Hot Topics + Legislative Updates

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Presentation Roadmap

Legislative Updates

- 2024 legislative session: highlights
- Other legal updates: HIPAA Privacy Rule changes

Hot Topic: Periodic Review and Expiration of Existing Rules ("Readoption")

- What is a rule?
- Origins of periodic review ("readoption")
- Periodic review last time
- Periodic review next time

Legislative Updates

2024 Legislative "Short Session"

Overall, a fairly quiet year for child and adolescent health!

- Compare to 2023: Parent's Bill of Rights, gender transition care for minors, Medicaid expansion, etc.

A few highlights:

- **Session Law (S.L.) 2023-96:** took effect July 1, 2024 and impacts Child Advocacy Centers (CACs)
  - Approx. 55 CACs in NC; help with child medical examinations (CMEs) and forensic interviewing
  - New law standardizes CACs, requires creation of multidisciplinary teams (MDTs), supports data sharing within MDTs
  - See this blog post for more: https://canons.sog.unc.edu/2024/06/child-advocacy-centers-child-medical-evaluations-and-multidisciplinary-team-information-sharing-new-law-goes-into-effect-on-july-1/

- **S.L. 2024-51 and -53:** Hurricane Helene relief and recovery
  - Example: $5 mil to NC Dept. of Public Instruction to support mental health services for impacted students (2024-53, Sec. 4A.8)

Other Legal Updates

Federal level: HHS announced amendment to the HIPAA Privacy Rule

3 types of disclosure of protected health information (PHI) that are now prohibited

- Can't use/share PHI for certain purposes, like prosecution/investigation of a person for lawful reproductive health care

4 types of disclosures of PHI that now require an attestation

- These are existing, permitted disclosures under HIPAA- but attestation required going forward
- Attestation = the requestor of the PHI promising they aren't trying to get around the new law and asking for PHI for one of the 3 impermissible purposes/disclosures (see above)

Compliance date: December 23, 2024

- For more information, see these two blog posts:
- https://canons.sog.unc.edu/2024/06/final-rule-reproductive-health-care/
- https://canons.sog.unc.edu/2024/07/hipaa-attestations/

Hot Topic: “Readoption” of Rules

Where Do “Rules” (Regulations) Fit In the Law?

