

CHAPTER 28
AGENCY PROCEDURE FOR RULE MAKING

657—28.1(17A) Applicability. Except to the extent otherwise expressly provided by statute, all rules adopted by the board of pharmacy, hereinafter referred to as “board,” are subject to the provisions of Iowa Code chapter 17A, the Iowa administrative procedure Act, and the provisions of this chapter.
[ARC 3641C, IAB 2/14/18, effective 3/21/18]

657—28.2(17A) Definitions.

“*Administrative rules review committee*” or “*ARRC*” means a bipartisan standing committee composed of five senators and five representatives that meets on a regular basis for the purpose of selectively reviewing rules whether proposed or in effect.

“*ARC*” means the governor’s administrative rules coordinator.

“*ARC number*” means the identification number assigned by the ARC to each rule making document.

“*Iowa Administrative Bulletin*” or “*IAB*” is the official biweekly publication that contains the text or texts of notices of intended action and of all adopted rules.

“*Notice of Intended Action*” means a published notice of the board’s intent to adopt, amend, or rescind one or more rules pursuant to Iowa Code section 17A.4(1).

[ARC 3641C, IAB 2/14/18, effective 3/21/18]

657—28.3(17A) Solicitation of comments before notice. In addition to seeking information by other methods, the board may, before publication of a Notice of Intended Action, solicit comments from the public on a subject matter of possible rule making by causing notice to be published in the Iowa Administrative Bulletin of the subject matter and indicating where, when, and how persons may comment.

[ARC 3641C, IAB 2/14/18, effective 3/21/18]

657—28.4(17A) Public rule-making docket. Proposed rule making is made available for inspection and comment by the public through the websites identified in this rule.

28.4(1) Proposed rule making. Each proposed rule making is published in the Iowa Administrative Bulletin and can be found on the state’s administrative rules website at rules.iowa.gov. Each proposed rule making is identified by agency and by ARC number and shall include information on the opportunity to directly submit public comments, suggestions, and objections regarding the proposed rule making, including the deadline for submission of such comments.

28.4(2) Rules tracker. The progress and current status of any proposed rule making may be viewed at www.legis.iowa.gov/law/administrativerules/tracker.

28.4(3) Board notification of proposed rule making. Persons desiring to receive copies of future Notices of Intended Action may subscribe on the board’s website at pharmacy.iowa.gov.

28.4(4) Public participation—written comments. For at least 20 days after publication of the Notice of Intended Action, persons may submit written comments on the proposed rule. Such written submissions shall identify the proposed rule to which they relate and shall be submitted to the Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or to the person designated in the Notice of Intended Action.

28.4(5) Public participation—public hearings. The board may, at any time, schedule a public hearing in accordance with rule 657—28.4(17A) on a proposed rule. The board shall schedule a public hearing on a proposed rule if, within 20 days after the published Notice of Intended Action, a written request for an opportunity to make oral presentations is submitted to the board by the ARRC, a governmental subdivision, an agency, an association having not less than 25 members, or at least 25 persons. The request shall contain the following information:

a. A request by one or more individual persons shall include the printed name, signature, address, telephone number, and email address of each person.

b. A request by an association shall contain a statement that the association has at least 25 members and include the printed name, signature, address, telephone number, and email address of an officer or designee of the association.

c. A request by an agency or governmental subdivision shall contain the printed name, signature, address, telephone number, and email address of an official having authority to act on behalf of the entity. [ARC 3641C, IAB 2/14/18, effective 3/21/18]

657—28.5(17A) Public hearing proceedings.

28.5(1) Applicability. This rule applies only to those public hearings in which an opportunity to make oral presentations is authorized or required by Iowa Code section 17A.4(1)“b.”

28.5(2) Scheduling and notice. A public hearing on a proposed rule may be held in one or more locations and shall not be held earlier than 20 days after notice of its location and time is published in the IAB. That notice shall also identify the proposed rule by ARC number and citation to the IAB.

28.5(3) Presiding officer. The board, a member of the board, or another person designated by the board who will be familiar with the substance of the proposed rule, shall preside at the oral proceeding on a proposed rule. If the board does not preside, the presiding officer shall prepare a memorandum for consideration by the board summarizing the contents of the presentations made at the oral proceeding unless the board determines that such a memorandum is unnecessary because the board will personally listen to or read the entire transcript of the oral proceeding.

