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NOTICE OF ADOPTED AMENDMENTS

1) Heading of the Part: Illinois Controlled Substances Act

2) Code Citation: 77 Ill. Adm. Code 3100

<u>Section Numbers:</u>	<u>Adopted Action:</u>
3100.10	Amendment
3100.20	Repealed
3100.40	Repealed
3100.50	Amendment
3100.60	Amendment
3100.70	Repealed
3100.80	Amendment
3100.85	Amendment
3100.90	Repealed
3100.100	Repealed
3100.110	Repealed
3100.120	Repealed
3100.130	Repealed
3100.140	Repealed
3100.150	Repealed
3100.160	Repealed
3100.170	Repealed
3100.180	Repealed
3100.190	Repealed
3100.200	Amendment
3100.210	Repealed
3100.220	Repealed
3100.230	Repealed
3100.240	Repealed
3100.250	Repealed
3100.260	Repealed
3100.270	Repealed
3100.280	Amendment
3100.290	Amendment
3100.300	Amendment
3100.310	Amendment
3100.320	Amendment
3100.330	Amendment
3100.340	Amendment

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3100.350	Amendment
3100.360	Amendment
3100.370	Amendment
3100.380	Amendment
3100.390	Amendment
3100.400	Amendment
3100.410	Amendment
3100.420	Amendment
3100.430	Amendment
3100.440	Amendment
3100.450	Amendment
3100.460	Amendment
3100.470	Repealed
3100.480	Amendment
3100.490	Repealed
3100.500	Amendment
3100.510	Amendment
3100.520	Amendment
3100.530	Amendment

- 4) Statutory Authority: Implementing and authorized by the Illinois Controlled Substances Act [720 ILCS 570]
- 5) Effective Date of Rule: February 27, 2015
- 6) Does this rulemaking contain an automatic repeal date? No
- 7) Does this rulemaking contain incorporations by reference? No
- 8) A copy of the adopted rule, including any material incorporated by reference, is on file in the principal office of the Division of Professional Regulation and is available for public inspection.
- 9) Notice of Proposal published in the *Illinois Register*: 38 Ill. Reg. 5705; March 7, 2014
- 10) Has JCAR issued a Statement of Objection to this rulemaking? No
- 11) Differences between Proposal and Final Version: Section 3100.310(e) was changed to simply require a basic alarm system that detects unauthorized entry into the pharmacy

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area. Section 3100.380 added a ban on practitioner self-dispensing, and Section 3100.400 was amended to clarify that prescriptions for Schedule II controlled substances could be submitted via fax in accordance with Section 313 of the Act. Numerous other technical changes and/or clarifications have also been made.

- 12) Have all changes agreed upon by the Agency and JCAR been made as indicated in the agreements issued by JCAR? Yes
- 13) Will this rulemaking replace an emergency rule currently in effect? No
- 14) Are there any rulemakings pending on this Part? No
- 15) Summary and Purpose of Rulemaking: This Part had not been substantially revised in more than 25 years. There have been numerous amendments to the Controlled Substances Act that have never been addressed in that time. PA 97-334 contained the most recent statutory changes to the Act which these adopted amendments implement. The adopted rule's intent is conformance of this Part to the Act and federal law. Included in the revisions is the repeal of numerous provisions relating to administrative and disciplinary functions that are provided for by other Department Rules or policies and are no longer pertinent. It adds definitions and the enhancement of Department regulatory oversight of the purchase, sale, and storage of controlled substances. It also includes a prohibition on practitioner self-prescribing of controlled substances, as well as a general clean up of the Part.
- 16) Information and questions regarding this adopted rule shall be directed to:

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

217/785-0813
fax: 217/557-4451

The full text of the Adopted Amendments begins on the next page:

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TITLE 77: PUBLIC HEALTH

CHAPTER XV: DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

PART 3100

ILLINOIS CONTROLLED SUBSTANCES ACT

Section	
3100.10	Definitions
3100.20	Copies of This Part (<u>Repealed</u>)
3100.30	Renewal Periods and Fees
3100.40	Time and Method of Payment (<u>Repealed</u>)
3100.50	Separate <u>LicensureRegistration</u> for Independent Activities
3100.60	Exempted Locations
3100.70	Requirements of Registration (<u>Repealed</u>)
3100.80	Exemption of Agents and Employees: Affiliated Practitioners
3100.85	Application for Mid-Level Practitioner Controlled Substances License
3100.90	Time for Application for Registration: Expiration Date (<u>Repealed</u>)
3100.100	Application Forms (<u>Repealed</u>)
3100.110	Filing of Application: Joint Filings (<u>Repealed</u>)
3100.120	Acceptance for Filing: Defective Applications (<u>Repealed</u>)
3100.130	Additional Information (<u>Repealed</u>)
3100.140	Amendments to and Withdrawal of Applications (<u>Repealed</u>)
3100.150	Certificate of Registration: Denial of Registration (<u>Repealed</u>)
3100.160	Suspension or Revocation of Registration (<u>Repealed</u>)
3100.170	Suspension of Registration Pending Final Order (<u>Repealed</u>)
3100.180	Extension of Registration (<u>Repealed</u>)
3100.190	Hearing Officer (<u>Repealed</u>)
3100.200	Hearings and Notices
3100.210	Procedures for Hearing (<u>Repealed</u>)
3100.220	Hearing – Pursuant to Paragraph 1305(b) (<u>Repealed</u>)
3100.230	Default Disposition of a Contested Case (<u>Repealed</u>)
3100.240	Recording of Testimony (<u>Repealed</u>)
3100.250	Recording of Hearing (<u>Repealed</u>)
3100.260	Rehearing (<u>Repealed</u>)
3100.270	Final Decisions and Orders (<u>Repealed</u>)
3100.280	Modification in <u>LicensureRegistration</u>
3100.290	Termination of <u>LicenseRegistration</u>
3100.300	Transfer of <u>LicenseRegistration</u>
3100.310	Security Requirements Generally

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3100.320	Factors in Evaluating Physical Security Systems
3100.330	Physical Security Controls for Non-Practitioners
3100.340	Physical Security Controls for Practitioners
3100.350	Other Security Controls for Practitioners
3100.360	Record and Inventorying Requirements Generally
3100.370	Persons Entitled to Issue Prescriptions
3100.380	Purpose of Issuance <u>Issue</u> of a Prescription
3100.390	Manner of Issuance of Prescription
3100.400	Requirement of Prescription <u>for Schedule II Controlled Substances</u>
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3100.460	Failure to Comply with Rules
3100.470	Address for Notices (<u>Repealed</u>)
3100.480	<u>Granting Variances</u> Suspension or Modification of Rules and Regulations
3100.490	Construction of Rules and Regulations (<u>Repealed</u>)
3100.500	<u>Ordering Schedule II Controlled Substances</u> Written Order
3100.510	<u>Paragraph 1312(d)</u> Record Keeping
3100.520	Emergency Medication Kits
3100.530	Transfer Between Pharmacies of Prescription Information for Refill Purposes

AUTHORITY: Implementing and authorized by the Illinois Controlled Substances Act [720 ILCS 570].

SOURCE: Rules and Regulations promulgated for the Administration of the Illinois Controlled Substances Act, effective October 22, 1975; amended at 3 Ill. Reg. 38, p. 277, effective September 20, 1979; amended at 4 Ill. Reg. 46, p. 1297, effective November 5, 1980; amended at 5 Ill. Reg. 3528, effective March 25, 1981; amended at 5 Ill. Reg. 8693, effective August 12, 1981; amended at 6 Ill. Reg. 10015, effective August 5, 1982; codified at 8 Ill. Reg. 543; amended at 8 Ill. Reg. 2498, effective February 9, 1984; amended at 8 Ill. Reg. 16344, effective August 23, 1984; amended at 11 Ill. Reg. 18246, effective October 27, 1987; transferred from Chapter VII, 77 Ill. Adm. Code 1650 (Department of Registration and Education) to Chapter XV, 77 Ill. Adm. Code 3100 (Department of Professional Regulation) pursuant to P.A. 85-225, effective January 1, 1988, at 12 Ill. Reg. 2922; amended at 20 Ill. Reg. 9063, effective July 1, 1996; amended at 24 Ill. Reg. 16672, effective October 27, 2000; emergency amendment at 28 Ill. Reg. 4985, effective March 5, 2004, for a maximum of 150 days; amended at 28 Ill. Reg. 9633, effective June 28, 2004; amended at 39 Ill. Reg. 3656, effective February 27, 2015.