Legislative Branch

Enacts statutes

Federal: Congress

NC: General Assembly

Executive Branch Agencies

Adopt administrative regulations

Federal: EPA, FDA, CDC, etc

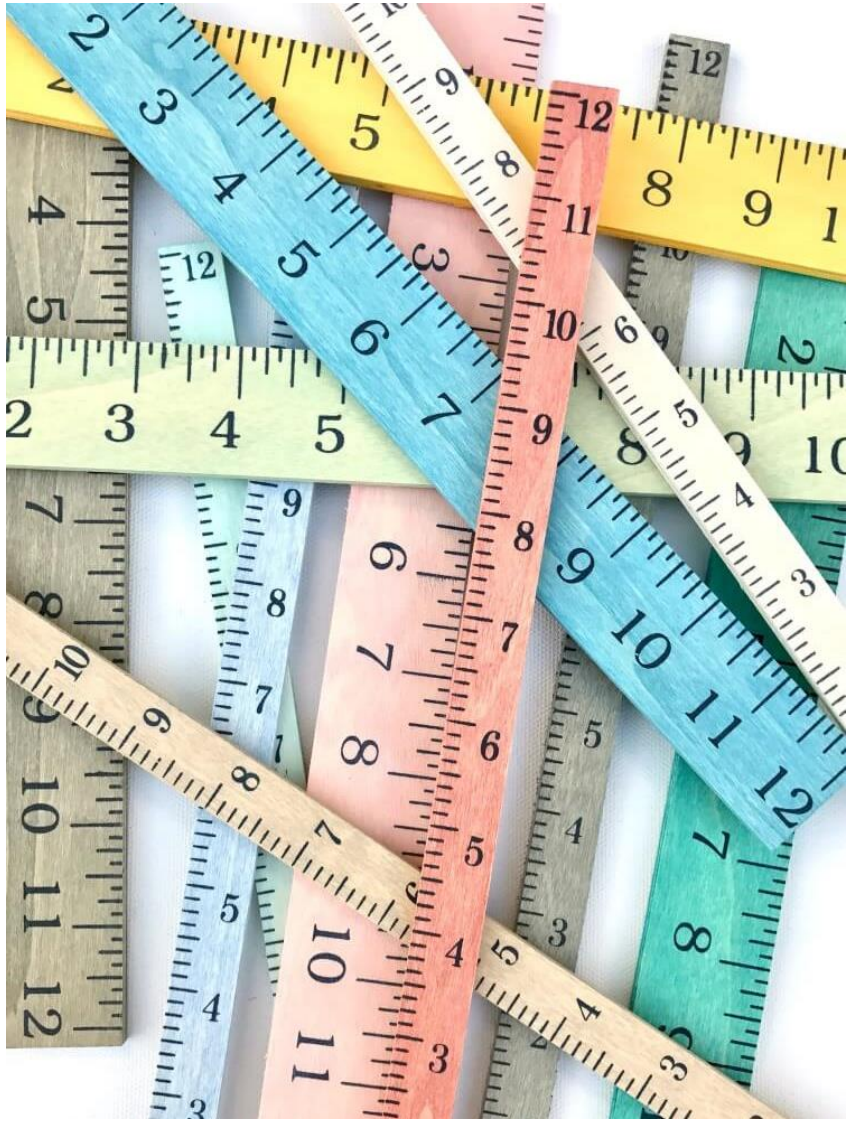
NC: NCDHHS, DEQ, etc

Courts

Interpret laws, create case law

Federal: SCOTUS, Circuit Courts, etc

NC: NC Supreme Court, COA, etc



What is a Rule?

G.S. 150B-2(8a): 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.

This means a rule is…

- Created by a NC agency or a licensing board
- Regulates some type of conduct
- Has the weight of law

What a Rule Is Not

- A “regulation” (not in NC, at least)
- Policy or guidance
- Budgetary policy
- Standards for internal management of an agency or a licensing board
- Repetition of statutes

Where Do I Find Rules?

Rules are found in the North Carolina Administrative Code (NCAC)

- Cited by Title – NCAC – Chapter – Section/Rule #
- For example: 10A NCAC 41A .0100

Organized by subject matter

The NCAC can be searched online at: http://reports.oah.state.nc.us/ncac.asp

Anatomy of a Rule

Rule Citation and Title

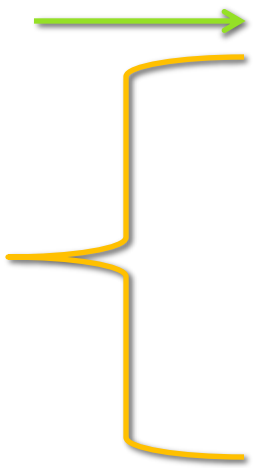
Tells you where the rule is found in the NCAC and its subject matter.

Rule Body

The substance of the rule.

History Note

Full of helpful information- tells you the rule's statutory authority, when it was first adopted, and when it was amended or repealed (if applicable).



10A NCAC 42B .0102 NEWBORN SCREENING

(a) The State Laboratory of Public Health will conduct screening for the core conditions listed on the Recommended Uniform Screening Panel developed by the Secretary of the United States Department of Health and Human Services and the Advisory Committee on Heritable Disorders of Newborns and Children (the "RUSP"), which is hereby incorporated by reference, including any subsequent editions and amendments, and available free of charge at https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/index.html. Specimens shall be submitted to this laboratory for screening in accordance with the procedures set forth in 10A NCAC 43H .0314.

(b) The process to develop and implement new screening for the conditions described in Paragraph (a) of this Rule shall begin after:

(1) the screening fee set out in Rule .0108 of this Section is adjusted, as permitted by G.S. 130A-125(c);

(2) funds exist to acquire instrumentation, equipment, Program supplies, and Program personnel; and

(3) the Program performs assay validations, implements preventative follow-up interventions, secures necessary infrastructure, and meets all federal, State, and local requirements.

History Note: *Authority G.S. 130A-88; 130A-125;*
Eff. October 1, 1985;
Amended Eff. September 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017;
Amended Eff. January 1, 2021.

