

CHAPTER 178
VARIANCES AND WAIVERS OF PUBLIC HEALTH
ADMINISTRATIVE RULES

641—178.1(17A,135) Waivers.

178.1(1) Definition. For purposes of this chapter, “a waiver or variance” means action by the department that suspends, in whole or in part, the requirements or provisions of a rule as applied to an identified person on the basis of the particular circumstances of that person. For simplicity, the term “waiver” shall include both a “waiver” and a “variance.”

178.1(2) Scope. This rule outlines generally applicable standards and a uniform process for the granting of an individual waiver from a rule adopted by the department in situations where no other more specifically applicable law provides for a waiver. To the extent another more specific provision of law governs the issuance of a waiver from a particular rule, the more specific provision shall supersede this rule with respect to any waiver from that rule.

178.1(3) Applicability. The department may only grant a waiver from a rule if the department has jurisdiction over the rule and the requested waiver is consistent with applicable statutes, constitutional provisions, or other provisions of law. The department may not waive requirements created or duties imposed by statute.

178.1(4) Criteria for waiver. In response to a petition completed pursuant to subrule 178.1(6), the department may in its sole discretion issue an order waiving in whole or in part the requirements of a rule if the department finds, based on clear and convincing evidence, all of the following:

- a. The application of the rule would impose an undue hardship on the person for whom the waiver is requested;
- b. The waiver from the requirements of the rule in the specific case would not prejudice the substantial legal rights of any person;
- c. The provisions of the rule subject to the petition for a waiver are not specifically mandated by statute or another provision of law; and
- d. Substantially equal protection of public health, safety, and welfare will be afforded by a means other than that prescribed in the particular rule for which the waiver is requested.

178.1(5) Filing of petition. A petition for a waiver must be submitted in writing to the department as follows:

- a. Application for license, registration, certification, or permit. If the petition relates to an application for license, registration, certification, or permit, the petition shall be made in accordance with the filing requirements for the application in question.
- b. Contested cases. If the petition relates to a pending contested case, the petition shall be filed in the contested case proceeding, using the caption of the contested case.
- c. Other. If the petition does not relate to an application or a pending contested case, the petition may be submitted to the department director.
- d. A petition is deemed filed when it is received at the department’s office. A petition should be sent to the Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319. The petition must be typewritten or legibly handwritten in ink and substantially conform to the form specified in 641—178.2(17A,135).

178.1(6) Content of petition. A petition for waiver shall include the following information where applicable and known to the requester:

- a. The name, address, and telephone number of the person for whom a waiver is being requested and a reference to any related contested case. The petition shall also include the name, address, and telephone number of the petitioner’s legal representative, if applicable, and a statement indicating the person to whom communications concerning the petition should be directed.
- b. A description and citation of the specific rule from which a waiver is requested.
- c. The specific waiver requested, including the precise scope and duration.
- d. The relevant facts that the petitioner believes would justify a waiver under each of the four criteria described in subrule 178.1(4). This statement shall include a signed statement from the petitioner

attesting to the accuracy of the facts provided in the petition and a statement of reasons that the petitioner believes will justify a waiver.

e. A history of any prior contacts between the department and the petitioner relating to the regulated activity, license, registration, certification, or permit affected by the proposed waiver, including a description of each affected license, registration, certification, or permit held by the requester, any formal charges filed, any notices of violation, contested case hearings, or investigations relating to the regulated activity, license, registration, certification or permit.

f. Any information known to the requester regarding the department's action in similar circumstances.

g. The name, address, and telephone number of any public agency or political subdivision that also regulates the activity in question or that might be affected by the granting of a waiver.

h. The name, address, and telephone number of any person who would be adversely affected by the granting of the petition.

i. The name, address, and telephone number of any person with knowledge of the relevant facts relating to the proposed waiver.

j. Signed releases of information authorizing persons with knowledge regarding the request to furnish the department with information relevant to the waiver.

178.1(7) Additional information. Prior to issuing an order granting or denying a waiver, the department may request additional information from the petitioner relative to the petition and surrounding circumstances. If the petition was not filed in a contested case, the department may, on its own motion or at the petitioner's request, schedule a telephonic or in-person meeting between the petitioner and the department director or the director's designee.

178.1(8) Notice. The department shall acknowledge a petition upon receipt. Except where otherwise provided by law, every petition shall be served by the petitioner upon each of the parties of record of the proceeding and on all other persons identified in the petition for waiver as affected by the petition, simultaneously with the filing. The petitioner shall serve the notice on all persons to whom notice is required by any provision of law and provide a written statement to the department attesting that notice has been provided. In addition, the department may give notice to other persons.

178.1(9) Hearing procedures. The provisions of Iowa Code sections 17A.10 to 17A.18A regarding contested case hearings shall apply to any petition for a waiver filed within a contested case. A person who objects to a denial of a waiver in proceedings other than a contested case hearing may make an informal appearance before the department director, or the director's designee, to request reconsideration.