28.5(4) Conduct of hearing. At a public hearing on a proposed rule, persons may make oral statements and make documentary and physical submissions, which may include data, views, comments or arguments concerning the proposed rule. Persons wishing to make oral presentations at such a proceeding are encouraged to notify the board at least one business day prior to the hearing and indicate the general subject of their presentations. At the hearing, those who participate shall indicate their names and addresses, identify any persons or organizations they may represent, and provide any other information relating to their participation deemed appropriate by the presiding officer. Hearings shall be open to the public and shall be recorded by stenographic or electronic means.

a. At the beginning of the public hearing, the presiding officer shall give a brief synopsis of the proposed rule, a statement of the statutory authority for the proposed rule, and the reasons for the board decision to propose the rule. The presiding officer may place time limitations on individual oral presentations when necessary to ensure the orderly and expeditious conduct of the hearing. To encourage joint oral presentations and to avoid repetition, additional time may be provided for persons whose presentations represent the views of other individuals as well as their own views.

b. Persons making oral presentations are encouraged to avoid restating matters which have already been submitted in writing.

c. To facilitate the exchange of information, the presiding officer may, where time permits, open the floor to questions or general discussion.

d. The presiding officer shall have the authority to take any reasonable action necessary for the orderly conduct of the meeting.

e. Physical and documentary submissions presented by participants in the hearing shall be submitted to the presiding officer. Such submissions become the property of the board.

f. The hearing may be continued by the presiding officer to a later time without notice other than by announcement at the hearing.

g. Participants in a public hearing shall not be required to take an oath or to submit to cross-examination. However, the presiding officer in a hearing may question participants and permit the questioning of participants by other participants about any matter relating to that rule-making proceeding, including any prior written submissions made by those participants in that proceeding; but no participant shall be required to answer any question.

h. The presiding officer in a hearing may permit rebuttal statements and request the filing of written statements subsequent to the adjournment of the oral presentations.

28.5(5) Additional information. In addition to receiving written comments and oral presentations on a proposed rule according to the provisions of this rule, the board may obtain information concerning a proposed rule through any other lawful means deemed appropriate under the circumstances.

28.5(6) Accessibility. The board shall schedule public hearings in rooms accessible to and functional for persons with physical disabilities. Persons who have special requirements should contact the board, telephone (515)281-5944, in advance to arrange access or other needed services.
[ARC 3641C, IAB 2/14/18, effective 3/21/18]

657—28.6(17A) Regulatory analyses.

28.6(1) Definition of small business. A “small business” is defined in Iowa Code section 17A.4A(8) “a.”

28.6(2) Regulatory analysis—economic impact. The board shall issue a regulatory analysis of a proposed board rule in response to a written request from the ARC or the ARRC. The regulatory analysis shall conform to the requirements of Iowa Code section 17A.4A.

28.6(3) Regulatory analysis—business impact. The board shall issue a regulatory analysis of a proposed board rule in response to a written request from one of the following. The regulatory analysis shall conform to the requirements of Iowa Code section 17A.4A.

- a. The administrative rules review committee;
- b. The administrative rules coordinator;
- c. At least 25 or more persons who sign the request provided that each represents a different small business;
- d. An organization representing at least 25 small businesses. That organization shall list the name, address, and telephone number of not less than 25 small businesses it represents.

28.6(4) Time period for analysis. Upon receipt of a timely request for a regulatory analysis, the board shall adhere to the time lines described in Iowa Code section 17A.4A.

28.6(5) Contents of request. A request for a regulatory analysis is made when it is mailed or delivered to the board. The request shall be in writing and satisfy the requirements of Iowa Code section 17A.4A.

28.6(6) Contents of concise summary. The contents of the concise summary shall conform to the requirements of Iowa Code section 17A.4A.

28.6(7) Publication of a concise summary. The board shall make available, to the maximum extent feasible, copies of the published summary in conformance with Iowa Code section 17A.4A.

28.6(8) Jobs impact statement. Pursuant to Iowa Code section 17A.4B, the board shall include in the preamble of each rule making a jobs impact statement, unless such statement is waived by the ARC. The board may seek and shall accept public comments and information from stakeholders relating to a jobs impact statement.

[ARC 3641C, IAB 2/14/18, effective 3/21/18]

657—28.7(17A,25B) Fiscal impact statement.

28.7(1) A proposed rule that mandates additional combined expenditures exceeding \$100,000 by all affected political subdivisions or agencies and entities which contract with political subdivisions to provide services shall be accompanied by a fiscal impact statement outlining the costs associated with the rule. A fiscal impact statement shall satisfy the requirements of Iowa Code section 25B.6.

