The Department of Financial and Professional Regulation is posting these proposed amendments in an effort to make the public aware of possible changes that may have an impact on the industry/profession.

The general public may submit written comments to the Department during the first 45-day public comment period. Any suggested changes will be considered by the Department and (if applicable) the appropriate Board.

These proposed amendments were published in the December 29, 2017 Illinois Register. The 45-day comment period will end February 9, 2018.

Please submit written comments to Craig Cellini as stated in the attached notice.

THESE PROPOSED CHANGES ARE NOT IN EFFECT AT THIS TIME AND THE ADOPTED RULES MAY DIFFER FROM THOSE ORIGINALLY PUBLISHED.

1) **Heading of the Part:** Pharmacy Practice Act

2) **Code Citation:** 68 Ill. Adm. Code 1330

3) **Section Numbers:** Proposed Actions:
   - 1330.510 Amendment
   - 1330.640 Amendment
   - 1330.660 Amendment
   - 1330.670 Repealed
   - 1330.680 Amendment

4) **Statutory Authority:** Implementing the Pharmacy Practice Act [225 ILCS 85] and authorized by Section 2105-15 of the Civil Administrative Code of Illinois [20 ILCS 2105/2105-15].

5) **A Complete Description of the Subjects and Issues Involved:** This is a complete rewriting of the pharmacy regulations for sterile and non-sterile compounding. The biggest change moves the standards for pharmacy compounding from those specifically set forth in rule to the standards developed by the United States Pharmacopeial-National Formulary (USP-NF). The USP-NF compounding standards are the national standard that is currently adopted by more than 35 states. Other changes include allowing pharmacies to sell limited quantities of non-sterile compounded products to practitioners for office use; and permits sterile compounding of veterinary products for office use and limited veterinary dispensing from office use stock. Additional changes include minor technical corrections to existing
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

telepharmacy regulations, plus expansion of the types of healthcare providers permitted to stock or restock an automated dispensing system under the control of a pharmacy but located in a facility, removing barriers for rural facilities that might otherwise face delay in stocking/restocking waiting for a pharmacist or pharmacy technician to arrive.

6) Any published studies or reports, along with the sources of underlying data, that were used when comprising this rulemaking, in accordance with 1 Ill. Adm. Code 100.355: None

7) Will this rulemaking replace any emergency rulemaking currently in effect? No

8) Does this rulemaking contain an automatic repeal date? No

9) Does this proposed rulemaking contain incorporations by reference? No

10) Are there any other proposed rulemakings pending on this Part? No

11) Statement of Statewide Policy Objectives (if applicable): This rulemaking will not require a local government to establish, expand or modify its activities in such a way as to necessitate additional expenditures from local revenues.

12) Time, Place, and Manner in which interested persons may comment on this proposed rulemaking: Persons who wish to comment on this proposed rulemaking may submit written comments no later than 45 days after the publication of this Notice to:

   Department of Financial and Professional Regulation
   Attention: Craig Cellini
   320 West Washington, 3rd Floor
   Springfield, IL 62786

   Phone: 217/785-0813   Fax: 217/557-4451

   All written comments received within 45 days after this issue of the Illinois Register will be considered.

13) Initial Regulatory Flexibility Analysis:

   A) Types of small businesses, small municipalities and not for profit corporations affected: Licensed pharmacists, pharmacy technicians, and pharmacies may be affected.
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

B) Reporting, bookkeeping or other procedures required for compliance: None

C) Types of professional skills necessary for compliance: Licensure pursuant to the Pharmacy Practice Act.

14) Regulatory Agenda on which this rulemaking was summarized: January 2016

The full text of the Proposed Amendments begins on the next page:
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

TITLE 68: PROFESSIONS AND OCCUPATIONS
CHAPTER VII: DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SUBCHAPTER b: PROFESSIONS AND OCCUPATIONS

PART 1330
PHARMACY PRACTICE ACT

SUBPART A: GENERAL PROVISIONS

Section 1330.10 Definitions
1330.20 Fees
1330.30 Unprofessional and Unethical Conduct
1330.40 Violations
1330.50 Vaccinations/Immunizations
1330.60 Internet Pharmacies
1330.70 Granting Variances
1330.80 Renewals
1330.90 Restoration of a Pharmacist License
1330.100 Continuing Education
1330.110 Confidentiality

SUBPART B: PHARMACY TECHNICIAN

Section 1330.200 Application for Certificate of Registration as a Pharmacy Technician
1330.210 Pharmacy Technician Training
1330.220 Application for Certificate of Registration as a Certified Pharmacy Technician

SUBPART C: PHARMACIST

Section 1330.300 Approval of Pharmacy Programs
1330.310 Graduates of Programs Outside the United States
1330.320 Application for Examination
1330.330 Examination for Licensure
1330.340 Application for Licensure on the Basis of Examination
1330.350 Endorsement

SUBPART D: PHARMACY LICENSURE
NOTICE OF PROPOSED AMENDMENTS

Section
1330.400 Application for a Pharmacy License
1330.410 Pharmacy Licenses
1330.420 Emergency Remote Temporary Pharmacy License

SUBPART E: TYPES OF PHARMACIES

Section
1330.500 Community Pharmacy Services
1330.510 Telepharmacy
1330.520 Offsite Institutional Pharmacy Services
1330.530 Onsite Institutional Pharmacy Services
1330.540 Nuclear Pharmacy Services
1330.550 Nonresident Pharmacies
1330.560 Remote Prescription/Medication Order Processing

SUBPART F: PHARMACY STANDARDS

Section
1330.600 Security Requirements
1330.610 Pharmacy Structural/Equipment Standards
1330.620 Electronic Equipment Requirements for Remote Pharmacies
1330.630 Sanitary Standards
1330.640 Pharmaceutical Compounding Standards
1330.650 Pharmacy Computer Regulations
1330.660 Pharmacist-in-Charge
1330.670 Compounded Sterile Preparation Standards (Repealed)
1330.680 Automated Dispensing and Storage Systems

SUBPART G: PHARMACY OPERATIONS

Section
1330.700 Patient Counseling
1330.710 Reporting Theft or Loss of Controlled Substances
1330.720 Transfer of Prescription
1330.730 Drug Prepackaging
1330.740 Multi-Med Dispensing Standards for Community Pharmacies
1330.750 Return of Drugs
1330.760 Electronic Transmission of Prescriptions
1330.770 Centralized Prescription Filling
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

1330.780  Change of Ownership of a Pharmacy
1330.790  Closing a Pharmacy
1330.800  Pharmacy Self-Inspection

AUTHORITY:  Implementing the Pharmacy Practice Act [225 ILCS 85] and authorized by Section 2105-15 of the Civil Administrative Code of Illinois [20 ILCS 2105/2105-15].


