

**State of Board of Health
Agenda
June 15, 2023 – 8:30 a.m.
Perimeter Center, Boardroom 2**

Call to Order and Welcome	Stacey Swartz, PharmD Nominating Committee Chair
Nomination of Officers	Nominating Committee Members

**State of Board of Health
Agenda
June 15, 2023 – 9:00 a.m.
Perimeter Center, Boardroom 2**

Call to Order and Welcome	Gary Critzer, Chair
Introductions	Mr. Critzer
Review of Agenda	Alexandra Jansson, MPP Sr. Policy Analyst
Approval of March 23, 2023 Minutes	Mr. Critzer
Commissioner’s Report	Karen Shelton, MD State Health Commissioner
Regulatory Action Update	Michael Capps, MPH Sr. Policy Analyst
Public Comment Period	
Break	
<u>Regulatory Action Items</u>	
Regulations Governing Vital Records 12VAC5-550 (Fast Track Amendments)	Seth Austin Director Office of Vital Records
Waterworks Operation Fee 12VAC5-600 (Proposed Amendments)	Dwayne Roadcap Director Office of Drinking Water
Regulations of the Patient Level Data System 12VAC5-217 (Fast Track Amendments)	Suresh Soundararajan Director Office of Information Management

Regulations for the Licensure of
Hospitals in Virginia
12VAC5-410
(Exempt Amendments)

Rebekah E. Allen, JD
Senior Policy Analyst
Office of Licensure and Certification

Report of the Nominating Committee

Dr. Swartz

Board Bylaws Review

Ms. Jansson

Other Business

Adjourn

**State Board of Health
March 23, 2023 - 9:00am
Perimeter Center, Boardroom 2**

Members Present: Gary Critzer, Chair; Michael Desjaton; Melissa Green; Anna Jeng, ScD; Lee Jones, DMD; Wendy Klein, MD, Vice Chair; Holly Puritz, MD; Jim Shuler, DVM; Stacey Swartz, PharmD; Ann B.R. Vaughters, MD; Mary Margaret Whipple.

Dr. Puritz attended remotely due to a family emergency from her home in Virginia Beach.

Members Absent: Patricia Kinser, PhD; Patricia O'Bannon; Maribel Ramos; and Elizabeth Ruffin Harrison.

VDH Staff Present: Michael Capps, Senior Policy Analyst; Kathryn Crosby, Chief Diversity, Equity, and Inclusion Officer; Tiffany Ford, Deputy Commissioner for Administration; Laurie Forlano, Acting State Epidemiologist; Robert Hicks, Deputy Commissioner of Public Health & Preparedness, and Acting Deputy Commissioner for Community Health Services; Joe Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs; Alexandra Jansson, Senior Policy Analyst; Christopher Lindsay, Chief Operating Officer; and Maria Reppas, Director, Office of Communications.

Other Staff Present: Robin Kurz, JD, Senior Assistant Attorney General; Leah Mills, Deputy Secretary for Health and Human Resources; Allyson Tysinger, Senior Assistant Attorney General/Section Chief

Dr. Puritz left the meeting at approximately 10:41 am. Dr. Jeng left the meeting at approximately 2:12 pm.

Call to Order

Mr. Critzer called the meeting to order at 9:03 am.

Introductions

Mr. Critzer welcomed those in attendance to the meeting. Mr. Critzer then started the introductions of the Board members and VDH staff present.

Mr. Critzer also read a letter from John Littel, Virginia's Secretary of Health and Human Resources, regarding Governor Glenn Youngkin's search for a Commissioner. There was discussion regarding the Board's concern about the delay in appointment of a new Commissioner.

Review of Agenda

Ms. Jansson reviewed the agenda and the items contained in the Board's binder. Based upon additional information from VDH that requires additional time to review, the Fast-Track action for 12VAC5-550 was moved to be deferred to the June board meeting by Dr. Swartz. Dr. Klein seconded the motion. The motion to approve the amendment was approved unanimously.

Approval of December 15th, 2022 Minutes

Mr. Critzer reviewed the minutes from the December meeting. It was noted that there was no mention of Dr. Klein acting as Chair following Mr. Critzer’s departure due to illness. Dr. Shuler made a motion to approve the minutes with a clarifying amendment and Mr. Desjaden seconded the motion. The minutes were approved as amended unanimously by voice vote.

Agency Report

Mr. Lindsay provided the Agency Report to the Board. He updated the Board on key issues and projects VDH is engaged in including:

- Behavioral Health Initiatives
- Partnership for Petersburg
- COVID-19 Update
- Maternal Health
- ARPA Projects
- Virginia Plan for Wellbeing/State Health Improvement Plan (SHIP)
- Public Health Policy Agenda

There was discussion regarding firearm related mortality and strategies for reduction; the men’s sexual health clinic in Petersburg; the addition of other epidemiological topic areas such as rising sexually transmitted infections, drug-resistant bacteria, and general surveillance; maternal mortality outcomes; and the dental workforce shortages. There were also requests from members to include more information at future meetings on maternal mortality and pregnancy loss, suicide prevention initiatives, and a more in depth look at the State Health Improvement Plan.

Public Comment Period

There were 16 persons signed up for public comment at the meeting. The Board’s public comment period allows for a 20-minute period with 2 minutes per person. A motion to extend the public comment period by 12 minutes to accommodate all speakers was made by Mr. Desjaden and seconded by Dr. Jones. The motion was passed by unanimous voice vote.

The sixteen speakers all spoke about COVID-19 vaccinations, the CDC childhood immunization schedule, and general comments regarding COVID-19 vaccination in children. Their names were: Geoffrey Akey, Linda Cox, Susan Franz, Ann Parker, Jennifer Herget, Barbara Henry, Lori Leonard, Sheila Furey, Ann Marie Smith, Sally Johnson, Robyn Middleton, Peter Meacham, Donna Meacham, Wendy Melton, Ruth Meacham, and Doris Knick. Written comments were submitted and can be found at the end of the minutes document.

Regulatory Action Update

Mr. Capps reviewed the summary of all pending VDH regulatory actions.

Since the December 2022 meeting, the Commissioner approved four regulatory actions on behalf of the Board while the Board was not in session. First, a result of periodic review and NOIRA for the Rules and Regulations Governing Outpatient Data Reporting (12VAC5-218). The NOIRA followed the result of the periodic review and will update the regulations to better align this chapter with inpatient-level data reporting requirement and expand outpatient reporting. A

second NOIRA was approved as well for the Rules and Regulations Governing the Construction and Maintenance of Migrant Labor Camps (12VAC5-501). This NOIRA followed a periodic review and will remove outdated information; add and amend text to reflect best practices and the latest science from industry, academia, public health experts, and other stakeholders; clarify regulatory and enforcement standards; and include any additional amendments deemed necessary in response to public comment or input from industry and subject matter experts. The Commissioner also approved a Final Exempt Action for the Virginia Radiation Protection Regulations (12VAC5-481). This regulatory action is intended to conform Virginia's regulations with recent changes in the Nuclear Regulatory Commission's (NRC) federal regulations.

Since the December 2022 meeting the Commissioner has not taken any non-regulatory action on behalf of the Board while the Board was not in session.

Mr. Capps advised the Board that there are 25 periodic reviews in progress:

- 12 VAC 5-67 Advance Health Care Directive Registry
- 12 VAC 5-110 Regulations for the Immunization of School Children
- 12 VAC 5-125 Regulations for Bedding and Upholstered Furniture Inspection Program
- 12 VAC 5-150 Regulations for the Sanitary Control of Storing, Processing, Packing or Repacking of Oysters, Clams and Other Shellfish
- 12 VAC 5-160 Regulations for the Sanitary Control of the Picking, Packing and Marketing of Crab Meat for Human Consumption
- 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 5-221 Virginia's Rules and Regulations Governing Cooperative Agreements
- 12 VAC 5-381 Home Care Organization Regulations
- 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 5-475 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 a Long-Term-Care Facility
- 12 VAC 5-520 Regulations Governing the State Dental Program Scholarship Program
- 12 VAC 5-530 Regulations Governing the Virginia Medical Scholarship Program
- 12 VAC 5-542 Rules and Regulations Governing the Virginia Nurse Practitioner / Nurse Midwife Scholarship Program
- 12 VAC 5-545 Guidelines for the Nurse Educator Scholarship
- 12 VAC 5-570 Commonwealth of Virginia Sanitary Regulations for Marinas and Boat Moorings
- 12 VAC 5-590 Waterworks Regulations
- 12 VAC 5-610 Sewage Handling and Disposal Regulations
- 12 VAC 5-613 Regulations for Alternative Onsite Sewage Systems

- 12 VAC 5-620 Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells
- 12 VAC 5-640 Alternative Discharging Sewage Treatment Regulations for Individual Single Family Dwellings
- 12 VAC 5-650 Schedule of Civil Penalties

An update regarding the Unified Regulatory Plan was given to the Board.

Fast Track Amendments to 12 VAC 5-620 Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells

Julie Henderson, Director of the Office of Environmental Health Services, presented the Fast Track Amendments to the Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems, Alternative Discharge Systems, and Private Wells. The purpose of the Fast-Track amendments is to conform the Regulations to the Appropriation Act and provide consistency for issuance of refunds pursuant to the Code.

Chapter 831 of the 2018 Acts of Assembly directed VDH to eliminate evaluation and design services provided by the local health departments for onsite sewage systems and private wells. Beginning July 1, 2019, all applicants were required to submit private sector evaluations and designs for onsite sewage systems unless the owner met the means testing requirements established in Chapter 831 (2018) or the hardship guidelines established by VDH. In addition to this legislation, Item 292, Chapter 2 of the 2018 Acts of Assembly, Special Session I (The 2018 Appropriation Act) required VDH to begin charging for certain onsite sewage system services previously provided at no cost to the applicant. These additional fees have remained in all subsequent Appropriation Acts.

Dr. Klein made a motion to approve the fast-track regulations with Dr. Shuler seconding. The fast track amendments were approved unanimously by voice vote.

Final Amendments to 12 VAC 5-125 Regulations for Bedding and Upholstered Furniture Inspection Program

Ms. Henderson presented the Final Amendments to the Regulations for Bedding and Upholstered Furniture Inspection Program. The proposed amendments from the Proposed stage intended to: i) update the regulation by reducing conflicts with other states' bedding and upholstered furniture regulations, ii) transparently outline existing requirements for use of animal hair, feathers, or down, iii) establish consumer notifications on law labels for the use of reclaimed and reprocessed materials, iv) clarify licensing and permitting requirements and operating standards, and v) address concerns expressed by the General Assembly and Office of the Attorney General regarding certain items in the regulation.

Upon conclusion of the proposed stage, the proposed text was further amended to improve clarity and formatting and align terminology to shifts in national standards since the proposed stage. The final text does not contain any substantive changes from the proposed stage. The agency will benefit from the clarity of the revisions, as they may reduce the time and effort staff spend on explaining procedures that are not well outlined in the current text. The agency also expects to observe a slight reduction in licensing administrative procedures (e.g. returned,

incomplete license applications).

Dr. Vaughters made a motion to approve the final regulations with Ms. Green seconding. There was discussion regarding insect infestations. The final amendments were approved unanimously by voice vote.

Notice of Intended Regulatory Action for 12 VAC 5-460 Regulations Governing Tourist Establishment Swimming Pools and Other Public Pools

Ms. Henderson presented the Notice of Intended Regulatory Action (NOIRA) for the Regulations Governing Tourist Establishment Swimming Pools and Other Public Pools. This action is the result of a periodic review and seeks to repeal and replace the regulatory text to ensure an effective regulatory program governing water facility safety is maintained throughout the Commonwealth. This action will: remove outdated information; add and replace text to reflect best practices and the latest science from industry, academia, public health experts, and other stakeholders; and clarify regulatory and enforcement standards.

The Department conducted a periodic review of the Regulations pursuant to Executive Order 14 (as amended, July 16, 2018). In its finding, filed on April 8, 2022, the Department recommended the regulation be amended. Through review of the proposed amendments and communication with the stakeholder workgroup, the Department found that the more appropriate action is to repeal and replace the Regulations. A previous NOIRA to amend the regulations was withdrawn on January 23, 2023 so VDH is introducing this NOIRA with the intention to repeal 12VAC5-460 and replace it with 12VAC5-461.

Dr. Jones made a motion to approve the NOIRA with Mr. Desjadon seconding. There was discussion regarding recreational aquatic permits, and the repeal and replace portion of this action. The NOIRA was approved unanimously by voice vote.

Proposed Amendments to 12 VAC 5-381 Regulations for the Licensure of Home Care Organizations

Rebekah E. Allen, Senior Policy Analyst with the Office of Licensure and Certification, presented the Proposed Amendments to the Regulations for the Licensure of Home Care Organizations in Virginia. The intent of this action is to adhere to the legislative mandate from the General Assembly by amending this Chapter to address remote supervision of personal care services by home care organizations. Chapter 470 of the 2021 Acts of Assembly, Special Session I amended Code of Virginia § 32.1-162.12 to direct the State Board of Health to promulgate regulations for home care organizations that govern the delivery of personal care services shall provide for supervision of home care attendants providing personal care services by a licensed nurse through use of interactive audio or video technology.

Dr. Klein made a motion to approve the proposed regulations with Dr. Swartz seconding. There was discussion regarding the remote supervision aspect of the regulation, the protections put in place, and the training requirements for HCO personnel.

There were four line amendments from Board members during the meeting. The first two were motioned by Mr. Desjadon and seconded by Dr. Jones. The first added a requirement that

informed consent include both written and oral information. The second clarified that for audio and visual recordings of sessions, separate consent is needed for (1) recording, (2) storing, and (3) use of said recordings for non-care purposes (e.g marketing or training). The third amendment added that care plans must include the rationale for permitting remote supervision. This was motioned by Dr. Vaughters and seconded by Mr. Desjadon. The final amendment was just to correct and update section numbering throughout, motioned by Dr. Vaughters and seconded by Dr. Jeng. All line amendments were adopted unanimously by voice vote. The proposed amendments were approved by unanimous voice vote.

Fast Track Amendments to 12 VAC 5-200 Regulations Governing Eligibility Standards and Charges for Medical Care Services to Individuals

Ms. Park presented the Fast Track Amendments to the Regulations Governing Eligibility Standards and Charges for Medical Care Services to Individuals. The purpose of this regulatory action is to make style revisions, remove redundancies, eliminate language that restates the Code of Virginia, clarify existing language, and address inconsistencies. Information in some sections will be moved to different sections for continuity of content. Some sections are unnecessary and will be removed. In addition, a specific, existing Code of Virginia reference has been inserted in one section, and a correction was added to a section number reference to the Omnibus Budget Reconciliation Act of 1981 that addresses the update to poverty guidelines. Finally, the language was updated to add WIC recipients to the Automatic Eligibility section for dental varnish services for children ages 6 months to 3 years.

The amendments are needed to update style, remove redundancies, add missing citations and clarify information. The regulation is essential in providing the local health department offices with clear information about determining whether a person is medically indigent and their eligibility to receive low- or no-cost medical services, therefore protecting the health, safety, and welfare of the citizens of the Commonwealth. The goal of these changes is to produce a more up-to-date regulation with no redundant language.

Ms. Green made a motion to approve the fast-track regulations with Dr. Jeng seconding. There was discussion regarding the definition of convenient price.

Mr. Desjadon suggested to amend the text to clarify the definition of non-chargeable services and clarifying convenient value. Dr. Jones made a motion to adopt the amendments to the fast-track regulations with Dr. Jeng seconding that motion. The line amendments passed unanimously by voice vote. The fast track amendments were approved as amended unanimously by voice vote.

Results of Periodic Review

Mr. Hilbert presented the following Results of Periodic Reviews in a bloc to the Board:

- 12 VAC 5-610 Sewage Handling and Disposal Regulations
- 12 VAC 5-150 Regulations for the Sanitary Control of Storing, Processing, Packing or Repacking of Oysters, Clams, and Other Shellfish
- 12 VAC 5-160 Regulations for the Sanitary Control of the Picking, Packing and Marketing of Crab Meat for Human Consumption

The Sewage Handling and Disposal Regulations (Regulations) are used to control the safe and sanitary collection, conveyance, transportation, treatment, and disposal of sewage by onsite sewage systems. The *Regulations* specifically address the design and installation of onsite sewage systems utilizing septic tank effluent. Septic tank effluent is raw sewage that is treated only to remove solids, fats, oils, and greases by passing through a septic tank before release to a soil dispersal system (drainfield). While no specific comments were received during the Periodic Review, the Office of Environmental Health Services (OEHS) intends to amend the Regulations to reflect changes in the onsite sewage industry and current best practices.

VDH has completed a Periodic Review of these regulations and has determined that 12VAC5-160 should be repealed, and that 12VAC5-150 should be amended

The Regulations for the Sanitary Control of Storing, Processing, Packing or Repacking of Oysters, Clams, and other Shellfish and the Regulations for the Sanitary Control of the Picking, Picking and Marketing of Crab Meat for Human Consumption are used to protect public health and safety as it pertains to crustacea (crab) and shellfish.

While no specific comments were received during the Periodic Reviews of both regulations, the Office of Environmental Health Services (OEHS) intends to amend Chapter 150 to reflect the OAG's advice and to repeal the Regulations for the Sanitary Control of the Picking, Picking and Marketing of Crab Meat for Human Consumption to remove overlapping requirements in the two sets of regulations as language from Chapter 160 can be incorporated into Chapter 150 and still maintain public health protections, safety, and welfare.

Dr. Klein made a motion to approve the Results of Periodic Review Bloc with Ms. Green seconding. The results of periodic review were approved unanimously by voice vote.

Legislative Update – 2023 General Assembly

Ms. Jansson presented a legislative update to the Board following the 2023 General Assembly Session. The presentation included the following bill topics of interest:

- Emergency Medical Services
- Maternal and Child Health
- Death Investigations
- Medical Facilities and COPN

Other bills of interest were SB 1344 related to independent operation of the City of Alexandria local health department; HB 2008 related to a tick-borne illnesses study; HB 2173/SB 1016 related to bedding and upholstered antique furniture exemption; and SB 1546 related to food permitted establishments.

There was discussion regarding Emergency Medical Services protocols and the ability to adopt a statewide protocol for Virginia, the timeframe related to SB 1232 regarding autopsies for decedents in custody of the Department of Corrections and the funding for the Medical Examiner to institute the new legislative mandates.

Budget Update

Ms. Gilliam presented a budget update to the Board regarding the Virginia Department of Health’s Budget for FY2023 and FY2024. The presentation included Budget Amendments for VDH programs and offices, Governors Budget Amendments, GA Budget Amendments still being considered, and Salary Adjustments.

There was discussion regarding abortion funding in Virginia following the proposed budget amendment, clarification on types of budget amendments, the workforce development budget funding, and future opportunities to discuss the current workforce development occurring in VDH.

Appointment of Nominating Committee

Mr. Critzer appointed Dr. Swartz as chair of the nominating committee with additional members Ms. Ramos and Dr. Jones. The nominating committee will meet prior to the June meeting to develop recommendations for the slate of Board officers for the next year to be voted on in the June meeting.

Other Business

Mr. Critzer brought forward the Virginia EMS Advisory Board’s Emergency Department overcrowding recommendations to ask the Board to consider addressing the issue. There was discussion regarding the parameters of the issue, the possibility of creating a preliminary joint report consisting of multiple agencies, and health care workforce issues. The Board requested that VDH convene a stakeholder workgroup, to include representatives from the Virginia Hospital and Healthcare Association along with representatives from the VDH Office of Emergency Medical Services and the VDH Office of Licensure and Certification, to review the issues identified in the document and report back to the Board at the June 2023 meeting.

Adjourn

The meeting adjourned at 2:23pm.

DMED DATA % increase in partial year of 2021 (Oct 19) compared to years 2016-2020 you can find the full graph on www.renz-law.com

<https://renz-law.com/attorney-tom-renz-whistleblowers-dmed-defense-medical-epidemiology-database-reveals-incredibly-disturbing-spikes-in-diseases-infertility-injuries-across-the-board-after-the-military-was-forced-to/> Scroll to the bottom and click on "NEXT DMED DATA" – but you really need to read this page before you click for the data.

	2016	2017	2018	2019	2020	2021 (partial year)	% increase
Diseases and Injuries (Ambulatory)	2,059,630	2,058,379	2,022,663	2,110,383	1,976,724	21,512,583	988.30%
Diseases and injuries (Hospitalization)	43,786	43,338	42,024	43,493	40,052	54,776	36.80%
Diseases of the Nervous System	82,435	81,998	81,382	85,012	80,786	863,013	968.30%
Malignant Neuroendocrine Tumor	167	135	98	113	117	440	276.10%
Acute Myocardial Infarct	324	370	376	366	372	1,650	343.50%
Acute Myocarditis	84	92	116	159	108	307	184.30%
Acute Pericarditis	535	538	522	531	499	850	70.30%
Pulmonary Embolism	678	701	668	716	968	3,489	260.40%
Congenital Malformations	11,710	11,131	10,456	11,081	10,153	18,951	86.70%
Nontraumatic Subarachnoid Hemorrhage	219	139	134	170	196	640	226.50%
Anxiety	37,011	36,667	36,145	37,762	37,870	931,791	2360.50%
Suicide	359	496	530	570	550	1798	226.90%
Neoplasms for All Cancers	41,557	39,139	37,756	38,889	36,050	114,645	218%
Cancer (Digestion)	660	654	633	602	704	4,060	476.70%
Cancer (Breast)	934	810	766	792	766	4,357	468.80%
Cancer (Testicular)	1,156	1,008	866	880	889	3,537	297.90%
Infertility (female)	2,261	2,262	2,243	2,340	2,262	11,748	419.40%
Dismenorrhea	3,104	3,403	3,481	3,943	3,900	12,539	221.50%
Ovarian Dysfunction	862	936	908	945	1,022	4,086	299.80%
Infertility (male)	2,187	2,287	2,037	2,152	1,990	8,365	320.40%
Guillian-Bare Syndrome	66	79	71	85	65	403	520%

friends
inlaws
friends
wife

friend's co-
worker
my main
my best
friend's husband
a friend

local school
nurse

friend's old
employee
died
cancer
a friend's
father died
friend's
cousin died
friend's sister
in law (died)
friend's
co-worker

neices friends
my daughter
my friend's
daughter

Acute Transverse Myelitis	46	57	48	35	34	202	494.10%
Seizures	196	148	130	150	123	489	297.60%
Narcolepsy Cataplexy	995	898	864	830	766	2,097	351.70%
Rhabdomyolysis	706	696	740	755	669	5,162	671.60%
Multiple Sclerosis	479	391	367	400	385	2750	614.30%
Migraine	15,734	15,714	16,462	17,116	16,311	73,490	351.70%
Blood Disorders	11,533	11,122	10,851	11,773	11,429	34,486	204.10%
Hypertension	2,308	2,323	2,363	2,392	2,415	53,846	2129.60%
Cerebral Infarct	887	848	858	888	887	3,438	293.70%

← cousin + delta antibodies

Stroke → friend's mom
friend's dad

heart attack → 2 of brother-in-law's coworkers
accountant's father (died)
family friend
husband's uncle - died

miscarriages → several of niece's friends

neonatal death (in Pfizer documents)
friend's niece - twin babies died

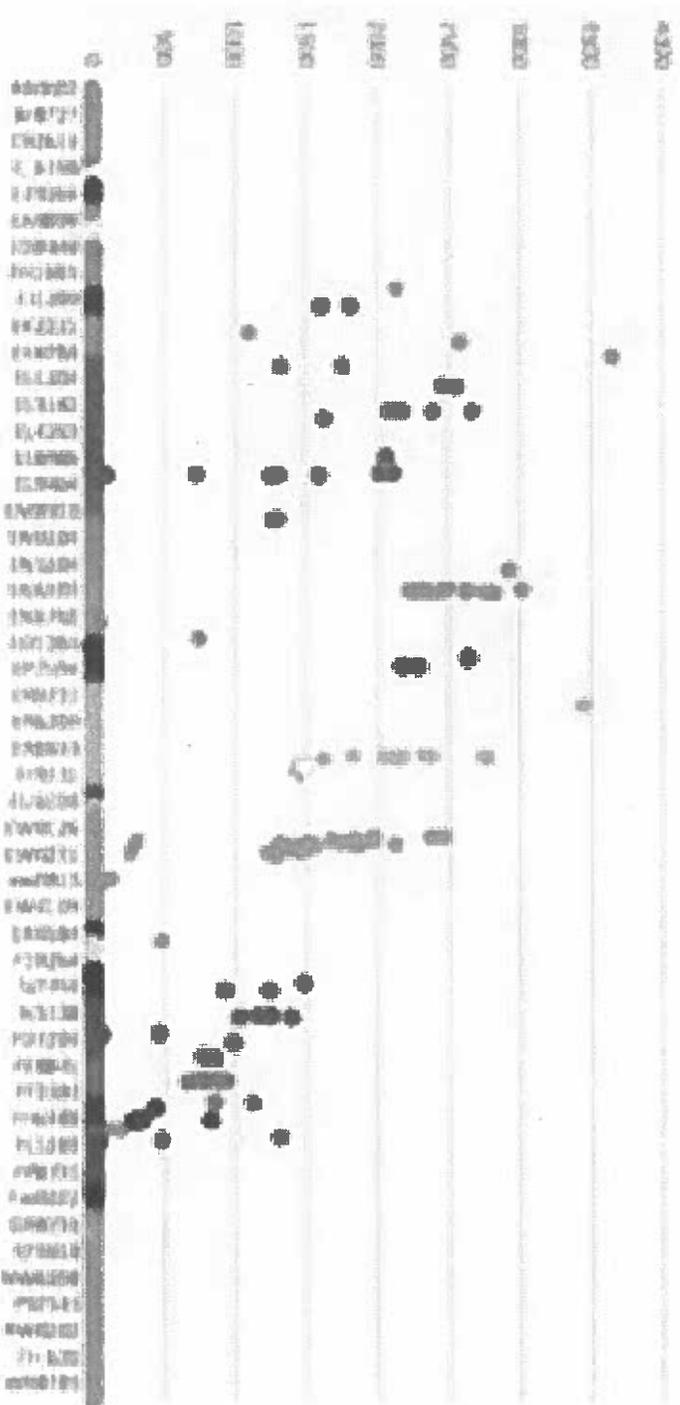
There are way too many "coincidences"

Stop the Shots!!!

VAERS Data demonstrates that specific lots across 50 States in the USA are associated with a 1000x higher rate of adverse events

Figure 1: Scatterplot

When Figure 1 is sorted alphabetically along the x-axis, the following pattern appears:



The future of VA depends on the health of the children. I believe we can agree on this fact. Today, by the time a baby is 6 months old if their parents are following the CDC schedule, they will likely have taken all the jabs many of you in this room have had in your entire lives!!

You've been indoctrinated by Rockefeller institutions that vaccines save lives. However, you're ignoring the fact that children are sicker today than ever before! This explains why you've added a **Suddenly Died Young** coordinator position doesn't it?!?

If you have been promoting or using products known as "Covid-19 vaccines" on patients since December 2020, you have been participating in fraud, mass murder and war crimes, because medical countermeasures (MCMs), covered countermeasures, and prototype products are DOD-contracted bioweapons intended and effective for injuring, sickening, and killing recipients.

You may not have known or understood your participation in fraud, mass murder and war crimes before today. I am now informing you; you have now been given notice.

CEASE AND DESIST from committing acts of additional fraud, mass murder and war crimes, effective as of the date of this notice, and immediately close your vaccination and immunization programs.

If you still think we are wrong it's because you're listening to the echo-chamber of lies- safe & effective and only concerned about collecting a pay check, it's time you hear from a few of the thousands of doctors calling to STOP THE SHOTS!

This video was created seven months ago now! <https://rumble.com/v1ees0f-right-docs-of-history-strike-back-stop-the-shots.html>

The Great Barrington declaration document alone was **signed by 47 thousand Dr's and over 16 thousand medical and public health scientists.** [Great Barrington Declaration \(gbdeclaration.org\)](http://GreatBarringtonDeclaration.org)

80 Pages of Peer Reviewed Medical Papers Submitted To Various Medical Journals, Evidencing A Multitude Of Adverse Events In Covid-19 Vaccine Recipients
[Updated Peer Reviewed medical papers submitted to various medical \(healthindependencealliance.com\)](http://UpdatedPeerReviewedmedicalpaperssubmittedtovariousmedical(healthindependencealliance.com))

Doris Knick 3/23/23

Children: This is about the children.

Whose children?

Mine? Yours?

Children have 99.997% chance of surviving Covid.

if you are sick child your chance of death is 1/100,000

If you are well child, chance of death is 1/2.5 million.

40% increase
death
400m.1 m → NIH

To date 95% of children have had covid at least once. Innate immunity is far superior than any vaccine. But I guess you ~~through~~ your training and knowledge out the window when the check from came in the mail or you took your shot.

This is all the time while shouting that there are no safe and effective medications. Ignoring all the decades of safety data on HCQ and Ivermectin and effective treatment protocols being used around the world. used world wide to protect people

In the old days, if a physician or nurse had a successful intervention, we tried to duplicate it.

Now, we fire, strip board certifications and dox physicians for saving lives.

Now lets talk about the the brilliant studies completed by pharmaceutical companies in conjunction with NIH and the DOD.

Pfizer biotech was based on 2000 children 1000 in each arm and conclusion were drawn on 16 cases.

In the studies, phase 3 clinical trials No data available on these important critical arms of study

1. They did not look at the rate of hospitalization
2. Did not look at the rate of multi system inflammatory illness
3. Sars-CO2 seroconversion
4. Rate asymptomatic infection.

Vaccine efficacy drops in 2-3 months and after that the vaccinated are more likely to be symptomatic. Thus the vaccine is actually harmful.

In pediatrics trial there is no long term comparisons of overall health or overall morbidity and mortality.

In pediatrics the control group was eliminated after 6 months.

Innate immunity:

Generalized more powerful than specific vaccine

skin tears

phagocytes

cells release inflammatory mediators.

Allow NK cells to work

Complement and proteins

CDC ever changing narrative:

1. mRNA can't cause infection
2. mRNA can't reverse transcription into our own cells
3. mRNA does not last long in blood

What should our kids be doing:

1. Playing outside with their friends and without masks.
2. Eating healthy food. Whole food.

Only 134 babies were involved in the trial. Are you going to tell parents that they should base their decisions on the hidden

True informed consent forbids coercion:

Thus pizza parties, gift cards and playing on sports team is all coercion. All under the guise of keeping people safe. That is until their son or daughter drops dead on the basketball court, jogging, cheering or watching cartoons.

VAMRA

Linda Cox, LCSW 3-23-23

I believe each person is entitled to informed consent when receiving any medication, oral/injectable or medical device.

Thus, I have a question: Why is it that, in all the ads placed on TV and in print, I have yet to hear any of the many adverse side effects reported in VAERS. In case you weren't already aware, I want to let you know this is illegal. When advertising a product, a pharmaceutical company must inform the consumer of the risks. You are acting as a surrogate for Pfizer Moderna and the other pharmaceutical companies. You are advertising a drug that neither prevents a person from getting covid or spreading covid, and you do **not** mention **any** of the severe side effects. There are 158,893 ~~side effects~~ side effects listed by Pfizer, and these were in just the first 12 weeks of the study. — 1500+ severe

The Virginia Department of Health website, as of March 22, 2023 was still stating:

"Side effects in infants and toddlers are usually mild in severity and resolved within a few days. Commonly reported side effects in the youngest age groups are pain at the injection site, fatigue, irritability and drowsiness. Fevers are also reported."

Your ad goes on to say:

"There is no evidence to suggest that COVID-19 vaccines impact children's growth or development, including impacts on brain development, bone development, or future fertility."

You fail to mention: death, myocarditis, pericarditis, seizure, ^{Guillain-Barre} gee-on 'barret' syndrome, neurologic injury, stroke, heart attack, infertility, menstrual dysfunction, miscarriage, still birth, decreased sperm counts and motility, and cancer.

As a parent, I find any ongoing advertising to be disturbing at the least, and firmly believe parents are entitled to compensation because of your misleading practice.

I am sure the Attorney General's office should be informed of this and will act on your behalf to correct your error. *they*

As I stated when I spoke during the last VDH meeting, I realize that it's extraordinarily painful for any of us to acknowledge, even just to ourselves, that we've made choices which endanger our children in any way. Be that as it may, refusing to make every effort to prevent further _____ is quite simply cowardly and unconscionable.

injury

Dear Board Members,

Donna Machen of Mathews, Virginia.

As I read a few quotes, please listen for a common theme.

“For if Men are to be precluded from offering their Sentiments on a matter, which may involve the most serious and alarming consequences, that can invite the consideration of Mankind, reason is of no use to us; the freedom of Speech may be taken away, and, dumb and silent we may be led, like sheep, to the Slaughter.” George Washington

“To not speak is to speak, to not act is to act.” (Deitrich Bonhoffer)

God says, “When I say unto the wicked, Thou shalt surely die; and thou givest him not warning, nor speakest to warn the wicked from his wicked way, to save his life; the same wicked man shall die in his iniquity; but his blood will I require at thine hand... Again, When a righteous man doth turn from his righteousness, and commit iniquity,... he shall die: because thou hast not given him warning...” Ezekiel 3:18, 20a

As a Christian, I am commanded to love my neighbors, the wicked and the righteous, which includes speaking warnings to both.

I am here to warn you that you cannot in good conscience add the Covid-19 shot to the Virginia Adolescent and Childhood Vaccination Schedule. The Supreme Court ruled in 2011 that Congress considers vaccines to be “unavoidably unsafe” due to adverse side effects. No vaccines are safe. They contain harmful ingredients.

Aluminum: Toxic to brain and kidneys.

Formaldehyde: Toxic to nerves, liver, and kidneys.

Proteins from Fetal Tissue: Taken from aborted babies; associated with an increased risk of autism.

Thimerosal: Contains fifty percent mercury, the second most poisonous element known to man.

Polysorbate 80: May cause blood clots, stroke, heart attack, and death.

With the Covid shot, we’ve hit the mother load of toxic damage. Spike protein, DNA altering mRNA, Polyethylene glycol, etc.

It is morally wrong to add this shot to the schedule. There are no proven benefits worth the risks. I’m giving you warning. Thank you for listening.

Important Facts

Number of studies linking vaccines to neurological and autoimmune issues common to autism: 130

Number of studies quoted by vaccine promoter Paul Offit showing no vaccine-autism link: 14

Rate of autism in the 1980s: 1 in 10,000

Rate of autism today: 1 in 59

Projected rate of autism in 2025: 1 in 2

Number of doses recommended by age six per the CDC vaccine schedule 1972: 2

Number of doses recommended by age six per the current CDC vaccination schedule: 50

Amount of aluminum in the four doses at the two month baby checkup: 1,225 mcg

Maximum allowable aluminum per day for intravenous parenteral feeding: 25 mcg

Amount of aluminum received by fully vaccinated eighteen-month old baby: 4,925 mcg

Number of studies proving safety of injecting aluminum into human infants: 0

Amount of mercury in liquid the EPA classifies as hazardous waste: 200 ppb

Amount of mercury in "trace," "thimerosal-free" vaccines: 2,000 ppb

Amount of mercury in some single-dose vaccines and some infant flu shots: 50,000 ppb

Amount of mercury in multi-dose flu vaccines, given to pregnant women: 50,000 ppb

Number of current vaccines proven effective: 0

Number of current vaccines proven safe: 0

Cost of caring for a child diagnosed with autism over his lifespan: \$3,000,000-\$5,000,000

Liability of vaccine manufacturers for vaccine injury: 0

Rate of asthma in vaccinated children: 6-15%

Rate of asthma in unvaccinated children: 0.2-3%

Rate of ADHD in unvaccinated children: 1-2%

Rate of ADHD in vaccinated children: 8-11%

Projected income to pharmaceutical industry from vaccines 2025: \$48 billion

References at www.westonaprice.org/wp-content/uploads/WAPFVaccinationIndex.pdf.

A Diet for Natural Immunity

A good diet can help children develop strong natural immunity to infectious and chronic disease without the risk of vaccinations:

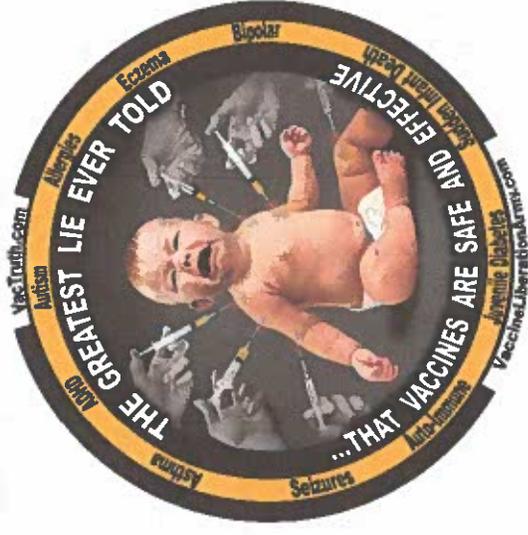
- Minimize sugar, additives and processed food.
- Raw whole milk is highly nourishing and contains many components that help build natural immunity.
- Vitamins A and D in cod liver oil provide powerful protection against disease.
- Cholesterol-rich foods like egg yolks, liverwurst, butter and cream help build a strong nervous system and support good gut integrity.
- Fermented foods like sauerkraut provide protective bacteria in the digestive tract.
- Gelatin-rich bone broth contributes to good gut integrity and helps detoxify.
- Vitamin C from fresh fruits and vegetables and from fermented foods like sauerkraut helps fight infectious illness.
- Red meat, seafood and kefir are good sources of zinc, which is an important nutrient for the immune system.