28.7(2) If the board determines at the time it adopts a rule that the fiscal impact statement upon which the rule is based contains errors, the board shall, at the same time, issue a corrected fiscal impact statement and publish the corrected fiscal impact statement in the Iowa Administrative Bulletin.

[ARC 3641C, IAB 2/14/18, effective 3/21/18]

657—28.8(17A) Time and manner of rule adoption.

28.8(1) Time of adoption. At least 35 days following publication of a Notice of Intended Action, the board may adopt a rule or terminate the rule making. Within 180 days after the date of publication of the notice or the deadline for public comments, whichever is later, the board shall adopt a rule or terminate the proceeding. Subsequent actions shall be published in the Iowa Administrative Bulletin.

28.8(2) Consideration of public comment. Before the adoption of a rule, the board shall consider fully all of the written submissions and oral submissions received in that rule-making proceeding, or any memorandum summarizing such oral submissions, and any regulatory analysis, jobs impact statement, or fiscal impact statement issued in that rule-making proceeding.

28.8(3) Reliance on board expertise. Except as otherwise provided by law, the board may use its own experience, technical competence, specialized knowledge, and judgment in the adoption of a rule. [ARC 3641C, IAB 2/14/18, effective 3/21/18]

657—28.9(17A) Variance between adopted rule and published notice of proposed rule adoption.

28.9(1) The board shall not adopt a rule that differs from the rule proposed in the Notice of Intended Action on which the rule is based unless:

- a. The differences are within the scope of the subject matter announced in the Notice of Intended Action and are in character with the issues raised in that notice; and
- b. The differences are a logical outgrowth of the contents of that Notice of Intended Action and the comments submitted in response thereto; and
- c. The Notice of Intended Action provided fair warning that the outcome of that rule-making proceeding could be the rule in question.

28.9(2) In determining whether the Notice of Intended Action provided fair warning that the outcome of that rule-making proceeding could be the rule in question, the board shall consider the following factors:

- a. The extent to which persons who will be affected by the rule should have understood that the rule-making proceeding on which it is based could affect their interests;
- b. The extent to which the subject matter of the rule or the issues determined by the rule are different from the subject matter or issues contained in the Notice of Intended Action; and
- c. The extent to which the effects of the rule differ from the effects of the proposed rule contained in the Notice of Intended Action.

28.9(3) Concurrent rule-making proceedings. Nothing in this rule disturbs the discretion of the board to initiate, concurrently, several different rule-making proceedings on the same subject with several different published Notices of Intended Action.

[ARC 3641C, IAB 2/14/18, effective 3/21/18]

657—28.10(17A) Exemptions from public rule-making procedures.

28.10(1) Emergency-adopted rule. To the extent the board for good cause finds that public notice and participation are unnecessary, impracticable, or contrary to the public interest in the process of adopting a particular rule, and with the prior approval of the ARRC and ARC, or if a statute so provides, the board may adopt that rule without publishing advance Notice of Intended Action in the Iowa Administrative Bulletin and without providing for written or oral public submissions prior to its adoption. The board shall incorporate the required finding and a brief statement of its supporting reasons in each rule adopted in reliance upon this subrule.

28.10(2) Notice of emergency-adopted rule. The board may, at any time, begin a standard rule-making proceeding for the adoption of a rule that is emergency-adopted without notice pursuant to subrule 28.10(1) and that is identical or similar to a rule it adopts in reliance upon subrule 28.10(1). After notice commenced pursuant to this subrule, the board may either readopt the rule it emergency-adopted without benefit of all usual procedures on the basis of subrule 28.10(1) or may take any other lawful action, including the amendment or repeal of the rule in question, with whatever further proceedings are appropriate.

[ARC 3641C, IAB 2/14/18, effective 3/21/18]

657—28.11(17A) Concise statement of reasons. When requested by a person, either prior to the adoption of a rule or within 30 days after its publication in the Iowa Administrative Bulletin as an adopted rule, the board shall issue a concise statement of reasons for the rule pursuant to Iowa Code section 17A.4(2). Requests for such a statement shall be in writing and be delivered to the Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. The request shall indicate

whether the statement is sought for all or only a specified part of the rule. Requests will be considered made on the date received.

[ARC 3641C, IAB 2/14/18, effective 3/21/18]

657—28.12(17A) Style and form. In preparing its rules, the board shall follow the uniform numbering system, form, and style prescribed by the administrative rules coordinator.

