February 29, 2016

Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, IA 50309-4688

To whom it may concern,

Pella Regional Health Center is requesting approval of a Tech Check Tech Program as described in 657.40.1-657.40.4 of the State of Iowa pharmacy regulations. This program would allow qualified and trained pharmacy technicians to provide the final check on cart fill medications and automatic dispensing cabinet fills that are manually picked by another pharmacy technician. The policy and procedure for this program is attached.

Our Tech-Check-Tech program would allow pharmacists to dedicate more time to clinical activities and improving patient care. At the same time, safeguards would be in place to ensure that the accuracy of cart fill medications is not compromised. Prior to becoming validated and providing the final check on any medications, the pharmacy technicians must demonstrate that they can check at least ***2500 doses*** with at least 99.8% accuracy. In addition, a pharmacist will provide the final check on a minimum of 10% of all medications that a validated pharmacy technician checks. The validated pharmacy technicians will be required to maintain an accuracy rate of at least 99.8% while checking medications. Finally, another licensed health care professional will provide a final check on each medication prior to its administration to a patient.

We will provide the board with our variance report every six months. This report will include information on validated pharmacy technician accuracy rates during both the training period and throughout the program.

Thank you for your consideration of this request. I would like to request an appearance at the ***May 3-4, 2016*** Board of Pharmacy meeting to discuss this request. I look forward to meeting with you and discussing this program further.

Sincerely,

Mindi Jorgenson, PharmD, CDE
Director of Pharmacy
Pella Regional Health Center
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IOWA BOARD OF PHARMACY

PURPOSE

The purpose of the tech check tech program at Pella Regional Hospital is to elevate the role and standards of pharmacy technicians and allowing pharmacist time to be shifted from distributive functions to cognitive functions. The tech check tech program cannot be used as a means to

A variance approval must be obtained from the Iowa Board of Pharmacy (IBP) prior to implementing TCT. A full-time Iowa licensed pharmacist at the site of practice will be identified as the TCT program coordinator and will be responsible for assuring compliance with associated policies and procedures. A complete list of technicians who have completed the TCT program and are in good standing should be kept by the TCT program coordinator. A quality assurance program shall be implemented to guarantee continued compliance and accuracy of the established TCT program at Pella Regional Health Center

RESPONSIBILITIES

Definitions

Automated dispensing cabinet (ADC) – is a computerized drug storage device or cabinet designed for hospitals (ex. Pyxis, Omnicell, AcuDose, etc.)

Tech-Check-Tech (TCT) – the process by which a technician verifies medications for distribution that another technician has filled

Validated pharmacy technician (VPT) – a technician who has successfully completed the TCT training program and has proven they can accurately verify medications picked by other technicians

VPT candidate – a technician currently completing the TCT training program with the goal of becoming a VPT

1. **Program Setup and Structure**
    a. State approval
        i. A TCT variance is required by the IBP, the site will acquire the variance approval prior to implementation of the TCT program
        ii. All documentation received from the IBP for written approval or variance approval will be kept in the site's records
        iii. Variance approvals and exemptions shall be reassessed when there is a change in regulations or a major change in practice at the site
    b. Site-specific leadership
        i. Each site seeking to initiate a TCT program must designate a coordinator for the TCT program at that site
            1. The designated coordinator should be a Iowa licensed pharmacist
            2. The designated coordinator should be a full-time employee at Pella Regional Health Center

ii. At least one trainer for the TCT program will be designated
    1. Designated trainers should be a Iowa licensed pharmacist or VPT who is routinely involved in the TCT program
    2. Designated trainers should be full-time employees at Pella Regional Health Center

