



Guide to Rule Making

(For the Citizens of Ohio)

The Ohio Department of Health • 246 N. High St., Columbus, Ohio 43215

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In Executive Order 2008-04S, Governor Strickland required that state agencies work as partners with businesses and individuals affected by regulations to identify and achieve regulatory goals. Accessibility, flexibility, respect, timely responsiveness, problem solving and continuous improvement must be hallmarks of Ohio's approach to regulatory activity. These objectives can only be achieved when the process by which regulations are enacted is transparent and accessible to persons outside of government and when those regulations are crafted so they are easy to understand by those affected.

This guide is required by Ohio Revised Code (ORC) 119.0311 and has been updated to reflect Executive Order 2008-04S. This guide is intended to help members of the public who participate, or may wish to participate, in the rulemaking process of the Ohio Department of Health (ODH).

Ohio Department of Health's Mission

*"To Protect and Improve the Health of All Ohioans
by Preventing Disease, Promoting Good Health and
Assuring Access to Quality Health Care"*

Ohio Department of Health's Vision

"Optimal Health for All Ohioans"



Agency Organization

Pursuant to section 3701.02 of the ORC, ODH consists of a Director of Health and a Public Health Council. Legislation passed by the General Assembly requiring ODH to establish rules dictates whether the rules are to be promulgated by the Director of Health or by the Public Health Council. The Public Health Council is made up of seven members appointed by the Governor and consists of the following:

- Three physicians who are licensed to practice medicine in the state;
- A pharmacist who is licensed to practice pharmacy in the state;
- A registered nurse who is licensed to practice nursing as a registered nurse in the state;
- A sanitarian who holds a valid certificate of registration as a sanitarian issued under section 4736.11 of the ORC;
- A member of the public who is not associated with or financially interested in the practice of medicine, nursing, pharmacy, or environmental health and is at least sixty years of age.

To achieve its mission, ODH is divided into the following three major program divisions and seventeen bureaus that implement Ohio's health regulations.

Division of Prevention – (614) 466-0302

Bureau of Environmental Health
Bureau of Infectious Disease Epidemiology and Surveillance
Bureau of Public Health Laboratories
Bureau of Radiation Protection
Bureau of HIV/AIDS, STD, and TB

Division of Family and Community Health Services – (614) 466-3263

Bureau of Child and Family Health Services
Bureau for Children with Medical Handicaps
Bureau of Early Intervention Services
Bureau of Nutrition Services
Bureau of Community Health Services

Division of Quality Assurance – (614) 466-7857

Bureau of Diagnostic Safety and Personnel Certification
Bureau of Long Term Care Quality
Bureau of Information and Operational Support
Bureau of Regulatory Compliance
Bureau of Community Health Care Facilities and Services

Bureau of Health Promotion and Risk Reduction (Healthy Ohio) – (614) 466-1663

Bureau of Public Health Preparedness – (614) 644-6133

Rule-making requirements and authorization

The ORC requires and authorizes ODH to adopt administrative rules. Rules are adopted pursuant to Chapter 119 or section 111.15 of the ORC, which become part of the Ohio Administrative Code (OAC). ODH may also adopt internal management rules.

What is a rule?

A rule is a regulation or standard, having a general and uniform operation, which is adopted, promulgated and enforced by any agency under the authority of the laws governing such agency.

Rule-making process

The rule-making process may be lengthy and complex, but in general, there are standard steps involved in the adoption of rules at ODH.

Internal drafting and review

ODH begins the rule-making process through an internal process in which the Agency identifies the need for a rule and develops a draft of the rule language. Often this is done in response to legislation enacted by the General Assembly. Once it is determined that a rule needs to be adopted, amended or rescinded, the specific program responsible for the rule prepares a draft, and may seek input from other ODH programs, external stakeholders and others known to be interested in the rule.

Interested party review

The interested party review process is designed to allow interested parties, stakeholders or citizens to make comments regarding the rule prior to adoption. ODH conducts the interested party review prior to formally filing the proposed rule with the Joint Committee on Agency Rule Review (JCARR).

Internal posting of draft rule

Once the draft rule is completed, it is posted on ODH's Web site, www.odh.ohio.gov/rules/odhrules.aspx. Interested parties are notified that the draft is available for review. A deadline for submitting comments is set by ODH. This time-frame is normally 30 days, but may be lengthened or shortened for various reasons.

E-Notification Process

Interested parties may also register to receive notification through the State of Ohio's Rules Electronic Notification System at www.business.ohio.gov/reform/ or through ODH's listservs. Once registered, individuals will receive notices and communications regarding the creation, amendment, rescission or continuation without change of any rule.

Consider interested party comments

ODH collects, reviews and considers each relevant comment, concern or question received during the draft review period. Based on the comments received, ODH may revise the draft rule as appropriate. The time needed to review and incorporate the comments received varies depending on the complexity of the comments.

Complete the Common Sense Business Regulation Checklist

This checklist is required by Executive Order 2008-04S, which calls for a review of new and current rules. The review is aimed at modifying or eliminating unnecessary or needlessly burdensome rules while establishing regulatory performance standards that will make Ohio a more competitive place to do business.