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Section 3100.10 Definitions

- a) ~~Authority: This Part is made and issued by the Department of Professional Regulation pursuant to the Illinois Controlled Substances Act [720 ILCS 570], which empowers the Department to promulgate rules relating to the registration and control of the manufacture, distribution and dispensing of controlled substances within this State.~~ b) **Definitions:** The following terms shall be defined as follows:

"Act" means the Illinois Controlled Substances Act [720 ILCS 570].

"Administration" means the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

"Address of Record" means the designated address recorded by the Department in the applicant's application file or the licensee's license file, as maintained by the Department's licensure maintenance unit.

~~"Basic Class" is defined as set forth in Title 21, Chap. II, Sec. 1301.02 of the Federal Regulations relating to Food and Drugs (21 CFR 1301.02).~~

"DEA Registration Controlled Substances Code Number" means the number assigned to controlled substances and controlled drug preparations by the Drug Enforcement Administration of the Department of Justice as defined by 21 CFR 1308.03 (April 1, 2014).

"Department" means the Department of Financial and Professional Regulation ~~of the State of Illinois.~~

"Director" means the Director of the Division ~~Department~~ of Professional Regulation with the authority delegated by the Secretary of the State of Illinois.

"Division" means the Department of Financial and Professional Regulation-Division of Professional Regulation.

~~"Hearing Officer" means either the Director or any person he/she appoints pursuant to Section 3100.190 of this Part. Such person shall have full~~

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~~power to receive evidence, decide evidentiary questions, issue subpoenas and otherwise conduct a hearing.~~

"Individual Practitioner" means a physician, dentist, veterinarian, podiatrist or ~~therapeutically certified~~ optometrist licensed in the State of Illinois to practice his/her profession, a licensed physician assistant with prescriptive authority who issues a prescription for a Schedule III, IV, or V controlled substance in accordance with Section 303.05 of the Act and the written supervision agreement guidelines required under Section 7.5 of the Physician Assistant Practice Act of 1987 [225 ILCS 95], or a licensed advanced practice nurse with prescriptive authority, in accordance with Section 303.05 of the Act and a written collaborative agreement as provided in Section under Sections 65-4015-15 and 15-20 of the ~~Nurse Nursing and Advanced Practice Nursing Act~~ [225 ILCS 65] except as provided in Section 3100.80(c).

~~"Institutional Practitioner" means a hospital or other party (other than an individual) licensed, registered or otherwise permitted by the State of Illinois to dispense a controlled substance in the course of professional practice but does not include a pharmacy.~~

"License" or "Licensure" encompasses licensure, registration, certification or other approval of an individual in accordance with State or federal statute.

"Mid-level Practitioner" means:

a physician assistant who has been delegated authority to prescribe through a written delegation of authority by a physician licensed to practice medicine in all of its branches, in accordance with Section 7.5 of the Physician Assistant Practice Act of 1987;

an advanced practice nurse who has been delegated authority to prescribe through a written delegation of authority by a physician licensed to practice medicine in all of its branches or by a podiatrist, in accordance with Section 65-40 of the Nurse Practice Act; or

an animal euthanasia agency.

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~~"Mid-Level Practitioner Controlled Substances License" is a license issued to a mid-level practitioner licensed physician assistant or licensed advanced practice nurse authorized to prescribe by a physician in accordance with the professional licensure Act of the profession or a euthanasia agency.~~

~~"Pre-printed Prescription" means a written prescription upon which the designated drug has been indicated prior to the time of issuance, including any pre-inked stamp that would be applied to a prescription blank. The term does not mean a written prescription that is individually generated by machine or computer in the prescriber's place of business.~~

~~"Registrant" means a person or party registered or licensed under or holding a certificate of registration or license pursuant to the Act.~~

~~"Rules" means this Part.~~

~~"Secretary" means the Secretary of the Department of Financial and Professional Regulation.~~

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.20 Copies of This Part (Repealed)

~~Copies of this Part will be furnished upon request directed to the Department of Registration and Education.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.40 Time and Method of Payment (Repealed)

~~Registration and renewal fees shall be paid at the time when the application for registration or renewal is submitted for filing. Payment should be made in the form of a certified or cashier's check or money order made payable to the Department of Registration and Education. Payments made in the form of stamps, foreign currency or third party endorsed checks will not be accepted.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

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Section 3100.50 Separate LicensureRegistration for Independent Activities

- a) The following groups of activities are deemed to be independent of each other:
- 1) Manufacturing controlled substances;
 - 2) Distributing controlled substances;
 - 3) Dispensing controlled substances listed in Schedules II through V;
 - 4) Conducting instructional activities with controlled substances listed in Schedules II through V;
 - 5) Conducting instructional activities with controlled substances listed in Schedule I;
 - 6) Conducting chemical analysis with controlled substances listed in any Schedule.
- b) Every person who engages in more than one group of independent activities shall obtain a separate licenseregistration for each group of activities, except as provided in this subsection. Any person, when licensedregistered to engage in the group of activities described in subsections (b)(1) through (6)each paragraph in this subsection, shall be authorized to engage in the coincident activities described in the specific subsectionthat paragraph without obtaining a registration to engage in thosesuch coincident activities, provided that, unless specifically exempted, he or she complies with all requirements and duties prescribed by law for persons licensedregistered to engage in thosesuch coincident activities:
- 1) A person licensedregistered to manufacture any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class, but no other substances or class thatwhich he or she is not licensedregistered to manufacture;
 - 2) A person licensedregistered to manufacture any controlled substance listed in Schedules II through V shall be authorized to conduct chemical analysis and pre-clinical research (including quality control analysis) with narcotic and non-narcotic controlled substances listed in those Schedules in which he or she is authorized to manufacture;

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- 3) A person authorized by the appropriate agencies of the State of Illinois and the federal government to conduct research with a ~~basic class of~~ controlled substance ~~listed in Schedule I~~ shall be authorized to manufacture ~~that substancesuch class~~ if and to the extent that ~~thesuch~~ manufacture is set forth in the research protocol filed with the application ~~for registration~~ and to distribute ~~that substancesuch class~~ to other persons authorized to conduct research with ~~that substancesuch class~~ or to conduct chemical analysis;
- 4) A person ~~licensed~~~~registered~~ to conduct chemical analysis with controlled substances shall be authorized:
- A) to manufacture and import ~~thosesuch~~ substances for analytical purposes, and distribute ~~thosesuch~~ substances to persons ~~licensed~~~~registered~~ or authorized to conduct chemical analysis, instructional activities or research with ~~thosesuch~~ substances or ~~persons who are~~ exempted from ~~licensure~~~~registration~~ pursuant to law; and,
- B) to export ~~thosesuch~~ substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries; ~~and~~
- 5) A person authorized by the appropriate agencies of the State of Illinois or the federal government to conduct research with controlled substances listed in Schedules II through V shall be authorized to conduct chemical analysis with controlled substances listed in those Schedules in which he ~~or she~~ is authorized to conduct research, to manufacture ~~thosesuch~~ substances if and to the extent that ~~thesuch~~ manufacture is authorized by the appropriate agency, and to distribute ~~thosesuch~~ substances to other persons ~~licensed~~~~registered~~ or authorized to conduct chemical analysis; or research with ~~thosesuch~~ substances and to persons exempted from ~~licensure~~~~registration~~ pursuant to law;
- 6) A person ~~licensed~~~~registered~~ to dispense controlled substances in Schedules II through V shall be authorized to conduct instructional activities with those substances.

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- c) A single license~~registration~~ to engage in any group of independent activities may include one or more controlled substances listed in the Schedules authorized in that group of independent activities.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.60 Exempted Locations

~~An office used by agents of a licensee where sales of controlled substances are solicited, made or supervised but that neither contains controlled substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders is exempt from licensure. The following locations shall be deemed not to be places where controlled substances are manufactured, distributed or dispensed:~~

- a) ~~A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of Paragraph 1302(c)(2) of the Act.~~
- b) ~~An office used by agents of a registrant where sales of controlled substances are solicited, made or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders.~~

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.70 Requirements of Registration (Repealed)

~~Persons Required to Register. Every person who manufactures, distributes, dispenses or prescribes any controlled substance or who proposes to engage in the manufacture, distribution, dispensing or prescribing of any controlled substance shall obtain a registration unless exempted by law. Only persons actually engaged in such activities are required to obtain registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder of a parent corporation or a corporation manufacturing controlled substances is not required to obtain a registration.)~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

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Section 3100.80 Exemption of Agents and Employees: Affiliated Practitioners