If Forced to Vaccinate...

- Wait until the child is at least three years old.
- Do not give more than one vaccination at a time.
- Never vaccinate when the child is sick.
- Be sure that the vaccines are thimerosal-free.
- Supplement the child with extra cod liver oil, vitamin C and B12 before and after each shot.
- Put your child to bed and keep him quiet for at least twenty-four hours after a shot.
- Do NOT give aspirin, tylenol or other NSAIDs either before or after a shot.
- Obtain a medical exemption if the child has had a bad reaction to a vaccination or has a family history of vaccine reactions, convulsions or neurological disorders, severe allergies and/ or immune system disorders.

Vaccination

The Most Important Decision
Parents Will Ever Make



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Wise Traditions

IN FOOD, FARMING AND THE
HEALING ARTS



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Myths and Truths About Vaccination

MYTH: Vaccination is the main contributor to the twentieth century decline in infectious disease.

TRUTH: Infectious diseases (measles, diphtheria, whooping cough and tetanus) were in steep decline before the advent of vaccinations, thanks to better sanitation, cleaner water and improved living conditions. Scarlet fever also declined, even though there has never been a vaccination for it.

MYTH: Vaccinated individuals do not put others at risk.

TRUTH: Public health officials are aware of the fact that vaccinated individuals can spread the disease for which they have been vaccinated for up to several weeks after getting the vaccine. Adults have contracted polio from their recently vaccinated infants.

MYTH: Vaccinations give life-long immunity.

TRUTH: Immunity from vaccinations is temporary at best; health officials now recommend booster shots at regular intervals because the immunity from vaccinations wears off. Outbreaks of measles and whooping cough have occurred in fully vaccinated populations.

MYTH: It was vaccinations that stopped the deadly plague of polio.

TRUTH: Polio can be triggered by nervous system poisoning from teething powders containing mercury (now banned) and pesticides like lead arsenate and DDT. Polio declined in the U.S. when DDT was outlawed. Polio is making a comeback in the U.S., but it is called by a different name—acute flaccid myelitis—which occurs most frequently in August and September when children are getting their vaccinations for school.

MYTH: Measles, mumps, whooping cough and chicken pox are life-threatening childhood diseases.

TRUTH: Death from these diseases in the U.S. is extremely rare, and basically non-existent in well nourished children. When contracted in childhood, these diseases are mild and give immunity for life; having these illnesses in childhood also protects us against more serious disease like cancer later in life. Whooping cough (pertussis) has actually become more virulent since the introduction of the pertussis vaccine.

MYTH: Vaccinations are completely safe.

TRUTH: The National Vaccine Injury Compensation Program has paid out over four billion dollars for vaccination injuries and death since 1989. These payments come from a tax on vaccines; the pharmaceutical companies that make the vaccines are free from all liability for damages caused by their products. Only a very small percentage of vaccination injuries are reported or receive compensation

MYTH: Vaccinations have been well tested for safety.

TRUTH: Most vaccines are rushed through the FDA approval process with very inadequate safety testing. There has been no safety testing at all for multiple vaccines given at one time.

MYTH: The anti-vaccination movement is something new and was started by a “fradulent” researcher named Andrew Wakefield, MD.

TRUTH: Dr. Wakefield’s findings have been scientifically corroborated. Since the first vaccinations, which were for small pox, citizens have mounted vigorous opposition after seeing adverse effects, including death, in their children from the vaccines. (The small pox vaccination was eventually discontinued because of frequent life-threatening reactions.)

For references and further information, visit westonaprice.org/vaccinations.

Harmful Ingredients in Vaccines

ALUMINUM: Toxic to brain and kidneys.

Children with autism have very high concentrations of aluminum in their brains.

AMINO ACIDS AND FOREIGN PROTEINS

INCLUDING EGG ALBUMIN: Associated with autoimmune disorders including type I diabetes.

FORMALDEHYDE OR FORMALIN: Embalming fluid; classified as a human carcinogen; toxic to nerves, liver and kidneys.

BENZETHONIUM CHLORIDE: Can cause seizures, coma, respiratory depression, central nervous system depression, convulsions and urinary system reaction.

GLUTARALDEHYDE: A disinfectant that can cause asthma, allergic reactions, respiratory problems and diarrhea.

PROTEINS FROM FETAL TISSUE: Taken from aborted babies; associated with an increased risk of autism.

THIMEROSAL: Contains 50 percent mercury, the second most poisonous element known to man. Even “thimerosal-free” vaccines contain traces of mercury.

MSG: MSG may cause migraine headaches, sleeping disorders, irritable bowel syndrome, asthma, diabetes, Alzheimer’s disease, Lou Gehrig’s disease, attention deficit disorder, seizures, stroke and anaphylactic reaction.

CTAB (CETYLTRIMETHYLAMMONIUM

BROMIDE): The Material Safety Data Sheet lists many serious health effects from CTAB.

2-PHENOXYETHANOL: Can cause headache, shock, convulsions, weakness, kidney damage, cardiac failure, kidney failure and death.

POLYSORBATE 80: Facilitates mercury and aluminum crossing the blood-brain barrier. May cause blood clots, stroke, heart attack and death.

The Supreme Court did not deem vaccines "unavoidably unsafe," Congress did

There is an error that is often made when we talk about the "Unavoidably Unsafe" status of FDA approved vaccines. It may seem like a small point, but it is important to be accurate.

Someone, somewhere, sometime, long, long ago and far away, said that, "The US Supreme Court has ruled that vaccines are unavoidably unsafe," referencing the use of the term in *Bruesewitz v. Wyeth*. And it has been repeated over and over. But it is not accurate.

Congress placed vaccines in that category, and SCOTUS was merely referencing the already established status of the products.

It is correct to say that "US Law regards vaccines as unavoidably unsafe."

But Congress itself did that, not the Supreme Court.

Feel free to remind a member of Congress of that fact if he makes the false claim that, "Vaccines Are Safe."

From Mary Holland JD, Director of the Graduate Legal studies program at NYU Law School:

"The key language about "unavoidable" side effects comes from the National Childhood Vaccine Injury Act, 42 USC 300aa-22, re manufacturer responsibility (see highlighted text below).

That language was based on language from the Second Restatement of Torts (a legal treatise by tort scholars), adopted by most state courts in the mid-1960's, that considered all vaccines as "unavoidably unsafe" products. The Restatement opined that such products, "properly prepared, and accompanied by proper directions and warnings, is not defective, nor is it unreasonably dangerous."

The *Bruesewitz v. Wyeth* case interpreted the highlighted text below from the National Vaccine Injury Act to find that it did not permit design defect litigation – that issue had been unclear since 1986, and different state high courts and federal circuits had decided the issue differently. So, Ginger is correct that the US Supreme Court never decided that vaccines are "unavoidably unsafe" directly, but it acknowledged that Congress considers them to be so.

Sec. 300aa-22. Standards of responsibility

(a) General rule

Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings

*(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted **from side effects that were unavoidable** even though the vaccine was properly prepared and was accompanied by proper directions and warnings.*

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act."

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Bruesewitz v. Wyeth LLC, 562 U.S. 223 (2011)

[Overview](#)

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09-152

March 8, 2010

October 12, 2010

Decided:

February 22, 2011

Syllabus

SYLLABUS

OCTOBER TERM, 2010

BRUESEWITZ V. WYETH LLC

SUPREME COURT OF THE UNITED STATES

BRUESEWITZ et al. v. WYETH LLC, fka WYETH, INC., et al.

certiorari to the united states court of appeals for the third circuit

No. 09–152. Argued October 12, 2010—Decided February 22, 2011

The National Childhood Vaccine Injury Act of 1986 (NCVIA or Act) created a no-fault compensation program to stabilize a vaccine market adversely affected by an increase in vaccine-related tort litigation and to facilitate compensation to claimants who found pursuing legitimate vaccine-inflicted injuries too costly and difficult. The Act provides that a party alleging a vaccine-related injury may file a petition for compensation in the Court of Federal Claims, naming the Health and Human Services Secretary as the respondent; that the court must resolve the case by a specified deadline; and that the claimant can then decide whether to accept the court’s judgment or reject it and seek tort relief from the vaccine manufacturer. Awards are paid out of a fund created by an excise tax on each vaccine dose. As a *quid pro quo*, manufacturers enjoy significant tort-liability protections. Most importantly, the Act eliminates manufacturer liability for a vaccine’s unavoidable, adverse side effects.

Hannah Bruesewitz’s parents filed a vaccine-injury petition in the Court of Federal Claims, claiming that Hannah became disabled after receiving a diphtheria, tetanus, and pertussis (DTP) vaccine manufactured by Lederle Laboratories (now owned by respondent Wyeth). After that court denied their claim, they elected to reject the unfavorable judgment and filed suit in Pennsylvania state court, alleging, *inter alia*, that the defective design of Lederle’s DTP vaccine caused Hannah’s disabilities, and that Lederle was subject to strict liability and liability for negligent design under Pennsylvania common law. Wyeth removed the suit to the Federal District Court. It granted Wyeth summary judgment, holding that the relevant Pennsylvania law was preempted by 42 U. S. C. §300aa–22(b)(1), which provides that “[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side-effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.” The Third Circuit affirmed.

Held: The NCVIA preempts all design-defect claims against vaccine manufacturers brought by plaintiffs seeking compensation for injury or death caused by a vaccine's side effects. Pp. 7–19.

(a) Section 300aa–22(b)(1)'s text suggests that a vaccine's design is not open to question in a tort action. If a manufacturer could be held liable for failure to use a different design, the "even though" clause would do no work. A vaccine side effect could always have been avoidable by use of a different vaccine not containing the harmful element. The language of the provision thus suggests the design is not subject to question in a tort action. What the statute establishes as a complete defense must be unavoidability (given safe manufacture and warning) with respect to the particular design. This conclusion is supported by the fact that, although products-liability law establishes three grounds for liability—defective manufacture, inadequate directions or warnings, and defective design—the Act mentions only manufacture and warnings. It thus seems that the Act's failure to mention design-defect liability is "by deliberate choice, not inadvertence." *Barnhart v. Peabody Coal Co.*, 537 U. S. 149, 168. Pp. 7–8.

(b) Contrary to petitioners' argument, there is no reason to believe that §300aa–22(b)(1)'s term "unavoidable" is a term of art incorporating Restatement (Second) of Torts §402A, Comment *k*, which exempts from strict liability rules "unavoidably unsafe products." "Unavoidable" is hardly a rarely used word, and cases interpreting comment *k* attach special significance only to the term "unavoidably unsafe products," not the word "unavoidable" standing alone. Moreover, reading the phrase "side effects that were unavoidable" to exempt injuries caused by flawed design would require treating "even though" as a coordinating conjunction linking independent ideas when it is a concessive, subordinating conjunction conveying that one clause weakens or qualifies the other. The canon against superfluity does not undermine this Court's interpretation because petitioners' competing interpretation has superfluity problems of its own. Pp. 8–12.

(c) The structure of the NCVIA and of vaccine regulation in general reinforces what §300aa–22(b)(1)'s text suggests. Design defects do not merit a single mention in the Act or in Food and Drug Administration regulations that pervasively regulate the drug manufacturing process. This lack of guidance for design defects, combined with the extensive guidance for the two liability grounds specifically mentioned in the Act, strongly suggests that design defects were not mentioned because they are not a basis for liability. The Act's mandates lead to the same conclusion. It provides for federal agency improvement of vaccine design and for federally prescribed compensation, which are other means for achieving the two beneficial effects of design-defect torts—prompting the development of improved designs, and providing compensation for inflicted injuries. The Act's structural *quid pro quo* also leads to the same conclusion. The vaccine manufacturers fund an informal, efficient compensation program for vaccine injuries in exchange for avoiding costly tort litigation and the occasional disproportionate jury verdict. Taxing their product to fund the compensation program, while leaving their liability for design defect virtually unaltered, would hardly coax them back into the market. Pp. 13–16.

561 F. 3d 233, affirmed.

Scalia, J., delivered the opinion of the Court, in which Roberts, C. J., and Kennedy, Thomas, Breyer, and Alito, JJ., joined. Breyer, J., filed a concurring opinion. Sotomayor, J., filed a dissenting opinion, in which Ginsburg, J., joined. Kagan, J., took no part in the consideration or decision of the case.

Dear Members of the Board,

Peter Machen, Mathews, VA

I am here today to speak in opposition to adding the Covid-19 jab to the schedule, I have gathered some facts to back it up. From 1990 to 2020 there were 8,481 total deaths reported to VAERS, from 2021 to 2023 when the Covid-19 Vaccines came out there was a spike from 8,481 to 35,838 deaths. It is unbelievable that the Covid jabs still exist. In 1976 the swine flu mass vaccination program was shut down after about 25 deaths and 550 cases of Gillian-Barre syndrome were reported. Yet the Covid -19 shot has killed thousands of people and they are still pushing it.

Here is the updated VAERS Data: *for Covid-19 Vaccine*

34,725 DEATHS

16,818 BELL'S PALSY

4,949 Miscarriages

18,820 Heart Attacks

26,636 Myocarditis

64,205 Permanently Disabled

36,950 Life Threatening

42,296 Severe Allergic Reaction

15,528 Shingles

This vaccines are deadly. The Supreme Court rulings have shown that vaccines are not safe. Stop the Shot!!

Ruth Machen, Mathews VA

We are losing freedom in this country. The flame is getting smaller every day. The founders created a government where the people are in charge and the government's main purpose is to protect that freedom. We have gone so far from that. If we continue this track, by the time I'm an adult the torch of freedom will have extinguished. We need to turn to God and stop trying to control people. You have a choice. You have a voice. You can do something to help so my generation will have freedom. We are in a very dangerous place if we do not even have bodily autonomy. It is a constitutional right and most of all it is a God-given right. When we see God given rights being trampled, how in the world do you think we will have any constitutional rights when I'm an adult? Your job as an American is to protect the precious flame of freedom for us. This is also a parental right. They are the parent's children not the states'. You have no right over them. Parents know their children and know what is best. Americans have the duty to investigate everything. Parents need informed consent. We have not seen much of that. You can do better. Virginia's children deserve better. Please do everything in your power to ensure that years from now, looking back, you will not regret taking the very lives of children. Please fight for us. Please ensure liberty and pass the torch to us that is bigger and brighter than ever before for the next generation.

Virginia Board of Health Meeting 23 March 2023
2 minutes on behalf of VAMFA
Lori D. Leonard, BS, DVM, VetMFHom

I am here today to persuade you, the Virginia Board of Health, to do the right thing. Take the right actions. Stand for the citizens of this glorious Commonwealth. Medical freedom people have addressed you before (at least 3 times recently) and you have done nothing.

I have a question for this Board on 23 March 2023: What planet have you been living on for the past three years? Clearly it is not the planet the rest of sane society is living on. Let me bring you up to speed so that you have complete understanding.

The inventors of spike protein are on record as stating that the untested, unproven mRNA bioweapon gene altering injections were created to cause disease as well as to have antibiotic resistance. This is no surprise, as much if not all of the research into these deadly jabs has been and continues to be funded by the (U.S.) Department of Defense (DoD) and DARPA (Defense Advanced Research Projects Agency). These are not health-promoting agencies.

Hundreds of doctors worldwide are on record stating that these C-19 bioweapons have caused diseases, permanent disability and death in all age groups.

The Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) wrongly, inhumanely, and negligently added the above products to be mandatory for adolescents, children, and infants. No one can, in good conscience, support such a threat to mankind.

I call for all mandates to be stopped immediately. The childhood and adult schedules must be suspended instantly, while multiple panels are convened to complete safety analysis of all products. This would include but not be limited to all mRNA injections, the "new" influenza shot, Monkey Pox, RSV, Shingles, pneumonia, HPV, Marburg, Ebola, HIV, and all livestock/avian injections using this technology.

VAMFA speech 23Mar23 VBH

FLCCCC
ALLIANCE

FRONT LINE COVID-19 CRITICAL CARE ALLIANCE
PROPHYLAXIS & TREATMENT PROTOCOLS FOR COVID-19

COVID-19 Vaccines

Safe and effective! I don't think so.

COVID-19
VACCINES



SAFE AND EFFECTIVE

Paul Marik MD, FCCM, FCCP

COVID-19
VACCINES



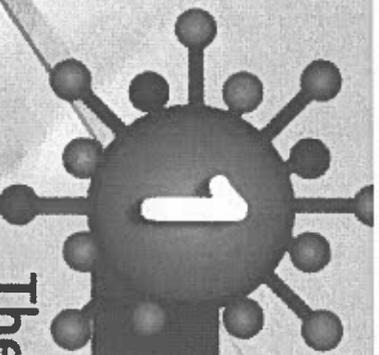
SAFE AND EFFECTIVE



Vaccines are

Safe and Effective





The safety of COVID-19 vaccines is a top priority. The U.S. vaccine safety system ensures that all vaccines are as safe as possible.



Executive Summary

1. "Vaccine" kills **2 per 1,000** (estimated 500,000 killed in America)
2. "Vaccine" has killed **30 per 1,000** of 65 and older
3. "Vaccine" has killed more people than the COVID virus by at least **5:1**
4. **5 to 10%** of our healthiest soldiers have been **DISABLED** by this "vaccine"

5. On average **8%** of recipients of these "vaccines" have suffered a serious adverse event

MATERNAL/CHILD HEALTH

6. Vaccination during the first trimester results in a miscarriage rate of **over 80%**

7. Vaccination has led to a decline in new births (fertility rate) of about **20%** across the globe

COVID-19
VACCINES



SAFE AND EFFECTIVE

Nothing says

“Trust the Science”

**like asking for the data
to be hidden for**

75 years



Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months



SAFE AND EFFECTIVE

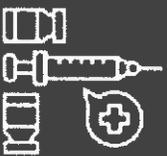
	Heart Attacks	COVID-19 Deaths	Deaths Table S4 Blinded Period	Deaths buried in study	Total Deaths
Vaccinated	5	1	15	5	20
Unvaccinated	1	2	14	0	14

CONCLUSIONS

Through 6 months of follow-up and despite a gradual decline in vaccine efficacy, BNT162b2 had a favorable safety profile and was highly efficacious in preventing Covid-19. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728.)

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months

COVID-19
VACCINES



SAFE AND EFFECTIVE

"of the 29 authors of this study, 18 are employees of Pfizer and hold stock in the company, one received a research grant from Pfizer during the study, and two reported Being paid 'personal fees' by Pfizer"

Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents

RESULTS

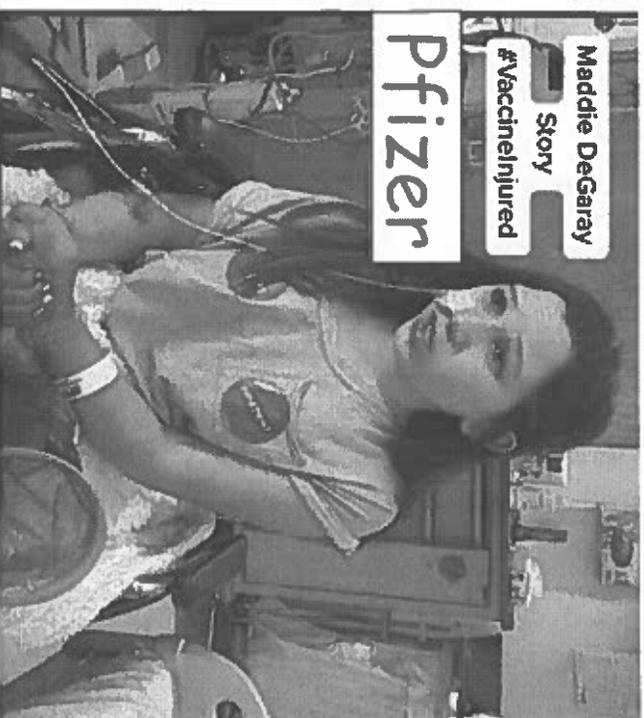
As has been found in other age groups, BNT162b2 had a favorable safety and side-effect profile, with mainly transient mild to-moderate reactogenicity (predominantly injection-site, fatigue and headache; **there were no vaccine related serious adverse events.**

CONCLUSIONS

The BNT162b2 vaccine in 12-to-15-year-old recipients had a favorable safety profile, produced a greater immune response than in young adults, and was highly effective against Covid-19. (Funded by BioNTech and Pfizer; C4591001 ClinicalTrials.gov number, NCT04368728.)

Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents

12-year-old Maddie de Garay: Hospitalized for 64 days



Maddie DeGaray

Story

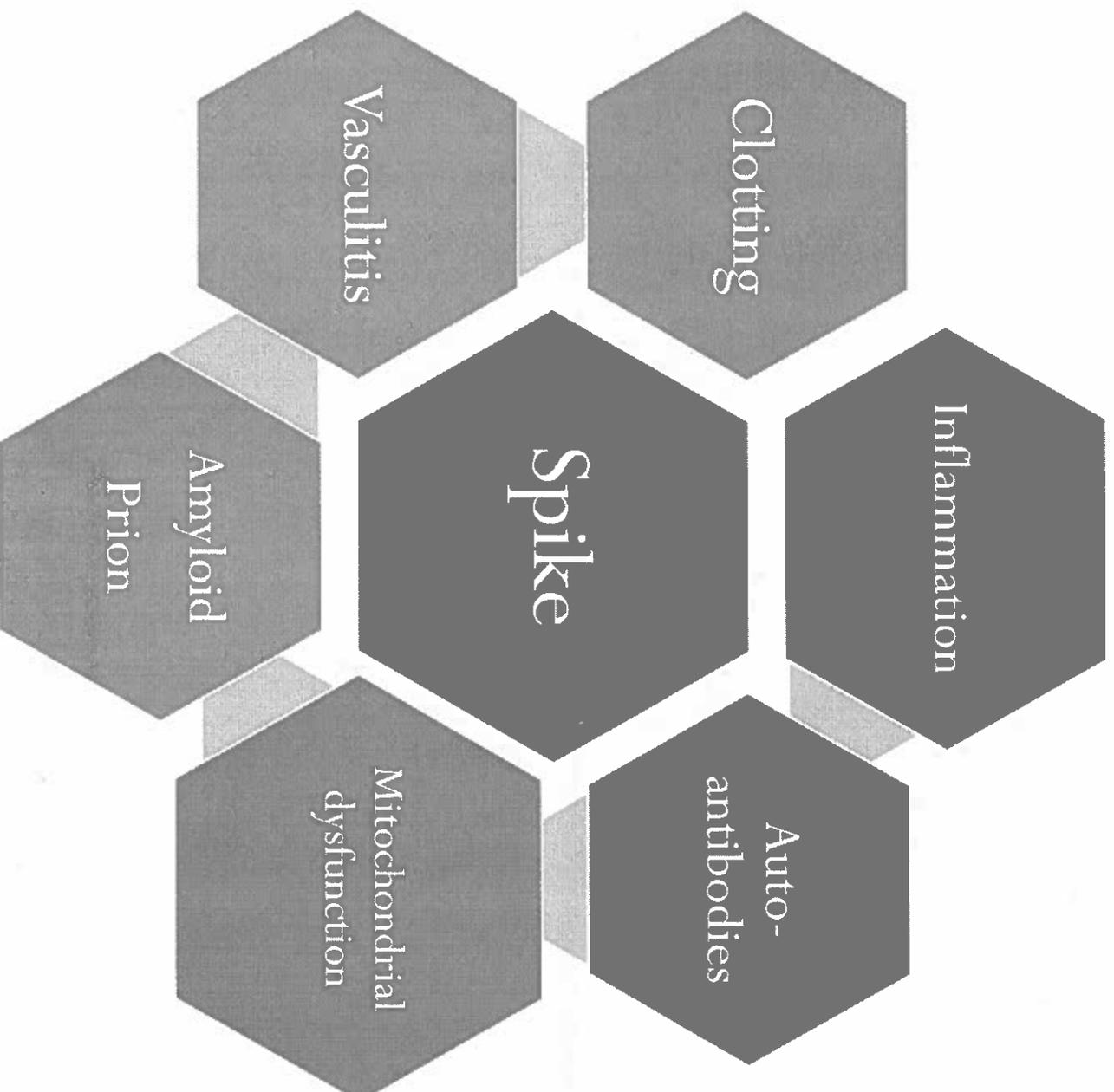
#VaccineInjured

Pfizer

- Severe Abdominal Pain (URA)
- Muscle Pain & Spasms all over body
- Tingling, Numbness & Weakness in Legs
- Gait Abnormality & Inability to Walk
- Sharp/Electric Pain - Neck down Spine
- Chest pain & Tachycardia
- Headache/Migraines
- Nauseas, Reflux, Vomiting & Dysphagia
- Diarrhea then Gastropareasis
- Cold/white fingers & toes
- Fever, sore throat, white tongue, ulcers
- Blood in her urine in 7 urinalysis
- Erratic blood pressure
- Abnormal blood tests
- Vulvar boil
- Irregular/Heavy Periods
- Vision Loss
- Tinnitus
- Brain fog/Mixing words
- Peeling feet
- Rash on her arms
- Dizziness and Fainting
- Verbal & Motor Tics
- Tremors
- Urinary Retention
- Fatigue

Not vaccine related: Functional abdominal pain

“Spike” Induced Disease



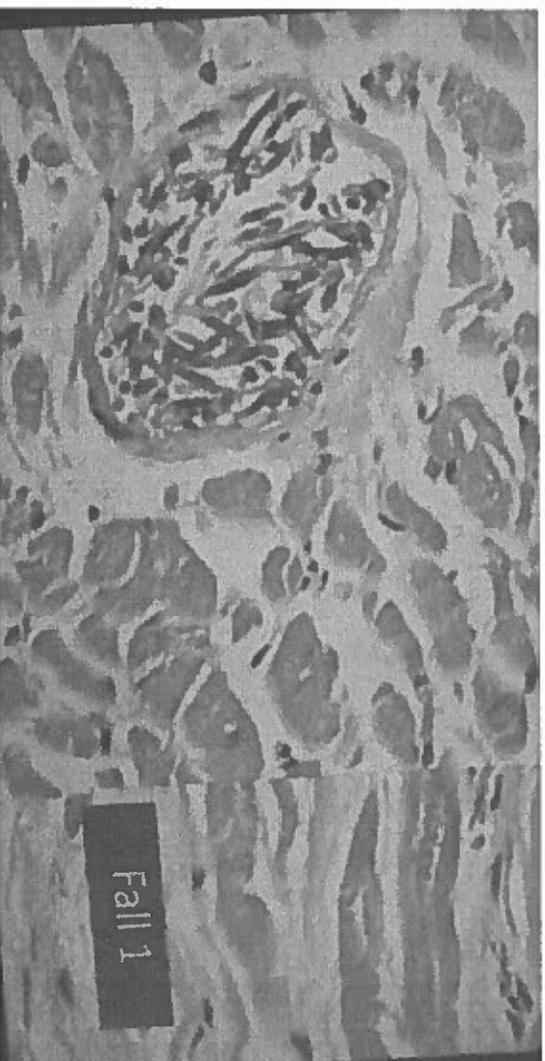
Pathologic Examination of 10 patients who died post vaccination by German Team of pathologists

https://odysee.com/@en:a5/PK_Tot-durch-Impfung_english:a

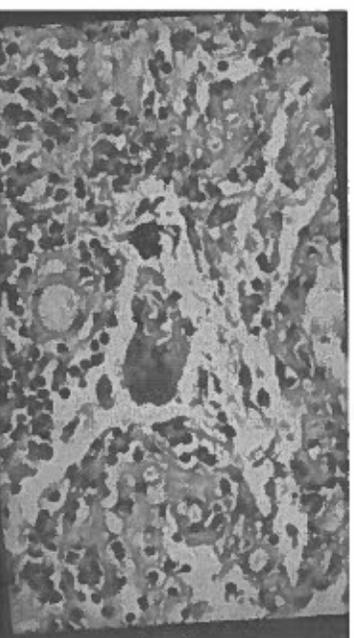
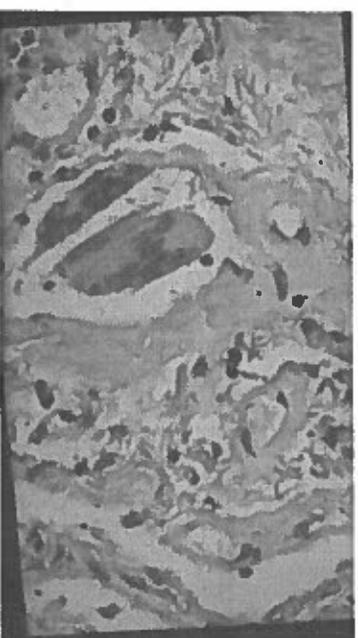
Main findings (in order of priority)

- Lymphocytic myocarditis
- Lymphocytic Alveolitis
- Lymphocytic vasculitis
- Other autoimmune phenomenon, leukocytoclastic vasculitis, Sjogren's disease, Hashimoto's disease
- Foreign Body Giant cell granuloma
 - All suggestive of an auto-immune process.

Vasculitis with endothelial shedding

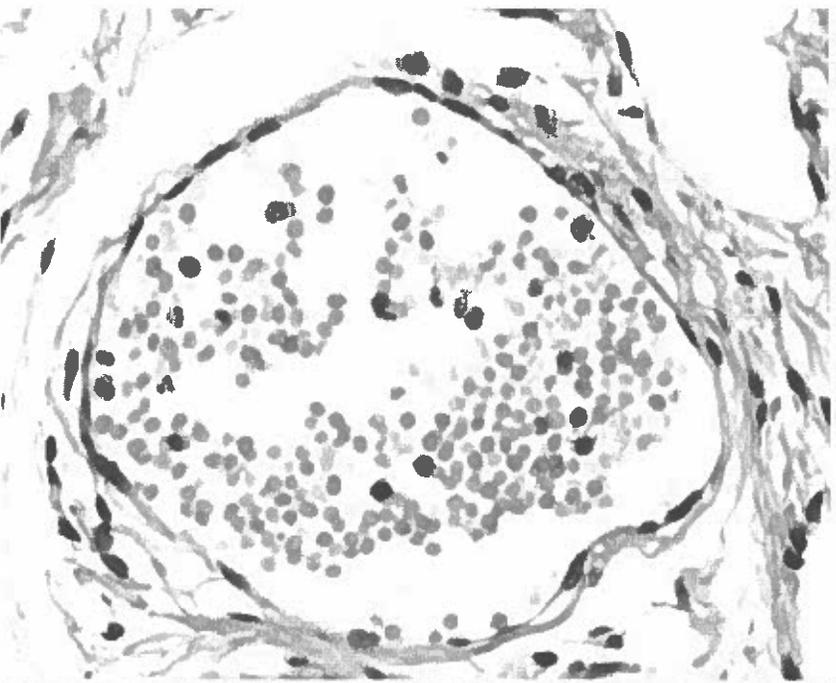


Fall 1



Endothelial destruction in a venule after vaccination

normal



vaccinated

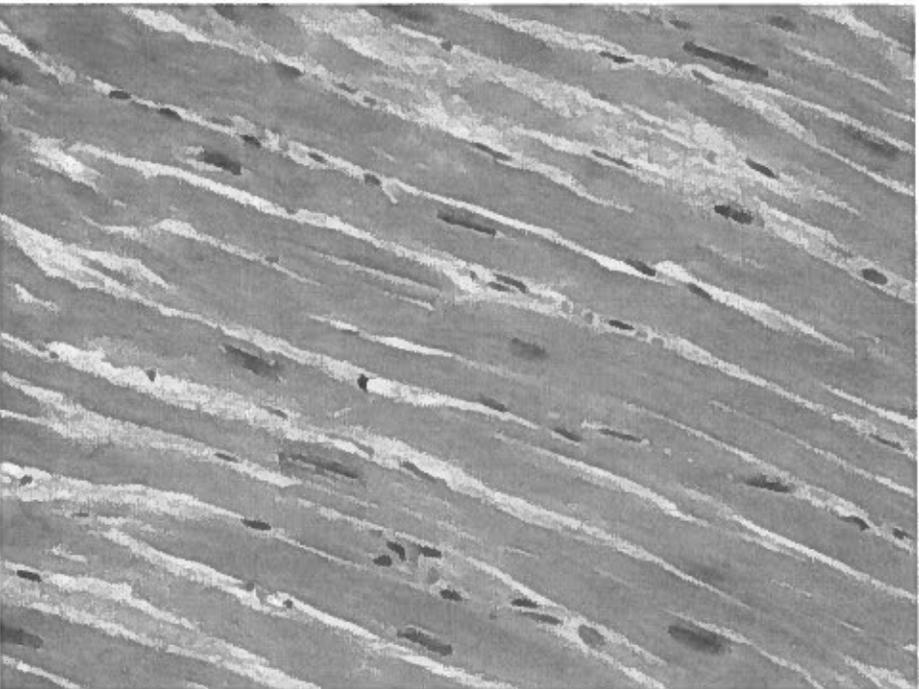


Spike endothelialitis

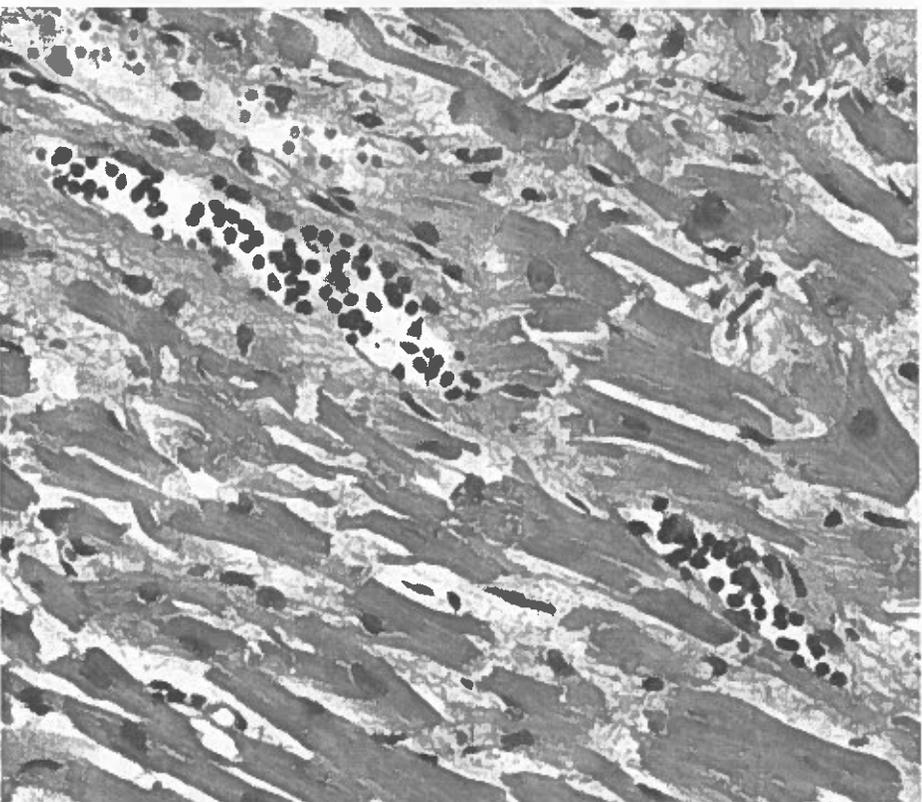


Vaccine induced Myocarditis

normal heart muscle

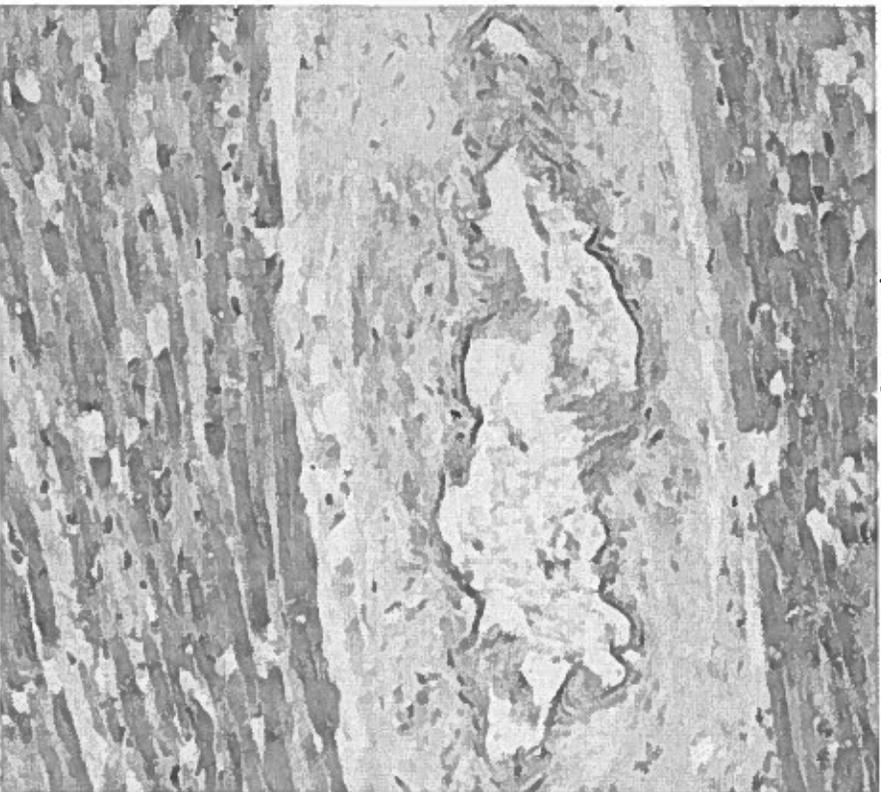


lymphocytes invading heart muscle



Spike protein vs. nucleocapsid expression in heart muscle

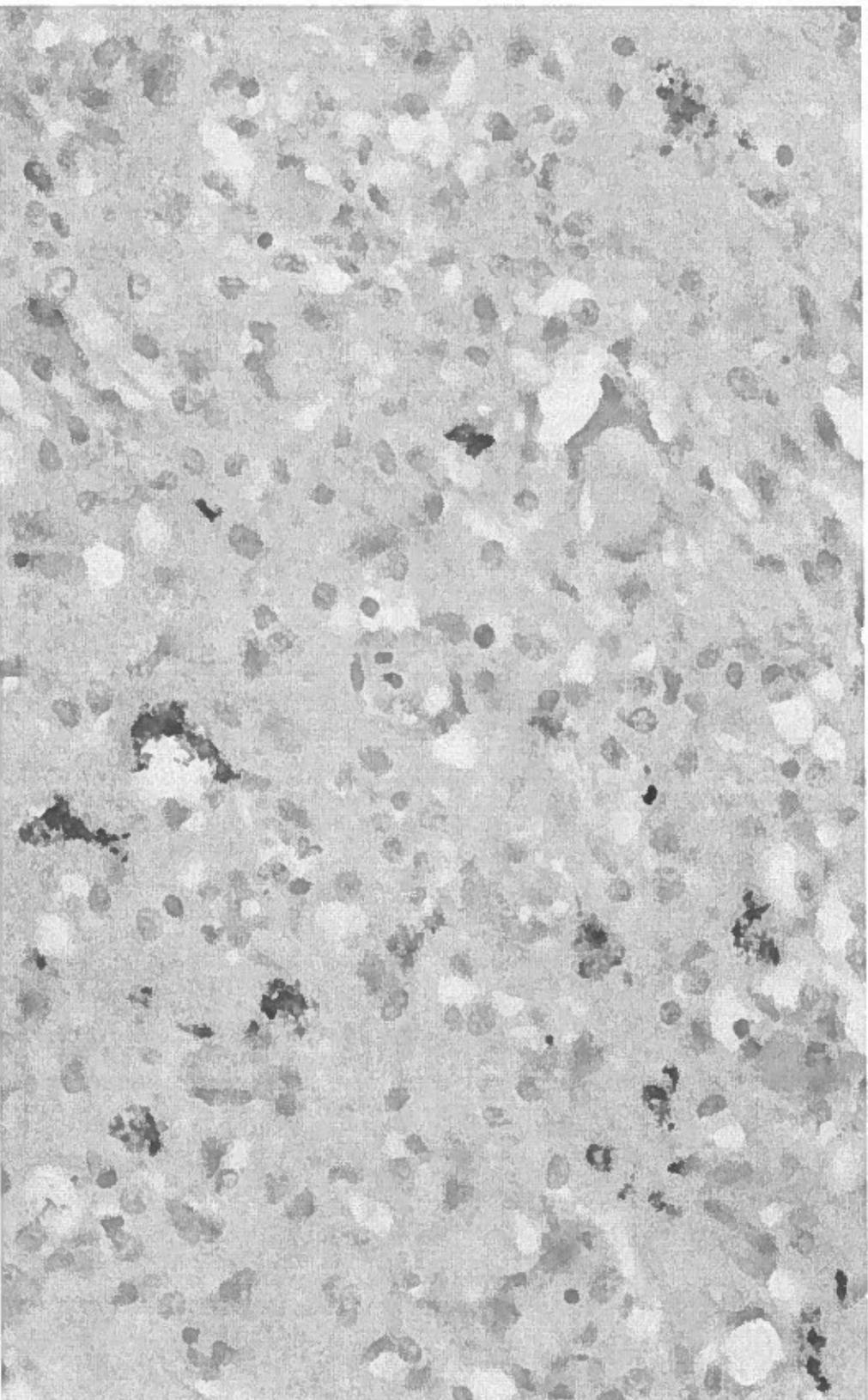
Spike protein



Nucleocapsid



Spike Protein in Brain Tissue



People Who Pushed Idea of Universal Vaccination Are ‘Guilty of Crimes Against Humanity’: Former Pfizer VP

By [Enrico Ingosa](#)

May 14, 2022 Updated: May 14, 2022

A   Print

Former Pfizer VP Michael Yeardon maintains that since the infection fatality ratio of COVID-19 has not been high, the vaccines should not have been mandated.