SUBPART E:  TYPES OF PHARMACIES

Section 1330.510  Telepharmacy

a)  Telepharmacy shall be limited to the types of operations described in this Section. Each site where such operations occur shall be a separately licensed pharmacy. Home pharmacies that are located outside of Illinois must be licensed as a nonresident pharmacy. Nonresident pharmacies shall abide by all Illinois laws and rules when filling prescriptions for Illinois residents, except that the
NOTICE OF PROPOSED AMENDMENTS

dispensing pharmacist and the pharmacist-in-charge shall not be required to be licensed in Illinois, except as otherwise provided in this Part.

b) Remote Dispensing Site

1) Written prescriptions presented to the remote dispensing site shall be scanned into the electronic data processing equipment to ensure initial dispensing and each refill and the original prescription may be viewed on the monitor at both the remote dispensing site and home pharmacy site. Unless otherwise provided by federal law, all written prescriptions shall be delivered to the home pharmacy for filing within 72 hours. Records shall be maintained at the home pharmacy in files separate from the home pharmacy files.

2) A remote site is considered to be under the supervision of the pharmacist-in-charge of the home pharmacy.

3) The remote site shall use its home pharmacy and pharmacy management system.

   A) The system shall assign consecutive prescription numbers.

   B) All records must be maintained at the home pharmacy.

   C) Prescriptions dispensed at the remote site shall be distinguishable from those dispensed from the home pharmacy.

   D) Daily reports must be separated for the home and remote site.

4) A pharmacist at the home pharmacy must verify each prescription before it leaves the remote site.

   A) Pharmacist and pharmacy technician initials or unique identifiers must appear on the prescription record and the prescription label.

   B) A pharmacist shall electronically compare via video link the stock bottle, drug dispensed, the strength and its beyond use date. The entire label must be checked for accuracy on the video link.
C) The remote dispensing site shall utilize a barcode system that prints the barcode of the stock bottle on the label of the dispensed drug. If the stock bottle does not have a barcode, the pharmacy shall create one. The technician shall scan both the stock bottle and the label of the dispensed drug to verify that the drug dispensed is the same as the drug in the stock bottle for each prescription dispensed.

D) A pharmacy may utilize a different electronic verification system that accomplishes the same purpose after review and approval of the Division.

5) Counseling must be done by a pharmacist via video link and audio link before the drug or medical device is released. The pharmacist providing counseling, pursuant to this subsection, must be employed or contracted by the home pharmacy or by a pharmacy contracted with the home pharmacy and have access to all relevant patient information maintained by the home pharmacy.

6) A pharmacist-in-charge or his or her designated pharmacist must complete monthly inspections of the remote site. Inspection criteria must be included in the policies and procedures for the site. The inspection report must be available on site for pharmacy investigator inspection.

7) Controlled substances shall be kept at the remote site in accordance with the Act and this Part. All records must be stored at the home pharmacy and at the remote site.

8) There shall be a working computer link, video link and audio link to a pharmacist at a home pharmacy whenever the prescription area is open to the public. The communication link must be checked daily and the remote site pharmacy must be closed if the link malfunctions, unless a pharmacist is physically present at the remote site.

A) The pharmacy technician located at the remote dispensing site must have one year of experience and be registered as a certified pharmacy technician, or be a student pharmacist.

B) New prescriptions received at the remote dispensing site may be entered into the remote computer system with all verification,
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

interaction, checking and profile review by the pharmacist at the home pharmacy.

C) Each pharmacist at the home pharmacy may electronically supervise no more than 3 remote sites that are simultaneously open.

9) The facility must have a sign clearly identifying it as a remote dispensing site.

10) Security of filled prescriptions must be maintained by storing them in a separate lock drawer or cabinet.

11) The facility shall have an area for patient consultation, exclusive of any waiting area.

c) Remote Consultation Site

1) These sites have no prescription inventory.

2) Only filled prescriptions, filled at the home pharmacy, with final patient labeling attached are allowed at these sites.

3) These sites must be staffed with a pharmacy technician or certified pharmacy technician who has the knowledge necessary to use computer audio/video link for dispensing and consultation to occur. Pharmacist and pharmacy technician initials or unique identifiers must appear on the prescription record and the prescription label.

4) Written prescriptions may be received at a remote consultation site. All written prescriptions presented at a remote consultation site shall be delivered to the home pharmacy within 72 hours.

5) Security of filled prescriptions must be maintained by storing them in a separate lock drawer or cabinet.

6) Recordkeeping shall be conducted by the pharmacist (time/date) when dispensing and counseling occurred.
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

7) The facility shall have a room for patient consultation exclusive of any waiting area.

8) The facility must have a sign clearly identifying it as a remote consultation site.

d) Automated Pharmacy Systems (Section 22(b) of the Act)

1) Remote Automated Pharmacy Systems (RAPS)

A) These devices shall maintain a prescription drug inventory that is controlled electronically by the home pharmacy or, when operated by a pharmacy contracted with the home pharmacy, by the contracted pharmacy, which shall be utilized to dispense patient specific prescriptions.

B) These systems shall have prescription inventory, which must be secured in an automated pharmacy system and electronically connected to and controlled by the home pharmacy.