- a) The requirement of ~~licensure~~registration is waived for any agent or employee of a person who is ~~licensed~~registered to engage in any group of independent activities (see Section 3100.50), if ~~the~~such agent or employee is acting in the usual course of his or her business or employment.
- b) An individual practitioner who is an agent or employee of another practitioner ~~licensed~~registered to dispense controlled substances may, when acting in the usual course of his or her employment, administer and dispense (other than by issuance of a prescription) controlled substances if and to the extent that ~~the~~such individual practitioner is authorized or permitted to do so by the employer or principal practitioner~~jurisdiction in which he practices~~, under the ~~licensure~~registration of the employer or principal practitioner, in lieu of being ~~licensed~~registered himself or herself.
- c) In a licensed hospital, hospital affiliate, or licensed ambulatory surgical treatment center ("institution") a licensed advanced practice nurse, acting pursuant to Section 65-45 of the Nurse Practice Act, or a physician assistant, acting pursuant to Section 7.7 of the Physician Assistant Practice Act of 1987, may be granted clinical privileges, including the authority to select, order and administer, and issue discharge prescriptions for, controlled substances under the DEA registration number of the hospital, hospital affiliate or licensed ambulatory surgical treatment center by whom he or she is employed.
- d)e) In a licensed hospital or affiliated training facility ("institution"), a~~A~~ holder of a Temporary ~~License~~Certificate of Registration, pursuant to Section ~~17-11a~~ of the Medical Practice Act [~~225 ILCS 60/17~~Ill. Rev. Stat. 1981, ch. 111, par. 4422], may select, order and administer, and issue discharge prescriptions for,~~dispense and prescribe~~ controlled substances under the DEA registration number of the hospital or affiliated training facility~~other institution which is registered and~~ by whom he or she is employed. ~~provided that:~~
- e) The exemptions provided for advanced practice nurses, physician assistants and temporary license holders in subsections (c) and (d) are subject to the following conditions:
- 1) The selection, ordering and administration of, and issuance of discharge prescriptions for, controlled substances~~Such dispensing or prescribing is~~

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done in the usual course of his or her professional practice or training program at such hospital or institution;

- 2) The institution by whom he or she is employed has verified that the individual practitioner is authorized by the institution's medical staff, or medical staff committee, to select, order and administer, and issue discharge prescriptions for, controlled substances;
- 3) The advanced practice nurse, physician assistant or temporary license holder is acting only within the scope of his or her employment;
- 2) ~~The hospital or other institution by whom he is employed has determined that such temporary certificate holder is so permitted to dispense or prescribe drugs by the state wherein he resides and holds a license to practice medicine in all its branches;~~
- 4)3) ~~The hospital or other institution~~ authorizes the temporary license holder, advanced practice nurse or physician assistant~~authorized such temporary certificate holder to~~ select, order and administer, and issue discharge prescriptions for, controlled substances~~dispense or prescribe~~ under the institution's~~hospital~~ registration and designates a specific internal code number for each temporary license holder, advanced practice nurse or physician assistant~~such temporary certificate holder~~ so authorized. The code number shall consist of numbers, letters, or a combination of numbers and letters thereof and shall be a suffix to the institution's Drug Enforcement Administration (DEA)~~Drug Enforcement Administration (DEA)~~ registration number, preceded by a hyphen (e.g., APO 123456-10 or APO 123456-A12); ~~and~~
- 5)4) A current list of internal codes and the corresponding temporary license holder, advanced practice nurse or physician assistant~~temporary certificate holder~~ is kept by the ~~hospital or other~~ institution and is made available at all times to other licensees~~registrants~~ and law enforcement agencies upon request for the purpose of verifying the authority of the temporary license holder, advanced practice nurse or physician assistant; ~~and prescribing temporary certificate holder.~~
- 6) A temporary license holder, advanced practice nurse or physician assistant shall include on all prescriptions issued by him or her the registration

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number of the institution, his or her specific internal code number, and his or her name.

- f) An official exempted from registration under the Act and this Part shall include on all prescriptions issued by him or her, his or her branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and his or her DOD identification number, in lieu of the license number of the practitioner required by this Part. The DOD identification number for a Public Health Service practitioner is his or her social security identification number. Each prescription shall have the name of the officer stamped or printed on it, as well as the signature of the officer.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.85 Application for Mid-Level Practitioner Controlled Substances License

- a) An individual applicant for a mid-level practitioner controlled substances license shall file an application on forms provided by the Department. The application shall include:
- 1) The physician assistant or advanced practice nurse license number. The license shall be active and in good standing;
 - 2) The license number and controlled substances license number of the delegating or collaborating physician or collaborating podiatrist;
 - 3) A delegation of controlled substances in Schedules III through V or any specific controlled substance in Schedule II shall be electronically input under rules set forth for DHS' Prescription Monitoring Program (77 Ill. Adm. Code 2080). A printout of the inputted delegation may serve as written notice of delegation of prescriptive authority if it is signed by the physician or podiatrist and indicating the schedule of controlled substances or the specific Schedule II controlled substances that the mid-level practitioner may dispense or prescribe is listed. A separate notice of prescriptive authority shall be submitted by each supervising or collaborating physician or collaborating podiatrist; and
 - 4) The required fee.

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- b) For physician assistant or advanced practice nurse controlled substance licenses issued on or after August 11, 2011 authorizing the prescribing and dispensing of Schedule II controlled substances, applicants must meet education requirements in accordance with Section 303.05 of the Act.
- c) Any advanced practice nurse or physician assistant who writes a prescription for a controlled substance without having valid prescriptive authority may be fined by the Department not more than \$50 per prescription, and the Department may take any other disciplinary action provided for in the Act.
- d) Nothing in this Section shall be construed to prohibit generic substitutions as provided in Section 25 of the Pharmacy Practice Act [225 ILCS 85/25].
- e) Pursuant to the Humane Euthanasia in Animal Shelters Act rules (68 Ill. Adm. Code 1248), a euthanasia agency applicant for a mid-level practitioner controlled substances license shall file an application on forms provided by the Department. The application shall include:
- 1) The euthanasia agency license number. The license shall be active and in good standing;
 - 2) The required fee as stated in Section 3100.30.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.90 Time for Application for Registration: Expiration Date (Repealed)

- a) ~~Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Director to such person.~~
- b) ~~A registered person who fails to file for renewal before the expiration date of his registration must apply for a new registration; his existing registration will expire on the date specified.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

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Section 3100.100 Application Forms (Repealed)

- a) ~~Forms for registration may be obtained by writing to the Department of Registration and Education, 320 West Washington Street, Springfield, Illinois 62786. Forms will be mailed, as applicable, to each registered person approximately 60 days before the expiration date of his registration; if any registered person does not receive such forms within 45 days before the expiration date of his registration, he must promptly give notice of such fact and request such forms by writing to the Department and the foregoing address.~~
- b) ~~Each application for registration to handle any basic class of controlled substance listed in Schedule I (except to conduct chemical analysis with such classes), and each application for registration to manufacture a basic class of controlled substance listed in Schedule II, shall include the Controlled Substance Code Number, as defined in Section 1650.10, for each basic class or substance to be covered by such registration.~~
- c) ~~Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.~~
- d) ~~Each application, attachment or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity.~~
- e) ~~An applicant may authorize one or more individuals to sign applications for the applicant by filing a power of attorney on a form to be designated by the Department for each such individual. The power of attorney shall be signed by a person who is authorized to sign applications and shall contain the signature of the individual being authorized to sign applications. The power of attorney shall be valid until revoked by the applicant.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.110 Filing of Application: Joint Filings (Repealed)

- a) ~~All applications for registration shall be submitted for filing to the Department. The appropriate registration fee and any required attachments must accompany the application.~~

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- b) ~~Any person required to obtain more than one registration may submit all applications in one package. Each application must be complete and should not refer to any accompanying application for required information.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.120 Acceptance for Filing: Defective Applications (Repealed)

- a) ~~Applications submitted for filing shall be stamped by the Department showing date of receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this Part generally will not be accepted for filing. In the case of minor defects as to completeness, the Department may accept the application for filing with a request to the applicant for additional information. A defective application will be returned to the applicant within 30 days following its receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time; the Department shall accept for filing any application upon resubmission by the applicant, whether complete or not.~~
- b) ~~Accepting an application for filing does not preclude any subsequent request for additional information pursuant to Section 1650.130 and has no bearing on whether the application will be granted.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.130 Additional Information (Repealed)

~~The Department may require an applicant to submit such documents or written statements of fact relevant to the application as it deems necessary to determine whether the application should be granted. The failure of an applicant to provide such documents or statements within 30 days after being requested to do so, without good cause shown for failure to answer within said time, or without a request for extension of time, shall be deemed to be a waiver by the applicant of any opportunity to present such documents or facts for consideration by the Department in granting or denying the application.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

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Section 3100.140 Amendments to and Withdrawal of Applications (Repealed)

