medications are not available for dispensing, this is a medication error. A Severity Level 1 error includes incidents in which the individual experienced no or minimal adverse consequences and no treatment or intervention other than monitoring or observation was required. Medication Errors: Severity Error 1 do not require a Critical Incident Report, but must be reported in Therap via GER.

Severity Level 2

Includes incidents in which the individual experienced short term, reversible adverse consequences that required treatment and/or interventions in addition to monitoring and observation. Medication Errors/ Events Severity Level 2 do not require a Critical Incident Report, but must be reported in Therap via GER.

Severity Level 3

Includes incidents in which the individual experienced life-threatening and/or permanent adverse consequences. - Critical Incident Report Required.

7) If the medication error/event resulted in serious adverse reactions (Severity Level 2 or 3) the supervisor/administrative staff will notify the Executive Director, Facility Administrator, or designee using the GER High Level notification process.

8) The Director of Nursing, Executive Director, Facility Administrator, or designee will assure that all medication events, including red-flag events, are entered into Therap as part of the board's/provider's medication error data collection system and will assure these data are available to the quality assurance and risk management staff/team for analysis, trend identification, and follow-up activity as needed.

9) DDSN may request all data related to medication error/event reporting at any time or during any of the board's/service provider's annual reviews. Medication Records, Medication Error Reports, and the monthly error rate calculations for each DDSN licensed service location must be available at the location site for the prior three (3) calendar month periods. Error rates for the current month must be documented and available by the last day of the following month.

Proactive Analysis

In order to be consistent with "best practice," medication error reduction efforts should possess the capability for both reactive and proactive analysis. Reactive analyses include efforts to improve understanding of specific medication errors and the analysis of aggregate medication error data. Proactive analysis includes individual refusals, "near misses" or other unsafe circumstances that may lead to a medication error in the future, and the analysis of errors that have occurred in other systems or settings. Providers are required to categorize the types of errors/events reported in their analysis. NCC MERP (2008) indicated "the value of medication error reports and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the health care organization's analysis of the information, and its actions to improve the system to prevent harm to patients." (http://www.nccmerp.org/statement-medication-error-rates)

The Code of Federal Regulations (CFR) has established the following method of calculating Medication Error Rates: "In calculating the percentage of errors, the numerator in the ratio is the total number of errors you observe, both significant and non-significant. The denominator is all doses being administered, plus the doses ordered, but not administered. The equation for calculating a medication error rate is as follows:

$$\text{Medication Error Rate} = \frac{\text{Number of Errors observed [discovered]}}{\text{Opportunities for Errors}} \times 100$$

As further guidance, the CFR provides the following example: If you observe the administration of drugs to 20 patients with a total of 47 doses administered (47 opportunities for errors) and at the completion of the reconciliation of your observation with physician's orders, you find that three (3) medication errors were made in administration and one (1) medication was omitted (ordered, but not administered), then the omitted dose is included in both the numerator and the denominator. Therefore, following the above formula, your equation would be as follows:

$$\frac{3+1}{47+1} \times 100 = 8.333\%$$

The definition can be referenced as follows in the Electronic Code of Federal Regulations: https://www.ecfr.gov/graphics/pdfs/ec01ja91.107.pdf. This method should be used for all DDSN Regional Centers and DDSN Contracted Residential and Day Service Locations as of December 1, 2017. A Medication Error Rate must be calculated for each setting, including individually licensed apartments.

For each DDSN licensed service location, boards/providers are required to record the monthly error rate expressed as a whole number with three (3) decimal points along with the number of errors/events. Error rates are not to be used as a substitute for the actual number of errors/events, as the rate could reflect .000, but there may be actual medication errors recorded.

For clarification, medications passed will include ALL medications (doses) at each licensed site (including individually licensed apartments): oral, injections, topical, drops, and breathing treatments. The medications include all prescribed medications and orders for over-the-counter products. A dose is the amount of medication that has been prescribed to be given at a specific time. For example: If the order is for 500 mgm of a drug and it is dispensed by the pharmacy in 250 mgm tablets, the individual would receive two (2) tablets which would be one dose. The Consulting Pharmacy can usually provide this information for providers.

This monthly error rate calculation will allow providers to incorporate data from individual locations into their Risk Management data to identify trends and work with specific areas to determine the need for more assistance and/or training. Any error/event reports should be developed based on the date of discovery of the medication error found during the month of review. Both Medication Errors and Documentation Errors are to be included in the Error Rate Calculation, but boards/providers may choose to document as two (2) separate rates. "Red Flag Events," such as refusals or "near misses," would not be included in the error rates, but there must be a medication error report completed to ensure appropriate follow-up.

Medication Records, Medication Error Reports, and the monthly error rate calculations for each service location must be available at the location site for the prior three (3) calendar month period. Error rates for any given month must be documented and available by the last day of the following month. Effective December 1, 2017, Medication Error Reports must be completed using the General Event Reporting Module on Therap, although providers may begin use of the GER immediately. Paper reports are required until the provider completes the transition to the GER.

Follow-up Activities

The purpose of recording and analyzing medication errors is to create a safer, healthier environment in which people live and work. If medication errors are recorded and analyzed, but no follow-up activities are implemented, then the purpose of the effort has not been achieved.

At the board/provider level, reactive and proactive analysis of trends should be coupled with appropriate corrective actions. These actions may include, but are not limited to, additional training (including medication technician certification), changes in procedure, securing additional technical assistance from a consulting pharmacist, and improving levels of supervision.

Each board/provider should adopt a method for documenting follow-up activities such as utilizing memoranda or the minutes of risk management/quality assurance meetings and quarterly oversight meetings required as part of the Medication Technician Certification program (DDSN Directive 603-13-DD). This information must be included as part of the data collection system related to medication error/event reporting. The provider must include this documentation in the Corrective Actions Taken or Plan of Future Corrective Actions fields in the Medication Error Report on Therap. This may be a part of the Reviewer's Comments in the GER before or after approval.

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Related Policies:

100-09-DD; 100-26-DD; 603-13-DD

To access the following attachments, please see the agency website page "Attachments to Directives" under this directive number at http://www.ddsn.sc.gov/about/directives-standards/Pages/AttachmentstoDirectives.aspx.

Attachment: DDSN Therap General Event Reporting Requirements