KERN HEALTH SYSTEMS

KERN HEALTH SYSTEMS POLICY AND PROCEDURES					
SUBJECT: Pharmaceutical Standards				POLICY #: 13.23-P	
DEPARTMENT: Pharmacy					
Effective Date: 05/2003	Review/Revised Date: 02/24/2024	DMHC	X	PAC	
		DHCS	X	QI/UM COMMITTEE	
		BOD		FINANCE COMMITTEE	

_____ Date _____
Emily Duran
Chief Executive Officer

_____ Date _____
Chief Compliance and Fraud Prevention Officer

_____ Date _____
Medical Director, Quality Improvement

_____ Date _____
Medical Director, Utilization Management

_____ Date _____
Director of Quality Improvement

_____ Date _____
Director of Pharmacy

POLICY

Kern Health Systems (KHS) expects the provider network to comply with all applicable local, State, and federal pharmaceutical standards. Corrective action will be taken as appropriate.

PROCEDURES

1.0 CRITERIA

Provider sites will be reviewed based on the criteria included in the *Department of Health Care Services (DHCS) Medi-Cal Managed Care Division (MMCD) Facility Checklist*. See *KHS Policy and Procedure 2.71-P - Facility Site Review and Medical Record Review* for details regarding the site review process. Other industry standards outside the Facility Site Review

are included in this policy which reflect best standard practices promoting member safety.

1.1 Drug Storage

All drugs must be kept in a locked storage area within the physician's office. This area must be locked at all times when not in use. The area may be kept unlocked during business hours only if it is inaccessible by unauthorized persons and authorized clinic personnel remain in the immediate area at all times. Keys must be available only to staff authorized by the physician to have access.[1] All drugs includes sample and over-the- counter drugs.[2] The physician is responsible for storage of all drugs, including samples.

Medication must be stored in accordance with the manufacturer's recommendations. All medications must be properly labeled. Open vials must be dated and initialed to indicate the date opened.

Medications must be kept separate from food, lab specimens, cleaning supplies, and other items that may potentially cause contamination. Internal and external medications must be stored separately. Separation by bins, etc., in the same cabinet or refrigerator is acceptable.

1.1.1 Refrigerated Drugs

Medications in refrigerator must be kept in a secured compartment that is separate from all other items in the refrigerator, including lab reagents, lab specimens or food. Vaccinations must not be kept in the refrigerator door. The refrigerator temperature must remain between 35 and 46 degrees Fahrenheit (2 and 8 degrees Celsius). Freezer temperature must remain at a maximum of 7 degrees Fahrenheit (-14 degrees Celsius). Refrigerator and temperature must be checked and logged daily. Sites with Vaccines for Children (VFC) must check and log refrigerator and temperature twice a day.

1.1.2 Controlled Substances

The Controlled Substances Act (21 CFR 1304.75) requires that controlled substances be stored separately from other drugs in a securely locked, substantially constructed cabinet. Written records must be maintained of inventory list(s) of controlled substances that includes the following information:

A. Provider's DEA (Drug Enforcement Administration) number
B. Name of medication
C. Original quantity of drug
D. Dose
E. Date
F. Name of patient receiving drug
G. Name of authorized person dispensing drug
H. Number of remaining doses

Personnel with authorized access to controlled substances include physicians, podiatrists, physician's assistants, licensed nurses and pharmacists.

1.2 Needles and Syringes

All needles and syringes must be stored in a secure manner. It is recommended that these items be stored in a locked area.

1.3 Expired Drugs

Providers must implement a routine procedure to check for expired drugs, including samples. All medications must be inventoried with the expiration dates listed. Expired drugs must be immediately discarded. The recommended expiration date may be used for vial medications unless particular matter is noted. Vials must be immediately discarded upon observation of particulate matter.