- a) ~~An application may be amended or withdrawn by the applicant without permission of the Department at any time before the date on which the applicant received a notice of hearing or denial of application pursuant to this Part. An application may be amended or withdrawn with permission of the Department at any time where good cause is shown by the applicant.~~
- b) ~~After an application has been accepted for filing, the request by the applicant that it be returned shall be deemed to be a withdrawal of the application.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.150 Certificate of Registration: Denial of Registration (Repealed)

- a) ~~The Department shall issue a certificate of registration to an applicant if the issuance of registration or renewal is proper under the applicable provisions of Paragraph 1303 of the Act. In the event that the issuance of registration or renewal is not proper, the Department shall deny the application. Before denying any application, the Department shall issue a notice of hearing to determine why registration should not be denied pursuant to Paragraph 1305(a) of the Act.~~
- b) ~~The certificate of registration shall contain the name, address and registration number of the registrant, the activity authorized by the registration, the Schedules (as set forth in Article II of the Act) of the controlled substances which the registrant is authorized to handle, and the expiration date of the registration.~~
- c) ~~The registrant shall prominently display the certificate of registration at the registered location.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.160 Suspension or Revocation of Registration (Repealed)

- a) ~~Before revoking or suspending any registration, the Director shall issue a notice of hearing to determine why registration should not be revoked or suspended and shall hold a hearing pursuant to Paragraph 1305 of the Act. Notwithstanding the requirements of this subsection, however, the Director may suspend any registration pending a final order pursuant to Paragraph 1305(b).~~

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- b) ~~Upon service of the Order of the Director suspending or revoking registration, the registrant shall immediately deliver his certificate of registration to the Department.~~
- e) ~~In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new certificate of registration for all substances not affected by such revocation or suspension; no fee shall be required to be paid for the new certificate of registration. The registrant shall deliver the old certificate of registration to the Department.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.170 Suspension of Registration Pending Final Order (Repealed)

- a) ~~In any case where the Director finds that there is an imminent danger to public health and safety, he may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of notice of hearing pursuant to Section 1650.200. If the Director so suspends, he shall serve, pursuant to Paragraph 1305(b):~~
 - 1) ~~An order of immediate suspension which shall contain a statement of his findings regarding the danger to the public health or safety, and~~
 - 2) ~~A notice of hearing on said suspension pursuant to Section 3100.220. The order of immediate suspension and hearing shall be served personally or by certified mail, return receipt requested, to the address given by registrant pursuant to Section 3100.470.~~
- b) ~~Upon service of the order of immediate suspension, the registrant shall promptly return his certificate of registration to the Department.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.180 Extension of Registration (Repealed)

~~In the event that an applicant for registration (who is doing business under a registration previously granted and not revoked or suspended) has applied for renewal at least 30 days before the date on which the existing registration is due to expire, and the Director has issued no order~~

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~~on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Director so issues his order. The Director may extend any other existing registration under the circumstances contemplated in this Section even though the registrant failed to apply for renewal at least 30 days before expiration of the existing registration, with or without request by the registrant, if the Director finds that such extension is not inconsistent with the public health or safety.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.190 Hearing Officer (Repealed)

~~Any hearing required by the Act or this Part to be held by the Department may be conducted by the Director or a qualified hearing officer named by the Director to hear the matter in the Director's place and stead.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.200 Hearings and Notices

Hearings shall be conducted in accordance with Section 305 of the Act and with 68 Ill. Adm. Code 1110.

- a) ~~Except as provided in Paragraph 1305(b) of the Act, if the Department seeks to deny, revoke, suspend or refuse to renew an application for registration or renewal, a hearing shall be held pursuant to the provisions of this Section as hereinafter set forth.~~
- b) ~~Not later than 30 days prior to the scheduled date of any hearing to be held pursuant to this Section, the Department shall give notice of such hearing to the registrant or applicant involved who is named as respondent and shall include the Department Complaint containing:~~
 - 1) ~~A statement of the time, date, location and nature of the proceeding;~~
 - 2) ~~The name of the hearing officer if a person other than the Director is to conduct the hearing;~~
 - 3) ~~A statement setting forth a list of the charges against such respondent~~

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~~including specifications of the acts complained of or in case of a denial of registration or renewal, the basis for such denial;~~

- ~~4) Reference to the Paragraphs of the Act and the particular rules allegedly violated and reference to the particular Paragraphs of the Act and particular rules granting authority and jurisdiction to the Department to conduct such hearing;~~
 - ~~5) Any other information which the Department may deem advisable or necessary to the adequate notification of such respondent;~~
 - ~~6) The time within which such respondent may file an Answer with the Department and where and to whom it must be sent. There is no need for respondent to file an Answer and all allegations of the Complaint will be deemed to be contested unless specifically admitted by the respondent.~~
- ~~e) All Notices, in connection with hearings specified in this Section, from and to the Department shall be sent by certified mail, return receipt requested, at the addresses provided for mailing notices pursuant to Section 3100.470. If an attorney enters his appearance for the respondent, then the respondent's notices shall thereafter be sent both to the respondent and to his attorney.~~
 - ~~d) If the respondent shall believe the hearing officer selected to conduct such hearing is prejudiced against such respondent or his attorney, such respondent shall make a request in writing to the Director, at least 14 days prior to the date set for the hearing, to substitute another hearing officer. Such request shall be accompanied by an affidavit setting forth the facts upon which such claim of prejudice is predicated signed by such respondent or officer thereof or the attorney engaged to represent such respondent. Upon receipt of such request, the Director shall make a determination based upon such evidence as he deems sufficient whether such prejudice to the rights of the respondent exists and the Director may appoint a substitute hearing officer if he finds there is prejudice.~~

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.210 Procedures for Hearing (Repealed)

- ~~a) The technical rules of evidence shall not apply at any hearing involving any registration or denial, revocation or suspension thereof. The parties shall be given~~

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~~an opportunity to present evidence and oral or written argument (or both) on any time issue of fact and law.~~

- b) ~~The burden of proof in any proceeding shall be upon the complainant therein, except that, in the case of any new matter introduced in connection with any affirmative defense, the burden of proof with respect thereto shall be upon the party which alleges such new matter. Any evidence having probative value in force, relevant and material to facts and issue, shall be admitted into the proceedings, subject only to the objections to the weight thereof as distinguished from admissibility, per se. Immaterial, irrelevant and unduly repetitious evidence shall be excluded. When the admissibility of evidence is in dispute and depends upon fairly arguable interpretations of law, such evidence shall be admitted.~~
- e) ~~Any party may submit evidence in rebuttal of surrebuttal.~~
- d) ~~A party may conduct examination or cross-examinations without rigid adherence to formal rules of evidence, provided the examination or cross-examination does not descend to sheer abuse or harassment of a witness and the examination or cross-examination can be shown to be necessary to full and fair disclosure of facts bearing upon matters in issue.~~
- e) ~~If the Director or hearing officer presiding determines that a witness is hostile or unresponsive, he may authorize the examination by the party calling such witness as if under cross-examination.~~
- f) ~~Any party may call any adverse party as a witness without vouching for his credibility and proceed to examine such adverse party as if under cross-examination. Any party calling a witness, upon a showing that he called the witness in good faith and is surprised by his testimony, may impeach that witness by evidence of prior inconsistent statements.~~
- g) ~~A deposition may be used in lieu of other evidence when taken in compliance with the Illinois Supreme Court rules governing evidence depositions in the Circuit Court of the State of Illinois.~~
- h) ~~Anything herein to the contrary notwithstanding, effect shall be given to the rules of privilege recognized by law with respect to any evidence presented or attempted to be presented.~~

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(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.220 Hearing – Pursuant to Paragraph 1305(b) (Repealed)

- a) ~~If the Director, pursuant to Paragraph 1305(b) of the Act, suspends a registration, a hearing thereon shall be set within the time prescribed by the Act. Notice of such hearing shall be served in accordance with Section 1650.170.~~
- b) ~~Notice of hearing pursuant to this Section shall contain the information required for notices sent pursuant to Section 1650.200.~~
- c) ~~The provisions of Section 1650.200(d) shall apply to a hearing hereunder except that the request for change in hearing officer shall be made at least 7 calendar days prior to the date of hearing unless the Director, upon good cause shown, waives the requirement.~~
- d) ~~Except as hereinbefore noted in this Section, all procedures relating to hearings as set forth in this Part shall apply.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.230 Default Disposition of a Contested Case (Repealed)

~~Unless otherwise provided by law, if a respondent fails to appear at any hearing after proper service of notice, without good cause shown, the hearing officer, if no continuance is granted, may proceed with the hearing and make his decision in the absence of such respondent.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.240 Recording of Testimony (Repealed)

