Statewide Public Health Rules in North Carolina

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1. What is an administrative rule?

A rule is a type of law that is made by an executive branch agency to implement or interpret a state or federal statute or a federal regulation. An executive branch agency has authority to adopt rules only when and to the extent a state or federal law authorizes it to do so.

2. Who makes the administrative rules that apply statewide?

The NC General Assembly has authorized a number of state agencies to adopt rules in different areas. The agency that makes most statewide public health rules is the NC Commission for Public Health. The Commission's rules are published in the North Carolina Administrative Code (NCAC) in Title 15A (most environmental health rules) and Title 10A (most other public health rules, including communicable disease, accreditation, and other topics). The NC Environmental Management Commission also has some rulemaking authority in the area of public health. It makes statewide rules regarding water sources, including rules governing local health departments' inspection and permitting of private drinking water wells.³

Other North Carolina agencies that make rules that may be of interest to public health agencies or employees include licensing boards (such as the Board of Nursing, or the Board of Environmental Health Specialist Examiners) and rulemaking bodies that address other issues that affect public health programs (for example, the NC Department of Health and Human Services adopts rules for North Carolina's Medicaid program).

3. Do administrative rules have the force of law?

Yes. People who are subject to a rule are legally obliged to comply with it. The rules can be enforced with the use of legal remedies, if necessary.

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¹ G.S. 150B-2(8a) defines a "rule" as "any agency regulation, standard, or statement of general applicability that implements or interprets an enactment of the General Assembly or Congress or a regulation adopted by a federal agency or that describes the procedure or practice requirements of an agency. The term includes the establishment of a fee and the amendment or repeal of a prior rule."

² G.S. 150B-19.1.

³ G.S. 87-97; 15A N.C.A.C. Subchapter 2C.

4. How are administrative rules made in North Carolina?

State agencies that are given rule-making authority must then comply with rule-making procedures set out in the NC Administrative Procedure Act.⁴ (Note that local board of health rule-making is *not* subject to the Administrative Procedure Act.)

The public has an interest in rulemaking, as rules can affect individual liberties or property rights. The procedures in the NC Administrative Procedures Act give the public notice and an opportunity to be heard in the rulemaking process. The Administrative Procedure Act defines and creates different procedures for three types of rules: permanent, temporary, and emergency rules.

Permanent rules. Most rules are intended to be permanent, which means they are expected to stay in place until they are repealed or a periodic rules review process determines they are no longer needed or desired. (There is more information about periodic rules review in the answer to questions 5 and 6.) The following is a very brief summary of the key steps in the process for adopting a permanent rule. It doesn't include all the nuances or details. In brief, the agency wishing to adopt a permanent rule must:

- Publish the text of the proposed rule in the <u>North Carolina Register</u> and on the agency's website.⁶
- Prepare or obtain a fiscal note for the proposed rule if a fiscal note is required.⁷
- Hold a public hearing on the proposed rule if the agency has received a written request for a public hearing within 15 days after publication in the North Carolina Register. (An agency may choose to hold a public hearing even if there is no request for one.)
- Accept comments on the text of the proposed rule for at least 60 days or until the date of a
 public hearing on the proposed rule, whichever is longer.
- Review the fiscal note and public comments on the rule.
- Take action on the proposed rule. If the agency adopts the proposed rule without substantial
 changes, the rule proceeds to the next steps. If the agency makes substantial changes, it must
 republish the rule and have another minimum 60-day comment period. If the agency fails to
 adopt the rule, the rule dies.
- Submit the adopted rule to the Rules Review Commission (RRC) within 30 days of adoption.

The RRC must review a permanent rule that is submitted on or before the 20th of the month by the last day of the next month. The next steps for the agency depend on the RRC's actions: ⁸

• If the RRC objects to the rule, the agency may allow the rule to die or may revise and return it to the RRC for another review.

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⁴ G.S. Chapter 150B, Article 2A. There are special exemptions that allow some agencies to use different procedures. However, the public health rules adopted by the Commission for Public Health and the Environmental Management Commission must follow the rule-making procedures in the Act.

⁵ Unless otherwise indicated, the steps in this description may be found in G.S. 150B-21.2.

⁶ G.S. 150B-19.1(c) requires publication on the agency's website.

⁷ G.S. 150B-21.4 specifies when a fiscal note is required.

⁸ The RRC's authority and procedures are found in G.S. 150B, Art. 2A, Part 3.

