Regulatory Analysis

Notice of Intended Action to be published: Iowa Administrative Code 481—Chapters 550 and 551 "Definitions; Licenses, Registrations, and Permits"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 124.303, 147.76, 147.80, 155A and 272C

State or federal law(s) implemented by the rulemaking: Iowa Code sections 124.302, 147.76 and 147.80 and chapters 155A and 272C

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

August 29, 2024	6200 Park Avenue, Suite 100
1 p.m.	Des Moines, Iowa

Virtual participation for the public hearing will be available on the Department of Inspections, Appeals, and Licensing website.

Public Comment

Any interested person may submit written comments concerning this Regulatory Analysis. Written comments in response to this Regulatory Analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

This proposed rulemaking is intended to establish a chapter for definitions to be adopted by reference in other chapters applicable to the Board of Pharmacy. The proposed rulemaking also establishes one chapter for the requirements to obtain and maintain a license, registration or permit to engage in the practice of pharmacy, handling of controlled substances, or distribution of prescription products in or into the state of Iowa. The proposed rules provide general requirements for applicants; notification requirements for licensees, registrants, and permittees; and specific requirements for each different type of license, registration or permit. Citations to 481—Chapters 552 through 557 refer to those chapters as proposed in Regulatory Analyses published herein (IAB 8/7/24).

Analysis of Impact

1. Persons affected by the proposed rulemaking:

- Classes of persons that will bear the costs of the proposed rulemaking:

The individuals and entities that will bear the costs of the proposed rulemaking are those that seek a license, registration or permit to engage in the licensed, registered or permitted activities within the practice of pharmacy, distribution of drugs, or handling of controlled substances.

- Classes of persons that will benefit from the proposed rulemaking:

The individuals who will benefit from the proposed rulemaking are the citizens of Iowa, who can be assured that individuals and entities involved in the licensed activities have met certain

requirements for a license, registration, or permit and that the Board has oversight to take disciplinary action when the standard of care has not been met in order to protect the health and safety of Iowans.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:

- Quantitative description of impact:

Besides the specific fees identified in the proposed rulemaking for initial licensure and renewal, some licensees, registrants or permittees would incur additional costs associated with attaining the minimum standard requirements for initial licensure or renewal. Specifically, an individual seeking a pharmacist license in Iowa would be required to graduate from an Accreditation Council for Pharmacy Education (ACPE)-accredited college of pharmacy or, if a graduate of a foreign pharmacy school, meet certain equivalency benchmarks. Additionally, a pharmacist license applicant is required to successfully pass competency examinations for minimum clinical and jurisprudence knowledge. The examinations are administered by an external partner. An individual seeking a pharmacist-intern registration would be required to be enrolled in the individual's first professional year at an ACPE-accredited college of pharmacy. An individual seeking a registration as a Certified Pharmacy Technician would be required to successfully complete an examination, and possibly a program, from an authorized credentialing body to determine minimum competence to be a nationally certified technician. An entity seeking a license to engage in drug distribution within the drug supply chain as a wholesale distributor or third-party logistics provider would be required to attain drug distributor accreditation from an authorized accrediting body. An entity seeking a license to distribute non-patient-specific compounded preparations as an outsourcing facility would be required to first register with the United States Food and Drug Administration (FDA).

- Qualitative description of impact:

The impact to patient safety is paramount for the Board. The minimum requirements for the various licenses, registrations, and permits are intended to ensure that competent individuals and entities are authorized to engage in the practice of pharmacy, the handling of controlled substances, and the distribution of drugs within the drug supply chain. Lack of minimum qualifications would presumably result in patient harm and, without such license, registration or permit, would result in the inability of the Board to take action to limit the harmful behavior.

3. Costs to the State:

- Implementation and enforcement costs borne by the agency or any other agency:

The Department currently employs 5.0 full-time equivalent (FTE) positions for licensing specialists to process applications for initial, renewal, and reactivation licenses, registrations and permits under the statutory oversight of the Board. The Department also employs 8.0 FTE positions for compliance officers to engage in routine inspections and to investigate complaints relating to such licenses, registrations, and permits under the Board's oversight. The Board meets six times per year to, in part, evaluate investigative reports or hold administrative hearings for contested cases. The cost of the Board meetings includes a $50 per diem as well as reimbursement of travel expenses for Board members who travel. Hybrid meetings are offered for the convenience of all participants.