~~At any hearing on denial, revocation or suspension of a registration, the testimony of witnesses may be recorded by mechanical, electrical, electronic or visual recording devices.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.250 Recording of Hearing (Repealed)

~~The record of any hearing shall include:~~

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- a) ~~The Complaint and Answer or other pleadings, if any;~~
- b) ~~The transcript of the proceedings including exhibits of evidence and the findings of fact, conclusions of law and recommendations of the hearing officer, the Director or hearing officer if a person other than the Director conducts such hearing, as the case may be;~~
- e) ~~The final order or determination made by the Director.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.260 Rehearing (Repealed)

- a) ~~Prior to the entry of a final order of denial of, revocation of or suspension of a registration, the hearing officer shall cause to be served upon the respondent a copy of such hearing officer's conclusions of law and fact and recommendations to the Director. Service shall be had personally or by registered mail upon respondent at the address set forth in Section 3100.470, and his attorney.~~
- b) ~~Within 20 days after such service, respondent may present to the Director, a motion in writing for a rehearing, which motion shall specify the particular grounds therefor. Notice of such motion shall be served upon the Director in person or by registered mail at the address set forth in Section 3100.470.~~
- e) ~~If the Director receives such notice for rehearing as set forth in subsection (b) above, or otherwise does not agree with the findings, conclusions or recommendations of the hearing officer, he may refer the matter back to the same or another hearing officer for rehearing.~~
- d) ~~Notice of rehearing shall be served in the same manner as for an original hearing hereunder and the rehearing shall be conducted in the same manner as an original hearing. The evidence received at the rehearing shall be included in the record for the Director's reconsideration and for judicial review.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.270 Final Decisions and Orders (Repealed)

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~~A final decision or order of the Director granting, denying, suspending or revoking a registration shall be made, within a reasonable period after hearing or rehearing, in writing or stated in the record and shall include findings of fact and conclusions of law, separately stated. Findings of fact shall be based exclusively on the evidence presented at the hearing, rehearing, or known to all parties and on matters officially noticed. Findings of fact, if set forth in statutory language, shall be accompanied by a concise and explicit statement of the underlying facts supporting them. A decision or order shall not be made except upon consideration of the record as a whole or such portion thereof as may be cited by any party to the proceeding and as supported by and in accordance with the competent material and substantial evidence. The order shall specify the date on which it shall take effect. A copy of the decision or order shall be delivered or mailed certified mail, return receipt requested, forthwith to each party or to his attorney of record, if he has one. The decision or order shall be sent to the party at the address specified by such party pursuant to Section 3100.470(b) by certified mail, return receipt requested.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.280 Modification in LicenseRegistration

~~Any licenseeregistrant may apply to modify his or her licenseeregistration to authorize the handling of additional controlled substances in the same manner as an original application for licensure on forms provided by the Division, by submitting a letter of request to the Director. The letter shall contain the registrant's name, address, registration number, and the substances and/or Schedules to be added to his registration and shall be signed by the same person who signed the most recent application for registration or renewal or by a person who is then authorized to sign for the former individual. The request for modification shall be handled in the same manner as an application for registration, including the payment of the required fee.~~

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.290 Termination of LicenseRegistration

- a) ~~The licenseeregistration of any person shall terminate if and when thatsuch person dies, ceases legal existence, discontinuesdiscontinued business or professional practice, has his or her primary professional license in any status other than active, or changes his or her name or address as shown on the licenseecertificate of registration.~~
- b) ~~Any licenseeregistrant who ceases legal existence, discontinues business or professional practice, or changes his or her name or address as shown on the~~

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~~licensee certificate of registration~~ shall notify the ~~Division~~Department promptly of ~~that such~~ fact within 10 days.

- c) ~~The license of an advanced practice nurse or physician assistant that has been delegated controlled substance prescriptive authority shall terminate when the delegated authority terminates. In the event of a change in name, the person may apply for a new certificate of registration in advance of the effective date of such change by filing an application and paying the appropriate fee in the same manner as an application for new registration. The application shall be handled in the same manner as an application for registration.~~
- d) ~~When a registrant notifies the Department of change in address, the Department shall issue an amended certificate of registration showing the new address. Such amended certificate must be displayed and otherwise used by the registrant as required by the Act and this Part for the display and use of the certificate which it replaces.~~

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.300 Transfer of LicenseRegistration

No ~~license registration~~ or any authority conferred thereby shall be assigned or otherwise transferred ~~except upon such conditions as the Department may specifically designate and then only pursuant to its written consent.~~

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.310 Security Requirements Generally

- a) All applicants and ~~licensees registrants~~ shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a person has provided effective controls against diversion, the ~~Division~~Department shall use the security requirements set forth in this Section herein as standards for the physical security controls and operating procedures necessary to prevent diversion. Substantial compliance with these standards may be deemed sufficient by the ~~Division~~Department after evaluation of the overall security system and needs of the applicant or licensee registrant.
- b) Physical security controls shall be commensurate with the Schedules, and

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quantity, type and form of controlled substances (e.g., bulk liquids or dosage units, usable powders or non-usable powders) in the possession of the ~~licensee~~registrant in normal business operations. When physical controls become inadequate as a result of a controlled substance being transferred to a different Schedule, or as a result of a non-controlled substance being listed on any Schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the ~~licensee~~registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A ~~licensee~~registrant may adjust physical security controls within the requirements set forth ~~in this Section herein~~ when the need for ~~those such~~ controls decreases as a result of a controlled substance being transferred to a different Schedule, or as a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of a controlled substance in the possession of the ~~licensee~~registrant during normal business operations.

- c) Any additional security evidence, including but not limited to: video surveillance, computer access logs or records, or falsified prescription/medical documentation that demonstrates or captures diversion or other illicit activity involving controlled substances shall be made available to the Division upon request, along with a copy of any DEA Form 106 filed pursuant to Section 3100.360(e).
- d) Personal bags of any kind, including but not limited to purses, handbags and backpacks, are prohibited in any area where controlled substances are handled and/or stored.
- e) A basic alarm system that detects unauthorized entry into the pharmacy area. This does not apply to 24-hour pharmacies that never close.
- f) All pharmacies are required to maintain a key to the licensed pharmacy area held by an employee of the pharmacy who is a licensed pharmacist or a registered pharmacy technician or certified pharmacy technician.
- e) ~~Physical security controls of locations registered under the federal Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 90-513, 84 Stat. 1236), shall be deemed to comply substantially with the standards set forth herein. Any new facilities or work or storage areas constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved, shall not necessarily be deemed to comply substantially with the standards set forth herein, notwithstanding that such facilities or work or storage~~

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~~areas have physical security controls similar to those previously approved.~~

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.320 Factors in Evaluating Physical Security Systems

In evaluating the overall security system of a ~~licensee~~~~registrant~~ or applicant necessary to maintain effective controls against theft or diversion of controlled substances, the ~~Division~~~~Department~~ may consider any of the following factors as it may deem relevant to the need for strict compliance with this Part:

- a) The type of activity conducted;
- b) The type and form of controlled substances handled;
- c) The quantity of controlled substances handled;
- d) The location of the premises and the relationship ~~those~~~~such~~ locations bear on security needs;
- e) The type of building construction comprising the facility and the general characteristics of the building or buildings;
- f) The type of vault, safe, and secure enclosures available;
- g) The type of closures on vaults, safes, and secure enclosures;
- h) The adequacy of key control systems and/or combination lock control systems;
- i) The adequacy of electric detection and alarm systems, ~~if any~~;
- j) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
- k) The adequacy of supervision over employees having access to manufacturing and storage areas;
- l)k) The procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel;

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- ~~m)l)~~ The availability of local police protection or of the licensee's/registrant's or applicant's security personnel; ~~and~~
- ~~n)m)~~ The adequacy of the licensee's/registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations; ~~and~~.
- ~~o)~~ The applicability of the security requirements contained in all federal, State and local laws and regulations governing the management of waste.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.330 Physical Security Controls for Non-Practitioners

Raw materials, bulk materials awaiting processing, and finished products ~~that~~which are controlled substances listed in any Schedule shall be stored in compliance with the physical security controls set forth in 21 CFR 1301.72 (April 1, 2014).~~one of the following secure storage areas:~~

- ~~a)~~ ~~Where small quantities permit, a safe:~~
- ~~1)~~ ~~Which safe has an Underwriters' Laboratories Burglary Rating of T-20, E or better, or the equivalent of such a safe;~~
 - ~~2)~~ ~~Which safe, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and~~
 - ~~3)~~ ~~Which safe, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon unauthorized entry, shall transmit a signal directly to a central protection company of a local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Department may approve.~~
- ~~b)~~ ~~A vault which is of substantial construction with a steel door, combination lock or key lock, and an alarm system.~~