Rulemaking Process

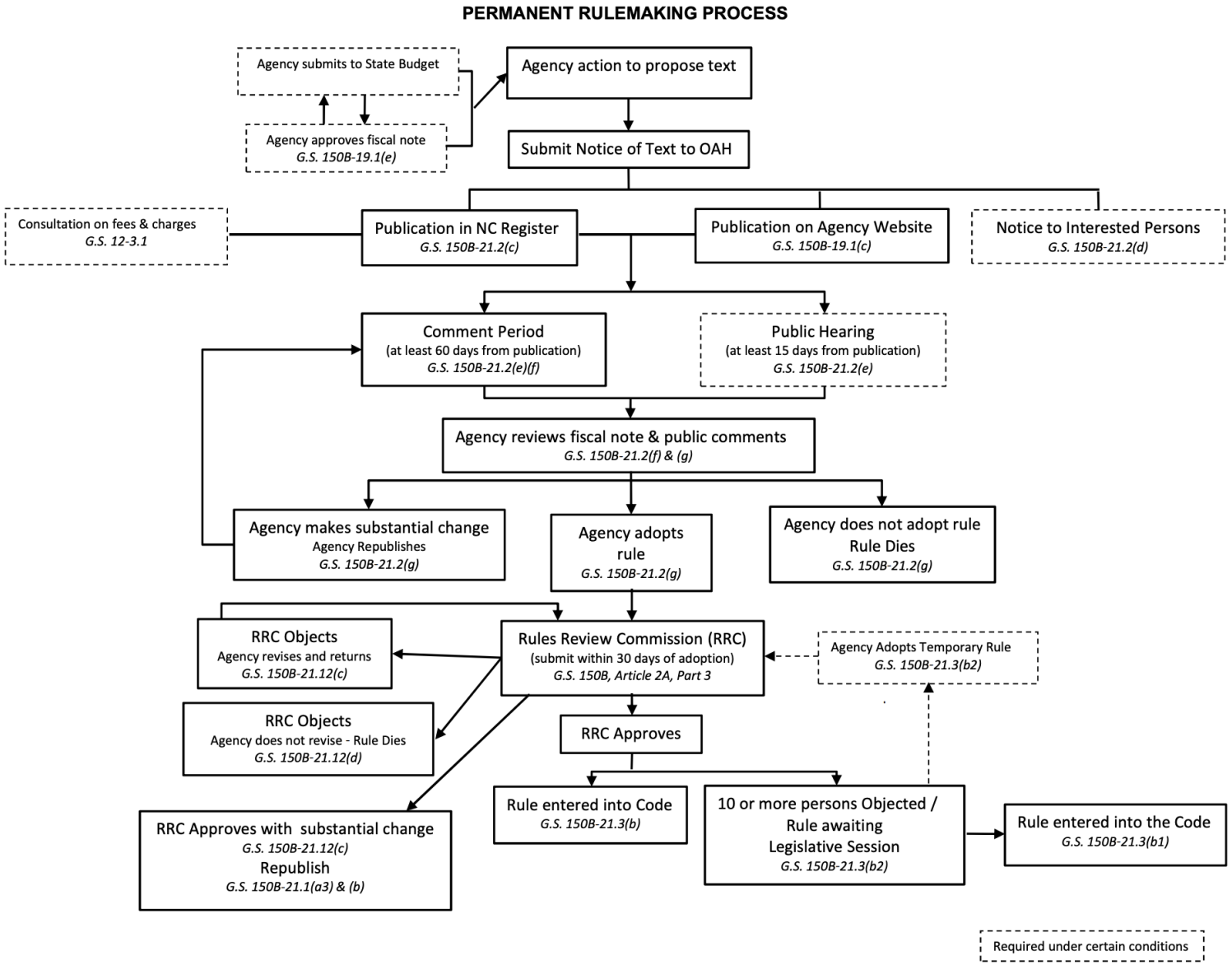
The rulemaking process is set out in **G.S. 150B, Art. 2A**

Rules can be:

- Adopted (creating a brand new rule)
- Amended (changing an existing rule)
- Repealed (removing an existing rule)

Why would you adopt, amend, or repeal a rule?

- NCGA passed a law requiring rulemaking action
- Changes to best practices, industry standards, scientific knowledge, etc.
- Petitioned to take up rulemaking action
- Court order



Permanent Rulemaking

- Most common type of rulemaking
- Typically takes 12 - 18 months
- Emphasizes transparency and democracy via public notice process and opportunity for the public to be heard

- The permanent rulemaking process is set out at **G.S. 150B-21.2**

Key Players: Rulemaking Bodies

Rulemaking is done by rulemaking bodies (“RMBs”)

- G.S. 150B refers to rulemaking bodies as “agencies”
- This presentation uses “RMBs” to avoid confusion with state executive branch agencies

Key Players: Rulemaking Bodies

Often called a “Commission” or a “Board”- typically corresponds to an agency or department

- Usually staffed by agency or department employees, including a rulemaking coordinator
- Ex.: North Carolina Commission for Public Health is staffed by NCDHHS, Division of Public Health

Members are typically appointed by the NCGA and/or the Governor and serve set terms

- State law may require that some members be experts/professionals in the subject matter area the RMB regulates

Meet on a regular schedule; option to hold special meetings

Subject to NC public records and open meetings laws

Key Players: Rulemaking Bodies

You may have heard of the…

- Local Government Commission
- NC Commission for Public Health
- NC Medical Board
- Real Estate Commission
- State Human Resources Commission
- Department of Environmental Quality
- Wildlife Resources Commission

But have you heard of the…?

