Board of Health Quarterly Meeting

September 19, 2024

Richmond, Virginia

WELCOME AND INTRODUCTIONS

AGENDA

Agenda	
Approval of June 13, 2024 Minutes	Gary Critzer, Chair
Commissioner's Report	Karen Shelton, MD State Health Commissioner
Regulatory Action Update	John Kotyk Legislative and Regulatory Coordinator
Public Comment Period	
Break	
Spotlight Presentation: Sickle Cell Program	Marcus C. Allen, MPH Director, Children and Youth with Special Health Care Needs Office of Family Health Services
Lunch Presentation: Kepone to Blue Zones - Hopewell, Virginia	Clifford Morris, MD President, Morris Cardiovascular and Risk Reduction Center Director, Hopewell Blue Zone Project
Regulations for the Virginia Immunization Information System 12VAC5-115 (Fast Track Amendments)	Laurie Forlano, DO State Epidemiologist and Director Office of Epidemiology
2025 Meeting Dates	Ms. Jansson
Other Business	
Adjourn	

MINUTES FROM JUNE 13, 2024

State Board of Health – Nominating Committee
June 13, 2024 – 9:00 a.m.
Norfolk State University

Members Present: Lee Jones, DMD; Melissa Green; and Elizabeth Ruffin Harrison

VDH Staff Present: Alexandra Jansson, Staff to the State Board of Health

Dr. Jones called the meeting to order at 9:00 a.m.

Ms. Harrison moved to nominate the following slate of officers: Gary Critzer, Chair; Dr. Melissa Nelson, Vice Chair; Michael Desjadon and Dr. Anna Jeng, Executive Committee members. The motion was seconded by Ms. Green. The motion was approved by unanimous voice vote.

The meeting adjourned at 9:02 a.m.

State Board of Health
June 13, 2024 - 9:30am
Norfolk State University

Members Present: Gary Critzer, Chair; Douglas Daniels, DVM; Michael Desjadon; Melissa Green; Elizabeth Ruffin Harrison; Anna Jeng, ScD; Lee Jones, DMD; Melissa Nelson, MD; Holly Puritz, MD; Maribel Ramos; Ann B.R. Vaughters, MD; Mary Margaret Whipple, and Yesli Vega

Ms. Whipple participated virtually for caregiver responsibilities from her home in Arlington. Dr. Vaughters participated virtually for personal reasons from her home in Goochland County.

Members Absent: Patricia Kinser, PhD, Vice Chair; Stacey Swartz, PharmD

Virginia Department of Health (VDH) Staff Present: Tami Beachum, Executive Assistant; Virginia Beach Health District; Kim Beazley, Director, Office of Licensure and Certification; Eric Bodin, Office of Licensure and Certification; Harry Bennett, VDH Agency Star; Paul Brumund, MHA, VCA, VDH Agency Star; Susan Fischer Davis, Chief Deputy Commissioner for Community Health Services; Melissa Dozier, Business Manager; Norfolk Health District Tiffany Ford, Deputy Commissioner for Administration; Susan Girois, Norfolk Health District Director; Joe Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs; Alexandra Jansson, Senior Policy Analyst; Kisha King, Executive Assistant; Norfolk Health District; John Kotyk, Regulatory and Legislative Coordinator; Kathy Lamm, Communications Director; Norfolk Health District; Christopher Lindsay, Chief Operating Officer; Caitlin S. Pedati, Virginia Beach Health District Director; Maria Reppas, Director, Office of Communications; John Ringer, Director of Public Health Planning and Evaluation; Karen Shelton, State Health Commissioner; Rachael Stradling, Acting Deputy Commissioner for Population Health and Preparedness and Acting Director, Office of Emergency Medical Services

Other Staff Present: Adam Hade, Assistant Attorney General, Office of the Attorney General; Jona Roka, Assistant Secretary, Office of the Secretary of Health and Human Resources

Call to Order
Mr. Critzer called the meeting to order at 9:37 am.

Introductions
Mr. Critzer welcomed those in attendance to the meeting. Mr. Critzer then introduced the Mayor of Norfolk, Dr. Kenneth Alexander for welcoming remarks. Additional opening remarks were received from Senior Advisor to the President for Governmental Affairs, Eric W. Claville, J.D. with Norfolk State University.

Review of Agenda
Ms. Jansson reviewed the agenda and the items contained in the Board's binder.

Approval of April 10, 2024 Minutes
The minutes from the April 10 meeting were reviewed. Dr. Nelson made a motion to approve the minutes, seconded by Dr. Jeng. The motion passed unanimously by voice vote.

Commissioner's Report
Dr. Shelton provided the Commissioner's Report to the Board. She updated the Board on key issues and projects VDH is engaged in including:

- Agency Stars
- Communicable Disease Update
- Health Director Meeting
- Hurricane and Extreme Heat Preparedness
- EMS Update
- Ballad Update
- Administrative Ecosystem Update
- Language Access

There was discussion regarding congenital syphilis cases, the screening process, physician engagement, and referral for appropriate treatment, VDH will continue to investigate each case. There was discussion about tickborne illness and increasing cases of Alpha-gal Syndrome. The importance of continued surveillance and obtaining reportable data with outcomes to enhance educational opportunities and the standards for physicians treating these illnesses was discussed. There was discussion concerning issues associated with the public health response to climate change and sea level rise, and the importance of cooperative efforts with partners. Finally, there was discussion pertaining to the VDH Cooperative Agreement with Ballad Health, and how cost of care is assessed when consumer options are limited. The importance of quality of care and access to care for consumers was discussed, as was enforcement options available to VDH as part of the Cooperative Agreement.

Regulatory Action Update
Mr. Kotyk reviewed the summary of all pending VDH regulatory actions.

There are 51 pending actions under development:

- 11 NOIRAs
- 10 proposed actions
- 8 final actions
- 23 fast track actions

Since the April 10, 2024, meeting the Commissioner has taken one regulatory action on behalf of the Board – approval of a Notice of Intended Regulatory Action (NOIRA) for the Sewage Handling and Disposal Regulations (12 VAC5-610). This action was initiated a result of a recent periodic review. Amendments will address changes to the industry and related best practices since the last comprehensive update to the Regulations more than 20 years ago, clarify existing requirements, and consider public comment and regulatory reduction where possible.

Mr. Kotyk advised the Board that there are 16 periodic reviews in progress:

- 12 VAC 5-67 Advance Health Care Directive Registry
- 12 VAC 5-125 Regulations for Bedding and Upholstered Furniture Inspection Program
- 12 VAC 5-215 Rules and Regulations Governing Health Data Reporting
- 12 VAC 5-216 Methodology to Measure Efficiency and Productivity of Health Care Institutions
- 12 VAC 5-217 Regulations of the Patient Level Data System
- 12 VAC 5-220 Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations
- 12 VAC 5-371 Regulations for the Licensure for Nursing Facilities
- 12 VAC 5-381 Home Care Organization Regulations
- 12 VAC 5-391 Regulations for the Licensure of Hospices
- 12 VAC 5-405 Rules Governing Private Review Agents
- 12 VAC 5-407 Regulations for the Submission of Health Maintenance Organization Quality of Care Performance Information
- 12 VAC 5-507 Guidelines for General Assembly Nursing Scholarships and Loan Repayment Program Requiring Service in Long-Term-Care Facility
- 12 VAC 5-520 Regulations Governing the State Dental Scholarship
- 12 VAC 5-545 Guidelines for the Nurse Educator Scholarship
- 12 VAC 5-590 Waterworks Regulations
- 12 VAC 5-620 Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells

Public Comment Period

There were no people signed up for the public comment period.

Lunch Presentation

Dr. Felicia Mebane, Director of the Center for Public Health Initiatives and Associate Dean at the Joint School of Public Health, Dr. Susan Girois, and Dr. Caitlin Pedati presented to the Board regarding the Norfolk and Virginia Beach Health Districts Community Health Needs Assessments.

The speakers addressed the following questions:

- What is the most important aspect of your role?
- What are two or three characteristics of your districts that impact health status?
- How are Community Health Assessments conducted, and what are the steps in the process?
- What types of decisions are driven by the results of the Community Health Assessment?
- What were the findings or results of your most recent Community Health Assessment?
- What are the next steps for your district with respect to the Community Health Assessment?

While Norfolk is an entirely urban district, Virginia Beach has urban, suburban and rural areas. Norfolk also has a far greater percentage of its population that is African-American. Both districts have a substantial percentage of their population that is related in some way to the military.

During their most recent Community Health Assessments, neither district was able to collect data from a random sample of their population. Each district did make substantial outreach efforts to draw representative samples, with particular focus on vulnerable populations. Norfolk's sample size was about 3,000 individuals while Virginia Beach's was about 750.

In terms of key public health issues identified during their community health assessments, in Virginia Beach, mental health, substance abuse and chronic disease concerns were most prevalent. In Norfolk, however, affordable housing, food insecurity and violence were the most prevalent issues identified, followed by mental health and substance abuse.

In terms of next steps, Dr. Pedati told the Board that a key purpose of the Community Health Assessment is to enable the district to prepare a Community Health Improvement Plan. The possibility of working directly with regional health systems on a combined community health needs assessment was discussed. Dr. Girois said that Norfolk intends to share the data from the Community Health Assessment with its stakeholders and partners, to get their further feedback. Dr. Girois described the concept of "Chief Health Strategist" to the Board. She also challenged the Board to hold health districts accountable to change health outcomes, while at the same time encouraging flexibility to respond to unique community needs.

Norfolk State University Highlights

William Bynum, Associate Director of Student Activities & Leadership, from Norfolk State University provided the Board with a brief overview of the University. The Norfolk State University athletics department is diverse. Men's teams are baseball, basketball, cross country, football, tennis, and track & field. Women's teams are basketball, bowling, cross country, softball, tennis, track & field, and volleyball. There is an 18:1 female to male ratio and the campus offers on-site dorms.

Programs with healthcare concentrations include healthcare administration, a joint program in medicine, nursing, master's in public health, and social work. Other popular programs are all

STEM majors, music, and new in 2024 is a drama-theater concentration.

The Norfolk State University Public Health initiative collaborative with Old Dominion University and Eastern Virginia Medical School was created to reduce health disparities and promote health equity. The initiative seeks to engage the community by promoting continued education from within and developing strong community partnerships.

Fast Track Amendments to Regulations Governing Durable Do Not Resuscitate Orders 12VAC5-66

Ms. Stradling, Acting Director of the Office of Emergency Medical Services presented the Fast Track Amendments to the Regulations Governing Durable Do Not Resuscitate Orders. The purpose of the amendments is to provide necessary updates to these regulations to better reflect current standards and practices, legal authority, and form and style requirements.

This regulatory action is necessary to ensure compliance with the Code of Virginia and to conform the regulations to the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*. By enacting these amendments, additional clarity and consistency of the regulations will help ensure that health care personnel, emergency medical services providers, and residents of the commonwealth can effectively access and understand the regulations governing DNR.

Dr. Nelson made a motion to approve the fast track amendments, seconded by Dr. Anna Jeng. The motion passed unanimously by voice vote.

Proposed Fast Track Amendments to Regulations Governing Cooperative Agreements 12VAC5-221

Ms. Beazley, Director, Office of Licensure and Certification (OLC) presented the Fast Track Amendments to the Regulations Governing Cooperative Agreements. The purpose of the amendments is to amend the chapter to address the public comment received during the 2024 periodic review of the regulation and to conform the regulations to the Virginia Registrar of Regulation's *Form, Style, and Procedure Manual for Publication of Virginia Regulations*. Amendments to the chapter will allow the regulation to be more easily understood by regulated entities and clarify and reduce regulatory requirements for both the department and the regulants.

The regulation is necessary for the protection of public health, safety, and welfare governing various types of arrangements among hospitals and health systems, including mergers and acquisitions, that otherwise might be anti-competitive within the meaning and intent of state and federal anti-trust laws.

The regulatory change is intended to address the need for updates to the language and style identified during the periodic review to make the regulation more understandable, and to address the public comments received regarding ongoing supervision of already approved cooperative agreements.

Dr. Puritz moved, and Ms. Ramos seconded, that the Fast Track Amendments be approved.

There was discussion pertaining to the fact that, under Virginia statute, a cooperative agreement is authorized only in far Southwest Virginia, and not anywhere else in the state. There was additional discussion concerning the role of the U.S. Federal Trade Commission with respect to cooperative agreements. There was further discussion concerning the provisions of the Virginia Order Authorizing a Cooperative Agreement, and the attached Conditions. There was discussion concerning that it is unknown what would happen to the Cooperative Agreement should Ballad Health be acquired by another entity. In response to the Board's questions, staff from the VDH OLC provided additional information how cost of care and quality of care are monitored under the Cooperative Agreement. There was discussion concerning the potential of cost reduction that in turn adversely affects the quality of care.

There was additional discussion concerning the proposed provisions of 12VAC5-221-95, and the extent to which those provisions address total cost of care and quality of care. After further discussion, Mr. Desjadon moved, and Dr. Puritz seconded, that the proposed text of 12VAC5-221-95 be amended by adding:

"A commitment to reduce the total cost of care, and improve the quality of care, in the region served by the new entity."

That motion was approved unanimously.

The original motion to approve the Fast Track Amendments was also approved unanimously.

Office of Emergency Medical Services, Interim Strategic Plan

Ms. Stradling, Acting Director, Office of Emergency Medical Services presented to the Board the Interim Strategic Plan for the Office of Emergency Medical Services (EMS). The Interim Plan focuses on essential functions such as EMS training, Certification and Regulation, and Trauma System administration. Mandated programs are to be operated in an efficient, timely and accountable manner. VDH will work with members of the EMS Advisory Board, EMS Agencies, EMS Council leaders, EMS Stakeholders, and community partners to create a Strategic and Operational plan for FY2025 and beyond that is built on the core public health mission of the Office of EMS. The intent is to expand and build competent, engaged, valued workforce increasing retention and engagement of all OEMS staff. The plan includes a provision to realign leadership structure and provide transparency in decision making as appropriate to OEMS staff, stakeholders, and EMS community.

Dr. Jones moved that the Interim Strategic Plan be approved, and Dr. Puritz seconded the motion. The motion passed by unanimous voice vote.

Electronic Meeting Policy

Ms. Jansson presented the updated Electronic Meeting Policy to the Board. All but one update was a non-discretionary change due to legislation passed in the 2024 General Assembly Session. One discretionary change in the process for requesting remote participation was made for ease of documenting in the minutes.

There was discussion by the Board regarding travel locations, the requirements, and limitations

related to utilizing state equipment if a Board member is traveling overseas. The preference is the member just report as absent rather than trying to participate remotely from a foreign country. A reminder was made that if more than 3 members will be participating in a virtual meeting from the same location, that meeting location will need to be noticed and open to the public.

A motion to approve the updated Electronic Meeting Policy was made by Dr. Puritz with Ms. Ramos seconding. The motion was approved unanimously.

Report of Nominating Committee

Dr. Jones provided the report of the Nominating Committee. The committee recommended Gary Critzer to continue to serve as Chairman of the Board; Dr. Melissa Nelson as Vice Chair, and Dr. Anna Jeng and Michael Desjadon as Executive Committee members. The committee report was approved unanimously by the Board.

Other Business

The following Board members have terms are ending on June 30, 2024: Holly Puritz, MD, Stacey Schwartz, PharmD, and Mary Margaret Whipple. The Board thanked them for their service.

Adjourn

The meeting adjourned at 1:17 pm.

