Legislative and Regulatory Update

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NC Health Directors' Legal Conference April 2024

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Legislative Update – Highlights

2023 Long Session Highlights

SL 2023-134 (H259) - Appropriations for:

- Local Health Departments: \$50,000 grant, in both years of the biennium, to each local health department for activities pertaining to the 10 essential public health services specified in G.S. 130A-1.1(b)
- Tobacco Prevention and Cessation: \$11,250,000 appropriated from the Juul Labs v. NC Settlement to DPH for evidence-based e-cigarette and nicotine dependence prevention and cessation and related activities
- Vital Records: \$5.0 million in FY 2023-24 and \$3.0 million in FY 2024-25 to digitize records
- OCME: To increase OCME capacity for autopsies and toxicology screenings; increase autopsy fee; and funding for newly created South Piedmont Autopsy Center and the East Carolina Autopsy Center
 - Also, provisions expanding professionals eligible to serve as county medical examiners and enabling appointment of temporary medical examiners during declared emergencies

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2023 Long Session Highlights

Provisions supporting harm reduction

- SL 2023-65 (H190) DHHS Agency Bill
 - Adds gabapentin to CSRS
 - · Requires e-prescribing of codeine cough syrup
 - · Adds OTC opioid antagonist to immunity law

Provisions supporting vaccination

 SL 2023-15, Sec. 3 (S206): Enables immunizing pharmacists (and pharmacy interns and technicians under the supervision of an immunizing pharmacist) to administer any vaccine recommended by ACIP to persons 18+ in accordance with written protocols

Medicaid Expansion

- SL 2023-7 (H76):
 - Launched Dec. 1, 2023
 - · Almost 350,000 enrolled as of February 1, 2024

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2023 Long Session Highlights

- Restrictions on Abortion
 - SL 2023-14 (S20) Care for Women, Children, and Families Act
 - Abortion remains legal in NC:
 - During the first 12 weeks of pregnancy
 - · Life-limiting medical emergency
 - · Through the 20th week, if a result of rape or incest
 - Through the 24th week, if a life-limiting anomaly in the fetus
 - https://www.ncdhhs.gov/assistance/north-carolina-reproductive-healthservices
- Restrictions Impacting Minors
 - SL 2013-16 (S49) Parental Bill of Rights
 - UNC SOG Health Law Bulletin No. 92, Consent to Care for Minor Patients: An Update on the Legal Landscape after SL 2023-106, Part III by Kirsten Leloudis (January 2024)

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What's next?

- Short Session begins April 24
- Awaiting Governor's Budget



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Regulatory Update – Periodic Review and Readoption

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What is administrative rulemaking?

- Administrative Rule 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.
- · State agency rulemaking must be:
 - Within a state agency's delegated statutory authority (as delegated by the General Assembly)
 - Done in compliance with the NC Administrative Procedure Act (G.S. 150B, Article 2A



SOURCE: G.S. Chapter 150B

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Rulemaking Key Players

- The Commission for Public Health (CPH) is the public health rulemaking body for North Carolina.
 - authorized and directed by the legislature to adopt rules to protect and promote the health of the public and to implement public health programs administered by the Division of Public Health
- The Rules Review Commission (RRC) is agency charged with reviewing and approving rules adopted by state agencies.
 - Comprised of 10 members appointed by the General Assembly
 - Determines whether rules meet certain criteria

SOURCE: G.S. 130A, Article 1A; G.S. 143B-30.1; G.S. 150B, Article 2A

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CPH Membership

- · 13 members; 4 year terms
- Prior to SL 2023-136 (S512)
 - 9 appointed by the Governor
 - 4 elected by the NC Medical Society
- After SL 2023-136 (S512) Effective 2/28/24*
 - 4 appointed by the General Assembly
 - · At-large members
 - Appointments Bill: SL 2023-148 (S761)
 - 5 appointed by the Governor
 - pharmacist, veterinarian, optometrist, dentist, registered nurse
 - Removed requirement for a registered engineer with experience in sanitary engineering or a soil scientist
 - 4 elected by the NC Medical Society

*Subject to and without waiver of the Governor's ongoing appeal

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Periodic Review and Expiration of Existing Rules

- Established by SL 2013-413; Amended by SL 2019-140
- Requires agencies to review their rules every 10 years to ensure the rules are still current, necessary, and within the agency's authority.
- There are two phases to the process:
 - Phase 1: Periodic Review
 - Phase 2: Readoption

Prior round of periodic review and readoption (2014-2023) is now complete!

