

CHAPTER 12
PRECURSOR SUBSTANCES

657—12.1(124B) Precursor substances program administrator. For the purpose of carrying out the regulatory provisions of Iowa Code chapter 124B, the executive secretary of the board of pharmacy examiners shall serve as the precursor substances program administrator.

657—12.2(124B) Precursor substance defined. Precursor substance is defined as follows:

12.2(1) For the purpose of this chapter a precursor substance is any of the following substances:

- a. Anthranilic acid and its salts;
- b. Benzyl Cyanide;
- c. Ephedrine, its salts, optical isomers, and salts of optical isomers;
- d. Ergonovine and its salts;
- e. Ergotamine and its salts;
- f. 3,4-methylenedioxyphenyl-2-propanone;
- g. N-acetylanthranilic acid and its salts;
- h. Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers;
- i. Phenylacetic acid and its salts;
- j. Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers;
- k. Piperidine and its salts;
- l. Pseudoephedrine, its salts, optical isomers, and salts of optical isomers;
- m. Methylamine, its salts, optical isomers, and salts of optical isomers;
- n. Ethylamine, its salts, optical isomers, and salts of optical isomers;
- o. D-lysergic acid, its salts, optical isomers, and salts of optical isomers;
- p. Propionic anhydride, its salts, optical isomers, and salts of optical isomers;
- q. Isosafrole, its salts, optical isomers, and salts of optical isomers;
- r. Safrole, its salts, optical isomers, and salts of optical isomers;
- s. Piperonal, its salts, optical isomers, and salts of optical isomers;
- t. N-methylephedrine, its salts, optical isomers, and salts of optical isomers;
- u. N-ethylephedrine, its salts, optical isomers, and salts of optical isomers;
- v. N-methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers;
- w. N-ethylpseudoephedrine, its salts, optical isomers, and salts of optical isomers;
- x. Hydriodic acid, its salts, optical isomers, and salts of optical isomers.

12.2(2) The definition in subrule 12.2(1) shall not include any drug that contains ephedrine, phenylpropanolamine, or pseudoephedrine or any cosmetic containing a precursor substance if the drug or cosmetic is lawfully sold, transferred, or furnished over the counter without a prescription in accordance with Iowa Code chapter 126.

657—12.3(124B) Revision of precursor substances list. The board of pharmacy examiners may add a substance to, or remove a substance from, the list of precursor substances in Iowa Code section 124B.2 or rule 12.2(124B). In determining whether to add or remove a substance from the list, the board shall consider the following:

1. The likelihood that the substance may be used as a precursor in the illegal production of a controlled substance.
2. The availability of the substance.
3. The appropriateness of including the substance under this chapter or under Iowa Code chapter 124.
4. The extent and nature of legitimate uses for the substance.

657—12.4(124B) Who must obtain a permit.

12.4(1) Persons who manufacture, wholesale, retail, or otherwise sell, transfer, or furnish in this state a precursor substance, and persons in this state who purchase, transfer, or otherwise receive a precursor substance from a source outside the state, shall obtain a permit on forms provided by the office of the precursor substances program administrator.

12.4(2) A permit is not required of a vendor of a drug containing ephedrine, phenylpropanolamine, or pseudoephedrine or of a cosmetic that contains a precursor substance if the drug or cosmetic is lawfully sold, transferred, or furnished either over the counter without a prescription in accordance with Iowa Code chapter 126 or with a prescription pursuant to Iowa Code chapter 155A.

657—12.5(124B) Permit and permit fee. For each permit or permit renewal to manufacture, wholesale, retail, sell, transfer, or furnish in this state a precursor substance, or to purchase, transfer, or receive a precursor substance from a source outside the state, permit applicants and permit holders shall pay an annual fee of \$100. A permit shall be effective for not more than one year from the date of issuance.

657—12.6(124B) Time and method of payment. Permit and renewal fees shall be paid at the time when the permit application is submitted for filing. Payment shall be made in the form of a personal, certified or cashier's check or money order made payable to the Iowa Board of Pharmacy Examiners for deposit in the general fund. Payments made in the form of stamps, foreign currency or third-party endorsed checks will not be accepted.

657—12.7(124B) Late application. Persons required to obtain a permit or renew a permit who file a late application shall pay an additional \$50 late payment fee.

657—12.8(124B) Time for application for permit. Any person who is required to obtain a permit may apply for a permit at any time. No person required to obtain a permit shall engage in any activity for which a permit is required until the application for a permit is granted and a permit certificate is issued by the precursor substances program administrator to such person.

657—12.9(124B) Expiration date for application for permit. Any person who holds a permit may apply to renew a permit not less than 30 days, nor more than 60 days, before the expiration date of the permit. A permit holder who fails to file a permit renewal at least 30 days before the expiration date of the permit must apply for a new permit; the existing permit will expire on the date specified.