Commissioner's Report

Dr. Karen Shelton
State Health Commissioner

Outline

Agency Stars
Key Personnel Changes
Communicable Disease Updates
Harmful Algal Blooms 2024
Emergency Preparedness
EMS Update
Veteran Suicide Prevention
Maternal Health Updates
Electronic Health Record Update
Language Access

Agency Stars

Erin Callas BSN, RN

Jessica Coughlin

Key Personnel Changes

Stephanie Dunkel – Deputy Commissioner for Population Health and Preparedness

Othello Dixon – Chief Information Security Officer

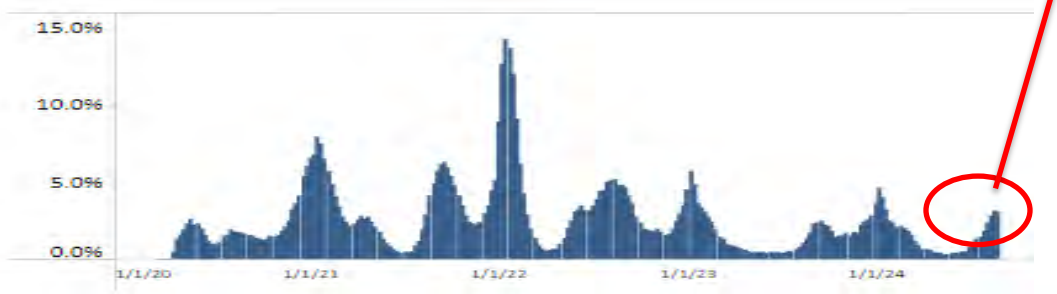
Saritha Gomadam, DO – Medical Officer

Billie Blair Taylor, MD – Medical Officer

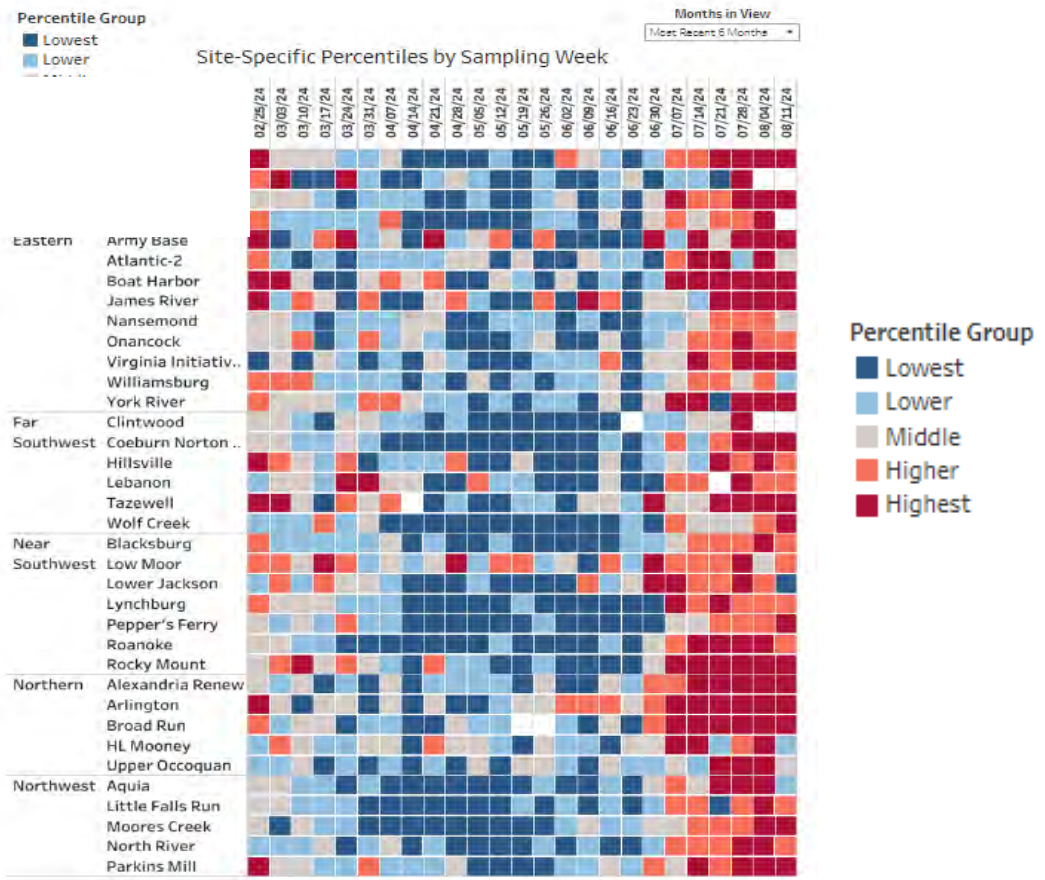
COVID-19: Recent Trends

Weekly Percent of Emergency Department Visits for Diagnosed COVID-19 in Virginia,
March 2024 – Present

Jan 2020 – Present



SARS-CoV-2 Wastewater Testing – Site-Specific Percentile Groups
February 2024 – August 11, 2024



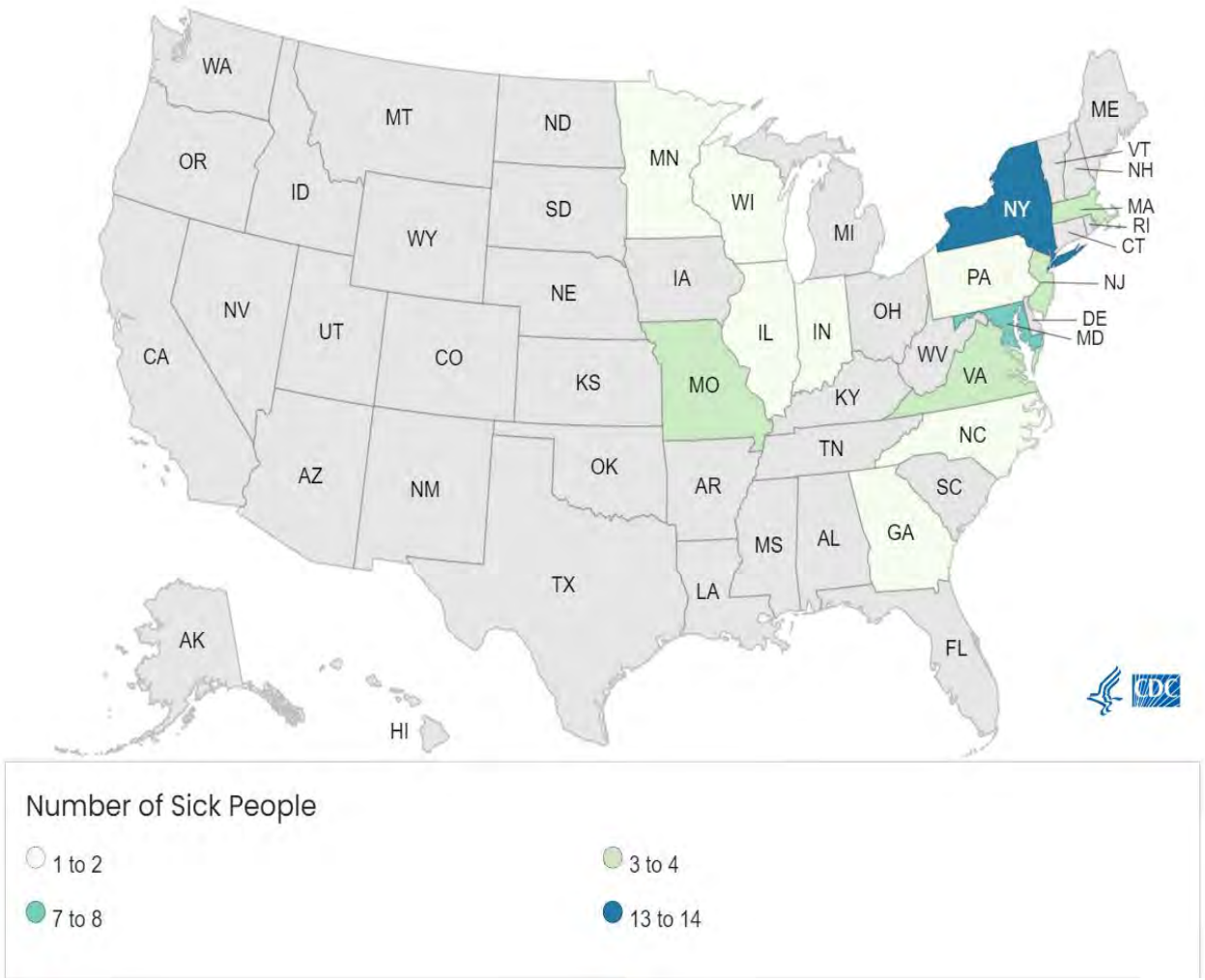
As of 8/20: https://www.vdh.virginia.gov/coronavirus/sars-cov-2-in-wastewater/ ; https://www.vdh.virginia.gov/coronavirus/see-the-numbers/covid-19-in-virginia/

VDH VIRGINIA DEPARTMENT OF HEALTH

COVID-19 Vaccine

- The 2024-2025 Pfizer and Moderna monovalent COVID-19 Vaccines were approved by the FDA on August 22. Novavax COVID-19 Vaccines are expected to receive FDA approval soon.
- 2024-2025 COVID-19 vaccines are updated to target KP.2 strain (JN. 1 lineage) which will provide better protection against currently circulating variants.
- FDA anticipates the composition of COVID-19 vaccines will be assessed annually, similar to seasonal flu vaccines.
- Everyone 6 months of age and up is recommended to receive a 2024-2025 COVID-19 vaccine with some exceptions with young children who may require additional doses if they have never received a dose before.
- CDC COVID-19 Bridge Program is no longer available. Pharmacies will no longer provide free vaccines to under and uninsured adults which is expected to cause some access issues as pharmacies account for the most COVID-19 doses administered in Virginia. Limited availability of vaccines will be through the Vaccines for Adults (VFA) program for under and uninsured adults.
- COVID-19 Vaccine will be available through the Vaccines for Children program.

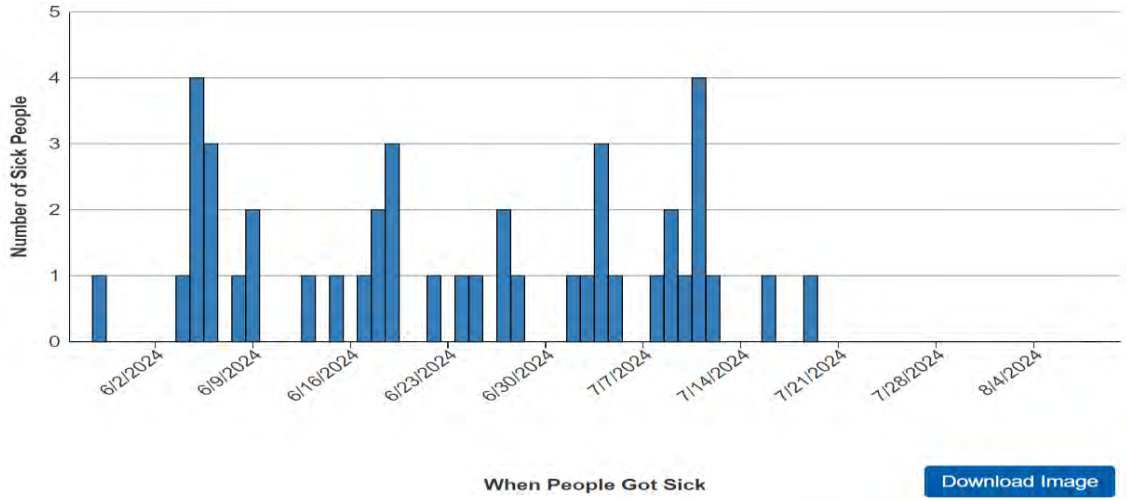
Listeria Outbreak Linked to Meats Sliced at Delis



CDC Map of where ill persons live
https://www.cdc.gov/listeria/outbreaks/delimeats-7-24/index.html

- As of 8/19/2024, there are 4* persons ill with listeriosis in VA who are included in this outbreak investigation.
  - One death, attributed to listeriosis, has been reported among the VA cases.
- Boar's Head has recalled 71 products after testing of liverwurst identified *Listeria*.

*the fourth case is not yet reported on the CDC webpage but will be included in future updates

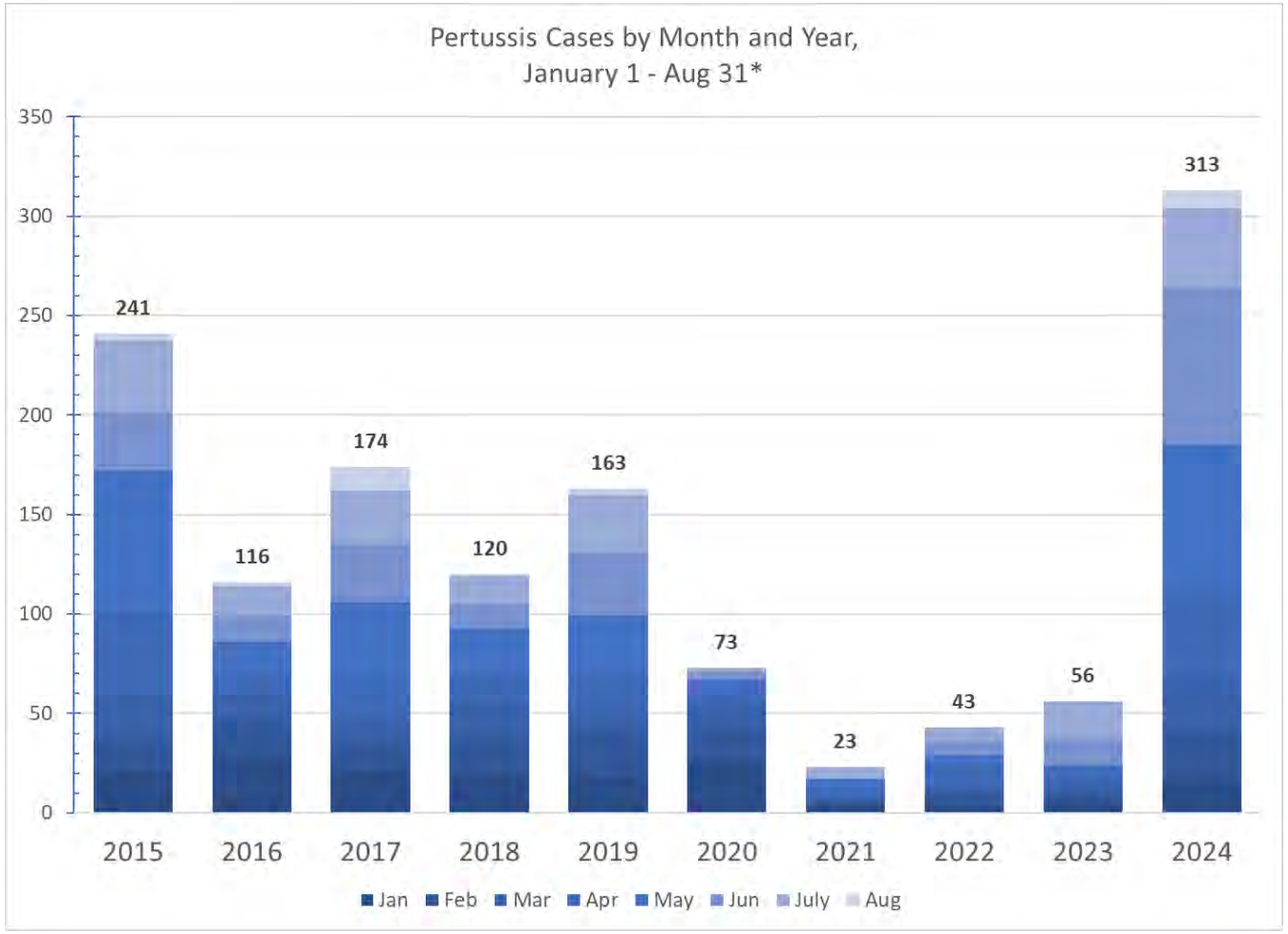


CDC Epi curve of when persons became ill
https://www.cdc.gov/listeria/outbreaks/delimeats-7-24/index.html

VDH VIRGINIA DEPARTMENT OF HEALTH

Pertussis Activity

- VDH is reporting an increase in pertussis (whooping cough). As of August 19, more than five times as many cases have been reported compared to the same time last year, exceeding pre-pandemic levels.
- This trend is linked to a rise in pertussis outbreaks in group settings, including universities, schools, religious communities and childcare settings.
- Nationally, pertussis cases are returning to pre-pandemic trends, with three times as many cases reported this year compared to the same time in 2023.
- Health care providers are recommended to maintain a heightened index of suspicion for pertussis and ensure all patients are up to date on DTaP or Tdap vaccination.



*August 2024 data is incomplete and subject to change.