SOURCE: G.S. 150B-21.3A

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Phase 1 - Periodic Review

- · Deadline for completion set by the RRC
- Agency to analyze and classify existing rules
 60-day public comment period on initial classifications
- Report of classifications due to RRC by the 20th of the month *prior* to the scheduled due date
- RRC to review the agency report and consult with the Joint Legislative Administrative Procedure Oversight Committee prior to finalizing the report

PREVIOUS PERIODIC REVIEW (2014-2023)

Action
Readopt
Remain
Expire

PERIODIC REVIEW – Starting 2024

Ciassification Determinations	ACTION
Necessary	Readopt
Unnecessary	Expire
	•

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Phase 1 - Periodic Review Classifications

Unnecessary

- "A rule the agency determines to be obsolete, redundant, or otherwise not needed." G.S. 150B-21.3A(a)(6).
- · Removed from the Code.

Necessary

- "Any rule other than an unnecessary rule." G.S. 150B-21.3A(a)(2a).
- Must be readopted as if they are new rules using the permanent rulemaking process, pursuant to G.S. 150B, Article 2A.

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Periodic Review Report Schedule

Periodic Rev	iew Schedule			
	2024	2025	2026	2027
Jan				
Feb				
Mar				367
Apr				
May				
June			44	99
July			35	
Aug	9			
Sept			170	
Oct		15		
Nov		67	57	
Dec	21		20	
Total	904			

This reflects # of rules in reports due these months.

https://www.oah.nc.gov/documents/rules/periodic-review-report-schedule-2024-2027/open

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Periodic Review Report Deadlines

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September 2026

Chapter 41 Epidemiology Health (5 subchapters)

Subchapter 41A (38 rules) — Communicable in the control of the
             15A NCAC 010 (9 rules) – EH Delegation of Authority
December 2024

    Subchapter 41B (30 rules) – Injury Control
    Subchapter 41D (5 rules) – Methamphetamine

              10A NCAC 45 (21 rules) – General Procedures for PH Programs

    Subchapter 45A – Payment Programs
    Subchapter 45B – Procedural Rules

                                                                                                                                                                                                                       Decontamination

    Subchapter 41F (3 rules) – Pesticide-Related Illness or

October 2025
               ET 2002

10A NCAC 47 (15 rules) – Information Services

Subchapter 47A – SCHS

Subchapter 47B – Cancer Registry

Subchapter 47C – Birth Defects Monitoring Program

    Subchapter 41G (2 rules) – Veterinary Public Health

    Subchapter 412 C, zules) – Veterlmary Public Realtin
    10A NCAC 42 (46 rules) – Laboratory Services
    Subchapter 42A – General Policies
    Subchapter 42B – Laboratory Sections
    Subchapter 42C – Milk and Water Laboratory Certification
November 2025
               10A NCAC 46 (16 rules) - Local Standards

    Subchapter 42D – Laboratory Certificatio

                10A NCAC 48 (51 rules) - Local Health Department Accreditation

    10A NCAC 43 – Personal Health (one subchapter)

                                 Subchapter 48A - LHD Accreditation Administration
                       ■ Subchapter 48B – LHD Accreditation Standards

    10A NCAC 44 (7 rules) – Postmortem Medicolegal Examination

                                                                                                                                                                                      November 2026
            Chapter 41 Epidemiology Health (one subchapter)

