ALABAMA STATE COMMITTEE OF PUBLIC HEALTH ALABAMA DEPARTMENT OF PUBLIC HEALTH ADMINISTRATIVE CODE

CHAPTER 420-1-2 OFFICE OF GENERAL COUNSEL RULE-MAKING PROCEDURES

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420-1-2-.01 Applicability.

This chapter prescribes general rule-making procedures that apply to the adoption, amendment and repeal of rules of the State Board of Health (hereinafter referred to as "the Board").

Author: John R. Wible

Statutory Authority: Code of Ala. 1975, \$\$22-2-2(6), 41-22-5. History: Filed July 20, 1990. Repealed and New Rule: Filed

February 21, 2007; effective March 28, 2007.

420-1-2-.02 Sources Of Proposed Rules.

Rules to be considered by the Board may be proposed in the following manner:

- (a) The adoption, amendment or repeal of a rule may be proposed to the Board by a member of the Board, the State Health Officer or any legislatively-created council or board dealing with public health.
- (b) Any person may petition the Board to adopt, amend or repeal a rule.

Author: John R. Wible

Statutory Authority: Code of Ala. 1975, \$\$22-2-2(6), 41-22-5, 41-22-8.

History: Filed July 20, 1990. Repealed and New Rule: Filed February 21, 2007; effective March 28, 2007.

420-1-2-.03 Register Of Regulations.

- (a) Records of the Board concerning rule-making actions, including notice of rule-making; comments received in response to those notices; petitions for rule-making; denials of petitions for rule-making; and final rules are maintained in a current register of regulations in the Office of General Counsel, State Board of Health, 201 Monroe Street, Suite 1540, Montgomery, Alabama 36104.
- (b) Any person may examine any registered material at that office and may obtain a copy of any registered material upon payment of costs in accordance with Rule 420-1-5-.04.

Author: John R. Wible

Statutory Authority: Code of Ala. 1975, \$\$22-2-2(6), 41-22-5, 41-22-7.

History: Filed July 20, 1990. Repealed and New Rule: Filed February 21, 2007; effective March 28, 2007.

420-1-2-.04 Right To Petition; Contents And Submission.

Any person may petition the Board to adopt, amend or repeal a rule by making and filing a written petition in accordance with the following:

- (a) A petition to adopt, amend or repeal a rule shall contain the following information:
 - (1) the name, address and telephone number of the person making the petition;
 - (2) a statement of the interest of the person making the petition; and the name, address and telephone number of the group or entity represented by the Petitioner, if any.
 - (3) the specific language of the rule proposed to be adopted, the proposed amendment, or the rule proposed to be repealed;
 - (4) all evidence, data and information on which the petitioner relies in support of the petition; and
 - (5) a statement of the petitioner's position on the considerations described in subparagraphs (b) through (g) of Rule 420-1-2-.05.
- (b) A petition for rule-making shall be filed with the State Health Officer by delivering the same, either personally or by

United States Mail as certified mail, return receipt requested, with instructions to the delivering postal employee to show to whom delivered, date of delivery, and address where delivered, to:

> State Health Officer Alabama Department of Public Health 201 Monroe Street, Suite 1552 Montgomery, Alabama 36104

Author: John R. Wible

Statutory Authority: Code of Ala. 1975, \$\$22-2-2(6), 41-22-8. History: Filed July 20, 1990. Repealed and New Rule: Filed

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420-1-2-.05 Consideration Of Petitions.

The Board shall give consideration to any petition for rule-making made and filed in accordance with Rule 420-1-2-.04. The Board may consider:

- (a) the views of the Department staff; and of other state agencies
- (b) whether the proposed rule adoption, amendment, or repeal is constitutional and within the statutory authority of the Department to adopt;
- (c) whether the proposed rule adoption, amendment, or repeal would promote the legislative intent and purposes of the statutes that the Department administers;
- (d) whether the petition is supported by such substantive, credible and relevant evidence, data and information as would reasonably support the proposed rule action.
- (e) whether the petitioner has had a prior opportunity to present relevant evidence, data and information on the subject matter of the petition and the petitioner failed to present such evidence, data or information;
- (f) whether alternative means of obtaining the same or similar relief are presently available to the petitioner or have in the recent past been made available to the petitioner;
- (g) the manner in which the proposed rule adoption, amendment, or repeal would impact the overall regulatory scheme of the Department and whether the proposed rule adoption, amendment, or repeal would promote the basic underlying public policies of the statutes and rules which the Department administers; and

(h) any other relevant factors, evidence, data or information.