C) A pharmacist must approve all the prescription orders before they are released from the RAPS.

D) Dispensing and counseling are performed by a pharmacist employed or contracted by the home pharmacy via audio and video link.

E) All filled prescription must have a label that meets the requirements of the Act attached to the final drug container.

F) The pharmacist-in-charge of the home pharmacy, or a designated registrant, shall conduct and complete monthly inspections of the RAPS. Inspection criteria must be included in the policies and procedures for the site. The report must be available to the pharmacy investigators when requested.

G) The RAPS must be licensed with the Division as an automated pharmacy system and will be subject to random inspection by pharmacy investigators. Notwithstanding that the RAPS shall possess a license, the home pharmacy shall remain responsible for
inventory control and billing. For purposes of random inspections, a pharmacist with access to the system must be available at the site within one hour, or as otherwise approved by the drug compliance investigator. In the event the Chief Pharmacy Coordinator determines that the RAPS poses a significant risk of patient harm, the RAPS must be disabled until such time as the pharmacist with access to the system is available to the site.

H) Medication dispensed at the automated pharmacy system site may only be packaged by a licensed manufacturer or repackager, or prepackaged by a licensed pharmacy in compliance with this Section. Prepackaging must occur at the home pharmacy, a pharmacy sharing common ownership with the home pharmacy, or a pharmacy that has contracted with the home pharmacy to perform prepackaging services. The following requirements shall apply whenever medications are prepackaged by a pharmacy other than the home pharmacy:

i) The prepackaging pharmacy shall be licensed in Illinois as a resident or nonresident pharmacy.

ii) The prepackaging pharmacy shall share a common database with the home pharmacy, or have in place an electronic or manual process to ensure that both pharmacies have access to records to verify the identity, lot numbers and expiration dates of the prepackaged medications stocked in the RAPS.

iii) The prepackaging pharmacy shall maintain appropriate records to identify the responsible pharmacist who verified the accuracy of the prepackaged medication.

I) Written prescriptions may be received at an RAPS. All written prescriptions presented to an RAPS shall be scanned utilizing imaging technology that permits the reviewing pharmacist to determine its authenticity. The sufficiency of the technology shall be determined by the Department. If sufficient technology is not used, the written prescriptions must be delivered to the home pharmacy and reviewed by a pharmacist prior to being dispensed to the patient.
2) Kiosk

A) A kiosk is a device that maintains individual patient prescription drugs that were verified and labeled at the home pharmacy.

B) A home pharmacy may only use the kiosk with prior approval of a patient.

C) A kiosk located on the same premises or campus of the home pharmacy shall operate under the same license as the home pharmacy. However, a kiosk must be licensed with the Division if it is not so located.

D) A kiosk shall:

i) When located on the same premises or campus as the pharmacy, inform a patient, if he or she is using the device when the pharmacy is open, that the patient may address questions and concerns regarding the prescription to a pharmacist at the pharmacy;

ii) When not located on the same premises or campus as the pharmacy, inform a patient, if he is using the device when the pharmacy is closed, that he or she may immediately direct any questions and concerns regarding the prescription to a licensed pharmacist via a pharmacy provided audio/video link;

iii) Inform a patient that a prescription is not available to be delivered by the device if the pharmacist has determined that he or she desires to counsel the patient in person regarding the prescription.

3) A pharmacy may use an automated pharmacy system to deliver prescriptions to a patient when the device:

A) Is secured against a wall or floor;
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

B) Provides a method to identify the patient and delivers the prescription only to that patient or the patient's authorized agent;

C) Has adequate security systems and procedures to prevent unauthorized access, to comply with federal and State regulations, and to maintain patient confidentiality;

D) Records the time and date that the patient removed the prescription from the system.

4) A licensed automated pharmacy system shall not be utilized by prescribers. Nothing in this Section shall prevent a prescriber from utilizing an automated pharmacy system in connection with his or her own dispensing. However, a prescriber may not utilize or access an automated pharmacy system licensed pursuant to this Section.

e) All pharmacists performing services in support of a remote dispensing site, remote consultation site, kiosk, or RAPS must display a copy or electronic image of their licenses at the remote site where they provide services, or shall otherwise make their license visible to the patient, and be licensed in this State, unless employed by a pharmacy licensed in Illinois as a nonresident pharmacy, in which case, the pharmacist providing the services shall hold an active license as a pharmacist in the state in which the nonresident pharmacy is located and only the pharmacist-in-charge of the remote site must be licensed in Illinois.

f) Each remote site must display a sign, easily viewable by the customer, that states:

1) The facility is a telepharmacy supervised by a pharmacist located at (address); and

2) The pharmacist is required to talk to you, over an audio/visual link, each time you pick up a prescription.

g) No remote site may be open when the home pharmacy is closed, unless a pharmacist employed or contracted by the home pharmacy, or by a pharmacy contracted with the home pharmacy, is present at the remote site or is remotely providing supervision and consultation as required under this Section.

(Source: Amended at 42 Ill. Reg. ____________, effective ________________ )
Section 1330.640  Pharmaceutical Compounding Standards

All pharmaceutical compounding standards, both sterile and non-sterile, shall be governed by the USP-NF, as set forth in the current edition of the United States Pharmacopoeia (USP) Compounding Compendium, with the exception of USP Chapter <800> as it pertains to the handling of hazardous drugs in healthcare settings. The minimum standards and technical equipment considered adequate for compounding drugs shall include:

a) A pharmacy may only dispense compounded drugs pursuant to a valid patient-specific prescription, except as provided in this Section. A storage area separate for materials used in compounding.

b) “Office use” means the administration of a non-patient specific compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center or pharmacy. “Office use” does not include a pharmacy’s delivery of a compounded drug to a prescribing practitioner’s office pursuant to a valid patient-specific prescription. Scales and balances for the compounding done in the pharmacy.