- Board of Crop Seed Improvement
- Sedimentation Control Commission
- Board of Refrigeration Contractors
- Radiation Control Commission
- Locksmith Licensing Board
- Cemetery Commission
- Board of Funeral Service

Key Players: Rulemaking Bodies

Where do RMBs get their authority to make rules?

- Rulemaking authority- sometimes called “statutory authority”- is granted to RMBs by the NCGA
  - Can be broad- “the Commission shall adopt rules as necessary to carry out this program”
  - Can narrow- “the Commission shall adopt rules governing the use of records from the NC Birth Defects Monitoring Registry for research studies initiated on or after January 1, 2023”

RMBs can only act within the scope of their authority

A Quick Note About Statutory Authority

Statutory authority is critical. RMBs cannot regulate something in rule unless they have statutory authority.

You can find the statutory authority for a specific rule by looking at the end of the rule

- Go to “History Note” and then “Authority”

Note: very old rules (pre-2000s) may have been adopted at a time when statutory authority was more broadly conceived

- This may lead to challenges during Periodic Review
- More on this later- stay tuned!

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§ 130A-125. Screening of newborns for metabolic and other hereditary and congenital disorders.

(a) The Department shall establish and administer a Newborn Screening Program. The program shall include, but shall not be limited to:

(1) Development and distribution of educational materials regarding the availability and benefits of newborn screening.

(2) Provision of laboratory testing.

(3) Development of follow-up protocols to assure early treatment for identified children, and the provision of genetic counseling and support services for the families of identified children.

(4) Provision of necessary dietary treatment products or medications for identified children as medically indicated and when not otherwise available.

(5) For each newborn, provision of physiological screening in each ear for the presence of permanent hearing loss.

(6) For each newborn, provision of pulse oximetry screening to detect congenital heart defects.

(b) The Commission shall adopt rules necessary to implement the Newborn Screening Program. The rules shall include, but shall not be limited to, the conditions for which screening is required. The Commission shall amend the rules as necessary to ensure that each condition listed on the Recommended Uniform Screening Panel developed by the Secretary of the United States Department of Health and Human Services and the Advisory Committee on Heritable Disorders of Newborns and Children (the RUSP) is included in the Newborn Screening Program within three years after being added to the RUSP, except that the Commission is exempt from rule making with respect to adding screening tests for Pompe disease, Mucopolysaccharidosis Type I (MPS I), and X-Linked Adrenoleukodystrophy (X-ALD). The Department of Health and Human Services shall provide a report to the Joint Legislative Oversight Committee on Health and Human Services 18 months after a condition is added to the RUSP. When a delay adding an RUSP-identified condition to the Newborn Screening Program exceeds three years, the Department shall provide a report on the status and reasons for the delay to the Joint Legislative Oversight Committee on Health and Human Services every six months following the three-year delay.

Key Players: Rulemaking Coordinators

Every agency is required by law to have one or more rulemaking coordinator(s) ("RMC")

- RMC duties are set out at **G.S. 150B-21**
- Responsible for overseeing all of the RMB's rulemaking
- Most RMCs wear other hats (e.g., serving as General Counsel)
- **A gatekeeper:** no rulemaking action happens without the RMC's involvement!

Key Players: Rulemaking Coordinators

NC Office of Administrative Hearings (OAH) maintains a list of RMCs for each RMB

- Available online at: https://www.oah.nc.gov/documents/rulemaking-coordinator-list
- Also tells you the NCAC citations for each RMB's rules

Other Key Players

Subject Matter Experts ("SMEs")

- Program staff who advise on rule content
- Work closely with the RMC- may draft rules for presentation to and approval by the RMB

Regulated Public

- The people who are subject to the rule(s)

Office of State Budget and Management (OSBM)

- Helps an agency determine if a fiscal note is needed
- Reviews and approves fiscal notes for all RMBs- historically, this was just one person at OSBM!

Other Key Players

Codifier of Rules

- OAH employee
- Responsible for publishing the NCAC

NC Rules Review Commission ("RRC")

- 10 members who are appointed by NCGA
- Reviews and approves/disapproves rules at the end of the rulemaking process- scope is limited to:
  - Is there statutory authority for the rule?
  - Is the rule clear and unambiguous?
  - Is the rule reasonably necessary?
  - Was the rulemaking process carried out in compliance with G.S. 150B?