Author: John R. Wible

Statutory Authority: Code of Ala. 1975, \$\$22-2-2(6), 41-22-8.

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420-1-2-.06 Disposition Of Petitions.

Within sixty days after a petition is filed with the State Health Officer in accordance with Rule 420-1-2-.04, the Board shall do one of the following, provided however, that upon written notice to the petitioner, such sixty-day period may be extended by the State Health Officer or the Board for not more than thirty days:

- (a) initiate rule-making proceedings in accordance with $\underline{\text{Code}}$ of Ala. 1975, $\S41-22-5$, as amended; or
- (b) deny the petition in writing on the merits stating the reasons therefore.

Author: John R. Wible

Statutory Authority: Code of Ala. 1975, §\$22-2-2(6), 41-22-8.

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February 21, 2007; effective March 28, 2007.

420-1-2-.07 Administrative Procedures For Rule-Making.

- (a) Except for the promulgation of an emergency rule, the State Health Officer, through the Agency Secretary, shall issue public notices of proposed rule-making.
- (b) Public Hearing.
 - (1) Prior to the taking of any action on a proposed rule, the Board shall allow all interested persons a reasonable opportunity to submit data, views or comments, either orally or in writing. A public hearing shall be scheduled. Notice of such hearing shall be published in the **Alabama Administrative Monthly**. Actual notice to interested groups, agencies or persons may be made at the direction of the State Health Officer.
 - (2) The State Health Officer shall appoint a hearing officer who shall be given full control over the proceeding of the hearing. He shall direct the hearing so as to eliminate repetition and keep order, and shall require statements to be as factual as possible.

- (3) All oral comments at the hearing shall be directed to the hearing officer. The hearing officer and members of the staff may question speakers if they so desire. Speakers will not be subject to questions from the audience.
- (4) A stenographic reporting or electronic recording of the proceedings shall be made. A verbatim transcript may be prepared if needed. When so prepared, it shall become a part of the hearing record.
- (5) Unless otherwise specified, all hearings shall be held in Montgomery, Alabama.
- (c) Contents of Written Comments. All written comments shall be stated plainly and concisely. Unless otherwise specified in a notice requesting comments, comments may not exceed 15 pages in length, but necessary attachments may be appended to the submission without regard to the 15-page limit.
- (d) Petition for Extension of Time to Comment. A petition for extension of time to submit comments must be received not later than 10 days before the expiration of the time stated in the notice. Petitions must be submitted to the State Health Officer, 201 Monroe Street, Suite 1552, Montgomery, Alabama 36104. The filing of the petition does not automatically extend the time for the petitioner's comments. Such a petition is granted only if the petitioner shows good cause for the extension and if the extension is consistent with the public interest. Under provisions of the Administrative Procedure Act, the agency has 90 days from the closing of the hearing record to adopt the final rule.
- (e) Emergency Rules. If the State Health Officer finds that there is an immediate danger to the public health, safety or welfare which requires the adoption of a rule with less than 35 days' notice or that the action is required by or to comply with a federal statute or regulation which requires adoption of a rule upon fewer than 35 days' notice and so states in writing his reasons for that finding, the State Health Officer may proceed without prior notice or hearing, or any abbreviated notice and hearing that he finds practical, and adopt an emergency rule.
 - (1) Emergency rules become effective immediately upon filing a copy of such with the Legislative Reference Service.
 - (2) Emergency rules are not valid for longer than 120 days, and shall not be renewable.
 - (3) The Board shall not adopt the same or a substantially similar emergency rule within one year unless it establishes that it could not have reasonably been foreseen during the initial 120 days that such emergency would continue or would likely occur within the next nine months.

- (4) A rule adopted under the emergency proceedings may be made a permanent rule by the Board by complying with all the provisions of the Alabama Administrative Procedure Act and these rules.
- (5) Emergency rules promulgated by the State Health Officer shall have the same force and effect as those adopted by the Board.
- (6) This rule applies only to emergency rules and not to emergency orders issued by the agency.
- (f) Publication and Effective Date of Rules. The Agency Secretary shall file each rule upon adoption by the Board. Such rule shall be effective 35 days after the filing unless the Board specifies a longer time.