Moreover, he heavily blasted the corporate media mantras that designate these as safe, effective, and necessary to end the CCP (Chinese Communist Party) virus pandemic.

Yeardon is a big pharma veteran with 32 years in the industry. He worked as the head of allergy and respiratory research at Pfizer from 1995 to 2011 and is the former founder and CEO of Ziarco, a biotech company acquired by Novartis. Furthermore, he has a doctorate in respiratory pharmacology and holds a Double First Class Honors degree in biochemistry and toxicology.

A shocking 1,223 deaths and 42,086 adverse events were reported to Pfizer from the first day of the Pfizer-BioNTech vaccine rollout on Dec. 1, 2020, to Feb. 28, 2021.

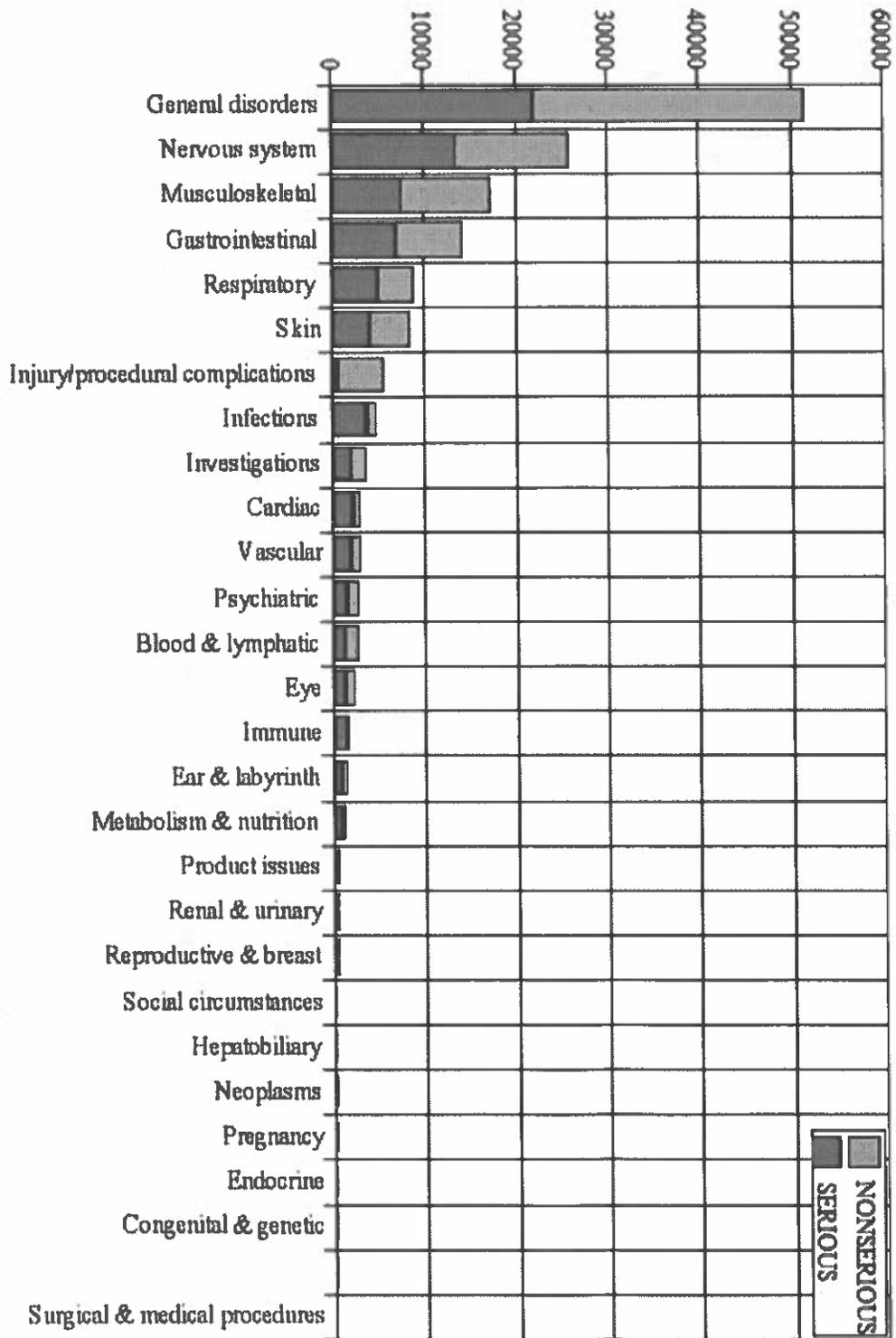
5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics	Relevant cases (N=42086)
Gender:	Female 29914
	Male 9182
	No Data 2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17 175 ^a
	18-30 4953
	31-50 13886
	51-64 7884
	65-74 3098
	≥ 75 5214
Case outcome:	Unknown 6876
	Recovered/Recovering 19582
	Recovered with sequelae 520
	Not recovered at the time of report 11361
	Fatal 1223
	Unknown 9400

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness



**5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT
REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021**

- 158 893 Adverse events
- 25,957 Nervous System Disorders
- 17,283 Musculoskeletal disorders
- 14,096 Gastrointestinal disorders
- 8,476 Skin and subcutaneous disorders
- 4,610 Infections

* ● Of the 32 pregnancies 28 resulted in fetal death (87%)*

MATERNAL HEALTH

Complications/ injuries caused by COVID injections

Over 2,400 peer-reviewed articles have been published on COVID vaccine injuries. Find links to these studies at [COVID Vaccine Injuries](#), [REACT19](#), and on [Substack](#). A selection of symptoms is listed below:

- Myocarditis, pericarditis, stress cardiomyopathy (contraction band necrosis)
- Takotsubo cardiomyopathy
- Acute coronary syndrome
- Hypertension
- MIS-V, Multisystem Inflammatory Syndrome
- Thrombosis, including pulmonary emboli and stroke (prothrombotic state)
- Cerebral venous thrombosis
- Thrombocytopenia
- Thrombotic thrombocytopenic purpura
- Idiopathic thrombocytopenic purpura
- Henoch Schönlein Purpura
- Immune-mediated hemolysis
- Reactivation and exacerbation of chronic underlying diseases/disorders
- Immune dysregulation
- Metabolic dysregulation (diabetes)
- Menstrual irregularities
- Menorrhagia
- Amenorrhea
- Spontaneous abortion
- Vulval and vaginal ulcers
- Vasculitis, including Leukocytoclastic vasculitis, Granulomatous vasculitis, microscopic polyangiitis
- Guillain-Barre Syndrome
- Acute Myelitis

Article

Cardiovascular Effects of the BNT162b2 mRNA COVID-19 Vaccine in Adolescents

Suyanee Mansanguan¹, Prakaykaew Charunwathana², Watcharapong Piyaphanee², Wilanee Dechkhajorn³, Akkapon Poolcharoen⁴ and Chayasin Mansanguan^{2*}

Abstract: This prospective cohort study enrolled students from two schools aged 13–18 years who received the second dose of the BNT162b2 mRNA COVID-19 vaccine. We enrolled 314 participants. Cardiovascular effects were found in 29.2% of patients. The most common cardiovascular effects were tachycardia (7.64%), shortness of breath (6.64%), palpitation (4.32%), chest pain (4.32%), and hypertension (3.99%). Seven participants (2.33%) exhibited at least one elevated cardiac biomarker or positive lab assessment.

Overall Batch Analyses %RNA integrity

EUROPEAN MEDICINES AGENCY



Drug Product batch number	%RNA integrity	Company
COVAC/270320 69	69	
BCV40420-A	75	Polymun
BCV40620-A	85	
BCV40620-B	86	
BCV40620-C	83	
BCV40620-D	77	
BCV40620-E	85	
BCV40720-A	71	
BCV40720-B	72	
BCV40720-C	69	
ED3938	62	
EE3813	63	
EE8492	55	Pfizer, Puurs (W5L5)
EE8493	55	

V-safe Covid Vaccine Adverse Health Impacts

(Official CDC Data)

10,108,273
 Total Individual Users

Health Impacts

Red Start Month

Max Care Type

Symptoms
 Checkboxes

Adverse Health Impacts

Unable normal activities
 Missed work/school
 Required medical care

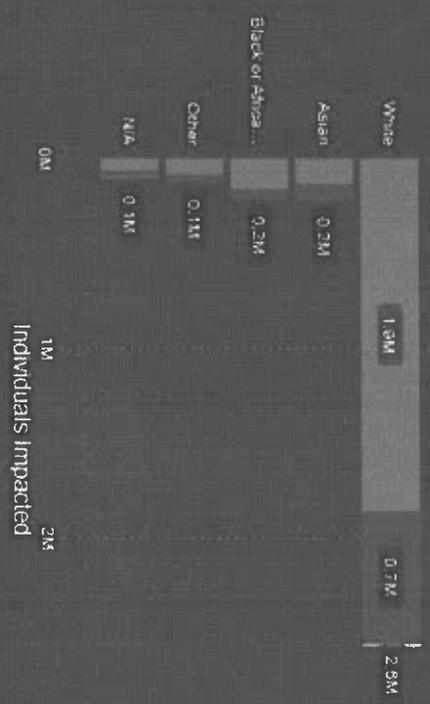


Impact Category: All

Vaccine Brand: All

Race and Sex

Female
 Male
 Other
 Unknown



Sex: All

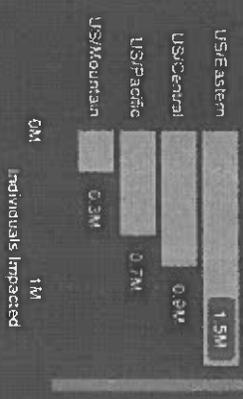
Age Group: All

Time Zone: Search

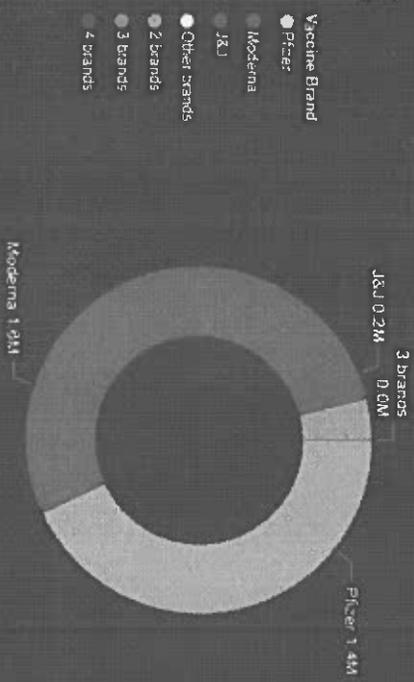
Race: Search

Search

Time Zones



Adverse Health Impact by Vaccine Brand



3,353,110
 Individuals Impacted

6,458,751
 Health Impacts Reported

Percent of v-safe users 3 years and older reporting seeking medical care after first dose of Pfizer covid vaccine in succeeding time intervals:

Time Interval	Percentage Reported Seeking Medical Care
Days 1 to 7	.32%
Days 8 to 14	.67%
Days 15 to 21	1.06%
Days 22 to 28	2.88%
Days 29 to 35	4.96%
Days 36 to 42	6.93%

Court Orders CDC to Release Data Showing 18 Million Vaccine Injuries in America

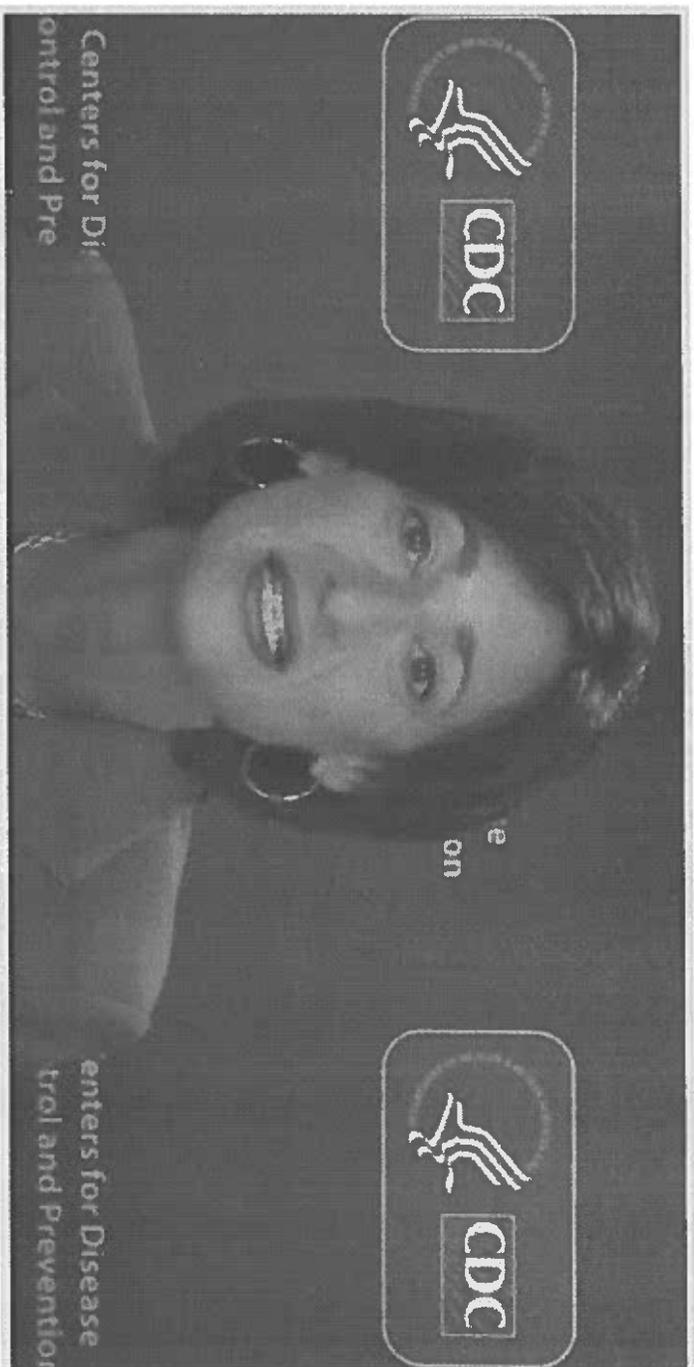
39.9k Shares

21.7k

15.8k

22

207



More than 18 million people were injured so badly by their first COVID shot from Pfizer or Moderna that they had to go to the hospital. That's according to the CDC's own internal data, which a court just ordered the federal agency to release to a watchdog group.

Instead of alerting the public to the incredible dangers of these shots and completely shutting down Joe Biden's mass vaccination mandates, the CDC covered up the info until it was forced to release. Everyone in a position of authority at the CDC should be fired for this. What good is a "public health" agency if it fails to alert the public that 8% of vaccine recipients are being hospitalized?

Do you believe you have experienced major side effects, minor side effects or no side effects from your COVID-19 vaccination?

Major side effects	7%
Minor side effects	34%
No side effects	56%
Not sure	4%

Survey of 1,000 US adults conducted November 30 - December 1, 2022
by Rasmussen Reports, MOE +/- 3%

SURVEY NAME

JULY 2 SURVEY

DATE

Sunday, July 3, 2022

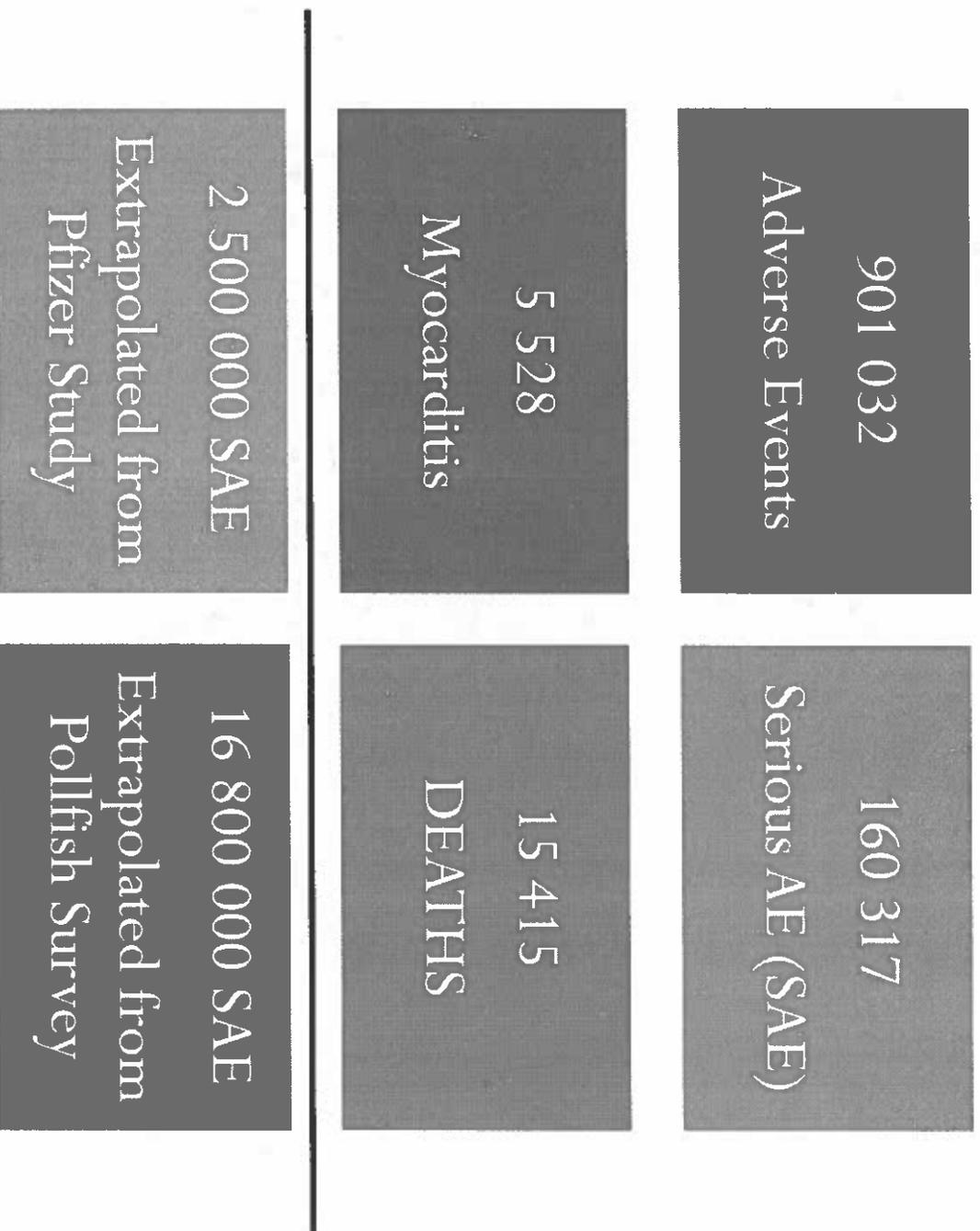
Were you injured from the COVID vaccine?

#	ANSWERS	ANSWERS(%)	COUNT	STRATIFIED ANSWERS(%)	STRATIFIED COUNT
A1	No	90.62%	338	91.09%	343.04
A2	Yes	9.38%	35	8.91%	33.57

POWERED BY



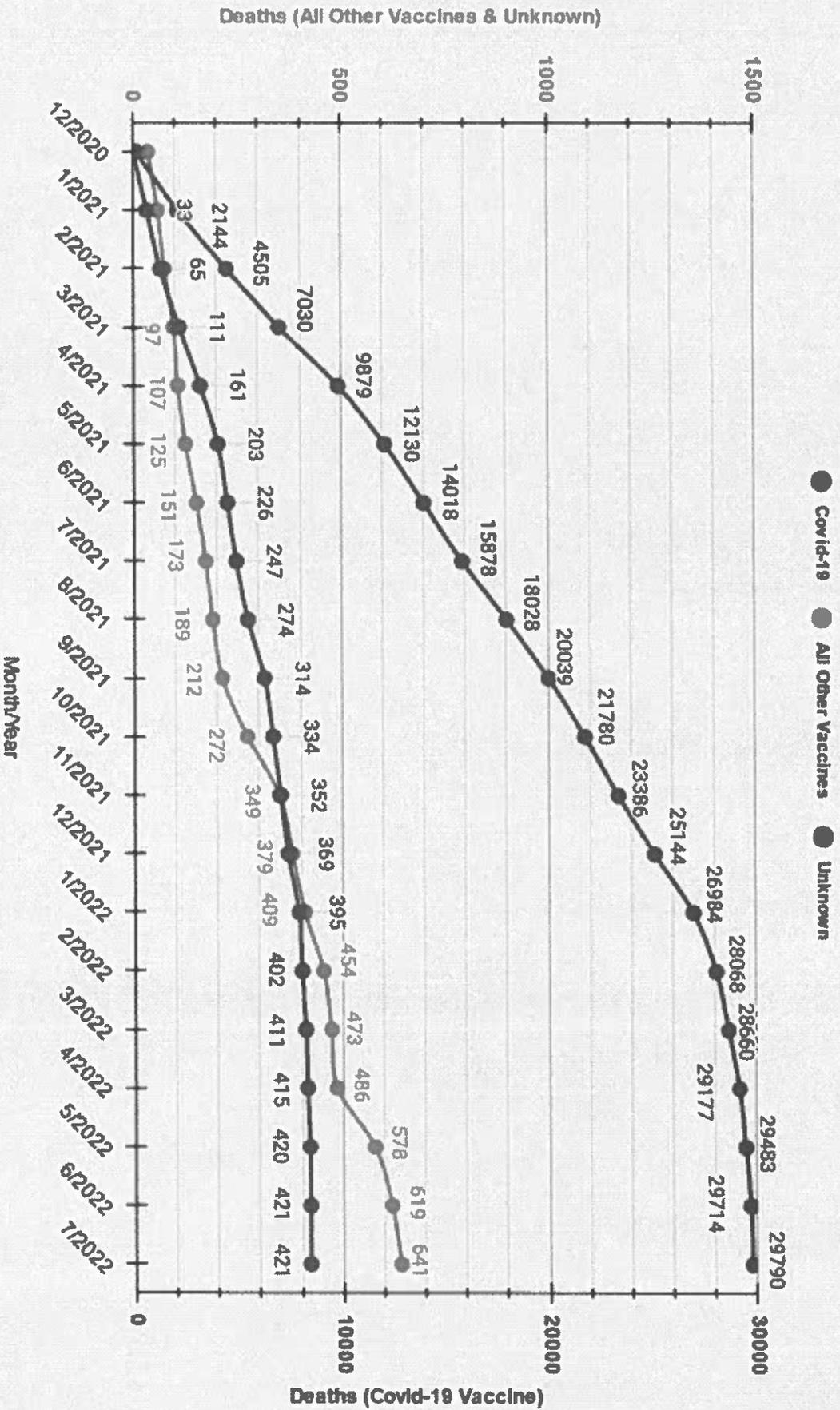
Vaccine Adverse Event Reporting System (VAERS)* Reports in the USA



As of November 18th, 2022. *Underreporting factor of at least 30X.

Cumulative Reported Deaths After Vaccination - 1.5 Year Summary

Data obtained from CDC's VAERS



Do you believe you have experienced major side effects, minor side effects or no side effects from your COVID-19 vaccination?

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Not sure	4%

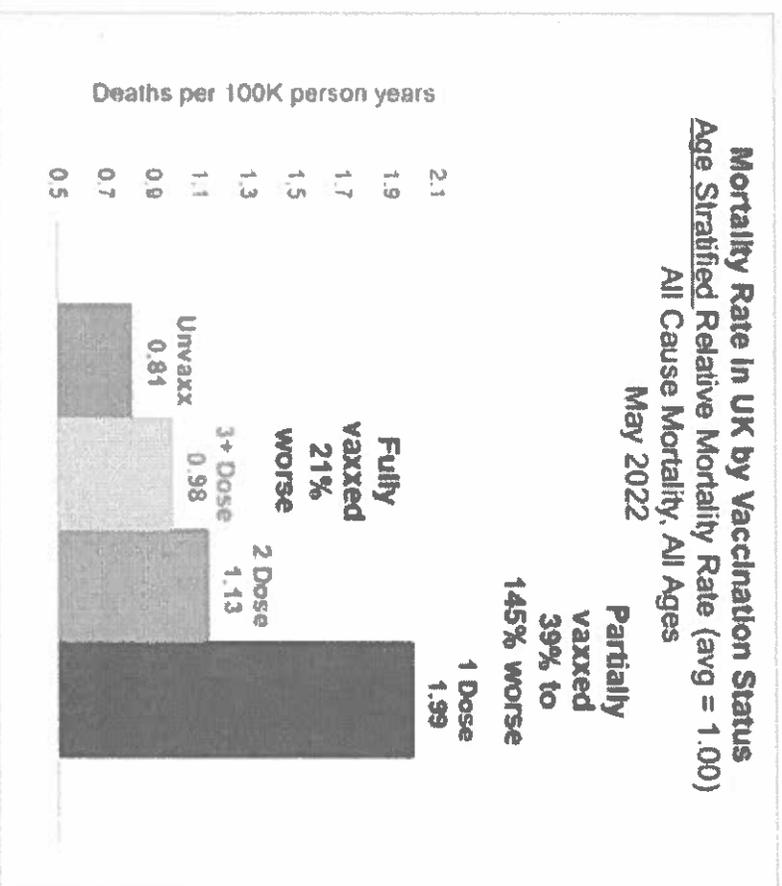
Survey of 1,000 US adults conducted November 30 - December 1, 2022
by Rasmussen Reports, MOE +/- 3%

All-Cause Mortality in the UK: Jan 2021-May 2022

AGE	Raw Death Counts by Non-Vax vs Ever Vaxed for Jan 2021 to May 2022			ENGLAND			All-CAUSE		
	COVID-19 Deaths			NON-COVID Deaths					
	Unvax	Evervax	E-U	Unvax	Evervax	E-U	Unvax	Evervax	E-U
90+	7191	9336	2145	11829	116270	104441	19020	125606	106586
85-89	6437	7870	1433	9707	94963	85256	16144	102833	86689
80-84	5841	6620	779	8887	84170	75283	14728	90790	76062
75-79	5044	4712	-332	8515	67288	58773	13559	72000	58441
70-74	4194	3031	-1163	8090	49631	41541	12284	52662	40378
65-69	3051	1776	-1275	6303	29422	23119	9354	31198	21844
60-64	2425	1162	-1263	5135	20397	15262	7560	21559	13999
55-59	1626	754	-872	4084	13903	9819	5710	14657	8947
50-54	1069	407	-662	3014	8471	5457	4083	8878	4795
45-49	597	223	-374	1965	4416	2451	2562	4639	2077
40-44	299	121	-178	1225	2480	1255	1524	2601	1077
35-39	238	71	-167	903	1410	507	1141	1481	340
30-34	129	40	-89	649	886	237	778	926	148
25-29	68	26	-42	525	577	52	593	603	10
20-24	43	16	-27	335	397	62	378	413	35
15-19	24	7	-17	265	225	-40	289	232	-57
10-14	9	3	-6	175	37	-138	184	40	-144
Summary			-2110			423337			421227

Mortality in UK is now +26% worse for vax'd than unvax'd

Adverse impact is greatest for partially vax'd and younger ages



- Partially vax'd show extremely high mortality, of up to +145% worse, across every age group.
- Fully vax'd mortality is 21% worse overall, and 49% worse for adults 18-49
- Older fully vax'd > age 50 still shows 17% favorable mortality, but trends imply reversal soon (& 90+ vax > unvax mortality)

NSW Health Surveillance Data

①

Rates per 1M Population by Vax Status*

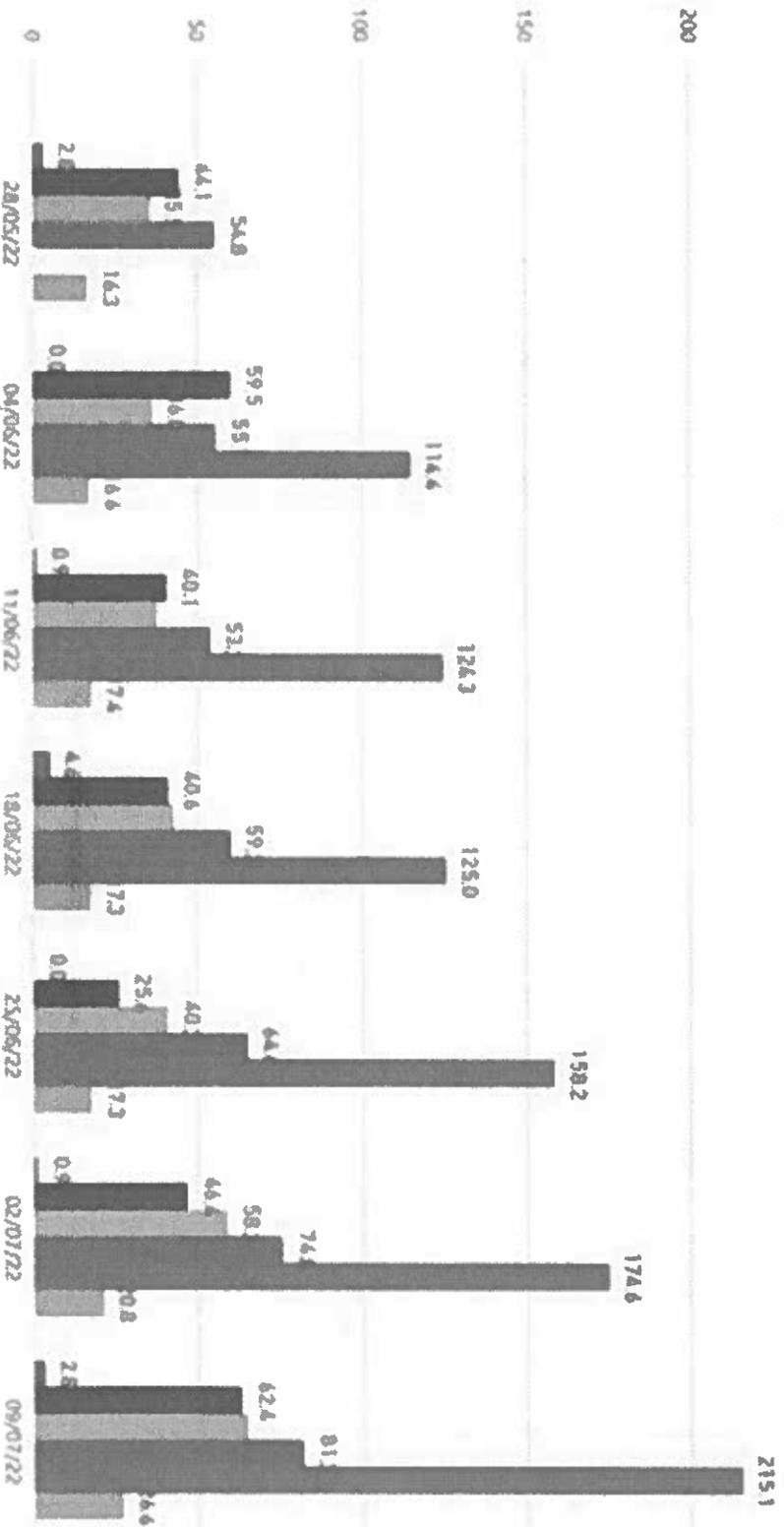
This interactive report is available at <https://bit.ly/3uj7T0G>

* (total measured events divided by the count of population with that vax status) times 1M

Rate of Cases No Dose Per 1M	1,772
Rate One Dose Per 1M	45.52
Rate Two Doses Per 1M	44.81
Rate Three Doses Per 1M	63.31
Rate Four + Doses Per 1M	151.93
Rate of Cases in Year/d Per 1M	62.96
Risk Multiplier Year/d vs Unvax'd	37.14
Rate Unknown Per 1M	18.89

Rate of events per 1M population by vaccination status count at the start of the observation week.