657—12.10(124B) Exemption of law enforcement officials. In order to enable law enforcement agency laboratories to obtain and transfer precursor substances for use as standards in chemical analysis, such laboratories shall annually obtain a permit to conduct chemical analysis. Such laboratories shall be exempted from payment of a permit fee. Laboratory personnel, when acting in the scope of their official duties, are deemed to be officials exempted by this rule. For purpose of this rule, laboratory activities shall not include field or other preliminary chemical tests by officials exempted by this rule.

657—12.11(124B) Application forms—contents—signature.

12.11(1) Application forms may be obtained at the board office or by writing to the Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. Forms will be mailed, as applicable, to each permit holder approximately 60 days before the expiration date of the permit; if any permit holder does not receive such forms within 45 days before the expiration date of the permit, the permit holder shall promptly give notice of the fact and request forms by writing to the board at the foregoing address.

12.11(2) 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.

12.11(3) 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 the chief executive officer of the applicant, if a corporation, corporate division, association, trust or other entity.

657—12.12(124B) Filing of application. All applications for a permit shall be submitted for filing to the Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. The appropriate permit fee and any required attachments must accompany the application.

657—12.13(124B) Acceptance for filing—defective applications.

12.13(1) Applications for a permit and a permit renewal submitted for filing are dated upon receipt. If found to be complete the application will be accepted for filing. Applications failing to comply with the requirements of this rule will not be accepted for filing. In the case of minor defects as to completeness, the board 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 14 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 board shall accept for filing any application upon resubmission by the applicant, whether complete or not.

12.13(2) Accepting an application for filing does not preclude any subsequent request for additional information and has no bearing on whether the application will be granted.

12.13(3) The board may require an applicant to submit 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 the applicant to provide such documents or statements within 14 days after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the board in granting or denying the application.

12.13(4) An application for a permit or permit renewal may be amended or withdrawn without permission of the board at any time before the date on which the applicant receives an order to show cause. An application may be amended or withdrawn with permission of the board at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest. After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

657—12.14(124B) Termination of permit. The permit of any person shall terminate if and when the person dies, ceases legal existence, discontinues business, or changes name or address as shown on the permit certificate. Any permit holder who ceases legal existence, discontinues business, or changes a name or address as shown on the permit certificate shall notify the board within 30 days of the occurrence. In the event of a change in name or address, the person may apply for a new permit certificate in advance of the effective date of the change by filing an application and paying the appropriate fee in the same manner as an application for a new permit.

657—12.15(124B) Refusal, suspension, or revocation of permit.

12.15(1) The board shall refuse, suspend, or revoke a permit upon finding that any conditions specified in Iowa Code section 124B.12 exist.

12.15(2) The board may suspend any permit for any period of time it determines to be justified upon the facts of the case.

12.15(3) All administrative matters pertaining to the suspension or revocation of a permit shall conform procedurally to the general provisions for suspension or revocation of an Iowa controlled substances registration contained in rules 657—10.7(124), 10.8(124), and 10.9(124).

657—12.16(124B) Security requirements generally. All applicants and permit holders shall provide effective controls and procedures to guard against theft and diversion of precursor substances. In order to determine whether a person has provided effective controls against diversion, the board shall use the security requirements set forth in rule 657—10.10(124) 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 board after evaluation of the overall security system and needs of the applicant or permit holder.

657—12.17(124B) Form of proper identification required for purchases of precursor substances.

12.17(1) Before selling, transferring, or otherwise furnishing any precursor substance specified in Iowa Code section 124B.2 or rule 12.2(124B) to a person in this state, a vendor shall require proper identification from the purchaser.

12.17(2) For purchases of precursor substances which are face-to-face, a vendor shall require proper identification from the purchaser as specified in Iowa Code section 124B.3.

12.17(3) For purchases of precursor substances which are not face-to-face, a vendor shall require a letter of authorization from the business or person who is making the purchase.

a. If the purchaser is a person, the letter shall include the following:

- (1) The name of the person,
- (2) The person's residential or mailing address (other than a post office box number),
- (3) Residential telephone number,
- (4) Place of employment including employer's address and telephone number,
- (5) Date of birth,
- (6) Place of birth,
- (7) Social security number,
- (8) The person's signature,
- (9) A description of how the substance will be used.

b. If the purchaser is a business, the letter shall include the following:

- (1) The name of the business,
- (2) The business address and telephone number,
- (3) A description of how the substance will be used,
- (4) The signature of an officer, agent, or employee of the business.

657—12.18(124B) Who must report.

12.18(1) A manufacturer, wholesaler, retailer, or other person who is required to report pursuant to Iowa Code chapter 124B, and who sells, transfers, or otherwise furnishes to any person in this state any precursor substance listed in Iowa Code section 124B.2 or rule 12.2(124B), shall file a report with the board.