c) Sterile compounding for office use is prohibited unless the pharmacy is in full compliance with 21 USC 353b, including registration as an Outsourcing Facility and a wholesale drug distributor pursuant to the Wholesale Drug Distribution Licensing Act. However, a sterile compounded drug may be delivered to the prescribing practitioner's office for administration to the patient for whom the drug was prescribed and compounded. An area of the pharmacy used for compounding activities.

d) A pharmacist may dispense and deliver a reasonable quantity of a non-sterile compounded drug to a practitioner for office use by the practitioner in accordance with this Section, provided:

1) The quantity of compounded drug does not exceed the amount a practitioner anticipates may be used in the practitioner's office before the expiration of the beyond use date of the drug;

2) The quantity of compounded drug is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice;
3) The quantity of compounded drug for any practitioner, and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines;

4) The compounded drug may only be administered to patients and may not be dispensed to patients or sold to any other person or entity;

5) The pharmacy shall maintain readily retrievable records of all compounded drugs ordered by practitioners for office use. The records must be maintained for a minimum of 5 years and shall include:

   A) The name, address and phone number of the practitioner ordering the compounded drug for office use and the date of the order;

   B) The name, strength and quantity of the compounded drug provided, including the number of containers and quantity in each;

   C) The date the drug was compounded;

   D) The date the compounded drug was provided to the practitioner; and

   E) The lot number and beyond-use date.

6) The pharmacy shall affix a label to any compounded drug that is provided for office use. The label shall include:

   A) The name, address and phone number of the compounding pharmacy;

   B) The name and strength of the preparation and a list of active ingredients and strengths. If the number of active ingredients would prohibit proper labeling, then the pharmacist shall provide to the practitioner a complete list of the active ingredients and strengths (including those on the label);

   C) The pharmacy's lot number and beyond-use date;
NOTICE OF PROPOSED AMENDMENTS

D) The quantity or amount in the container;

E) The appropriate ancillary instructions, such as storage instructions, cautionary statements, or hazardous drug warning labels when appropriate; and

F) The statement "For Office Use Only – Not for Resale".

7) Sale of compounded drugs for office use may not exceed 5% of the annual dollar purchases of prescription drugs by the pharmacy as provided in 68 Ill. Adm. Code 1510.10.

e) All pharmacies that compound drugs must maintain, at a minimum, the following standards and equipment: A logbook or record keeping system to track each compounded prescription and the components used.

1) A separate storage area for materials used in compounding.

2) Scales with sufficient accuracy for the products to be compounded.

3) An area of the pharmacy used exclusively for sterile compounding activities, if a pharmacy compounds sterile products.

4) A logbook or record keeping system to track each compounded drug and the lot number and beyond-use date of components used. This applies to each non-sterile compounded drug and each sterile compounded drug with a beyond-use date greater than 24 hours.

5) The current edition of the USP Compounding Compendium. This publication may be in electronic format and/or available via the internet.

6) If engaged in veterinary drug compounding, “Plumb’s Veterinary Drug Handbook” or any other similar publication approved by the Division.

7) Consumable materials, as appropriate to the pharmacy services provided at that specific pharmacy, such as filter paper, powder papers, empty capsules, ointment jars, bottles, vials, safety closures, powder boxes, labels and distilled water.
NOTICE OF PROPOSED AMENDMENTS

8) In addition to labeling requirements of the Act and this Part, compounded preparations dispensed to patients shall have on the label or an auxiliary label the following: “This prescription was specifically compounded in our pharmacy for you at the direction of your prescriber.”

9) Sales of compounded drugs to other pharmacies not under common ownership, or to clinics, hospitals or manufacturers, other than as provided in subsection (d), are not allowed, except for sales provided by pharmacies contracted to provide centralized prescription filling services pursuant to Section 25.5 of the Act, including compounding in anticipation of receiving a prescription or order based on routine, readily observed dispensing patterns.

f) For sterile compounding, a pharmacy must comply with the following additional requirements: A book or reference containing formulas with directions for compounding. The books and references may be in electronic format and/or available via the Internet.

1) The following current resource materials and texts shall be maintained in the pharmacy, which may be in electronic format and/or available via the internet:

A) Copies of the Act and this Part, the Illinois Controlled Substances Act [720 ILCS 570] and 77 Ill. Adm. Code 3100, 21 CFR (Food and Drugs), and the Illinois Hypodermic Syringes and Needles Act [720 ILCS 635];

B) One compatibility reference, such as:

   i) ASHP's Handbook on Injectable Drugs;

   ii) King's Guide to Parenteral Admixtures; or

   iii) Any other Division approved publication;

C) A file or reference on extended (more than 24 hours) stability data given to finished preparations.

2) Staffing. A pharmacist shall be accessible at all times to enable each licensed facility to respond to patients’ and health professionals' questions
and needs. A 24-hour telephone number shall be included on the prescription label of compounded drugs and medication infusion devices if used off site.

3) Drug Distribution and Control

A) Patient Profile or Medication Record System. A pharmacy generated patient profile or medication record system shall be maintained, in addition to the prescription file. The patient profile or medication record system shall contain, at a minimum:

i) Patient's full name;

ii) Date of birth or age;

iii) Gender;

iv) Compounded sterile preparations dispensed;

v) Date dispensed, if off site;

vi) Date compounded;

vii) Drug content and quantity;

viii) Patient directions, if preparation is administered off site;

ix) Other drugs or supplements the patient is receiving, if provided by the patient or his or her agent; and

x) Known drug sensitivities and allergies to drugs and foods.

B) Labeling. Each compounded sterile preparation dispensed to patients shall be labeled with the following information, using a permanent label:

i) Name, address and telephone number of the licensed pharmacy, if not used within the facility;

ii) Date dispensed and identifying number, if used off site;
iii) Patient's full name and room number, if applicable;

iv) Name of each drug component, strength and amount;

v) Directions for use and/or infusion rate, if used off site;

vi) Prescriber's full name, if used off site;

vii) Required controlled substances transfer warnings, when applicable;

viii) Beyond-use date, and time if appropriate;

ix) If used offsite, identity of compounding and dispensing pharmacist, or other authorized individual; and

x) Auxiliary label with storage requirements, if applicable.