File the proposed rule with JCARR

When the draft rule is complete, either the Director of Health or Public Health Council, as appropriate, file it with JCARR, the Secretary of State, the Legislative Service Commission (LSC) and the Office of Entrepreneurship and Small Business. The Secretary of State maintains copies of the proposed rules. LSC reviews the proposed rule to ensure that it is properly formatted and codified. The Office of Entrepreneurship and Small Business maintains a copy of the rule so that small businesses and organizations have the opportunity review the rule. When the rule has been filed with JCARR, it is called a "proposed rule." ODH submits a Rule Summary and Fiscal Analysis (RSFA) with the proposed rule. Among other things, the RSFA provides a summary of the proposed rule and states the legal basis for the rule. The RSFA also estimates the budgetary effect of the proposed rule and estimates the cost of compliance by all directly affected persons. The proposal to JCARR starts the 65-day JCARR jurisdiction. Within the first 31-40 days of that jurisdiction, the Director or Public Health Council, as appropriate, will hold a public hearing to provide an opportunity for anyone to provide oral testimony on the rule.

Public notice, comment period and hearing

When the rule is proposed, ODH issues a public notice of the proposal and begins the formal public comment period. The public comment period usually ends on the day of the public hearing. ODH conducts public hearings for all new, amended and rescinded rules. A public hearing is the public's opportunity to provide oral testimony or comments for the record. Those who choose not to provide oral testimony are encouraged to submit their comments in writing via mail or facsimile to the Office of General Counsel. Written comments are also maintained as part of the record. ODH considers all relevant comments when deciding whether to adopt, amend or rescind a rule. Public hearing notices are posted on the Register of Ohio's Web site (www.registerofohio.state.oh.us) and sent to interested parties on the mailing list maintained by the department.

Consider public comments

Written and oral comments received during the public comment period receive the same consideration. ODH carefully reviews all submitted comments and may revise the proposed rule as appropriate.

JCARR hearing and jurisdiction

JCARR's primary function is to review rules in accordance with Ohio's rule-making statutes. JCARR, part of the Ohio Legislature, consists of five State Representatives and five State Senators. JCARR has 65 days to review the rule to ensure:

- the rules do not exceed the scope of the rule-making agency's statutory authority;
- the rules do not conflict with another rule of that agency or another rule-making agency;
- the rules do not conflict with the intent of the legislature in enacting the statute under which the rule is proposed; and,
- the rule-making agency has prepared a complete and accurate rule summary and fiscal analysis of the proposed rule, amendment or rescission (Section 127.18 of the ORC) and, if the agency has incorporated text or other material by reference, the agency has met the standards stated in sections 121.72, 121.75 or 121.76 of the ORC.

At the public meeting JCARR members may question representatives from state agencies about any concerns they have regarding a rule and members of the public have an opportunity to bring any concerns they have to JCARR's attention. JCARR's meeting dates and the rules on their agenda may be obtained from their website: www.jcarr.state.oh.us or by calling (614) 466-4086.

Within the last 41 to 65 days of JCARR jurisdiction, JCARR holds a hearing to accept comments on the proposed rule. Based on the comments received, JCARR may take action to stop the adoption of the rule for the duration of that General Assembly.

Finalize the rule

Following the 65-day JCARR jurisdiction, the Director of Health or the Public Health Council, as appropriate, adopts the rule and establishes the date the rule becomes effective. The rule may take effect no sooner than the tenth day after the day on which the rule is filed in final form. Once the rule is adopted, it is subject to appeal. The adoption of the final rule is published in the Register of Ohio at www.registerofohio.state.oh.us.

Emergency rules

In extraordinary circumstances, ODH may bypass most of this procedure and adopt emergency rules. This requires an order of the Governor finding that an emergency exists and suspending the normal procedural requirements of Ohio Revised Code Chapter 119. Emergency rules automatically expire after 90 days, unless, in the interim, the Agency has gone through the normal Chapter 119 rule-making procedure.

Public involvement and how to participate

While ODH has a legal duty to implement legislation through the adoption of rules, ODH needs and welcomes input from members of the public who are affected by the rules. Their expertise and perspective help assure the rules will have both a sound factual and legal basis. There are many opportunities for the public to participate in the rule-making process. Some of the simplest, and most effective ways, are described here.

- Sign up for the interested party list to receive notification of rule-making activities. To sign up, go to www.odh.ohio.gov/rules/odhrules.aspx or email your contact information to odhrules@odh.ohio.gov. You may also sign up for one of ODH's listservs to receive additional information including updates to Agency policies and guidance documents.
- Sign up for the State of Ohio's Rules E-Notification System at www.business.ohio.gov/reform/. Once registered, you will be notified electronically about agency rule actions. The Rules E-Notification System notifies interested parties and allows comment feedback during the executive order review of rules for selected state agencies. This notification and comment feedback period will be conducted in concert with ODH's established interested party review period.
- Review and comment on draft rules.
- Serve on advisory committees and participate in meetings with associations and advocacy groups.
- Review the rule proposal and public hearing notices.
- Attend ODH and JCARR public hearings.

Resources

- Joint Committee on Agency Rule Review www.jcarr.state.oh.us
- E-Notification System www.business.ohio.gov/reform
- ODH Rules and Laws www.odh.ohio.gov/rules/odhrules.aspx
- Register of Ohio www.registerofohio.state.oh.us

Who to contact:

If you have a question regarding the rule-making process, please contact ODH's Office of General Counsel. If your question concerns a particular rule or technical requirement, please contact the appropriate division/bureau listed on the front of this guide.

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