Author: John R. Wible

Statutory Authority: Code of Ala. 1975, \$\$22-2-2(6), 41-22-8. History: Filed July 20, 1990. Amended: Filed June 19, 1991. Repealed and New Rule: Filed February 21, 2007; effective March 28, 2007.

420-1-2-.08 Advisory Boards.

Except for the adoption of an emergency rule, the Board shall not adopt a rule governing the operation of a "hospital," as that term is defined at Code of Alabama 1975, §22-21-20, without the prior advice and approval of the Licensure Advisory Board established by Code of Alabama 1975, §22-21-27. The chairperson of the Licensure Advisory Board, or another member designated by the chairperson, shall attest in writing to the Licensure Advisory Board's approval of any such rule, so that such attestation may be submitted to the Board for consideration.

Author: John R. Wible

Statutory Authority: Code of Ala. 1975, §§22-2-2(6), 22-21-27, 22-21-281, 41-22-4.

History: Filed July 20, 1980. Repealed and New Rule: Filed February 21, 2007; effective March 28, 2007.

420-1-2-.09 Waivers Or Variances.

(a) The State Health Officer or the Board may grant a waiver or variance from any rule, except that no waiver or variance may be granted for any provision that restates a statutory requirement or defines any term. "Waiver" or "variance" means that the application of a rule, or a particular provision of a rule, has been suspended for the time and/or in the manner specified by order of the Board or the State Health Officer. Waivers or

variances may be of general application or apply only to specified persons or entities.

- (b) Upon request of the staff of the Department of Public Health or on his or its own motion, the State Health Officer or the Board may grant a waiver or a variance to the application of any rule as to the public in general, when such waiver or variance is based upon a compelling public health need, or a threatened public health emergency, or the occurrence of an event or circumstance that makes strict compliance with a rule highly impractical or impossible.
- (c) The State Health Officer shall report variances and waivers to the Board.
- (d) A current or prospective licensee, permittee, or registrant directly affected by a provision of a rule may request a waiver or variance from said rule. To be considered for a waiver or variance, the licensee, permittee, or registrant must demonstrate the following:
 - (1) Conditions are such that the licensee, permittee, or registrant cannot meet the rule provision for which the waiver or variance is sought; and
 - (2) Approval of the waiver or variance will not unreasonably increase the risk of harm to the public or undermine the public health purpose furthered by the rule.
- (e) An application for waiver or variance must be presented in writing to the State Health Officer or his duly authorized representative or as otherwise provided by rule. The application may be in letter format, but it must contain the following: the name, address, and phone number of the licensee, permittee, or registrant; a specific statement of the particular rule or rules for which a waiver or variance is sought; the period of time for which a waiver or variance is sought; and the specific information and evidence supporting the request. Documentary evidence may be attached to the application.
- (f) Following receipt of a properly submitted and complete application for waiver or variance, the State Health Officer or the Board may grant the requested waiver or variance. The waiver or variance shall continue for the period of time stated. The State Health Officer or the Board may alter, amend or revoke the waiver or variance upon notice to the licensee, permittee, or registrant, whenever circumstances or conditions change or there is an amendment to the rule for which a waiver or variance was granted.
- (g) An application for waiver or variance that does not comply with the requirements of this rule may be denied. If the application or supporting documents are discovered to be false or

inaccurate, the application may be denied or if the waiver or variance has already been granted, it may be revoked.

- (h) Waivers and variances are not favored actions, and may be granted only where, in the judgment of the State Health Officer or the Board, the conditions of this rule have been satisfied.
- (i) The application to grant a waiver or variance is also subject to other rules of the Board in program specific areas. Except as otherwise provided by law or rule, where there is a conflict between the rules pertaining to program specific areas and the provisions of this rule, the provisions of this rule shall take precedence.

Author: John R. Wible

Statutory Authority: Code of Ala. 1975, §\$22-2-2(6), 22-21-28. History: New Rule: Filed June 29, 2001; effective August 3, 2001. Repealed and New Rule: Filed February 21, 2007; effective March 28, 2007. Repealed and New Rule: Filed October 19, 2007; effective November 23, 2007.