

CHAPTER 1
PURPOSE AND ORGANIZATION
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 9]

657—1.1(17A) Description and organization.

1.1(1) Description of agency. The board derives its authority for regulating the practice of pharmacy and for regulating the legal distribution and dispensing of prescription drugs and precursor substances throughout the state from Iowa Code chapters 124, 124A, 124B, 126, 147, 155A, 205, and 272C.

1.1(2) Organization of agency. The board is comprised of five pharmacist members and two representatives of the general public, all appointed by the governor; they are assisted by an administrative staff headed by an executive secretary appointed by the board.

1.1(3) Purpose. The responsibilities of the board include but are not limited to:

a. Licensing of qualified applicants to the practice of pharmacy by examination, renewal, and reciprocity under the provisions of Iowa Code chapters 147 and 155A.

b. Development and administration of a program of continuing education to ensure continued competency of individuals licensed by the board. Authority for this function comes from Iowa Code chapter 272C.

c. Regulating the legal distribution of prescription drugs through the licensing of pharmacies and wholesalers under the authority of Iowa Code chapter 155A.

d. Regulating the legal distribution of controlled substances through the registration of pharmacies, physicians, physician assistants, advanced registered nurse practitioners, dentists, podiatric physicians, veterinarians, optometrists, hospitals, health care facilities, researchers, analytical laboratories, teaching institutions, and controlled substance manufacturers and distributors throughout the state under the authority of Iowa Code chapter 124.

e. Perform compliance investigations and audits of all persons registered pursuant to Iowa Code chapter 124. These investigations and audits are conducted to ensure accountability for all controlled substances covered under this chapter.

f. Regulating the legal distribution of precursor substances through the issuance of permits to vendors and recipients of precursor substances throughout the state under the authority of Iowa Code chapter 124B.

1.1(4) Information. Members of the general public may obtain information or submit requests relative to the practice of pharmacy, continuing education for pharmacists, or the legal distribution and dispensing of prescription drugs, or any other matters relating to the function of the board, to the Executive Secretary/Director, Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. Procedures for obtaining this information may be found in 657—Chapter 14.

1.1(5) Public meetings. All meetings of the board shall be open and public and all citizens of Iowa shall be permitted to attend any meeting except, as provided by statute, for some exceptional reason so compelling as to override the general public policy in favor of public meetings and as permitted by Iowa Code section 21.5. Closed meetings shall only be by affirmative public vote of either two-thirds of the members of the board or all of the members present at the meeting.

a. Meetings of the board shall be held in Des Moines, Iowa, except as designated otherwise by the chairperson.

b. The board shall set the dates of its meetings at the first meeting following May 1 of each fiscal year. Notices of meetings shall be routinely posted in the space set aside for that purpose in the governor's office and in the office of the board.

c. Special meetings of the board may be called by the chairperson or upon written request of four of its members.

(1) The reason for calling a special meeting shall be recorded in the minutes.

(2) Special meetings, although advance notice cannot be published, shall be open to the citizens of Iowa except as otherwise provided in statute.

d. The executive secretary shall keep a record of all minutes of the board and these minutes shall be open to the public for inspection.

e. Members of the general public may obtain the date, time, and location of board meetings by submitting a request to the Executive Secretary/Director, Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688.

f. A majority of the members of the board shall constitute a quorum.

657—1.2(17A,124,124A,124B,126,147,155A,205) Disciplinary action.

1.2(1) License denial, revocation or suspension. Pursuant to 657—Chapters 35 and 36, the board may deny, restrict, revoke or suspend a license to practice pharmacy for grounds stated in Iowa Code sections 147.55 and 155A.12. Pursuant to 657—Chapters 35 and 36, the board may deny, revoke or suspend a license to operate a pharmacy for grounds stated in Iowa Code section 155A.13A or 155A.15, as appropriate. Pursuant to 657—Chapters 35 and 36, the board may deny, revoke or suspend a license to operate a wholesale drug distribution facility doing business in Iowa for grounds stated in Iowa Code section 155A.17.

1.2(2) Controlled substance registration denial, revocation or suspension. Pursuant to 657—Chapters 35 and 36, the board may deny, restrict, revoke or suspend registration for grounds stated in Iowa Code sections 124.303 and 124.304.

1.2(3) Permit denial, revocation or suspension. Pursuant to 657—Chapters 35 and 36, the board may refuse, suspend, or revoke a permit to handle precursor substances for grounds stated in Iowa Code section 124B.12.