- If the RRC approves a permanent rule only with substantial changes, the agency must republish the rule for reconsideration in accordance with the normal procedures for *temporary* rules.
- If the RRC approves the rule without substantial changes, it is entered into the NCAC and becomes effective on the first day of the month following the month in which the RRC approves it or on a later effective date specified by the agency—unless the RRC receives written objections to the rule from 10 or more persons before 5:00 p.m. of the day after the day the RRC approves the rule. Any person may object to the adoption of a permanent rule and request legislative review. If 10 or more people submit their written objections within the statute's timeframe, then the rule is subject to legislative disapproval. Legislative disapproval occurs only when the legislature is in session and is achieved by passing a bill specifically disapproving the rule. In this context, "disapproval" doesn't simply mean the legislature doesn't like it it means the rule dies. There are some timelines in the statute for the disapproval process, but a rule that is subjected to this process may have a long wait before it is either finally adopted or killed. 9

Temporary rules. An agency may adopt a temporary rule when it finds that immediate adoption is required for one of several reasons, including a serious and unforeseen threat to the public health, safety or welfare; recent changes in federal or state budget policies; a recent federal regulation; or a recent court order. The following is a very brief summary of the key steps in the process for adopting a temporary rule. It doesn't include all the nuances or details. In brief, the agency wishing to adopt a temporary rule must:

- At least 30 business days before adoption:
 - Submit the text of the proposed temporary rule to the Codifier of Rules, which must publish the rule text on the Office of Administrative Hearings' website within 5 business days.
 - Notify interested parties of its intent to adopt the rule and the date and place of a public hearing on the temporary rule.
- Accept written comments on the proposed temporary rule for at least 15 days before adoption.
- Hold at least one public hearing on the proposed temporary rule within 5 days after publication of the proposed temporary rule and notification of interested parties.
- Prepare a written statement of the need for a temporary rule explaining why a temporary rule is required and why adhering to the permanent rulemaking procedures would be contrary to the public interest.
- The agency may adopt the rule after the public hearing has been held, the public comment period has ended, and at least 30 days have passed since the rule was submitted to the Codifier of Rules and interested parties were notified.
- The agency must then submit the temporary rule to the RRC for review. The RRC must act within 15 days and must approve the rule if it determines the criteria for temporary rulemaking are met.

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⁹ G.S. 150B-21.3.

¹⁰ G.S. 150B-21.1(a).

¹¹ Unless otherwise indicated, the steps in this description may be found in G.S. 150B-21.1.

- o If approved, the temporary rule is returned to the Office of Administrative Hearings for publication.
- If the RRC determines the rule does not meet the criteria for approval as a temporary rule it must immediately notify the head of the agency that it objects to the rule. Upon receipt of the objection, the agency may submit additional findings, rewrite the rule, or allow the rule to die.

Emergency rules. An agency may adopt an emergency rule without prior notice or with abbreviated notice if the agency finds that adherence to the usual notice and hearing requirements would be contrary to the public interest, and that immediate adoption of the rule is required by a serious and unforeseen threat to the public health or safety. The emergency rulemaking process is very abbreviated compared to permanent or temporary rulemaking. Emergency rules are reviewed by the Codifier of Rules rather than the RRC. Emergency rules are short-term and expire no later 60 days after their publication in the North Carolina Register, unless a temporary rule to replace the emergency rule has been submitted to the RRC during that timeframe.

5. Do permanent rules expire after some period of time?

Until very recently the answer was no, but now it's yes. In the past, most statewide rules remained in effect indefinitely, unless and until they were amended or repealed. While any rule *could* be given a "sunset" or expiration date, most public health rules did not have these, and there was no mandatory process for periodically reviewing rules to ensure that they were up-to-date (though agencies could voluntarily review rules at any time).

The Regulatory Reform Act of 2013 instituted a mandatory periodic review of statewide rules.¹³ Each state rule-making agency is required to review all of its rules at least once every 10 years. The schedule for reviewing rules is developed by the NC Rules Review Commission. Any rule that is not reviewed on schedule will automatically expire (with a limited exception for rules that were adopted to conform to or implement federal laws).

6. What is the process for periodic review of statewide rules?

Each agency must review the rules affecting its programs and categorize each rule according to the definitions in Table 1. The agency's categorizations are considered the initial determination of the rule's status. The agency's initial determinations must be put into a report, which is made available for public comment. After the public comment period, the agency must review and prepare a brief response addressing the public comments. The agency must then submit a report to the Rules Review Commission, which reviews the report and makes its determinations about each rule. The Rules Review Commission's determinations are not final until the Commission consults with the Joint Legislative

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¹² G.S. 150B-21.1A.

¹³ S.L. 2013-413, sec. 3.(b), codified at G.S. 150B-21.3A.

Administrative Procedure Oversight Committee. Once the consultation requirement is satisfied, the category to which a rule was ultimately assigned determines what happens to the rule: whether it expires, continues in place without further action, or is required to go through the rule-making process for re-adoption as if it were a new rule.

Category	Definition	Result
Necessary with substantive public interest	 Rule is necessary but one or more of the following apply: Agency has received public comments on rule within past two years Rule affects property interest of the regulated public Agency knows or suspects any person may object to rule 	Rule must be readopted, following the rule-making process as if it were a new rule
Necessary without substantive public interest	Rules is necessary but none of the criteria for substantive public interest apply	Rule continues in effect without further action
Unnecessary	Rule is obsolete, redundant, or otherwise not needed	Rule expires

7. Have North Carolina's public health rules been through this process yet?

The review of North Carolina's public health rules has been underway since early 2014, and is scheduled to be completed by the end of 2018. The schedule for the statewide rules review is available on the website of the Office of Administrative Hearings, Rules Division. A schedule that organizes the rules by the agency that is responsible for the rules is at http://www.ncoah.com/rules/Schedule%20-%20Breakdown%20by%20Agency.pdf.