



Guide to in the Rule-making Process

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Mission and Structure of the Board

The mission of the State of Ohio Board of Pharmacy is to act efficiently, consistently, and impartially in the public interest to pursue optimal standards of practice through communication, education, legislation, licensing, and enforcement.

The State of Ohio Board of Pharmacy is the single state agency in Ohio responsible for administering and enforcing laws governing the legal distribution of drugs. The Board consists of nine members who are appointed by the Governor for terms of four years. Eight of the members are licensed pharmacists who represent, to the extent practicable, each phase of pharmacy practice. One member represents the public.

Since the State of Ohio Board of Pharmacy is responsible for administering and enforcing the drug laws of Ohio, the Board licenses:

- Pharmacists (ORC Chapter 4729.)
- Pharmacy Interns (ORC Chapter 4729.)
- Pharmacy Technicians (ORC Chapter 4729.)
- Terminal and Wholesale Distributors of Dangerous Drugs (ORC Chapter 4729.)
- Manufacturers and Wholesalers of Controlled Substances (ORC Chapter 3719.)
- Home Medical Equipment Service Providers (ORC Chapter 4752.)
- Medical Marijuana Dispensaries and Patients/Caregivers (ORC Chapter 3796.)

The Board is also responsible for regulating the legal distribution of dangerous drugs in Ohio and ensuring the quality of all drugs administered, prescribed, dispensed by prescription, or sold over-the-counter (O.R.C. Chapter 3715.). The State of Ohio Board of Pharmacy can discipline its licensees and registrants for violations of both federal and state laws governing the legal distribution of drugs. The Board has the responsibility of investigating and presenting evidence of violations of any of the federal or state drug laws by any person to the appropriate court (federal, state, or municipal) for prosecution of the offender (ORC Chapter 2925.).

Introduction

The law governing the practice of pharmacy and the distribution of dangerous drugs in Ohio has two components. The first is through statutes enacted by the Ohio General Assembly and codified in the Ohio Revised Code (ORC). The second is by rule, developed and enacted by the State of Ohio Board of Pharmacy codified in the Ohio Administrative Code (OAC). Rules provide the detail that clarifies and amplifies the provisions of the Ohio Revised Code and have the force and effect of law. Rules cannot change the provisions of or exceed the scope of authorization in the Ohio Revised Code.

77 South High Street, 17th Floor, Columbus, Ohio 43215



The process by which regulatory agencies adopt administrative rules may appear, at times, dauntingly complex. The process is designed, however, to offer the public and other interested and affected parties an opportunity to provide input regarding the content of any rule being considered. This guide has been published to assist members of the public who participate, or who may wish to participate, in the Board's rule-making process.

Rule Making Authority

An agency's authority to adopt administrative rules is found in Ohio Revised Code, and is generally of two types: general rule-making authority and issue-specific rule-making authority. The Board has the general authority to adopt rules related to the practice of pharmacy and the legal distribution of dangerous drugs in sections 4729.26, 3719.28 and 3715.69 of the Revised Code.

Specific authorizations or requirements for the Board to adopt rules related to specific legislative initiatives can be found in other language in the Pharmacy Board statutes. All rules of the Pharmacy Board can be found in Chapter 4729 of the Ohio Administrative Code.

Rules Process

Prior to the initiation of the formal rules process, the Board must decide that it needs to propose to change an administrative rule. Typically, the Board decides to propose a change due to the following reasons:

- The Board is directed by the legislature to write rules to explain or assist in the administration of new pieces of legislation related to the practice of pharmacy or distribution of drugs;
- Issues that come to the attention of the Board from its licensees, its staff and the public, and, in some of those cases, the Board may also decide that the best way to address the issue is through administrative rule; and
- Chapter 119. of the Revised Code requires that each state agency review each of its rules every five years. In any year, 20 percent of the Board's rules are scheduled to be reviewed, and each must then go through the formal rule-making process.

The following is a step-by-step process of the Board's rule-making process:

Note: For more information about the Ohio Medical Marijuana Control Program rules, visit:

<https://medicalmarijuana.ohio.gov/>

Step 1: Rules Review Committee

With limited exceptions, proposed rules and rules up for their five-year review are vetted by the Board's Rules Review Committee. This committee is composed of pharmacists from a number of practice settings. The committee typically meets quarterly.

The Board established the Medical Equipment Services Advisory Council to advise the Board on issues specific to the licensure and regulation of home medical equipment service providers. The Council will be tasked with the review of all Home Medical Equipment Service Provider rules.

Step 2: Approval for Filing by the Board

Once reviewed by the Rules Review Committee or Medical Equipment Services Advisory Council, the Board then reviews the rules and approves for filing with the Common Sense Initiative (CSI) and then the Joint Committee on Agency Rule Review (JCARR).

Step 3: Common Sense Initiative (CSI)

Prior to filing with JCARR, **all rules** (including no-change rules) may be vetted through the Common Sense Initiative (CSI), operated by the Lt. Governor's Office. Review by CSI is normally required for all rules that meet at least one of the following adverse business impact criteria:

- Requires a license, permit, or any other prior authorization to engage in or operate a line of business;
- Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action, for failure to comply with its terms; or
- Requires specific expenditures or the report of information as a condition of compliance.