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

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Section 3100.340 Physical Security Controls for Practitioners

- a) Controlled substances listed in ~~Schedules~~Schedule I and II shall be stored in a securely locked, substantially constructed cabinet.
- b) Controlled substances listed in Schedules ~~H~~, III, IV and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies ~~and institutional practitioners (as defined under federal statutes)~~ may disperse ~~those~~such substances throughout the stock of non-controlled substances in ~~such~~ a manner so as to obstruct the theft or diversion of the controlled substances.
- c) This Section shall also apply to non-practitioners authorized to conduct instructional activities or chemical analysis under another registration.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.350 Other Security Controls for Practitioners

- a) The ~~licensee~~registrant shall not employ as an agent or employee who has access to controlled substances any person who has had an application for DEA registration or state controlled substances license~~registration~~ denied, ~~or~~ has had his or her DEA registration or state controlled substances license~~registration~~ suspended or revoked, ~~or~~ has surrendered his or her DEA registration~~federal~~ or state controlled substances license in lieu of discipline~~registration~~ or has been convicted of a violation of state or federal law relative to the manufacture, distribution, dispensing or possession of controlled substances.
- b) The Director, for good cause shown, may, in his or her discretion, waive the requirement of subsection (a), ~~above~~.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.360 Record and Inventorying Requirements Generally

- a) Every ~~licensee~~registrant shall keep records and maintain inventories in conformance with the record keeping and inventorying requirements of federal law, including the requirements prescribed in 21 CFR Part 1304 (April 1, 2014)~~of Title 21 of the Code of Federal Regulations~~, and, for pharmacies, the rules

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promulgated pursuant to the Pharmacy Practice Act (68 Ill. Adm. Code 1330).

- b) All prescription information for electronic controlled substance prescriptions shall be readily retrievable and immediately available to any Division inspector upon request.
- c) Every licensee shall conduct an annual inventory that includes an inventory with an actual count of the inventory on hand for all Schedule II Controlled Substances and an approximate inventory for all Schedule III, IV and V Controlled Substances. The inventory shall be maintained for a period of not less than 5 years.
- d) After a loss or theft of controlled substances, a licensee shall conduct an approximate count inventory with a start date of the last inventory for the controlled substance that was either lost or stolen.
- e) In every instance that a licensee is required by 21 CFR 1301.76 (April 1, 2014) to file with the DEA a Report of Theft or Loss of Controlled Substances (Form 106), a copy shall be sent to the Division within one business day after submission to the DEA, along with the printed name of the person who signed the form. Failure to do so may result in discipline of the licensee. This information should be sent to the Drug Compliance Unit of the Division.
- f) The following shall apply to all licensed pharmacies:
 - 1) Every licensee shall keep a suitable book, file or electronic record keeping system in which shall be preserved for a period of not less than 5 years the original, or an exact, unalterable image, of every written prescription and the original transcript or copy of every verbal prescription filled, compounded or dispensed. The book or file of prescriptions shall at all reasonable times be open to inspection by the duly authorized agents or employees of the Division.
 - 2) Every prescription filled or refilled shall contain in the prescription record the unique identifiers of the persons authorized to practice pharmacy under the Pharmacy Practice Act who fills or refills the prescription.

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- 3) Records kept pursuant to this Section may be maintained in an alternative data retention system, such as a direct digital imaging system, provided that:
- i) The records maintained in the alternative data retention system contain all of the information required in a manual record;
 - ii) The data processing system is capable of producing a hard copy of the electronic record on the request of the Division, its representative, or other authorized local, State, or federal law enforcement or regulatory agency;
 - iii) The digital images are recorded and stored only by means of a technology that does not allow subsequent revision or replacement of the images; and
 - iv) The prescriptions may be retained in written form or recorded in a data recording processing system, provided that the order can be produced in printed form upon lawful request.
- 4) As used in subsection (f)(3), "digital imaging system" means a system, including people, machines, methods of organization and procedures, that provides input, storage, processing, communications, output and control functions for digitized representations of original prescription records.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.370 Persons Entitled to Issue Prescriptions

- a) A prescription for a controlled substance may be issued only by an individual practitioner who ~~is~~:
- 1) Holds an active professional license in Illinois as an individual practitioner~~Authorized to prescribe controlled substances by the State of Illinois;~~ and
 - 2) Holds an active controlled substances license under the Act~~Deemed registered or is exempted from licensure registration pursuant to Section 3100.80~~Paragraph 1302 of the Act.

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- b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner pursuant to the directions and order of ~~the that said~~ practitioner in conformance with Section 312 of the Act.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.380 Purpose of Issuance~~Issue~~ of a Prescription

- a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription within the meaning and intent of Section 312~~Paragraphs 1308-1312~~ of the Act, but that is not, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.
- b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.
- c) A prescription may not be issued for the dispensing of narcotic drugs listed in any Schedule to a narcotic drug dependent person for the purpose of continuing his or her dependence upon such drugs, except in the case of the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.
- d) A practitioner shall not self-prescribe or self-dispense controlled substances. A practitioner may not prescribe controlled substances to an immediate family member unless there is a bona fide practitioner-patient relationship and appropriate records are maintained for all treatment of the family member.
- e) The provisions of the federal Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act) (21 USC 801 et seq.) also apply and all federal

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regulations (74 Fed. Reg. 15596 (April 6, 2009)) adopted under that Act are hereby incorporated by reference.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.390 Manner of Issuance of Prescription

- a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and DEA federal registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g., "J. H. Smith" or "John H. Smith"). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner except in the instances of a Schedule II prescription, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by this Part.
- b) A practitioner may sign a paper prescription in the same manner as he or she would sign a check or legal document (e.g., J.H. Smith or John H. Smith). When an oral order is not permitted, paper prescriptions shall be written with ink or printed and shall be manually signed by the practitioner. A computer-generated prescription that is printed out or faxed by the practitioner must be manually signed.
- c) A prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the Act and this Part. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form required by this Part. Neither a pharmacist nor a pharmacy technician may act as an agent for a practitioner.
- d) Prescriptions sent via a facsimile transmission do not constitute electronic prescriptions in accordance with Section 311.5 of the Act.

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- e) Electronic prescribing is permitted as described in Section 311.5 of the Act.
- b) ~~Any person referred to in Section 3100.80 who is exempted from registration under statute or this Part shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in statute or this Part, in lieu of the registration number of the practitioner required by this Part. Each prescription shall have the name of the person so specified by Section 1650.80 printed on it.~~
- e) ~~An official exempted from registration under statute shall include on all prescriptions issued by him, his branch of service or agency (e.g., "U. S. Army" or "Public Health Service") and his service identification number, in lieu of the registration number of the practitioner required by these regulations. The service identification number for a Public Health Service practitioner is his social security identification number. Each prescription shall have the name of the officer stamped or printed on it, as well as the signature of the officer. Public Health Service practitioners shall issue prescriptions for Schedule II controlled substances on conventional prescription forms, not triplicate prescription blanks.~~

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.400 Requirement of Prescription for Schedule II Controlled Substances

- a) A pharmacist may fill a Schedule II controlled substance prescription ~~only upon a written or electronic prescription that conforms~~triplicate prescription blank and in accordance with the requirements of Section 311.5 or 312~~Paragraph 1314 of the Act, respectively, and the requirements of this Part, except a prescription issued by a Public Health Service practitioner or out-of-state practitioner may be filled when written upon a conventional prescription form.~~
- b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his or her professional practice subject to the Act and this Part.
- c) Changes in a Prescription
- 1) A pharmacist may not change the following components of a prescription for a Schedule II controlled substance:

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- A) Date written, or add the date;
 - B) Name of the patient;
 - C) Name of the prescriber, or add a signature; and
 - D) Name of the drug.
- 2) Any other components of a prescription for a Schedule II controlled substance may be changed after consultation with the prescriber.
- e) ~~An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.~~
- d) In an emergency situation, as defined by subsection (e), ~~below~~, a pharmacist, in accordance with requirements in 21 CFR Section 1306.11(d) (April 1, 2014) ~~of Title 21 of the Code of Federal Regulations~~ and Section 309 Paragraph 1309 of the Act, may fill an oral prescription for a Schedule II controlled substance ~~prescription which is oral or written on a form other than a triplicate prescription blank.~~
- e) For the purposes of authorizing an oral prescription of a controlled substance listed in Schedule II of the Act, the term "emergency situation" means those situations in which the prescribing practitioner determines that:
- 1) Immediate ~~That immediate~~ administration of the controlled substance is necessary for proper treatment of the intended ultimate user; ~~and~~
 - 2) No ~~That no~~ appropriate alternative treatment is available, including administration of a drug that ~~which~~ is not a controlled substance under Schedule II of the Act; and
 - 3) It ~~That it~~ is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

