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RULES:
855-041-5100, 855-041-5120, 855-041-5130, 855-041-5140, 855-041-5150, 855-041-5160, 855-041-5170

REPEAL: 855-041-5100

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: OAR 855-041-5100 through OAR 855-041-5170: Repeals regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-5100~~
~~Definitions~~
~~(1) "Error" in Automated Distribution Cabinet (ADC) is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date in a line item. All errors in a line item counts as one error.¶~~
~~(2) "Error" in a unit of use cart is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date. All errors in any single dose count as one error.¶~~
~~(3) "Line Item" is a checking unit for ADC restocking (example: one specific drug and dose, regardless of quantity).¶~~
~~(4) "Technician Checker" is an Oregon certified technician who has completed the TCVP validation process and is currently authorized to check another technician's work.¶~~
~~(5) "Technician Checking Validation Program (TCVP)" is a program that uses a technician checker to check functions completed by another technician.¶~~
~~(6) "Unit Dose" is the physical quantity of a drug product designed to be administered to a patient specifically labeled to identify the drug name, strength, dosage amount and volume, if applicable. The unit dosed drug can be obtained from the manufacturer or repackaged from an external re-packager. A drug may be repackaged on-site through a batch repackaging process that includes a pharmacist as a check. Unit dose examples include oral solids individually packaged by a manufacturer or re-packaged, oral liquids drawn up in a labeled oral syringe, all individually labeled injectable products, and pre-mixed IV products.¶~~
~~NOTE: Technician Checking Validation Program (TCVP) The TCVP is a tool to allow the re-direction of a pharmacist from a distributive task to a cognitive task. It is designed to allow a pharmacist to improve patient safety by focusing on assessing the accuracy and (appropriateness of the medications ordered and on educating staff and patients. The development of individualized training programs is the responsibility of each pharmacy in order to tailor the program to the patient population and medication distribution system of the institution.~~

~~Assessment questions must be tailored to the site and be changed periodically as appropriate. It is the responsibility of the pharmacist-in-charge to ensure that all training is completed and documented prior to a technician (performing as a technician checker.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-5120

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: OAR 855-041-5100 through OAR 855-041-5170: Repeals regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-5120~~
~~Hospital and Pharmacist in Charge Requirements~~
~~(1) Only a hospital pharmacy may apply to participate in a TCVP. To participate in the TCVP, the hospital pharmacy must meet the following requirements:¶~~
~~(a) The hospital pharmacy must develop policies and procedures for the TCVP to include a list of high-risk medications that are excluded from the TCVP. The policies and procedures for the TCVP must be available in the pharmacy for board inspectors.¶~~
~~(b) The hospital pharmacy must obtain approval from the appropriate committee before the TCVP can be implemented;¶~~
~~(c) The hospital pharmacy must have a drug distribution system that is structured to allow for one additional check of the distributed medications by a licensed nurse or other licensed health care professional with authority to administer medications after the delivery of checked medications; and¶~~
~~(d) The Pharmacist-in-Charge is responsible for the TCVP and will document any error, or irregularity in the quality assurance documentation records.¶~~
~~(2) A hospital may not operate a TCVP without prior written approval from the Oregon Board of Pharmacy. To apply for approval, the hospital must submit the following to the Board:¶~~
~~(a) Copies of written training material that will be used to train technicians as technician checkers;¶~~
~~(b) Copies of quality assurance documentation records and forms that will be used to evaluate the technician checkers and the proposed TCVP;¶~~
~~(c) Copies of the policy and procedures for the proposed TCVP; and¶~~
~~(d) A description of how the proposed TVCP will improve patient safety by focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients.¶~~
~~(e) Other items as requested by the Board.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-5130

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: OAR 855-041-5100 through OAR 855-041-5170: Repeals regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-5130~~
~~Technician Eligibility and Training~~
~~(1) Only Oregon certified technicians who undergo specific training may work as technician checkers. The training must include the following:¶~~
~~(a) A minimum of one year of drug distribution experience;¶~~
~~(b) Didactic lecture or equivalent training with a self-learning packet;¶~~
~~(c) Practical sessions that consist of individual training in checking a cart fill or ADC that is provided by a pharmacist; and¶~~
~~(d) Initial Validation Process as described in OAR 855-041-5140(1).¶~~
~~(2) The practical training sessions must include:¶~~
~~(a) The trainee observing a technician checker or pharmacist performing the checking process that the trainee is learning;¶~~
~~(b) The trainee performing the initial check with a pharmacist verifying all doses;¶~~
~~(c) The trainee completing the validation process with a pharmacist verifying all doses;¶~~
~~(d) The introduction of artificial errors into a live or simulated environment, to monitor the ability of the technician to catch errors. Artificial errors introduced into the live environment, which are not corrected by the technician, must be removed.¶~~
~~(e) The pharmacist must document and notify a technician checker of any errors found during training.¶~~
~~(3) If at any time a TCVP technician loses his or her validation the technician must be retrained and revalidated before acting as a technician checker.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-5140

