Ohio Administrative Code

Rule 5122-2-13 Medication practices in regional psychiatric hospitals.

Effective: April 4, 2022

(A) The purpose of this rule is to ensure safe and quality patient care by establishing standards that govern all aspects of medication practices within inpatient settings of the regional psychiatric hospitals (RPHs). Medication practices will reaffirm patients' rights to receive appropriate medication treatment and participate actively in treatment decisions.

(B) The following definitions apply to this rule in addition to those specified in rule 5122-1-01 of the Administrative Code:

(1) "Administration" means the direct application of a single drug to the body of a patient either by injection, inhalation, ingestion, or any other means.

(2) "Certified pharmacy technician" means an individual who is registered with the state board of pharmacy as a certified pharmacy technician under section 4729.901 of the Revised Code.

(3) "Chief clinical officer" and "CCO" mean the medical director of an RPH as defined in division (K) of section 5122.01 of the Revised Code.

(4) "Computerized physician order entry" and "CPOE" mean the computer program by which a prescriber can order a medication.

(5) "Dispensing" refers to the final association of a medication with a particular patient pursuant to a lawful prescription of a prescriber, and assuming responsibility for the activities involved in filling the prescription.

(6) "Emergency" means an impending or crisis situation which creates circumstances demanding immediate actions for prevention of injury to the patient or others, as determined either by a physician, registered nurse, or physician assistant.

(7) "Hazardous medication" means a medication that is potentially genotoxic, carcinogenic, teratogenic, or can cause developmental toxicity if improperly handled. A list of these medications is published by the national institute for occupational safety and health of the United States centers for disease control and prevention and updated as needed.

(8) "High risk medication" means a medication that has an increased risk of causing significant pertinent harm or death if it is misused or used in error.

(9) "Informed consent" means a process that requires a prescriber to give a patient or legal guardian all information necessary to make an informed decision to either undergo or refuse a proposed treatment or medication, including the following components: nature of the treatment or medication; the potential benefits, risks, or possible side effects or consequences associated with taking or not agreeing to the recommended treatment or medication; any alternative treatments available to the patient; and determination that the patient has the capacity to give or withhold informed consent.

(10) "Medication" or "drug" means a natural or chemical substance that exerts a pharmacological effect intended for the purpose of treatment, prevention, or diagnostic studies of illness.

(11) "Medication reconciliation" means the gathering of data on medications that were prescribed prior to admission and using the data in the selection of medications that are prescribed during the patient's hospital stay. Upon discharge or transfer, a list of medications currently prescribed is also shared with the next provider of services.

(12) "Medication with abuse potential" means a controlled substance as defined in section 802(6) of the "Controlled Substances Act," 21 U.S.C. 802(6), as amended, or a non-controlled medication with recognized potential for abuse.

(13) "Pharmacist" means a person licensed under Chapter 4729. of the Revised Code to engage in the practice of pharmacy.

(14) "Physician" means a person licensed under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(15) "Prescriber" has the same meaning as in section 4729.01 of the Revised Code, except that it excludes a veterinarian licensed under Chapter 4741. of the Revised Code.

(16) "Prescribing" means an order for one or more medications issued.

(17) "PRN order" means an order for a medication that is given only when a patient manifests a specific clinical condition and consents to take the medication.

(18) "Prescription drug" means a medication dispensed only upon a prescription or includes on the manufacturer's label the wording, "Rx only," or the statement, "Caution: federal law prohibits dispensing without prescription."

(19) "Psychotropic medication" means a medication that has specific and intended effects on central nervous system functions and is ordinarily used to treat disorders of thought, perception, mood, or behavior.

(20) "Standing orders" means an established, routine, or special order from a prescriber and approved by the CCO that is applicable to the general population of a unit, ward, or RPH as opposed to an individual.

(21) "Telephone order" means an order transmitted by telephone.

(22) "Verbal order" means an order spoken aloud by a prescriber in the presence of the person authorized to receive the order.

(23) "Verification" means the professional clinical review of a patient's medication profile by a pharmacist for dose, schedule, medication allergies, drug-drug interactions, drug-food interactions, and drug-disease interactions prior to the dispensing of a new medication.