Doses Summary ● No dose ● One dose ● Two doses ● Three doses ● Four + doses ● Unknown

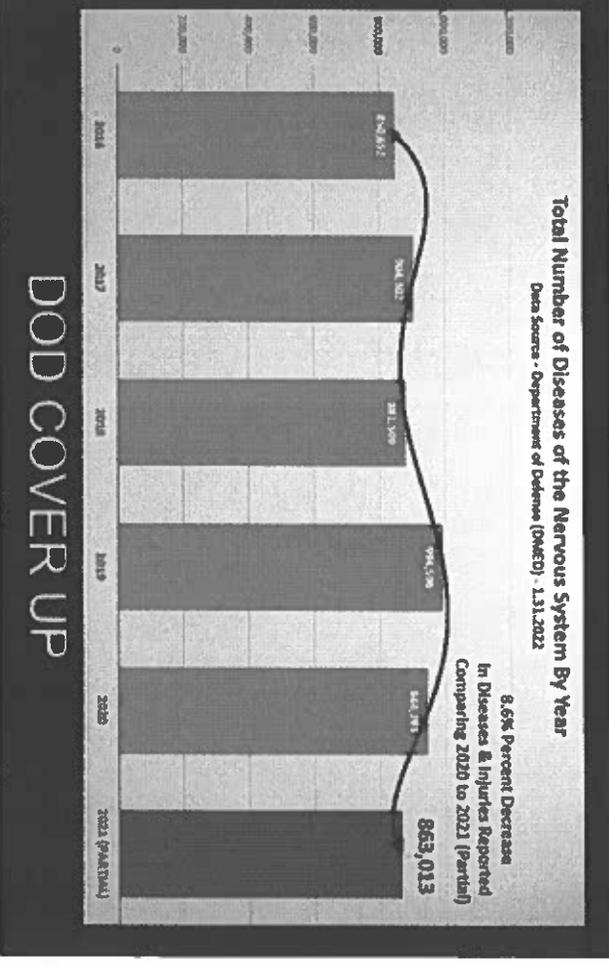
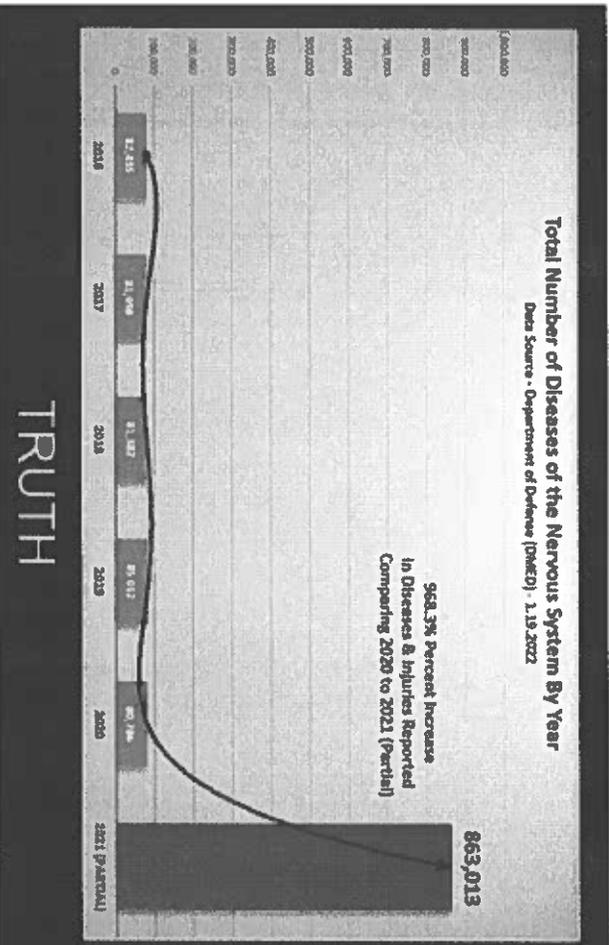


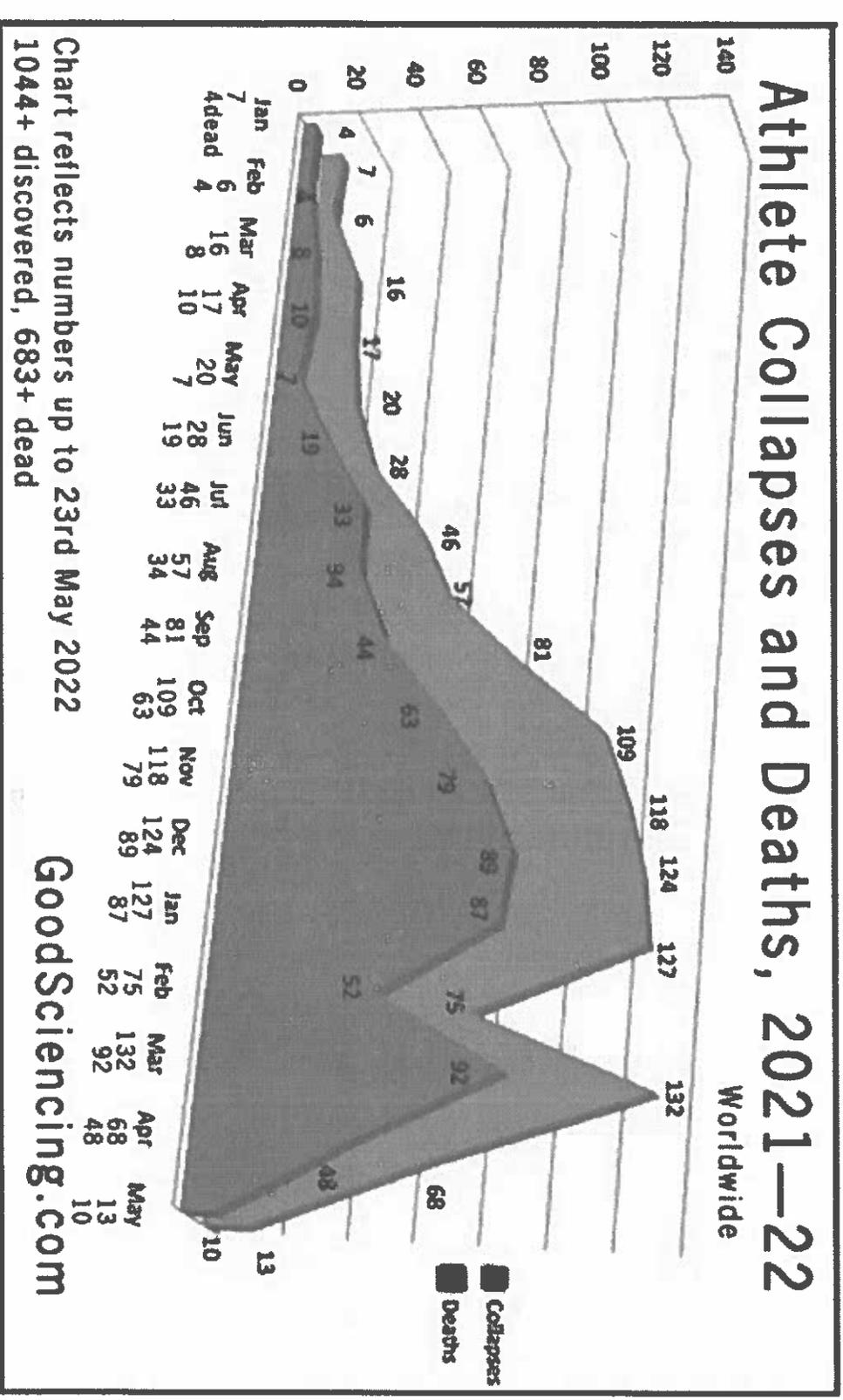
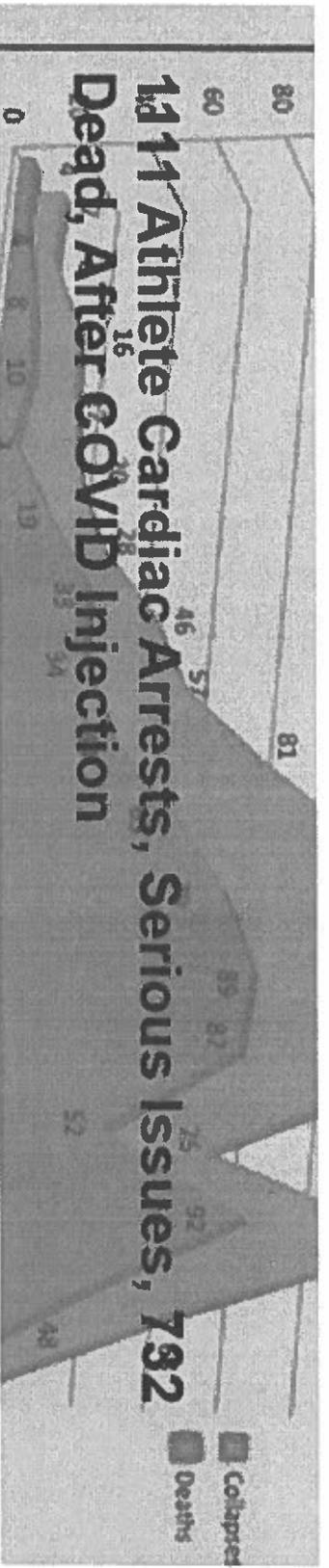
Page 2 of 2

Renz Whistleblowers DMED DATA Reveals Incredibly Disturbing Spikes in Vaccine Injuries Across the Board

- 279% SPIKE in Miscarriages
- 487% SPIKE in Breast Cancer
- 1048% SPIKE in the Nervous System
- 155% SPIKE in Birth Defects
- 350% SPIKE in Male Infertility
- 369% SPIKE in Testicular Cancer
- 2181% SPIKE in Hypertension
- 664% SPIKE in Malignant Neoplasms
- 680% SPIKE in Multiple Sclerosis
- 551% SPIKE in Guillain-Barre Syndrome
- 468% SPIKE in Pulmonary Embolism
- 302% SPIKE in Tachycardia
- 452% SPIKE in Migraines
- 471% SPIKE in Female Infertility
- 437% SPIKE in Ovarian Dysfunction
- 269% SPIKE in Myocardial infarction
- 291% SPIKE in Bell's palsy
- 467% SPIKE in Pulmonary Embolism

Safe and effective??





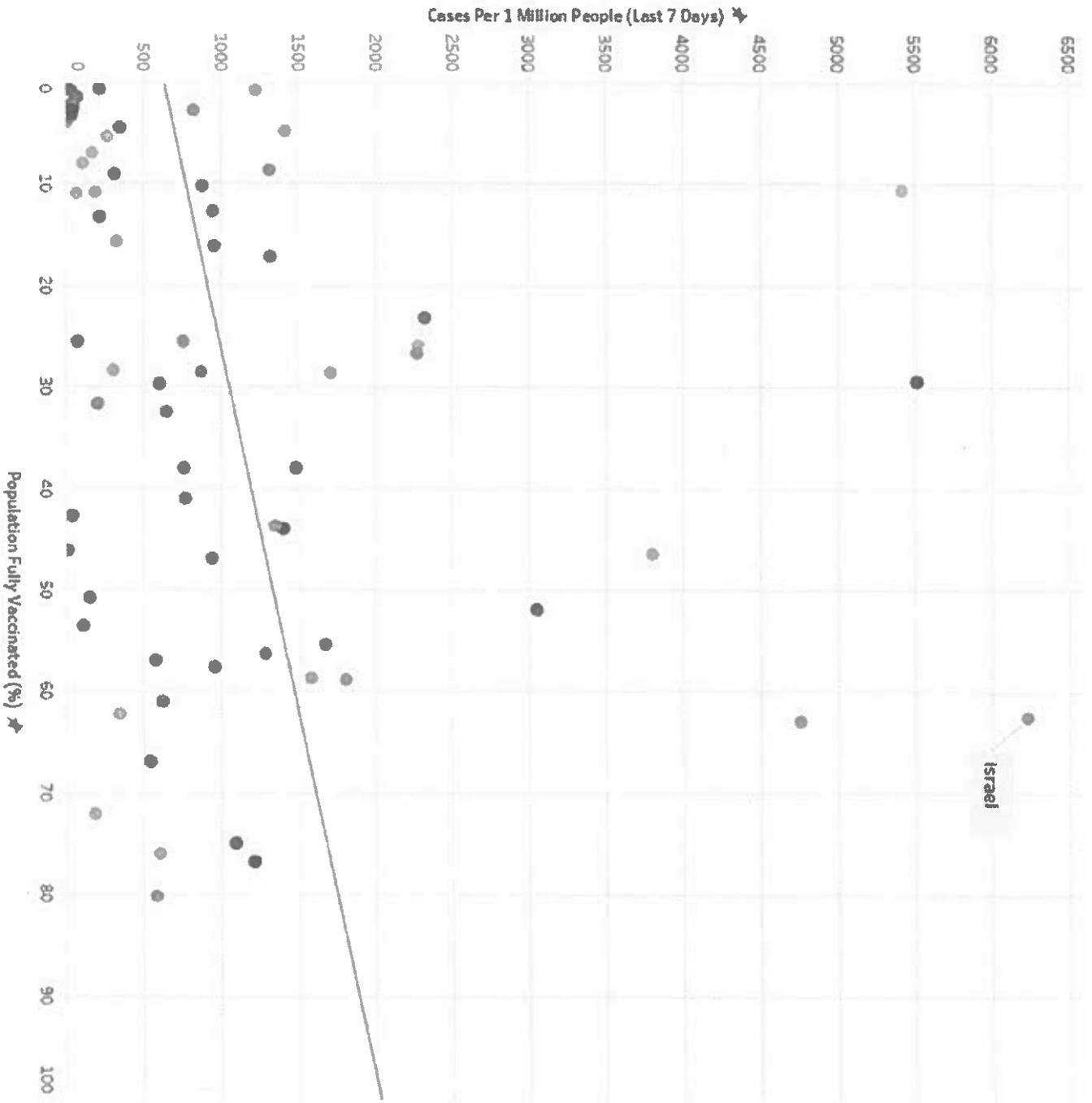
Athlete collapses and deaths chart from 1st January 2021 to 23rd May 2022. Good Sciencing.

CORRESPONDENCE

Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States

S. V. Subramanian^{1,2}  · Akhil Kumar³

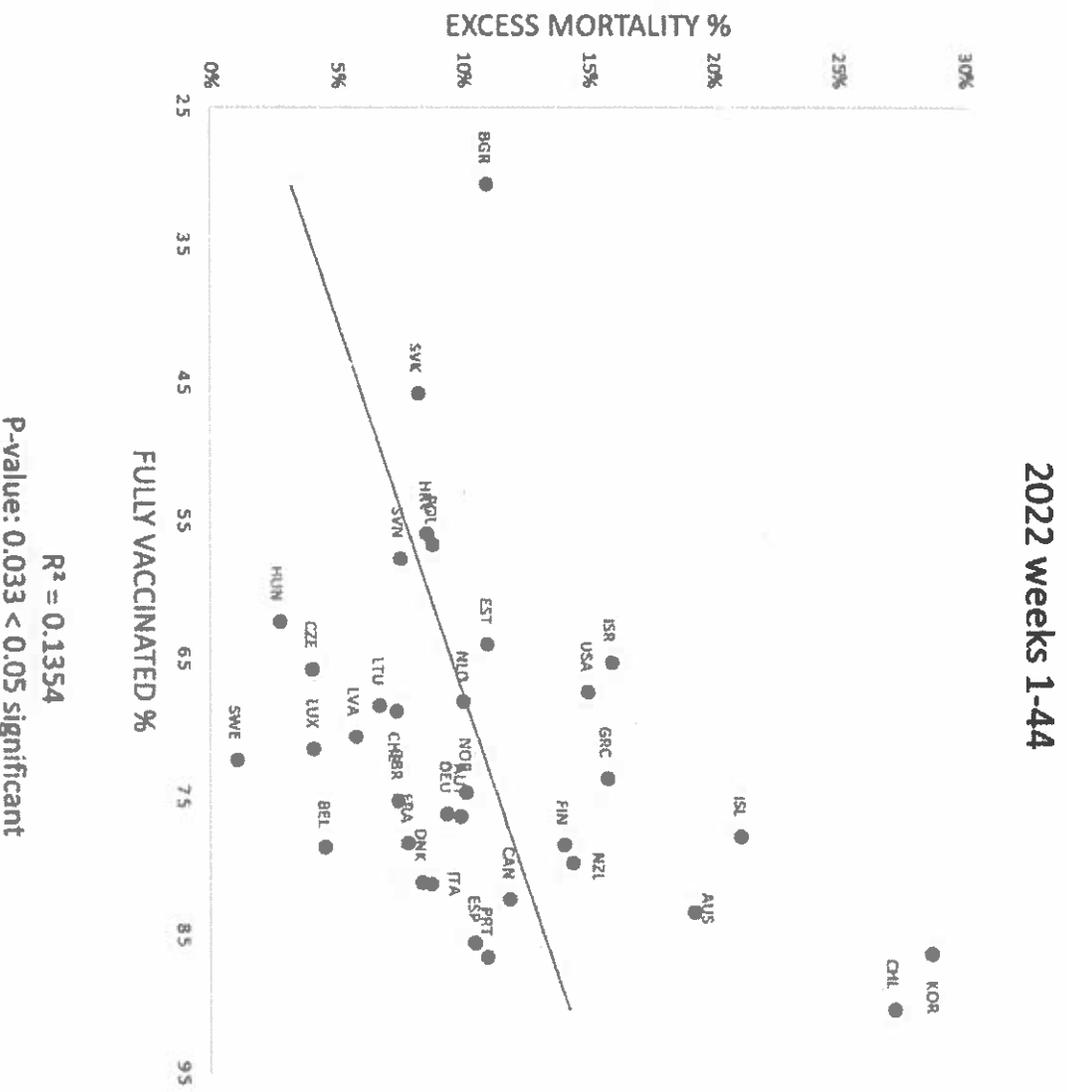
The trend line suggests a marginally positive association such that countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people. Notably, Israel with over 60% of their population fully vaccinated had the highest COVID-19 cases per 1 million people



The Devil's Advocate: An Exploratory Analysis of 2022 Excess Mortality

What is causing excess deaths: Covid, long-covid, lockdowns, healthcare or the vaccines?

Norman Fenton and Martin Neil



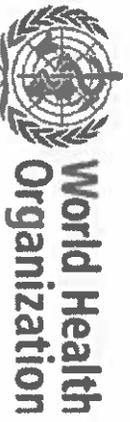
VigiAccess™



WHO Collaborating Centre for
International Drug Monitoring

Medicine	Year started reporting	Deaths	Adverse events
Ivermectin	1992	25	6 558
Remdesivir	2020	579	7 798
Tocilizumab	2005	786	47 345
COVID-19 vaccines	2021	23 018*	4 804 663
Tetanus vaccine	1968	32	15 647
Measles vaccine	1992	35	6 445
Acetaminophen (Tylenol)	1968	3 865	> 146 000

* Underreporting by a factor of a least 30x





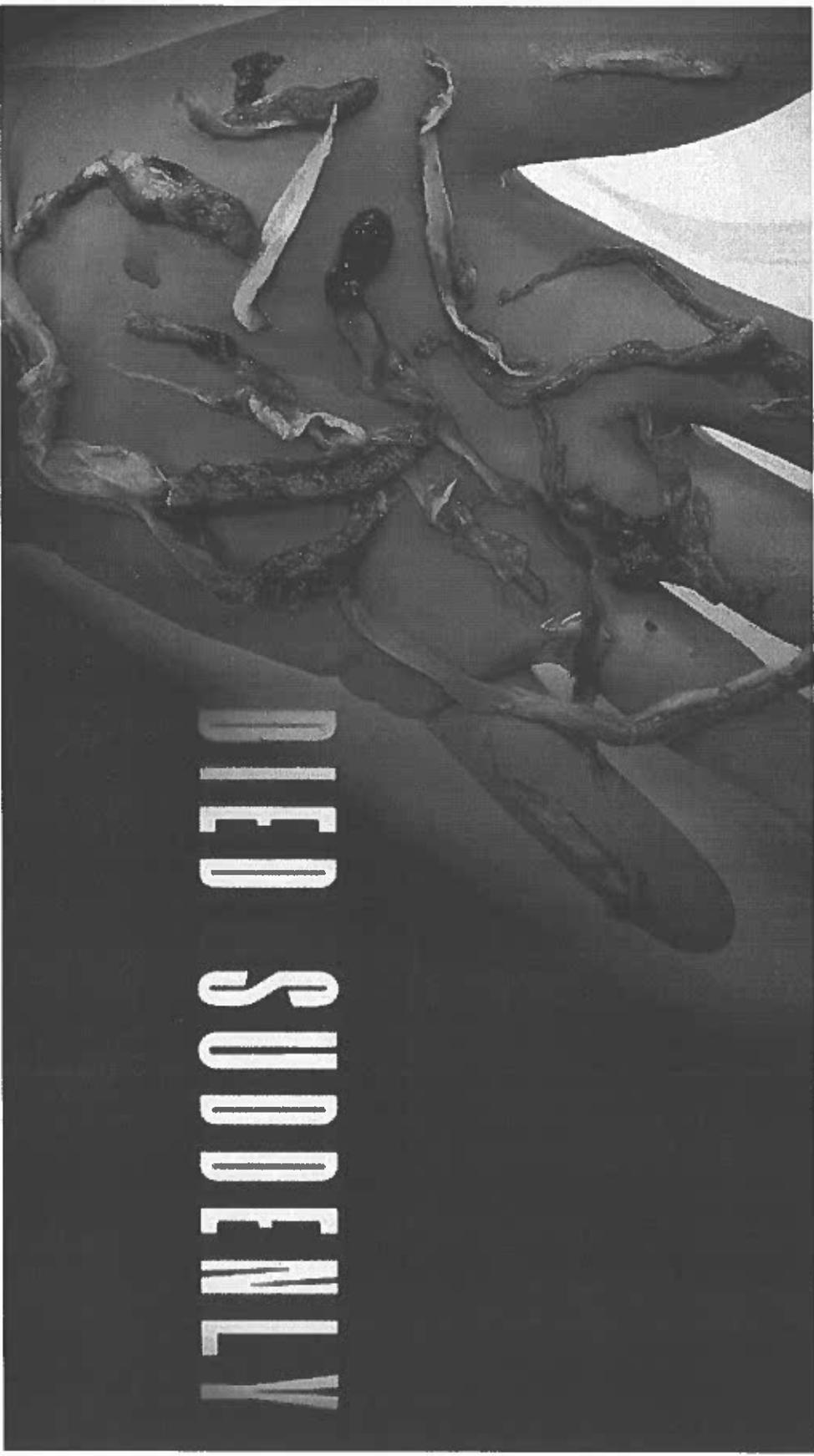
World Health Organization

VigiAccess was launched by the World Health Organization (WHO) in 2015 to provide public access to information in VigiBase, the WHO global database of reported potential side effects of medicinal products.

Vaccine or Drug Name	Total ADRs	Years
Mumps vaccine	711	1972-2021
Rubella vaccine	2,621	1971-2021
Ivermectin	5,705	1992-2021
Measles vaccine	5,827	1968-2021
Penicillin nos	6,684	1968-2021
smallpox vaccine	6,891	1968-2021
chloroquine	7,139	1968-2021
tetanus vaccine	15,085	1968-2021
Hydroxychloroquine	32,641	1968-2021
Hepatitis A vaccine	46,773	1989-2021
Benzylpenicillin	51,327	1968-2021
Rotavirus vaccine	68,327	2000-2021
Accutane	70,719	1983-2021
Vancomycin	71,159	1974-2021
Hepatitis B vaccine	104,619	1984-2021
Polio vaccine	121,988	1968-2021
Meningococcal vaccine	126,412	1976-2021
Ibuprofen	166,709	1969-2021
Ibuprofen	169,359	1968-2021
Aspirin	184,481	1968-2021
Pneumococcal vaccine	234,783	1980-2021
Influenza vaccine	272,202	1968-2021
Covid-19 vaccine	2,457,386	2020-2021

www.vigiaccess.org

Updated Nov. 12th 2021



DIED SUDDENLY

PREMIUM

ENTERTAINMENT NEWS

Lisa Marie Presley, Only Child of Elvis, Dead at 54

By [Caden Pearson](#)

January 12, 2023 Updated: January 12, 2023

A  Print



Lisa Marie Presley attends the Handprint Ceremony honoring Priscilla Presley, Lisa Marie Presley And Riley Keough at TCL Chinese Theatre in Hollywood, California, on June 21, 2022. (Jon Kopaloff/Getty Images)

Los Angeles County paramedics were called to a home in Calabasas at 10:37 a.m. after receiving a report of a woman in full cardiac arrest. Property records show that the house belonged to Lisa Marie Presley.



Lisa Marie

March 12, 2022 at 4:14 PM · 🌐

The last two years have been years of significant change in our lives. The COVID-19 didn't only take our jobs and security, it took our lives.

The idea of having a regular life like we used to, going out with family and friends and having quality time with them, motivated me to get vaccinated because I'm not only protecting myself, I'm also protecting others.

I can't lie, I was nervous initially, but I made my decision and I have no regrets!

To be informed about how best to protect ourselves and our loved ones is the smartest thing we can do. I chose the vaccine. Why did you decide to get vaccinated?

The vaccines prevent serious illness, hospitalization, and death from COVID-19. The COVID-19 vaccines are free, even if you don't have health insurance or aren't a U.S. citizen.

Please visit <https://bit.ly/elbeacon> to join the El Beacon initiative to promote the COVID-19 vaccines and boosters.

#ElBeacon @elbeaconcomunidad #ad #austin #texas #fashion #fashionblogger #austinblogger

DIED SUDDENLY

Terrifying moment Canadian TV reporter appears to faint live on air

17-Year-Old High School Student in Ohio Dies Suddenly From "Cardiac Arrest" While at School

Vegas high school flag football player dies after collapsing

Kindergarten Student in Ohio Dies Suddenly

Air Force Academy Offensive Lineman and Cadet Hunter Brown Dies Suddenly While Walking to Class

College Basketball Player Imo Essien Collapses Minutes Into Game — Clutches Chest

Rising MMA star Victoria 'The Prodigy' Lee dies at age of 18

16-Year-Old Basketball Player Suffers Stroke While in School

Second High School Student Dies Suddenly Within a Week in Las Vegas After Suffering from Cardiac Arrest

ABC 10News producer Erica Gonzalez dies

DIED SUDDENLY

Alarming Number of Sudden Cardiac Deaths in US
Athletes Following Vaccination

25-year-old former college football player dies suddenly

Amazon Worker Dies After Collapsing on Floor Unnoticed
17-Year-Old Gillette Basketball Player Dies Unexpectedly On Monday

Adam Rich, Child Actor Who Starred on 'Fight Is Enough,' Dead at 54

Lisa Marie Presley, daughter of Elvis, dies aged 54

Former First Round NFL Pick Rashard Anderson Dead At 45

Rugby League in mourning after sudden death of 18-year-old Salford Red Devils hooker who represented England Community Lions at youth level

Uche Nwaneri, former Jaguars offensive lineman, dead at 38

High School Student Develops Blood Clots in His Brain 9 Days Following Vaccine - Medical Records State "Adverse Reaction to the Vaccine"

Regina's sports community mourns sudden passing of Theo Gibbs

The sports community was left reeling by sudden death of 18-year-old Theo Gibbs.

Gregory Yee, former Post and Courier breaking news and crime reporter, dies at 33

DIED SUDDENLY

Heather Kleiman Lansing MI, Longtime Grand Ledge High School athletic trainer has died

Teenage boy dies on Christmas Day after suffering series of strokes

Birch Run police officer suddenly dies

Colleagues remember Lowcountry attorney David Aylor after his sudden death

West Side arts organization reeling after leader Jon Veal dies at 30

Eastchester father, owner of pizzerias suddenly dies at 52

Taylor Brice Lejeune, TikTok Star Known as Waffler69, Dead at 33

95 Percent of Corpses Had Received COVID Vaccination Within 2 Weeks of Death: Funeral Director

Former Detroit news anchor dies one day after receiving COVID-19 vaccine

St. Catharines social justice advocate dies suddenly on Dec. 31

6-Year-Old Canadian Child Dies Suddenly After Suffering "Massive Stroke" – Doctor Diagnosed her with "Myocarditis due to the Flu"

DIED SUDDENLY

Heartbreak as another young ice hockey player dies suddenly after suffering stroke complications

Guggenheim Partners CIO Scott Miner dies unexpectedly

City of Klawock's police chief dies unexpectedly

Sudden Death Of Devoted Sussex County Mom At 46 Prompts Wave Of Community Support

Body positivity TikToker Megha Thakur dies suddenly and unexpectedly'

Basketball community mourns sudden and unexpected death of 17-year-old Max Sorenson

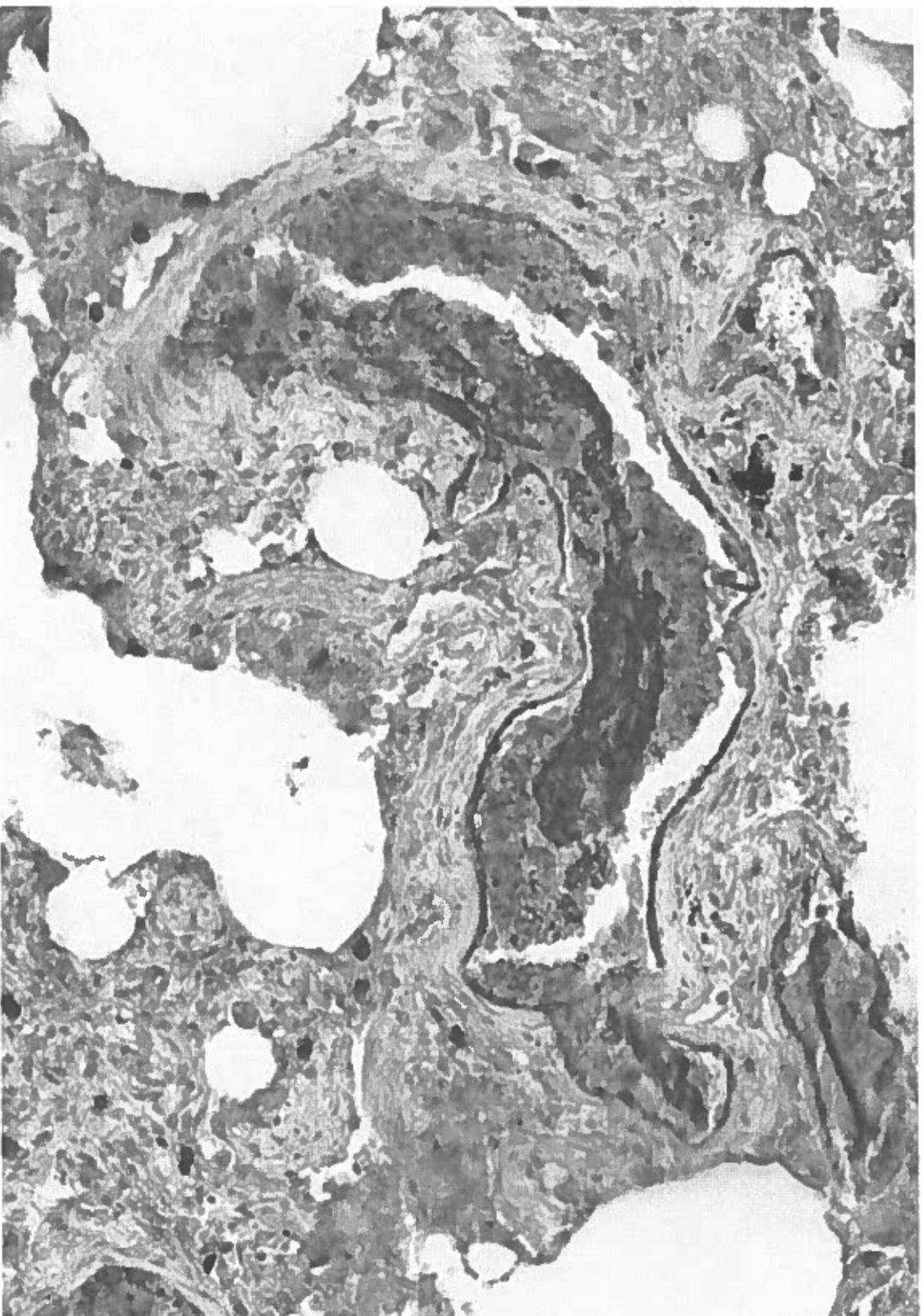
Heartbreak as Oklahoma State University student, 20, dies unexpectedly before Christmas

'Sweet and bright' girl, 15, dies suddenly after collapsing at school

'One in a zillion' mum-of-four dies suddenly after cardiac arrest

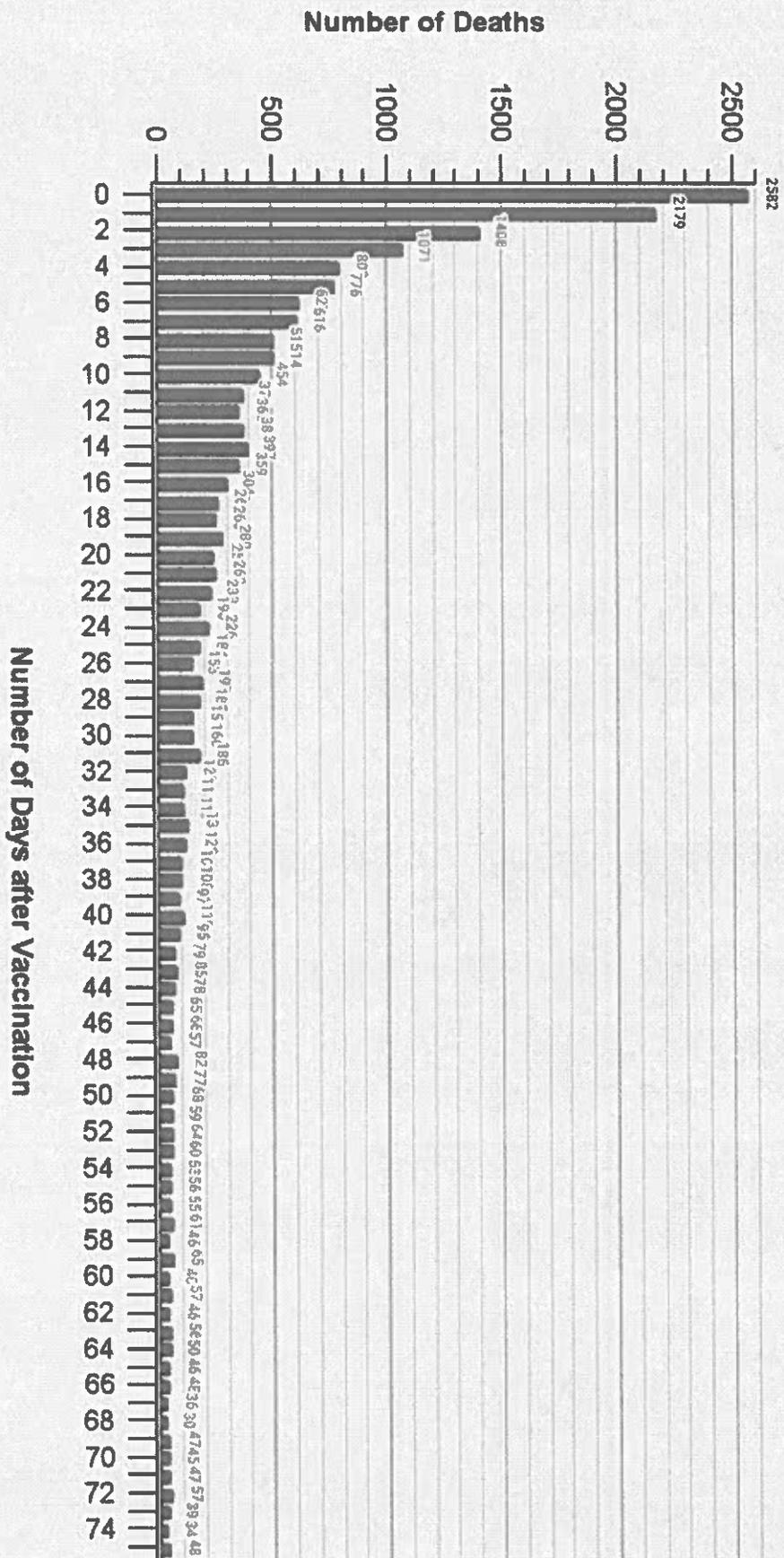
Auto Manager, Aspiring Tattoo Artist Mason Werkheiser Of Northampton County Dies Suddenly, 21

Intravascular Thrombus- Spike Protein Positive



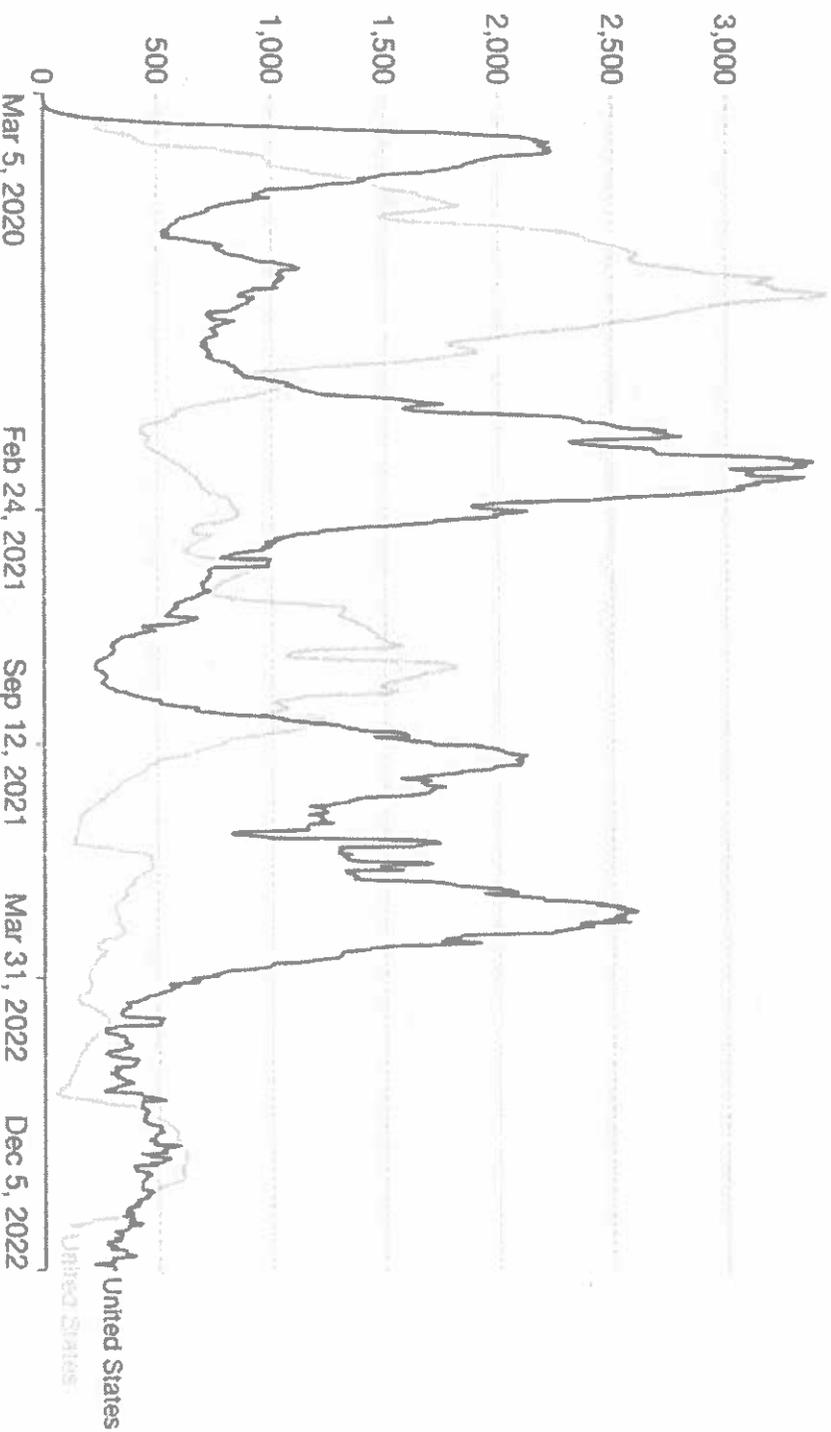
Number of Deaths by Days After COVID-19 Vaccination