The CSI process provides entities that may be impacted by the rule the opportunity to provide comment. This process takes approximately 16 business days and all CSI postings for public comment (commonly referred to as business impact analyses) are posted to the Board's proposed rules web page (www.pharmacy.ohio.gov/proposed). CSI will issue a recommendation to the Board based upon the feedback provided during the comment period.

Step 4: Joint Committee on Agency Rule Review (JCARR)

If the Board receives a favorable recommendation from CSI, it will formally file the rules with the Joint Committee on Agency Rule Review (JCARR).

Step 5: Public Hearing

As part of the JCARR process the Board holds a public hearing between 30 – 41 days after the rules have been filed with JCARR. This allows the Board to receive additional input on the rules. All public hearing notices are posted to the Board's proposed rules web page (www.pharmacy.ohio.gov/proposed).

On the date, time and place designated in the notice, the Board will conduct a public hearing at which any person affected by the proposed action of the Board or any member of the public may testify.

Public hearing notices and copies of the proposed or amended rules are also available on the register of Ohio's web site: <http://www.registerofohio.state.oh.us/>

Once the hearing record is closed, the Board will review and consider all the testimony at a regularly scheduled meeting. The Board may decide to proceed with the rules unchanged, it may withdraw the rule, or it may make changes to the rule based on the testimony received and refile it at a later date.

PLEASE NOTE: The Board is not required to hold a public hearing on rules that are subject to five-year review in which no changes are made.

Step 6: JCARR Hearing

The rules are then reviewed by JCARR, a 10-member legislative panel, at a public meeting of the committee to determine if they violate any of the following:

- a. Do the rules exceed the agency's statutory authority;
- b. Do the rules conflict with an existing rule of that agency or another state agency;
- c. Do the rules conflict with legislative intent;
- d. Has the rule-making agency prepared a complete and accurate rule summary and fiscal analysis of the proposed rule, amendment, or rescission (ORC 127.18);
- e. Has the rule-making agency met the incorporation by reference standards for a text or other material as stated in ORC sections 121.72, 121.75, or 121.76; and,
- f. If the rule has an adverse impact on business (ORC 107.52), that the rule-making agency has demonstrated through the business impact analysis (BIA), the Common Sense Initiative Office (CSI) recommendations and the agency's memorandum of response to the CSI recommendations, that the rule's regulatory intent justifies its adverse impact on business.

Step 7: Rules Adoption

After complying with the filing provisions of Chapter 119. of the Revised Code, and when the time for legislative review and invalidation (i.e. JCARR's jurisdiction) has expired, the Board may issue an order adopting the proposed rule and must designate the effective date of the rule, which shall not be earlier than the tenth day after it has been filed in its final form. When the rule is adopted, the final language will be posted on the Register of Ohio and on the Board's web site (www.pharmacy.ohio.gov/rulechanges).

Public Participation in the Rules Process

The Board of Pharmacy values the input of the public in its rule-making process, and commits to continue to make every reasonable effort to ensure that the public has the opportunity to provide that input at every step of the process.

- Initiating the discussion: The public is encouraged to bring issues of concern to the attention of the Board. Members of the public may submit concerns online by visiting www.pharmacy.ohio.gov/contact.
- During the process of rule formulation: Members of the public may attend meetings of the Board's Rules Review Committee or the Medical Equipment Services Advisory Council.
- During the Common Sense Initiative comment process: Members of the public can submit comments to the Common Sense Initiative when the Board posts the required business impact analysis to its website (www.pharmacy.ohio.gov/proposed).

- *At the public rules hearing:* Testimony may be presented at the public rules hearing by any person. Those who intend to testify at the hearing are asked to complete a witness slip upon their arrival at the hearing, and witnesses are called to testify in the order in which the slips are received. Board members may ask questions of a witness or may place a time limit on a witness's oral testimony to assure that all who wish to testify can be heard. For those preferring to testify in writing, the Board of Pharmacy will accept written testimony. A person who presents testimony in writing is not required to appear at the hearing. Written remarks may be submitted to the Board by mail, fax, or email any time prior to the hearing and until such time as the hearing record is closed.
- *At the JCARR hearing:* This hearing is the final opportunity for the public to provide comments about the rules. The comments before JCARR may only address the six issues within JCARR's jurisdiction as listed above.

Conclusion

The Board relies upon public input to guide its rule-making activities and encourages feedback and comments on its rules. If you would like to be placed on the Board's mailing list to receive notice of all meetings of the Board, please visit: <http://www.pharmacy.ohio.gov/RSS/Subscription.aspx>.

If you have any questions regarding the information in this guide, or would like more detailed information on the rule-making process, please contact the Board office (www.pharmacy.ohio.gov/contact).

Helpful Links

Ohio Revised Code: <http://codes.ohio.gov/orc/4729>

Ohio Administrative Code: <http://codes.ohio.gov/oac/4729>

Registrar of Ohio: <http://www.registerofohio.state.oh.us/>

Common Sense Initiative:
<http://www.governor.ohio.gov/PrioritiesandInitiatives/CommonSenseInitiative.aspx>

Joint Committee on Agency Rule Review: <http://www.jcarr.state.oh.us/>

Ohio Medical Marijuana Control Program: <https://medicalmarijuana.ohio.gov/>