C) The pharmacist-in-charge shall ensure that records are maintained for 5 years and are readily retrievable and in a format that provides enforcement agents an accurate and comprehensive method of monitoring distribution via an audit trail. The records shall include at least the following information:

i) Patient profile;

ii) Medication record system; and

iii) Purchase records.

4) Delivery Service. The pharmacist-in-charge shall assure the environmental control of all preparations shipped or delivered off site. Therefore, any compounded, sterile pharmaceutical must be shipped or delivered to a patient in temperature controlled (as defined by USP Standards) delivery containers.

5) Emergency Medications. Pharmacies that dispense compounded sterile preparations to patients in facilities off site or for administration in the patient's residence shall stock supplies and medications appropriate for
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

treatment of allergic or other common adverse effects, to be dispensed upon the prescription or order of an authorized prescriber.

g) Notwithstanding any other provision of this Section, a pharmacy may compound sterile and non-sterile products for office use by a veterinarian. The veterinarian may dispense up to a 7-day supply of a veterinary drug product that is a compounded preparation, initially intended for office use, to a client with whom the veterinarian has a veterinarian-client-patient relationship, as defined in the Veterinary Medicine and Surgery Practice Act of 2004 [225 ILCS 115]. If the compounded veterinary drug product is intended for more than a seven-day supply, then an animal-patient-specific prescription is required to be issued by the prescribing veterinarian. The pharmacy operations manual shall contain the policies and procedures pertinent to the level of complexity and the size of the compounding operations of the practice at that specific pharmacy. Electronic versions are acceptable.

h) It shall be the ongoing responsibility of the pharmacist-in-charge to ensure that all pharmacists, student pharmacists, registered certified pharmacy technicians, and registered pharmacy technicians who participate in compounding activities are adequately trained for the type of compounding in which they participate. Documentation of this training shall be maintained by the pharmacy at all times. Consumable materials, as appropriate to the pharmacy services provided at that specific pharmacy, such as filter paper, powder papers, empty capsules, ointment jars, bottles, vials, safety closures, powder boxes, labels and distilled water.

i) Any pharmacy that, after initial licensure, chooses to add sterile compounding to the services it provides must be inspected by, and the compounding area must be approved by, the Department. It shall be the responsibility of the Pharmacist-in-Charge to notify the Department and arrange for the inspection. The pharmacy may compound drug products to be used by practitioners in their office for administration to patients.

j) For the purposes of this Section, “off-site” for all pharmacies, other than an onsite institutional pharmacy, means outside the licensed premises of a pharmacy. “Off-site” for an onsite institutional pharmacy means outside the institution within which the pharmacy is located. Sales of compounded drugs to other pharmacies not under common ownership, or to clinics, hospitals or manufacturers are not allowed, except for sales provided by pharmacies contracted to provide centralized prescription filling services pursuant to Section 25.5 of the Act.
including compounding in anticipation of receiving a prescription or order based on routine, readily observed dispensing patterns.

(Source: Amended at 42 Ill. Reg. ____________, effective __________________)

Section 1330.660  Pharmacist-in-Charge

a) No pharmacy shall be granted a license without a pharmacist being designated on the pharmacy license as pharmacist-in-charge.

b) A pharmacy shall have one pharmacist-in-charge who shall be routinely and actively involved in the operation of the pharmacy.

c) A pharmacist may be the pharmacist-in-charge for more than one pharmacy; however, the pharmacist-in-charge must work an average of at least 8 hours per week at each location where he or she is the pharmacist-in-charge. If a pharmacist in charge is on a leave of more than 90 days, a new pharmacist-in-charge must be designated.

d) The responsibilities of the pharmacist-in-charge shall include:

1) Supervision of all activities of all employees as they relate to the practice of pharmacy;

2) Establishment and supervision of the method and manner for storage and safekeeping of pharmaceuticals, including maintenance of security provisions to be used when the pharmacy is closed (see Section 1330.600); and

3) Establishment and supervision of the recordkeeping system for the purchase, sale, delivery, possession, storage and safekeeping of drugs.

e) The operations of the pharmacy and the establishment and maintenance of security provisions are the dual responsibility of the pharmacist-in-charge and the owner of the pharmacy.

f) Within 30 days after a change of a pharmacist-in-charge, the Division shall be notified in writing by the departing pharmacist-in-charge.
g) In addition to notifying the Division within 30 days, the departing pharmacist-in-charge shall, on the effective date of the change, inventory the following controlled substances:

1) All Schedule II drugs, as defined in the Illinois Controlled Substances Act, by actual physical count; and

2) All other scheduled drugs, as defined in the Illinois Controlled Substances Act, by estimated count.

h) The inventory described in subsection (g) shall constitute, for the purpose of this Section, the closing inventory of the departing pharmacist-in-charge and the initial inventory of the incoming pharmacist-in-charge. This inventory record shall be preserved in the pharmacy for a period of 5 years. An affidavit attesting to the completion of the inventory and preservation of the inventory record, bearing the date of the inventory and the name and signatures of the departing and the incoming pharmacist-in-charge, shall be submitted to the Division at its principal office within 30 days after the change in the pharmacist-in-charge.

i) In the event the departing pharmacist-in-charge refuses to complete the inventory as provided for in subsection (g), or that pharmacist-in-charge is incapacitated or deceased, the initial inventory for the incoming pharmacist-in-charge shall be the inventory as completed by the incoming pharmacist-in-charge. The incoming pharmacist-in-charge will not be responsible for any discrepancy that may exist in the inventory prior to his or her initial inventory.

j) When the accuracy, relevance or completeness of any submitted documentation is questioned by the Division, because of a lack of information, discrepancies or conflicts in information given, or a need for clarification, the registrant will be required to:

1) Provide information as may be necessary; and/or

2) Appear for an interview before the Board to explain the relevance or sufficiency, clarify information given, or clear up any discrepancies or conflict of information.

k) Records shall be retained as provided for in Section 18 of the Act. Invoices for all legend drugs shall be maintained for a period of 5 years either on site or at a
central location where records are readily retrievable. Invoices shall be maintained on site for at least one year from the date of the invoice.

l) Whenever a pharmacy intends on changing or adding to the type of pharmacy services it offers, as listed in Sections 1330.500, 1330.510, 1330.520, 1330.530, 1330.540, and 1330.560 and 1330.640, it shall notify the Division no less than 30 days prior to the change or addition.

