## ARTICLE XLV PUBLIC INFORMATION, PROCEEDINGS ON PROPOSED REGULATIONS AND DECLARATORY OPINIONS

### A. METHOD OF OPERATION OF BOARD OF PHARMACY

**1. Scope**. Part A of these Rules is promulgated pursuant to Mississippi Code Section 25-43-2.104 of the Administrative Procedures Law.

**2. Description of Mississippi State Board of Pharmacy**. Reference is made to the Mississippi Pharmacy Practice Act, Mississippi Code Section 73-21-69, et seq. which creates and sets out the duties and responsibilities of the Mississippi Pharmacy Board.

**3. Public Information**. The public may obtain information regarding operations and responsibilities of the Mississippi Board of Pharmacy, the Pharmacy Practice Act and Board Regulations and other pertinent information by contacting the Board office at 204 Key Drive, Suite C, Madison, Mississippi 39110, 601-605-5388. Additional information is available on the Mississippi Board of Pharmacy Website at the Board's website at www.mbp.state.ms.us. Requests for Declaratory Opinions may be made pursuant to Part C of these rules.

### B. ORAL PROCEEDINGS ON PROPOSED REGULATIONS

**1.Scope**. These rules set forth the Mississippi Board of Pharmacy, hereinafter "Board," rules governing the form and content of requests for all oral proceedings held for the purpose of providing the public with an opportunity to make oral presentations on proposed new regulations and amendments to regulations before the Board pursuant to §25-43-3.104.

**2.When Oral Proceedings will be Scheduled on Proposed Regulations**. The Board will conduct an oral proceeding on a proposed regulation or amendment if requested by a political subdivision, an agency or ten (10) persons in writing within twenty (20) days after the filing of the notice of the proposed regulation.

**3. Request Format**. Each request must be printed or typewritten, or must be in legible handwriting. Each request must be submitted on standard business letter-size paper (8-1/2 inches by 11 inches). Requests may be in the form of a letter addressed to the Board and signed by the requestor(s).

**4. Notification of Oral Proceeding**. The date, time and place of all oral proceedings shall be filed with the Secretary of State's office and mailed to each requestor. The oral proceedings will be scheduled no earlier than twenty (20) days from the filing of this information with the Secretary of State.

**5. Presiding Officer**. The Board President or his designee, who is familiar with the substance of the proposed regulation, shall preside at the oral proceeding on a proposed regulation.

**6. Public Presentations and Participation.**

(a) At an oral proceeding on a proposed regulation, persons may make oral statements and make documentary and physical submissions, which may include data, views, comments or arguments concerning the proposed regulation.

(b) Persons wishing to make oral presentations at such a proceeding shall notify the Board at least one business day prior to the proceeding and indicate the general subject of their presentations. The presiding officer in his or her discretion may allow individuals to participate that have not previously contacted the Board.

(c) At the proceeding, 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.

(d) The presiding officer may place time limitations on individual oral presentations when necessary to assure the orderly and expeditious conduct of the oral proceeding. 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.

(e) Persons making oral presentations are encouraged to avoid restating matters that have already been submitted in writing.

(f) There shall be no interruption of a participant who has been given the floor by the presiding officer, except that the presiding officer may in his or her discretion interrupt or end the partisan's time where the orderly conduct of the proceeding so requires.

**7. Conduct of Oral Proceeding.**

(a) Presiding officer. The presiding officer shall have authority to conduct the proceeding in his or her discretion for the orderly conduct of the proceeding. The presiding officer shall (i) call proceeding to order; (ii) give a brief synopsis of the proposed regulation, a statement of the statutory authority for the proposed regulation, and the reasons provided by the Board for the proposed regulation; (ii)call on those individuals who have contacted the Board about speaking on or against the proposed regulation; (iii) allow for rebuttal statements following all participant's comments; (iv) adjourn the proceeding.

(b) Questions. The presiding officer, where time permits and to facilitate the exchange of information, may open the floor to questions or general discussion. The presiding officer may question participants and permit the questioning of participants by other participants about any matter relating to that regulation-making proceeding, including any prior written submissions made by those participants in that proceeding; but no participant shall be required to answer any question.

(c) Physical and Documentary Submissions. Submissions presented by participants in an oral proceeding shall be submitted to the presiding officer. Such submissions become the property of the Board and are subject to the Board's public records request procedure.

(d) Recording. The Board may record oral proceedings by stenographic or electronic means.

## C. DECLARATORY OPINIONS

**1. Scope.** These rules set forth the Mississippi Board of Pharmacy, hereinafter "Board," rules governing the form and content of requests for declaratory opinions, and the Board's procedures regarding the requests, as required by Mississippi Code Section 25-43-2.103. These rules are

intended to supplement and be read in conjunction with the provisions of the Mississippi Administrative Procedures Law, which may contain additional information regarding the issuance of declaratory opinions. In the event of any conflict between these rules and the Mississippi Administrative Procedures Law, the latter shall govern.

**2. Persons Who May Request Declaratory Opinions**. Any person with a substantial interest in the subject matter may request a declaratory opinion from the Board by following the specified procedures. "Substantial interest in the subject matter" means: an individual, business, group or other entity that is directly affected by the Board's administration of the laws within its primary jurisdiction. "Primary jurisdiction of the Board" means the Board has a constitutional or statutory grant of authority in the subject matter at issue.

**3. Subjects Which May Be Addressed In Declaratory Opinions**. The Board will issue declaratory opinions regarding the applicability to specified facts of: (1) a statute administered or enforceable by the Board or (2) a regulation promulgated by the Board. The Board will not issue a declaratory opinion regarding a statute or regulation which is outside the primary jurisdiction of the Board.