- Anticipated effect on state revenues:

The licensing fees would not impact state revenues since the licensing fees are retained within the Licensing and Regulation Fund established by 2023 Iowa Acts, Senate File 557. The proposed singular initial application fee for a pharmacist license applicant would result in lower funds for the Licensing and Regulation Fund with the elimination of the initial pharmacist license application processing fee ($72), separate application fee for examination retake requests ($36), and fee for a temporary license ($20) for a license by license transfer applicant. When the Board takes public disciplinary action in which a civil penalty is assessed, such penalty is deposited into the State's General Fund.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

The Board believes that the minimum requirements for a license, registration or permit within the practice of pharmacy, the handling of controlled substances, and the distribution of drugs is justified to prevent the burden and cost of patient harm by ensuring minimum competency and regulatory oversight for the authorized activity. The cost of inaction would be increasing the potential for public harm that would continue unchecked without review prior to initial licensure, periodic compliance inspections, and complaint investigations. In large part, the license, registration and permit requirements mirror those required in many other states.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

When attempting to achieve the intended outcome of minimum standards for allowing an individual or entity to engage in the practice of pharmacy, the handling of controlled substances, or distribution in the drug supply chain to prevent public harm, the Board cannot identify less costly or less intrusive methods. Certainly, lower standards could be considered to lower the barrier of entry to practice, but such lowering of standards would be anticipated to increase the potential for public harm.

6. Alternative methods considered by the agency:

- Description of any alternative methods that were seriously considered by the agency:

Since the federal Drug Supply Chain and Security Act (DSCSA) was enacted in 2012, the Board has considered the licensing requirements for wholesale distributors and third-party logistics providers. Alternative methods that have been considered by the Board have included elimination of licensure of any kind to defer to the FDA for regulatory oversight as well as removal of the state requirement for drug distributor accreditation. The Board has consistently rejected those options in support of continued state licensure with an accreditation requirement. For pharmacist license applicants, the Board has considered the elimination of the jurisprudence examination but has continued to determine that the demonstration of competence in the area of federal and state laws, rules and regulations is necessary to ensure the minimum standard of practice.

- Reasons why alternative methods were rejected in favor of the proposed rulemaking:

As it relates to licensure and drug distributor accreditation requirements for those involved in the drug supply chain, the Board has recognized that the vast majority of entities in the drug supply chain are located outside the state of Iowa, which results in either significant increases in costs for the State to conduct routine inspections of those locations intending to ship drug products into this state or relying on the regulatory authority of the other 49 states and territories to do the same. The Board has determined that it cannot reasonably rely on the scrutiny of other states with whose processes it is not familiar and therefore can only be ensured with the minimum standard of accreditation. The Board acknowledges that FDA regulations are still pending that, once published as final, may ultimately not include an accreditation requirement. In that case, the federal DSCSA prohibits states from having more or less strict licensing standards from those determined by FDA. If or when FDA regulations are finalized that do not include an accreditation requirement, the Board will modify its requirements in accordance with federal law. As noted above for pharmacists, the Board has determined that demonstrating jurisprudence competence as a minimum requirement is necessary to ensure a minimum standard of practice by pharmacists practicing in this state.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.

- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

While not specifically identified in this proposed rulemaking, any licensee, registrant, or permittee is authorized to petition the Board for a waiver of Board rules that are not also required by the Iowa Code (in accordance with 481—Chapter 6). This opportunity is available to any business entity regardless of its size. A petition for waiver of one or more Board rules will include information that would demonstrate how the petitioner would continue to protect the public by alternative means if the rule is waived, in whole or in part.

Text of Proposed Rulemaking

ITEM 1. Adopt the following **new** 481—Chapter 550:

CHAPTER 550
DEFINITIONS

481—550.1(124,147,155A,272C) Definitions. For the purposes of 481—Chapters 550 through 557, and in addition to the definitions found in Iowa Code sections 124.101 and 155A.3, the following definitions apply:

"3PL" means third-party logistics.