HPAI Response/Pertinent Updates

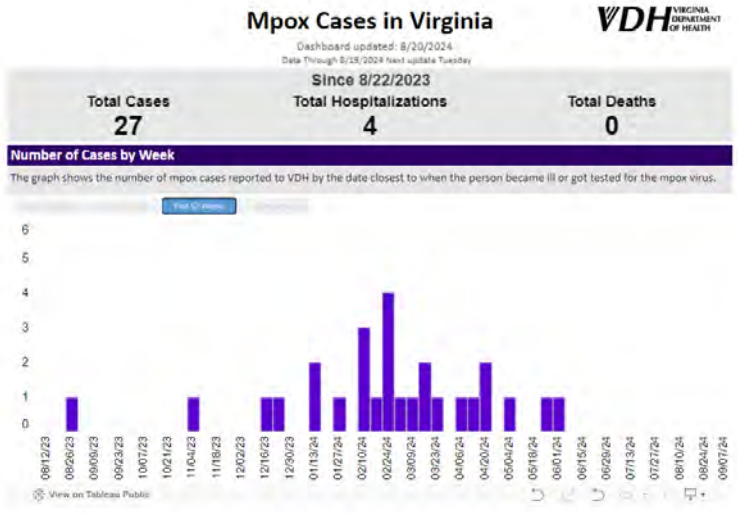
- No human or animal cases reported in Virginia
- VDH continues to communicate with both internal and external partners for situational awareness and planning
  - Next phase of planning includes outreach re: seasonal influenza vaccination dairy associated stakeholders
- Total dairy premises affected in US: 192 farms across 13 states
- Total reported human cases in the US: 14
  - Four following exposure to infected dairy cattle (Texas, Michigan (2), Colorado)
  - 10 following exposure to infected poultry (1 in 2022, 9 in 2024, all Colorado)
- In partnership with the VDEM Logistics Support and Coordination Center (LSCC), the VDH Office of Emergency Preparedness and Office of Epidemiology distributed 120 pallets (~2.6 million pieces) of PPE to dairy farmers, slaughterhouses, and milk processing facilities, among others.

As of 8/20: https://www.aphis.usda.gov/livestock-poultry-disease/avian/avian-influenza/hpai-detections/hpai-confirmed-cases-livestock
As of 8/20: https://www.cdc.gov/bird-flu/situation-summary/index.html

Mpox Update

- CDC Health Alert: Mpox transmission in DRC with spread to neighboring countries
- WHO declaration that mpox is a public health emergency of international concern
- Risk for Clade I in U.S. general population is very low and no Clade I cases reported in U.S.
- VDH asks that providers have heightened suspicion in recent travelers or their close contacts and request clade testing at DCLS if appropriate
- Vaccination is recommended for people in the U.S. who have been exposed to mpox or who are at risk

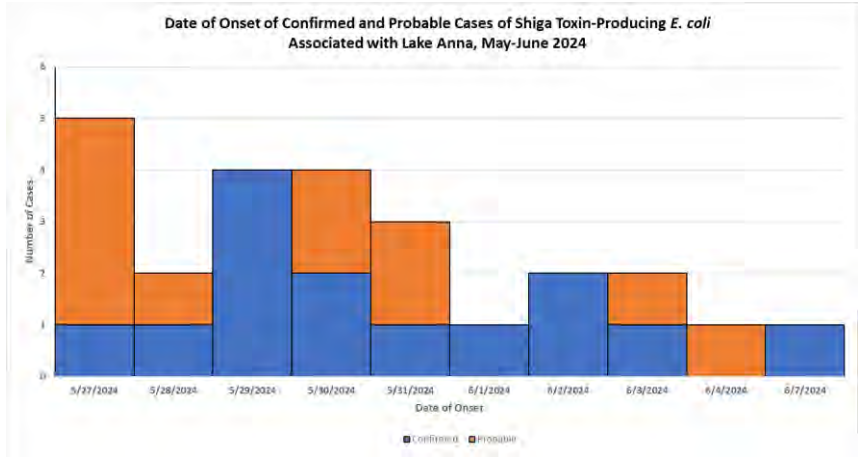
https://www.cdc.gov/poxvirus/mpox/outbreak/2023-drc.html



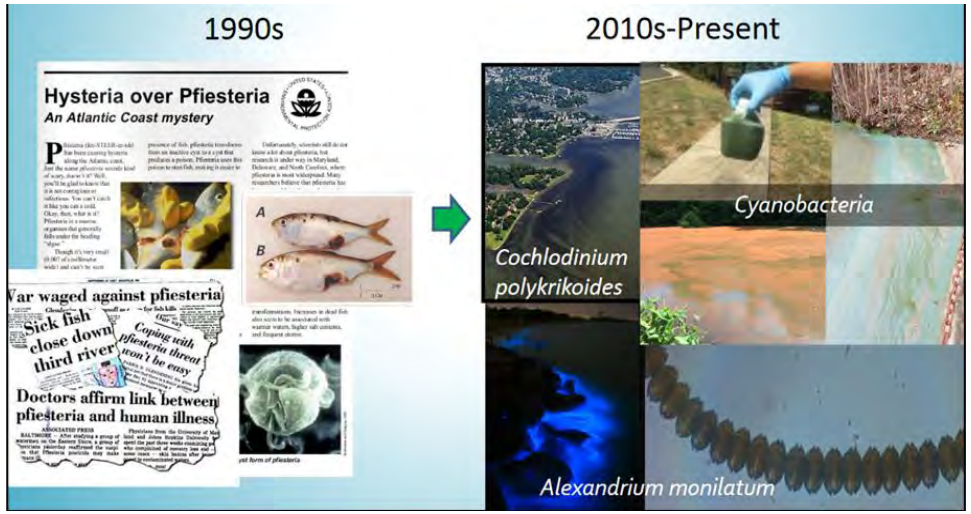
Lake Anna Response-Summary

- Shiga toxin-producing *Escherichia coli* (STEC) outbreak following Memorial Day weekend lake exposure
- Epidemiologic investigation
  - 25 Confirmed and Probable STEC cases
    - 23 Primary STEC (had lake exposure)
    - 2 Secondary STEC (close contact with a primary case)
    - 7 hemolytic uremic syndrome (HUS)
  - Enhanced surveillance through July 17
- Environmental investigation
  - Fecal indicator bacteria levels (samples collected June 11, 17 and 25) from selected sites
    - Below level of public health concern
  - STEC-specific water testing (samples collected on June 25) from four sites
    - Genetic material from non-0157 STEC bacteria identified at 3 sites, but live bacteria could not be isolated.
- Conclusion
  - Investigation closed June 28, two incubation periods after the last case
  - While a source was not identified, STEC infections were likely a result of exposure to lake water over Memorial Day weekend
  - Environmental pollution can occur from: heavy rains, livestock, failing septic systems, boating discharge, and swimmers

Photo: Virginia Department of Conservation and Recreation, accessed 26 July, 2024, https://www.dcr.virginia.gov/state-parks/lake-anna



Harmful Algal Blooms 2024



Exposure routes:

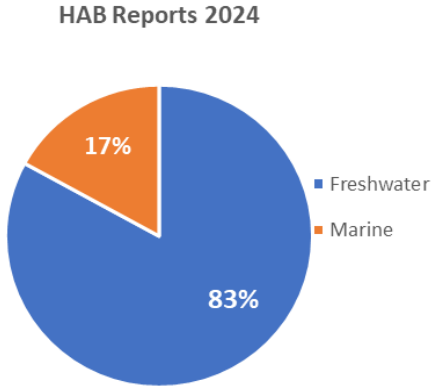
consumption
- --shellfish/finfish
- --drinking water
- --recreational

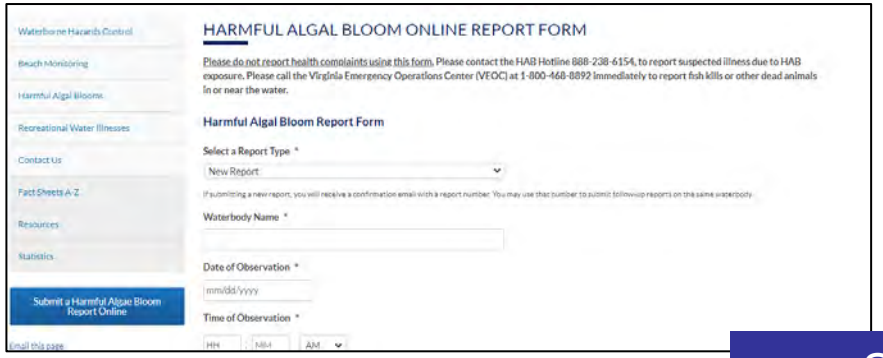
Inhalation (aerosols)

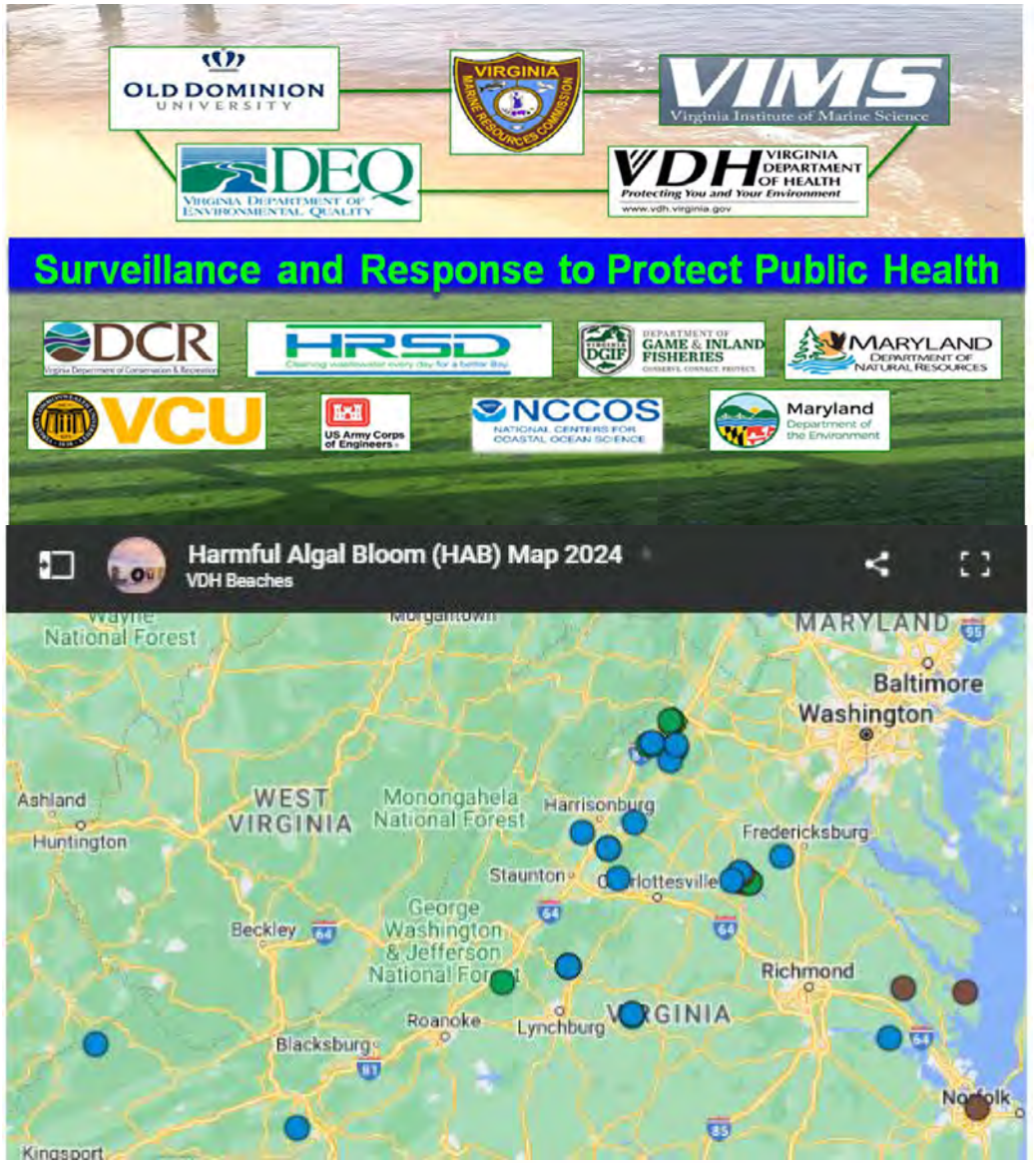
dermal absorption

OHHABS – voluntary reporting of blooms, human, and animal illness complaints to CDC

OHHABS ONE HEALTH Harmful Algal Bloom System







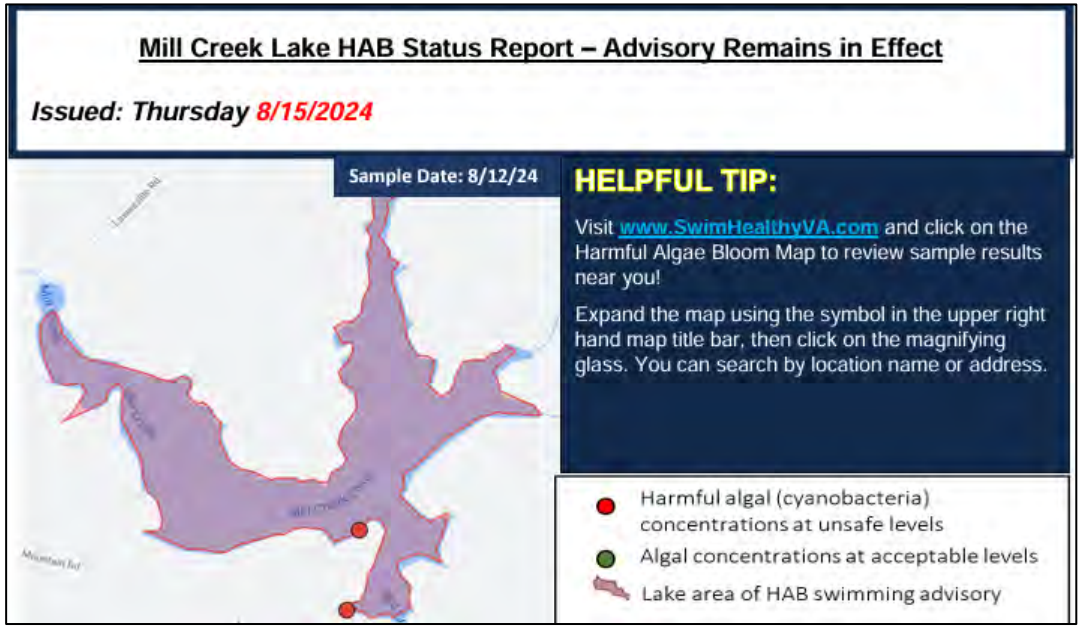
www.SwimHealthyVa.com

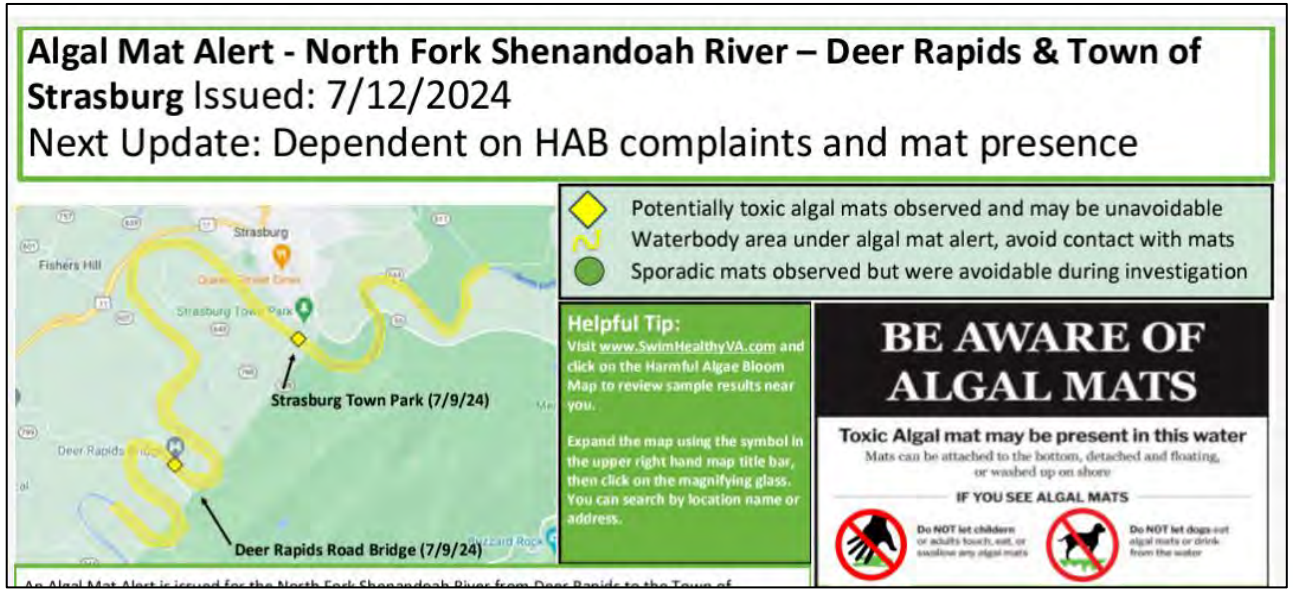
VDH Virginia Department of Health

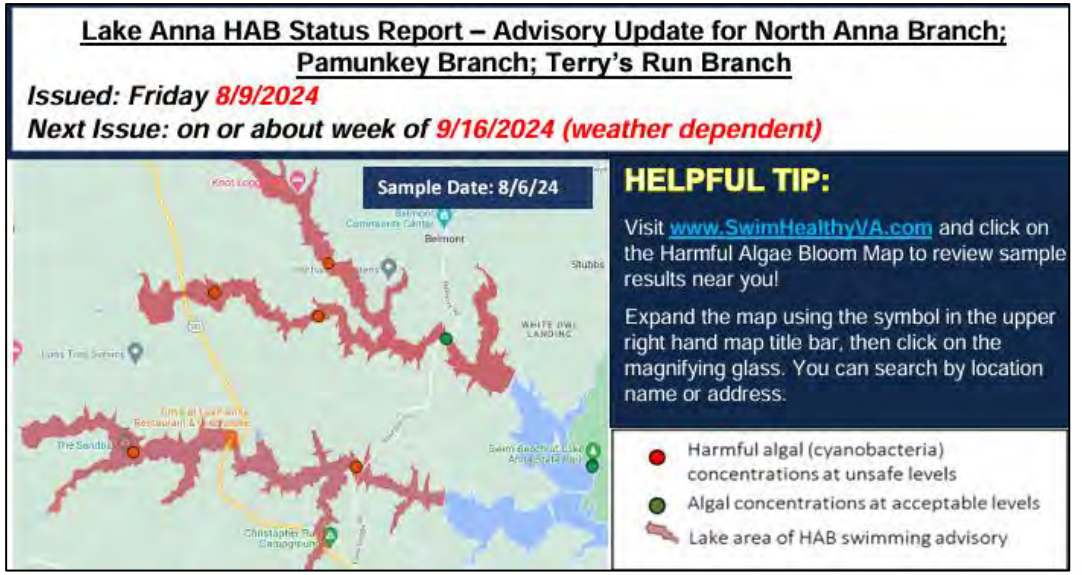
Harmful Algal Blooms 2024

4 Advisories issued in 2024:
- Lake Anna (active)
- Mill Creek Lake (active)
- Holliday Lake (lifted)
- Cave Mountain Lake (lifted)