Subchapter 41C (44 rules) – Occupational Health
                                                                                                                                                                                          O Chapter 41 Epidemiology Health (one subchapter)
                                                                                                                                                                                                                     Subchapter 41H (57 rules) - Vital Records
                                                                                                                                                                                      December 2026
                10A NCAC 39 (17 rules) - Adult Health
                                                                                                                                                                                                       10A NCAC 43 - Personal Health (four subchapters)

    Subchapter 39A – Chronic Disease (HMAP)
    Subchapter 39B – Commission of Anatomy

    Subchapter 43A (8 rules) – Family Planning
    Subchapter 43B (5 rules) – Maternal Health
    Subchapter 43F (4 rules) – NBS Program

    Subchapter 43F (4 rules) – NBS Program.
    Subchapter 43K (3 rules) – NBS for CCHD

            10A NCAC 43 – Personal Health (4 subchapters)
                                                                                                                                                                                      March 2027
                             Subchapter 43G (4 rules) – Developmental Evaluation
                                Centers: Specialized Services Branch (Early Intervention)
                                                                                                                                                                                                          • .1000, .1200-.1800, .2100, .2300-.2600, .2800, .2900, .3100-.3300, .3500, .3600, and .3800
                             Subchapter 43H (12 rules) – Sickle Cell Syndrome: Genetic
                              Counseling
Subchapter 43I (1 rule) – Summer Food Service Program
                                                                                                                                                                                      TBD (expected - June 2027)
                              Subchapter 43J (1 rule) – Children and Adult Care Food
Program
                                                                                                                                                                                                       15A NCAC 18E (99 rules) – Wastewater Treatment & Dispersa
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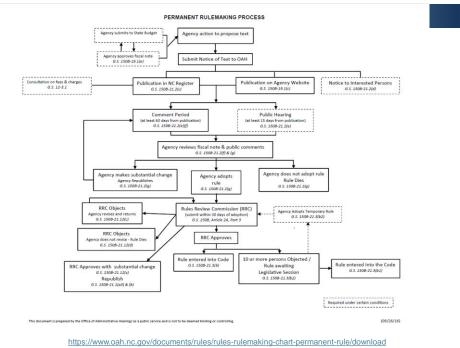
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Phase 2 – Readoption

- The deadline to readopt is set by the RRC in consultation with agency – following periodic review.
- Readoption = adoption through the permanent rulemaking process by the date established and filed with the RRC within 30 days of readoption.



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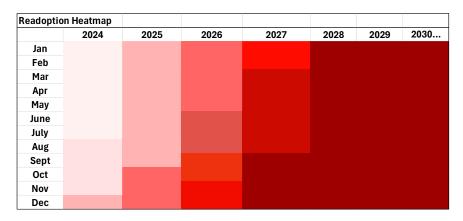
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Before commencing rulemaking...

- · Discuss with stakeholders
- · Draft rule language
- · Identify state, local, and private fiscal impacts and draft fiscal note (if applicable)
- Secure NC Office of State Budget and Management (OSBM) approval of the fiscal note (if applicable)

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Readoption Heatmap*



*This is an approximation. It assumes many or most public health rules will be determined necessary (which is TBD) and subject to readoption. Readoption deadlines are not set until the periodic review report is reviewed by the Rules Review Commission. Deadlines are approved by the Rules Review Commission following consultation with the rulemaking agency.

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How does this compare to last time?

 Only a quarter of the rules in the code were readopted in the last round of periodic review.

PREVIOUS PERIODIC REVIEW (2014-2023)

Classification Determinations	Action	% Rules Across All Agencies
Necessary <u>with</u> substantive public interest	Readopt	26%
Necessary <u>without</u> substantive public interest	Remain	61%
Unnecessary	Expire	13%

 In this round, to remain in the code, a rule <u>must</u> be readopted.

SOURCE: NC OAH, Periodic Review and Expiration of Existing Rules Presentation (October 2023)

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Why does this matter?

- There will be updates and changes to existing public health regulatory frameworks.
- This will decrease bandwidth for other rule changes.
- DPH will be seeking input from you and your teams on readoption rulemaking efforts. Stay tuned!