"ACPE" means the Accreditation Council for Pharmacy Education.

"AMDS" means an automated medication dispensing system.

"Board" means the board of pharmacy.

"Certified pharmacy technician" or *"certified technician"* means an individual who holds a valid current national certification and who has registered with the board as a certified pharmacy technician.

"CFR" means the United States Code of Federal Regulations.

"CGMP" means current good manufacturing practices.

"Change of ownership" occurs when the owner listed on the pharmacy's most recent application changes.

"Continuing education" means a structured educational activity that is applicable to the practice of pharmacy, that promotes problem solving and critical thinking, and that is designed or intended to support the continuing development of pharmacists while maintaining and enhancing their competence in the practice of pharmacy.

"CSA" means the Iowa Controlled Substances Act.

"DEA" means the United States Drug Enforcement Administration.

"DSCSA" means the federal Drug Supply Chain Security Act, Part II of the Drug Quality and Security Act, as codified in 21 U.S.C. §360eee-1 and 360eee-2 as created November 27, 2013.

"EMS program" means an emergency medical services program that is licensed with the bureau of emergency and trauma services.

"FDA" means the United States Food and Drug Administration.

"FPGEC" means the Foreign Pharmacy Graduate Examination Committee.

"MPJE, Iowa Edition" means the Multistate Pharmacy Jurisprudence Examination that is specific to the state of Iowa.

"NABP" means the National Association of Boards of Pharmacy.

"NAPLEX" means the North American Pharmacist Licensure Examination.

"National pharmacy technician certification" means documentation of the successful completion of a program and examination, including renewal, for the certification of pharmacy technicians that is accredited by the National Commission for Certifying Agencies.

"NCDQS" means the National Coalition for Drug Quality and Security.

"NDC" means national drug code.

"Office use" means the utilization of a compounded preparation from an outsourcing facility for direct patient administration by a health care practitioner in the normal course of professional practice or for dispensing by a heath care practitioner or a pharmacy pursuant to a patient-specific prescription for patient self-administration.

"PMP" means the Iowa prescription monitoring program.

"Preceptor" means an Iowa-licensed pharmacist in good standing.

"U.S.C." means the United States Code.

"USP" means the United States Pharmacopoeia.

This rule is intended to implement Iowa Code sections 124.302, 147.76 and 147.80 and chapters 155A and 272C.

ITEM 2. Adopt the following **new** 481—Chapter 551:

CHAPTER 551
LICENSES, REGISTRATIONS, AND PERMITS

481—551.1(124,147,155A,272C) Definitions. The definitions found in 481—Chapter 550 are incorporated by reference into these rules.

481—551.2(124,124B,147,155A,272C) General requirements.

551.2(1) *Issuance.* The board will issue or renew a license, registration or permit upon receipt of a completed application and determination that the applicant has satisfied the requirements of applicable statutes and any additional criteria specified by these rules. A license or registration is necessary prior to engaging in the authorized activity into, out of, or within this state. A permit is necessary prior to engaging in the authorized activity in this state. Except as provided in these rules, the expiration date for any newly issued license, registration or permit will be extended by one year when the initial license, registration or permit is issued within two months of the standard expiration date.

551.2(2) *Board forms.* Initial applications, renewal applications, and other forms used for licensure, registration, or other purposes will be on board forms unless specified in these rules.

551.2(3) *Fees.*

a. Fees are nonrefundable and nontransferable and will be considered a repayment receipt as defined in Iowa Code section 8.2.

b. Fees apply to applications submitted for initial, changed and renewed licenses, registrations or permits or for a criminal history background check, when applicable.

c. A license, registration or permit will be invalidated when the method of payment is returned or rejected.

551.2(4) *Criminal history background check.* The fee for a criminal history background check is $45 and, in accordance with Iowa Code section 155A.40, will be necessary for:

a. Pharmacists.

b. Outsourcing facility supervising pharmacists, except as provided in subparagraph 551.14(2)*"a"*(1).

c. Wholesale distributor and 3PL facility managers, except as provided in paragraphs 551.13(3)*"a"* and 551.16(3)*"a."*

551.2(5) *Separate locations.* Each separate business location wherein activities occur that require a license, registration or permit will be separately licensed, registered or permitted.