1 Alert issued in 2024:
- North Fork Shenandoah River







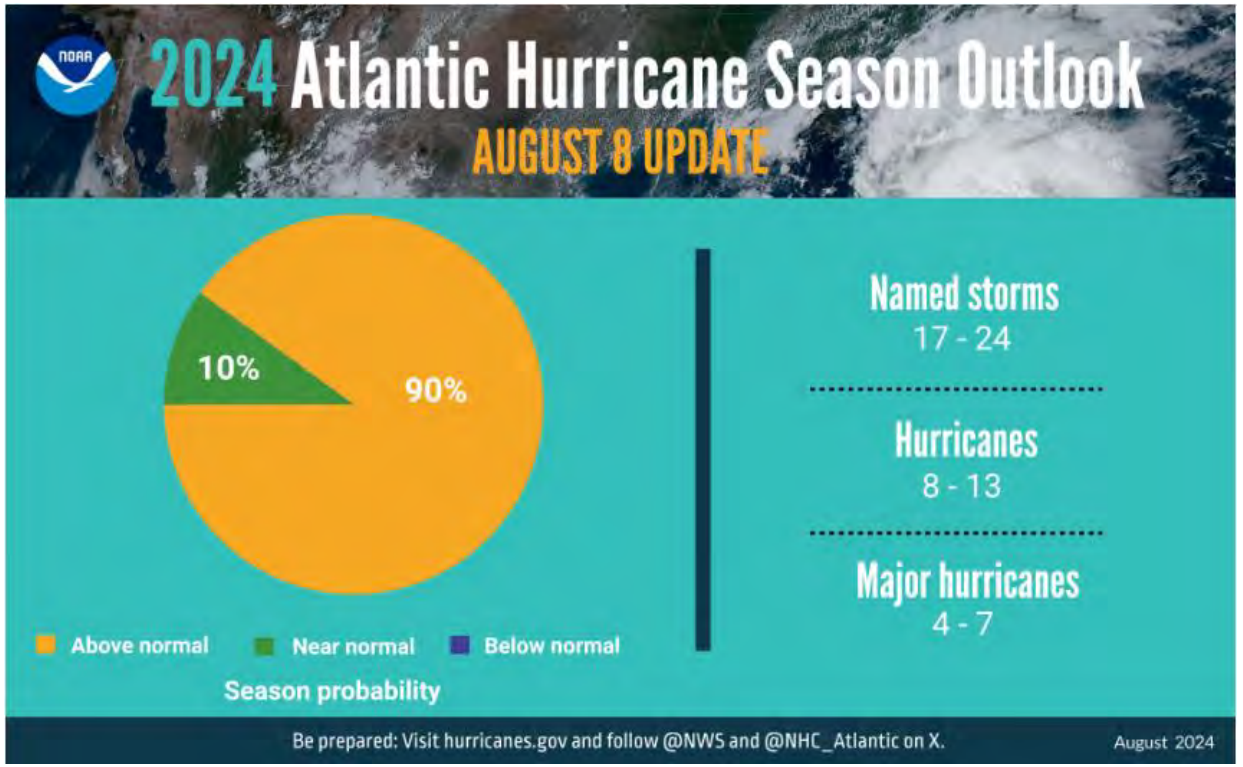
Hurricane and Extreme Heat Preparedness

- **Ongoing interagency collaboration** with the Virginia Department of Social Services (VDSS), Virginia Department of Emergency Management (VDEM), and other Virginia Emergency Support Team (VEST) agencies to ensure readiness during hurricane season

- **Planning, Training and Exercising**
  - Disaster Shelter Training Courses
    - Health and Medical Fundamentals
    - Environmental Health
    - Nursing
  - Regional Tabletop Exercises
  - VDH Mass Care Plan updates
  - Virginia Emergency Support Team Exercise (VESTEX)
  - COVEOP Hurricane and Tropical Storm Response Annex updates

- **Public Information and Education**
  - Heat safety messaging
  - Social Media Toolkit

- **Public Health Surveillance**
  - Syndromic Surveillance on Heat-Related Illnesses



South Hill Warehouse Fire Event

- On July 6, 2024, a passenger vehicle crashed into a utility pole and two 125-gallon propane tanks. One of the propane tanks erupted into flames that initiated the fire at the Nutrien Ag. warehouse in South Hill. The warehouse stored fertilizers, herbicides, fungicides, and pesticides. The locality issued a voluntary one-half mile evacuation notice due to the unknown hazards associated with the fire and the fire-fighting activities.
- The fire was put out by July 8 after hundreds of thousands of gallons of water to fight the fire, mixed with various chemicals, discharged to a storm drain near the intersection of two watersheds. One watershed drained from Dockery Creek to the Roanoke River and Lake Gaston; the other watershed drained from Mountain creek to the Meherrin River toward the Town of Lawrenceville and the City of Emporia, which used the Meherrin River as a water source.
- No drinking water intakes were affected by the release event toward Dockery Creek.
- VDH had multiple offices involved, including ODW, OEHS, and OEP.
  - OEP provided on-site coordination with DEQ, EPA, and Nutrien Ag.
- 24/7 monitoring and effort for several days.
- Concerns included: drinking water, private wells, indoor air quality, skin exposures, fish and wildlife
- No drinking water impacts.

PHOTOS: Massive fire destroys fertilizer warehouse in South Hill (wtvr.com)

Wilderness Water Treatment Plant Response

- On 8/21/24 the Rapidan Service Authority (RSA), received complaints of a “diesel fuel” or “WD-40” smell in the drinking water.
- A similar odor was then detected at the plant itself.
- RSA staff shut down the water treatment plant and sent a notice to not use the water until further notice.
- Specimen collection for testing and visual observations of the river water, treatment plant facilities and treated water began immediately and continues as of 8/27.
- The Do Not Use Advisory was later changed to a Do Not Drink on 8/24.
- On 8/27 the Do Not Drink Advisory was lifted after laboratory sampling data over multiple days demonstrated that the drinking water fully complies with federal and state standards.

- On 8/22/24 a Unified Command structure was established including VDH ODW, Orange County, Rapidan Service Authority, DEQ, and the Rappahannock-Rapidan Health District (RRHD).
  - Operations section staffed by VDH ODW and OEHS staff.
  - Planning section staffed by VDH ODW and OEP staff.
  - A Joint Information Team was established with VDEM, VDH, DEQ, and Orange County communications teams.
  - An incident website was created to keep the public informed.
  - 15 RRHD Medical Reserve Corps Volunteers assisted VDEM and Orange County in staffing a Water Distribution POD from 8/22-8/24.

Office of Emergency Medical Services

- Awaiting final review to release report
- Fitch and Associates are finalizing their report of recommendations for the future of OEMS
- Working through the findings of the CARE Report and ensuring that the recommended action plan is implemented.
- We will be working with the Governor's EMS Advisory Board and Community partners to create a strategic work plan that will be present to the Board of Health in mid 2025.

Veteran Suicide Prevention

VDH is designated as the lead agency for youth suicide prevention in Virginia pursuant to Virginia Code §32.1-73.7 (2001).

VDH does not directly implement Veteran programs, but supports partner organizations engaged with Service Members, Veterans, and their Families (SMVF) through:

- Co-leading a new effort with the Virginia Department of Veterans Services related to Suicide Mortality Review. Virginia is one of the first 13 states participating.
- Supporting the Virginia Governor's Challenge. Virginia was one of the first states to develop a statewide collaborative effort through the Governor's Challenge to combine Veterans Affairs and Health and Human Services efforts to reduce Veteran suicide.
- Participating in the VISR* pilot, a statewide effort to enhance suicide prevention, risk screening, and safety planning in community settings for SMVF populations.
- Delivering the Virginia Lock & Talk, a lethal means safety training which provides information and resources to community members on lethal means safety and how to speak to individuals about medication and firearm safety.

*Virginia Identify SMVF, Screen for Suicide Risk, and Refer for Services pilot or VISR

Maternal Health

- Office of the Secretary of Health and Human Resources convened a Maternal Health Roundtable in February 2024
  - Healthy Moms, Healthy Families, Healthy Communities
  - 80 multisector partners attended
  - Focused on data to drive solutions to improve maternal health outcomes for all Virginians
  - Highlighted lessons learned from 12 month postpartum care in Medicaid
  - Emphasized a whole health approach to maternal health care
  - Stressed the benefits of a community-based approach for support pregnant Virginians

Maternal Health

- The Secretary's Office, in partnership with VDH and Department of Medical Assistance Services, continues engagement through a Maternal Health lunch and learn series
  - Maternal Mental Health – mental health, substance use, and postpartum loss
    - VMAP Moms+
    - Postpartum support Virginia
    - Project Link
    - Residential services for pregnant and parenting women with substance use disorder

Maternal Health

- Maternal Cardiovascular Care lunch and learn
  - Cardiovascular disease is a leading cause of maternal mortality
  - Moms Under Pressure
    - Health education of hypertensive disorders of pregnancy
    - Support to self-monitor blood pressure during pregnancy
    - Huddle Up Moms as an exemplar
  - Uplifting the voices of moms with lived experience
    - Jasmine Brunson, maternal cardiovascular event survivor and advocate

Maternal Health

- In-person convening in Roanoke focused on maternal mental health and substance use in rural communities
  - Highlighted care experiences from practicing obstetrician specializing in substance use disorder treatment and a practicing reproductive psychiatrist
  - Emphasized importance of peer support for pregnant women with substance use disorder
  - Elevated voices of local doulas and behavioral health providers
  - Attendees provided feedback on challenges
    - More to come as feedback is synthesized into concrete action steps

Maternal Health

- Governor Youngkin issued Executive Order 32 to reestablish the Task Force on Maternal Health Data and Quality Measures
  - SHHR leading two-year effort with support from VDH and DMAS
  - Clear charge to evaluate and make recommendations to improve maternal health data collection
  - Efforts will inform policies to improve care, quality, and outcomes
- Data to assess:
  - Demographic data
  - Prenatal and Postpartum care and postpartum depression data
  - Barriers to data collection
  - Maternal health benefit requirements
  - Social Determinants of Health screening
  - Data 1 year after delivery
- Develop recommendations, based upon best practices, for standard quality metrics on maternal care.

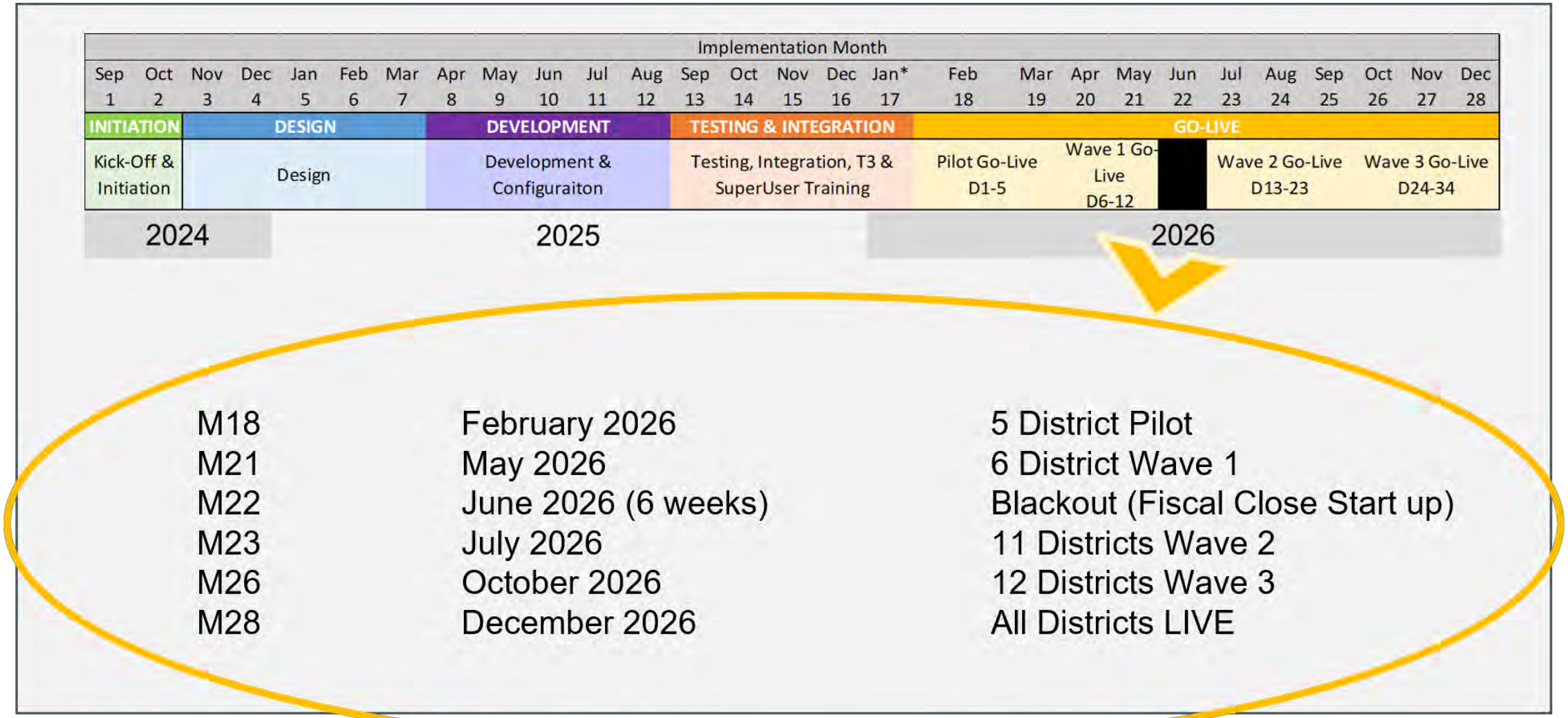
Electronic Health Record Update: Kickoff

Contract signed August 6, 2024 with Oracle Health

Details through December 2024:

- August: Pre-Implementation Activities
- September: Project Kick-Off
  - Off-site in-person scheduled for September 17, 2024
- October: Current State Assessment – Oracle Health on-site
- November - December: Design Working Sessions

Electronic Health Record Update: Timeline



M18	February 2026	5 District Pilot
M21	May 2026	6 District Wave 1
M22	June 2026 (6 weeks)	Blackout (Fiscal Close Start up)
M23	July 2026	11 Districts Wave 2
M26	October 2026	12 Districts Wave 3
M28	December 2026	All Districts LIVE

Language and Disability Access

Provide meaningful access for Virginians with Limited English Proficiency to VDH programs, services, and information

Interpreter training for bilingual staff

- 40/60-hour medical training qualification
- 68 bilingual employees have registered for the training in different languages: Spanish, Arabic, Haitian Creole, and Dari.