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Environmental Health Legislative and Regulatory Update

Environmental Health – Legislative Update

Session Law 2023-134 (H259)—2023 Appropriations Act

Provided funding to establish an On-Site Water Protection Training Team (3 FTEs).



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Environmental Health – Training Team

- ➤ Branding as the Specialty Wastewater Improvement and Field Training Team (SWIFT).
- > Idea is to help bring intern training to LHDs or regions
- ➤ Goals:
 - Improve training for interns
 - · Decrease time to receive authorizations
 - · Provide more mid-career training



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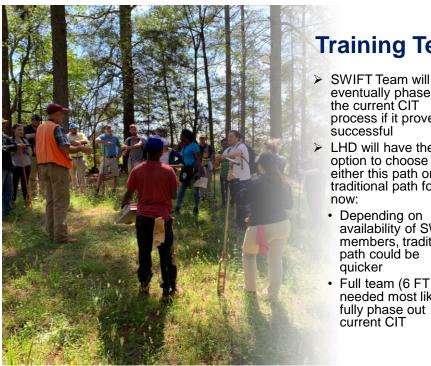
Environmental Health – Training Team

SWIFT Team will provide:

- > Guided, structured training
- Assignments, one-on-one mentoring, regional training with peers
- > Team members will determine when interns are properly trained and ready to begin the authorization process
- Goal is to have interns authorized no more than 4 months after date of hire and, ideally, within 3 months of hire.

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Training Team

- eventually phase out the current CIT process if it proves
- LHD will have the option to choose either this path or traditional path for
- Depending on availability of SWIFT members, traditional path could be
- Full team (6 FTE's) needed most likely to fully phase out

Environmental Health Training Team

- > SWIFT Team will:
 - Help reduce errors
 - Increase knowledge
 - Help prevent legal action
 - Produce more competent, confident workforce
- Hope to carry this model to all Branches in the EH Section



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Environmental Health – Legislative Update

Session Law 2023-129 (H125)—Health and Human Services Workforce Act

- Amended the definition of a bar in the sanitation statutes section.
- Restored the jurisdiction to inspect bars that sell food and drink (other than food used as a garnish).



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Bar Legislation/Session Law 2023-129

- Prior to 2013, bars which sold certain food for sale to the public were subject to health inspections.
- ➤ In 2013, private bars were designated as exempt from health inspections.
- ➤ In 2022, the ABC Omnibus bill expanded exemption from private bars to any establishment classified as a "bar" regardless of whether they prepare or serve food.

And most recently:

➤In 2023, session law changed inspection and permitting requirements for certain bars that serve time and temperaturecontrolled foods. It requires these bars to obtain a permit from the local health department.

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Bar Legislation/Session Law 2023-129

- ➤ The 2023 law excludes bars that:
 - · Only use food as a garnish
 - Do not prepare or serve food for pay
 - Serve pre-packaged time and temperature-controlled foods that the customer opens
 - Are designated as a private club under G.S. 18B-1000(5)
- ➤ Impacted bars are only those which prepare and serve food that requires time and/or temperature control (e.g., meat, poultry & seafood) just like the food regulated in 39,000 establishments in NC.

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Bar Legislation/Session Law 2023-129

- ▶84 bars permitted and 144 bars are in plan review at this time.*
- We estimate that about the same number (or fewer) haven't yet begun the permitting process.
- Bars are concerned about:
 - Lack of time to make the required improvements
 - Inadequate equipment
 - Lack of a funding source to make required improvements
 - Lack of available space for the type of food service desired

*As of March 21, 2024.

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Bar Legislation/Session Law 2023-129

- ➤What we've done:
 - Worked with stakeholders since October 2, 2023, the effective date of SL 2023-129
 - Developed & distributed a list of "Frequently Asked questions" to Local Health Departments, the NC Restaurant and Lodging Association, and the NC Bar Owners Association
 - On March 19, issued a memo providing an extension to October 1, 2024 to come into compliance
 - Regional staff have assisted (and continue to assist) counties, bars to troubleshoot issues

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<u>Session Law 2023-90</u> (H628)—Amend On-Site Wastewater/Environment Statutes

Legislative Update

- > Amended various laws and fees that affect onsite wastewater.
- Established a Registered Environmental Health
 - Associate certification (Effective May 1, 2024)
 An individual with an Associate's degree and 15 hours of sciences is eligible to become a Registered Environmental Health Associate (RĔHA).