(Source: Amended at 42 Ill. Reg. ____________, effective ________________)

Section 1330.670  Compounded Sterile Preparation Standards (Repealed)

a) This Section sets forth standards for pharmacies whose practice includes the preparation, labeling and distribution of compounded sterile preparations pursuant to prescriptions or medication orders, as defined in the Act. These activities may include, but are not limited to:

1) Sterile preparation of parenteral therapy and parenteral nutrition;

2) Sterile preparations of cytotoxic or antineoplastic agents; and

3) Other sterile preparations to be used topically or internally by humans or animals.

b) Definitions

1) "Barrier Isolation Chamber" means an apparatus designed to provide a Class 5, 6 or 7 environment, as spelled out in ISO (International Organization for Standardization) 14644-1, for preparation of sterile preparations using solid walls rather than air movement (laminar air flow) to create a critical zone for preparation handling, a high efficiency particulate air (HEPA) filtration system that conditions the air flowing through the unit to remove initial particles and particles generated within the controlled environment, and a means by which preparations are introduced and people interact with the preparation being prepared within the unit.

2) "Biological Safety Cabinet" or "BSC" means a containment unit suitable for the preparation of low to moderate risk agents when there is a need for
protection of the preparation, personnel and environment, according to ISO 14644-1.

3) "Compounded Sterile Preparation" or "CSP" means a sterile pharmaceutical that has been prepared by a pharmacist, or under the supervision of a pharmacist. It shall be a preparation prepared for or in anticipation of a specific patient prescription or medication order issued by a prescribing practitioner. The preparation may include commercially available dosage forms that may need to be altered by the pharmacist to meet a specific patient's need.

4) "Cytotoxic" means a pharmaceutical that has the capability of killing living cells. These agents shall include, but are not limited to, agents classified as cancer chemotherapeutic, carcinogenic, mutagenic and antineoplastic.

5) "Laminar Airflow Hood" means an apparatus designed to provide a Class 5, 6 or 7 environment, as spelled out in ISO 14644-1 for preparation of sterile products using air circulation in a defined direction that passes through a HEPA filter to remove the initial particles and particles generated within the controlled environment.

6) "Parenteral" means sterile preparations of drugs for injection through one or more layers of the skin.

7) "Terminal" means a patient whose medical condition indicates his or her life expectancy to be 6 months or less.

e) Physical Requirements of Pharmacies Preparing Compounded Sterile Preparations

1) The pharmacy shall have a designated area for preparing compounded sterile preparations. The area shall be designed to minimize outside traffic and airflow disturbances from activity within the facility. It shall be of sufficient size to accommodate a laminar airflow hood (LAF), barrier isolation chamber or BSC and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation and security. It shall be ventilated in a manner so as not to interfere with the equipment specified in this subsection (c)(1).
2) The licensed pharmacy preparing compounded sterile preparations shall have the following:

A) LAF workstation
   i) LAF shall be certified annually in accordance with ISO 14644-1;
   ii) In the event the preparation apparatus is moved from its site of certification, recertification shall occur prior to resumption of use for compounding sterile preparations;
   iii) Prefilters shall be inspected, replaced or cleaned per manufacturer specifications monthly and documentation of this maintained;

B) Sink with hot and cold running water, which is convenient to, but apart from, the compounding area;

C) National Institute for Occupational Safety and Health (NIOSH) approved disposal containers for used needles, syringes, etc., and, if applicable, cytotoxic waste from the preparation of chemotherapy agents;

D) Biohazard cabinetry for environment control when cytotoxic compounded sterile preparations are prepared;

E) Refrigerator and/or freezer with a thermometer or temperature recording device; and

F) Temperature controlled containers for off-site deliveries.

3) The following current resource materials and texts shall be maintained in the pharmacy:

A) American Hospital Formulary Service;

C) One compatibility reference such as:

i) Trissel's Handbook on Injectable Drugs;

ii) King's Guide to Parenteral Admixtures; or

iii) Any other Division approved publication;

D) A file or reference on extended (more than 24 hours) stability data given to finished preparations.

d) Staffing. A pharmacist shall be accessible at all times at each licensed facility to respond to patients' and health professionals' questions and needs. A 24-hour telephone number will be included on all labeling of compounded medication and medication infusion devices if used off site.

e) Drug Distribution and Control

1) Patient Profile or Medication Record System. A pharmacy-generated patient profile or medication record system shall be maintained in addition to the prescription file. The patient profile or medication record system shall contain, at a minimum:

A) Patient's full name;

B) Date of birth or age;

C) Gender;

D) Compounded sterile preparations dispensed;

E) Date dispensed, if off site;

F) Drug content and quantity;

G) Patient directions, if preparation being administered off site;

H) Identifying number;
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

I) Identification of dispensing pharmacist and, if applicable, pharmacy technician;

J) Other drugs or supplements the patient is receiving, if provided by the patient or his or her agent;

K) Known drug sensitivities and allergies to drugs and foods;

L) Diagnosis; and

M) Lot numbers of components or individual medicine if the compounded sterile preparation is not used within 48 hours after preparation.