[ARC 3641C, IAB 2/14/18, effective 3/21/18]

657—28.13(17A) Board rule-making record.

28.13(1) Requirement. The board shall maintain an official rule-making record for each rule it proposes by publication in the Iowa Administrative Bulletin of a Notice of Intended Action or adopts. The rule-making record and materials incorporated by reference shall be available for public inspection.

28.13(2) Contents. The board rule-making record shall contain:

a. Copies of all publications in the Iowa Administrative Bulletin with respect to the rule or the proceeding upon which the rule is based;

b. All written petitions, requests, and submissions received by the board, and all other written materials of a factual nature as distinguished from opinion that are relevant to the merits of the rule and that were created or compiled by the board and considered by the board, in connection with the formulation, proposal, or adoption of the rule or the proceeding upon which the rule is based, except to the extent the board is authorized by law to keep them confidential; provided, however, that when any such materials are deleted because they are authorized by law to be kept confidential, the board shall identify in the record the particular materials deleted and state the reasons for that deletion;

c. Any official transcript of oral presentations made in the proceeding upon which the rule is based or, if not transcribed, the stenographic record or electronic recording of those presentations, and any memorandum prepared by a presiding officer summarizing the contents of those presentations;

d. A copy of any regulatory analysis or fiscal impact statement;

e. A copy of the rule and any concise statement of reasons prepared for that rule;

f. All petitions for amendment of, or repeal or suspension of, the rule;

g. A copy of any objection to the rule filed by the administrative rules review committee, the governor, or the attorney general pursuant to Iowa Code section 17A.4(6), and any board response to that objection;

h. A copy of any significant written criticism of the rule, including a summary of any petitions for waiver of the rule; and

i. A copy of any executive order concerning the rule.

28.13(3) Effect of record. Except as otherwise required by a provision of law, the board rule-making record required by this rule need not constitute the exclusive basis for board action on that rule.

28.13(4) Maintenance of record. The board shall maintain the rule-making record for a period of not less than five years from the later of the date the rule to which it pertains became effective or the date of the Notice of Intended Action. The board shall maintain a record of significant written criticism as described in paragraph 28.13(2) “g,” “h,” or “i,” for a period of not less than five years from the date of the written criticism.

[ARC 3641C, IAB 2/14/18, effective 3/21/18]

657—28.14(17A) Filing of rules. The board shall file each rule the board adopts with the office of the administrative rules coordinator. The filing shall be executed as soon after adoption of the rule as is practicable. In filing a rule, the board shall use the standard form prescribed by the administrative rules coordinator.

[ARC 3641C, IAB 2/14/18, effective 3/21/18]

657—28.15(17A) Effectiveness of rules prior to publication.

28.15(1) Grounds. The board may make a rule effective after its filing at any stated time prior to 35 days after its indexing and publication in the Iowa Administrative Bulletin if it finds that a statute so provides, the rule confers a benefit or removes a restriction on some segment of the public, or that the

effective date of the rule is necessary to avoid imminent peril to the public health, safety, or welfare. The board shall incorporate the required finding and a brief statement of its supporting reasons in each rule adopted in reliance upon this subrule.

28.15(2) *Special notice.* When the board makes a rule effective prior to its indexing and publication in reliance upon the provisions of Iowa Code section 17A.5(2) “b,” the board shall employ all reasonable efforts to make its contents known to the persons who may be affected by that rule prior to the rule’s indexing and publication. The term “all reasonable efforts” requires the board to employ the most effective and prompt means of notice rationally calculated to inform potentially affected parties of the effectiveness of the rule that is justified and practical under the circumstances considering the various alternatives available for this purpose, the comparative costs to the board of utilizing each of those alternatives, and the harm suffered by affected persons from any lack of notice concerning the contents of the rule prior to its indexing and publication.

[ARC 3641C, IAB 2/14/18, effective 3/21/18]

657—28.16(17A) Review by board of rules. Over each five-year period of time beginning July 1, 2012, the board shall conduct an ongoing and comprehensive review of all the board’s rules pursuant to Iowa Code section 17A.7(2). The purpose of the review is to identify and eliminate all rules that are outdated, redundant, or inconsistent or incompatible with statute, other board rules, or rules of other agencies. When the board’s five-year review of its rules is completed, the board shall summarize the results and provide the summary to the ARC and the ARRC.

[ARC 3641C, IAB 2/14/18, effective 3/21/18]

These rules are intended to implement Iowa Code sections 17A.1 through 17A.9A.

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