RRC Counsel

- Review rules submitted to RRC and recommends approval/disapproval by RRC

Origins of Periodic Review ("Readoption")

In 2013, the legislature enacted S.L. 2013-413

- Established **G.S. 150B-21.3A**, "Periodic Review and Expiration of Existing Rules"

Purpose: to ensure that RMB's rules are reviewed on a regular basis and that outdated or unnecessary rules are updated or taken off the books

Periodic Review (“Readoption”)

Requires RRC to establish a process by which all RMBs will revisit all of their rules

- The process that was created is called “Periodic Review” or “Readoption”
- Periodic review/readoption happens every 10 years
  - First Periodic Review ran from 2014-2023
  - About to begin the second Periodic Review in 2024

- Agencies do not get 10 years to review their rules
  - Rules are grouped by chapter and agencies are given deadlines somewhere within the 10 year period for each “group” of rules

How Do Rules + Readoption Impact My Work?

In North Carolina, rules set legal standards and requirements for many areas, including:

- Communicable disease control
- Sanitation and safety in daycares, nursing homes, restaurants, hotels, hospitals, jails, etc.
- Vital records management (birth and death registration and certificates)
- Childhood immunizations
- Clean drinking water and waste management
- Public benefit program operations (e.g., SNAP, WIC, Medicaid)
- Licensure and discipline of health professionals
- Local health department accreditation, mandatory services, and minimum staffing
- And more!

Periodic Review: Last Time Around

All agency rules are divided into three categories:

Necessary without Substantive Public Interest	Necessary with Substantive Public Interest	Unnecessary
Agency wants to keep the rule in the NCAC and has not received a public comment concerning the rule in the last 2 years	Agency wants to keep the rule in the NCAC and has received a public comment concerning the rule	Agency has reviewed the rule and determined it's no longer needed
No action- rule gets to stay in the NCAC as it is	Agency must "readopt" the rule by going through the permanent rulemaking process	No action- rule will expire and be removed from NCAC after the rule's deadline for Periodic Review passes

Periodic Review: This Time Around

All agency rules are divided into **two** categories:

Necessary without Substantive Public Interest	Necessary ~~with Substantive Public Interest~~	Unnecessary
Agency [illegible] to ke[illegible] rule in the NCAC [illegible] eceived a public comm[illegible] cerning the rule in the [illegible]	Agency wants to keep the rule in the NCAC ~~and has received a public comment concerning the rule~~	Agency has reviewed the rule and determined it's no longer needed
No ac[illegible] ule gets t[illegible] in the NC[illegible] t is	Agency must "readopt" the rule by going through the permanent rulemaking process	No action- rule will expire and be removed from NCAC after the rule's deadline for Periodic Review passes

What Happens If An Agency Misses a Periodic Review Deadline?

The rules expire from the NCAC

- They cease to exist- can only be put back in the NCAC by going through permanent rulemaking as if adopting brand new rules

What Does All of This Mean?

RMBs will be required to readopt ***hundreds*** or even ***thousands*** of rules

- Huge lift for RMBs, agency staff, RRC, and RRC counsel
- Hard work- a lot of rules are old and must be significantly revised to meet current rulemaking standards (if possible)

What Does This Mean? cont.

Rules (the law) will change

- Every rule must be readopted or allowed to expire
- Readopted rules that are more recent may only need small changes, but…
  - Older rules (of which there are many) will likely need to be significantly re-written to meet current rulemaking standards; some old language may not be possible to preserve (even if re-written)
  - Challenges with statutory authority

Looking Forward

Be aware of the rules that impact your area of work and their Periodic Review ("readoption") deadlines

- Find the RMC for rules of interest on the OAH site + get added to interested persons list
- Monitor public notices on RMB/agency website
- Attend public hearings to learn more about upcoming changes
- Be aware that rules are going to change- sometimes a little, sometimes a lot
- Be sensitive to the fact that this is a big lift for agency/RMB staff!

References + Additional Resources

NC Laws

- G.S. 150B (the "Administrative Procedure Act")
- G.S. 150B-21.3A ("Periodic Review and Expiration of Existing Rules")

Other References

- North Carolina Administrative Code: http://reports.oah.state.nc.us/ncac.asp
- OAH Rulemaking Coordinator List: https://www.oah.nc.gov/documents/rulemaking-coordinator-list
- OAH Style Guide: https://www.oah.nc.gov/documents/rules/administrative-rule-style-guide-updated-april-2021/download

Additional Resources

- OAH Website on Periodic Review and Expiration of Existing Rules: https://www.oah.nc.gov/rules-division/periodic-review-and-expiration-existing-rules
- North Carolina Register: https://www.oah.nc.gov/rules-division/north-carolina-register

Image References

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Questions?

Thank you for your time.

If you have additional questions at a later date, please send me an email or give me a call.

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