Ohio Administrative Code

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

Effective: August 25, 2016

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

(B) This rule applies to all RPHs inpatient settings operated by the Ohio department of mental health and addiction services. Community support network (CSN) programs operated by an RPH shall meet the requirements established under rule 5122-29-05 of the Administrative Code.

(C) The following definitions shall apply to this rule in addition to those appearing 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) Allied health professional means an advanced practice registered nurse or physician assistant licensed under the laws of this state.

(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 physician or other licensed/certified 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 physician or other licensed/certified 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 or registered nurse or physician assistant.

(7) "Hazardous medication" means a medication which is potentially genotoxic, carcinogenic, teratogenic, or can cause developmental toxicity, if improperly handled. A list of these medications is published by occupational safety and health administration (OSHA) and updated yearly.

(8) "High risk medication" means a medication which has potential side effects which are known or suspected to cause adverse, potentially life-threatening reactions or lasting serious health impairment.

(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 and/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/drug" means a natural or chemical substance, that exerts a pharmacological effect, intended to be used 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/transfer a list of medications currently prescribed is also shared with the next provider of services.

(12) "Medication with abuse potential" means a medication, compound, mixture, preparation, or substance included in schedule I, II, III, IV, or V of "The Controlled Substance Act" or other non-controlled medication with recognized potential for abuse.

(13) "Physician" means a person licensed under the laws of this state to practice medicine.

(14) "Prescriber" means a person licensed/certified under the laws of Ohio to prescribe medication. This includes physicians, dentists, optometrists, podiatrists, advanced practice registered nurses/nurse practitioners with prescribing authority and physician assistants with a certificate to prescribe.

(15) "Prescribing" means an order for medication(s) issued.

(16) "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.

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

(18) "Psychotropic medication" means medication which has specific and intended effects on the central nervous system functions and which is ordinarily used to alter disorders of thought, perception, mood, or behavior.

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

(20) "Telephone order" means an order transmitted via the telephone.

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

(22) "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.

(D) Prescribing practices.

(1) All medications shall be prescribed as deemed medically appropriate pursuant to a physical and

psychiatric evaluation. Prescribing practices shall be in compliance with state/federal laws, and standards of accrediting/certifying entities.

(2) All medications shall be prescribed consistent with department policies and clinical practice guidelines. Medications shall not be prescribed or administered in quantities which prevent a patient from participating in psycho-social treatment.

(3) Each patient's medication regimen shall be reviewed and evaluated by the attending physician at time intervals established by RPH policies, but at least monthly. Documentation of this evaluation shall 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 shall 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 shall be conducted by the RPH CCO/designee.

(5) RPH policies and procedures shall 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 and recorded by a registered nurse, licensed practical nurse or registered pharmacist. All telephone orders must be countersigned, dated and timed, after review by the prescriber or covering prescriber, within forty-eight hours, unless a shorter time interval is specified within RPH policy. The order shall be written down and then "read back" by the RN/pharmacist to the prescriber to ensure the correctness of the order.

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

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

(9) PRN medication orders must specify indication for its use. If more than one PRN medication is

ordered for the same indication, the orders must contain clear instructions for the relationship between their administrations (e.g., conjointly, in what sequence, etc.).

(10) Medication orders shall be time-limited in accordance with applicable state and federal laws and regulations, but in no case shall medication orders exceed three hundred sixty-five days. (See appendix A to this rule). Renewal of the medication orders shall 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 shall be prohibited, except as approved by the RPH medical staff organization.

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

(E) Documentation.

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

(1) Rationale for the use of each prescribed medication, including the increase/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.

(F) Pharmacy/dispensing practices

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

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

(3) The pharmacy shall maintain a medication profile for each patient and a pharmacist must clinically review this profile prior to the dispensing of the medication, in the process of verification. Medication profiles will be in accordance with Ohio drug laws, RPH policies, and standards of accrediting or certifying entities. When deemed necessary, the pharmacy shall notify the appropriate clinician(s) of problems existing within a medication regimen. This notification shall be documented. When a drug is not available in a particular dose, the pharmacist may substitute with other dosage strengths available as long as the total combined doses equals the dose ordered by the physician/prescriber. The prescriber will not be required to enter/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 semi-professional or clerical assistance in activities which do not require professional judgment. These activities must be supervised by a licensed pharmacist.

(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 must be accompanied by appropriate accountability records, and shall be issued, stored, and secured in accordance with Ohio drug laws. Prescription drugs issued as floor stock shall not be in excessive quantities and shall be periodically reconciled with the corresponding accountability sheets.

(6) Pharmacies that provide a contingency drug cabinet/automated dispensing machine (ADM) shall maintain the cabinet/(ADM) in a secure area other than the pharmacy. RPH policy shall 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 on a monthly basis. Inspections will be documented and discrepancies identified, communicated, and corrected. Medications must 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.

(G) Record keeping

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

(H) Clinical responsibilities

(1) RPH pharmacists shall participate in clinical activities regarding medications. RPH policies and procedures shall 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 designee.

(I) Administration practices

(1) All medication orders shall 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 guideline MD-11 "Guidelines for OhioMHAS Informed

Consent"); or

(b) When administering over the counter medications; or

(c) As authorized by a court.

(3) After verification of the identity of the patient, medications shall 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 shall be exercised in the administration of medications.

(5) Medication must always 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 shall be permitted only when a specific order is written by the patient's prescriber and as specified by RPH policy.

(7) Medication shall 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 MD-03 "Medication Errors") and/or adverse drug reactions (ADR) shall be immediately reported to the patient's physician (or covering physician) and documented per department policy.

(J) Education/competency/performance improvement

(1) Physicians, other prescribers, nurses, and pharmacists shall hold current, valid, professional licenses and be in good standing with their licensing boards. All of these disciplines shall assist in educating direct care personnel regarding appropriate medication practices. The content of this rule shall be a part of employee orientation. Physicians, other prescribers, nurses, and pharmacists shall provide education and information relating to medication to staff, patients, and family.

(2) The competency of each physician, other prescriber, nurse, and pharmacist shall 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 shall develop and implement a performance improvement program that addresses significant areas of medication standards of practice.

(K) Quality assurance/performance improvement

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

(2) RPHs shall establish mechanisms to encourage a culture of safety that includes:

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

(See OhioMHAS policy MD-03, "Medication Errors").

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

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

(L) Implementation

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