178.1(10) Ruling. An order granting or denying a waiver shall be in writing and shall contain a reference to the particular person and rule or portion thereof to which the order pertains, a statement of the relevant facts and reasons upon which the action is based, and a description of the precise scope and duration of the waiver if one is issued.

a. Department discretion. The final decision on whether the circumstances justify the granting of a waiver shall be made at the sole discretion of the department upon consideration of all relevant factors. Each petition for a waiver shall be evaluated by the department based on the unique, individual circumstances set out in the petition.

b. Burden of persuasion. The burden of persuasion rests with the petitioner to demonstrate by clear and convincing evidence that the department should exercise its discretion to grant a waiver from a department rule.

c. Narrowly tailored exception. A waiver, if granted, shall provide the narrowest exception possible to the provisions of a rule.

d. Administrative deadlines. When the rule from which a waiver is sought establishes administrative deadlines, the department shall balance the special individual circumstances of the petitioner with the overall goal of uniform treatment of all similarly situated persons.

e. Conditions. The department may place any condition on a waiver that the department finds desirable to protect the public health, safety, and welfare.

f. Time period of waiver. A waiver shall not be permanent unless the petitioner can show that a temporary waiver would be impracticable. If a temporary waiver is granted, there is no automatic right

to renewal. At the sole discretion of the department, a waiver may be renewed if the department finds that grounds for a waiver continue to exist.

g. Time for ruling. The department shall grant or deny a petition for a waiver as soon as practicable but, in any event, shall do so within 120 days of its receipt unless the petitioner agrees to a later date. However, if a petition is filed in a contested case, the department shall grant or deny the petition no later than the time at which the final decision in that contested case is issued.

h. When deemed denied. Failure of the department to grant or deny a petition within the required time period shall be deemed a denial of that petition by the department. However, the department shall remain responsible for issuing an order denying a waiver.

i. Service of order. Within seven days of its issuance, any order issued under this rule shall be transmitted to the petitioner or the person to whom the order pertains and to any other person entitled to such notice by any provision of law.

178.1(11) Public availability. All orders granting or denying a waiver petition shall be indexed, filed, and available for public inspection as provided in Iowa Code section 17A.3. Petitions for a waiver and orders granting or denying a waiver petition are public records under Iowa Code chapter 22. Some petitions or orders may contain information the department is authorized or required to keep confidential. The department may accordingly redact confidential information from petitions or orders prior to public inspection.

178.1(12) Summary reports. Semiannually, the department shall prepare a summary report identifying the rules for which a waiver has been granted or denied, the number of times a waiver was granted or denied for each rule, a citation to the statutory provisions implemented by these rules, and a general summary of the reasons justifying the department’s actions on waiver requests. If practicable, the report shall detail the extent to which the granting of a waiver has affected the general applicability of the rule itself. Copies of this report shall be available for public inspection and shall be provided semiannually to the administrative rules coordinator and the administrative rules review committee.

178.1(13) Cancellation of a waiver. A waiver issued by the department pursuant to this rule may be withdrawn, canceled, or modified if, after appropriate notice and hearing, the department issues an order finding any of the following:

- a.* The petitioner or the person who was the subject of the waiver order withheld or misrepresented material facts relevant to the propriety or desirability of the waiver; or
- b.* The alternative means for ensuring that the public health, safety and welfare will be adequately protected after issuance of the waiver order have been insufficient; or
- c.* The subject of the waiver order has failed to comply with all conditions contained in the order.

178.1(14) Violations. A violation of a condition in a waiver order shall be treated as a violation of the particular rule for which the waiver was granted. As a result, the recipient of a waiver under this rule who violates a condition of the waiver may be subject to the same remedies or penalties as a person who violates the rule at issue.

178.1(15) Defense. After the department issues an order granting a waiver, the order is a defense within its terms and the specific facts indicated therein only for the person to whom the order pertains in any proceeding in which the rule in question is sought to be invoked.

178.1(16) Judicial review. Judicial review of the department’s decision to grant or deny a waiver petition may be taken in accordance with Iowa Code chapter 17A.

641—178.2(17A,135) Sample petition for waiver. A petition for waiver filed in accordance with 641—178.1(17A,135) must meet the requirements specified therein and must substantially conform to the following form:

| | | |
|---|---|---------------------------------|
| BEFORE THE DEPARTMENT OF PUBLIC HEALTH | | |
| Petition by (name of petitioner) for the waiver/variance of (insert rule citation) relating to (insert the subject matter). | } | PETITION FOR WAIVER/VARIANCE |

1. Provide petitioner's (person asking for a waiver or variance) name, address, and telephone number. Also include the name, address, and telephone number of the petitioner's legal representative, if applicable, and a statement indicating the person to whom communications concerning the petition should be directed.
 2. Describe and cite the specific rule from which a waiver is requested.
 3. Describe the specific waiver requested, including the precise scope and time period for which the waiver will extend.
 4. Explain the relevant facts and reasons that the petitioner believes justify a waiver. Include in your answer all of the following:
 - a. Why applying the rule would result in undue hardship to the petitioner;
 - b. Why waiving the rule would not prejudice the substantial legal rights of any person;
 - c. Whether the provisions of the rule subject to the waiver are specifically mandated by statute or another provision of law; and
 - d. How substantially equal protection of public health, safety, and welfare will be afforded by a means other than that prescribed in the particular rule for which the waiver is requested.
 5. Provide a history of any prior contacts between the department and petitioner relating to the regulated activity, license, registration, certification or permit that would be affected by the waiver. Include a description of each affected license, registration, certification, or permit held by the petitioner, any formal charges filed, any notices of violation, any contested case hearings held, or any investigations related to the regulated activity, license, registration, certification, or permit.
 6. Provide information known to the petitioner regarding the department's action in similar circumstances.
 7. Provide the name, address, and telephone number of any public agency or political subdivision that also regulates the activity in question or that might be affected by the granting of the petition.
 8. Provide the name, address, and telephone number of any person or entity that would be adversely affected by the granting of the waiver.
 9. Provide the name, address, and telephone number of any person with knowledge of the relevant facts relating to the proposed waiver.
 10. Provide signed releases of information authorizing persons with knowledge regarding the request to furnish the department with information relevant to the waiver.
- I hereby attest to the accuracy and truthfulness of the above information.

 Petitioner's signature

 Date

These rules are intended to implement Iowa Code section 17A.9A and chapter 135.

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