551.2(6) *Complete applications.* An application is considered complete when all application information and fees are submitted to the board.

551.2(7) *Incomplete applications.* Applications that remain incomplete after six months from the date of initial board receipt will expire, except that applications for pharmacist licensure will expire:

a. After one year for an application for license transfer.

b. After two years for an application for license by examination or score transfer.

551.2(8) *Inspections.*

a. Prior to the issuance of a new license, registration or permit for any business that will maintain prescription drugs or for any individual CSA registrant who will maintain controlled substances, an inspection will be required, except as provided for limited distributors pursuant to subrule 551.15(1).

b. Any CSA registrant that does not maintain stocks of controlled substances will provide notice to the board at least 30 days prior to procuring controlled substances, and an inspection will be required prior to storage of controlled substances at the registered location.

551.2(9) *Denial of license, registration or permit.*

a. Grounds for denial. The board or authorized delegate may deny the issuance or renewal of a license, registration or permit for:

(1) Any violation of the laws of this state, another state, or the United States by the applicant relating to prescription drugs, controlled substances, or nonprescription drugs or for a violation of any rule of the board.

(2) The receipt of a certificate of noncompliance from child support services of the department of health and human services or the centralized collection unit of the department of revenue.

(3) The furnishing of false or fraudulent information in the application process.

(4) Noncompliance with licensing or practice standards under previously granted licenses, registrations or permits.

(5) Any other factors or qualifications the board considers relevant to and consistent with public health and safety.

b. Appeal of denial. An individual whose application is denied may, within 30 days after issuance of the notice of denial, appeal to the board for reconsideration of the application.

551.2(10) *Renewals.* Renewal applications will be submitted to the board in accordance with Iowa Code section 147.10.

551.2(11) *Untimely renewals or change applications.* Any licensee, registrant or permittee that fails to timely apply for renewal or change is provided a 30-day grace period to submit an application. The applicant may continue engaging in the authorized activity while the application is pending. Untimely applications will be subject to a late penalty fee that is equal to the application fee.

551.2(12) *Expired licenses, registrations or permits—reactivation.* Any licensee, registrant or permittee that fails to apply for renewal or change within the 30-day grace period may not engage in the authorized activity until the license, registration or permit is reactivated. An application will be subject to a fee of four times the application fee, except as provided herein.

a. A reactivation fee will not be assessed when the applicant voluntarily cancelled the license, registration or permit when the applicant discontinued the authorized activity.

b. The reactivation fee for a wholesale distributor or 3PL provider license will be $2,000.

c. The reactivation fee for a pharmacist license will be $630.

d. The reactivation fee for a limited distributor license will be $500.

e. The reactivation fee for a precursor substances permit will be $360.

551.2(13) *Termination of licenses, registrations or permits.*

a. A business license, registration or permit will terminate when the business ceases to legally exist or discontinues business.

b. An individual license or registration will automatically terminate upon the death of the individual or upon the issuance of a superseding license or registration (e.g., issuance of a pharmacist license will result in the termination of the individual's intern registration).

c. When a license or registration was issued by the board based on an underlying license, certificate or other credential and the underlying license, certificate or credential expires or is suspended or revoked, the board may take action to suspend or revoke the license or registration. Board action will not be taken against a pharmacist license issued by license transfer when the pharmacist's original license upon which license transfer was granted expires.

551.2(14) *Voluntary cancellations.*

a. Businesses and CSA registrants who stock controlled substances.

(1) A licensee, registrant or permittee may voluntarily request cancellation via written notice to the board at least 30 days prior to the discontinuation of business. The notice will include the following information: licensee, registrant or permittee name and address; license, registration or permit number; anticipated date of business discontinuation; and, if applicable, the identification of the licensee, registrant or permittee to whom drugs and records will be transferred. A cancelled license, registration or permit is not subject to expired status or reactivation requirements.