**4. Circumstances In which Declaratory Opinions Will Not Be Issued**. The Board may, for good cause, refuse to issue a declaratory opinion. The circumstances in which declaratory opinions will not be issued include, but are not necessarily limited to:

(a) lack of clarity concerning the question presented;

(b) there is pending or anticipated litigation, administrative action, or other adjudication which may either answer the question presented by the request or otherwise make an answer unnecessary;

(c) the statute or regulation on which a declaratory opinion is sought is clear and not in need of interpretation to answer the question presented by the request;

(d) the facts presented in the request are not sufficient to answer the question presented;

(e) the request fails to contain information required by these rules or the requestor failed to follow the procedure set forth in these rules;

(f) the request seeks to resolve issues which have become moot, or are abstract or hypothetical such that the requestor is not substantially affected by the statute or regulation on which a declaratory opinion is sought;

(g) no controversy exists concerning the issue as the requestor is not faced with existing facts or those certain to arise which raise a question concerning the application of the statute or regulation;

(h) the question presented by the request concerns the legal validity of a statute or rule;

(i) the request is not based upon facts calculated to aid in the planning of future conduct but is, instead, based on past conduct in an effort to establish the effect of that conduct;

(j) no clear answer is determinable;

(k) the question presented by the request involves the application of a criminal statute or a sets of facts which may constitute a crime;

(l) the answer to the question presented would require the disclosure of information which is privileged or otherwise protected by law from disclosure;

(m) The question is currently the subject of an Attorney General's opinion request or has been answered by an Attorney General's opinion;

(n) A similar request is pending before this Board or any other agency or a proceeding is pending on the same subject matter before any agency, administrative or judicial tribunal, or where such a opinion would constitute the unauthorized practice of law.

(o) Where issuance of a declaratory opinion may adversely affect the interests of the State, the Board or any of their officers or employees in any litigation which is pending or may reasonably be expected to arise;

(p) The question involves eligibility for a license, permit, registration or other approval by the Board or some other agency, and there is a statutory or regulatory application process by which eligibility for said license, permit, registration or other approval would be determined.

**5. Written Request Required**. Each request must be printed or typewritten, or must be in legible handwriting. Each request must be submitted on standard business letter-size paper (8-1/2 inches by 11 inches). Requests may be in the form of a letter addressed to the Board.

**6. Where to Send Requests**. All requests must be mailed, delivered or transmitted via facsimile to the Board. The request shall clearly state that it is a request for a declaratory opinion. No oral, telephone requests or email requests will be accepted for official opinions.

**7. Name, Address and Signature of Requestor**. Each request must include the full name, telephone number, and mailing address of the requestor. All requests shall be signed by the person filing the request, who shall attest that the request complies with the requirements set forth in these rules, including but not limited to a full, complete, and accurate statement of relevant facts and that there are no related proceedings pending before any other administrative or judicial tribunal.

**8. Question Presented**. Each request shall contain the following:

(a) a clear and concise statement of all facts on which the opinion is requested;

(b) a citation to the statute or regulation at issue;

(c) the question(s) sought to be answered in the opinion, stated clearly;

(d) a suggested proposed opinion from the requestor, stating the answers desired by petitioner and a summary of the reasons in support of those answers;

(e) the identity of all other known persons involved in or impacted by the described factual situation, including their relationship to the facts, name, mailing address and telephone number; and

(f) a statement to show that the person seeking the opinion has a substantial interest in the subject matter.

**9. Time for Board's Response.** Within forty-five (45) days after the receipt of a request for a declaratory opinion which complies with the requirements of these rules, the Board shall, in writing:

(a) issue a declaratory opinion regarding the specified statute or regulation as applied to the specified circumstances;

(b) decline to issue a declaratory opinion, stating the reasons for its action; or

(c) agree to issue a declaratory opinion by a specified time but not later than ninety (90) days after receipt of the written request;

The forty-five (45) day period shall begin running on the first State of Mississippi business day on or after the request is received by the Board, whichever is sooner.

**10. Opinion Not Final for Sixty Days.** A declaratory opinion shall not become final until the expiration of sixty (60) days after the issuance of the opinion. Prior to the expiration of sixty (60) days, the Board may, in its discretion, withdraw or amend the declaratory opinion for any reason which is not arbitrary or capricious. Reasons for withdrawing or amending an opinion include, but are not limited to, a determination that the request failed to meet the requirements of these rules or that the opinion issued contains a legal or factual error.

**11. Notice by Board to third parties.** The Board may give notice to any person, agency or entity that a declaratory opinion has been requested and may receive and consider data, facts, arguments and opinions from other persons, agencies or other entities other than the requestor.

**12. Public Availability of Requests and Declaratory Opinions.** Declaratory opinions and requests for declaratory opinions shall be available for public inspection and copying in accordance with the Public Records Act and the Board's public records request procedure.

All declaratory opinions and requests shall be indexed by name and subject. Declaratory opinions and requests which contain information which is confidential or exempt from disclosure under the Mississippi Public Records Act or other laws shall be exempt from this requirement and shall remain confidential.

**13. Effect of a Declaratory Opinion.** The Board will not pursue any civil, criminal or administrative action against a person who is issued a declaratory opinion from the Board and who, in good faith, follows the direction of the opinion and acts in accordance therewith unless a court of competent jurisdiction holds that the opinion is manifestly wrong. Any declaratory opinion rendered by the Board shall be binding only on the Board and the person to whom the opinion is issued. No declaratory opinion will be used as precedent for any other transaction or occurrence beyond that set forth by the requesting person.