1.2(4) Pharmacy technician registration denial, revocation or suspension. Pursuant to 657—Chapters 35 and 36, the board may deny, suspend, or revoke a pharmacy technician registration for grounds stated in Iowa Code section 155A.6.

1.2(5) Pharmacist-intern registration denial, revocation or suspension. Pursuant to 657—Chapters 35 and 36, the board may deny, suspend, or revoke a pharmacist-intern registration for grounds stated in Iowa Code section 155A.6.

657—1.3(17A,124,126,147,155A,205,272C) Waivers or variances from rules.

1.3(1) Applicability. This rule governs waivers or variances from board rules in the following circumstances: The board has exclusive rule-making authority to promulgate the rule from which the waiver or variance is requested or has final decision-making authority over a contested case in which the waiver or variance is requested; and no statute or rule otherwise controls the grant of a waiver or variance from the rule from which the waiver or variance is requested.

a. The board may grant a waiver of, or variance from, all or part of a rule.

b. No waiver or variance may be granted from a requirement which is imposed by statute. Any waiver or variance must be consistent with state and federal statutes.

1.3(2) Criteria. A waiver or variance under this rule may be granted only upon showing that:

a. Substantially equal protection of health, safety, and welfare will be afforded by a means other than that prescribed in the particular rule for which the variance or waiver is requested;

b. Because of special circumstances, either the requester is unable to comply with the particular rule without undue hardship or compliance with the particular rule would be unnecessarily and unreasonably costly and would serve no public benefit; and

c. Provision of a waiver or variance under the circumstances would not adversely impact an overall goal of uniform treatment of all licensees.

1.3(3) Request. A request for a waiver or variance shall be submitted in writing to the board as follows:

a. License, registration, or permit application. If the request relates to an application for, or limitation on, a license, registration, or permit, the request shall be made in accordance with the filing requirements for the license, registration, or permit in question.

b. Contested case. If the request relates to a pending contested case, the request shall be filed in the contested case proceeding.

c. Other. If the request does not relate to a particular license, registration, or permit and is not related to a pending contested case, the request may be submitted to the executive secretary/director of the board.

1.3(4) Elements. A request for waiver or variance shall include the following information where applicable:

a. The name, address, and telephone number of the person requesting the waiver or variance and the person's representative, if any.

b. The specific rule or portion of a rule from which a waiver or variance is requested.

c. The nature of the waiver or variance requested, including any alternative means or other condition or modification proposed to achieve the purpose of the rule.

d. An explanation of the reason for the waiver or variance, including all material facts relevant to grant the waiver or variance in question.

e. Any necessary releases of information authorizing persons with knowledge to disclose relevant information to the board.

1.3(5) Ruling. The board shall respond in writing to all requests. The ruling shall include the reason for granting or denying the request and, if approved, the time period during which the waiver or variance is effective. The board may condition the grant of waiver or variance on such reasonable conditions as are appropriate to achieve the objectives of the particular rule in question through alternative means.

1.3(6) Public availability. All final rulings in response to requests for waivers or variances shall be indexed and available to members of the public at the board office.

1.3(7) Voiding or cancellation. A waiver or variance is void if the material facts upon which the request is based are not true or if material facts have been withheld. The board may at any time cancel a waiver or variance upon appropriate notice and hearing if the board finds that the facts as stated in the request are not true, material facts have been withheld, the alternative means of compliance provided in the waiver or variance have failed to achieve the objectives of the statute, or the requester has failed to comply with conditions set forth in the waiver or variance approval.

1.3(8) Violations. Violation of conditions in the waiver or variance approval is the equivalent of violation of the particular rule for which the waiver or variance is granted and is subject to the same remedies or penalties.

1.3(9) Appeals. Any request for an appeal from a decision granting or denying a waiver or variance shall be in accordance with the procedures provided in Iowa Code chapter 17A. An appeal shall be taken within 30 days of the issuance of the ruling in response to the request unless a contrary time is provided by rule or statute.

This rule is intended to implement Iowa Code sections 17A.22, 124.301, 126.17, 147.76, 155A.2, 205.11, 205.13, 272C.3, and 272C.4.

657—1.4(155A) Voluntary surrender of a license. Rescinded IAB 2/19/92, effective 3/25/92.

These rules are intended to implement Iowa Code sections 17A.3, 17A.7, 17A.9, 124.303, 124.304, and 147.14.

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