2. Training Procedures

a. Technician eligibility
    i. In order to be eligible for participation in the Pella Regional Health Center TCT training program, a pharmacy technician must meet one of the following criteria be a full time pharmacy technician at Pella Regional Health Center for at least 2 years.
    ii. Each technician selected should have a history of completing tasks with fine attention to detail

b. Self-learning and practical teaching
    i. Each VPT candidate will complete the VPT Self-training Packet as a first step towards certification
    ii. After completion of all modules, VPT candidates will complete the TCT Didactic Exam and must pass with a 90% or higher to continue VPT training
    iii. After completion of the TCT Didactic Exam, VPT candidates will complete one-on-one training with a TCT trainer
        1. The TCT trainer will follow the TCT Practical Training/Teaching Checklist **(Appendix A)**
        2. Trainers will observe and assess the VPT candidates' ability and document it on the TCT Validation Competency Assessment Checklist **(Appendix B)**
        3. A minimum of 24 hours of practical training is required
    iv. Upon completion of practical training, VPT candidates will complete a final assessment
        1. Final assessment will be observed by the designated TCT trainer
        2. Documentation of assessment will be made on the TCT Validation Competency Assessment Checklist **(Appendix B)**

3. Validation

a. Upon successful completion of training, the VPT candidate shall participate in a final validation period

b. Cart Fill
    i. A total of 2500 consecutive doses (divided over at least five separate audits) must be checked with 99.8% accuracy
    ii. Validation audits will be conducted by a supervising Iowa licensed pharmacist who will check each dose initially checked by the VPT candidate to assure accuracy
    iii. Any errors found to be due to improper checking will be recorded by the auditing pharmacist on the Initial Validation Error Log Form **(Appendix C)** and discussed with the VPT candidate

iv. All audit results will be maintained by the designated TCT program coordinator (in hard copy form or scanned electronic images) in a quality assurance file and electronically in the supplied Excel® file **(Appendix D)**.
v. Artificial errors will be introduced at a frequency of 0.2% and will be documented in the Artificial Error Log Form **(Appendix E)**
vi. Examples of potential artificial errors to introduce during the auditing period are included as an appendix **(Appendix F)**
vii. If a technician fails in the first attempt to achieve 99.8% checking accuracy during the validation period
    1. During their first attempt
        a. They must reread the self-learning packet
        b. They must complete an additional 24 hours of one-on-one practical training
        c. Once completed, they may re-attempt the validation process
    2. During their second attempt at validation
        a. The technician is no longer eligible to complete TCT training

c. Automated Dispensing Cabinets (ADCs)
i. At least 500 consecutive line items (divided over at least 5 separate audits) must be checked with 99.8% accuracy
ii. Validation audits will be conducted by a supervising registered pharmacist who will check each dose initially checked by the VPT candidate to assure accuracy
iii. Any errors found to be due to improper checking will be recorded by the auditing pharmacist on the Initial Validation Error Log Form **(Appendix C)** and discussed with the VPT candidate
iv. All audit results will be maintained by the designated TCT program coordinator (in hard copy form or scanned electronic images) in a quality assurance file and electronically in the supplied Excel® file **(Appendix D)**
v. Artificial errors will be introduced at a frequency of 0.2% and will be documented in the Artificial Error Log Form **(Appendix E)**
vi. Examples of potential artificial errors to introduce during the auditing period are included as an appendix **(Appendix F and G)**
vii. If a technician fails in the first attempt to achieve 99.8% checking accuracy during the validation period
    1. During their first attempt
        a. They must reread the self-learning packet
        b. They must complete an additional 24 hours of one-on-one practical training
        c. Once completed, they may re-attempt the validation process
    2. During their second attempt at validation

a. The technician is no longer eligible to complete TCT training

4. **Quality Assurance**
   a. Upon completion of the Pella Regional Health Center VPT program, individual VPT accuracy will be audited and recorded every time TCT duties are performed
   b. The auditing pharmacist must check a minimum of 10% of the doses checked by the VPT
      i. The number of pharmacist-checked QA doses must be documented on the Quality Assurance Error Log **(Appendix H)**
      ii. Any errors that are discovered must also be documented on the log **(Appendix H)** and discussed with the VPT
   c. At the end of each month, the QA logs must be turned into the designated TCT program coordinator for electronic entry in the supplied Excel® file **(Appendix I)**
      i. The hard copies or scanned images should be maintained on file
   d. Procedure for VPTs that do not obtain or exceed 99.8% accuracy
      i. If the accuracy of the VPT is less than 99.8% over the lesser of a six month period or for the first 2000 validation doses within a six month period, the VPT is required to be re-trained (written training, practical experience) and re-validated (validation of 2500 checked doses with 99.8% accuracy)
      ii. If the accuracy of the VPT is less than 99.8% on more than four occasions in a year, the VPT will be relieved from their VPT checking status for six months. The VPT may be re-trained (written training, practical experience) and re-validated (validation of 2500 checked doses with 99.8% accuracy) after the six month period
      iii. If the re-validated VPT has less than 99.8% accuracy on any occasion during the three months following their six-month leave, they are no longer eligible for VPT status
   e. Inactivity of VPT
      i. If a VPT does not perform TCT for more than two months, re-validation (99.8% accuracy, 2500 doses) should be done with the first check upon return to TCT duties
      ii. If the VPT does not check for four months, they must be re-trained (written training, practical experience) and re-validated (validation of 2500 checked doses with 99.8% accuracy)

