Comments from the KPhA Academy of Consultant Pharmacists  
RE: Working Draft – 201 KAR 2:___. Pharmacy Services in Long Term Care Facility (LTCF)  
For meeting on April 22nd, 2015

Purpose: This document is to share the comments from the KPhA Academy of Consultant Pharmacists with the LTC Regulation Committee. These comments are based on the latest revision from Board of Pharmacy Regulations Committee dated 9/11/14.

Section 1. Definitions
No issues or comments

Section 2. General Requirements
(3)(b)(c) Emergency Drugs
No issues. However, per 902 KAR 55:070 from the Cabinet of Health and Family Services, controlled substances in an emergency kit are limited to quantities of 6 items, 6 doses deep. The KPhA Academy of Consultant Pharmacists and KY ASCP chapter are requesting a meeting with OIG to expand this number. If the language regarding specific quantity limits of “6 items, 6 deep” is also added to the LTC Regulation then the quantity restriction, which is already in place through 902 KAR 55:070, would be appearing in two regulations from two different governing bodies. If the controlled drug quantities are changed following a meeting with the OIG, and 902 KAR 55:070 is changed accordingly, it would also require a change to the LTC regulation. We recommend that these quantity limits not be included in the LTC Regulations to prevent the need for changing the LTC regulations if in fact the Cabinet of Health and Family Services change their requirements. Therefore it is recommended that the LTC Regulations reference the requirements of 902 KAR 55:070, but not the quantity limits themselves.

(4)(a)(b) Long Term Care Facility Pharmacy Stock
Pharmacy stock in the LTCF is being limited in number to 150 non-controlled medications, 15 deep. In order to stock non-controlled medications in a quantity greater than 150 items, the PIC can request a waiver from the BOP based upon evidence of use.

Issue: Due to the increasing nature of acute situations when residents 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 stocked in the facility. The number of admissions into a LTCF has increased in frequency. Many of the admissions occur after hours when the physician has completed their rounds at the hospital and office visits for the day. Acute stays tend to include multiple changes of medication orders 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 including members of the Academy have a concern with restricting the number of medications stocked in the LTCF. Most automated dispensing systems are designed to secure several hundred medications. This not only includes tablets and capsules, but can include any type of drug formulation including topicals, ears, eyes and nose products, injectables, IV antibiotics, etc. Limiting the number of “pharmacy stock” medications prevents the timely administration of such medications to the patient in the LTCF.
**Solution**

The solution that was presented to the BOP regulations committee is the same as the one presented about the number of medications stocked in an emergency kit. The (ADS) 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 the pharmacy will have written policies and procedures in place for system operation, safety, security, accuracy access and malfunction. The quality assurance committee in the LTCF that consists of a pharmacist, medical director and director of nursing should be able to use their clinical judgment to determine the number of appropriate drugs to be stocked in the emergency kit. A greater number of non-controlled medications used as “pharmacy stock” medications will provide for timely administration of medications to the resident and reduce the risk of an adverse drug reaction. Also, this process would eliminate the need for a waiver.

**Section 3. Assuring Rational Drug Therapy**

No issues or comments

**Section 4. Automated Pharmacy System in a LTCF**

No issues or comments

**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 routinely on-site at the LTCF on a daily basis. Requiring a pharmacist to be on-site in order for a pharmacist intern or certified pharmacy technician to stock the machine (insert medications into the ADS) negates the ability to utilize an ADS in a long-term care setting.

**Solution:** The various types of automated dispensing systems that utilize barcode technology in ADS have the ability to verify that the selected medication correctly matches the medication being retrieved or distributed. For the ADS’ that utilize these types of advanced technologies the medications could be loaded by either a certified pharmacy technician or licensed professional staff member of the LTCF. They would insert the medications into the proper slot of the cabinet in the machine, which would be verified by barcode technology. The technology in these types of devices will prevent the wrong NDC from being obtained. If the ADS in the LTCF does not utilize the technology as stated in the regulation (i.e. barcode, microchip) then the pharmacy group agrees that the current standard in the draft above should apply whereby the device would be loaded by a pharmacist intern or a certified pharmacy technician, under the general supervision of a pharmacist on-site.
Also, the Academy advocates that if the stipulation that a pharmacist must be on-site when the device is loaded remains, that a registered technician be able to load the device, when under the general supervision of a pharmacist.