Data obtained from CDC's VAERS



Death after the Vaccine may Peak after 5 months

% increase in daily deaths from 2020 to 2021, SSA Master death file, Ages 15-55
Max Increase 60% on 9/9/2021



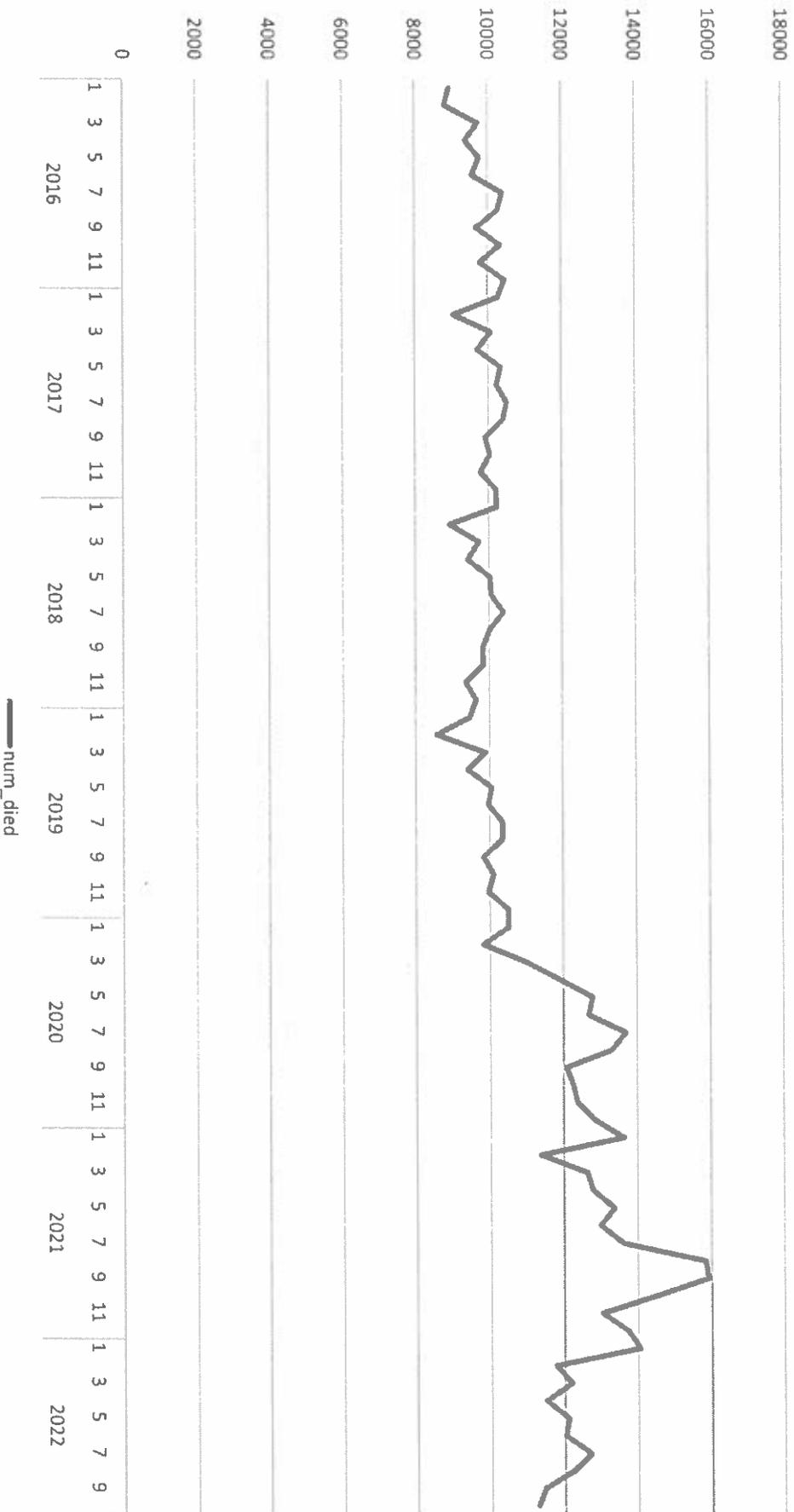
Source: Johns Hopkins University CSSE COVID-19 Data

CC BY

Daily Covid-19 Deaths (dark green) VS Daily Covid-19
Vaccines Administered (light green)

Death after the Vaccine may Peak after 5-7 months

SSA Master death file, Monthly Deaths, Ages 18-40



Life Insurance Payouts Jumped 163% During First Year Of Vaccine Rollout

📅 June 19, 2022 📌 NEWS

Authored by Margaret Menge via Crossroads Report,

Five months after breaking the story of the CEO of One America insurance company saying **deaths among working people ages 18-64 were up 40% in the third quarter of 2021**, I can report that a **much larger life insurance company, Lincoln National, reported a 163% increase in death benefits paid out under its group life insurance policies in 2021.**

This is according to the annual statements filed with state insurance departments — statements that were provided exclusively to Crossroads Report in response to public records requests.

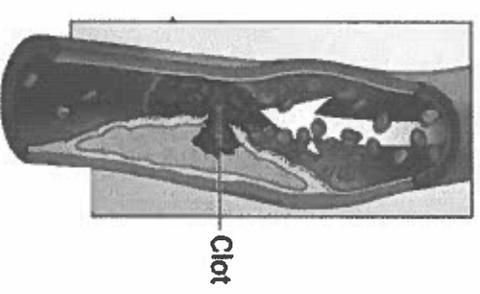
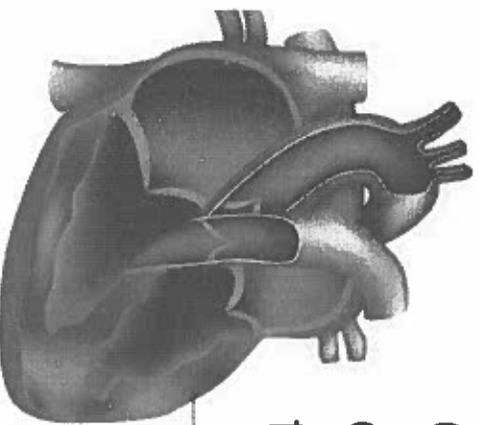
The reports show a more extreme situation than the 40% increase in deaths in the third quarter of 2021 that was cited in late December by One America CEO Scott Davison — an increase that he said was industry-wide and that he described at the time as “unheard of” and “huge, huge numbers” and the highest death rates that have *ever been seen in the history of the life insurance business.*

The annual statements for Lincoln National Life Insurance Company show that the company paid out in death benefits under group life insurance policies a little over **\$500 million** in 2019, about **\$548 million** in 2020, and a stunning **\$1.4 billion** in 2021.

Revised time Course of Vaccine Deaths

Major vessel thrombosis

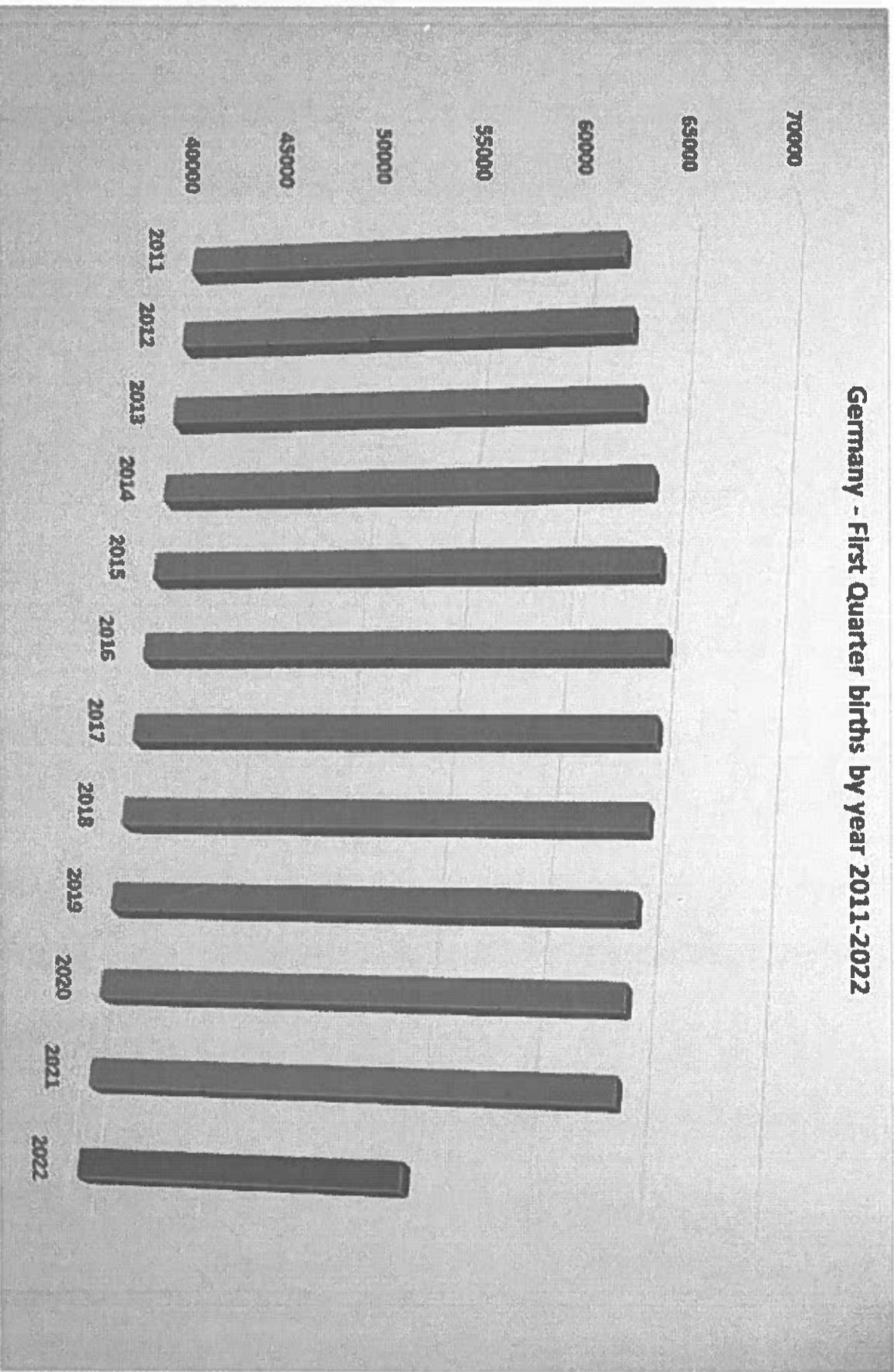
Catecholamine induced
coagulative necrosis
followed by myocarditis



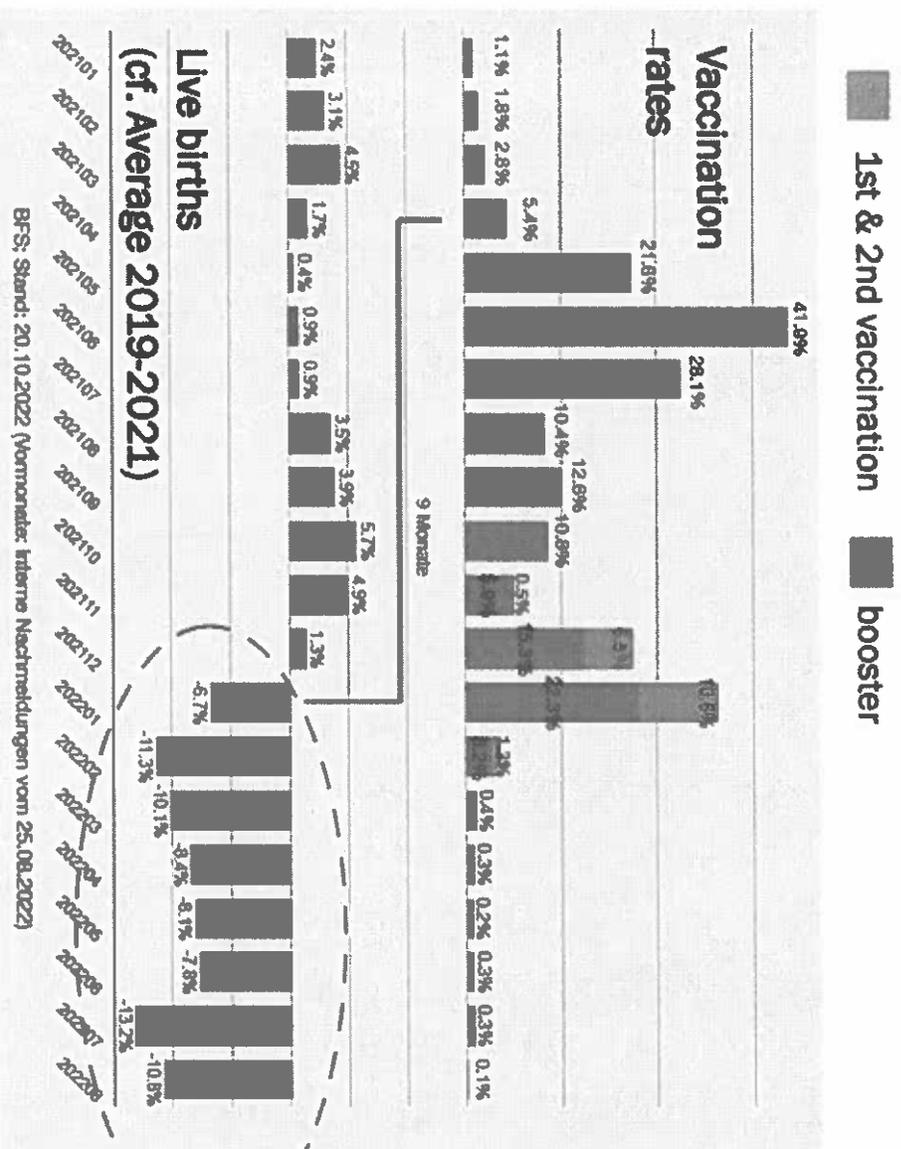
Day 1-14

4-6 Months

Germany - First Quarter Births by year 2011-2022

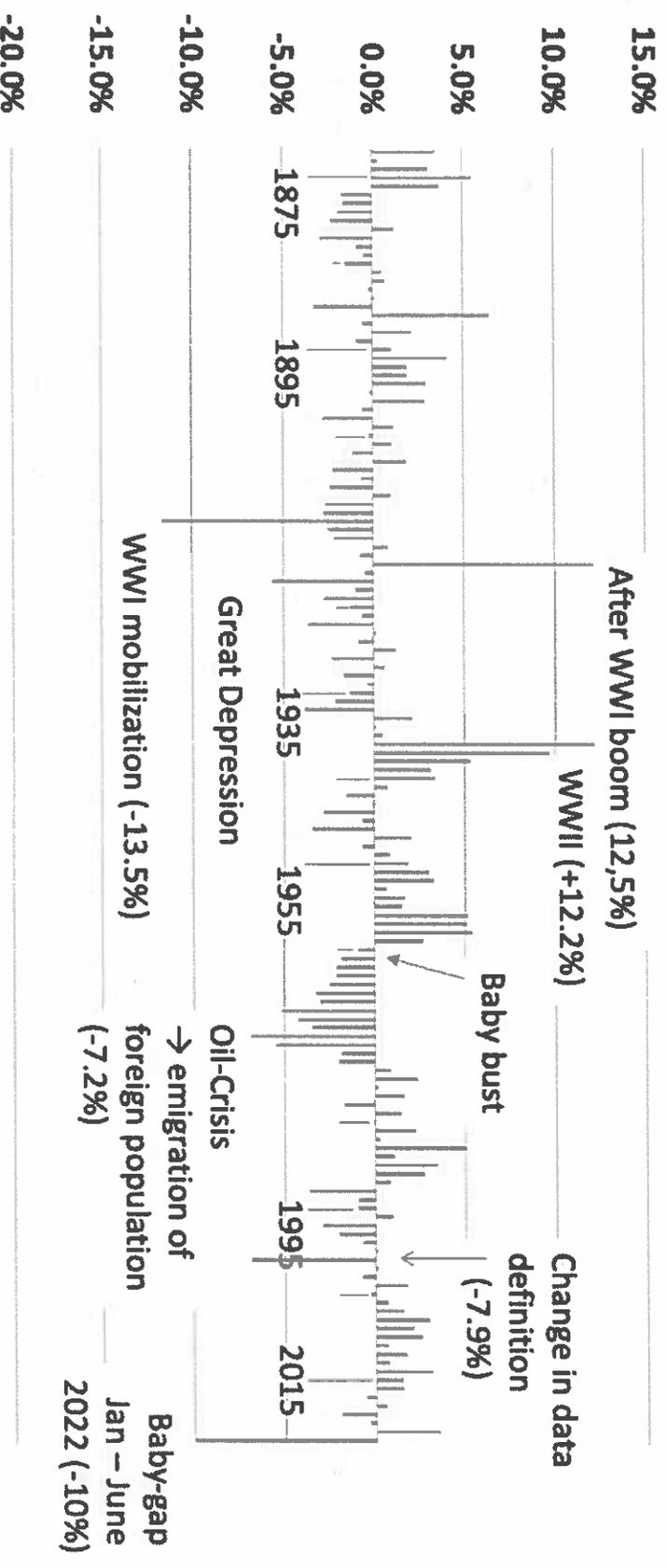


Massive decline in births



- Birth decline 9 months after vaccination peak
- Average decline -10%
- Strongest birth rate decline in over 100 years

Annual change in the number of births (1872 - 2022)





Florida Surgeon General Dr. Joseph Ladapo in Clearwater, Fla. on Oct. 15, 2022. (York Du/The Epoch Times)

PREMIUM

VACCINES & SAFETY

Florida Surgeon General: Data Show Messenger RNA COVID-19 Vaccines Shouldn't Be Given to Young Men

By [Zachary Stieber](#) and [Jan Jekielek](#)

October 18, 2022 Updated: October 18, 2022

A 

 Print

COVID-19 vaccines can kill you

COVID-19 vaccines increase risk for infection, serious illness, and death

We made a mistake. We shouldn't have recommended that people get the shots. Sorry about that.

All vaccines are unsafe. Andrew Wakefield was right.



Data from December 2000 to July 2021

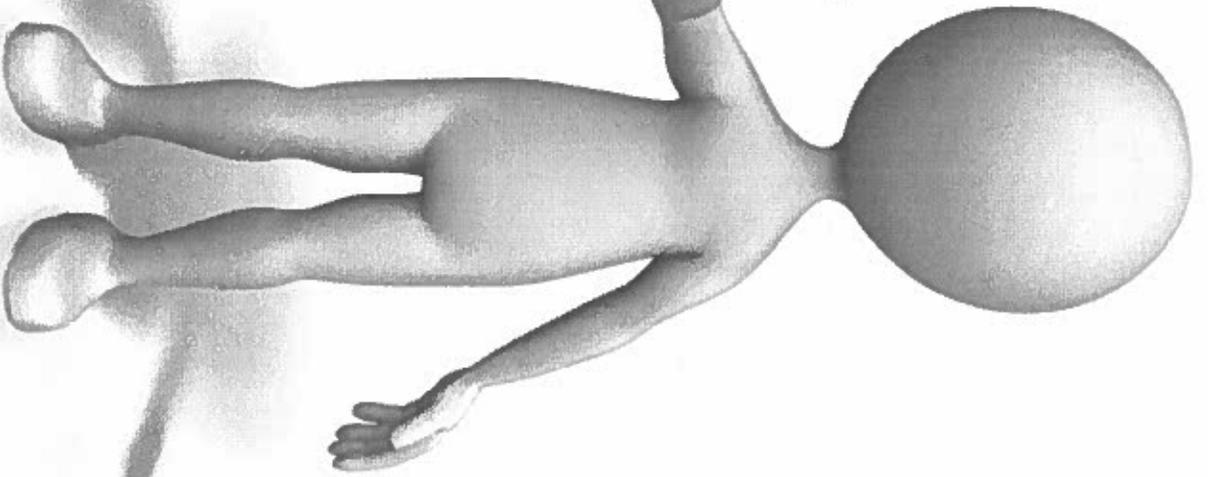
bit.ly/MMWR7043e2



19/2/2021

MMWR

Thank you



In a lawsuit against the US Health and Human Resource Services, according to the US Health and Human Resource Services, people under the age of 70 have a 99.97% overall survival rate of Covid-19. This is one in thousands. Zero healthy children have died from Covid.

Part of one of the lawsuits against the US Health and Human Resource Services states: "The emergency declaration and its multiple renewals are illegal, since in fact there is no underlying emergency. Assuming the accuracy of Defendants' COVID-19 death data, SARSCoV-2 has an overall survivability rate of 99.8% globally, which increases to 99.97% for persons under the age of 70, on a par with the seasonal flu. However, Defendants' data is deliberately inflated. On March 24, 2020, DHHS changed the rules applicable to coroners and others responsible for producing death certificates and making "cause of death" determinations — exclusively for COVID-19. The rule change states: "COVID-19 should be reported on the death certificate for all decedents where the disease caused or is assumed to have caused or contributed to death." In fact, DHHS statistics show that 95% of deaths classed as "COVID-19 deaths" involve an average of four additional co-morbidities. The CDC knew "...the rules for coding and selection of the underlying cause of death are expected to result in COVID-19 being the underlying cause more often than not." - <https://renz-law.com/wp-content/uploads/M-for-PI-file-stamped.pdf> – link to lawsuit

<https://www.nationalreview.com/corner/a-childs-chances-of-surviving-a-covid-19-infection-99-995-percent/> **A Child's Chances of Surviving a COVID-19 Infection: 99.995 Percent** – "Via the *Wall Street Journal*, a statistic from a new comprehensive study that should be cited early and often whenever anyone starts making noises about [reverting back to distance learning when kids go back to school in autumn](#): "Some 99.995 percent of the 469,982 children in England who were infected during the year examined by researchers survived." Underlying health conditions, especially serious brain or nerve-related disabilities, increased the risk of dying of COVID-19. No child with a stand-alone diagnosis of asthma, diabetes, epilepsy or Down syndrome died from COVID-19."

- X Covid Vaccine Adverse events reported to VAERS for Children Age 5-17 as of 6/17/22: Deaths: 116 / Permanently Disabled: 461 / Myocarditis: 1,335
- X The Covid-19 vaccines have more adverse events reported than all other existing vaccines combined since the vaccine program began.
- X In the Pfizer trials for children age 6 months to 4 years, over 2/3 of the vaccine group dropped out and did not complete the trial. WHY?
- X In the Moderna trials, severe adverse events were 500% (6-23 months) and 342% (2–5-year-olds) higher than the placebo. (Some European countries are limiting the use of this vaccine in younger ages amid concerns over cardiovascular side effects.)

X The original Pfizer vaccine trial data released, under court order showed over 1,200 deaths and over 1,000 different adverse events in the first 90 days.

X NO trial data on the co-administration of the COVID-19 shots with other childhood injections and likelihood of interactions and complications are unknown.

<https://www.fda.gov/media/159195/download>

<https://rumble.com/vw1dkp-rfk-jr.-the-vaers-under-system-undercounts-vaccine-injuries-by-as-much-as-9.html> - VAERS under reporting by as much as 99%

Go to www.openvaers.com – click on the 3 lines at the top left – click on the “Red Box” Summaries.

Lazarus Report <https://decodingthedeception.com/document-knowledge-base-2/the-lazarus-report/> - scroll down to the results.

Why did the FDA want to hide the Pfizer trial findings for 75 years? Why did they have to be FOIA'd for the information when they were claiming to be transparent? Why did they want to redact information from the report even after a Texas judge ordered them to be released?

There was a Federal court case in Texas that ended in January of 2022. The FDA wanted the Pfizer documents sealed until 2097 (75 years). This was denied by a judge and all the documents will be released within 8 months. The first 55,000 documents were released on March 1, 2022. See the link below. At the bottom of the article there is a link to read the judge's order.

<https://www.fdanews.com/articles/206113-federal-judge-tells-fda-it-must-make-public-55000-pages-a-month-of-pfizer-vaccine-data>

<https://icandecide.org/press-release/breaking-news-ican-obtains-court-order-requiring-cdc-to-release-v-safe-data-that-includes-over-137-million-health-entries-made-after-covid-19-vaccines/> “ICAN OBTAINS COURT ORDER REQUIRING CDC TO RELEASE V-SAFE DATA THAT INCLUDES OVER 137 MILLION HEALTH ENTRIES MADE AFTER COVID-19 VACCINES”

Why did the CDC have to be sued twice to release this data? [HTTPS://ICANDECIDE.ORG/V-SAFE-DATA/](https://icandecide.org/v-safe-data/) - see data. Out of 10.1 million participants, 1.2 million were unable to do their normal activities, 1.3 million were unable to work or attend school, and .8 million had to get care from a doctor or healthcare professional.

I went to a school board meeting almost a year ago. Why were they discussing having funds for athletes with cardiovascular issues? I have not seen this in all the years that my children went to public schools. My youngest graduated in 2018.

Remember the Swine flu in 2009? 25 people died and at least 500 got Gillane Barre' from the vaccine and the FDA stopped its sale and use for the flu. 1223 people died in the Covid vaccine

Pfizer trials as of February 28, 2021 – see page 7 (hold up report). Why weren't the vaccines stopped in February 2021? Why did the FDA have to be FOIA'd for this information?
<https://rumble.com/v1au4d5-60-minutes-swine-flu-1976-corruption.html> - Swine Flu Vaccine on 60 minutes

<https://www.latimes.com/archives/la-xpm-2009-apr-27-sci-swine-history27-story.html> - Gillane Barre' and 25 deaths from Swine Flu vaccine.

<https://www.publicrelationscanada.com/post/fda-pfizer-report-1223-deaths-150-000-serious-adverse-events-occurred-in-the-first-3-months> - 1223 deaths in first 3 months

To find this in the full document, go to <https://phmpt.org/pfizers-documents/> type in the search bar 5.3.6 (as seen at the top of the report I printed) – for the 1223 deaths, see page 7 (also attached), for the adverse reactions go to pages 30 – 38. Please note that these are only the side effects known as of February 28, 2021.

The DMED data (Defense Medical Epidemiology Database) report for 10 months in 2021 compared to 2016 – 2020 shows a 299.80% increase – an average of less than 1,000 reports a year to 4,086 reports in 2021. Infertility went up from an average of 2,200 – 2,300 per year to 11,748 in 10 months of 2021, a 419.40% increase in 2021. Two of my friends' daughters have not had a menstrual cycle since they had their Covid 19 shot. One of the adverse reactions my daughter has is menstrual issues. Will they be able to have children? Without having had any long-term studies, what will this do to the reproductive system of children? Why did the DOD change the data from 2016 – 2020 to reflect 2021 after Attorney Thomas Renz presented this information in a Senate hearing on January 24, 2021?

Also in the DMED Data, neurological issues increase by 968.30% in 10 months of 2021 compared to 2016 – 2020 – from an average of 80-82,000 to 863,013 in 2021.

I am sure you know what the DOD is, but do you know about DMED? DMED is the most accurate health data in the world. It is only for our military. Basically, every time a soldier or military person goes to a military doctor, they document why the soldier is there. So, if they have a migraine it is noted, if they have an ingrown toenail, it is noted... The CDC, the FDA, the WHO – all watch this data to know what is happening. On January 24, 2022, there was a Senate hearing called "COVID-19, a Second Opinion". Below is a link to one of the condensed versions. There is a link to the entire hearing at the bottom of this 30-minute video. There was also a Senate hearing in 2021 – I think last March (about suppressed early treatment).

<https://capefearbeacon.com/senator-ron-johnsons-second-opinion-panel-carpet-bombs-truth-on-the-covid-19-response/>

Seen in the above video, Attorney Thomas Renz brought some of the DMED data to the Senate hearing in January. The day after the Senate Hearing, the DOD shut down DMED and changed all the data from 2016 – 2020 to reflect 2021 and stated that all the information from 2016 - 2020 was incorrect. Attorney Thomas Renz with a group of lawyers have lawsuits based on this data. All this information can be found in the link below. Scroll to the bottom and click on

“NEXT DMED DATA” – but you really need to read this page before you click for the data. I have also attached a PDF (excel spreadsheet) of this data so that you can see it all in one place.

<https://renz-law.com/attorney-tom-renz-whistleblowers-dmed-defense-medical-epidemiology-database-reveals-incredibly-disturbing-spikes-in-diseases-infertility-injuries-across-the-board-after-the-military-was-forced-to/>

This is also from the DMED Data:

“Day 0 – 555 deaths after receiving their 1st dose of the COVID vaccine

Day 1 – 1,137 new deaths

Day 2 – 1,492 new deaths

Day 3 – 1,654 new deaths

Day 4 – 1,750 new deaths

Day 5 – 1,876 new deaths” – and it goes on – you can find this information here:

<https://renz-law.com/nuremburg20/>

Why is information being censored? The U.S. House Covid Select Committee Hearing was in the beginning of March. Why was it removed from YouTube?

<https://www.youtube.com/live/YAeRV81LdG8> - YouTube U.S. House Select Committee Hearing
“This video has been removed by the uploader” WHY? IT’S A SENATE HEARING. What are we not supposed to hear?

Zero healthy children have died from Covid. What are the chances of them having neurological issues, or reproductive issues, or heart issues from these shots? Keep these shots off the childhood schedule!

I have emailed and am leaving a copy with documentation to back all my statements.

In a lawsuit against the US Health and Human Resource Services, according to the US Health and Human Resource Services, people under the age of 70 have a 99.97% overall survival rate of Covid-19. Zero healthy children have died from Covid.

Covid Vaccine Adverse events reported to VAERS for Children Aged 5-17 as of June 17, 2022: 116 Deaths, 461 Permanently Disabled, 1,335 with Myocarditis.

Remember the Swine flu in 2009? 25 people died and approximately 500 got Gillane Barre' from the vaccine and the FDA stopped its sale and use for the flu. 1223 people died in the Covid vaccine Pfizer trials as of February 28, 2021 – see page 7 (hold up report). Why weren't the vaccines stopped in February 2021? Why did the FDA have to be FOIA'd for this information?

The Covid-19 vaccines have more adverse events reported than all other existing vaccines combined since the vaccine program began.

Why did the FDA want to hide the Pfizer trial findings for 75 years? Why did they have to be FOIA'd for the information when they were claiming to be transparent? Why did they want to redact information from the report even after a Texas judge ordered them to be released?

Why did the CDC have to be sued twice to release the V-Safe data? This is the CDC's data.

I went to a school board meeting almost a year ago – in spring 2022. Why were they discussing having funds for athletes that have cardiovascular issues? I have not seen this in all the years that my children when to public schools. My youngest graduated in 2018.

The Department of Defense's report for 10 months in 2021 compared to 2016 – 2020 shows a 299% increase in Ovarian Dysfunction – an average of 934 reports a year to 4,086 reports in 2021. Infertility went up from an average of 2,274 per year to 11,748 in 10 months of 2021, a 419% increase in 2021. What will this shot do to the reproductive systems of children? Why did the DOD change the data from 2016 – 2020 to reflect 2021 after Attorney Thomas Renz presented this information in a Senate hearing on January 24, 2021?

Neurological issues increase by 968% in 10 months of 2021 compared to 2016 – 2020 – from an average of 82,000 a year to 863,000 in 2021.

Zero healthy children have died from Covid. What are the chances of them having neurological issues, or reproductive issues, or heart issues from these shots? Keep these shots off the childhood schedule.

www.phmp.org

click on documents

Search 5.3.6 go to page 7 for 1223-fatal

BNT162b2

5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

**5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT
REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021**

Report Prepared by:

Worldwide Safety

Pfizer

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Page 1

FDA-CBER-2021-5683-0000054

Table 1 below presents the main characteristics of the overall cases.

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

	Characteristics	Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17	175 ^a
	18-30	4953
	31-50	13886
	51-64	7884
	65-74	3098
	≥ 75	5214
	Unknown	6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in **Figure 1**, the System Organ Classes (SOCs) that contained the greatest number ($\geq 2\%$) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).



In Your Mission statement

You “serve as the primary advocate and representative of the citizens of the Commonwealth in achieving optimal health.”

Considering injecting this mRNA Experiment into VA Children is the polar opposite of your Mission

You Also LIST C “Cases”, and Number of V’s given, BUT You do NOT LIST Any of the Side Effects OR Reported V Injuries – This is Unacceptable.

Again, I Opposed the C19 V being considered, or added to the Childhood Vaccine Schedule in VA.

Thank You

Ann Parker
Campbell County School Board

Vision

Become the healthiest state in the nation.

With Proven VAERS Deaths/Injuries as
result of C19 V – Can't accomplish

Mission

To protect the health and promote the well-
being of all people in Virginia.

C19 V in Children would do the opposite

Core Values

Our culture values service, equity and
making data-informed decisions.

Equity? The C19 V has massive Data proving our African-American Citizens suffer the
worst from this shot. This alone should Support a Pause on All C 19 V's.

As a mother of a V injured Child I Object to Adding C19 V to the Childhood Schedule

The CDC maintains Children are the Lowest Demographic for Risk of Illness

+ a slide shown today shows decrease in cases

What Determinations are used to Decide a New V is Added? Your Current VA Childhood V Schedule Clearly States **“Vaccine-Preventable Diseases and the Vaccines that Prevent Them”**

The CDC and this Board have admitted the C19 V does NOT PREVENT Infection

Which makes it CLEAR, the C19 V Does NOT meet the Criteria for Approval - PERIOD

From the Onset of this Issue – This Board and VDH should have been Informing the Public of the Side Effects of the V’s, and the publics’ Right to Informed Consent, as well as their Right to Apply for a Waiver to OPT OUT.

Yet Richmond remained Silent – Inaction is Still Action, which renders each of you Complicit and Liable.

*IF You move forward, you MUST REQUIRE –
DISCLOSURE of V Side Effects 1st, followed by
SIGNED Parental Consent, PRIOR to Injection.*

I have 3 sons, Not once, has a Hospital or Doctor provided me any Information until After the injections were given. Nor was I informed of Waivers or Opt Out Options. As a result, 1 of my sons is on the Spectrum and will need interventions for life.

If only this Board, the VDH or 1 Medical Professional had told me I had a choice.

You are still Running Promotions for

Wear a Face Covering

For your safety and the safety of others. [Download printable promotional posters](#)

& Promote Getting a V

Therefore You MUST also provide Promotional Materials and Require they be posted where any V's or Medical Care is given.

These posters can simply say...

**“INFORMED CONSENT is YOUR RIGHT –
PRIOR TO ANY TREATMENTS”**

www.phmp.org
click on documents
search 5.3.6 - go to page 7 for 1223 fatal

BNT162b2

5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

Report Prepared by:

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I'm a mother and a grandmother. I have vaccine injured friends and family, including my daughter, a cousin having heart surgery ~~and~~ and my husband's uncle died of a heart attack 2 days after the booster. I could go on.
I have emailed and am leaving a copy with documentation to back all my statements.

In a lawsuit against the US Health and Human Resource Services, according to the US Health and Human Resource Services, people under the age of 70 have a 99.97% overall survival rate of Covid-19. Zero healthy children have died from Covid.

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Why did the CDC have to be sued twice to release the V-Safe data? This is the CDC's data. *There were 10,108,273 individual users and 6,458,761 health impacts reported*
I went to a school board meeting almost a year ago – in spring 2022. Why were they discussing having funds for athletes that have cardiovascular issues? I have not seen this in all the years that my children when to public schools. My youngest graduated in 2018.

The Department of Defense's report for 10 months in 2021 compared to 2016 – 2020 shows a 299% increase in Ovarian Dysfunction – an average of 934 reports a year to 4,086 reports in 2021. Infertility went up from an average of 2,274 per year to 11,748 in 10 months of 2021, a 419% increase in 2021. What will this shot do to the reproductive systems of children? Why did the DOD change the data from 2016 – 2020 to reflect 2021 after Attorney Thomas Renz presented this information in a Senate hearing on January 24, 2021?

Neurological issues increase by 968% in 10 months of 2021 compared to 2016 – 2020 – from an average of 82,000 a year to 863,000 in 2021.

