

State of Ohio Board of Pharmacy - Hearing Summary Report

Hearing Date: 2/28/2020

Today's Date: 3/2/2020

Rule Number(s):

Rule Number	Type	Description
4729:5-9-01	New	Definitions.
4729:5-9-02	New	Institutional pharmacies.
4729:5-9-02.1	New	Minimum standards for institutional pharmacies.
4729:5-9-02.2	New	Security, storage and control of dangerous drugs in an institutional
		pharmacy.
4729:5-9-02.3	New	Record keeping at an institutional pharmacy.
4729:5-9-02.4	New	Dispensing of controlled substances by an institutional pharmacy.
4729:5-9-02.5	New	Patient profiles.
4729:5-9-02.6	New	Pharmacist drug utilization review.
4729:5-9-02.7	New	Medication orders for inpatients and outpatient prescriptions.
4729:5-9-02.8	New	Labeling of prescriptions for patients.
4729:5-9-02.9	New	Licensure of outpatient institutional pharmacies.
4729:5-9-02.10	New	Temporary absence of a pharmacist in an institutional pharmacy.
4729:5-9-02.11	New	Dispensing customized patient medication packages by an
		institutional pharmacy.
4729:5-9-02.12	New	Drugs repackaged or relabeled by an institutional pharmacy.
4729:5-9-03	New	Institutional facilities.
4729:5-9-03.1	New	Contingency drugs in an institutional facility and emergency access
		to an institutional pharmacy.
4729:5-9-03.2	New	Security, storage and control of dangerous drugs in an institutional
4		facility.
4729:5-9-03.3	New	Record keeping in an institutional facility.
4729:5-9-03.4	New	Automated drug storage systems in an institutional facility.
4729:5-9-03.5	New	Hospital self-service employee prescription kiosks.
4729:5-9-03.6	New	Point of care locations in an institutional facility.
4729:6-3-08	Amend	Distributor of dangerous drugs samples and complimentary
4700 (5 00	A	supplies.
4729:6-5-02	Amend	Wholesale distributors - recordkeeping.
4729:6-6-01	Amend	Virtual wholesalers - general operations.
4729:6-7-01	Amend	Brokers - general operations.
4729:6-8-02	Amend	Manufacturers - recordkeeping.
4729:6-9-02	Amend	Repackagers - recordkeeping.
4729:6-10-02	Amend	Outsourcing facilities - recordkeeping. Third party logistics providers recordkeeping.
4729:6-11-02 4729-17-01	Amend	Third party logistics providers - recordkeeping.
4729-17-01	Rescind	Definitions; institutional facility.
	Rescind	Responsible person for an institutional pharmacy. Security and control of drugs in an institutional facility.
4729-17-03	Rescind	
4729-17-04	Rescind	Records; institutional pharmacy.

77 South High Street, 17th Floor, Columbus, Ohio 43215

4729-17-05	Rescind	Controlled substance recordkeeping.
4729-17-06	Rescind	Institutional point of care location.
4729-17-07	Rescind	Temporary absence of a pharmacist in an institutional pharmacy.
4729-17-08	Rescind	Minimum standards for an institutional pharmacy.
4729-17-09	Rescind	Drug orders for patients of an institutional facility.
4729-17-10	Rescind	Labeling of prescriptions for patients of an institutional facility.
4729-17-11	Rescind	Hospital self-service employee prescription kiosks.
4729-17-13	Rescind	D.E.A. numbers for hospital employed prescribers.

<u>List organizations or individuals giving or submitting testimony before, during or after public hearing and indicate the rule number(s) in question.</u>

Rule 4729:5-9-03.4

- Ohio Society of Anesthesiologists
- Ohio State Medical Association

Rules 4729:5-9-02.12

Cleveland Clinic

Rule 4729:5-9-02.6

- Harry Reinhart, Attorney for John J. O'Connell, the former Director of Pharmacy at Mt. Carmel West Hospital
- Bob Bennett, OSU College of Pharmacy

Consolidated Summary of Comments Received

Rule 4729:5-9-03.4

Both associations expressed concern about the thirty-minute lockout from the automated drug storage system (for non-controlled anesthesia drugs). They have requested that the time limited for the systems be limited to no more than the time of the surgical procedure when the anesthesiologist is immediately present within the system.

Rule 4729:5-9-02.12

The rule outlines that repacked medications do not exceed the expiration date on the manufacturer's container or six months from the date the drug was originally packaged, whichever date is earlier. The Cleveland Clinic requested that the rule be modified from six months to one year for repackaged medications.

Rule 4729:5-9-02.6

Expressed concerns about the retrospective review of drugs within an institutional facility. They are requesting modifications to reduce what is perceived to be overly broad requirements for having a pharmacist review the appropriate nature of drugs dispensed to patients residing within an institutional facility.

Incorporated Comments into Rule(s) / Comments not Incorporated into Rule(s)

- The following rules were placed in *to be refiled* (TBR) status to permit further review and consultation with stakeholders: 4729:5-9-03.4, 4729:5-9-02.12, and 4729:5-9-02.6.
- Additionally, rule 4729:5-9-02.3 was also placed in TBR status for additional review at the request of the Board.
- An updated hearing summary report will be submitted to JCARR in April once the review of the comments is completed.