(2) A business that dispenses or distributes prescription or nonprescription products will provide written notice to its customers at least 30 days prior to the discontinuation of business that will include the anticipated date of business discontinuation and the identification of the licensee, registrant or permittee to whom the customers' records will be transferred.

b. Individuals. An individual licensee or registrant may voluntarily request cancellation via written notice to the board. Except as provided herein for pharmacists, a licensee or registrant who requests voluntary cancellation is not subject to expired status or reactivation requirements. A pharmacist who voluntarily surrendered the license is subject to the reinstatement requirements pursuant to 645—Chapter 11.

551.2(15) *Grounds for discipline.*

a. In addition to the grounds for discipline identified in 645—Chapter 13, the board may take disciplinary action against a license or registration for the following:

(1) Distribution of drugs for other than lawful purposes, which includes but is not limited to the distribution of counterfeit drugs and the disposition of drugs in violation of Iowa Code chapters 124, 126, and 155A.

(2) Obtaining, diverting, possessing, or attempting to obtain or possess prescription drugs without lawful authority, including but not limited to forging or altering a prescription for personal use or for distribution.

(3) Practicing pharmacy, or assisting in the practice of pharmacy, while under the influence of alcohol, illicit substances, or prescription drugs or substances for which the licensee does not have a lawful prescription or while impaired by the use of legitimately prescribed prescription drugs.

(4) Noncompliance with a child support order or with a written agreement for payment of child support as evidenced by a certificate of noncompliance issued pursuant to Iowa Code chapter 252J.

b. The board will not suspend or revoke the license of a person who is in default or is delinquent on repayment or a service obligation under federal or state postsecondary educational loans or public or private services-conditional postsecondary tuition assistance solely on the basis of such default or delinquency.

551.2(16) *Agency rules adopted by reference.* The board adopts by reference the following agency rules:

a. Military service, veteran reciprocity, and spouses of active-duty service members as found in 481—Chapter 7.

b. Contested cases and informal settlement as found in 645—Chapter 11.

c. Discipline as found in 645—Chapter 13.

d. Licensing and child support noncompliance, student loan repayment noncompliance, and nonpayment of state debt as found in 481—Chapter 8.

e. Use of criminal convictions in eligibility determinations and initial licensing decisions as found in 645—Chapter 14.

481—551.3(124,124B,147,155A,272C) Notifications to the board.

551.3(1) *Criminal convictions and pleas.* Within 30 days of adjudication, any conviction of or entry of a plea of guilty, nolo contendere, or no contest to a crime, other than a minor traffic offense, including if the judgment of conviction or sentence is deferred, will be reported to the board. Notification will include an unredacted copy of the final order of judgment. The notification requirement applies to:

a. An individual licensee or registrant.

b. A business licensee, registrant or permittee or any owner, supervising pharmacist or facility manager when the conviction is related to the practice of pharmacy or the distribution of drugs.

551.3(2) *Disciplinary action.* Any disciplinary action in another state or federal jurisdiction of a licensee, registrant or permittee or an owner, supervising pharmacist or facility manager of a license, registration or permit relating to the practice of pharmacy or the distribution of drugs will be reported to the board within 30 days of adjudication. Notification will include an unredacted copy of the action or order. Disciplinary action includes but is not limited to citations; reprimands; fines; restrictions; probation; or surrender, suspension or revocation of the license, registration, or permit.

551.3(3) *Individual licensee or registration changes.* Within 30 days of a change to the following, the licensee or registrant will provide the updated information to the board via written notice or via the board's online licensing database:

a. Address.

b. Email address.

c. Telephone number.

d. Pharmacy of employment, if applicable.

e. Name, of which a written notice will include evidence of the legal name change.

481—551.4(147,155A,272C) Pharmacists.

551.4(1) *License by examination or score transfer.* An applicant for licensure by examination or score transfer will satisfy the requirements of Iowa Code sections 155A.8 and 155A.9 and do the following:

a. Graduate from an ACPE-accredited college of pharmacy within the United States, or, if a graduate of a foreign college of pharmacy, submit FPGEC certification and preceptor affidavit(s) of satisfactory completion of internship in accordance with subrule 551.6(3).

b. Pass the following examinations:

(1) NAPLEX. NAPLEX score transfers are accepted for one year from the date of the examination.

