Pharmacy Examining Board

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Automated Technology Final Check Pilot Program Information

Authority:
Pursuant to Wisconsin Stat. § 450.02(3r)(a), this pilot program is related to the practice of pharmacy or prescription verification and the Board determines that the program will improve the safety, quality or efficiency of the practice of pharmacy in this state. **The Board may modify the parameters of the Pilot Program at any time and participants shall remain in the Pilot Program at the discretion of the Board.**

Purpose: The purpose of the Automated Technology Final Check Pilot Program (ATFC) is to study the safety, quality, and efficiency of automated technology to make the final check on the accuracy and correctness of the final dispensed medication. Implementation of an Automated Technology Final Check Pilot Program is not intended to reduce pharmacist staffing levels but is intended to increase the availability of the pharmacist for involvement for other patient care activities.

Waives: Phar 7.01(1)(c) and (d), Wis. Admin. Code

Pilot Duration: October 1, 2016 to September 30, 2019 (or promulgation of rules whichever is sooner).

Pharmacy Eligibility:

1. The pharmacy shall be located and licensed in the state of Wisconsin.
2. A supervising pharmacist, licensed in the state of Wisconsin, shall be identified for each pharmacy to be accountable for the operations and outcomes of the ATFC program. The final checks made by the automated technology will be considered delegated acts of the supervising pharmacist. In the event of change of the supervising pharmacist, the managing pharmacy shall notify the Board of change within 5 days on a Board approved form.
3. The automated technology shall be located within the licensed pharmacy.

Program Requirements:

1. Automated Technology Validation
    a. Initial Validation: In order to become a validated automated technology, the following requirements must be met and maintained:
        i. The automated technology must use barcodes or machine readable technology to complete the final check.
        ii. The automated technology shall make a final check on the accuracy and correctness of at least 2500 final checks and achieve an accuracy rate of 99.8% or greater.
        iii. A pharmacist shall audit 100% of the final checks made by the automated technology during the validation process.
    b. Re-validation:
        i. The automated technology shall be revalidated if the software is upgraded or any component of the automated technology responsible for the accuracy of the final check is replaced, or serviced outside of the manufacturer's standard maintenance recommendations.
2. Eligible Medications
    a. Medications shall be contained in a final package from a manufacturer or if packaged in the pharmacy a licensed pharmacist has ensured that the packaging process results in a final package that is labeled with the correct drug name, dose, strength, form, control or lot number, and beyond use date.
    b. The supervising pharmacist shall ensure a process is in place for a pharmacist to prospectively review the clinical appropriateness of the medication order prior to leaving the pharmacy.
    c. The medication shall be administered by an individual authorized to administer medications at the institution where the medication is administered.

3. Policies and Procedures
    a. Each pharmacy shall maintain policies, procedures, and training materials for ATFC program that will be made available to the Board upon request. These policies and procedures shall include a plan for completing the manufacturer's recommended maintenance and quality assurance measures.
4. Records
    a. Each pharmacy shall maintain records for 5 years, available to the Board upon request, of the following:
        i. All initial validation and revalidation records of each automated technology that include the dates that the validation occurred, the number of final checks performed, the number of final check errors, and overall accuracy rate.
        ii. Names the supervising ATFC pharmacist including start date and end date of supervision responsibilities.
        iii. Documentation of the completion of the manufacturer's recommended maintenance and quality assurance measures
        iv. Documentation of the dates of all software upgrades
        v. Documentation of all service performed outside of the manufacture's standard maintenance recommendations
5. Reporting Requirements
    a. The supervising pharmacist of the ATFC program shall annually submit to the Board, on a form approved by the Board, all of the following:
        i. Total number of automated technology final checks
        ii. Total number of automated technology final checks audited by a pharmacist
        iii. Total number of errors identified in the automated final check pharmacist audit that were of the type of wrong drug, wrong dose, or wrong dosage form
        iv. Total number of pharmacist hours reallocated to other patient care activities and description of those activities

Application: The managing pharmacist shall submit a Board approved application and receive approval of the Board to participate in the Pilot Program.