12.18(2) A manufacturer, wholesaler, retailer, or other person who is required to report pursuant to Iowa Code chapter 124B, and who purchases, transfers, or otherwise receives a precursor substance from a source outside the state, shall file a report with the board.

12.18(3) The reporting requirements of subrule 12.18(1) do not apply to any of the following:

- a.* A licensed pharmacist or other person authorized under Iowa Code chapter 155A to sell or furnish a precursor substance upon the prescription of a practitioner.
- b.* A practitioner who administers or furnishes a precursor substance to a patient.
- c.* A manufacturer, wholesaler, retailer, or other person who holds a permit issued by the board and who sells, transfers, or otherwise furnishes a precursor substance to a practitioner or a pharmacy as defined in Iowa Code section 155A.3.

12.18(4) A manufacturer, wholesaler, retailer, or other person who is required to report pursuant to Iowa Code chapter 124B and subrule 12.18(1) or 12.18(2), or a person listed as an exemption under Iowa Code section 124B.6 or subrule 12.18(3), shall report to the board either of the following occurrences:

- a.* Loss or theft of a precursor substance.
- b.* A difference between the amount of a precursor substance shipped and the amount of a precursor substance received.

657—12.19(124B) Frequency of reports.

12.19(1) Persons who manufacture, wholesale, retail, or otherwise sell, transfer, or furnish in this state a precursor substance shall submit a report of the transaction to the board at least 21 days prior to the delivery of a precursor substance to a recipient. Regular, repeated transactions of a particular precursor substance between a vendor and a recipient may be reported monthly pursuant to the provisions of Iowa Code section 124B.4.

12.19(2) A manufacturer, wholesaler, retailer, or other person who purchases, transfers, or otherwise receives a precursor substance from a source outside the state shall submit a report of such transaction to the board within 14 days of the receipt of that substance.

12.19(3) A manufacturer, wholesaler, retailer, or other person who is required to report pursuant to Iowa Code chapter 124B and subrules 12.18(1) and 12.18(2), or a person listed as an exception under Iowa Code section 124B.6 or subrule 12.18(3), shall report missing quantities of a precursor substance within seven days of knowledge of the loss or occurrence.

657—12.20(124B) Reporting forms—contents—signature. Reporting forms may be obtained at the board office or by writing to the Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688.

12.20(1) Each form which reports the sale, transfer, or other furnishing of a precursor substance shall contain the following information:

- a.* Name of substance;
- b.* Quantity of substance;
- c.* Date sold, transferred, or furnished;
- d.* Name and address of business or person selling, transferring, or furnishing the substance;
- e.* The signature of the person selling, transferring, or furnishing the substance or the signature of an officer, agent, or employee of a business selling, transferring, or furnishing the substance;
- f.* Name and address of person or business purchasing or receiving the substance.

12.20(2) Each form which reports the receipt of a precursor substance shall contain the following information:

- a.* Name of substance;
- b.* Quantity of substance;
- c.* Date received;
- d.* Name and address of person or business receiving the substance;
- e.* The signature of the person receiving the substance or the signature of an officer, agent, or employee of a business receiving the substance;
- f.* Name and address of the person or business selling, transferring, or furnishing the substance.

12.20(3) In lieu of an approved form the board will accept a copy of an invoice, packing list, or other shipping document which contains the applicable information set forth in subrule 12.20(1) or 12.20(2). Under this option purchase price information appearing on the document may be deleted.

12.20(4) Each form which reports a missing quantity of a precursor substance shall contain the following information:

- a.* Name of substance missing;
- b.* Quantity of substance missing;
- c.* Date on which the substance was discovered to be missing;
- d.* Name and address of person or business reporting the missing quantity;
- e.* The permit number of the person or business reporting the missing quantity, if applicable;
- f.* The signature of the person reporting the missing quantity or the signature of an officer, agent, or employee of a business reporting the missing quantity;
- g.* The name and address of the person who transported the precursor substance and the date of shipment, if applicable.

657—12.21(124B) Monthly reporting option.

12.21(1) Permit holders who regularly transfer the same precursor substance to the same recipient may apply to the board for authorization to submit the report of said transactions on a monthly basis. Requests for monthly reporting authorization must be received at the board office at least 14 days prior to the board meeting at which the request will be considered. The board will review each request to determine if the requirements of Iowa Code chapter 124B are met and will notify the permit holder of its decision and the reporting format that will be authorized.

12.21(2) Permit holders may also petition the board to accept the monthly report on a computer-generated basis. If approved, the report may be furnished in hard copy or on board-approved data storage methods. The permit holder will be responsible for the accuracy of the report and the prompt correction of any data entry or transmission errors.

12.21(3) The authorization to use monthly reports or computer-generated monthly reports may be rescinded at the board's discretion and with 30 days' notice.

These rules are intended to implement Iowa Code chapter 124B.

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