Appendix A: Tech-Check-Tech Practical Teaching/Training Checklist

VPT Candidate Name: _____

1. The training pharmacist, TCT program coordinator or designated trainer will base the practical simulated one-on-one training on the provided criteria below
2. Initial and date each box when both the trainee and trainer are certain that each topic has been adequately covered
3. Upon successful completion of this checklist, the technician will be ready for their initial validation

TCT Training	Tech	RPh	Date	Comments
Technician able to describe local cart fill process				
Technician can describe how the ADC restocks are processed and organized				
Technician can describe the different dosage forms (ex: unit dose tabs, caps, oral solution, injection, packet, suppository, patches, oral syringes, etc.)				
Technician can adequately identify everything on the medication check sheet (ex: patient name, room number, MRN, order number, medication, strength, quantity)				
Technician can accurately read and interpret the medication label on all types of medications (ex: drug, strength, route, expiration date)				
Technician can check all of the medications for the cart fill thoroughly and in a systematic manner without skipping any drawers				
When the technician identifies an error, they can resolve the error. This is completed prior to distribution to patient care areas. (This will be evaluated during validation period.)				
Technician provides feedback and suggestions for improvement to the dispensing technician on the errors identified				
Checking is completed in a timely manner				
Technician understands the importance of notifying the pharmacist in a timely manner that carts are checked and ready for auditing				
Technician is capable of describing common errors when checking medications (dosage forms, quantity, expiration date, etc.)				

Comments:

Supervisor Signature _____ Date_____

Appendix B: Tech-Check-Tech Validation Competency Assessment Checklist

VPT Candidate Name _____ Date_____

Evaluating Pharmacist _____Date_____

This form should be completed during the technician's validation period. This evaluation will serve as a guide for the evaluating pharmacist to assess the practical training that the VPT candidate has received. The evaluating pharmacist should check either "yes" or "no" for each of the criteria below. The "yes" box should only be checked if the pharmacist auditor, TCT program coordinator, or designated trainer is certain that each point has been adequately met.

TCT Evaluation Criteria	Yes	No	Evaluating RPh	Date
Technician will be observed for [INSERT SITE SPECIFIC TIME PERIOD]				
All manually filled doses are checked thoroughly and in a systematic manner without skipping drawers				
The technician documents doses checked and completion of cart fill/ADC restock				
Checking is completed in a timely manner (record the number of minutes)				
Errors identified from the cart fill/ADC restock are resolved prior to distribution to the floors				
The technician provides feedback and suggestions for improvement to the technician filler on the errors identified				
Pharmacist is notified in a timely manner that carts are checked and ready for auditing				
Technician is capable of describing common errors when checking medications (dosage form, strength, quantity, expiration date, etc.)				

Comments:

Supervisor Signature _____ Date_____

Appendix C: Initial Validation Error Log Form

VPT Candidate Name: _____

Validation Type: _____ Cart Fill/Cassettes _____ ADC

- An auditing staff pharmacist should complete this form after the VPT candidate has completed the didactic and simulated practical training successfully.
- Once the VPT candidate finishes, the auditing pharmacist will double-check each dose/line item for accuracy.
- Any errors found to be due to improper checking by the VPT candidate will be documented below and discussed with the VPT candidate and filling technician. Each error discovered should be documented on a separate line even if it is a recurrent error.
- Once the audit is complete, the pharmacist will file this from in the corresponding folder for the program coordinator to transcribe into the electronic database and be properly filed.
- To complete the validation, a technician must check at least 2500 doses (cart fill) or 500 line items (ADC) during at least 5 separate audits while maintaining 99.8% accuracy.

