Section 1. Definitions
No issues

Section 2. General Requirements

(3)(b)(c) Emergency Drugs
Per 902 KAR 55:070, controlled substances in quantities of 6 drugs, 6 doses each are permitted (a total of 36 items). In order to include non-controlled substance emergency drugs in the emergency kit, in a quantity greater than 36 items, the PIC can request a waiver based upon evidence of use.

Issue: Due to the increasing nature of acute situations when patients are admitted to the nursing home after being discharged from a hospital after hours and require pain medications and due to the number of patients serviced by one pharmacy, the maximum number of controlled substances stocked in the emergency kit is typically required (36 items). This means that in order to stock non-controlled, emergency drugs such as nitroglycerin tablets, adrenalin injection for anaphylaxis reactions, glucose, injectable antibiotics, etc. a waiver is required by the Board of Pharmacy. It will be cumbersome, difficult to track and very non-efficient to have different stock in emergency kits in the LTCF. The Board of Pharmacy may also have a difficult time tracking this information from multiple requests by multiple pharmacies. In addition, the same restrictions would apply to the automated dispensing system (ADS). The machine dispenses the correct strength, dosage form and quantity of the drug prescribed and complies with recordkeeping and security safeguards designed for the system. (refer to Section 5. (2) Recordkeeping requirements). A quality assurance program will monitor the performance of the machine and have written policies and procedures in place for system operation, safety, security, accuracy access and malfunction. There should be no restrictions on the number of non-controlled, emergency drugs in an ADS.

The solution presented to the BOP regulations committee that was rejected, was not to limit the number of non-controlled medications in an emergency kit, outside of the 36 controlled substance items and to allow the quality assurance committee consisting of a pharmacist, medical director and director of nursing to use clinical judgment in determining the number of appropriate drugs to be stocked in the emergency kit. This process would eliminate the need for a waiver.

(4)(a)(b) Long Term Care Facility Pharmacy Stock
Pharmacy stock is being limited in number to 150 non-controlled medications, 15 deep. The PIC can request from the Board a waiver to increase the number of non-controlled substance items to be placed in pharmacy stock based upon evidence of use.

Issue: Similar to the issue regarding emergency drugs in Section 2. (3)(b)(c), due to the increasing nature of acute situations when patients are admitted to the nursing home after being discharged from a hospital and the number of LTCF that now have short stay rehabilitation units, a higher number of medications may need to be stock in the facility. Acute stays tend to include multiple changes to medications while in the LTCF, unlike years before when medications were rarely changed, once stabilized on maintenance medications. Some of the members of the pharmacist group working with the regulations committee have a concern with the restriction on the number of medications stocked, both as ‘manual’ stock in a kit and automated dispensing system stock. The automated dispensing system is designed to allow for up to several hundred medications if necessary. This not only includes tablets and capsules, but can include any type of drug formulation including topicals, ears, eyes and
nose products, injectables, etc. When these drug formulations are added, it greatly increases the number of medications necessary to treat the patient in a safe and timely manner.

The solution presented to the BOP regulations committee that was rejected, was to allow the quality assurance committee consisting of a pharmacist, medical director and director of nursing to use clinical judgment in determining the appropriate number of drugs to be stocked as pharmacy stock. This process would eliminate the need for a waiver. The machine dispenses the correct strength, dosage form and quantity of the drug prescribed and complies with recordkeeping and security safeguards designed for the system. (refer to Section 5.(2) Recordkeeping requirements).

Section 3. Assuring Rational Drug Therapy
No issues

Section 4. Automated Pharmacy System in a LTCF
No Issues

Section 5. Standards. An Automated Pharmacy System

(5) Stocking Medications
The language in the draft regulation states: The stocking of all medications in the automated pharmacy system shall be done by a pharmacist, or pharmacist intern, or certified pharmacy technician, who shall be under the immediate supervision of a pharmacist on-site; if the automated pharmacy system utilizes bar-coding technology, microchip, or other technologies to ensure that the containers which have been checked by a pharmacist are accurately loaded into the automated pharmacy system, the stocking may be performed by a pharmacist intern or a certified pharmacy technician, who shall be under the general supervision of a pharmacist on-site.

Issue: A consultant pharmacist is not on-site at the LTCF on a daily basis. Furthermore, an automated dispensing system that utilizes the technology mentioned above has a fool proof system that will not allow anyone to access the medication prior to inserting medication cabinets into the machine located at the LTCF. Requiring a pharmacist to be on-site in order for a pharmacist intern or certified pharmacy technician to stock the machine negates the ability to utilize an ADS in a long-term care setting.
Solution: The machine contains individual cabinets for each medication. The cabinet is filled in the pharmacy and checked by a pharmacist. The cabinet is then sealed by one the technologies available. The sealed cabinet would be delivered by pharmacy personnel to the LTCF and insert the cabinet into the proper slot in the machine.