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- f) Notwithstanding any other provision in this Section, prescriptions for Schedule II controlled substances may be sent to a pharmacy via facsimile in accordance with Section 313 of the Act.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.410 Refilling of Prescription

- a) Each refilling of a prescription of a controlled substance listed in Schedules III, IV or V:
- 1) shall be entered on the back of the prescription or in the electronic prescription record;~~and~~
 - 2) shall indicate the date, quantity, and name or initials of the dispensing pharmacist for each prescription; ~~and~~
 - 3) shall be dated by the pharmacist as of the date of dispensing; ~~and~~
 - 4) shall state the amount dispensed.
- b) If the pharmacist merely signs or initials and dates the back of the prescription, he or she shall be deemed to have dispensed a refill for the full face amount of the prescription.
- c) A pharmacist may contact the prescriber to refill a Schedule III, IV or V controlled substance only at the request of a patient or patient's representative. The patient's agreement to utilize a pharmacy auto-fill program, medication adherence plan or long term care or similar related care contract constitutes a request from the patient.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.420 Partial Filling of Prescriptions

- a) The partial filling of a prescription for a controlled substance listed in Schedules ~~III, IV~~ IV or V is permissible within 6 months after the date on which the prescription was issued provided that:

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- 1) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed;
 - 2) Each partial filling is recorded in the same manner as a refilling, but shall not be considered a refill.
- b) When Partial Filling of a Schedule II Controlled Substance is Permissible
- 1) Except as provided in ~~subsections~~subparagraph (b)(2), ~~below,~~ the partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he or she makes a notation of the quantity supplied on the face of the written prescription, ~~(or~~ written record of the emergency oral prescription, or in the electronic prescription record). The remaining portion of the prescription may be filled within 72 hours ~~after~~ the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.
 - 2) A prescription~~Prescriptions~~ for Schedule II controlled substances written for ~~a patient~~patients in a long term care facility~~Long Term Care Facilities~~ (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities, to include individual dosage units. If there is any question whether the patient may be classified as having a terminal illness, contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is terminally ill or an LTCF patient. A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. The total quantity of Schedule

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II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions, for patients in [ana LTCF](#) ~~or for patients with a medical diagnosis documenting a terminal illness~~, shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

- 3) Information pertaining to current Schedule II prescriptions for patients in [ana LTCF](#) ~~or for patients with a medical diagnosis documenting a terminal illness~~ may be maintained in a computerized system if this system has the capability to permit:
 - A) Output (display or printout) of the original prescription number, date of issue, [identification of prescribing individual practitioner](#), identification of patient, [address of the identification of LTCF or address of the hospital or residence of the terminally ill patient](#), identification of medication authorized (to include dosage form, strength and quantity), listing of partial fillings that have been dispensed under each prescription and the information required in [subsections](#)~~subparagraph~~ (b)(2), ~~above~~.
 - B) Immediate (real time) updating of the prescription record each time a partial filling of the [Schedule II](#) prescription is conducted.
 - C) Retrieval of partially filled Schedule II prescription information is the same as required by [21 CFR Section 1306.22\(b\)\(4\) and \(5\) \(April 1, 2014\) of Title 21 of the Code of Federal Regulations](#) for Schedule III and IV prescription refill information.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.430 Prescriptions from Out-of-State Practitioners and Exempt Federal Practitioners

- a) ~~Notwithstanding any other provision of this Part, Illinois pharmacists may fill prescriptions for controlled substances issued by a practitioner actively licensed in another United States jurisdiction and who holds an active DEA registration in conformance with the Act and this Part. Every pharmacist who fills an emergency Schedule II prescription, or a Schedule II prescription issued by an out-of-state practitioner or an exempt federal practitioner, shall make a copy and endorse on~~

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~~the reverse side of such copy the name and address of the pharmacy, the date when filled and the signature of the pharmacist who filled such prescription and forward said copies as set forth in Paragraph 1311 of the Act.~~

- b) ~~For purposes of this Section, an out-of-state practitioner is one who is of a category licensed in this state to issue prescriptions.~~

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.440 Authority to Make Inspections

- a) In carrying out its functions under the Act, the ~~Division, Department~~ through its inspectors, is authorized in accordance with ~~Section 302 Paragraph 1302~~ of the Act to enter controlled premises and conduct administrative inspections of those premises, thereof with subpoena or notice, during regular business hours and without disrupting patient care, for the purpose of:
- 1) Inspecting, copying and verifying the correctness of records, reports or other documents required to be kept or made under the Act and this Part. Upon the Division's request, the licensee's agent or employee shall produce those records. ~~the rules promulgated under the Act, including, but not limited to, inventory and other records required to be kept pursuant to this Part, order form records required to be kept pursuant to this Part, prescription and distribution records required to be kept pursuant to this Part, shipping records identifying the name of each carrier used and the date and quantity of each shipment, and storage records identifying the name of each warehouse used and the date and quantity of each storage;~~
 - 2) Inspecting within reasonable limits and in a reasonable manner all pertinent equipment, finished and unfinished controlled substances and other substances or materials, containers and labeling found at the controlled premises relating to the Act;
 - 3) Making a physical inventory of all controlled substances on hand at the premises;
 - 4) Collecting samples of controlled substances or precursors or any other relevant evidence (in the event any samples are collected during an inspection, the inspector shall issue a receipt for ~~thesuch~~ samples to the

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owner, operator or agent in charge of the premises);

- 5) ~~Checking of records and information on distribution of controlled substances by the registrant as they relate to total distribution of the registrant (i.e., has the distribution in controlled substances increased markedly within the past year and, if so, why?); and~~
 - 6) ~~Except as provided by law, all other things therein (including records, files, papers, processes, controls and facilities) appropriate for verification of the records, reports and documents referred to above or otherwise bearing on the above provisions of the Act and the rules thereunder.~~
- b) Refusal by the ~~licensee, registrant or~~ owner, operator, agent or other person in charge of the controlled premises to allow inspection and fully comply with the inspection pursuant to this Part, shall constitute a basis for suspension or revocation of registration.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.450 Inspections

- a) An inspection shall be carried out by an inspector or designee from the ~~Division~~Department authorized by the Act or other Illinois statute to carry out ~~thesuch~~ inspection.
- b) ~~TheSuch~~ inspector or designee upon entry shall:
 - 1) State the purpose of his or her inspection to the owner, operator, agent or other person in charge of the premises to be inspected.
 - 2) Present appropriate credentials to ~~thesuch~~ owner, operator, agent or other person in charge ~~for making such inspection~~.
- c) Appropriate credentials for the making of ~~ansuch~~ inspection shall include but are not limited to a duly issued identification card, badge, etc., of the Division for the inspector or designee.
 - 1) ~~Duly issued identification card, badge, etc., of the Department for such inspector;~~

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- 2) ~~Notice of inspection issued by the Department containing:~~
- A) ~~The name and title of the owner, operator, agent or other person in charge of the premises;~~
 - B) ~~The controlled premises name;~~
 - C) ~~The controlled premises address to be inspected;~~
 - D) ~~The date of the inspection; and~~
 - E) ~~The signature of the inspector.~~
- d) A designee is an employee of the Division with the training and expertise equivalent to an inspector of the Division.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.460 Failure to Comply with Rules

- a) Failure of a ~~licensee~~registrant to comply with ~~this Part~~the rules as set forth herein constitutes a basis for revocation, ~~or suspension or other discipline of the licensee's license~~such registrant's certificate of registration.
- b) Failure of an applicant ~~for registration~~ to comply with this Part as applicable to ~~that~~such applicant constitutes a basis for denial of ~~license~~such application.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.470 Address for Notices (Repealed)

- a) ~~Unless the Act or this Part otherwise provides, all notices required by this Part to be sent to the Department or Director shall be sent to the Department of Professional Regulation, 100 West Randolph, Suite 9-300, Chicago, Illinois 60601, by certified mail, return receipt requested.~~
- b) Street Address

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- 1) ~~Every applicant or registrant shall provide the Department with an address to which all communications from the Department to such applicant or registrant shall be sent. Such address shall be an actual street address and shall include the city or town, state and zip code number.~~
- 2) ~~Furnishing of post office box numbers or other forms of address shall not constitute sufficient compliance with subsection (b)(1).~~
- e) ~~The address required by subsection (b) shall be provided by the applicant or registrant either as part of his/her application for registration or renewal or by letter to the Department.~~

(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.480 Granting Variances~~Suspension or Modification of Rules and Regulations~~

The Director may grant variances from this Part in individual cases when he or she finds that:

- a) the provision from which the variance is granted is not statutorily mandated;
- b) no party will be injured by the granting of the variance; and
- c) the rule from which the variance is granted would, in the particular case, be unreasonable or unnecessarily burdensome.