Date	Auditing RPh	# Doses Checked	Type of Error Identified*	# Doses Filled Wrong	Artificial Errors Resolved	% Accuracy (total # of errors/ total # checked doses)
TOTALS						

<u>*Type of Error Code</u>

A = Incorrect drug
B = Incorrect strength
C = Incorrect dosage form
D = Extra/Insufficient Quantity
E = Omitted medication
F = Other

Supervisor Signature: _____ Date: _____

Appendix D

Technician Initial Validation Log

Technician name:

Date	Validating RPh	# Doses Checked	# of Incorrect Doses Identified	Type of Errors Identified *	Percent Accuracy
					#DIV/0!
					#DIV/0!
					#DIV/0!
					#DIV/0!
					#DIV/0!
					#DIV/0!
					#DIV/0!
					#DIV/0!
					#DIV/0!
					#DIV/0!
					#DIV/0!
					#DIV/0!
TOTALS		0	0		#DIV/0!

* Type of error code: A = Incorrect drug; B = Incorrect strength; C = Incorrect dosage form; D = Incorrect quantity of doses; E = Omitted medication; F = Other (please describe)

Appendix E: Artificial Error Log Form

VPT Candidate Name: _____

Validation Type: _____ Cart Fill/Cassettes _____ ADC

- An auditing staff pharmacist should complete this form after the VPT candidate has successfully completed the self-learning packet and simulated practical training.
- Once the VPT candidate finishes, the auditing pharmacist will double-check each dose/line item for accuracy.
- Any artificial errors introduced in the audit will be documented on this form. This will be used to ensure the errors are identified and removed before dispensing.
- Once the audit is complete, the pharmacist will file this in the corresponding folder for the program coordinator to transcribe into the electronic database and be properly filed.
- Artificial errors need to be introduced in the validation process at a rate of 0.2% (5 errors per 2500 doses for cart fill; 1 error per 500 line items for ADC).

Date	Auditing RPh	Type of Error Introduced*	Description	Was the error caught by the VPT candidate?	Was the error removed?
TOTALS					

<u>*Type of Error Code</u>

A = Incorrect drug
B = Incorrect strength
C = Incorrect dosage form
D = Extra/Insufficient quantity
E = Omitted medication
F = Other

Supervisor Signature: _____ Date: _____

Appendix F: Examples of Artificial Errors to Introduce for Cart Fill

Patient #	Name	Order Number
00000001	**PATIENT, JOHN**	
	1 dalteparin 5000 unit/0.2 mL injection	31647853
	1 famotidine 20 mg/2 mL injection (tablet instead of injection in pocket)	31692827
00000002	**PATIENT, SALLY**	
	1 nimodipine 30mg/1 mL oral soln (expired oral soln in pocket)	31689794
	2 ondansetron 4 mg/2 mL injection	31679794
00000003	**PATIENT, JENNIFER**	
	2 heparin 5000 unit injection (3 injections in pocket)	31706732
00000004	**PATIENT, ALAN**	
	1 lidocaine 5% patch	31587390
	1 nicotine 21 mg/24 hour patch (14mg/24hr patch in pocket)	31583063
00000005	**PATIENT,BRYAN**	
	2 guaiFENesin 200 mg/10 mL oral soln (1 guaifenesin 100mg/5mL in pocket)	31670469
	4 ipratropium 0.02% nebulizer solution	31620971
	2 metoprolol tartrate 12.5 mg half tablet (succinate dosage form in pocket)	31679391
	1 nystatin 500,000 U/5 mL oral susp	31620965
0000006	**PATIENT, JAMES**	
	1 dexamethasone 10mg/mL (droperidol 5mg/2 mL injection in pocket)	31654667

Appendix G

Appendix R: Examples of Artificial Errors to Introduce for Automated Dispensing Cabinets