Translate critical, frequently used agency documents – and post to the Translation Library

- Have translated 33 documents into 11 languages
- Documents from Epidemiology, Environmental Health Services, Community Health Services, and Family Health Services

Language and Disability Access

State Funding Opportunity from DSS

- The 2024-2026 state budget appropriates $2 million in FY25
- Requesting funding for training an additional 80 bilingual staff members, expanding the translation library (75 additional documents), Language Access Equipment (to support remote interpretation in local health departments), Accessibility Enhancements (to improve capacity for serving people with disabilities), and training in cultural humility.

Language and Disability Access Workgroup

- 19 members representing 12 Health Districts and 7 Offices providing direct services
- First meetings (listening session) on Monday, August 19 & Wednesday, August 21

Draft Language and Disability Access Plan

- Conducting a VDH Language Access Needs Assessment – First section of the Language and Disability Access Plan
- On November 25th workgroup will review the first draft of the Language and Disability Access Plan

Questions?

REGULATORY ACTION UPDATE

State Board of Health
Regulatory Action Update
September 19, 2024

Overview of Pending Regulatory Actions:

There are 55 pending actions under development:

- 13 NOIRAs
- 10 proposed actions
- 8 final actions
- 24 fast track actions

A spreadsheet containing additional detail concerning each of these actions is attached.

A NOIRA is the first stage in the standard rulemaking process in Virginia. It describes the nature and scope of the regulatory changes being considered. Should a NOIRA be approved, the next stage in the rulemaking process (the proposed stage) would involve the drafting of actual amending regulatory language for consideration. The proposed stage—if approved—is in turn followed by the final stage. Each of these three stages includes a public comment period.

The Virginia Administrative Process Act (§ 2.2-4000 et. seq. of the Code of Virginia) provides that certain types of regulatory actions are exempt from certain requirements of the state regulatory process. This includes regulatory actions that are:

i. Necessary to conform to changes in Virginia statutory law or the appropriation act where no agency discretion is involved, or
ii. Necessary to meet the requirements of federal law or regulations, provided such regulations do not differ materially from those required by federal law or regulation, and the Registrar has so determined in writing.

The Administrative Process Act also describes a "Fast Track" rulemaking process, which is utilized for regulations that are expected to be noncontroversial. The Fast Track process generally involves an action with a single stage.

Regulatory Actions Taken by the Commissioner on Behalf of the Board pursuant to § 32.1-20 of the Code of Virginia since the June 13, 2024 Board Meeting while the Board was not in Session:

Approved a Notice of Intended Regulatory Action (NOIRA) for the Sanitary Regulations for Hotels (12VAC5-431)

- This action is being initiated a result of a recent periodic review. Amendments will remove outdated information, reflect best practices and the most up-to-date scientific information, and consider public comment and regulatory reduction where possible.

Non-Regulatory Actions Taken by the Commissioner on Behalf of the Board since the June 13, 2024 Board Meeting while the Board was not in Session:

None

Periodic Review of Regulations

The process for conducting periodic reviews of regulations is governed by the Virginia Administrative Process Act and Executive Order 19 (2022).

All regulations are to be reviewed every four years to determine whether they should be continued without change or be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact on small businesses in a manner consistent with the stated objectives of applicable law.

VDH has 16 periodic reviews in progress:

Chapter		Status
12 VAC 5-67	Advance Health Care Directive Registry	Result under OCOM review
12 VAC 5-125	Regulations for Bedding and Upholstered Furniture Inspection Program	Intend to issue result after current action becomes effective.
12 VAC 5-215	Rules and Regulations Governing Health Data Reporting	Result under OCOM review
12 VAC 5-216	Methodology to Measure Efficiency and Productivity of Health Care Institutions	Result under OCOM review
12 VAC 5-217	Regulations of the Patient Level Data System	Result under OCOM review
12 VAC 5-220	Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations	Result under OCOM review
12 VAC 5-371	Regulations for the Licensure of Nursing Facilities	Issued with NOIRA, Result will be published with Proposed stage.
12 VAC 5-381	Home Care Organization Regulations	Issued with NOIRA, Result will be published with Proposed stage.
12 VAC 5-391	Regulations for the Licensure of Hospices	Result under OCOM review
12 VAC 5-405	Rules Governing Private Review Agents	Result under OCOM review
12 VAC 5-407	Regulations for the Submission of Health Maintenance Organization Quality of Care Performance Information	Result under OCOM review
12 VAC 5-507	Guidelines for General Assembly Nursing Scholarships and Loan Repayment Program Requiring Service in a Long-Term-Care Facility	Result under OCOM review
12 VAC 5-520	Regulations Governing the State Dental Scholarship Program	Intend to issue result after current action becomes effective.
12 VAC 5-545	Guidelines for the Nurse Educator Scholarship	Result under OCOM review
12 VAC 5-590	Waterworks Regulations	Result under OCOM review
12 VAC 5-620	Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells	Intend to issue result after current action becomes effective.

Executive Branch Review Activity Completed since the June 13, 2024 Board Meeting:

The Department of Planning and Budget completed the review of:

- Fast Track Amendments to the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations (12VAC5-220)
- NOIRA for the Sanitary Regulations for Hotels (12VAC5-431)
- Proposed Amendments to the Regulations for Summer Camps (12VAC5-440)

The Secretary of Health and Human Resources completed the review of:

- Final Amendments to the Rainwater Harvesting Systems Regulations (12VAC5-635)

The Office of Regulatory Management completed the review of:

- Final Amendments to the Private Well Regulations (12VAC5-630)

The Governor approved:

- Final Amendments to the Private Well Regulations (12VAC5-630)

PUBLIC COMMENT

Public Comment Period

- There is a two minute time limit for each person to speak.
- We will be calling from the list in the room.
- After the 2 minute public comment limit is reached we will let you complete the sentence and move on to the next attendee.
- We will call the name of the person on list and also the name of the person is next on the list.

SPOTLIGHT PRESENTATION: SICKLE CELL PROGRAM

Sickle Cell Programs

Marcus C. Allen, MPH

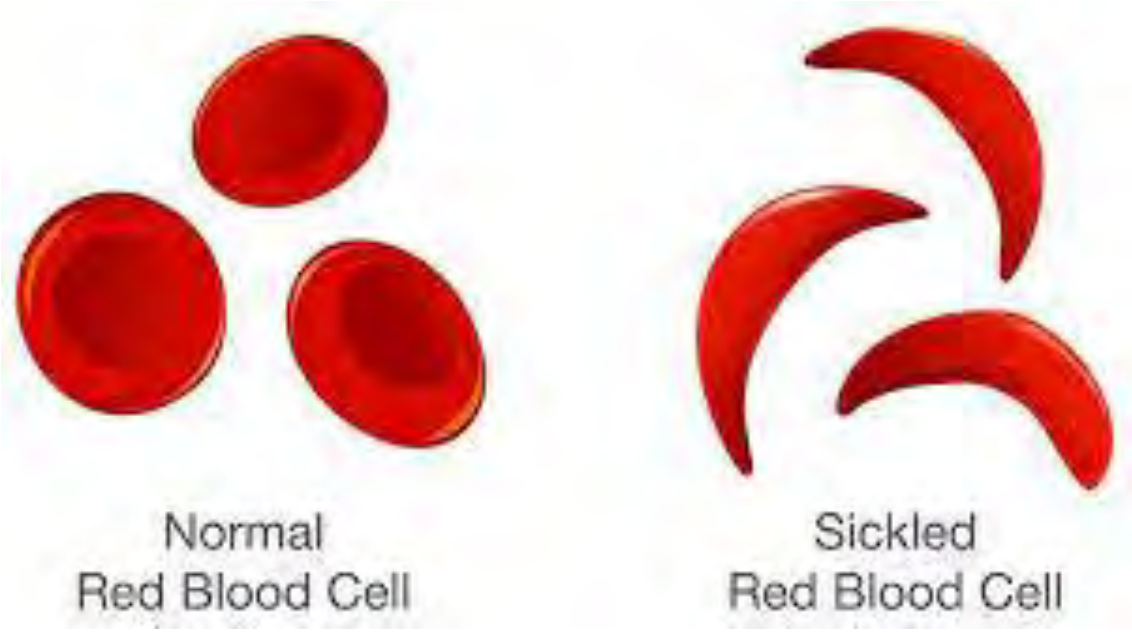
Children and Youth with Special Health Care Needs Program Director

Outline

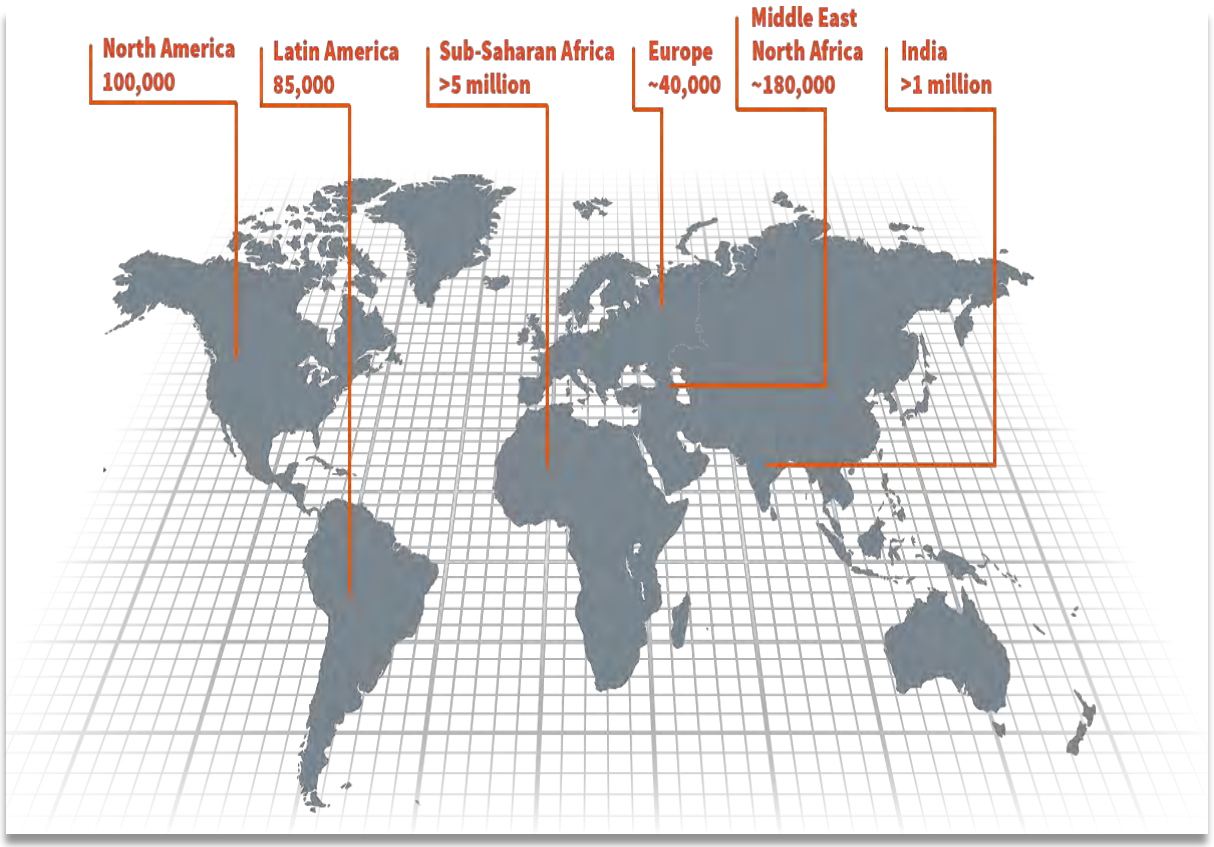
What is Sickle Cell Disease
Data and Statistics
Newborn Screening Bloodspot Program
Structure of VDH Sickle Cell Program
Virginia Sickle Cell Awareness Program (VASCAP)
Pediatric Comprehensive Sickle Cell Clinic Network
Adult Comprehensive Sickle Cell Clinic Network
2024 General Assembly
Plans for Future/Next Steps
Questions
Additional Information

What Is Sickle Cell Disease

- A collective term used to describe a group of inherited blood disorders that affect the shape and function of the red blood cell (RBC)
- RBCs form crescent or sickle shape and slow or block blood flow
- Constant breakdown of damaged RBCs
- Results in pain and damage to multiple organs
- Trait vs sickle cell disease



Data and Statistics



- Sickle Cell Disease (SCD) affects approximately 6,400,000 people worldwide
- SCD affects approximately 100,000 Americans
- Globally, about 300,000 babies are born every year with SCD
- Approximately 300,000,000 people have sickle cell trait

Data and Statistics

Virginia

- In 2023, there were 58 newborns who screened positive for SCD in Virginia through newborn screening
- The number of people in Virginia with SCD is unknown
- Pediatric and adult clinical partners serve about 1,800 clients
- Detailed newborn screening data is available on VDH's website

Newborn Screening Dried Bloodspot Program

- Sickle cell is part of the panel of 30+ conditions
- Sickle Cell Coordinator responsible for assuring entry into care
- Confirmed infants referred to sickle cell clinic in their region and PCP notified
- Program has contributed to improvement in life expectancy

Structure of VDH Sickle Cell Program

- Virginia Sickle Cell Awareness Program (VASCAP)
- Pediatric Comprehensive Sickle Program
- Adult Comprehensive Sickle Cell Program
- New Sickle Cell Disease Registry

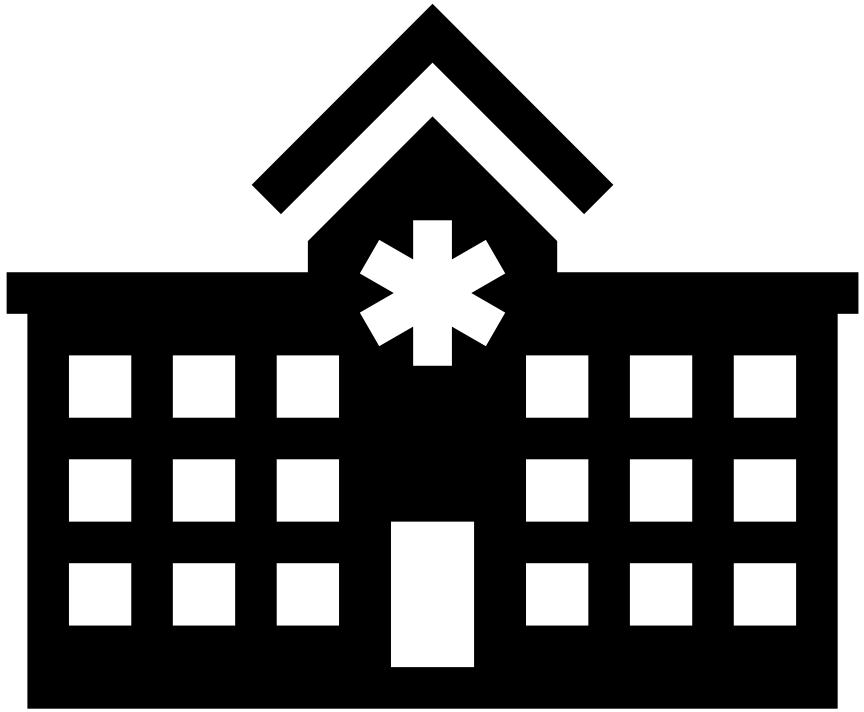
Virginia Sickle Cell Awareness Program (VASCAP)

- Scope and content in 12VAC5-191-300 of Administrative Code
- Promotes awareness of sickle cell disease
- VDH partners with local health districts to screen clients
- VDH publishes resources such as pamphlets, awareness buttons, church fans
- VDH has partnered with Radio One to air awareness ads on local urban radio stations