(C) Prescribing practices

(1) All medications will be prescribed as deemed medically appropriate pursuant to a physical and psychiatric evaluation. Prescribing practices will be in compliance with state and federal laws as well

as standards of accrediting or certifying entities.

(2) All medications will be prescribed consistent with department policies and clinical practice guidelines. Medications will not be prescribed or administered in quantities that prevent a patient from participating in psychosocial treatment.

(3) Each patient's medication regimen will be reviewed and evaluated by the attending physician at time intervals established by RPH policies, but at least monthly. Documentation of this evaluation will be made in the patient's medical record.

(4) When the prescribing of two medications from the same psychotropic medication class is indicated, the reasons for prescribing more than one medication from the same class will be documented by the prescriber in the patient's record. If the concomitant use of three antipsychotic medications occurs for greater than sixty days, a review will be conducted by the RPH CCO or the CCO's designee.

(5) RPH policies and procedures will address high risk medications, hazardous medications, and medications with abuse potential.

(6) Medications may be prescribed on the basis of a telephone order only when received, recorded, and "read back" by a registered nurse, licensed practical nurse, or pharmacist to ensure correctness of the order. All telephone orders are to be countersigned, dated, and timed after review by the prescriber who gave the order, generally within seventy-two hours, unless a shorter time interval is specified in RPH policy.

(7) Telephone orders will be limited to the specific circumstances described in RPH policy.

(8) Verbal orders may only be used in an emergency situation. Verbal orders will be signed, dated, and timed by the prescriber within one hour.

(9) Medication orders will specify indication for use. If more than one PRN medication is ordered for the same indication, the orders will contain clear instructions for the relationship between their administrations (e.g., conjointly, in what sequence, etc.).

(10) Medication orders will be time-limited in accordance with applicable state and federal laws and regulations, but in no case will non-controlled medication orders exceed three hundred sixty-five days. Orders for controlled medications will not exceed one hundred eighty days. (See appendix A to this rule.) Renewal of medication orders will be done by the prescriber in a timely fashion to avoid missed doses and other complications.

(11) For patients who lack a payer source for medication, the prescriber may order up to a fifteen day supply of medication to be dispensed to the patient at discharge. For patients with a payer source, the prescriber may order up to a three day supply to be dispensed at discharge, along with a prescription for up to thirty days of medication to be filled after discharge. Larger amounts may be given with CCO approval.

(12) Standing orders will be prohibited, except as approved by the RPH medical staff organization.

(13) The prescriber will perform medication reconciliation as part of the admission and discharge processes, as well as throughout the hospitalization as appropriate.

(D) Documentation

The prescriber will document in the progress notes of the patient's medical record justification of the use of medications. Documentation will include but is not limited to:

(1) Rationale for the use of each prescribed medication, including the increase or decrease in dose or form of the same medication;

(2) Rationale for a change to a different medication;

(3) Rationale for cessation of a given medication; and

(4) Periodic review and evaluation of the patient's response to the medication regimen.

(E) Pharmacy/dispensing practices

(1) The pharmacy is responsible for procurement, distribution, and drug control within the RPH. Pharmacy operations will comply with state and federal drug laws, regulations, and standards of accrediting or certifying entities. The pharmacy will maintain an up-to-date policy and procedure manual.

(2) The pharmacy will, in accordance with Ohio drug laws, receive medication orders through the CPOE program or in written form. Procedures for receipt of medication orders will be specified in RPH policies. The pharmacy will dispense medications only upon the order of a prescriber.

(3) The pharmacy will maintain a medication profile for each patient and a pharmacist is to clinically review this profile prior to the dispensing of each medication, in the process of verification. Medication profiles will be maintained in accordance with Ohio drug laws, RPH policies, and standards of accrediting or certifying entities. When deemed necessary, the pharmacy will notify the appropriate clinicians of problems existing within a medication regimen. This notification will be documented. When a drug is not available in a particular dose, the pharmacist may substitute with other dosage strengths available if the total combined dose equals the dose ordered by the prescriber. The prescriber will not be required to enter or write a new order as no new order is generated. Example: "valproic acid five hundred mg is substituted with valproic acid two hundred fifty mg two tablets."

(4) The pharmacy may have a certified pharmacy technician stock automated drug storage systems and replenish floor stock if a pharmacist is readily available to answer the technician's questions, routinely verifies that the technician is completing these tasks properly, and assumes full responsibility for the technician's activities.