2) Labeling. Each compounded sterile preparation dispensed to patients shall be labeled with the following information, using a permanent label:

A) Name, address and telephone number of the licensed pharmacy, if not used within facility;

B) Administration date and identifying number if used on site, date dispensed, and identifying number if used off site;

C) Patient's full name and room number, if applicable;

D) Name of each drug, strength and amount;

E) Directions for use and/or infusion rate if used off site;

F) Prescriber's full name if used off site;

G) Required controlled substances transfer warnings, when applicable;

H) Beyond-use date and time;

I) Identity of pharmacist compounding and dispensing, or other authorized individual; and

J) Auxiliary labels - storage requirements, if applicable.
3) The pharmacist-in-charge shall ensure that records are maintained for 5 years and are readily retrievable and in a format that provides enforcement agents an accurate and comprehensive method of monitoring distribution via an audit trail. The records shall include at least the following information:

A) Patient profile;
B) Medication record system;
C) Purchase records; and
D) Lot numbers of the components used in compounding sterile prescriptions/orders traceable to a specific patient, if not included on patient profile and if the preparation is not utilized within 48 hours after preparation.

f) Delivery Service. The pharmacist-in-charge shall assure the environmental control of all preparations shipped or delivered off site. Therefore, any compounded, sterile pharmaceutical must be shipped or delivered to a patient in temperature controlled (as defined by USP Standards) delivery containers.

g) Cytotoxic Drugs. The following additional requirements are necessary for those licensed pharmacies that prepare cytotoxic drugs:

1) Safety and containment techniques or devices for compounding cytotoxic drugs shall be used.
2) Disposal of cytotoxic waste shall comply with all applicable local, State and federal requirements.
3) Prepared doses of cytotoxic drugs shall be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.
ILLINOIS REGISTER

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

h) Emergency Medications. Pharmacies that dispense compounded sterile preparations to patients in facilities off site or in the patient's residence shall stock supplies and medications appropriate for treatment of allergic or other common adverse effects, to be dispensed upon the prescription or order of an authorized prescriber.

(Source: Repealed at 42 Ill. Reg. ____________, effective _________________)

Section 1330.680 Automated Dispensing and Storage Systems

a) This Section sets forth standards for pharmacies whose practice includes the use of automated dispensing and storage systems. Automated dispensing and storage systems shall not be used in nuclear pharmacies.

b) Automated Dispensing and Storage Systems

1) Documentation as to type of equipment, serial numbers, content, policies and procedures, and locations shall be maintained on-site in the pharmacy for review by the Division. Documentation shall include, but not be limited to:

   A) Name and address of the pharmacy or facility where the automated dispensing and storage system is operational;

   B) Manufacturer's name and model;

   C) Quality assurance policy and procedures to determine continued appropriate use and performance of the automated device; and

   D) Policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, controlled substances, data retention or archival, definitions, downtime procedures, emergency or first dose procedures, inspection, installation requirements, maintenance, medication security, quality assurance, medication inventory, staff education and training, system set-up and malfunction.

2) Automated dispensing and storage systems shall be used only in settings that ensure medication orders and prescriptions are reviewed by a
pharmacist in accordance with established policies and procedures and good pharmacy practice. This provision shall not apply when used as an after-hours cabinet or emergency kit as provided in Section 1330.530(e).

3) Automated dispensing and storage systems shall have adequate security systems and procedures, evidenced by written pharmacy policies and procedures, to:

A) Prevent unauthorized access or use;
B) Comply with any applicable federal and State regulations; and
C) Maintain patient confidentiality.

4) Records and/or electronic data kept by automated dispensing and storage systems shall meet the following requirements:

A) All events involving access to the contents of the automated dispensing and storage systems must be recorded electronically;

B) Records must be maintained by the pharmacy and must be readily available to the Division. The records shall include:
   i) Identity of system accessed;
   ii) Identification of the individual accessing the system;
   iii) Type of transaction;
   iv) Name, strength, dosage form and quantity of the drug accessed;
   v) Name of the patient for whom the drug was ordered;
   vi) Identification of the registrants stocking or restocking and the pharmacist checking for the accuracy of the medications to be stocked or restocked in the automated dispensing and storage system; and
vii) Such additional information as the pharmacist-in-charge may deem necessary.

5) The stocking or restocking of all medications in the automated dispensing and storage systems shall be accomplished by registrants under the Act, or alternatively, the pharmacist in charge may designate a facility’s appropriately trained faculty employee that is licensed pursuant to the Nurse Practice Act [225 ILCS 65], or Physician Assistant Practice Act of 1987 [225 ILCS 95] to perform the stocking or restocking. A pharmacist-in-charge who delegates stocking/restocking in this manner shall remain responsible for ensuring that the automated dispensing and storage system is stocked/restocked accurately and in accordance with established, written pharmacy policies and procedures.

6) All medications stored in the automated dispensing and storage systems shall be packaged as a unit of use for single patient use (e.g., unit dose tab/cap, tube of ointment, inhaler, etc.) and labeled as specified in this subsection (b)(6):

A) Sterile solutions to which a drug or diluent has been added, or that are not in their original manufacturer's packaging, shall contain the following information on the outer label:

i) Name, concentration and volume of the base sterile solution;

ii) Name and strength of drugs or diluent added;

iii) Date and beyond use date of the admixture. The beyond use date, unless otherwise specified in the individual compendia monograph, shall be no later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged; and

iv) Reference code to identify source and lot number of drugs or diluent added.

B) Non-parenterals repackaged for future use shall be identified with the following information:
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

i) Brand and/or generic name;

ii) Strength (if applicable);

iii) Beyond use date. Unless otherwise specified in the individual monograph, the beyond use date shall be no later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged; and

iv) Reference code to identify source and lot number.

C) Exceptions to the "unit of use" requirements in this subsection (b)(6) are as follows:

i) Injectable medications stored in their original multi-dose vial (e.g., insulin, heparin) when the medication may be withdrawn into a syringe or other delivery device for single patient use; or

ii) Over-the-counter (OTC) products stored in their original multi-dose container (e.g., antacids, analgesics) when the medication may be withdrawn and placed into an appropriate container for single patient use.