VIRGINIA
Sickle Cell
awareness
PROGRAM

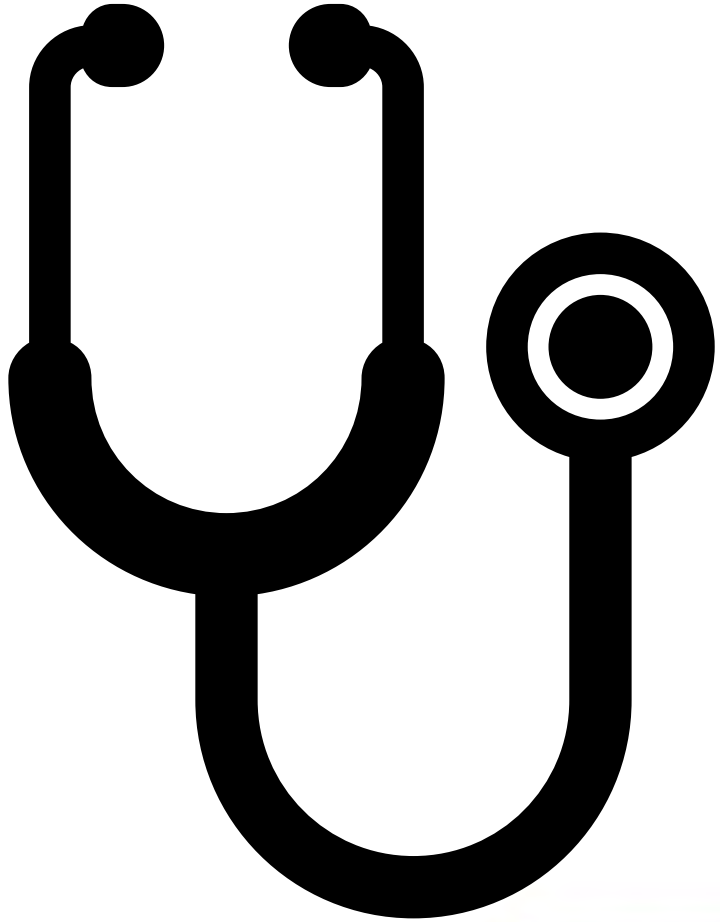
Pediatric Comprehensive Sickle Cell Clinic Network

- Scope and content in 12VAC5-191-320 of Administrative Code
- Entry into care is paramount
- VDH has strong relationships with 5 clinical partners (VCU, UVA, Carilion, CHKD, PSV)
- Coordination of care is an essential function
- Transition to adulthood emphasized (partnership with adult centers)



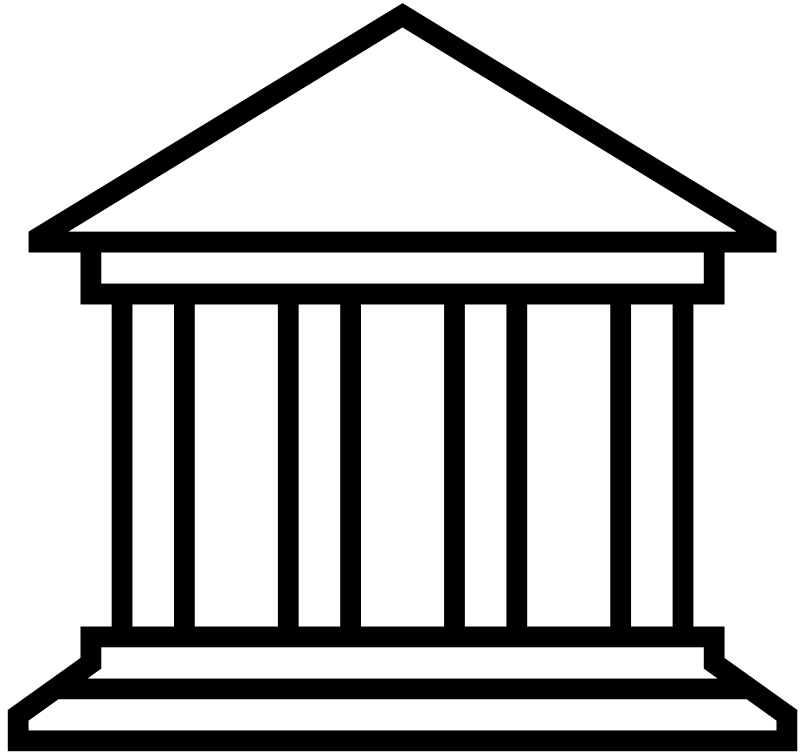
Adult Comprehensive Sickle Cell Clinic Network

- Scope and content in 12VAC5-191-340 of Administrative Code
- Mirrors pediatric clinic network-care coordination and transition
- Regulations were effective in 2021 and RFP issued fall of 2021
- Partners include UVA, VCU, Carilion, INOVA
- EVMS contract is being finalized



2024 General Assembly

- HB 252- Statewide Sickle Cell Registry
  - Established a state sickle cell disease registry
- HB 255- Adult Wellness Screening
  - Encourages sickle cell trait/disease screening testing
  - Voluntary



Plans for Future/Next Steps

- Continue to develop adult clinic program to reduce morbidity/mortality among population
- Replace recent vacant statewide sickle cell coordinator
- Develop and launch registry with feedback from experts
- Hire registry staff (epidemiologist, registry coordinator)
- Use registry data to help inform decision making on public health aims for sickle cell disease

Questions?

Additional Information

Program contact Marcus.Allen@vdh.virginia.gov

More information:

https://www.vdh.virginia.gov/sickle-cell-programs/

LUNCH PRESENTATION:

KEPONE TO BLUE ZONES – HOPEWELL, VIRGINIA

Regulations for Virginia Immunization Information System 12VAC5-115 Fast Track Amendments

Laurie Forlano, DO
State Epidemiologist & Director
Office of Epidemiology

COMMONWEALTH of VIRGINIA

Department of Health

Karen Shelton, MD
State Health Commissioner

P O BOX 2448
RICHMOND, VA 23218

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: July 26, 2024

TO: Virginia State Board of Health

FROM: Laurie Forlano, DO, MPH
Director, Office of Epidemiology and State Epidemiologist

SUBJECT: Fast Track Action - Amend Virginia Immunization Information System (VIIS) Regulations (12VAC5-115) following 2024 Periodic Review

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Enclosed for your review and approval is a Fast Track action to amend the Virginia Immunization Information System (VIIS) Regulations ("regulations").

The regulations govern a system containing birth to death immunization histories of individuals by merging data from various sources to ensure that public health information associated with immunization records is kept in an efficient, inclusive, and secure system. This system is vital to ensure immunization data is readily available to providers and other health care entities to ensure they can provide timely and appropriate patient care. Public health efforts to control and prevent vaccine-preventable diseases and effectively respond to public health emergencies (e.g., pandemics) could be negatively affected without VIIS regulations in place.

The intent of this regulatory action is to amend the chapter governing VIIS as per the 2024 periodic review decision. This amendment adds, removes, and updates regulatory language to enhance clarity; clarifies required and authorized participants in the VIIS system; updates the VIIS registration, onboarding, and training processes; clarifies authorized use of VIIS to protect patient confidentiality; updates the VIIS opt-out process; clarifies VIIS access and reactivation processes; and updates the list of demographic information required to be reported and the timing of VIIS immunization data reporting.

The State Board of Health is requested to approve the Fast Track action. Should the Board approve the action, the amendments will be submitted to the Executive Branch review process. Following Executive Branch review and approval, the proposed regulatory text will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. A 30-day public comment period will begin. Fifteen days after the close of the public comment period, the regulation will become effective.

townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-115
VAC Chapter title(s)	Virginia Immunization Information System (VIIS) Regulations
Action title	Amend Regulation Following Periodic Review
Date this document prepared	7/26/24

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The Virginia Immunization Information System (VIIS) Regulations (12VAC5-115) address the effective administration of a system containing birth to death immunization histories of individuals by merging data from various sources. The regulations described in 12VAC5-115 set clear guidance for all providers and health care entities on the appropriate use of the Virginia Immunization Information System by defining protocols related to authorized participants, registration procedures, patient confidentiality, security, data entry and quality assurance, data release, data access, and forms.

The regulations described in 12VAC5-115 are necessary to protect the public health, safety, and welfare of individuals in the Commonwealth of Virginia by ensuring that public health information associated with immunization records is kept in an efficient, inclusive, and secure system. This system is vital to ensure immunization data is readily available to providers and other health care entities to ensure they can provide timely and appropriate patient care. Public health efforts to control and prevent vaccine-

preventable diseases and effectively respond to public health emergencies (e.g., pandemics) could be negatively affected without VIIS regulations in place.

The impetus for this regulatory action is the periodic review of 12VAC5-115, which resulted in a decision to amend the regulation. This amendment adds, removes, and updates regulatory language to enhance clarity; clarifies required and authorized participants in the VIIS system; updates the VIIS registration, onboarding, and training processes; clarifies authorized use of VIIS to protect patient confidentiality; updates the VIIS opt-out process; clarifies VIIS access and reactivation processes; and updates the list of demographic information required to be reported and the timing of VIIS immunization data reporting.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

Board – State Board of Health
VDH – Virginia Department of Health
VIIS – Virginia Immunization Information System

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

Consistent with Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track rulemaking process.

The impetus for this regulatory action is the periodic review of 12VAC5-115, which resulted in a decision to amend the regulation.

This regulatory amendment includes 1) technical changes to regulatory language; 2) clarifications on VIIS required and authorized participants, authorized use, and access and reactivation processes; 3) updates to registration, onboarding, and training processes, as well as to demographic information and timing of VIIS immunization data reporting. This rulemaking is expected to be noncontroversial as amendments to the regulations are either 1) technical or clarifying in nature or 2) intended to align the regulations with current standards of practice. Further, no comments were received during the periodic review public comment period. Therefore, this action is appropriate for the fast-track rulemaking process.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

The State Board of Health is the promulgating agency. Va. Code § 32.1-12 authorizes the Board to "make, adopt, promulgate and enforce such regulations and provide for reasonable variances and exemptions therefrom as may be necessary to carry out the provisions of [Title 32.1] and other laws of the Commonwealth administered by it, the Commissioner or the Department."

Va. Code § 32.1-46.01 requires the Board to establish the VIIS and to promulgate regulations to implement the VIIS.

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it is intended to solve.

The impetus for this regulatory action is the periodic review of 12VAC5-115, which resulted in a decision to amend the regulation. This regulatory action is needed to clarify and update the regulation for the regulated public to reflect current VIIS practices, and to maximize VIIS capabilities to positively impact public health. The regulatory changes include streamlined immunization data record-keeping and provider access to comprehensive immunization records, leading to better informed patient care and, potentially, improved patient outcomes, and are essential to protect the health, safety, or welfare of citizens.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

The amendments will:

- Update three definitions;
- Add, remove, and update regulatory language to enhance clarity;
- Clarify required and authorized participants in the VIIS system;
- Update the VIIS registration, onboarding, and training processes;
- Clarify authorized use of VIIS to protect patient confidentiality;
- Update the VIIS opt-out process;
- Clarify the VIIS access and reactivation processes; and
- Update list of demographic information required to be reported and the timing of VIIS immunization data reporting, including the removal of social security number as a required field to reduce regulatory burden.

Issues

Identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or

amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

The primary advantages to the public include 1) streamlined immunization data record-keeping and provider access to comprehensive immunization records, leading to better informed patient care and, potentially, improved patient outcomes; 2) improved electronic VIIS registration, onboarding, and training processes that may reduce costs to health care providers and health care entities through increased efficiency and reduced manual paperwork; and 3) simplified patient opt-out of VIIS through an electronic form.

The primary advantages to the agency or the Commonwealth include 1) clarification of the regulation to improve regulatory understanding and compliance by regulants; 2) streamlined immunization data record-keeping and provider access to comprehensive immunization records, leading to better informed patient care and, potentially, improved patient outcomes; 3) improved electronic VIIS registration, onboarding, and training processes that may reduce costs to health care providers and health care entities through increased efficiency and reduced manual paperwork; and 4) simplified patient opt-out of the VIIS through an electronic form.

No disadvantages to the public or the Commonwealth have been identified.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

None of these requirements is more restrictive than federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

No other state agency would be particularly affected by this regulatory change.

Localities Particularly Affected

All localities who are subject to these regulations would be equally affected by these regulatory changes.

Other Entities Particularly Affected

All health care entities and health care providers who are subject to these regulations would be equally impacted by these regulatory changes.

Economic Impact

Consistent with § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	No direct or indirect economic impact.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	No direct economic impact. There may be indirect economic impact to state agencies required to report immunization data to VIIS. State agencies required to report immunization data to VIIS may incur personnel costs related to mandatory input of patient immunizations if they are reporting manually. Conversely, a savings may be realized as electronic registration, onboarding, and reporting of immunization-related data may be more cost effective than faxing or mailing paper reports. There may also be a reduction in staffing costs through more efficient processes and a reduction in labor necessary to process paper forms.
For all agencies: Benefits the regulatory change is designed to produce.	Benefits the regulatory change is designed to produce for state agencies include 1) clarification of the regulation to improve regulatory understanding and compliance by regulants; 2) streamlined immunization data record-keeping and provider access to comprehensive immunization records, leading to better informed patient care and, potentially, patient outcomes; 3) improved electronic VIIS registration, onboarding, and training processes that may reduce costs to health care providers and health care entities through increased efficiency and reduced manual paperwork; and 4) simplified patient opt-out of the VIIS through an electronic form.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees or revenues resulting from the regulatory change.	Analysis provided on Table 2 of the ORM Economic Impact form.
Benefits the regulatory change is designed to produce.	Analysis provided on Table 2 of the ORM Economic Impact form.

Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Analysis provided on Tables 3 and 4 of the ORM Economic Impact form.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	Analysis provided on Tables 3 and 4 of the ORM Economic Impact form.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	Analysis provided on Tables 3 and 4 of the ORM Economic Impact form.
Benefits the regulatory change is designed to produce.	Analysis provided on Tables 3 and 4 of the ORM Economic Impact form.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

There are no viable alternatives to the regulatory change. The Board is required, pursuant to § 32.1-46.01 to promulgate regulations to implement the VIIS.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B of the Code of Virginia, describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

There are no alternative regulatory methods to achieve the statutory requirement in § 32.1-46.01 of the Code of Virginia. The regulations are already designed to minimize administrative burden and achieve the intent of the legislative mandate.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

Consistent with § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The State Board of Health is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Karen Mask, Senior Policy Analyst for the Virginia Department of Health Office of Epidemiology, 109 Governor Street, Richmond, VA, 23219, (804) 654-9351, and Karen.Mask@vdh.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or

agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
115-10	N/A	This section includes definitions	**Change:** The definitions for "heath care entity", "health care provider", and "health plan" were updated to reference the respective definitions in § 32.1-127.1:03 of the Code of Virginia. **Intent:** The intent is to tie the definitions to the Code definitions. There is no substantive change to the meaning or use of the terms. **Rationale:** The rationale is to ensure consistency with the Code. Subsection B of § 32.1-46.01 requires that those three terms be defined as in the cited Code section. **Likely Impact:** The likely impact of this change is improved consistency with the Code.
115-20	N/A	This section addresses authorized participants in the VIIS system.	**Change:** Updates language to reflect health care provider and health care entities required or authorized to participate in VIIS per §§ 32.1-127.1:03, 8.01-581.1, and 32.1-46.01 of the Code of Virginia. **Intent:** The intent of this change is to clarify both the required and authorized VIIS user populations for the regulated public. **Rationale:** The rationale for this change is to improve the clarity of the regulation and to align the regulation with §§ 32.1-127.1:03, 8.01-581.1, and 32.1-46.01 of the Code of Virginia. **Likely Impact:** The likely impact of this change is better understanding of who is

			required and who is authorized to utilize VIIS.
115-30	N/A	This section addresses VIIS registration procedures and requirements.	**Change:** Section edits: • Relocates provisions from subsection A to section 115-20 • Updates language to reflect current electronic VIIS registration versus paper forms. • Clarifies VDH and participant organization responsibilities regarding VIIS training and onboarding. • Specifies that all data entered by an organization or participant will remain in the system in the event that organization or participant access is terminated. **Intent:** The intent of the change is to reflect current VIIS electronic registration, onboarding, and data retention procedures and to clarify VDH and participant organization VIIS training and onboarding responsibilities. **Rationale:** The rationale for this change is to improve the clarity of the regulation and update the regulation to reflect current VIIS practice. **Likely Impact:** The likely impact of the change is a reduction in regulatory burden on regulants due to fewer required forms and more streamlined electronic VIIS processes and better regulation clarity among regulants.
115-40	N/A	This section addresses patient confidentiality in VIIS	**Change:** Section edits: • Adds language stating that VIIS patient level data may only be used for purposes listed in § 32.1-46.01 of the Code of Virginia. • Adds language clarifying that VIIS patient level data may not be used to determine if an employee is in compliance with the immunization policies of the employer (this is not a purpose listed in § 32.1-46.01). • Updates language regarding the VIIS opt-out process. • Relocates examples of activities that may jeopardize the security of VISS from subsection B of section 50 to subsection B of section 40.