Zero healthy children have died from Covid. What are the chances of them having neurological issues, or reproductive issues, or heart issues from these shots? Keep these shots off the childhood schedule.

with 89% or 8 million requiring medical care,
1.2 million unable to do normal activities
1.3 million missed work/school
1.8 million required medical care

Barbara Henry, Williamsburg

I am here again today to oppose the "Covid 19" experimental gene therapy injection proposed for children, and I hope that my comments are unnecessary at this point; that it has been decided that putting these injections on the childhood schedule is not only useless, but dangerous.

As you certainly must know by now, this product neither protects against infection, nor prevents transmission. I repeat. Neither protects against infection, nor prevents transmission

Unless you've been highly pressured to promote this product, I find it amazing that this non- FDA approved, toxic, spectacularly failed experimental product is even still around. The safety signals are off the charts!

Never reached herd immunity
Covid is over. What's the "vaccine" for???

Children were never susceptible to Covid.

The shots don't work. We know the shot's effectiveness wanes after three months... are we going to vaccinate four times a year? How stupid is that?

The shots have proven to have NEGATIVE EFFICACY. It's the vaccinated that are getting sick.

The reports from around the world are simply staggering. Fertility issues, miscarriages, myocarditis, brain inflammation, strokes, heart attacks, blood clots, sudden virulent cancers, EVEN IN YOUNG CHILDREN, and so much more.

I personally know several unfortunate individuals whose health has been severely compromised, and one death, shortly after accepting this "SAFE AND EFFECTIVE" shot.

AND MOST IMPORTANTLY OF ALL: HOW DO YOU HAVE INFORMED CONSENT WITH SECRET INGREDIENTS? THIS PRODUCT IS ANYTHING, BUT "SAFE AND EFFECTIVE".

We look to this Board to protect our Health. Putting this mRNA EXPERIMENTAL, non-FDA approved, mystery gene therapy injection on the childhood immunization schedule is literally, a crime against humanity.

The future of VA depends on the health of the children. I believe we can agree on this fact. Today, by the time a baby is 6 months old if their parents are following the CDC schedule, they will likely have taken all the jabs many of you in this room have had in your entire lives!!

You've been indoctrinated by Rockefeller institutions that vaccines save lives. However, you're ignoring the fact that children are sicker today than ever before! This explains why you've added a **Suddenly Died Young** coordinator position doesn't it?!?

If you have been promoting or using products known as "Covid-19 vaccines" on patients since December 2020, you have been participating in fraud, mass murder and war crimes, because medical countermeasures (MCMs), covered countermeasures, and prototype products are DOD-contracted bioweapons intended and effective for injuring, sickening, and killing recipients.

You may not have known or understood your participation in fraud, mass murder and war crimes before today. I am now informing you; you have now been given notice.

CEASE AND DESIST from committing acts of additional fraud, mass murder and war crimes, effective as of the date of this notice, and immediately close your vaccination and immunization programs.

If you still think we are wrong it's because you're listening to the echo-chamber of lies- safe & effective and only concerned about collecting a pay check, it's time you hear from a few of the thousands of doctors calling to STOP THE SHOTS!

This video was created seven months ago now! <https://rumble.com/v1ees0f-right-docs-of-history-strike-back-stop-the-shots.html>

The Great Barrington declaration document alone was **signed by 47 thousand Dr's and over 16 thousand medical and public health scientists.** [Great Barrington Declaration \(gbdeclaration.org\)](http://gbdeclaration.org)

80 Pages of Peer Reviewed Medical Papers Submitted To Various Medical Journals, Evidencing A Multitude Of Adverse Events In Covid-19 Vaccine Recipients
[Updated Peer Reviewed medical papers submitted to various medical \(healthindependencealliance.com\)](http://healthindependencealliance.com)

Doris Knick 3/23/23

Signatures

As infectious disease epidemiologists and public health scientists we have grave concerns about the damaging physical and mental health impacts of the prevailing COVID-19 policies, and recommend an approach we call Focused Protection.

Total Signatures

936,437

Concerned Citizens

872,942

Medical & Public Health Scientists

16,039

Medical practitioners

47,456

[READ THE DECLARATION](#)

[SIGN THE DECLARATION](#)

[READ THE FREQUENTLY ASKED QUESTIONS](#)

Acute Transverse Myelitis	46	57	48	35	34	202	494.10%
Seizures	196	148	130	150	123	489	297.60%
Narcolepsy Cataplexy	995	898	864	830	766	2,097	351.70%
Rhabdomyolysis	706	696	740	755	669	5,162	671.60%
Multiple Sclerosis	479	391	367	400	385	2750	614.30%
Migraine	15,734	15,714	16,462	17,116	16,311	73,490	351.70%
Blood Disorders	11,533	11,122	10,851	11,773	11,429	34,486	204.10%
Hypertension	2,308	2,323	2,363	2,392	2,415	53,846	2129.60%
Cerebral Infarct	887	848	858	888	887	3,438	293.70%

← cousin + don't understand

Stroke → friend's mom
friend's dad

heart attack → 2 of brother-in-law's coworkers
accountant's father (died)
family friend
husband's uncle - died

miscarriages → several of niece's friends

neonatal death (in Pfizer documents)
- friend's niece - twin babies died

Let Doctors
Be Doctors!

There are way too many "coincidences"

Stop the Shots!!!

Medical Freedom!

SB 793
792
833
972
876

HB 1397
2160
2276
2280

www.phmp.org
click on "documents"
Search 5.3.6

BNT162b2

5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

pgs. 30-38 - Adverse Event Reports

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

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APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Anti-acetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

coronary; Arthralgia; Arthritis; Arthritis enteropathic; Ascites; Aseptic cavernous sinus thrombosis; Aspartate aminotransferase abnormal; Aspartate aminotransferase increased; Aspartate-glutamate-transporter deficiency; AST to platelet ratio index increased; AST/ALT ratio abnormal; Asthma; Asymptomatic COVID-19; Ataxia; Atheroembolism; Atonic seizures; Atrial thrombosis; Atrophic thyroiditis; Atypical benign partial epilepsy; Atypical pneumonia; Aura; Autoantibody positive; Autoimmune anaemia; Autoimmune aplastic anaemia; Autoimmune arthritis; Autoimmune blistering disease; Autoimmune cholangitis; Autoimmune colitis; Autoimmune demyelinating disease; Autoimmune dermatitis; Autoimmune disorder; Autoimmune encephalopathy; Autoimmune endocrine disorder; Autoimmune enteropathy; Autoimmune eye disorder; Autoimmune haemolytic anaemia; Autoimmune heparin-induced thrombocytopenia; Autoimmune hepatitis; Autoimmune hyperlipidaemia; Autoimmune hypothyroidism; Autoimmune inner ear disease; Autoimmune lung disease; Autoimmune lymphoproliferative syndrome; Autoimmune myocarditis; Autoimmune myositis; Autoimmune nephritis; Autoimmune neuropathy; Autoimmune neutropenia; Autoimmune pancreatitis; Autoimmune pancytopenia; Autoimmune pericarditis; Autoimmune retinopathy; Autoimmune thyroid disorder; Autoimmune thyroiditis; Autoimmune uveitis; Autoinflammation with infantile enterocolitis; Autoinflammatory disease; Automatism epileptic; Autonomic nervous system imbalance; Autonomic seizure; Axial spondyloarthritis; Axillary vein thrombosis; Axonal and demyelinating polyneuropathy; Axonal neuropathy; Bacterascites; Baltic myoclonic epilepsy; Band sensation; Basedow's disease; Basilar artery thrombosis; Basophilopenia; B-cell aplasia; Behcet's syndrome; Benign ethnic neutropenia; Benign familial neonatal convulsions; Benign familial pemphigus; Benign rolandic epilepsy; Beta-2 glycoprotein antibody positive; Bickerstaff's encephalitis; Bile output abnormal; Bile output decreased; Biliary ascites; Bilirubin conjugated abnormal; Bilirubin conjugated increased; Bilirubin urine present; Biopsy liver abnormal; Biotinidase deficiency; Birdshot chorioretinopathy; Blood alkaline phosphatase abnormal; Blood alkaline phosphatase increased; Blood bilirubin abnormal; Blood bilirubin increased; Blood bilirubin unconjugated increased; Blood cholinesterase abnormal; Blood cholinesterase decreased; Blood pressure decreased; Blood pressure diastolic decreased; Blood pressure systolic decreased; Blue toe syndrome; Brachiocephalic vein thrombosis; Brain stem embolism; Brain stem thrombosis; Bromsulphthalein test abnormal; Bronchial oedema; Bronchitis; Bronchitis mycoplasmal; Bronchitis viral; Bronchopulmonary aspergillosis allergic; Bronchospasm; Budd-Chiari syndrome; Bulbar palsy; Butterfly rash; C1q nephropathy; Caesarean section; Calcium embolism; Capillaritis; Caplan's syndrome; Cardiac amyloidosis; Cardiac arrest; Cardiac failure; Cardiac failure acute; Cardiac sarcoidosis; Cardiac ventricular thrombosis; Cardiogenic shock; Cardiolipin antibody positive; Cardiopulmonary failure; Cardio-respiratory arrest; Cardio-respiratory distress; Cardiovascular insufficiency; Carotid arterial embolus; Carotid artery thrombosis; Cataplexy; Catheter site thrombosis; Catheter site vasculitis; Cavernous sinus thrombosis; CDKL5 deficiency disorder; CEC syndrome; Cement embolism; Central nervous system lupus; Central nervous system vasculitis; Cerebellar artery thrombosis; Cerebellar embolism; Cerebral amyloid angiopathy; Cerebral arteritis; Cerebral artery embolism; Cerebral artery thrombosis; Cerebral gas embolism; Cerebral microembolism; Cerebral septic infarct; Cerebral thrombosis; Cerebral venous sinus thrombosis; Cerebral venous thrombosis; Cerebrospinal thrombotic

tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

infection; Herpes zoster; Herpes zoster cutaneous disseminated; Herpes zoster infection neurological; Herpes zoster meningitis; Herpes zoster meningoencephalitis; Herpes zoster meningomyelitis; Herpes zoster meningoradiculitis; Herpes zoster necrotising retinopathy; Herpes zoster oticus; Herpes zoster pharyngitis; Herpes zoster reactivation; Herpetic radiculopathy; Histone antibody positive; Hoigne's syndrome; Human herpesvirus 6 encephalitis; Human herpesvirus 6 infection; Human herpesvirus 6 infection reactivation; Human herpesvirus 7 infection; Human herpesvirus 8 infection; Hyperammonaemia; Hyperbilirubinaemia; Hypercholia; Hypergammaglobulinaemia benign monoclonal; Hyperglycaemic seizure; Hypersensitivity; Hypersensitivity vasculitis; Hyperthyroidism; Hypertransaminaemia; Hyperventilation; Hypoalbuminaemia; Hypocalcaemic seizure; Hypogammaglobulinaemia; Hypoglossal nerve paralysis; Hypoglossal nerve paresis; Hypoglycaemic seizure; Hyponatraemic seizure; Hypotension; Hypotensive crisis; Hypothenar hammer syndrome; Hypothyroidism; Hypoxia; Idiopathic CD4 lymphocytopenia; Idiopathic generalised epilepsy; Idiopathic interstitial pneumonia; Idiopathic neutropenia; Idiopathic pulmonary fibrosis; IgA nephropathy; IgM nephropathy; Iliad nerve paralysis; Iliad nerve paresis; Iliac artery embolism; Immune thrombocytopenia; Immune-mediated adverse reaction; Immune-mediated cholangitis; Immune-mediated cholestasis; Immune-mediated cytopenia; Immune-mediated Encephalitis; Immune-mediated encephalopathy; Immune-mediated endocrinopathy; Immune-mediated enterocolitis; Immune-mediated gastritis; Immune-mediated hepatic disorder; Immune-mediated hepatitis; Immune-mediated hyperthyroidism; Immune-mediated hypothyroidism; Immune-mediated myocarditis; Immune-mediated myositis; Immune-mediated nephritis; Immune-mediated neuropathy; Immune-mediated pancreatitis; Immune-mediated pneumonitis; Immune-mediated renal disorder; Immune-mediated thyroiditis; Immune-mediated uveitis; Immunoglobulin G4 related disease; Immunoglobulins abnormal; Implant site thrombosis; Inclusion body myositis; Infantile genetic agranulocytosis; Infantile spasms; Infected vasculitis; Infective thrombosis; Inflammation; Inflammatory bowel disease; Infusion site thrombosis; Infusion site vasculitis; Injection site thrombosis; Injection site urticaria; Injection site vasculitis; Instillation site thrombosis; Insulin autoimmune syndrome; Interstitial granulomatous dermatitis; Interstitial lung disease; Intracardiac mass; Intracardiac thrombus; Intracranial pressure increased; Intrapericardial thrombosis; Intrinsic factor antibody abnormal; Intrinsic factor antibody positive; IPEX syndrome; Irregular breathing; IRVAN syndrome; IVth nerve paralysis; IVth nerve paresis; JC polyomavirus test positive; JC virus CSF test positive; Jeavons syndrome; Jugular vein embolism; Jugular vein thrombosis; Juvenile idiopathic arthritis; Juvenile myoclonic epilepsy; Juvenile polymyositis; Juvenile psoriatic arthritis; Juvenile spondyloarthritis; Kaposi sarcoma inflammatory cytokine syndrome; Kawasaki's disease; Kayser-Fleischer ring; Keratoderma blenorrhagica; Ketosis-prone diabetes mellitus; Kounis syndrome; Lafora's myoclonic epilepsy; Lamb's exereescences; Laryngeal dyspnoea; Laryngeal oedema; Laryngeal rheumatoid arthritis; Laryngospasm; Laryngotracheal oedema; Latent autoimmune diabetes in adults; LE cells present; Lemierre syndrome; Lennox-Gastaut syndrome; Leucine aminopeptidase increased; Leukoencephalomyelitis; Leukoencephalopathy; Leukopenia; Leukopenia neonatal; Lewis-Sumner syndrome; Lhermitte's sign; Lichen planopilaris; Lichen planus; Lichen sclerosus; Limbic encephalitis; Linear IgA disease; Lip oedema; Lip swelling; Liver function test abnormal; Liver function test decreased; Liver function test increased; Liver induration; Liver injury; Liver iron concentration abnormal; Liver iron concentration

increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

neuropathy; Optic perineuritis; Oral herpes; Oral lichen planus; Oropharyngeal oedema; Oropharyngeal spasm; Oropharyngeal swelling; Osmotic demyelination syndrome; Ovarian vein thrombosis; Overlap syndrome; Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection; Paget-Schroetter syndrome; Palindromic rheumatism; Palisaded neutrophilic granulomatous dermatitis; Palmoplantar keratoderma; Palpable purpura; Pancreatitis; Panencephalitis; Papillophlebitis; Paraneoplastic pneumonia; Paradoxical embolism; Parainfluenzae viral laryngotracheobronchitis; Paraneoplastic dermatomyositis; Paraneoplastic pemphigus; Paraneoplastic thrombosis; Paresis cranial nerve; Parietal cell antibody positive; Paroxysmal nocturnal haemoglobinuria; Partial seizures; Partial seizures with secondary generalisation; Patient isolation; Pelvic venous thrombosis; Pemphigoid; Pemphigus; Penile vein thrombosis; Pericarditis; Pericarditis lupus; Perihepatic discomfort; Periorbital oedema; Periorbital swelling; Peripheral artery thrombosis; Peripheral embolism; Peripheral ischaemia; Peripheral vein thrombus extension; Periportal oedema; Peritoneal fluid protein abnormal; Peritoneal fluid protein decreased; Peritoneal fluid protein increased; Peritonitis lupus; Pernicious anaemia; Petit mal epilepsy; Pharyngeal oedema; Pharyngeal swelling; Pityriasis lichenoides et varioliformis acuta; Placenta praevia; Pleuroparenchymal fibroelastosis; Pneumobilia; Pneumonia; Pneumonia adenoviral; Pneumonia cytomegaloviral; Pneumonia herpes viral; Pneumonia influenza; Pneumonia measles; Pneumonia mycoplasma; Pneumonia necrotising; Pneumonia parainfluenzae viral; Pneumonia respiratory syncytial viral; Pneumonia viral; POEMS syndrome; Polyarteritis nodosa; Polyarthritis; Polychondritis; Polyglandular autoimmune syndrome type I; Polyglandular autoimmune syndrome type II; Polyglandular autoimmune syndrome type III; Polyglandular disorder; Polymicrogyria; Polymyalgia rheumatica; Polymyositis; Polyneuropathy; Polyneuropathy idiopathic progressive; Portal pyaemia; Portal vein embolism; Portal vein flow decreased; Portal vein pressure increased; Portal vein thrombosis; Portosplenomesenteric venous thrombosis; Post procedural hypotension; Post procedural pneumonia; Post procedural pulmonary embolism; Post stroke epilepsy; Post stroke seizure; Post thrombotic retinopathy; Post thrombotic syndrome; Post viral fatigue syndrome; Postictal headache; Postictal paralysis; Postictal psychosis; Postictal state; Postoperative respiratory distress; Postoperative respiratory failure; Postoperative thrombosis; Postpartum thrombosis; Postpartum venous thrombosis; Postpericardiotomy syndrome; Post-traumatic epilepsy; Postural orthostatic tachycardia syndrome; Precerebral artery thrombosis; Pre-eclampsia; Preictal state; Premature labour; Premature menopause; Primary amyloidosis; Primary biliary cholangitis; Primary progressive multiple sclerosis; Procedural shock; Proctitis herpes; Proctitis ulcerative; Product availability issue; Product distribution issue; Product supply issue; Progressive facial hemiatrophy; Progressive multifocal leukoencephalopathy; Progressive multiple sclerosis; Progressive relapsing multiple sclerosis; Prosthetic cardiac valve thrombosis; Pruritus; Pruritus allergic; Pseudovasculitis; Psoriasis; Psoriatic arthropathy; Pulmonary amyloidosis; Pulmonary artery thrombosis; Pulmonary embolism; Pulmonary fibrosis; Pulmonary haemorrhage; Pulmonary microemboli; Pulmonary oil microembolism; Pulmonary renal syndrome; Pulmonary sarcoidosis; Pulmonary sepsis; Pulmonary thrombosis; Pulmonary tumour thrombotic microangiopathy; Pulmonary vasculitis; Pulmonary veno-occlusive disease; Pulmonary venous thrombosis; Pyoderma gangrenosum; Pyostomatitis vegetans; Pyrexia; Quarantine; Radiation leukopenia; Radiculitis

brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thromboecytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type I diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;Vllth nerve paralysis;Vllth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;Xllth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

Great Barrington Declaration

As infectious disease epidemiologists and public health scientists we have grave concerns about the damaging physical and mental health impacts of the prevailing COVID-19 policies, and recommend an approach we call Focused Protection.

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The Great Barrington Declaration

The Great Barrington Declaration – As infectious disease epidemiologists and public health scientists we have grave concerns about the damaging physical and mental health impacts of the prevailing COVID-19 policies, and recommend an approach we call Focused Protection.

Coming from both the left and right, and around the world, we have devoted our careers to protecting people. Current lockdown policies are producing devastating effects on short and

long-term public health. The results (to name a few) include lower childhood vaccination rates, worsening cardiovascular disease outcomes, fewer cancer screenings and deteriorating mental health – leading to greater excess mortality in years to come, with the working class and younger members of society carrying the heaviest burden. Keeping students out of school is a grave injustice.

Keeping these measures in place until a vaccine is available will cause irreparable damage, with the underprivileged disproportionately harmed.

Fortunately, our understanding of the virus is growing. We know that vulnerability to death from COVID-19 is more than a thousand-fold higher in the old and infirm than the young. Indeed, for children, COVID-19 is less dangerous than many other harms, including influenza.

As immunity builds in the population, the risk of infection to all – including the vulnerable – falls. We know that all populations will eventually reach herd immunity – i.e. the point at which the rate of new infections is stable – and that this can be assisted by (but is not dependent upon) a vaccine. Our goal should therefore be to minimize mortality and social harm until we reach herd immunity.

The most compassionate approach that balances the risks and benefits of reaching herd immunity, is to allow those who are at minimal risk of death to live their lives normally to build up immunity to the virus through natural infection, while better protecting those who are at highest risk. We call this Focused Protection.

Adopting measures to protect the vulnerable should be the central aim of public health responses to COVID-19. By way of example, nursing homes should use staff with acquired immunity and perform frequent testing of other staff and all visitors. Staff rotation should be minimized. Retired people living at home should have groceries and other essentials delivered to their home. When possible, they should meet family members outside rather than inside. A comprehensive and detailed list of measures, including approaches to multi-generational households, can be implemented, and is well within the scope and capability of public health professionals.

Those who are not vulnerable should immediately be allowed to resume life as normal. Simple hygiene measures, such as hand washing and staying home when sick should be practiced by everyone to reduce the herd immunity threshold. Schools and universities should be open for in-person teaching. Extracurricular activities, such as sports, should be resumed. Young low-risk adults should work normally, rather than from home. Restaurants and other businesses should

open. Arts, music, sport and other cultural activities should resume. People who are more at risk may participate if they wish, while society as a whole enjoys the protection conferred upon the vulnerable by those who have built up herd immunity.

On October 4, 2020, this declaration was authored and signed in Great Barrington, United States, by:

Dr. Martin Kulldorff, professor of medicine at Harvard University, a biostatistician, and epidemiologist with expertise in detecting and monitoring infectious disease outbreaks and vaccine safety evaluations.

Dr. Sunetra Gupta, professor at Oxford University, an epidemiologist with expertise in immunology, vaccine development, and mathematical modeling of infectious diseases.

Dr. Jay Bhattacharya, professor at Stanford University Medical School, a physician, epidemiologist, health economist, and public health policy expert focusing on infectious diseases and vulnerable populations.

SIGN THE DECLARATION

Co-signers

Medical and Public Health Scientists and Medical Practitioners

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Dr. Matthew Strauss, critical care physician and assistant professor of medicine, Queen's University, Canada

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Dr. Michael Levitt, biophysicist and professor of structural biology, Stanford University, USA. Recipient of the 2013 Nobel Prize in Chemistry.

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Dr. Yaz Gulnur Muradoglu, professor of finance, director of the Behavioural Finance Working Group, Queen Mary University of London, England

Sign the Declaration

Your Name *

**Peer Reviewed Medical Papers Submitted To Various Medical Journals, Evidencing A
Multitude Of Adverse Events In Covid-19 Vaccine Recipients**

Myocarditis (includes terms: Inflammatory Heart Reactions & Myocardial)

An inflammation of the heart muscle (myocardium). The inflammation can reduce the heart's ability to pump and cause rapid or irregular heart rhythms (arrhythmias). Signs and symptoms of myocarditis include chest pain, fatigue, shortness of breath, and rapid or irregular heartbeats. In a small percentage of cases persons with myocarditis can be at risk of sudden death following strenuous activity. Some sufferers of myocarditis may require heart surgery or a heart transplant later in life.

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4. Acute symptomatic myocarditis in seven adolescents after Pfizer-BioNTech COVID-19 vaccination: <https://pediatrics.aappublications.org/content/early/2021/06/04/peds.2021-052478>
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223. the culprit: <https://pubmed.ncbi.nlm.nih.gov/34702550/>
224. A case of acute encephalopathy and non-ST-segment elevation myocardial infarction after vaccination with mRNA-1273: possible adverse effect: <https://pubmed.ncbi.nlm.nih.gov/34703815/>
225. Acute myocardial infarction within 24 hours after COVID-19 vaccination: is Kounis syndrome Clinical and histopathologic spectrum of delayed adverse skin reactions after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34292611/>.
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Thrombosis (Includes terms: Thrombotic & Thromboembolic & Thromboembolism)

There are three categories of causes of thrombosis: damage to the blood vessel (catheter or surgery), slowed blood flow (immobility), and/or thrombophilia (if the blood itself is more likely to clot).

1. Three cases of acute venous thromboembolism in women after vaccination against COVID-19: <https://www.sciencedirect.com/science/article/pii/S2213333X21003929>
2. Acute thrombosis of the coronary tree after vaccination against COVID-19: <https://www.sciencedirect.com/science/article/abs/pii/S1936879821003988>
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7. Covid-19 vaccine-induced thrombosis and thrombocytopenia: a commentary on an important and practical clinical dilemma: <https://www.sciencedirect.com/science/article/abs/pii/S0033062021000505>
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10. The roles of platelets in COVID-19-associated coagulopathy and vaccine-induced immune thrombotic immune thrombocytopenia (covid): <https://www.sciencedirect.com/science/article/pii/S1050173821000967>
11. Roots of autoimmunity of thrombotic events after COVID-19 vaccination: <https://www.sciencedirect.com/science/article/abs/pii/S1568997221002160>
12. Thrombotic immune thrombocytopenia induced by SARS-CoV-2 vaccine: <https://www.nejm.org/doi/full/10.1056/nejme2106315>
13. Thrombosis and thrombocytopenia after vaccination with ChAdOx1 nCoV-19: [https://www.nejm.org/doi/full/10.1056/NEJMoa2104882?query=recirc curatedRelated article](https://www.nejm.org/doi/full/10.1056/NEJMoa2104882?query=recirc%20curatedRelated%20article)
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15. Post-mortem findings in vaccine-induced thrombotic thrombocytopenia (covid-19): <https://haematologica.org/article/view/haematol.2021.279075>
16. Comparison of vaccine-induced thrombotic episodes between ChAdOx1 nCoV-19 and Ad26.COV.2.S vaccines: <https://www.sciencedirect.com/science/article/abs/pii/S0896841121000895>
17. Hypothesis behind the very rare cases of thrombosis with thrombocytopenia syndrome after SARS-CoV-2 vaccination: <https://www.sciencedirect.com/science/article/abs/pii/S0049384821003315>
18. Primary adrenal insufficiency associated with thrombotic immune thrombocytopenia induced by the Oxford-AstraZeneca ChAdOx1 nCoV-19 vaccine (VITT): <https://www.sciencedirect.com/science/article/pii/S0953620521002363>
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33. Laboratory testing for suspicion of COVID-19 vaccine-induced thrombotic (immune) thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34138513/>
34. Intracerebral haemorrhage due to thrombosis with thrombocytopenia syndrome after COVID-19 vaccination: the first fatal case in Korea: <https://pubmed.ncbi.nlm.nih.gov/34402235/>
35. Risk of thrombocytopenia and thromboembolism after covid-19 vaccination and positive SARS-CoV-2 tests: self-controlled case series study: <https://pubmed.ncbi.nlm.nih.gov/34446426/>
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37. Primary adrenal insufficiency associated with thrombotic immune thrombocytopenia induced by Oxford-AstraZeneca ChAdOx1 nCoV-19 vaccine (VITT): <https://pubmed.ncbi.nlm.nih.gov/34256983/>
38. Thromboaspiration infusion and fibrinolysis for portomesenteric thrombosis after administration of AstraZeneca COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34132839/>
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33. Immune thrombosis and thrombocytopenia (VITT) associated with the COVID-19 vaccine: diagnostic and therapeutic recommendations for a new syndrome: <https://pubmed.ncbi.nlm.nih.gov/33987882/>
34. Laboratory testing for suspicion of COVID-19 vaccine-induced thrombotic (immune) thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34138513/>
35. Intracerebral haemorrhage due to thrombosis with thrombocytopenia syndrome after COVID-19 vaccination: the first fatal case in Korea: <https://pubmed.ncbi.nlm.nih.gov/34402235/>
36. Risk of thrombocytopenia and thromboembolism after covid-19 vaccination and positive SARS-CoV-2 tests: self-controlled case series study: <https://pubmed.ncbi.nlm.nih.gov/34446426/>
37. Vaccine-induced immune thrombotic thrombocytopenia and cerebral venous sinus thrombosis after covid-19 vaccination; a systematic review: <https://pubmed.ncbi.nlm.nih.gov/34365148/>.
38. Primary adrenal insufficiency associated with thrombotic immune thrombocytopenia induced by Oxford-AstraZeneca ChAdOx1 nCoV-19 vaccine (VITT): <https://pubmed.ncbi.nlm.nih.gov/34256983/>
39. Cerebral venous thrombosis and vaccine-induced thrombocytopenia. a. Oxford-AstraZeneca COVID-19: a missed opportunity for a rapid return on experience: <https://pubmed.ncbi.nlm.nih.gov/34033927/>
40. Immune thrombocytopenia in a 22-year-old post Covid-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/33476455/>
41. Secondary immune thrombocytopenia (ITP) associated with ChAdOx1 Covid-19 vaccine: case report: <https://pubmed.ncbi.nlm.nih.gov/34377889/>
42. Thrombosis with thrombocytopenia syndrome (TTS) following AstraZeneca ChAdOx1 nCoV-19 (AZD1222) COVID-19 vaccination: risk-benefit analysis for persons <60 years in Australia: <https://pubmed.ncbi.nlm.nih.gov/34272095/>
43. Bilateral superior ophthalmic vein thrombosis, ischemic stroke and immune thrombocytopenia after vaccination with ChAdOx1 nCoV-19: <https://pubmed.ncbi.nlm.nih.gov/33864750/>
44. Risk of thrombocytopenia and thromboembolism after covid-19 vaccination and positive SARS-CoV-2 tests: self-controlled case series study: <https://pubmed.ncbi.nlm.nih.gov/34446426/>

45. First dose of ChAdOx1 and BNT162b2 COVID-19 vaccines and thrombocytopenic, thromboembolic and hemorrhagic events in Scotland: <https://pubmed.ncbi.nlm.nih.gov/34108714/>
46. Thrombocytopenia after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34332437/>.
47. A case of multiple thrombocytopenia and thrombosis following vaccination with ChAdOx1 nCoV-19 against SARS-CoV-2: <https://pubmed.ncbi.nlm.nih.gov/34137813/>
48. Vaccine-induced thrombotic thrombocytopenia: the elusive link between thrombosis and adenovirus-based SARS-CoV-2 vaccines: <https://pubmed.ncbi.nlm.nih.gov/34191218/>
49. Acute ischemic stroke revealing immune thrombotic thrombocytopenia induced by ChAdOx1 nCoV-19 vaccine: impact on recanalization strategy: <https://pubmed.ncbi.nlm.nih.gov/34175640/>
50. Procoagulant antibody-mediated procoagulant platelets in immune thrombotic thrombocytopenia associated with SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34011137/>.
51. Thrombotic thrombocytopenia after vaccination with COVID-19: in search of the underlying mechanism: <https://pubmed.ncbi.nlm.nih.gov/34071883/>
52. Thrombosis and SARS-CoV-2 vaccines: vaccine-induced immune thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34237213/>.
53. Acquired thrombotic thrombocytopenic thrombocytopenic purpura: a rare disease associated with the BNT162b2 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34105247/>.
54. Immune complexes, innate immunity and NETosis in ChAdOx1 vaccine-induced thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34405870/>.
55. Immune-mediated thrombocytopenic purpura after Pfizer-BioNTech COVID-19 vaccine in an elderly woman: <https://pubmed.ncbi.nlm.nih.gov/34513446/>
56. Immune-mediated thrombocytopenia associated with Ad26.COV2.S vaccine (Janssen; Johnson & Johnson): <https://pubmed.ncbi.nlm.nih.gov/34469919/>.
57. Transient thrombocytopenia with glycoprotein-specific platelet autoantibodies after vaccination with Ad26.COV2.S: case report: <https://pubmed.ncbi.nlm.nih.gov/34516272/>.
58. COVID-19 vaccine, immune thrombotic thrombocytopenia, jaundice, hyperviscosity: concern in cases with underlying hepatic problems: <https://pubmed.ncbi.nlm.nih.gov/34509271/>.
59. Immune thrombocytopenia after vaccination during the COVID-19 pandemic: <https://pubmed.ncbi.nlm.nih.gov/34435486/>
60. Vaccine-induced thrombocytopenia with severe headache: <https://pubmed.ncbi.nlm.nih.gov/34525282/>
61. Vaccine-induced immune thrombotic thrombocytopenia causing a severe form of cerebral venous thrombosis with a high mortality rate: a case series: <https://pubmed.ncbi.nlm.nih.gov/34393988/>.

62. Adenovirus interactions with platelets and coagulation and vaccine-associated autoimmune thrombocytopenia thrombosis syndrome: <https://pubmed.ncbi.nlm.nih.gov/34407607/>.
63. Australian and New Zealand approach to the diagnosis and treatment of vaccine-induced immune thrombosis and immune thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34490632/>
64. An observational study to identify the prevalence of thrombocytopenia and anti-PF4 / polyanion antibodies in Norwegian health care workers after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/33909350/>
65. A rare case of thrombosis and thrombocytopenia of the superior ophthalmic vein after ChAdOx1 nCoV-19 vaccination against SARS-CoV-2: <https://pubmed.ncbi.nlm.nih.gov/34276917/>
66. Thrombosis and severe acute respiratory syndrome Coronavirus 2 vaccines: vaccine-induced immune thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34237213/>.
67. Renal vein thrombosis and pulmonary embolism secondary to vaccine-induced thrombotic immune thrombocytopenia (VITT): <https://pubmed.ncbi.nlm.nih.gov/34268278/>.
68. Limb ischemia and pulmonary artery thrombosis after ChAdOx1 nCoV-19 vaccine (Oxford-AstraZeneca): a case of vaccine-induced immune thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/33990339/>.
69. A case of vaccine-induced immune-immune thrombotic thrombocytopenia with massive arteriovenous thrombosis: <https://pubmed.ncbi.nlm.nih.gov/34059191/>
70. Thrombocytopenia in an adolescent with sickle cell anemia after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34331506/>
71. Vaccine-induced thrombocytopenia with severe headache: <https://pubmed.ncbi.nlm.nih.gov/34525282/>
72. ChAdOx1 interacts with CAR and PF4 with implications for thrombosis with thrombocytopenia syndrome: <https://www.science.org/doi/10.1126/sciadv.abl8213>
73. Lethal vaccine-induced immune thrombotic immune thrombocytopenia (VITT) following announcement 26.COVID.S: first documented case outside the U.S.: <https://pubmed.ncbi.nlm.nih.gov/34626338/>
74. A prothrombotic thrombocytopenic disorder resembling heparin-induced thrombocytopenia after coronavirus-19 vaccination: <https://europepmc.org/article/PPR/PPR304469435>.
75. VITT (vaccine-induced immune thrombotic thrombocytopenia) after vaccination with ChAdOx1 nCoV-19: <https://pubmed.ncbi.nlm.nih.gov/34731555/>
76. Vaccine-induced immune thrombotic thrombocytopenia (VITT): a new clinicopathologic entity with heterogeneous clinical presentations: <https://pubmed.ncbi.nlm.nih.gov/34159588/>
77. Treatment of acute ischemic stroke associated with ChAdOx1 nCoV-19 vaccine-induced immune thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34461442/>
78. Cerebral venous sinus thrombosis after vaccination: the UK experience: <https://pubmed.ncbi.nlm.nih.gov/34370974/>

Tiny purple, red, or brown spots on the skin. They usually appear on your arms, legs, stomach, and buttocks. You might also find them inside your mouth or on your eyelids. These pinpoint spots can be a sign of many different conditions — some minor, others serious. They can also appear as a reaction to certain medications. Though petechiae look like a rash, they're actually caused by bleeding under the skin.

1. Petechiae and peeling of fingers after immunization with BTN162b2 messenger RNA (mRNA)-based COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34513435/>
2. Petechial rash associated with CoronaVac vaccination: first report of cutaneous side effects before phase 3 results: <https://ejhp.bmj.com/content/early/2021/05/23/ejhp2021-002794>

Purpura Annularis Telangiectodes

An uncommon pigmented purpuric eruption, which is characterized by symmetrical, purpuric, telangiectatic, and atrophic patches with a predilection for the lower extremities and buttocks.

1. Purpuric rash and thrombocytopenia after mRNA-1273 (Modern) COVID-19 vaccine: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7996471/>
2. Generalized purpura annularis telangiectodes after SARS-CoV-2 mRNA vaccination: <https://pubmed.ncbi.nlm.nih.gov/34236717/>

Pulmonary Embolism

Pulmonary embolism is a blockage in one of the pulmonary arteries in your lungs. In most cases, pulmonary embolism is caused by blood clots that travel to the lungs from deep veins in the legs or, rarely, from veins in other parts of the body (deep vein thrombosis). Because the clots block blood flow to the lungs, pulmonary embolism can be life-threatening.

1. Pulmonary embolism, transient ischemic attack, and thrombocytopenia after Johnson & Johnson COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34261635/>
2. A case of acute pulmonary embolism after immunization with SARS-CoV-2 mRNA: <https://pubmed.ncbi.nlm.nih.gov/34452028/>

Psoriasis

A chronic autoimmune condition that causes the rapid buildup of skin cells. This buildup of cells causes scaling on the skin's surface. Inflammation and redness around the scales is fairly common. Typical psoriatic scales are whitish-silver and develop in thick, red patches. Sometimes, these patches will crack and bleed.

1. Onset / outbreak of psoriasis after Corona virus ChAdOx1 nCoV-19 vaccine (Oxford-AstraZeneca / Covishield): report of two cases: <https://pubmed.ncbi.nlm.nih.gov/34350668/>
2. Exacerbation of plaque psoriasis after COVID-19 inactivated mRNA and BNT162b2 vaccines: report of two cases: <https://pubmed.ncbi.nlm.nih.gov/34427024/>

Miller Fisher Syndrome

A rare acquired nerve disease related to Guillain-Barré syndrome (GBS). Features include weakness of the eye muscles causing difficulty moving the eyes; impaired limb coordination and unsteadiness; and absent tendon reflexes.