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: OAR 855-041-5100 through OAR 855-041-5170: Repeals regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-5140~~
~~Initial Validation Process and Quality Assurance Process~~
~~(1) Initial Validation Process: The initial process to validate a trainee's ability to accurately check another technician's work must include:¶~~
~~(a) Unit of Use: For initial validation of a trainee to check a unit of use cart fill, the trainee must obtain a 99.8% accuracy rate in 1500 total doses, divided among five separate training checks. A trainee who makes more than three errors in 1500 doses fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.¶~~
~~(A) In each initial validation check, a pharmacist must check the accuracy of all unit of use medications after the trainee has checked them. The pharmacist must document any errors in the unit of use cart and discuss them with the trainee.¶~~
~~(B) In each initial validation check, the pharmacist will introduce at least three errors. The pharmacist coordinating the training check will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.¶~~
~~(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.¶~~
~~(b) ADC or non-emergent trays and kits: For initial validation of a trainee to fill ADC or non-emergent trays and kits, the trainee must obtain a 99.8% accuracy rate in 500 total line items, divided among five separate training checks. A trainee who makes more than one error in 500 line items fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.¶~~
~~(A) In each initial validation check, a pharmacist must check the accuracy of all ADC or non-emergent tray or kit medications after the trainee has checked them. The pharmacist must document any errors and discuss them with the trainee.¶~~
~~(B) In each initial validation check, the pharmacist will artificially introduce at least three errors. The pharmacist will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.¶~~
~~(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.¶~~
~~(2) Quality Assurance Process: The Quality Assurance Process that ensures on-going competency of technician checkers must include:¶~~
~~(a) Quality checks conducted in the same manner as the applicable initial validation process described in section one of this rule, except that the quality check sample must consist of at least 300 doses for technicians checking unit of use carts and at least 100 line items for technicians checking ADC or non-emergent trays and kits.¶~~
~~(b) The quality checks must occur on random and unannounced dates and times.¶~~
~~(c) A technician checker who makes more than one error fails the quality check and may not work as a technician checker unless the technician first passes a second quality check within 30 days of the failed quality check. If the technician does not pass the second quality check within 30 days, the technician must be retrained and revalidated before working as a technician checker.¶~~
~~(d) The results of each quality check must be documented, including the total number of doses or line items checked, a description of each error, the total number of errors, and the percent error rate. Documentation must be retained in the quality assurance file.¶~~
~~(3) Timing and Frequency of Quality Checks: A technician checker must undergo a quality check at least monthly. A technician checker who has successfully completed three consecutive monthly quality checks must be checked at least quarterly for at least one year. A technician checker who has successfully completed four consecutive quarterly quality checks must be checked at least every six months.¶~~
~~(4) A technician checker who does not perform TCVP duties for more than six months must undergo initial validation as described in section one of this rule.¶~~
~~(5) A description of the quality assurance process must be included in the hospital's and the pharmacy's quality assurance program and error reporting system.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-5150

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: OAR 855-041-5100 through OAR 855-041-5170: Repeals regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-5150~~
~~Checking Procedure~~
~~(1) A technician checker must use the following procedure when checking another technician's work:¶~~
~~(a) A pharmacy technician fills the medication for the cart fill or ADC restocking batch or non-emergent trays and kits.¶~~
~~(b) A technician checker must check the accuracy of cart fill batches or ADC or non-emergent trays and kits. The technician checker shall review the medications for the correct drug, dose, dosage form, and quantity and must review the expiration dates of medications.¶~~
~~(c) If the technician checker discovers a filling error the technician checker must record the error and return the product to the technician who originally filled it, if available, or to another technician. The filling technician must correct the error and the technician checker must check the correction. A pharmacist or another technician checker must check any cart fill batches, ADC or non-emergent tray or kit, or medication corrections filled by a technician checker¶~~
~~(d) If a technician checker is not available, then all doses must be checked by a pharmacist.¶~~
~~(2) This checking process continues until all doses have been checked and determined to be correct.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-5160

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: OAR 855-041-5100 through OAR 855-041-5170: Repeals regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-5160~~
~~Eligible Specialized Functions~~
~~(1) The following specialized functions are eligible for participation in the TCVP:¶~~
~~(a) Cart fill;¶~~
~~(b) ADC batch replacement; and¶~~
~~(c) Non-Emergent kits and trays.¶~~
~~(2) Upon written request, the Board may permit additional specialized functions if to do so will further public health or safety. A waiver granted under this section shall be effective only when issued in writing and approved by the Board.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-5170

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: OAR 855-041-5100 through OAR 855-041-5170: Repeals regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-5170~~
~~Records~~
~~(1) Unless specified otherwise, all records and documentation required by these rules must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.¶~~
~~(2) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety and welfare. Records must include:¶~~
~~(a) Technician checker training documents;¶~~
~~(b) List of high risk medications;¶~~
~~(c) Documentation of any errors, irregularities and results of each initial validation check.¶~~
~~(d) Documentation of quality assurance and forms used to evaluate the technician checker including:¶~~
~~(A) Total number of doses or line item checks;¶~~
~~(B) Description of errors;¶~~
~~(C) Total number of errors; and¶~~
~~(D) Percent error rate.¶~~
~~(e) Documentation of the initial validation check.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~