(5) Patient-specific prescription drugs will be dispensed, packaged, stored, and labeled as required by Ohio drug laws. Prescription drugs that are emergency supplies or floor stock will be accompanied by appropriate accountability records and be issued, stored, and secured in accordance with Ohio drug laws. Prescription drugs issued as floor stock will not be in excessive quantities and will be periodically reconciled with the corresponding accountability sheets.

(6) Pharmacies that provide a contingency drug cabinet or automated dispensing machine (ADM)

will maintain the cabinet or ADM in a secure area other than the pharmacy. RPH policy will specify personnel who may access the contingency supply and address accountability of the medications.

(7) The pharmacy is responsible for the safe and secure storage of all medication. All areas within the RPH where medications are stored will be inspected in accordance with RPH policies and procedures. Inspections will be documented and discrepancies identified, communicated, and corrected. Medications will be properly stored in all areas of the RPH with respect to appropriate space, temperature, light, moisture, segregation, and security.

(8) The pharmacy will dispense medications in compliance with department policies, directives, guidelines, and protocols.

(F) Record keeping

The pharmacy will maintain appropriate and current licenses with the Ohio board of pharmacy and the U.S. drug enforcement administration, as well as maintain records as required by Ohio and federal drug laws to ensure a complete audit trail of accountability.

(G) Clinical responsibilities

(1) RPH pharmacists will participate in clinical activities regarding medications. RPH policies and procedures will define these clinical activities.

(2) An RPH may establish additional policies which outline clinical pharmacy practices consistent with the Revised Code and under the supervision of the CCO or the CCO's designee.

(H) Administration practices

(1) All medication orders will have the authority of a privileged and licensed prescriber's signature or other means of order authentication when CPOE is used.

(2) Medications may be administered to patients only with a documented informed consent, except:

(a) In emergency situations (see OhioMHAS policy MED-11 MHAS informed consent policy for RPHs);

(b) When administering over the counter medications; or

(c) As authorized by a court.

(3) After verification of the identity of the patient, medications will be administered only by a clinician appropriately licensed by the state and deemed competent to do so by the RPH.

(4) Sound and prudent professional judgment will be exercised in the administration of medications.

(5) Medication is always to be verified with the order prior to transcription and administration, although medication may be administered prior to pharmacist review of the order in emergency situations as identified by the terms "emergency" or "stat" in the order.

(6) Self-administration of medication by a patient will be permitted only when a specific order for self-administration is written by the patient's prescriber and self-administration is authorized by RPH policy.

(7) Medication will be administered by the established standard drug administration schedule of the RPH unless otherwise specified by the prescriber.

(8) Medication errors of level 1 or greater (as defined by OhioMHAS policy MED-03 medication errors) or adverse drug reactions (ADR) shall be immediately reported to the patient's physician (or covering physician) and documented per department policy.

(I) Education/competency/performance improvement

(1) Prescribers, nurses, and pharmacists will hold current, valid professional licenses and be in good standing with their licensing boards. They will provide education and information relating to medication to staff, patients, and families. The content of this rule will be a part of RPH employee orientation.

(2) The competency of each prescriber, pharmacist, and nurse will be monitored, evaluated, and documented on an ongoing basis as part of the RPH performance improvement program and consistent with RPH policies, procedures, and competency plans.

(3) Each RPH will develop and implement a performance improvement program that addresses significant areas of medication standards of practice.

(J) Quality assurance/performance improvement

(1) RPHs will establish mechanisms that make patient safety in the area of medication use a high priority.

(2) RPHs will establish mechanisms to encourage a culture of safety that includes both of the following:

(a) Reporting of ADRs, near miss errors, and all medication errors. (Reporting of medication errors shall not result in any retaliatory action against the reporting person.)

(b) Analysis of medication use processes through failure mode effects analysis to reduce or eliminate potential errors.

(See OhioMHAS policy MED-03 medication errors.)

(3) RPHs will establish mechanisms in coordination with the hospital services pharmacy and therapeutics committee to disseminate to clinicians current information on prevention of errors and potential areas for improvement of medication use.

(K) Implementation

(1) The chief executive officer of each RPH will be responsible for implementation of this rule through RPH policy.

(See, also, appendix A to this rule.)