Quantity Needed	Correct Item per Label	Error	Type of Error
3	0.9% Sodium Chloride w/20 mEq KCl #3	0.45% Sodium Chloride w/20 mEq KCl #3	Product
15	Ondansetron 4 mg/2 mL vials #15	Ondansetron 4 mg/2 mL vials #14	Count
7	Heparin 1000 units/mL 10 mL vials #7	Heparin 5000 unit/mL 10mL vials #7	Strength
22	Acetaminophen 325 mg tablets #22	Acetaminophen 325 mg suppository #22	Dosage form
8	Furosemide 10 mg/mL 2 mL vials #8	Furosemide 10 mg/mL 4 mL vials #8	Volume
13	Hydroxyzine 10 mg tabs #13	Hydralazine 10 mg tabs #13	Product
17	Aspirin 81 mg tabs #17	Aspirin 81 mg tabs #17 (expiration date: 12/1/12)	Expired
6	Ceftriaxone 1 g vials #6	Cefoxitin 1 g vials #6	Product
10	Phenytoin 50 mg/mL 5 mL vial #10	Phenytoin 50 mg/mL 5 mL vial #11	Quantity
26	Acetaminophen 500 mg tabs #26	Acetaminophen 325 mg tabs #26	Strength

Appendix H: Quality Assurance Error Log

VPT Name: _____ Date: _____

- The VPT should fill out the upper log to track the errors they discovered and corrected.
- A pharmacist must perform a daily quality assurance audit of the medications checked by the VPT prior to their delivery to the floors. This audit will consist of at least 10% of all manually picked doses for the total cart fill and/or ADC restock each day.
- All errors observed by the pharmacist conducting the audit will be recorded on the lower table and discussed with the VPT. This form should be given the TCT program coordinator for record keeping and database entry.

VPT Checking Log				
Cart Fill or ADC?	**# of Doses Checked**	**# of Doses with Errors**	**Type of Filling Error***	**Corrected? (Y/N)**

*Type of error code: A = Incorrect drug; B = Incorrect strength; C = Incorrect dosage form
D = Extra/Insufficient quantity of doses; E = Omitted medication; F = Other

Pharmacist Checking Log				
Cart Fill or ADC?	**# of Doses Checked by VPT**	**# of Doses Checked by RPh**	**# of Doses/Line Items with Errors**	**Type of Filling Error***

VPT Signature: _____ Date: _____

Pharmacist Signature: _____ Date: _____

Appendix I

Cart Fill / Replenishment 6 Month Tracking

Technician:

OVERALL TOTALS FOR TECHNICIAN

Month	Total Doses Checked by Tech	Doses Double Checked by RPh	% Checked by RPh	# Errors Found	Tech Accuracy Rate
January	0	0	#DIV/0!	0	#DIV/0!
February	0	0	#DIV/0!	0	#DIV/0!
March	0	0	#DIV/0!	0	#DIV/0!
April	0	0	#DIV/0!	0	#DIV/0!
May	0	0	#DIV/0!	0	#DIV/0!
June	0	0	#DIV/0!	0	#DIV/0!
July	0	0	#DIV/0!	0	#DIV/0!
August	0	0	#DIV/0!	0	#DIV/0!
September	0	0	#DIV/0!	0	#DIV/0!
October	0	0	#DIV/0!	0	#DIV/0!
November	0	0	#DIV/0!	0	#DIV/0!
December	0	0	#DIV/0!	0	#DIV/0!

DAILY LOGS

Month	Date	Total Doses Checked by Tech	Doses Double Checked by RPh	% Checked by RPh	# Errors Found	Tech Accuracy Rate	RPh Checker
January				#DIV/0!		#DIV/0!	
				#DIV/0!		#DIV/0!	
				#DIV/0!		#DIV/0!	
				#DIV/0!		#DIV/0!	
				#DIV/0!		#DIV/0!	
February				#DIV/0!		#DIV/0!	
				#DIV/0!		#DIV/0!	
				#DIV/0!		#DIV/0!	
				#DIV/0!		#DIV/0!	
				#DIV/0!		#DIV/0!	
March				#DIV/0!		#DIV/0!	
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April				#DIV/0!		#DIV/0!	
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May				#DIV/0!		#DIV/0!	
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June				#DIV/0!		#DIV/0!	
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September				#DIV/0!		#DIV/0!	
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