(2) MPJE, Iowa Edition.

551.4(2) *License transfer—general requirements.* An applicant is eligible for license transfer when the applicant:

a. Holds a current and unencumbered license in a state or territory of the United States; and

b. Passes the MPJE, Iowa Edition.

551.4(3) *License fee and duration.* The license fee is $180, and the license will expire on June 30 two years after initial licensure.

551.4(4) *Renewal standard.*

a. Continuing education. Except for the first renewal following licensure by examination, a pharmacist will complete at least 30 hours of continuing education (CE) since the date of issuance or last renewal of the license as a condition for license renewal. The type of CE completed shall be sufficient to meet the standard of care for the pharmacist's specific practice setting and be provided by an accredited CE provider. The following will be deemed compliant with the CE hours:

(1) Active-duty military personnel serving honorably during the renewal period.

(2) Nonresident pharmacists who are actively licensed in the state in which they live and who do not practice in Iowa.

b. Child and dependent adult abuse training. A pharmacist who, in the course of employment or professional practice, examines, attends, counsels, or treats a minor or dependent adult will provide evidence of completion of training relating to the identification and reporting of child abuse or dependent adult abuse in accordance with Iowa Code section 232.69(3)*"b"* or 235B.16(5)*"b,"* respectively.

481—551.5(155A) Nonresident pharmacists in charge. Unless currently licensed as a pharmacist in Iowa, the pharmacist in charge of an Iowa-licensed nonresident pharmacy will be registered.

551.5(1) *Registration fee and duration.* The registration fee is $75, and the registration will expire annually on December 31.

551.5(2) *Change.* Within 30 days of a change to the home state license or registration information or status, the registrant will provide written notice of the change to the board.

481—551.6(155A) Pharmacist-interns.

551.6(1) *Registration required.* Unless currently licensed as a pharmacist in Iowa, an individual completing an internship, fellowship, or residency experience will be registered.

551.6(2) *Registration fee and duration.* The registration fee is $30, and the registration will expire one year following graduation from a college of pharmacy, following completion of a residency or fellowship, upon withdrawal from a college of pharmacy, or upon pharmacist licensure in Iowa, whichever occurs first.

551.6(3) *Internship credit.* Credit for internship hours completed in Iowa will only be granted for the pharmacy practice experience completed under the supervision of a preceptor during the period the pharmacist-intern was registered. Internship hours will remain valid for application for licensure by examination or score transfer pursuant to rule 481—551.4(147,155A,272C) for three years from the earlier of the date of graduation from an ACPE-accredited college of pharmacy or the expiration of the pharmacist-intern registration.

481—551.7(155A) Pharmacy technicians. Prior to engaging in technical functions in an Iowa pharmacy, an individual will register pursuant to this rule.

551.7(1) *Technician trainee.* An individual who does not hold current and active national pharmacy technician certification will register as a technician trainee. The registration fee is $20, and the registration will expire one year after initial registration. When necessary due to exceptional circumstances, a technician trainee will be limited to one renewal.

551.7(2) *Certified pharmacy technician.* An individual who holds current and active national pharmacy technician certification will register as a technician. The registration fee is $20 per annum, and the registration will expire on the date that the technician's national certification expires.

481—551.8(155A) Pharmacy support persons. The registration fee is $25, and the registration will expire on the second last day of the birth month following initial registration.

481—551.9(124) CSA—individuals.

551.9(1) *Registration for independent activities.* A separate registration will be necessary for each separate independent activity as provided in 21 CFR §1301.13 as amended April 11, 2022.

551.9(2) *Registration for separate locations—exemption.* Notwithstanding subrule 551.2(5), a registered prescriber will not be required to obtain a separate registration for each additional location where the prescriber prescribes or administers controlled substances but does not procure or maintain stocks of controlled substances under the prescriber's registration.

551.9(3) *Registration fee and duration.*

a. Researchers. The registration fee is $90, and the registration will expire on the second last day of the month following initial registration.

b. Practitioners. The registration fee is $45 per annum, and the registration will expire on the date that the practitioner's Iowa professional license expires.