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	Environmental Health Associate (NEW May 1, 2024)	Environmental Health Specialist
Degree Required by NCGS 90A	Associates, bachelor's, or graduate degree from an EHAC program. Associates, bachelor's, or graduate degree with a minimum of 15 semester hours of physical, biological, natural, life or health sciences	Bachelor's or graduate degree from an EHAC program or, Bachelor's degree or graduate degree in public health and one year of experience in the field of environmental health practice; or Bachelor's degree or graduate degree with a minimum of 30 semester hours or 45 quarter hours in the physical, biological, natural, life, or health sciences and one year of experience in the field of environmental health practice.
License or Certification Required	Complete specialized instruction and training offered by the environmental health section of DPH.	Must be eligible to meet the requirements for registration or license as an Environmental Health Specialist.

	Environmental Health Associate (NEW May 1, 2024)	Environmental Health Specialist
Environmental Health Duties Allowable under 90A	Can perform the following duties under the direct supervision of a registered environmental health specialist (90A-52 (b)(1): Permitting and inspections of private water wells. Inspections of Category I food establishments, temporary food establishments, and limited food service establishments. Inspections of lodging establishments. Permitting and inspections of any Type II or Type III on-site wastewater systems, including system layouts and existing wastewater systems. Inspections of migrant housing. Inspections of private, public, and religious schools. Inspections of local confinement facilities. Inspections of residential care facilities	Can perform all the duties listed in the Associate column, plus: Permit or inspect Type IV, V, and VI wastewater systems (i.e., more advanced systems). Inspect Category II, III, and IV food establishments (the majority of restaurants in NC that pose a higher risk of foodborne illness). Inspect childcare facilities. Inspect tattooing facilities. Conduct lead investigations for lead-poisoned children. Inspect public swimming pools and spas.

	Environmental Health Associate (NEW May 1, 2024)	Environmental Health Specialist
Environmental Health Practice area restrictions	An Environmental Health Associate cannot perform the following duties:	None
	Permit or inspect Type IV, V, and VI wastewater systems (i.e., more advanced systems).	
	Inspect Category II, III, and IV food establishments (the majority of restaurants in NC that pose a higher risk of foodborne illness).	
	Inspect childcare facilities.	
	Inspect tattooing facilities.	
	Conduct lead investigations for lead- poisoned children.	
	Inspect public swimming pools and spas.	
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Environmental Health – Legislative Update

<u>Session law 2023-77</u> (H627)—On-Site Wastewater Rules Implementation

Made changes to 15A NCAC 18E (On-Site Wastewater Rules) which took effect January 1, 2024.

<u>Session Law 2023-65</u> (H190)—Dept. of Health and Human Services Revisions

Consistent with the National Environmental Health Association REHS credential, included a provision that broadens the sciences needed to become a Registered Environmental Health Specialist (REHS). In addition, it provides a graduate with a bachelor's degree or postgraduate degree in public health to become a REHS.

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Environmental Health – Legislative Update

Potential Legislation in 2024

- ➤ More 18E changes are imminent.
- ➤ Bar bill changes?
- > What else is coming?



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Environmental Health - New Rules

- The new 18E wastewater rules are now in effect
 - Most challenging set of rules for our Section to get approved ever
 - First complete overhaul of these rules in over 40 vears
 - Growing pains as with all new rules
 - · Expect more legislative changes this year
- Working on new Authorization rules, 15A NCAC 010 .0100

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Environmental Health - New Rules

- Working on new Authorization rules, 15A NCAC 010 .0100
 - · Department rules, not CPH rules
 - · Current rules are outdated
 - Clarity
 - Incorporates the new REHA
 - Hope to have these in effect by next spring, if not sooner