D) The pharmacy providing services to the University of Illinois College of Veterinary Medicine shall be exempt from the requirement that all medications stored in the automated dispensing and storage systems be packaged as a unit for single patient use. This exemption is solely for dispensing medications to animals.

7) For medication removed from the system for on-site patient administration, the system must document the following information:

A) Name of the patient or resident;

B) Patient's or resident's unique and permanent identifier, such as admissions number or medical records number;

C) Date and time medication was removed from the system;
NOTICE OF PROPOSED AMENDMENTS

D) Name, initials or other unique identifier of the person removing the drug; and

E) Name, strength and dosage form of the drug or description of the medical device removed. The documentation may be on paper, via electronic media or via any other media or mechanisms as set forth by the Act or this Part or as approved by the Division.

8) The automated dispensing and storage systems shall provide a mechanism for securing and accounting for medications once removed from and subsequently returned to the automated dispensing and storage systems (e.g., return bin). No medication or device shall be returned directly to the system for immediate reissue or reuse by a non-registrant under the Act. Medication or devices once removed shall not be reused or reissued except for:

A) Medical devices that can be properly sanitized prior to reuse or reissue; and

B) Medication that is dispensed and stored under conditions defined and supervised by the pharmacist and are unopened in sealed, intact and unaltered containers that meet the standards for light, moisture and air permeation as defined by the current USP/NF, or by the USP Conventions, Inc.

9) The automated dispensing and storage systems shall provide a mechanism for securing and accounting for wasted medications or discarded medications.

10) The quality assurance documentation for the use and performance of the automated dispensing and storage systems shall include at least the following:

A) Safety monitors (e.g., wrong medications removed and administered to patient); and

B) Accuracy monitors (e.g., filling errors, wrong medications removed); and
C) Security monitors (e.g., unauthorized access, system security breaches, controlled substance audits).

11) Errors in the use or performance of the automated dispensing and storage systems resulting in patient hospitalization or death shall be reported to the Division by the pharmacist-in-charge within 30 days after acquiring knowledge of the incident.

12) Policy and procedures for the use of the automated dispensing and storage systems shall include a requirement for pharmacist review of the prescription or medication order prior to the system profiling and/or removal of any medication from the system for immediate patient administration. This does not apply to the following situations:

A) The system is being used as an after-hours cabinet for medication dispensing in the absence of a pharmacist (see Section 1330.530(e)(1));

B) The system is being used in place of an emergency kit (see Section 1330.530(e)(2));

C) The system is being used to provide access to medication required to treat the immediate needs of a patient (see Section 1330.530(e)(3)). A sufficient quantity to meet the immediate needs of the patient may be removed until a pharmacist is on duty and available to review the prescription or medication order. A pharmacist shall check the orders promptly once on duty (e.g., floor stock system, emergency department, surgery, ambulatory care or same day surgery, observation unit, etc.).

13) Policies and procedures for the use of the automated dispensing and storage systems shall include the following:

A) List of medications to be stored in each system;

B) List of medications qualifying for emergency or first dose removal without pharmacist prior review of the prescription or medication order.
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

14) The pharmacist-in-charge shall maintain or have access to all records or documentation specified in this Section for 5 years or as otherwise required by law.

15) A copy of all pharmacy policies and procedures related to the use of an automated dispensing and storage system shall be maintained at all locations where the system is being used.

c) Duties and Responsibilities of the Pharmacist-in-Charge

1) The pharmacist-in-charge shall be responsible for:

   A) Assuring that the automated dispensing and storage system is in good working order and accurately provides the correct strength, dosage form and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards;

   B) Establishment of a quality assurance program prior to implementation of an automated dispensing and storage system and the supervision of an ongoing quality assurance program that monitors appropriate use and performance of the automated dispensing and storage system, evidenced by written policies and procedures developed by the pharmacy;

   C) Providing the Division with written notice 30 days prior to the installation of, or at the time of removal of, an automated storage and dispensing system. The notice must include, but is not limited to:

      i) The name and address of the pharmacy;

      ii) The address of the location of the automated dispensing and storage system, if different from the address of the pharmacy;

      iii) The automated dispensing and storage system's manufacturer and model;

      iv) The pharmacist-in-charge; and
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

v) A written description of how the facility intends to use the automated storage and dispensing system;

D) Determining and monitoring access to and the limits on access (e.g., security levels) to the automated storage and dispensing system. Access shall be defined by policies and procedures of the pharmacy and shall comply with State and federal regulations.

2) Additional responsibilities of the pharmacist-in-charge or pharmacist designated by the pharmacist-in-charge shall include:

A) Authorizing the assigning of access to, discontinuing access to, or changing access to the system;

B) Ensuring that access to the medications complies with State and federal regulations, as applicable; and

C) Ensuring that the automated dispensing and storage system is stocked/restocked accurately and in accordance with established, written pharmacy policies and procedures.

d) An automated dispensing and storage system is authorized for use in any licensed hospital, long-term care facility, or hospice residence ("facility"). For all nonresident pharmacies, the pharmacist-in-charge and all pharmacy personnel who provide services while physically present at a facility located in Illinois must be licensed in Illinois. In addition to compliance with all other provisions in this Section, an automated dispensing and storage system shall comply with the following:

1) Drugs in the automated dispensing and storage system are not considered dispensed until removed from the system by authorized personnel at the facility, after being released by the pharmacy pursuant to a prescription, unless otherwise provided for in this Part.

2) Only the doses of medication needed for contemporaneous administration may be removed from the automated pharmacy system at one time.

3) Automated dispensing and storage systems utilized at a facility shall operate under the same license as the pharmacy utilizing it.
NOTICE OF PROPOSED AMENDMENTS

4) All records shall be maintained for a period of 5 years either at the pharmacy providing services to the facility or a central location where records are readily retrievable.

5) Only pharmacies under common ownership may share an automated pharmacy system at a facility.

(Source: Amended at 42 Ill. Reg. ____________, effective ________________ )