551.9(4) *Exempt from registration—affiliated interns, residents, or foreign physicians.* An individual practitioner who is an intern, resident or foreign physician employee is exempt from registration when practicing under the registration of the employer hospital or institution, provided the practitioner is:

a. Authorized to perform the activity, and the activity is limited to the authorized scope under the practitioner's professional license.

b. Assigned a unique internal code, which is maintained in the hospital or institution's records, to be appended to the end of the hospital's or institution's DEA registration number.

551.9(5) *Changes.* Within 30 days of a change to the registered location or substances authorized, the registrant will provide the updated information to the board via written notice or via the board's online licensing database.

481—551.10(124,155A) Pharmacies.

551.10(1) *License types.* Licensed pharmacy types include:

a. General pharmacy.

b. Hospital pharmacy.

c. Telepharmacy.

d. Limited-use pharmacy.

e. Nonresident pharmacy.

551.10(2) *License fee and duration.* The license fee is $135, and the license will expire annually on December 31.

551.10(3) *Changes.*

a. Written notice. Within 30 days of a change, except as provided herein, the pharmacy will provide the updated information to the board via a board form.

(1) Pharmacist in charge, except that notification of a change of pharmacist in charge of a nonresident pharmacy will be submitted within ten days of the change.

(2) Ownership.

b. Application. A licensee will seek modification of the pharmacy license for the following changes via submission of a completed application and fee prior to the effective date of the change, except as provided herein:

(1) Name.

(2) Location, except for a temporary relocation of limited duration due to an exceptional circumstance. An application will be submitted at least 30 days prior to the anticipated relocation.

(3) License type. An application will be submitted at least 30 days prior to the anticipated change.

481—551.11(124) CSA—businesses.

551.11(1) *Registration for independent activities.* A separate registration will be necessary for each separate independent activity as provided in 21 CFR §1301.13 amended April 11, 2022.

551.11(2) *Separate registrations for separate locations.*

a. A separate registration will be necessary for each location where controlled substances are manufactured, distributed, imported, exported, dispensed, stored, or collected for the purpose of disposal unless exempt from registration pursuant to Iowa Code section 124.302(2) or as provided in 21 CFR §1301.12 amended February 28, 2024.

b. A separate registration for a pharmacy will not be required when providing an emergency kit of limited drug quantities to an entity authorized to administer such emergency drugs, such as a care facility or EMS program.

551.11(3) *Registration fee, duration, and exemptions.*

a. The registration fee is $45 per annum and will expire on the second last day of the month following initial registration, except that the expiration may be aligned with the entity's underlying business license, if applicable.

b. The registration fee is waived for federal, state, and local law enforcement agencies and the following federal and state institutions: hospitals; health care or teaching institutions; and analytical laboratories authorized to possess, manufacture, distribute, and dispense controlled substances in the course of official duties.

551.11(4) *Changes.*

a. Written notification. Within 30 days of a change to the following, the registrant will provide the updated information to the board via a board form or via the board's online licensing database:

(1) Substances authorized.

(2) Responsible individual, except as required in subparagraph 551.11(4)*"b"*(2).

(3) Ownership.

b. Application. A CSA—business registrant will seek modification of the registration for the following changes via submission of an application and fee within 30 days of the change, except as provided herein:

(1) Location. For an instate registrant, an application will be submitted at least 30 days prior to the change of location.

(2) Responsible individual for outsourcing facilities, third-party logistics providers, and wholesale distributors.

(3) Name.

481—551.12(124B) Precursor substances.

551.12(1) *Permit fee and duration.* The permit fee is $180, and the permit will expire annually on December 31.

551.12(2) *Exemptions.* A permit is not required for the distribution of exempt chemical mixtures or for transactions deemed excluded by 21 CFR Part 1310 as amended October 31, 2023.

481—551.13(155A) Wholesale distributors.

551.13(1) *License standards.*

a. To be eligible for licensure as a wholesale distributor, each application will include evidence of:

(1) Surety bond or equivalent security pursuant to the DSCSA.