1. Miller Fisher syndrome after Pfizer COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34817727/>.
2. Miller Fisher syndrome after 2019 BNT162b2 mRNA coronavirus vaccination: <https://pubmed.ncbi.nlm.nih.gov/34789193/>.

Nephrotic Syndrome

Kidney disorder that causes your body to pass too much protein in your urine. Nephrotic syndrome is usually caused by damage to the clusters of small blood vessels in your kidneys that filter waste and excess water from your blood

1. Nephrotic syndrome after ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: <https://pubmed.ncbi.nlm.nih.gov/34250318/>.
2. New-onset nephrotic syndrome after Janssen COVID-19 vaccination: case report and literature review: <https://pubmed.ncbi.nlm.nih.gov/34342187/>

Macroscopic Hematuria

Visible blood in the urine causing it to be discoloured pink, red, brownish-red or tea-coloured.

1. Hematuria, a generalized petechial rash and headaches after Oxford AstraZeneca ChAdOx1 nCoV-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34620638/>
2. A case of outbreak of macroscopic hematuria and IgA nephropathy after SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/33932458/>

Bullous Drug Eruption

Refers to adverse drug reactions that result in fluid-filled blisters or bullae. Blistering may be localised and mild, or widespread and severe, even life-threatening.

1. Bullous drug eruption after the second dose of COVID-19 mRNA-1273 (Moderna) vaccine: Case report: <https://www.sciencedirect.com/science/article/pii/S1876034121001878>.

2. Widespread fixed bullous drug eruption after vaccination with ChAdOx1 nCoV-19: <https://pubmed.ncbi.nlm.nih.gov/34482558/>

Hemophagocytic lymphohistiocytosis

An aggressive and life-threatening syndrome of excessive immune activation. It most frequently affects infants from birth to 18 months of age, but the disease is also observed in children and adults of all ages.

1. Hemophagocytic lymphohistiocytosis after vaccination with ChAdOx1 nCov-19: <https://pubmed.ncbi.nlm.nih.gov/34406660/>.
2. Hemophagocytic lymphohistiocytosis following COVID-19 vaccination (ChAdOx1 nCoV-19): <https://pubmed.ncbi.nlm.nih.gov/34862234/>

Pulmonary Embolism

Pulmonary embolism is a blockage in one of the pulmonary arteries in your lungs. In most cases, pulmonary embolism is caused by blood clots that travel to the lungs from deep veins in the legs or, rarely, from veins in other parts of the body (deep vein thrombosis). Because the clots block blood flow to the lungs, pulmonary embolism can be life-threatening.

1. Isolated pulmonary embolism after COVID vaccination: 2 case reports and a review of acute pulmonary embolism complications and follow-up: <https://pubmed.ncbi.nlm.nih.gov/34804412/>
2. Myocardial infarction, stroke, and pulmonary embolism after BNT162b2 mRNA COVID-19 vaccine in persons aged 75 years or older: <https://pubmed.ncbi.nlm.nih.gov/34807248/>

Neuromyelitis Optica

also called NMO or Devic's disease, is a rare yet severe demyelinating autoimmune inflammatory process affecting the central nervous system. It specifically affects the myelin, which is the insulation around the nerves

1. Beware of neuromyelitis optica spectrum disorder after vaccination with inactivated virus for COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34189662/>
2. Neuromyelitis optica in a healthy woman after vaccination against severe acute respiratory syndrome coronavirus 2 mRNA-1273: <https://pubmed.ncbi.nlm.nih.gov/34660149/>

Shingles (includes term: Herpes zoster)

a reactivation of the chickenpox virus in the body, causing a painful rash.

1. Shingles-like skin lesion after vaccination with AstraZeneca for COVID-19: a case report: <https://pubmed.ncbi.nlm.nih.gov/34631069/>
2. Recurrent herpes zoster after COVID-19 vaccination in patients with chronic urticaria on cyclosporine treatment – A report of 3 cases: <https://pubmed.ncbi.nlm.nih.gov/34510694/>

Blood Clots

A gelatinous mass of fibrin and blood cells formed by the coagulation of blood.

1. Blood clots and bleeding after BNT162b2 and ChAdOx1 nCoV-19 vaccination: an analysis of European data: <https://pubmed.ncbi.nlm.nih.gov/34174723/>

Thrombophilia

A blood disorder that makes the blood in your veins and arteries more likely to clot. This is also known as a "hypercoagulable" condition because your blood coagulates or clots more easily.

1. Antiphospholipid antibodies and risk of thrombophilia after COVID-19 vaccination: the straw that breaks the camel's back?: <https://docs.google.com/document/d/1XzajasO8VMMnC3CdxSBKks1o7kiOLXEQ>

ITTP episode

A rare, life-threatening thrombotic microangiopathy caused by severe ADAMTS13 (a disintegrin and metalloproteinase with thrombospondin motifs 13) deficiency, recurring in 30–50% of patients.

1. First report of a de novo iITTP episode associated with a COVID-19 mRNA-based anti-COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34105244/>

Refractory Status Epilepticus

Can be defined as status epilepticus (seizures) that continues despite treatment with benzodiazepines and one antiepileptic drug. RSE should be treated promptly to prevent morbidity and mortality; however, scarce evidence is available to support the choice of specific treatments.

1. New-onset refractory status epilepticus after chadox1 ncov-19 vaccination: <https://www.sciencedirect.com/science/article/pii/S0165572821001569>

Central Serous Retinopathy

A medical condition where fluid builds up behind the retina in the eye. It can cause sudden or gradual vision loss as the central retina detaches. This central area is called the macula.

1. Acute-onset central serous retinopathy after immunization with COVID-19 mRNA vaccine: <https://www.sciencedirect.com/science/article/pii/S2451993621001456>.

Cutaneous Reactions

A group of potentially lethal adverse drug reactions that involve the skin and mucous membranes of various body openings such as the eyes, ears, and inside the nose, mouth, and lips.

1. Late cutaneous reactions after administration of COVID-19 mRNA vaccines: <https://www.sciencedirect.com/science/article/pii/S2213219821007996>

Prion Disease

Prion diseases comprise several conditions. A prion is a type of protein that can trigger normal proteins in the brain to fold abnormally. Prion diseases or transmissible spongiform encephalopathies (TSEs) are a family of rare progressive neurodegenerative disorders that affect both humans and animals. They are distinguished by long incubation periods, characteristic spongiform changes associated with neuronal loss, and a failure to induce inflammatory

1. COVID-19 RNA-based vaccines and the risk of prion disease: <https://scivisionpub.com/pdfs/covid19rna-based-vaccines-and-the-risk-of-prion-disease-1503.pdf>

Pregnant Woman

See below studies.

1. This study notes that 115 pregnant women lost their babies, out of 827 who participated in a study on the safety of covid-19 vaccines: <https://www.nejm.org/doi/full/10.1056/NEJMoa2104983>.

Process-Related Impurities

See below studies.

1. Process-related impurities in the ChAdOx1 nCov-19 vaccine: <https://www.researchsquare.com/article/rs-477964/v1>

CNS Inflammation

A disease that causes inflammation of the small arteries and veins in the brain and/or spinal cord. The brain and spinal cord make up the CNS. Intense interest in inflammation in the CNS has arisen from its potential role in diseases including acute brain injury, stroke, epilepsy, multiple sclerosis, motor neurone disease, movement disorders and Alzheimer's disease, and more recently some psychiatric disorders.

1. COVID-19 mRNA vaccine causing CNS inflammation: a case series: <https://link.springer.com/article/10.1007/s00415-021-10780-7>

CNS Demyelination

a demyelinating disease is any condition that results in damage to the protective covering (myelin sheath) that surrounds nerve fibers in your brain, optic nerves and spinal cord. When the myelin sheath is damaged, nerve impulses slow or even stop, causing neurological problems.

1. A systematic review of cases of CNS demyelination following COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34839149/>

Orofacial

An orofacial myofunctional disorder (OMD) is when there is an abnormal lip, jaw, or tongue position during rest, swallowing or speech.

1. Reported orofacial adverse effects from COVID-19 vaccines: the known and the unknown: <https://pubmed.ncbi.nlm.nih.gov/33527524/>

Brain Haemorrhage (Includes Term: Lobar Hemorrhage)

An emergency condition in which a ruptured blood vessel causes bleeding inside the brain.

1. Fatal brain haemorrhage after COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/33928772/>

Varicella Zoster Virus

The varicella-zoster virus (VZV) is so named because it causes two distinct illnesses: varicella (chickenpox), following primary infection, and herpes zoster (shingles), following reactivation of latent virus. Varicella is a highly contagious infection with an incubation period of 10–21 days, most commonly 14–16 days, after which a characteristic rash appears. Acute varicella may be complicated by secondary bacterial skin infections, haemorrhagic complications, cerebellitis, encephalitis, and viral and bacterial pneumonia.

1. Acute retinal necrosis due to varicella zoster virus reactivation after vaccination with BNT162b2 COVID-19 mRNA: <https://pubmed.ncbi.nlm.nih.gov/34851795/>.

Nerve And Muscle Adverse Events

Many different possible neurologic adverse events including encephalitis, myelopathy, aseptic meningitis, meningoradiculitis, Guillain-Barré-like syndrome, peripheral neuropathy (including mononeuropathy, mononeuritis multiplex, and polyneuropathy) as well as myasthenic syndrome.

1. Nerve and muscle adverse events after vaccination with COVID-19: a systematic review and meta-analysis of clinical trials: <https://pubmed.ncbi.nlm.nih.gov/34452064/>.

Oculomotor Paralysis

Defines the decreased strength of a muscle, which produces a reduced rotational movement of the eyeball in the direction corresponding to the paralysed muscle. Partial deficit is called paresis, while full deficit is called paralysis.

1. Transient oculomotor paralysis after administration of RNA-1273 messenger vaccine for SARS-CoV-2 diplopia after COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34369471/>

Parsonage-Turner Syndrome

An neurological disorder characterized by rapid onset of severe pain in the shoulder and arm. This acute phase may last for a few hours to a few weeks and is followed by wasting and weakness of the muscles (amyotrophy) in the affected areas.

1. Parsonage-Turner syndrome associated with SARS-CoV-2 or SARS-CoV-2 vaccination. Comment on: "Neuralgic amyotrophy and COVID-19 infection: 2 cases of accessory spinal nerve palsy" by Coll et al. Articular Spine 2021; 88: 10519: <https://pubmed.ncbi.nlm.nih.gov/34139321/>.

Acute Macular Neuroretinopathy

A rare, acquired retinal disorder characterised by transient or permanent visual impairment accompanied by the presence of reddish-brown, wedge-shaped lesions in the macula, the apices of which tend to point towards the fovea.

1. Bilateral acute macular neuroretinopathy after SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34287612/>

Lipschütz ulcers (Vaginal ulcers)

Acute genital ulceration, also known as "Lipschütz ulcer" or "ulcus vulvae acutum," is an uncommon, self-limited, nonsexually transmitted condition characterized by the rapid onset of painful, necrotic ulcerations of the vulva or lower vagina.

1. Lipschütz ulcers after AstraZeneca COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34366434/>.

Amyotrophic Neuralgia

A disorder characterized by episodes of severe pain and muscle wasting (amyotrophy) in one or both shoulders and arms. Neuralgic pain is felt along the path of one or more nerves and often has no obvious physical cause.

1. Amyotrophic Neuralgia secondary to Vaxzevri vaccine (AstraZeneca) COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34330677/>

Polyarthralgia

Pain in multiple joints. Symptoms may include pain, tenderness, or tingling in the joints and reduced range of motion. Polyarthralgia is similar to polyarthritis, but it doesn't cause inflammation. Lifestyle changes, home remedies, and medication can help manage the symptoms.

1. Polyarthralgia and myalgia syndrome after vaccination with ChAdOx1 nCoV-19: <https://pubmed.ncbi.nlm.nih.gov/34463066/>

Thyroiditis

The swelling, or inflammation, of the thyroid gland and can lead to over- or under-production of thyroid hormone. A thyroid storm -- or thyroid crisis -- can be a life-threatening condition. It often includes a rapid heartbeat, fever, and even fainting. Symptoms may include pain in the throat, feeling generally unwell, swelling of the thyroid gland and, sometimes, symptoms of an overactive thyroid gland or symptoms of an underactive thyroid gland.

1. Three cases of subacute thyroiditis after SARS-CoV-2 vaccination: post-vaccination ASIA syndrome: <https://pubmed.ncbi.nlm.nih.gov/34043800/>.

Keratolysis (also termed: corneal melting)

A common prelude to the development of corneal perforation. This process occurs from conditions such as infections, sterile inflammation, or surgical/chemical injury to the cornea. Collectively, these conditions are a significant cause for blindness world-wide.

1. Bilateral immune-mediated keratolysis after immunization with SARS-CoV-2 recombinant viral vector vaccine: <https://pubmed.ncbi.nlm.nih.gov/34483273/>.

Arthritis

The swelling and tenderness of one or more joints. The main symptoms of arthritis are joint pain and stiffness, which typically worsen with age. The most common types of arthritis are osteoarthritis and rheumatoid arthritis.

1. Reactive arthritis after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34033732/>.

Thymic hyperplasia

A condition in which the thymus gland is inflamed. It is often accompanied by autoimmune diseases such as systemic lupus erythematosus, myasthenia gravis and rheumatoid arthritis.

1. Thymic hyperplasia after Covid-19 mRNA-based vaccination with Covid-19: <https://pubmed.ncbi.nlm.nih.gov/34462647/>

Tolosa-Hunt syndrome

A rare disorder characterized by severe periorbital headaches, along with decreased and painful eye movements (ophthalmoplegia). Symptoms usually affect only one eye (unilateral). In most cases, affected individuals experience intense sharp pain and decreased eye movements.

1. Tolosa-Hunt syndrome occurring after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34513398/>

Hailey-Hailey disease

Also known as benign chronic pemphigus, is a rare skin condition that usually appears in early adulthood. The disorder is characterized by red, raw, and blistered areas of skin that occur most often in skin folds, such as the groin, armpits, neck, and under the breasts.

1. Hailey-Hailey disease exacerbation after SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34436620/>

Acute lympholysis

The destruction of lymph cells.

1. Rituximab-induced acute lympholysis and pancytopenia following vaccination with COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34429981/>

Interstitial lung disease

Describes a large group of disorders, most of which cause progressive scarring of lung tissue. The scarring associated with interstitial lung disease eventually affects your ability to breathe and get enough oxygen into your bloodstream.

1. Vaccine-induced interstitial lung disease: a rare reaction to COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34510014/>.

Vesiculobullous cutaneous reactions

A vesiculobullous lesion of the skin encompasses a group of dermatological disorders with protean clinicopathological features. They usually occur as a part of the spectrum of various infectious, inflammatory, drug-induced, genetic, and autoimmune disorders.

1. Vesiculobullous cutaneous reactions induced by COVID-19 mRNA vaccine: report of four cases and review of the literature: <https://pubmed.ncbi.nlm.nih.gov/34236711/>

Hematologic conditions

Disorders of the blood and blood-forming organs.

1. Collection of complement-mediated and autoimmune-mediated hematologic conditions after SARS-CoV-2 vaccination: <https://ashpublications.org/bloodadvances/article/5/13/2794/476324/Autoimmune-and-complement-mediated-hematologic>

Hemolysis

The destruction of red blood cells.

1. COVID-19 vaccines induce severe hemolysis in paroxysmal nocturnal hemoglobinuria: <https://ashpublications.org/blood/article/137/26/3670/475905/COVID-19-vaccines-induce-severe-hemolysis-in>

Headache

See below papers.

1. Headache attributed to COVID-19 (SARS-CoV-2 coronavirus) vaccination with the ChAdOx1 nCoV-19 (AZD1222) vaccine: a multicenter observational cohort study: <https://pubmed.ncbi.nlm.nih.gov/34313952/>

Acute Coronary Syndrome

Any condition brought on by a sudden reduction or blockage of blood flow to the heart.

1. Mrna COVID vaccines dramatically increase endothelial inflammatory markers and risk of Acute Coronary Syndrome as measured by PULS cardiac testing: a caution: https://www.ahajournals.org/doi/10.1161/circ.144.suppl_1.10712

ANCA Glomerulonephritis

is the term we use when ANCA vasculitis has affected or involved the kidneys, and when this happens there is inflammation and swelling in the kidney filters, meaning that the body's own immune system injures its cells and tissues.

1. ANCA glomerulonephritis following Modern COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34081948/>

Neurologic Phantosmia

is an olfactory hallucination perceived when no odorants are present. Both the olfactory distortions are typically described as unpleasant.

1. Unique imaging findings of neurologic phantosmia after Pfizer-BioNtech COVID-19 vaccination: a case report: <https://pubmed.ncbi.nlm.nih.gov/34096896/>

Uveitis (includes terms: bilateral)

is a form of eye inflammation. It affects the middle layer of tissue in the eye wall (uvea). Uveitis warning signs often come on suddenly and get worse quickly. They include eye redness, pain and blurred vision.

1. Bilateral uveitis after inoculation with COVID-19 vaccine: a case report: <https://www.sciencedirect.com/science/article/pii/S1201971221007797>

Pathophysiologic Alterations

Deranged function in an individual or an organ due to a disease. For example, a pathophysiologic alteration is a change in function as distinguished from a structural defect.

1. Extensive investigations revealed consistent pathophysiologic alterations after vaccination with COVID-19 vaccines: <https://www.nature.com/articles/s41421-021-00329-3>

Gross Hematuria (Includes term: Acral Hemorrhage)

produces pink, red or cola-colored urine due to the presence of red blood cells. It takes little blood to produce red urine, and the bleeding usually isn't painful. Passing blood clots in your urine, however, can be painful. Bloody urine often occurs without other signs or symptoms.

1. Gross hematuria after severe acute respiratory syndrome coronavirus 2 vaccination in 2 patients with IgA nephropathy: <https://pubmed.ncbi.nlm.nih.gov/33771584/>

Inflammatory Myositis

inflammatory myopathies are a group of diseases that involve chronic (long-standing) muscle inflammation, muscle weakness, and, in some cases, muscle pain. Myopathy is a general medical term used to describe a number of conditions affecting the muscles. All myopathies cause muscle weakness.

1. Inflammatory myositis after vaccination with ChAdOx1: <https://pubmed.ncbi.nlm.nih.gov/34585145/>

Still's Disease

is a rare type of inflammatory arthritis that features fevers, rash and joint pain. Some people have just one episode of adult Still's disease. In other people, the condition persists or recurs. This inflammation can destroy affected joints, particularly the wrists.

1. An outbreak of Still's disease after COVID-19 vaccination in a 34-year-old patient: <https://pubmed.ncbi.nlm.nih.gov/34797392/>

Pityriasis Rosea

a skin rash that sometimes begins as a large spot on the chest, abdomen or back, followed by a pattern of smaller lesions.

1. Case report: Pityriasis rosea-like rash after vaccination with COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34557507/>

Acute Eosinophilic Pneumonia

is the acute-onset form of eosinophilic pneumonia, a lung disease caused by the buildup of eosinophils, a type of white blood cell, in the lungs. It is characterized by a rapid onset of shortness of breath, cough, fatigue, night sweats, and weight loss.

1. Acute eosinophilic pneumonia associated with anti-COVID-19 vaccine AZD1222: <https://pubmed.ncbi.nlm.nih.gov/34812326/>.

Sweet's Syndrome

is an uncommon skin condition marked by a distinctive eruption of tiny bumps that enlarge and are often tender to the touch. They can appear on the back, neck, arms or face. Sweet's syndrome, also called acute febrile neutrophilic dermatosis, is an uncommon skin condition.

1. Sweet's syndrome after Oxford-AstraZeneca COVID-19 vaccine (AZD1222) in an elderly woman: <https://pubmed.ncbi.nlm.nih.gov/34590397/>

Sensorineural Hearing Loss

Hearing loss caused by damage to the inner ear or the nerve from the ear to the brain. Sensorineural hearing loss is permanent.

1. Sudden sensorineural hearing loss after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34670143/>.

Serious Adverse Events Among Health Care Professionals

See below paper.

1. Prevalence of serious adverse events among health care professionals after receiving the first dose of ChAdOx1 nCoV-19 coronavirus vaccine (Covishield) in Togo, March 2021: <https://pubmed.ncbi.nlm.nih.gov/34819146/>.

Toxic Epidermal Necrolysis

A life-threatening skin disorder characterized by a blistering and peeling of the skin. This disorder can be caused by a drug reaction—often antibiotics or anticonvulsives.

1. A case of toxic epidermal necrolysis after vaccination with ChAdOx1 nCoV-19 (AZD1222): <https://pubmed.ncbi.nlm.nih.gov/34751429/>.

Ocular Adverse Events

The majority of ocular immune-related adverse events (irAEs) are mild, low-grade, non-sight threatening, such as blurred vision, conjunctivitis, and ocular surface disease.

1. Ocular adverse events following COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34559576/>

Depression

A common and serious medical illness that negatively affects how you feel, the way you think and how you act. Depression causes feelings of sadness and/or a loss of interest in activities you once enjoyed.

1. Depression after ChAdOx1-S / nCoV-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34608345/>.

Pancreas Allograft Rejection

the body's blood cells identify the pancreas as foreign and begin mounting an army of cells to attack the transplanted organ. Although acute rejection can happen at any time, about 15 to 25% of pancreas acute rejection occurs within the first three months after transplant.

1. Pancreas allograft rejection after ChAdOx1 nCoV-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34781027/>

Acute Hemichorea-Hemiballismus

Hemiballismus is characterized by high amplitude, violent, flinging and flailing movements confined to one side of body and hemichorea is characterized by involuntary random-appearing irregular movements that are rapid and non-patterned confined to one side of body.

1. Acute hemichorea-hemiballismus after COVID-19 (AZD1222) vaccination: <https://pubmed.ncbi.nlm.nih.gov/34581453/>

Alopecia Areata

Sudden hair loss that starts with one or more circular bald patches that may overlap. Alopecia areata occurs when the immune system attacks hair follicles and may be brought on by severe stress.

1. Recurrence of alopecia areata after covid-19 vaccination: a report of three cases in Italy: <https://pubmed.ncbi.nlm.nih.gov/34741583/>

Graves' Disease

is an autoimmune disorder that causes hyperthyroidism, or overactive thyroid. With this disease, your immune system attacks the thyroid and causes it to make more thyroid hormone than your body needs. The thyroid is a small, butterfly-shaped gland in the front of your neck. Thyroid hormones control how your body uses energy, so they affect nearly every organ in your body—even the way your heart beats. If left untreated, hyperthyroidism can cause serious problems with the heart, bones, muscles, menstrual cycle, and fertility. During pregnancy, untreated hyperthyroidism can lead to health problems for the mother and baby. Graves' disease also can affect your eyes and skin.

1. Two cases of Graves' disease after SARS-CoV-2 vaccination: an autoimmune / inflammatory syndrome induced by adjuvants: <https://pubmed.ncbi.nlm.nih.gov/33858208/>

Cardiovascular Events

refer to any incidents that may cause damage to the heart muscle.

1. Cardiovascular, neurological, and pulmonary events after vaccination with BNT162b2, ChAdOx1 nCoV-19, and Ad26.COV2.S vaccines: an analysis of European data: <https://pubmed.ncbi.nlm.nih.gov/34710832/>

Metabolic Syndrome

A cluster of conditions that increase the risk of heart disease, stroke and diabetes.

1. Change in blood viscosity after COVID-19 vaccination: estimation for persons with underlying metabolic syndrome: <https://pubmed.ncbi.nlm.nih.gov/34868465/>

Eosinophilic Dermatitis

Eosinophilic skin diseases, commonly termed as eosinophilic dermatoses, refer to a broad spectrum of skin diseases characterized by eosinophil infiltration and/or degranulation in skin lesions, with or without blood eosinophilia. The majority of eosinophilic dermatoses lie in the allergy-related group, including allergic drug eruption, urticaria, allergic contact dermatitis, atopic dermatitis, and eczema.

1. Eosinophilic dermatosis after AstraZeneca COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34753210/>.

Hypercoagulability

the tendency to have thrombosis as a result of certain inherited and/or acquired molecular defects. Clinical manifestations of hypercoagulability can be devastating and even lethal

1. COVID-19 vaccine in patients with hypercoagulability disorders: a clinical perspective: <https://pubmed.ncbi.nlm.nih.gov/34786893/>

Neuroimaging Findings in Post COVID-19 Vaccination

see paper below.

1. Spectrum of neuroimaging findings in post-CoVID-19 vaccination: a case series and review of the literature: <https://pubmed.ncbi.nlm.nih.gov/34842783/>

Urticaria

A rash of round, red welts on the skin that itch intensely, sometimes with dangerous swelling, caused by an allergic reaction.

1. Increased risk of urticaria/angioedema after BNT162b2 mRNA COVID-19 vaccination in health care workers taking ACE inhibitors: <https://pubmed.ncbi.nlm.nih.gov/34579248/>

Central Vein Occlusion

Is a blockage of this vein that causes the vein to leak blood and excess fluid into the retina. This fluid often collects in the area of the retina responsible for central vision called the macula. When the macula is affected, central vision may become blurry. The second eye will develop vein occlusion in 6-17% of cases. There's no cure for retinal vein occlusion. Your doctor can't unblock the retinal veins. What they can do is treat any complications and protect your vision.

1. Central retinal vein occlusion after vaccination with SARS-CoV-2 mRNA: case report: <https://pubmed.ncbi.nlm.nih.gov/34571653/>.

Thrombophlebitis

A condition in which a blood clot in a vein causes inflammation and pain.

1. Idiopathic external jugular vein thrombophlebitis after coronavirus disease vaccination (COVID-19): <https://pubmed.ncbi.nlm.nih.gov/33624509/>.

Squamous Cell Carcinoma

A slow-growing type of lung cancer.

1. Squamous cell carcinoma of the lung with hemoptysis following vaccination with tozinameran (BNT162b2, Pfizer-BioNTech): <https://pubmed.ncbi.nlm.nih.gov/34612003/>

Chest Pain

See paper below

1. Chest pain with abnormal electrocardiogram redevelopment after injection of COVID-19 vaccine manufactured by Moderna: <https://pubmed.ncbi.nlm.nih.gov/34866106/>

Acute Inflammatory Neuropathies

Encompass groups of heterogeneous disorders characterized by pathogenic immune-mediated hematogenous leukocyte infiltration of peripheral nerves, nerve roots or both, with resultant demyelination or axonal degeneration or both, and the pathogenesis of these disorders remains elusive.

1. Reporting of acute inflammatory neuropathies with COVID-19 vaccines: subgroup disproportionality analysis in Vigibase: <https://pubmed.ncbi.nlm.nih.gov/34579259/>

Brain Death

Irreversible cessation of all functions of the entire brain, including the brain stem. A person who is brain dead is dead.

1. Brain death in a vaccinated patient with COVID-19 infection: <https://pubmed.ncbi.nlm.nih.gov/34656887/>

Kounis Syndrome

is the concurrence of acute coronary syndromes with conditions associated with mast cell activation, such as allergies or hypersensitivity and anaphylactic or anaphylactoid insults that can involve other interrelated and interacting inflammatory cells behaving as a 'ball of thread'.

1. Kounis syndrome type 1 induced by inactivated SARS-COV-2 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34148772/>

Angioimmunoblastic T-cell Lymphoma

is a type of peripheral T-cell lymphoma. It is a high grade (aggressive) lymphoma that affects blood cells called T cells. High grade lymphomas tend to grow more quickly than low grade lymphomas. AITL usually affects older people, typically around the age of 70, is typically aggressive with a median survival of fewer than 3 years, even with intensive treatment.

1. Rapid progression of angioimmunoblastic T-cell lymphoma after BNT162b2 mRNA booster vaccination: case report: <https://www.frontiersin.org/articles/10.3389/fmed.2021.798095/>

Gastroparesis

A condition that affects the stomach muscles and prevents proper stomach emptying.

1. Gastroparesis after Pfizer-BioNTech COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34187985/>

Asthma

a condition in which a person's airways become inflamed, narrow and swell and produce extra mucus, which makes it difficult to breathe. Asthma can be minor or it can interfere with daily activities. In some cases, it may lead to a life-threatening attack.

1. Colaneri, M., De Filippo, M., Licari, A., Marseglia, A., Maiocchi, L., Ricciardi, A., . . . Bruno, R. (2021). COVID vaccination and asthma exacerbation: might there be a link? *Int J Infect Dis*, 112, 243-246. doi:10.1016/j.ijid.2021.09.026. <https://www.ncbi.nlm.nih.gov/pubmed/34547487>

Safety in Adolescents

see below paper

1. Dimopoulou, D., Spyridis, N., Vartzelis, G., Tsolia, M. N., & Maritsi, D. N. (2021). Safety and tolerability of the COVID-19 mRNA-vaccine in adolescents with juvenile idiopathic arthritis on treatment with TNF-inhibitors. *Arthritis Rheumatol*. doi:10.1002/art.41977. <https://www.ncbi.nlm.nih.gov/pubmed/34492161>

2. Hause, A. M., Gee, J., Baggs, J., Abara, W. E., Marquez, P., Thompson, D., . . . Shay, D. K. (2021). COVID-19 Vaccine Safety in Adolescents Aged 12-17 Years – United States, December 14, 2020–July 16, 2021. *MMWR Morb Mortal Wkly Rep*, 70(31), 1053-1058. doi:10.15585/mmwr.mm7031e1. <https://www.ncbi.nlm.nih.gov/pubmed/34351881>

Safety Monitoring of the Janssen Vaccine

see below paper

1. Shay, D. K., Gee, J., Su, J. R., Myers, T. R., Marquez, P., Liu, R., . . . Shimabukuro, T. T. (2021). Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine – United States, March–April 2021. *MMWR Morb Mortal Wkly Rep*, 70(18), 680-684. doi:10.15585/mmwr.mm7018e2. <https://www.ncbi.nlm.nih.gov/pubmed/33956784>

Myocardial Injury

refers to the cell death of cardiomyocytes and is defined by an elevation of cardiac troponin values. It is not only considered a prerequisite for the diagnosis of myocardial infarction but also an entity in itself and can arise from non-ischaemic or non-cardiac conditions.

1. Acute myocardial injury after COVID-19 vaccination: a case report and review of current evidence from the Vaccine Adverse Event Reporting System database: <https://pubmed.ncbi.nlm.nih.gov/34219532/>
2. Deb, A., Abdelmalek, J., Iwuji, K., & Nugent, K. (2021). Acute Myocardial Injury Following COVID-19 Vaccination: A Case Report and Review of Current Evidence from Vaccine Adverse Events Reporting System Database. *J Prim Care Community Health*, 12, 21501327211029230. doi:10.1177/21501327211029230. <https://www.ncbi.nlm.nih.gov/pubmed/34219532>

Autoimmune Inflammatory Rheumatic Diseases

Rheumatic diseases are autoimmune and inflammatory diseases that cause your immune system to attack your joints, muscles, bones and organs. Rheumatic diseases are often grouped under the term “arthritis” — which is used to describe over 100 diseases and conditions.

1. Furer, V., Eviatar, T., Zisman, D., Peleg, H., Paran, D., Levartovsky, D., . . . Elkayam, O. (2021). Immunogenicity and safety of the BNT162b2 mRNA COVID-19 vaccine in adult patients with autoimmune inflammatory rheumatic diseases and in the general population: a multicentre study. *Ann Rheum Dis*, 80(10), 1330-1338. doi:10.1136/annrheumdis-2021-220647. <https://www.ncbi.nlm.nih.gov/pubmed/34127481>

Neurological Autoimmune Diseases

If you have a neurological autoimmune disease, your immune system may be overly active and mistakenly attack healthy cells. These include central nervous system demyelinating disorders such as multiple sclerosis and neuromyelitis optica, paraneoplastic, and other autoimmune encephalomyelitis and autoimmune inflammatory myositis and demyelinating neuropathies.

1. Neurological autoimmune diseases after SARS-CoV-2 vaccination: a case series: <https://pubmed.ncbi.nlm.nih.gov/34668274/>.

V-REPP

vaccine-related eruption of papules and plaques.

1. Clinical and pathologic correlates of skin reactions to COVID-19 vaccine, including V-REPP: a registry-based study: <https://www.sciencedirect.com/science/article/pii/S0190962221024427>

Herpes Simplex Virus

A virus causing contagious sores, most often around the mouth or on the genitals.

1. Varicella zoster virus and herpes simplex virus reactivation after vaccination with COVID-19: review of 40 cases in an international dermatologic registry: <https://pubmed.ncbi.nlm.nih.gov/34487581/>

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BREAKING AAPS STATEMENT CALLING FOR MORATORIUM ON COVID-19 SHOT MANDATES AND GENETIC INJEC...

VACCINES APRIL 24, 2021

Open Letter from Physicians to Universities: Allow Students Back Without COVID Vaccine Mandate

Clinical trials will continue for at least two years before the FDA can even consider approval of these vaccines as effective and safe.

4. The COVID-19 vaccines on the market in the U.S., mRNA (Moderna and Pfizer) and DNA (Johnson & Johnson – Janssen), have caused notable side effects, pathology and even death (4.178 deaths [per VAERS](#) as of May 5, 2021). These adverse reactions result in absence from school and work, hospital visits, and even loss of life.[\[vi\]](#)
5. College-age women may be at unique risk for adverse events following administration of the experimental COVID vaccinations currently available. According to the CDC, all cases of life-threatening blood clots, subsequent to receiving the J&J vaccine, reported so far in the United States, occurred in younger women.[\[vii\]](#) The vast majority of cases of anaphylaxis have also occurred in women.[\[viii\]](#) In addition, “women are reporting having irregular menstrual cycles after getting the coronavirus vaccine,”[\[ix\]](#) and 95 miscarriages have been reported to the U.S. Vaccine Adverse Effects Reporting System (VAERS) following COVID vaccination as of April 24, 2021.[\[x\]](#)
6. Recent research data demonstrates that the spike protein, present on the SARS-CoV-2 virus and the induced primary mechanism of action of COVID-19 vaccines, are the primary cause of disease, infirmity, hospitalization and death.[\[xi\]](#)
7. Students who have had self-limited cases of COVID-19 already possess antibodies, activated B-cells, activated T-cells (detectable by lab testing). This durable, long-term immunity would not only prevent them from getting recurrent COVID-19, but would also represent herd immunity to protect others in the college or university community. [\[xii\]](#),[\[xiii\]](#)
8. COVID-19 convalescent students may be harmed by college and university policy requiring COVID-19 vaccines.[\[xiv\]](#) They already have extensive immunity and would be likely harmed from a forced confrontation with COVID-19 vaccine induced spike protein causing autoimmune reactions leading to illness and possible death.[\[xv\]](#)
9. Students and their families may justifiably believe these policies discriminate against individuals who aren’t candidates for this vaccine, have pre-existing conditions, previous COVID-19 disease, cite religious objections, or are otherwise exercising their freewill choosing not to participate in this optional vaccine experiment. Refer to the Nuremberg

10. Institutional policies that permit faculty to choose or refuse vaccination, but do not allow students the same options, raise equal protection constitutional issues.
11. The ADA, Americans with Disabilities Act, requires “reasonable accommodations,” be provided based on an individual’s own unique health situation. This includes rejection of an experimental vaccine intervention which may exacerbate known health problems and thereby cause harm.
12. Colleges and Universities should consider whether they might be liable for damages, poor health outcomes, and loss of life due to mandatory COVID-19 vaccination policies. [\[xvii\]](#)
13. “Positive cases,” as defined by laboratory testing alone, may be false positive testing errors or asymptomatic infection that is not clinically proven to spread disease.
14. Ambulatory outpatient early treatment for SARS-CoV-2 infection / COVID-19 has been demonstrated effective in adults.[\[xviii\]](#)
15. Informed consent is the standard for all medical interventions. The FDA factsheet for the healthcare provider reads, “The recipient or their caregiver has the option to accept or refuse (Pfizer-BioNTech) vaccine.”

Please reverse your decision to mandate experimental COVID-19 vaccines before more students are harmed and make the vaccines rightfully optional. Both unvaccinated and vaccinated students should be permitted on campus. Thank you for your time and attention. We would appreciate hearing back from you as soon as possible and welcome further discussion with you and other leaders at your institution.

Sincerely,

Paul M. Kempen, M.D., Ph.D. – AAPS President (2021)

References

[ii] <https://apnews.com/article/us-colleges-divided-student-coronavirus-vaccination-8c46ab65afc4538cb060c320ed94fc54>

[iii] <https://newjersey.news12.com/rowan-stockton-universities-will-not-require-covid-19-vaccine-to-attend>

[iv] <https://www.andrewboston.org/2021/04/audio-dr-andrew-boston-with-wpros-matt-allen-4-5-21-discussing-roger-williams-universitys-mandatory-fall-2021-covid-19-vaccination-for-students-absent-any-reference-to-their-ext/>

[v] <https://pubmed.ncbi.nlm.nih.gov/33667243/>

[vi] <https://www.nydailynews.com/coronavirus/ny-covid-ohio-student-death-johnson-shot-20210416-hm54bbifnvgc7ggxzc4cxrvpui-story.html>

[vii] <https://www.cdc.gov/media/releases/2021/fda-cdc-lift-vaccine-use.html>

[viii] <https://jamanetwork.com/journals/jama/fullarticle/2776557>

[ix] <https://www.ajc.com/life/women-reporting-irregular-menstrual-cycle-after-vaccination/XRN2P4FOWRAV7DIPYTU2MO67VA/>

[x] <https://wonder.cdc.gov/vaers.html>

[xi] <https://www.qeios.com/read/26GTOD.2/pdf>

[xii] <https://www.nature.com/articles/s41577-020-00436-4>

[xiv] <https://www.aier.org/article/if-you-had-covid-do-you-need-the-vaccine/>

[xv] <https://noorchashm.medium.com/uregnt-fda-communication-catastrophic-blood-clot-risk-absent-medical-necessity-of-covid-19-a6bb35b806df>

[xvi] <http://www.cirp.org/library/ethics/nuremberg/>

[xvii] <https://thehill.com/regulation/labor/541173-first-case-against-mandatory-vaccination-filed-in-new-mexico-dention-center?rl=1>

[xviii] <https://rcm.imrpress.com/EN/10.31083/j.rcm.2020.04.264>

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Help Us Fight Back!