~~This Part may be suspended or modified by the Director of the Department, in whole or in part, in the interests of justice. The Department, by and through its Director, reserves the right to waive compliance with any of this Part whenever, in the Director's judgment, no party will be injured thereby.~~

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.490 Construction of Rules and Regulations (Repealed)

~~This Part should not be construed to abrogate, modify or limit any rights, privileges or immunities granted or protected by the Constitution or laws of the State of Illinois nor to deny any person life, liberty or property without due process of law.~~

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(Source: Repealed at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.500 Ordering Schedule II Controlled Substances~~Written Order~~

- a) ~~Schedule II controlled~~Controlled substances ~~identified below~~ shall be distributed ~~to a licensee and received by a licensee~~registrant to another registrant only upon completion of an Administration Form 222~~pursuant to a written order~~:
- 1) ~~which are listed under Schedule I or II of the Schedules of Controlled Substances provided by the Illinois Controlled Substances Act or the rules prescribed by the Illinois Dangerous Drugs Commission; and~~
 - 2) ~~which are not listed under Schedule I or II of the Schedules of Controlled Substances of either the federal Controlled Substances Act or Title 21 of the Code of Federal Regulations.~~
- b) ~~Such written order:~~
- 1) ~~shall contain the following information:~~
 - A) ~~name, address and Drug Enforcement Administration ("DEA") registration number of the ordering registrant;~~
 - B) ~~name, address and DEA registration number of the selling or transferring registrant;~~
 - C) ~~name of the drug ordered;~~
 - D) ~~finished or bulk form and strength of the article (e.g., 50 mg. tablet);~~
 - E) ~~number of the units or volume in each container (e.g., 100-tablet bottle, one ml. ampoule, 10 ml. vial);~~
 - F) ~~number of containers ordered; and~~
 - G) ~~name and quantity per unit of the controlled substances contained in the article ordered if not in pure form (e.g., Talwin Comp. 12.5 mg. per tablet); and~~

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- 2) ~~shall be signed and dated by a person authorized to execute federal order forms or his attorney in fact.~~
- be) The original of ~~the Administration Form 222~~~~such written order~~ shall be maintained by the selling or transferring ~~licensee~~~~registrant~~ for a period of two years with such other controlled substances records as shall be maintained by ~~the licensee~~~~such registrant~~. A copy of ~~the Administration Form 222~~~~such written order~~ shall be maintained by ~~the ordering licensee~~~~registrant~~ for a period of two years ~~with such other controlled substances records as shall be maintained by such registrant.~~

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.510 ~~Paragraph 1312(d)~~ Record Keeping

Records for dispensing and administering required by Section 312(d) of the ~~Illinois Controlled Substances Act (Ill. Rev. Stat. 1985, ch. 56, par. 1312(d))~~ shall be kept in accordance with 21 CFR 1304 (April 1, 2014), as follows:

- a) ~~Schedule H~~
- 1) ~~Designated Products~~
- A) ~~Designated products dispensed, but not administered, by an individual practitioner shall be recorded on an official triplicate prescription blank. A legible duplicate prescription blank shall be sent to the Department by the 15th day of the month following the month in which the controlled substance was dispensed. The original of the prescription blank shall be retained by the practitioner for two years and kept separately from prescription blanks recording actual prescriptions. Prescription blanks required by this Section shall be marked with a "D" in the upper right hand corner.~~
- B) ~~Designated products administered by an individual practitioner shall be recorded on a separate document entitled "Patient Controlled Substances Record."~~

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- 2) ~~Non-Designated Products~~
~~Schedule II controlled substances which are not designated products and which are dispensed or administered by an individual practitioner shall be recorded on a separate document entitled "Patient Controlled Substances Record."~~
- b) ~~Schedules III, IV and V~~
~~Schedules III, IV and V controlled substances which are dispensed by an individual practitioner shall be recorded on a separate document entitled "Patient Controlled Substances Record." This subsection (b) does not apply to Schedules III, IV and V controlled substances administered by an individual practitioner.~~
- e) ~~All Patient Controlled Substances Records, for Schedules II through V, required by this Section shall be maintained in the same place and shall be arranged alphabetically by drug or substance, with a separate record for each dosage form. For each instance of dispensing or administering, the "Patient Controlled Substances Record" shall contain an entry with the following information:~~
- 1) ~~The date of dispensing or administering;~~
 - 2) ~~The name of the patient to whom the drug or substance was dispensed or administered;~~
 - 3) ~~The quantity (number of units or volume) dispensed or administered; and~~
 - 4) ~~The name or initials of the individual who dispensed or administered the controlled substance on behalf of the individual practitioner, if not dispensed or administered by the practitioner himself.~~

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.520 Emergency Medication Kits

Long term care facilities may store controlled substances in ~~an~~the emergency medication kit if permitted by the licensing regulations of the Illinois Department of Public Health for the facility's particular level of care ("DPH Standards"). The following requirements must be met when controlled substances are stored in emergency medication kits:

- a) Controlled substances for emergency medication kits must be obtained from a

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DEA registered hospital, pharmacy or practitioner.

- b) Emergency medication kits shall be safeguarded as provided in DPH Standards.
- c) Only the director of nursing services, registered nurse on duty, licensed practical nurse on duty, or consultant pharmacist or practitioner shall have access to controlled substances stored in emergency medication kits.
- d) No more than ~~10~~^{ten} different controlled substances shall be placed in an emergency medication kit, and there shall be no more than three single, injectible doses of each controlled substance.
- e) Controlled substances in emergency medication kits may be administered only under the emergency conditions set forth in DPH Standards and only by registered nurses, licensed practical nurses or practitioners, in compliance with [Paragraphs 21 CFR 1306.11 and 1306.21 \(April 1, 2014\) of Title 21 of the Code of Federal Regulations](#).
- f) A proof-of-use sheet shall be contained in the emergency medication kit for each separate controlled substance included. Entries shall be made on the proof-of-use sheet by the nursing staff or practitioner when any controlled substances from the kit are used. The consultant pharmacist shall receive and file for two years a copy of all completed proof-of-use sheets.
- g) Whenever the emergency medication kit is opened, the consultant pharmacist shall be notified within 24 hours. During any period that the emergency kit is opened, a shift count shall be done on all controlled substances until the kit is closed or locked by the consultant pharmacist. Shift counts are not mandatory when the kit is sealed. Proper forms for shift counts shall be contained in the emergency medication kit.
- h) The consultant pharmacist shall check the controlled substances in the emergency medication kit at least monthly and so document inside the kit.
- i) Failure to comply with any provision of this Section, or of any applicable provision of ~~State~~^{state} or federal statutes or regulations pertaining to controlled substances will result in loss of the privilege of having or placing controlled substances in emergency medication kits.

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(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)

Section 3100.530 Transfer Between Pharmacies of Prescription Information for Refill Purposes

Transfer between pharmacies of prescription information shall be done in accordance with 68 Ill. Adm. Code 1330.720 (rules of the Pharmacy Practice Act).

- a) ~~The one-time transfer of original prescription information for a controlled substance listed in Schedules III, IV or V of the Illinois Controlled Substances Act (Ill. Rev. Stat. 1981, ch. 56½, pars. 1207-1212) for the purpose of refill dispensing is permissible between pharmacies on a one-time basis subject to the following requirements.~~
- b) ~~The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist completes the following steps:~~
 - 1) ~~Invalidates the prescription by writing the word "VOID" on the face of same.~~
 - 2) ~~Records on the reverse of the invalidated prescription the name, address and the DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.~~
 - 3) ~~Records the date of the transfer and the name of the pharmacist transferring the information.~~
- e) ~~The pharmacist receiving the transferred prescription information shall take the following steps:~~
 - 1) ~~Write the word "transfer" on the face of the transferred prescription.~~
 - 2) ~~Provide all information required to be on a prescription pursuant to Section 3100.390 and include:~~
 - A) ~~Date of issuance of original prescription;~~
 - B) ~~Original number of refills authorized on original prescription;~~

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- ~~C) Date of original dispensing;~~
 - ~~D) Number of valid refills remaining and date of last refill;~~
 - ~~E) Pharmacy's name, address, DEA registration number and date original prescription information was transferred;~~
 - ~~F) Name of transferor pharmacist.~~
- ~~3) Both the original and transferred prescription must be maintained for a period of two years from the date of last refill.~~
- d) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferral as described in subsections (a) and (b) above.

(Source: Amended at 39 Ill. Reg. 3656, effective February 27, 2015)