			• Adds pulping and incineration as acceptable methods of immunization record destruction. **Intent:** The intent of the change is to clarify allowable use of VIIS and the VIIS opt-out process. The change expands pathways to compliance with secure record disposal methods. **Rationale:** The rational for this change is to improve the clarity of the regulation and align the regulation with § 32.1-46.01 of the Code of Virginia; and to allow additional methods of secure document disposal. **Likely Impact:** The likely impact of this change is better understanding of allowable usage of VIIS and better clarity among the regulants. Regulants may begin to pulp or incinerate copies of immunization records.
115-50	N/A	This section addresses the security requirements to participate in the VIIS system	**Change:** Updates language to reflect current VIIS sign-on, data protection, and account reactivation requirements. Removes nonregulatory language in subsection A. Relocates provisions from subsection B to section 40. **Intent:** The intent of the change is to update the regulation to reflect current VIIS practice and provide clarity to regulants. Remove nonregulatory or unnecessary language. Clarify reactivation procedures after account is automatically inactivated. **Rationale:** The rationale for this change is to improve the clarity of the regulation and update the regulation to reflect current VIIS practice. **Likely Impact:** The likely impact of this change is better clarity among the regulants.
115-60	N/A	This section addresses data population of VIIS.	**Change:** Section edits: • Updates language to reflect current titles of VDH offices. • Clarifies existing data transmission methods, including with VDH vital statistic information.

			• Changed timing of immunization data reporting to within three days of vaccine administration. • Updates patient demographic information required to be reported to VIIS: Patient name and birth date are the only two fields required for record acceptance. Gender, telephone number, email, home address, race, ethnicity, birthplace, and mother's maiden name are now only required if available. • Removes patient social security number as a field required for reporting. • Clarified data quality review and notice procedures, including adding a 30-day requirement to resolve rejected records. Additional updates to this section include non-substantive changes for language and style consistency. **Intent:** The intent of this change is to update the regulation to reflect current VIIS practice and to conform to the Virginia Registrar's *Form, Style and Procedure Manual for Publication of Virginia Regulations*. The change also reflects the existing operation of the system with regard to record rejection and minimum data field requirements. **Rationale:** The rationale for this change is that these changes reflect current standards of practice, reduce data reporting requirements, reflect data reporting capabilities in the current environment, and align the regulation with § 32.1-46.01 of the Code of Virginia. Most data submissions occur on a daily basis, changing the submission window from 7 to 3 days aligns the few manual submissions with the rest of the data reported to VIIS. The current language requires rejected record resolution "in a timely way," which is not an objective or enforceable standard. 30 days is objective, enforceable, and a reasonable amount of time. **Likely Impact:** The likely impact of this change is better clarity of the regulation and better understanding of the data

			reporting requirements by regulants. Manual data submissions will be sent within 3 days of vaccination administration. Rejected records will be updated by the participant within 30 days of notice that the record was rejected.
115-70	N/A	This section specifies requirements regarding the release of VIIS data.	**Change:** Updates language to reflect current technology and consistent use of the term VIIS "participant" throughout the regulation. Removes subsection B. Removes requirement to contact VDH before disclosing data as required or permitted by state or federal law. **Intent:** The intent of this language is to conform to current industry practice and to the Virginia Registrar's *Form, Style and Procedure Manual for Publication of Virginia Regulations*. **Rationale:** The rationale for this change is to improve the clarity of the regulation and conform to the form and style guidelines. Subsection B was duplicative of the information in subsection A, and was unnecessary. If VDH or an external participant in VIIS were to disclose VIIS information for a purpose explicitly required or permitted by state or federal law, VDH does not need to approve that disclosure in advance. **Likely Impact:** The likely impact of this change is better clarity among the regulants. Required or permitted disclosures may take place with a lower administrative burden.
Forms (12VAC5-115)	N/A	Current documents listed in the Forms section: • Administrator Information • Electronic Data Exchange with VIIS • Information Systems Security Access Agreement • Organization Information, VIISORG • Memorandum of Agreement between Virginia Department of Health/Division of Immunization (VDH/DOI) and VIIS Organization	**Change:** Removes all forms except the VIIS patient opt-out form. Replaces the opt-out form with a link to the new electronic form. **Intent:** The intent of this change is to remove VIIS-related forms that are no longer used by VDH from the regulation. **Rationale:** The rationale for this change is that the VIIS system collects necessary registration, user, security, and confidentiality agreement information electronically, removing the need for paper forms and manual processes. The electronic opt-out form will be much easier to use for patients.

		Interested in Data Exchange • Virginia Immunization Information System (VIIS) Opt-In of VIIS • Virginia Immunization Information System (VIIS) Opt-Out of VIIS • VIIS Security Policy and User Confidentiality Agreement • VIIS User Acknowledgement Page • VIIS User Signature Page	**Likely Impact:** The likely impact is a reduction in regulatory burden on regulants due to fewer required forms and more streamlined electronic VIIS processes.

Office of Regulatory Management

Economic Review Form

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5 - 115
VAC Chapter title(s)	Virginia Immunization Information System (VIIS) Regulations
Action title	Amendment Resulting from Periodic Review
Date this document prepared	7/22/24
Regulatory Stage (including Issuance of Guidance Documents)	Fast Track

Cost Benefit Analysis

Complete Tables 1a and 1b for all regulatory actions. You do not need to complete Table 1c if the regulatory action is required by state statute or federal statute or regulation and leaves no discretion in its implementation.

Table 1a should provide analysis for the regulatory approach you are taking. Table 1b should provide analysis for the approach of leaving the current regulations intact (i.e., no further change is implemented). Table 1c should provide analysis for at least one alternative approach. You should not limit yourself to one alternative, however, and can add additional charts as needed.

Report both direct and indirect costs and benefits that can be monetized in Boxes 1 and 2. Report direct and indirect costs and benefits that cannot be monetized in Box 4. See the ORM Regulatory Economic Analysis Manual for additional guidance.

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

(1) Direct & Indirect Costs & Benefits (Monetized)	**<u>Overall changes in the action</u>** Direct Costs: There are no direct monetized costs associated with any of the proposed regulatory changes. Indirect Costs: There are no indirect monetized costs associated with any of the proposed regulatory changes. Direct Benefits: Replacing or removing seven VIIS-related manual forms/processes and transitioning activities to the electronic portal is likely to improve efficiency of VIIS registration, onboarding, and reporting of immunization-related data. For health care providers and health care entities required to report, it could be more cost effective compared to faxing or mailing paper reports because those methods cost money for postage, fax lines, and paper. There may also be a reduction in staffing costs through more efficient processes and a reduction in labor necessary to process paper forms. Indirect Benefits: There are no indirect monetized benefits associated with any of the proposed regulatory changes. **<u>Specific changes</u>** Amended regulation to change VIIS registration, onboarding, and training from a manual process with paper forms to an electronic process to reflect current practice. • Direct monetized benefits: Streamlining VIIS registration, onboarding, and training processes electronically may reduce costs to health care providers and health care entities through improved processes, increased efficiency, and reduction in manual paperwork. VDH is not able to quantify the direct monetary benefit of this regulatory change. The potential cost savings are difficult to quantify as costs will vary based on the salary of the employee entering data, the volume of immunizations administered at a practice, data exchange costs from electronic health record vendors, and employee efficiency while entering VIIS data. Amended language to transition the VIIS opt-out process from a written notification to an electronic form. • Direct monetized benefits: Streamlining the VIIS opt-out processes electronically may reduce costs to health care providers and health care entities through improved processes, increased efficiency, and reduction in manual paperwork. VDH is not able to quantify the direct monetary benefit of this regulatory change.

	The following changes have no direct or indirect monetized costs or benefits: • Updated definitions for "heath care entity", "health care provider", and "health plan" to reference the respective definitions in § 32.1-127.1:03 of the Code of Virginia • Clarifications to the regulatory language were made to ensure consistency throughout the regulation, provide clarity to regulants, and to conform to the Virginia Registrar's *Form, Style and Procedure Manual for Publication of Virginia Regulations.* • Clarified required and authorized VIIS participant groups and VIIS purpose to align with §32.1-127.1:03, §8.01-581.1, and §32.1-46.01 of the Code of Virginia. • Amended language to reflect that the use of VIIS is limited to purposes listed in subsection A of §32.1-46.01 and does not include employers using VIIS to verify vaccination status of employees. • Added pulping and incineration as acceptable methods of immunization record destruction. • Amended language to reflect current standards of practice for VIIS system sign-on and account reactivation. • Clarified the demographic information that is required to be reported and removed demographic data that is not required to be reported to VIIS and changed reporting timeline to within three days of vaccine administration, which affects only manual data submissions. • Replaced the patient opt-out form with a link to the new electronic form. Removed references to unnecessary documents listed in the Forms Section.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Net Monetized Benefit	$0	
(4) Other Costs & Benefits (Non-Monetized)	Non-monetized benefits: Some of these changes could result in more efficient reporting practices and eliminate redundant data reporting.	
(5) Information Sources	N/A	

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: The current regulation affects health care providers, local health departments, and other entities that provide patient immunizations. These health care entities incur personnel costs related to mandatory input of patient immunizations into VIIS if they are reporting manually. Over 90% of immunization records received in VIIS are sent electronically through data exchange. The actual costs are difficult to quantify as costs will vary based on the salary of the employee entering data, the volume of immunizations that are administered at a practice, data exchange costs from electronic health record vendors, and employee efficiency while entering VIIS data. Additional costs may include computer equipment and internet access, but these costs would be negligible as health care entities would likely have computer equipment and internet access with or without these requirements. Indirect Costs: There are no monetized indirect costs associated with maintaining the current regulations. Direct Benefits: There are no monetized direct benefits associated with maintaining the current regulations. Indirect Benefits: There are no monetized indirect benefits associated with maintaining the current regulations.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Net Monetized Benefit	$0	

(4) Other Costs & Benefits (Non-Monetized)	If the regulations are maintained as currently written, health care providers, local health departments and other health care entities will maintain the same level of burden associated with immunization data reporting and efficiencies and modernization of the immunization data reporting process (VIIS) will be thwarted. This will result in less timely data, a decreased ability for health care providers to make appropriate immunization decisions for their patient population, and potential negative impact on the reduction of vaccine-preventable diseases.
(5) Information Sources	N/A

Table 1c: Costs and Benefits under Alternative Approach(es)

(1) Direct & Indirect Costs &	VDH has not identified any viable alternative approaches beyond those described in the proposed action.

Benefits (Monetized)		
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Net Monetized Benefit	$0	
(4) Other Costs & Benefits (Non-Monetized)	N/A	
(5) Information Sources	N/A	

Impact on Local Partners

Use this chart to describe impacts on local partners. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 2: Impact on Local Partners

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: Any clinics owned/operated by local government, such as local health departments, are affected by this regulation. Health care clinics will incur personnel costs related to mandatory input of patient immunizations into VIIS if they are reporting manually. Over 90% of immunization records received in VIIS are sent electronically through data exchange. The actual costs are difficult to quantify as costs will vary based on the salary of the employee entering data, the volume of immunizations administered at a practice, data exchange costs from electronic health record vendors, and employee efficiency while entering VIIS data. Additional costs may include computer equipment and internet access, but these costs would be negligible as clinics would likely have computer equipment and internet access with or without these requirements. For the purposes of this Form, VDH has assumed that all monetizable costs will be borne by health care providers. Some or all the costs may, however, be passed along to families in the form of higher health care costs. Indirect Costs: There are no monetized indirect costs on local partners associated with this action. Direct Benefits: This amendment streamlines VIIS through the use of electronic processes reducing the use of paper forms and manual registration, training, and data submission processes. This amendment

	may reduce costs to local partners through improved processes and increased efficiency. The potential cost savings are difficult to quantify as costs will vary based on the salary of the employee entering data, the volume of immunizations administered at a practice, data exchange costs from electronic health record vendors, and employee efficiency while entering VIIS data. Indirect Benefits: There are no monetized indirect benefits on local partners associated with this action.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0 (but see explanation above)	(b) $0 (but see explanation above)

(3) Other Costs & Benefits (Non-Monetized)	Benefits: (1) Health care providers have access to complete patient immunization records, enabling them to make appropriate and timely patient care decisions when treating patients. (2) VDH has access to patient immunization data, enabling the state agency to make appropriate and timely public health decisions, assess immunization coverage rates, and provide direction to health care providers and the public. (3) Enables VDH the ability to provide insurance carriers with Healthcare Effectiveness Data and Information Set (HEDIS) data which is used to evaluate program effectiveness. (4) Enables VDH to create and publish vaccination dashboards to inform the public about coverage for vaccine-preventable diseases in Virginia.
(4) Assistance	N/A
(5) Information Sources	N/A

Impacts on Families

Use this chart to describe impacts on families. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 3: Impact on Families

(1) Direct & Indirect Costs &	Direct Costs: There are no monetized direct costs on local partners associated with this action.

Benefits (Monetized)	Indirect Costs: Any costs incurred by families would be a result of a business choosing to pass staff costs along to consumers. These costs should be negligible. Direct Benefits: There are no monetized direct benefits on local partners associated with this action. Indirect Benefits: There are no monetized indirect benefits on local partners associated with this action.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0 (but see explanation above)	(b) $0 (but see explanation above)

(3) Other Costs & Benefits (Non-Monetized)	Benefits: (1) Enhanced health care services - health care providers have access to complete patient immunization records, enabling them to make appropriate and timely patient care decisions when treating patients. (2) Enhanced public health services - VDH has access to patient immunization data, enabling the state agency to make appropriate and timely public health decisions and provide direction to health care providers and the public. (3) Patients have direct access to COVID-19 immunization records through a VDH-created electronic interface and all immunization records through a request process.
(4) Information Sources	N/A

Impacts on Small Businesses

Use this chart to describe impacts on small businesses. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 4: Impact on Small Businesses

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: Small Businesses, such as health care providers, are affected by this regulation. Small businesses will incur personnel costs related to mandatory input of patient immunizations into VIIS if they are reporting manually. Over 90% of immunization records received in VIIS are sent electronically through data exchange. The actual costs are difficult to quantify as costs will vary based on the salary of the employee entering data, the volume of immunizations that are

	administered at a practice, data exchange costs from electronic health record vendors, and employee efficiency while entering VIIS data. Additional costs may include computer equipment and internet access, but these costs would be negligible as clinics would likely have computer equipment and internet access with or without these requirements. For the purposes on this Form, VDH has assumed that all monetizable costs will be borne by health care providers. Some or all the costs may, however, be passed along to families in the form of higher health care costs. Indirect Costs: There are no monetized indirect costs on local partners associated with this action. Direct Benefits: This amendment streamlines VIIS through the use of electronic processes reducing the use of paper forms and manual registration, training, and data submission processes. This amendment may reduce costs to local partners through improved processes and increased efficiency. The potential cost savings are difficult to quantify as costs will vary based on the salary of the employee entering data, the volume of immunizations administered at a practice, data exchange costs from electronic health record vendors, and employee efficiency while entering VIIS data. Indirect Benefits: There are no monetized indirect benefits on local partners associated with this action.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0 (but see explanation above)	(b) $0 (but see explanation above)

(3) Other Costs & Benefits (Non-Monetized)	Benefits: (1) Health care providers have access to complete patient immunization records, enabling them to make appropriate and timely patient care decisions when treating patients. (2) VDH has access to patient immunization data, enabling the state agency to make appropriate and timely public health decisions, assess immunization coverage rates, and provide direction to health care providers and the public. (3) Enables VDH the ability to provide insurance carriers with Healthcare Effectiveness Data and Information Set (HEDIS) data which is used to evaluate program effectiveness. Enables VDH to create and publish vaccination dashboards to inform the public about coverage for vaccine-preventable diseases in Virginia.

(4) Alternatives	N/A
(5) Information Sources	N/A

Changes to Number of Regulatory Requirements

Table 5: Regulatory Reduction

For each individual action, please fill out the appropriate chart to reflect any change in regulatory requirements, costs, regulatory stringency, or the overall length of any guidance documents.