(2) Current drug distributor accreditation by NABP, NCDQS, or another accreditation body approved by the board. New applicants located in Iowa that undergo an opening inspection will not be obligated to provide evidence of accreditation for initial licensure.

b. In the event the requirements in paragraph 551.13(1)*"a"* directly conflict with any federal law or regulation, the federal law or regulation will supersede the requirements in paragraph 551.13(1)*"a."*

551.13(2) *License fee and duration.* The license fee is $750, and the license will expire annually on December 31.

551.13(3) *License changes.*

a. Written notice. A licensee will provide written notice to the board within 30 days of:

(1) The designation of a temporary facility manager who will not be subject to a criminal history background check.

(2) A change of business type.

(3) A change of ownership.

b. Application. A licensee will seek modification of the license for the following changes via submission of an application and fee. A resident licensee will submit the application at least 30 days prior to the anticipated change, and, except as provided, a nonresident licensee will submit the application within 30 days of the licensee's receipt of an updated license from the home state regulatory authority, if applicable, reflecting the change.

(1) Name.

(2) Location.

(3) Permanent facility manager. A licensee will submit an application within 30 days of the identification of a new permanent facility manager and within 90 days of the initial vacancy.

481—551.14(155A) Outsourcing facilities.

551.14(1) *License fee and duration.* The license fee is $400, and the license will expire annually on December 31.

551.14(2) *License changes.*

a. Written notice. A licensee will provide written notice to the board via a board form within 30 days of:

(1) The designation of a temporary supervising pharmacist who will not be subject to a criminal history background check.

(2) A change of ownership.

b. Application. A licensee will seek modification of the license for the following changes via submission of an application and fee. Except as provided herein, a resident licensee will submit the application at least 30 days prior to the anticipated change and a nonresident licensee will submit the application within 30 days of the change to the FDA registration or home state license, if applicable, reflecting the change.

(1) Name.

(2) Location.

(3) Permanent supervising pharmacist. A licensee will submit an application identifying the new permanent supervising pharmacist within 30 days of the identification of the permanent supervising pharmacist and within 90 days of the initial vacancy.

481—551.15(155A) Limited distributors.

551.15(1) *Self-inspection.* Each application for a limited distributor license will include a completed self-inspection.

551.15(2) *License fee and duration.* The license fee is $175, and the license will expire annually on December 31.

551.15(3) *License changes.*

a. Written notice. The licensee will provide written notice within 30 days of a change of:

(1) Facility manager.

(2) Business type.

(3) Ownership.

b. Application. Modification of the license for the following changes will be pursuant to the submission of an application and fee at least 30 days prior to the change, except as provided herein, for a resident licensee and within 30 days of the change to the home state license for a nonresident licensee, if applicable, reflecting the change.

(1) Name.

(2) Location.

481—551.16(155A) Third-party logistics providers.

551.16(1) *License standards.*

a. To be eligible for licensure, each application will include evidence of current drug distributor accreditation by NABP, NCDQS, or another accreditation body approved by the board. New applicants located in Iowa that undergo an opening inspection will not be obligated to provide evidence of accreditation for initial licensure.

b. In the event the requirements in this subrule directly conflict with any federal law or regulation, the federal law or regulation will supersede the requirements herein.

551.16(2) *License fee and duration.* The license fee is $750, and the license will expire annually on March 31.

551.16(3) *License changes.*

a. Written notice. A licensee will provide written notice to the board within 30 days of:

(1) The designation of a temporary facility manager who will not be subject to a criminal history background check.

(2) A change of ownership.

b. Application. A licensee will seek modification of the license for the following changes via submission of an application and fee. A resident licensee will submit the application at least 30 days prior to the anticipated change, and, except as provided, a nonresident licensee will submit the application within 30 days of the licensee's receipt of an updated license from the home state regulatory authority, if applicable, reflecting the change.

(1) Name.

(2) Location.

(3) Permanent facility manager. A licensee will submit an application within 30 days of the identification of a new permanent facility manager and within 90 days of the initial vacancy.

These rules are intended to implement Iowa Code sections 124.302, 147.76 and 147.80 and chapters 155A and 272C.