All prescription drugs not bearing a manufacturer's expiration date pursuant to Code of Federal Regulations Title 21 §211.137 are deemed to have expired and may not be manufactured, distributed, held for sale, or dispensed by any manufacturer, distributor, pharmacist, pharmacy, or other person authorized to dispense such drugs.[3]

1.4 Sample Drugs

Distribution of sample medications must be documented in a sample log that contains the following items:

A. Patient name
B. Drug
C. Dose
D. Route
E. Number distributed
F. Manufacturer
G. Lot number
H. Expiration date

Distribution of the sample medications must also be documented in the medical record. Providers are discouraged from providing samples; however, if samples are given to the patient, the entire course of therapy must be covered by the samples. Medications provided as samples do not establish a continuity precedent and, therefore, do not obligate coverage by KHS.

Providers are prohibited from selling sample medications.

1.5 Prescription Pads

Prescription pads must be secured and inaccessible to patients and visitors. Providers may not supply any individual with a blank prescription form.

1.6 Drug Administration and Dispensing

Providers must not dispense drugs to any individual that is not his/her patient.

Medications must be prepared in a clean area and must fulfill labeling requirements. Providers must check expiration date prior to administration or dispensing. The patient's medical record must reflect the following information on all administered/dispensed/prescribed drugs:

A. Drug

B. Dose
C. Route
D. Date
E. Time

A physician, podiatrist or pharmacist must not dispense any prescription, except in a container that meets the requirements of State and federal law and is correctly labeled with all of the following[4]:

A. Except where the prescriber orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.
B. Directions for the use of the drug
C. Name of the patient or patients
D. Name of the prescriber
E. Date of issue
F. Name and address of the pharmacy and prescription number or other means of identifying the prescription. A physician or podiatrist does not have to label a prescription with a number.
G. Strength
H. Quantity
I. Expiration date
J. Manufacturer's lot number
K. Condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription

2.0 TRAINING AND MONITORING

Training on pharmaceutical guidelines is provided to KHS providers through the distribution of this document to participating providers.

Monitoring of compliance with pharmaceutical guidelines is performed during facility site reviews in accordance with DHCS APL 22-017, Primary Care Provider Site Reviews: Facility Site Review and Medical Record Review, and Policy and Procedure 2.71-P - Facility Site Review and Medical Record Review. KHS Quality Improvement nurses provide training to providers found to be out of compliance.

3.0 DISCIPLINARY ACTION

Providers who fail to follow the procedures contained in this policy will be subject to disciplinary action in accordance with KHS Policy and Procedure 4.48-P, Provider Disciplinary Action.

REFERENCES

- DHCS All Plan Letter 22-017, Primary Care Provider Site Reviews: Facility Site Review and Medical Record Review
- Policy and Procedure 2.71-P, Facility Site Review and Medical Record Review

Revision 2024-02: Per CMO, updates made to signatories to include Medical Directors and remove CMO. **Review 2023-09:** Annual policy review, signatories were updated, no major revisions were required**. Revision 2022-11:** Updates to QI policy references made by Director of QI. **Revision: 2022-06:** Policy renumbered from Quality Improvement, 2.24-P, to Pharmacy Department**.** Policy received approval from the DMHC on 11/16/2022. On 11/18/2022, DHCS accepted the policy under the File and Use criteria. **Revision 2016-12:** Policy reviewed by QI Supervisor. Updated signatory list. **Revision 2013-08:** Policy reviewed by Director of Quality Improvement, Health Education and Disease Management. No revision need, titles updated. **Revision 2010-06**: Revised by Director of Quality Improvement, Health Education and Disease Management. **Revision 2009-10:** Revised per Corporate Pharmacist to mirror Policy 13.01-P §9.0 Sample Medications. **Revision 2006-05:** Revised per DHS Workplan Comments 7c (04/26/06). **Revision 2005-04**: Revised per request of Corporate Pharmacist. **Revision 2003-06**: Revised per DHS comment 2/27/02 and 03/04/03. **Revision 2002-01**: Created upon DHS suggestion that sample provider policies be included in the KHS Provider Administration Manual.

[1] Business and Professions Code §4051.3.; Title 16 CCR §1356.32.
[2] California Medical Board
[3] Title 16 CCR §1718.1
[4] CDHS Full Scope Facility Site Review Survey (used as a reference in DHS Workplan Comments 7c dated 04/26/26).