Change in Regulatory Requirements

VAC Section(s) Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
12VAC5-115-10	**(M/A):**	**0**	0	0	0
	(D/A):	**0**	0	0	0
	(M/R):	**0**	0	0	0
	(D/R):	**0**	0	0	0
12VAC5-115-20	**(M/A):**	**0**	0	0	0
	(D/A):	**2**	+1	0	+1
	(M/R):	**0**	+1	0	+1
	(D/R):	**0**	0	0	0
12 VAC5-115-30	**(M/A):**	**0**	0	0	0
	(D/A):	**3**	0	0	0
	(M/R):	**1**	0	-1	-1
	(D/R):	**11**	0	-3	-3
12VAC5-115-40	**(M/A):**	**0**	0	0	0
	(D/A):	**3**	0	0	0
	(M/R):	**0**	0	0	0
	(D/R):	**7**	0	0	0
12VAC5-115-50	**(M/A):**	**0**	0	0	0
	(D/A):	**4**	0	0	0
	(M/R):	**0**	0	0	0
	(D/R):	**5**	0	-4	-4
12VAC5-115-60	**(M/A):**	**0**	0	0	0
	(D/A):	**11**	0	-3	-3
	(M/R):	**0**	0	0	0
	(D/R):	**9**	+1	0	+1
12VAC5-115-70	**(M/A):**	**1**	0	0	0
	(D/A):	**3**	0	-1	-1
	(M/R):	**1**	0	0	0

	(D/R):	**1**	0	0	0
	Grand Total of Changes in Requirements:	**(M/A): 0**			
		(D/A): -3			
		(M/R): 0			
		(D/R): -6			

Key:

Please use the following coding if change is mandatory or discretionary and whether it affects externally regulated parties or only the agency itself:

(M/A): Mandatory requirements mandated by federal and/or state statute affecting the agency itself

(D/A): Discretionary requirements affecting agency itself

(M/R): Mandatory requirements mandated by federal and/or state statute affecting external parties, including other agencies

(D/R): Discretionary requirements affecting external parties, including other agencies

Other Decreases or Increases in Regulatory Stringency (if applicable)

VAC Section(s) Involved*	**Description of Regulatory Change**	**Overview of How It Reduces or Increases Regulatory Burden**
12VAC5-115-40 (D)	Added pulping and incineration as acceptable methods of immunization record destruction.	Increases available pathways to compliance for regulants,
12VAC5-115-60 (C)	Decrease immunization administration reporting time frame from seven (7) days to three (3) days.	The regulatory change reduces the amount of time health care providers have to report to VIIS any immunizations administered. This change is minimal as the immunization data exchange occurs automatically each night. The reduced submission timeframes will only affect a small number of manual data submissions.
12VAC5-115-60 (D)	Remove social security number from the list of demographic information to be reported to VIIS.	Removal of one of the pieces of demographic information required to be reported to VIIS.

Project 7833 – Fast Track

Department of Health

Chapter 115 Amendments Resulting from Periodic Review 2024

12VAC5-115-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Commissioner" means the State Health Commissioner or his designee.

"Data exchange" means electronically sending immunization information from an existing information system to VIIS and being able to retrieve information from VIIS.

"De-duplication" means the process in information systems that matches incoming data with existing client records and merges those identified as the same client.

"Health care entity" means ~~any health care provider, health plan, or health care clearinghouse.~~ the same as in § 32.1-127.1:03 of the Code of Virginia.

"Health care provider" means ~~those entities listed in § 8.01-581.1 of the Code of Virginia, except that state-operated facilities shall also be considered health care providers for the purposes of this section. Health care provider shall also include all persons who are licensed, certified, registered, or permitted or who hold a multistate licensure privilege issued by any of the health regulatory boards within the Department of Health Professions, except persons regulated by the Board of Funeral Directors and Embalmers or the Board of Veterinary Medicine.~~ the same as in § 32.1-127.1:03 of the Code of Virginia.

"Health plan" means ~~an individual or group plan that provides or pays the cost of medical care and shall include any entity included in such definition as set out in 45 CFR 160.103.~~ the same as in § 32.1-127.1:03 of the Code of Virginia.

"Participant" means a person or organization with a VIIS account.

"Patient" means the client who is receiving health services.

"Public health emergency" means any (i) public health event caused by an act of bio-terrorism or vaccine-preventable disease outbreak or (ii) other public health event resulting from natural or human cause.

"Security role" means the level of security assigned to a participant that determines what information the individual may access in the application and what system functions may be performed.

"VDH" or "Department of Health" means the Virginia Department of Health.

"Virginia Immunization Information System" or "VIIS" means the statewide immunization registry.

"VITA" means the Virginia Information Technologies Agency.

12VAC5-115-20. Authorized participants.

A. ~~Health care providers, including but not necessarily limited to any physician, physician assistant, nurse practitioner, registered nurse, school nurse, pharmacist, or any entity listed in the definition of "health care provider" in § 8.01-581.1 of the Code of Virginia, are authorized to participate in VIIS.~~ A health care provider in the Commonwealth that administers immunizations shall report to VIIS pursuant to § 32.1-46.01 and this chapter. No health care provider required to report patient immunization information to VIIS pursuant to § 32.1-46.01 shall be required to pay a fee to VDH to participate in VIIS.

B. ~~Any health care entity may participate as long as it is licensed or certified in Virginia to deliver or support health care services or public health, requires immunization data to perform the health service function, and uses VIIS only for exchanging information on persons for whom it~~

~~provides services.~~ A health care entity is authorized to participate in VIIS so long as the health care entity is licensed or certified in Virginia to deliver or support health care services or public health and requires immunization data to support a purpose listed in subsection A of § 32.1-46.01.

C. Other state or regional immunization registries may ~~exchange data with VIIS. They may~~ share data and have access to data from VIIS by contacting the VIIS program manager and complying with the registration procedure ~~discussed~~ in 12VAC5-115-30.

D. VDH shall give access to VIIS under the condition that having access to immunization information is required to perform the job function of the participant. The VIIS program manager or designee shall assign the security role of the participant based on his needs and job responsibilities.

~~E. Access to VIIS requires only Internet access and is free to participants.~~

12VAC5-115-30. Registration procedures.

A. ~~Participation in VIIS is mandatory for any health care provider, as defined in § 32.1-127.1:03 of the Code of Virginia, in the Commonwealth that administers immunizations.~~ To gain access to VIIS, an authorized participant shall complete the VIIS electronic registration process. The participant shall complete the electronic registration process every year as directed by VDH.

1. Registration shall require the participant to assure compliance with necessary confidentiality and security access provisions that specify security procedures to ensure that VIIS data are protected from unauthorized view and access.

B. ~~Completed registration forms from authorized participants must be processed and~~ VDH must approve the registration ~~approved by VDH~~ before granting the participant access to the system ~~is allowed. Registration will require the participant to assure compliance with necessary confidentiality and security access provisions that specify security procedures to ensure that VIIS~~

~~data are protected from unauthorized view and access. The participant shall update and submit the forms to VDH every year~~ .

C. ~~Once the participant is approved, the participant shall sign a participant registration agreement with VDH.~~ VDH ~~will then provide training and~~ shall confirm the participant completed VDH specified training and then activate the participant in the VIIS system.

D. ~~Qualifying~~ A qualifying participant ~~organizations~~ organization shall designate an administrator for their organization. The administrator may then allow VIIS access by an employee in the administrator's organization and, in doing so, shall assume responsibility for registering that person, ~~obtaining the most recent security forms that specify~~ ensuring the employee is trained and has reviewed the ~~VITA or~~ VDH security requirements for VIIS , ~~retaining all completed user forms,~~ assigning the security role of the ~~user~~ participant , accepting legal responsibility for the ~~employee's~~ participant's proper use of VIIS, and terminating access to VIIS if the ~~employee~~ participant is noncompliant with VIIS requirements or no longer requires access.

E. ~~Terminate organizational participation by notifying VDH in writing. All~~ If a participant's access is terminated, the data entered by ~~that organization~~ the participant shall remain in the system.

12VAC5-115-40. Patient confidentiality.

A. ~~Access to VIIS information is authorized only under the condition that access to individual immunization information is required to perform the participant's job function.~~ A participant may only access individual immunization information within VIIS that is required to perform the participant's job function.

B. ~~Participants shall not~~ No participant may conduct any activity that jeopardizes the proper function or security of VIIS ~~.~~ , including sharing of sign-on information, allowing unauthorized view of VIIS screens, or failing to log off VIIS when leaving a workstation. A participant may only use

VIIS patient level data for a purpose listed in subsection A of § 32.1-46.01 ~~They shall use patient data only as authorized by law and this chapter~~ and must immediately notify the patient and VDH of any breach of personal privacy or confidentiality.

C. No employer may access an employee's patient level data in VIIS for the purpose of determining if the employee is in compliance with the employer's immunization policies.

~~C.~~ ~~Patients shall have the opportunity to~~ D. A patient may opt-out of VIIS by ~~doing one of the following:~~

~~1. Contacting their health care provider to allow the viewing of their immunizations only by that provider who administered them ; or~~

~~2. Contacting VDH in writing requesting to be taken out of VIIS and have their record no longer viewable.~~ completing the electronic VDH Opt-Out Form specifying their opt-out preferences.

~~D.~~ E. Patient immunization records ~~shall~~ may not be copied except for authorized use. ~~These~~ The copies ~~shall~~ may not be left where they are visible by unauthorized personnel and shall be shredded , pulped, or incinerated before disposal.

~~E.~~ F. VIIS records shall be treated with the same confidentiality and privacy as any other health record. ~~Any~~ VDH shall immediately suspend a participant's system access privileges for inappropriate use of VIIS records ~~shall result in immediate suspension of participant privileges~~ and shall conduct an investigation ~~conducted by VDH . Additional~~ . VDH may take additional actions ~~may be taken~~ pursuant to § 32.1-27 of the Code of Virginia. The VIIS program manager may reinstate privileges.

~~F.~~ G. Nothing in this chapter alters the provision in 45 CFR Part 164 that permits covered health care entities to disclose protected health information to a public health authority without individual authorization.

12VAC5-115-50. Security.

~~A. After VDH gives access to a VIIS participant, a secure connection is established between his browser and VIIS. The system is password protected.~~

~~B. Participants shall ensure that employees with authorized access do not disclose their user identification code or password to anyone, have physical security and password-enabled screen savers on computers accessing VIIS, make every effort to protect VIIS screens from unauthorized view, and log off the system whenever leaving the VIIS workstation.~~

~~C.~~ A. The VIIS system ~~, which is maintained on a secure website,~~ shall automatically inactivate a user session after a predetermined period of inactivity ~~. The inactivation period is~~ as determined by VITA security policy.

~~D.~~ B. The VIIS system shall inactivate ~~user accounts~~ a participant's account, denying access to the system when ~~participants have~~ the participant has not logged into the system after a predetermined period of time ~~. This inactivation period is~~ , as determined by VITA security policy. ~~The administrator must reactivate the account.~~ If the participant requests reactivation of the account, VDH shall review the request and may reactivate the account, granting continued access to VIIS.

~~E.~~ C. There shall be a secure encrypted connection , as determined by VITA or VDH, between VIIS and the participating organization sending or receiving data if data exchange is performed. ~~The encryption process will be determined by VITA or VDH or both.~~

12VAC5-115-60. Population of VIIS.

A. The VDH ~~Divisions~~ Division of Immunization and Office of Vital Records shall have an agreement to populate demographic information in VIIS with birth certificate data. Death certificate data ~~are~~ shall be used to make the VIIS record no longer viewable. ~~Data exchange shall be~~

~~performed on a periodic basis, but at least monthly.~~ The data shall be transmitted via electronic data exchange.

B. ~~Each~~ A participant shall make every effort to ensure the accuracy of all immunization and demographic information and shall include enough identifying information to allow for de-duplication of patients.

C. Data shall be reported in VIIS either by online data entry or by data exchange of files from other information systems. ~~The participating provider or the health plan billed for the immunization shall report.~~ Reporting shall occur within ~~seven~~ three days of vaccine administration ~~for online data entry participants~~ . ~~For data exchange participants, reporting shall occur within seven days of receipt of the information.~~

D. Both demographic and immunization data shall be reported ~~by the participant~~ for each immunization administered.

1. Patient demographic information shall include ~~, but is not limited to,~~ the patient's name ~~,~~ and date of birth in order to be accepted by VIIS. ~~, gender, telephone number, home address, birth place, and mother's maiden name.~~ The following information is required, if available: gender, telephone number, email, home address, race, ethnicity, birthplace, and mother's maiden name. ~~The social security number, if provided, shall be encrypted by the application, appear as asterisks, and shall not print out on reports for that patient. The application shall allow only exact matches when the social security number is used for search purposes.~~

2. Patient immunization information shall include ~~, but is not limited to,~~ the type of immunization administered using industry standards such as vaccine groups, Health Level 7 codes, or Current Procedural Terminology codes; date the immunization was administered; identity of the health care provider who administered the vaccine;

manufacturer; trade name; lot number; and, if present, any contraindications or religious or medical exemptions.

E. Participants in data exchange shall provide an acceptable level of data quality, such as correct data fields, data accuracy, and enough information to correctly merge with existing patients. Upon initial data delivery, and periodically thereafter, VDH shall review data ~~shall be reviewed~~ to determine data quality and shall notify a participant if the data quality is not acceptable, including notice of any rejected records . ~~Any~~ The participant shall resolve a rejected ~~records shall be resolved by the participant~~ record in a timely ~~way~~ manner, not to exceed 30 days after notice from VDH . VDH may suspend system privileges and take additional action in accordance with § 32.1-27 of the Code of Virginia for ~~any organization~~ a participant that knowingly submits inaccurate data or repeatedly provides an unacceptable level of data quality .

F. If insufficient information is reported to allow de-duplication of patients, VDH shall place incoming data ~~will be placed~~ in a pending file and ~~must be~~ and merge the data manually ~~merged~~, if appropriate. All participants shall identify a contact to work with VDH on pending files.

G. VDH shall incorporate immunization data pursuant to subsection E of § 32.1-46 of the Code of Virginia into VIIS by data exchange from other immunization systems, patient care management billing systems, or information systems to the extent possible.

12VAC5-115-70. Release of VIIS data.

A. ~~Specific~~ Individual patient data ~~shall~~ may not be disclosed except to the extent required or permitted by state and federal law or regulations ~~, after contacting VDH. VDH will verify the source of the request~~ .

B. ~~Specific patient data may be disclosed to health care entities to the extent required or permitted by state and federal law or regulations. See subsection E of § 32.1-46 and § 32.1-127.1:03 of the Code of Virginia.~~

~~C.~~ Patient data shall be erased when no longer needed, when ~~the computer~~ IT equipment is being terminated, or in accordance with a data sharing agreement or a participant registration agreement with VDH.

~~D.~~ C. Aggregate data from which personal identifying data has been removed or redacted may be released for the purposes of statistical analysis, research, or reporting only after approval by VDH.

~~E. Any~~ D. VDH shall immediately suspend a participant's system access privileges for inappropriate use of VIIS data ~~shall result in immediate suspension of user privileges~~ and ~~result in~~ shall conduct an investigation ~~conducted by VDH . Additional~~ VDH may take additional actions ~~may be taken~~ in accordance with § 32.1-27 of the Code of Virginia. The VIIS program manager may reinstate privileges upon satisfactory completion of required remedial actions and guarantee of proper use of VIIS in the future.

FORMS (12VAC5-115)

~~Administrator Information, VIISADM (eff. 10/2012)~~

~~Electronic Data Exchange with VIIS (eff. 10/2012)~~

~~Information Systems Security Access Agreement (eff. 10/2012)~~

~~Organization Information, VIISORG (eff. 10/2012)~~

~~Memorandum of Agreement between Virginia Department of Health/Division of Immunization (VDH/DOI) and VIIS Organization Interested in Data Exchange (8/2011)~~

~~Virginia Immunization Information System (VIIS) Opt-In of VIIS (reviewed 6/2015)~~

~~Virginia Immunization Information System (VIIS) Opt-Out of VIIS (reviewed 6/2015)~~

Virginia Immunization Information System (VIIS) Opt-Out of VIIS (reviewed 05/2024)

~~VIIS Security Policy and User Confidentiality Agreement (rev. 5/2019)~~

212 ~~VIIS User Acknowledgement Page~~

213 ~~VIIS User Signature Page~~

2025 MEETING DATES

Proposed Dates

Thursday, March 20
Travel Meeting (Mt. Rogers Health District): Tuesday, June 10 through Friday, June 13
Thursday, October 2
Friday, December 12

<u>Holidays of interest:</u>
Easter – April 20, 2025
Memorial Day – May 26, 2025
Juneteenth – June 19, 2025
Labor Day – September 1, 2025
Thanksgiving – November 27, 2025

OTHER BUSINESS

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