Contributions to the American Health Legal Foundation (AHLF) help continue the fight to stop the war on doctors and patients.

Commissioner's Report

Karen Shelton, MD
State Health Commissioner
Virginia Department of Health

Outline

Agency Stars

Maternal Health

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Public Health Policy Fellows Program

**VDH Follow-up to Joint Commission on Health Care Study of Structure and Financing of Local
Health Departments**

Public Health Policy Agenda Development Process

Agency Stars

Sirah Yoo

Anthony Salgado

Maternal Health

- Maternal mental health (MMH) is a priority in the Title V Maternal and Child Health Block Grant
 - The Pregnancy Risk Assessment Monitoring System (PRAMS) survey tracks maternal mental health conditions (such as depression and anxiety). As of 2021:
 - Before pregnancy: 14% reported experiencing depression
 - During pregnancy: 16.2% and 25.0% reported experiencing depression and anxiety, respectively
 - Postpartum: 11.3% reported experiencing depression since birth
 - Starting FY23, 23 Local Health Districts are currently doing work related to MMH
 - Activities include screening, education, referrals, maternal mental health hotline, and provider relationship building
- Home Visiting programs (MIECVH enrollees, Healthy Start, Resource Mothers) conduct depression screenings
 - In FY22 MIECHV grant period, 366 of 455 (80.4%) enrollees received screenings on time.
 - In FY23 Healthy Start grant period, 119 of 127 (94%) participants received depression screenings.
 - In FY22 Resource Mothers grant period, 284 of 414 (68.6%) participants received depression screenings.

Maternal Health

- Staff from OFHS have worked on an office-wide maternal mental health action plan to support efforts in addressing maternal mental health.
- HHS Office on Women's Health *State, Local, Territorial, and Tribal Partnership Programs to Reduce Maternal Deaths due to Violence*
 - VDH received one of 14 awards to reduce maternal deaths (pregnant and postpartum) due to homicide and suicide
 - Some activities include bidirectional linkage to care model between OB-GYN and pediatric clinics for pregnant/postpartum mothers experiencing maternal mental health challenges; prenatal class curriculum focused on maternal mental health, pregnant/postpartum experiences and relaxation of expectations, resilience skills building, and providing resources; enhancing data/surveillance around maternal mental health.

Substance Misuse Including EO26/fentanyl response

Right Help Right Now

- VDH is involved in workstreams pertaining to supporting targeted programs for substance use prevention (naloxone distribution, CHR)

Senate Bill 1415

- Naloxone Distribution Plan and Report to GA –September 1, 2023
- Begin development of Opioid Impact Reduction Registry-September 1, 2023

Executive Order 26

- Develop a plan to utilize and fund wastewater surveillance for fentanyl
- Plan to address the fentanyl crisis with strategies including increased naloxone distribution and public awareness campaigns
- Develop plan to report data with VSP Fusion Center and participate in the Framework for Addiction Analysis and Community Transformation (FAACT)
- Assist localities in establishing overdose fatality review teams

Substance Misuse Including EO26/fentanyl response

VDH Overdose Prevention Workgroup

- Offices of Family Health Services and Epidemiology co-lead
- Whole of agency effort: OCME, OEMS, OIM, OEHS, LHDs
- Includes a VDH Overdose Surveillance Workgroup (Epidemiologists and Informaticians/Data Scientists)

VDH Overdose Prevention Plan

- Goal: Reduce drug overdose death rate
- Prevention; Surveillance; Planning; Coordination and Management; Linkage to Care; MAT, CHR, Naloxone; Evaluation and Communication

Resources and Accomplishment Highlights

- SAMHSA State Opioid Response (via DBHDS) and General Funds
 - VDH has distributed >100,000 naloxone kits since July 2022
 - Two new authorized comprehensive harm reduction (CHR) sites were added in 2023 to date
- CDC Overdose Data to Action- ends August 2023 (new award begins August 2023)
 - Accomplishments: Data analysis and dissemination, improved surveillance, opioid cost calculator, PMP integration across 5,000 clinical work sites, public facing social media campaign

Partnership for Petersburg



The new CDC Infrastructure grant budget has been approved. Two new FTEs will be hired in the next 2-3 months, and four contractors will continue aiding Petersburg's public health efforts.

Water and wastewater work improvements are continuing on the Poor Creek Project.

The Immunization Clinic continues to include additional afternoon hours and the Men's Sexual Health Clinic continues to operate after-hours access (5-8pm on the 2nd and 4th Monday of the month).

The new Virginia Community Resource Center recently opened on Washington Street.

Multiple Revive trainings have recently been held to train residents on naloxone use.

Projects Funded by American Rescue Plan Act (ARPA)

Admin Ecosystems

- **VDH IT Service Portal** (powered by ServiceNow) has enabled the agency to efficiently manage **IT service requests** at both Central Office and LHDs
- Work underway to transform **financial management** across the agency by modernizing processes and increase efficiencies
- Deploying **process automation** to decrease manual workload across the agency.

Broadband *

- **30 sites have upgraded broadband.** Sites are receiving higher speeds, averaging a 7-8x increase from before.
- **63 sites have completed construction** and are ready for VITA / Verizon to set up broadband services. Daily meetings occurring between VDH and VITA / Verizon ensure completion of broadband upgrade as soon as possible.
- **54 sites are undergoing construction** for the broadband project. 10 remaining sites are moving to new locations and begin construction in mid-Summer 2023.

Oral Health

- **Partnering with Richmond-based non-profit organization, Virginia Health Catalyst (VHC),** to implement public oral health project with the goals of strengthening public oral health, implementing more holistic health standards, improving patient experience, and better coordinating care across organizations
- **Launched two teledentistry pilot programs to provide oral health services to HIV+ and OBGYN patients,** increasing access to dental care for vulnerable populations
- Worked with VCU to convene a taskforce on Virginia's dental workforce, which identified the need for additional professionals classified as Dental Assistant IIs. Since then, VHC has worked with a **community college in Southwest VA** to establish a program to train **Dental Assistant IIs**; an additional program at another community college is anticipated for this fall
- Implementing a **Value-Based Care pilot program** at two safety net clinics focused on improving quality outcomes in safety net settings

* Site numbers as of May 18, 2023.

Projects Funded by American Rescue Plan Act (ARPA)

Records Management

- 1,248 banker boxes of documents purged since January 2023
- RFP for statewide scanning and document preparation vendor completed and winner announced on [insert date]
- Six offices have completed the scoping and planning phase and are ready to begin scanning.
- Coordinated work with the Electronic Health Records project on the plan to scan clinical documents.

LHD Maintenance Project

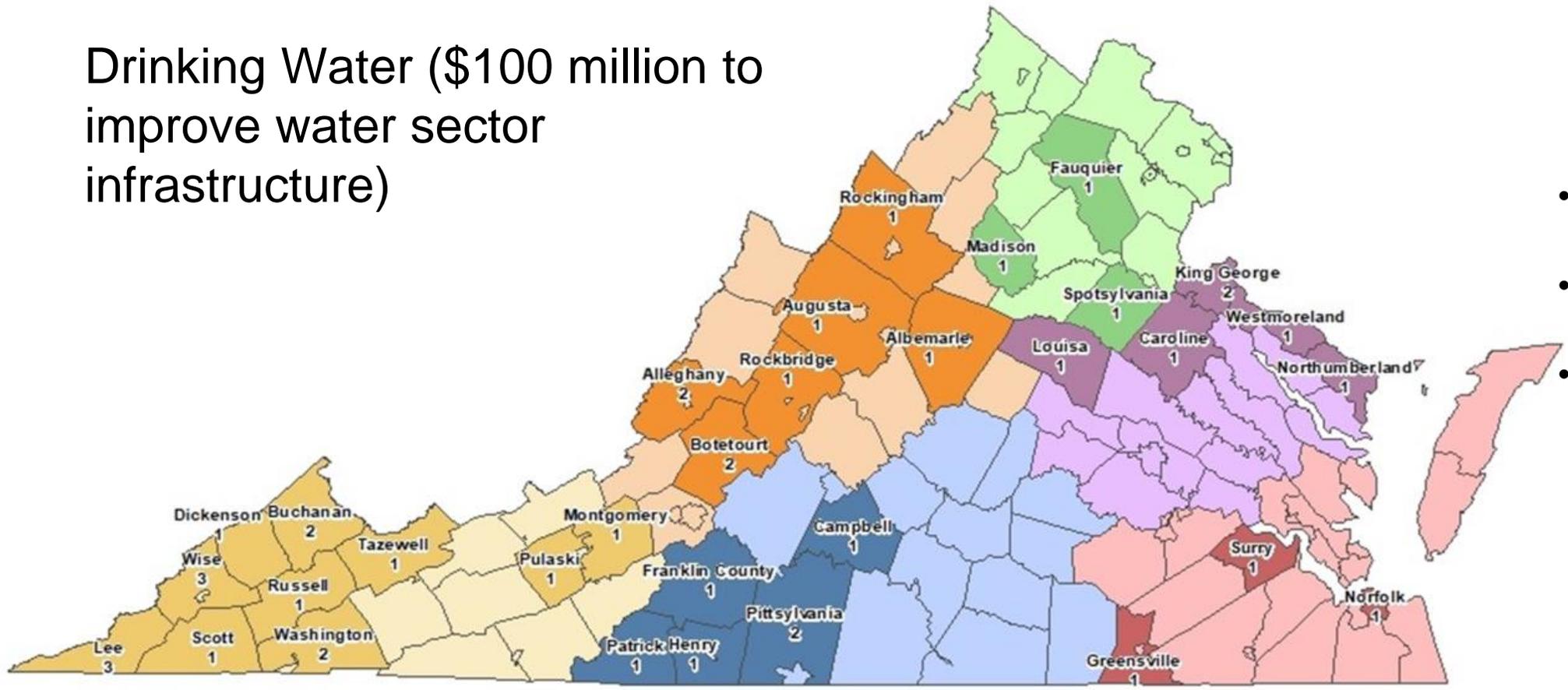
- Tenant improvement agreements have been distributed to 45 site owners with the intent of installing generators to support vaccine storage, upgrading HVAC systems and implementing site security upgrades.
- Teleconferencing upgrades have been performed in 18 James Madison Building Rooms. Overall, 77 systems have been upgraded or installed at Virginia Department of Health sites across the commonwealth.
- 17 sites have been identified to be the first to have wireless access point upgrades (WiFi) with more to follow the initial pilot effort.

Update on EHR RFP Process

- VDH is using a competitive procurement to solicit proposals from vendors for a public health EHR.
- VDH has received vendor responses and completed vendor product demonstrations.
- VDH will enter contract negotiations with the vendor(s) deemed to represent the best value to the Commonwealth.
- VDH expects to award a contract in late 2023.

Projects Funded by American Rescue Plan Act (ARPA)

Drinking Water (\$100 million to improve water sector infrastructure)



- 42 projects approved to date (37 with signed funding agreements)
- \$84.9 million obligated
- \$9.7 million disbursed to date
- Focused on small, disadvantaged communities; those with health violations or risk abandonment

Public Health Infrastructure Grant

Purpose: To ensure that every U.S. community has the people, services, and systems needed to promote and protect health, and ultimately, **lead to accelerated prevention, preparedness, and response to emerging health threats, and improved outcomes for other public health areas.**

GRANT OVERVIEW

- **Total Initial Funding: \$67,585,543**
 - \$20,528,466 for Local Health Districts (LHDs)
 - \$30,857,500 for Central Offices, trainings, etc.
 - \$16,200,000 for DBHDS and DCLS
- **Funding Period: 5-year period of performance (*December 1, 2022 – November 30, 2027*)**
- Additional funding is being awarded above the \$67M for use in Data Modernization efforts

Grant Funding Structure	
A1: Workforce ¹	\$64,755,336
A2: Foundational Capabilities	\$2,830,207 (Y1)
A3: Data Modernization	\$12,178,291

¹A1 funding obligated as a one-time lumpsum

²Sum of entire A1 allocation and Y1 of A2 allocations



Positions Funded Under Grant

- **73 Total Positions Funded**
 - 50 FTE/Wage Positions Funded, 30 of which will be a continuation of positions currently funded by the CDC Public Health Workforce Grant
 - 23 Contractor/Consultant Positions Funded, 12 of which will be a continuation of positions currently funded by the CDC Public Health Workforce Grant

Budget Categories ²			
Salaries	\$12,868,025	Travel	\$767,628
Fringe	\$4,666,908	Contractual	\$35,901,967
Consultant	\$6,592,288	Other	\$4,096,144
Equipment	\$0	Indirect Costs	\$1,943,072
Supplies	\$749,511		
Total			\$67,585,543

Public Health Infrastructure Grant

Key Initiatives



Retention Initiatives

Addressing public health needs by supporting initiatives targeting the retention of talent.



Professional Development

Developing new and existing talent at VDH to strengthen foundational capabilities.

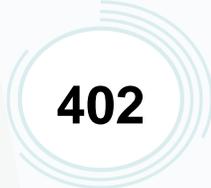


Public Health Messaging

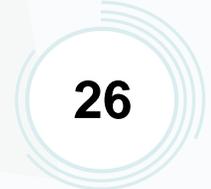
Supporting infrastructure to effectively distribute public health information.

Spotlight: VDH Internship Academy

VDH has initiated its inaugural Internship Academy for 2023, with its first class of interns starting the week of May 22.



Number of Applicants



Number of Incoming interns

VDH will assess this pilot project for the first year, based on evaluation activities to be conducted in July/August 2023.

Hurricane 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
- **Planning, Training and Exercising**
 - Disaster Shelter Training Courses
 - Health and Medical Fundamentals
 - Environmental Health
 - Nursing
 - VDH Mass Care Plan
 - Virginia Emergency Support Team Exercise (VESTEX)
 - State-Coordinated Regional Shelter Exercise
- **Public Information and Education**
- **Public Health Surveillance**

VDH Virginia Department of Health May 4 at 11:01 AM ·

Be prepared for hurricane season by knowing what to do during a storm. Whether you've evacuated or are sheltering in place, know what to expect from the hazards you may face. Remain vigilant, stay up-to-date with the latest forecasts and alerts, and continue to listen to local officials.

<http://ow.ly/Pmzx50NN1HT>

Hurricane Preparedness weather.gov/hurricane

Stay Protected During Storms

- Stay in your safe places from water & wind
- Have a way to get weather alerts and forecast updates
- Keep in mind that impacts can be felt far from the coast
- Listen to local officials & avoid travel unless ordered to evacuate

VDH participated in National Hurricane Preparedness Week April 30 – May 6, 2023, and shared preparedness messaging on social media

Public Health Policy Fellows Program

Program will provide an evidence-based, non-partisan, and engaging educational experience for participants (Fellows) in order to:

- Increase the understanding of and appreciation of public health and Virginia's public health system among Virginia's policy makers and other key stakeholders;
- Create an environment in which trust can be restored to Virginia's public health system;
- Foster a climate more conducive to research-informed public policy decisions beneficial to Virginians and Virginia's public health system; and
- Develop public health champions among policy makers and stakeholders external to VDH.

Program content, structure and timetable is under development in coordination with the Office of the Secretary of Health and Human Resources

Funded with \$100,000 from CDC Public Health Infrastructure Grant

VDH Follow-up to Joint Commission on Health Care Study of Structure and Financing of Local Health Departments

The [JCHC Study on Structure and Financing of Local Health Departments](#) identified eleven policy options including those focused on: cooperative budget funding, performance management, community health assessments/community health improvement plans, availability of clinical services,, data infrastructure, loan repayment programs for staff, targeted salary increases for staff, regional operations and facilities management positions, and communications.

JCHC adopted only one policy option – budget amendment for targeted salary increases; budget amendment was not approved by General Assembly

JCHC sent a letter to Commissioner requested that VDH convene a stakeholder workgroup to 1) prioritize the policy options; 2) identify any additional policy options; and 3) provide cost estimates/funding recommendations.

VDH is working with Office of Secretary of Health and Human Resources to develop a plan for convening workgroup, preparing information to present to the workgroup, and reporting back to the General Assembly.

Public Health Policy Agenda

- GOAL: Develop proactive, research-based recommendations for Virginia's public health policy in coordination with relevant stakeholders that will be championed by VDH and our partners.
- Alignment with SHA/SHIP processes, VDH's Strategic Plan, Administration priorities, Local Health Districts, etc.



- Current priorities and activities:
 - Continued socialization within the agency and encouragement to participate
 - Partnership with Public Health Academic Advisory Council as a source of Problem Statements and research
 - Ongoing process evaluation as Problem Statements begin to move through.

Public Health Policy Agenda

Problem Statements

Problem Scope

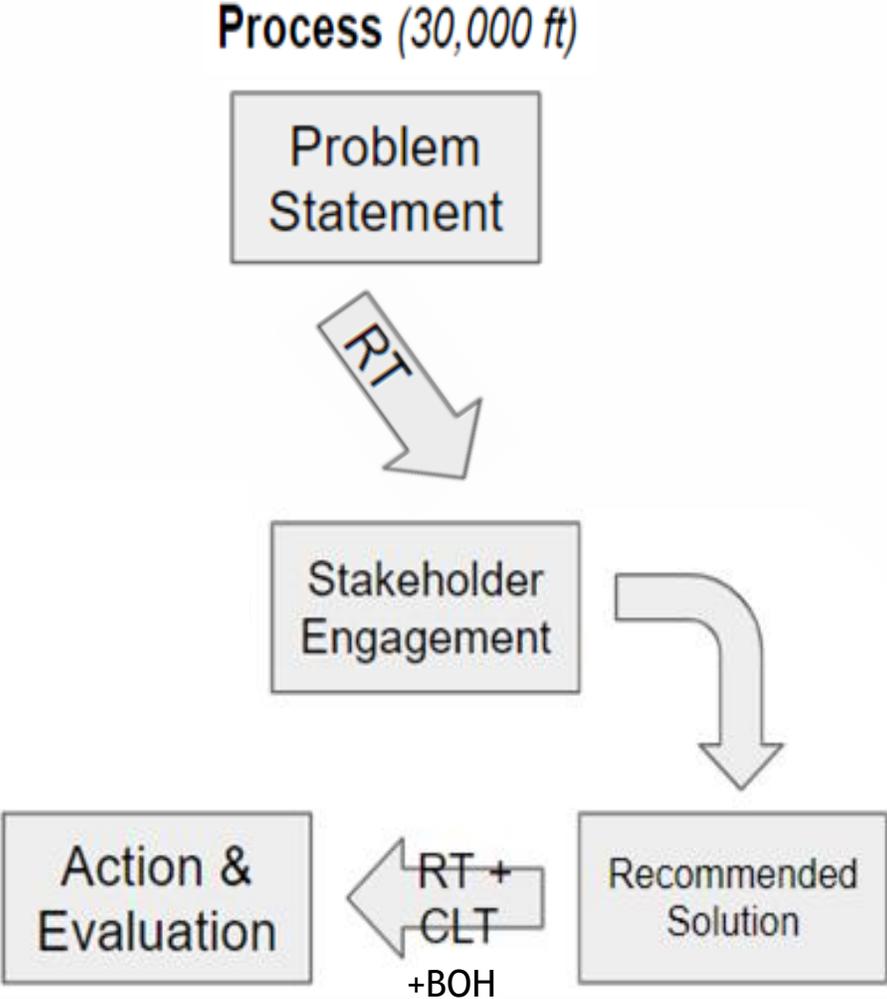
- What is the problem & how do we know?

Interdependencies

- Who should be at the table?

Problem Statements currently in process touch on:

- Health Equity and Social Determinants of Health
- Infection Control and Prevention
- Maternal Health



Questions?

**State Board of Health
Regulatory Action Update
June 15, 2023**

Overview of Pending Regulatory Actions:

There are 46 pending actions under development:

- 8 NOIRAs
- 12 proposed actions
- 7 final actions
- 19 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.-20 of the Code of Virginia since the March 23, 2023 Board Meeting while the Board was not in Session:

(Parham Jaber, MD – Acting) Approved Result of Periodic Review of Regulations – Commonwealth of Virginia Sanitary Regulations for Marinas and Boat Moorings (12VAC5-570)

The decision resulting from the periodic review of Chapter 570 is to amend the Regulations to simplify the application process for the industry, improve the administration and enforcement of marina standards, reduce administrative burden to regulants, and incorporate public comments, as appropriate.

Approved Result of Periodic Review of Regulations – Regulations for the Immunization of School Children (12VAC5-110)

The decision resulting from the periodic review of Chapter 110 is to **retain** the Regulations as is.

Non-Regulatory Actions Taken by the Commissioner on Behalf of the Board since the March 23, 2023 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.

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 21 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 5-221[†] Virginia's Rules and Regulations Governing Cooperative Agreements
- 12 VAC 5-381^{**} Home Care Organization Regulations
- 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 5-475^{††} 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 a Long-Term-Care Facility
- 12 VAC 5-520^{*} Regulations Governing the State Dental Scholarship Program
- 12 VAC 5-530^{††} Regulations Governing the Virginia Medical Scholarship Program
- 12 VAC 5-542^{††} Rules and Regulations Governing the Virginia Nurse Practitioner / Nurse Midwife Scholarship Program
- 12 VAC 5-545[†] Guidelines for the Nurse Educator Scholarship
- 12 VAC 5-590^{*} Waterworks Regulations
- 12 VAC 5-613[†] Regulations for Alternative Onsite Sewage Systems
- 12 VAC 5-620[†] Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells
- 12 VAC 5-640[†] Alternative Discharging Sewage Treatment Regulations for Individual Single Family Dwellings

12 VAC 5-650[†] Schedule of Civil Penalties

[†]The Results of Periodic Review for 14 chapters are due to the Regulatory Coordinator before the September Board Meeting.

^{††} The Result of Periodic Review has been submitted and is under OCOM review.

*The Result of Periodic Review will be concluded after the current regulatory actions amending these chapters are effective.

**The Notice of Periodic Review for this chapter was issued with a Notice of Intended Regulatory Action. The result will be included in the Proposed stage.

Executive Branch Review Activity Completed since the March 23, 2023 Board Meeting:

The Office of the Attorney General certified:

- Fast Track amendments to the Rules and Regulations Governing Campgrounds (12VAC5-450)

The Department of Planning and Budget completed the review of:

- NOIRA for the Regulations Governing Tourist Establishment Swimming Pools and Other Public Pools (12VAC5-460)

The Office of Regulatory Management completed the review of:

- Proposed Regulations for Disease Reporting and Control (12VAC5-90)

The Governor completed the review of:

- Proposed Regulations for Disease Reporting and Control (12VAC5-90)

SFY 2024 Unified Regulatory Plan

Pursuant to Executive Order 19 (2022) and the Office of Regulatory Management's (ORM) Procedures for Review of State Regulations, each agency is required to submit an annual Unified Regulatory Plan (URP) that details the anticipated regulatory actions and changes to the agency's guidance documents for a state fiscal year. VDH's SFY2024 URP is due to ORM by June 30, 2023.

Regulatory Reduction

ORM released a guide for agencies toward achieving the Administration's goal of reducing discretionary regulations by 25% by the end of the 2025. Office-level policy staff are currently in the process of establishing our "baseline" count of regulatory requirements, which is due to ORM by July 31, 2023. We will be encouraging use of periodic reviews as major opportunities to consider options for regulatory reduction.



COMMONWEALTH of VIRGINIA

Karen E. Shelton, MD
State Health Commissioner

Department of Health
P O BOX 2448
RICHMOND, VA 23218

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

MEMORANDUM

DATE: April 13, 2023

TO: Virginia State Board of Health

FROM: Seth Austin, Director of the Office of Vital Records

SUBJECT: Amending regulations following statutory changes – 12VAC5-550

The purpose of the proposed amendments is to update definitions in the Virginia Administrative Code (12VAC5-550-5) to provide clarity to Virginia regulations; repeal sections (12VAC5-550-20; 12VAC5-550-30, 12VAC5-550-50, 12VAC5-550-60) which are not regulatory in nature; updates forms used by sections impacted by the action (12VAC5-550-140, 12VAC5-550-9998); and conforms the requirements of the following sections to the Code of Virginia:

- 12VAC5-550-440, 12VAC5-550-450, 12VAC5-550-460: Amending death certificates and requirements to conform with §32.1-269.1
- 12VAC5-550-125: Stillbirth certificate fee removal to conform with §32.1-.258.1
- 12VAC5-550-520: Updating fees for vital records requests, amendments or delayed registrations to conform with §32.1-273
- 12VAC5-550-320: Change of sex on birth certificate requirements to conform with §32.1-261
- 12VAC5-550-130: Removing the item “race” on marriage and divorce certificates to conform with §§32.1-267, 32.1-268 and 32.1-268.1

The Board of Health is requested to approve the Fast Track Action; if approved it shall be published in the Virginia Register of Regulations. A 30-day public comment period will begin and a public comment forum will open on the Virginia Regulatory Town Hall website. The regulations will become effective 15-days after the public comment period ends unless there is objection by member(s) of the applicable committee of the Senate or House of Delegates, member(s) of the Joint Commission on Administrative Rules, or 10 or more members of the public; in which case the Fast Track regulation will serve as Notice of Intended Regulatory Action and the standard rulemaking process shall be followed to promulgate the regulation.



townhall.virginia.gov

Fast track Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-550
VAC Chapter title(s)	Board of Health Regulation Governing Vital Records
Action title	Amend Regulations Following Statutory Changes
Date this document prepared	4/12/2023

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 fast track action amends the Regulations to reflect several recent changes in the Code of Virginia, including changes to §§ 32.1-258.1, 32.1-269.1, 32.1-261, and 32.1-267. Several sections will be repealed, as these sections are not regulatory in nature. The amendment to 12VAC5-550-520 changes the certification fee from \$10 to \$12 because this fee was changed in the Code and implemented several years ago.

Chapter 171 of the 2022 Acts of Assembly removed the authority to charge a fee to obtain a stillbirth certificate. The business operations of the Office of Vital Records have already been changed to conform to the new law, but the regulations have not yet been changed. Chapters 209, 210, and 211 of the 2020 Acts of Assembly removed race from the data to be collected regarding marriages, divorces, and annulments. Chapters 465 and 466 of the 2020 Acts of Assembly amended the process to change one’s sex on a birth certificate. Chapters 116 and 117 of the 2022 Acts of Assembly changed the process and timelines associated with amending a death certificate.

The amendments improve the regulatory language used in the Virginia Administrative Code so that both the public and government organizations have better direction concerning the responsibilities and requirements needed to perform their duties. This should reduce time spent dealing with challenges to processes that are presented by members of the public and will make the operations of the Office of Vital Records more efficient.

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.

There are no acronyms used in this Agency Background Document that are not also defined in the “Definitions” section of the regulation.

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.

Chapter 171 (2022) removed the authority to charge a fee to obtain a stillbirth certificate for unintended, intrauterine fetal deaths. Chapters 209, 210, and 211 (2020) removed race from the data to be collected regarding marriages, divorces, and annulments. Chapters 465 and 466 (2020) amended the process to change one’s sex on a birth certificate. Chapters 116 and 117 (2022) changed the process and timelines associated with amending a death certificate. Additionally, sections 20, 30, 50, and 60 will be repealed because the provisions do not meet the statutory definition of a “regulation” in § 2.2-4001.

The rulemaking is expected to be non-controversial because the substantive changes being made are to comply with changes to the Code of Virginia. Additionally, the style and form changes are not substantive but will make the regulations clearer and more readable for both the public and agency staff.

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 regulation is promulgated by the State Board of Health under the authority of §§ 32.1-12 and 32.1-250 of the Code of Virginia.

Section 32.1-12 grants the Board of Health the legal authority to make, adopt, promulgate, and enforce regulations necessary to carry out the provisions of Title 32.1 of the Code and other laws of the Commonwealth administered by it. Section 32.1-250 of the Code of Virginia requires the Board of Health to install, maintain and operate the only system of vital records throughout the Commonwealth.

Specific changes being made are authorized by Chapters 209, 210, 211, 465, and 466 (2020) and 116, 117, and 171 (2022). The fee amount in Section 520 is being updated to reflect the amount in Item 290 A, Chapter 2 of the 2022 Acts of Assembly, Special Session I.

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.

This fast track action is essential to ensure the regulations that govern the business processes of the VDH Office of Vital Records are in conformance with provisions of the Code of Virginia. This fast track action also seeks to increase the clarity, accuracy, and completeness of the regulations governing vital records.

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.

- 12VAC5-550-5. Definitions are updated to make the Regulations easier to understand.
- 12VAC5-550-20, 12VAC5-550-30, 12VAC5-550-50, and 12VAC5-550-60 have been repealed. These provisions do not meet the statutory definition of a "regulation" in § 2.2-4001 and are unnecessary.
- 12VAC5-550-125. Certificate of birth resulting in a stillbirth for unintended, intrauterine fetal deaths. The changes remove the fee for this type of vital record.
- 12VAC5-550-130. Marriage return and certificate items. The changes identify the specific form that will be used for this action, which facilitates the removal of race as a certificate item.
- 12VAC5-550-140. Report of divorce or annulment. The changes identify the specific form that will be used for this action, which facilitates the removal of race as a certificate item.
- 12VAC5-550-320. Change of Sex. The changes identify the specific form that will be used for this action, clarify the language, and conform the regulation to the Code of Virginia.
- 12VAC5-550-440. Applications for correction. The changes update the timeframe for amending a death certificate and clarify how the amendment can be accomplished consistent with the Code.

- 12VAC5-550-450. Evidence required for corrections or amendments. The changes add to and clarify the requirements for changes made to a death record.
- 12VAC5-550-460. Methods of correcting or altering certificates. The changes define “amendment” to bring consistency and clarity to the regulations.
- 12VAC5-550-520. Fees. This fee is being updated to reflect Item 290 A, Chapter 2 of the 2022 Acts of Assembly, Special Session I.
- 12VAC5-550-9998 FORMS. Forms that are only used internally by OVR staff are being removed, the effective dates of all necessary forms are being updated, along with links to the documents.

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, the Agency, and the Commonwealth include the enhanced integrity of the regulations governing vital records and in turn the system of vital records within the Commonwealth. There are no known disadvantages to the public, regulated entities, business entities, or the Commonwealth.

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.

There are no requirements of this proposal that are more restrictive than applicable 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 agency will be affected by these fast track amendments.

- Localities Particularly Affected: There are no localities that will be affected by these fast track amendments.
- Other Entities Particularly Affected: Members of the public filing or amending vital records are affected by the process changes – however, because the regulatory changes are to comply with previous changes in the Code, no other entity will be affected solely by the 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

<i>For your agency:</i> projected costs, savings, fees, or revenues resulting from the regulatory change, including: a) fund source/fund detail; b) delineation of one-time versus ongoing expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	The projected cost to the Virginia Department of Health to implement and enforce this regulatory proposal is negligible. It will not interrupt or affect business operations within the Office of Vital Records.
<i>For other state agencies:</i> projected costs, savings, fees, or revenues resulting from the regulatory change, including a delineation of one-time versus ongoing expenditures.	There is no projected cost to other state agencies to implement and enforce this regulatory proposal.
<i>For all agencies:</i> Benefits the regulatory change is designed to produce.	None.

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.	Implementing and enforcing this regulatory proposal will not produce a cost to any localities.
Benefits the regulatory change is designed to produce.	None.

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.	The analysis has been reported in tables 1a, 3, and 4 on the ORM Economic Review form.
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<p>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:</p> <ul style="list-style-type: none"> 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. 	<p>The analysis has been reported in tables 1a, 3, and 4 on the ORM Economic Review form.</p>
<p>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:</p> <ul style="list-style-type: none"> 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. 	<p>The analysis has been reported in tables 1a, 3, and 4 on the ORM Economic Review form.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The analysis has been reported in tables 1a, 3, and 4 on the ORM Economic Review form.</p>

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.

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

There are no viable alternatives to the proposal considered. The regulatory action is necessary to make corrections to the existing regulations, provide clarification to regulatory language, and add additional regulatory sections required by changes to the Code of Virginia.

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.

No alternative regulatory methods are available to the agency. These changes are being made to comply with the Code of Virginia and make non-substantive changes for the purpose of clarity and readability; they do not address compliance and reduce reporting requirements, and the regulations do not impact small businesses.

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 describe the nature of, and reason for, your objection to using this process.

The Virginia Department 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 website at: <https://townhall.virginia.gov>. Comments may also be submitted by mail, email, or fax to

Yolanda Aponte, Office of Vital Records,
 P. O. Box 1000
 Richmond, VA 23218,
 Phone: (804) 482-7939,
 Fax: (804) 662-6256,
 Email: yolanda.aponte@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
12VAC5-550-5		<p>"In addition to the words and terms defined in § 32.1-249 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:</p> <p>...</p> <p>"Primary evidence" means valid first-hand documentation established before the registrant's 18th birthday, such as school admission records, physician's records, immunization records, passport, federal census abstracts, baptismal records and insurance applications.</p> <p>"Registrant" means the person whose personal information is registered and filed in the systems of vital records.</p> <p>"Secondary evidence" means valid documentation established after the registrant's eighteenth birthday such as marriage records, child's birth certificate, school records, social security records, driver's records, work permit and employment records. Such evidence must be at least five years old."</p>	<p>CHANGE: The definition of "primary evidence" is being updated to replace the words "such as" with "including." The definition for "registrant" is being updated to mean the person whose personal information is "<u>primarily registered on a vital record...</u>" (new language underlined.) The definition of "secondary evidence" is being updated to replace "such as" with "including," make a style change, and remove reference to the requirement that the evidence be at least five years old. A definition for "registrar" is also being added.</p> <p>INTENT: The intent is to increase the clarity of those definitions being amended. The update to the definition of "registrant" is intended to specify the person considered to be a registrant, as the information of more than one person may be included on a vital record. For example, a parent's information is included on their child's birth certificate, but the child is considered the registrant. The intent of adding a definition for "registrar" is to be able to identify tasks that can be performed by the State Registrar or any other in the Commonwealth.</p> <p>RATIONALE: The rationale is that clearer regulations are better for the public and for agency staff administering them. The definition for "secondary evidence" also contained a substantive requirement, which should not be included in a "Definitions" section.</p> <p>LIKELY IMPACT: The likely impact is that the regulations will be more readable.</p>
12VAC5-550-20		<p>This section identified the purpose of the regulations.</p>	<p>CHANGE: The section is being repealed</p> <p>INTENT: The intent is to repeal non-regulatory provisions, which are unnecessary.</p> <p>RATIONALE: The rationale is that the provisions are not regulatory in nature pursuant to the definition of a regulation in § 2.2-4001. The Registrar of Regulations, pursuant to 1VAC7-10-40 (C) has the authority to omit non-regulatory and unnecessary provisions from publication.</p>

			<p>LIKELY IMPACT: The regulations will be shorter and not contain unnecessary language.</p>
<p>12VAC5-550-30</p>		<p>This section identifies the “administration” of the chapter.</p>	<p>CHANGE: The section is being repealed</p> <p>INTENT: The intent is to repeal non-regulatory provisions, which are unnecessary.</p> <p>RATIONALE: The rationale is that the provisions are not regulatory in nature pursuant to the definition of a regulation in § 2.2-4001. By nature of being promulgated by the Board of Health under its basic laws, the administration of the chapter is already set forth in the Code of Virginia. The Registrar of Regulations, pursuant to 1VAC7-10-40 (C) has the authority to omit non-regulatory and unnecessary provisions from publication.</p> <p>LIKELY IMPACT: The regulations will be shorter and not contain unnecessary language.</p>
<p>12VAC5-550-50</p>		<p>This section indicates that the Administrative Process Act (APA) applies to the regulation.</p>	<p>CHANGE: The section is being repealed</p> <p>INTENT: The intent is to repeal non-regulatory provisions, which are unnecessary.</p> <p>RATIONALE: The rationale is that the provisions are not regulatory in nature pursuant to the definition of a regulation in § 2.2-4001. The APA applies without including a statement to that effect in the regulation. The Registrar of Regulations, pursuant to 1VAC7-10-40 (C) has the authority to omit non-regulatory and unnecessary provisions from publication.</p> <p>LIKELY IMPACT: The regulations will be shorter and not contain unnecessary language.</p>
<p>12VAC5-550-60</p>		<p>“The board reserves the right to authorize any procedure for the enforcement of this chapter that is not inconsistent with the provisions set forth herein and the provisions of Chapter 7 of Title 32.1 of the Code of Virginia.”</p>	<p>CHANGE: The section is being repealed</p> <p>INTENT: The intent is to repeal non-regulatory provisions, which are unnecessary. The Registrar of Regulations, pursuant to 1VAC7-10-40 (C) has the authority to omit non-regulatory and unnecessary provisions from publication.</p> <p>RATIONALE: The rationale is that the provisions are not regulatory in nature pursuant to the definition of a regulation in § 2.2-4001. The section does not define or specify any specific power or procedure to be followed by a regulated entity or by the</p>

			<p>agency, and the Board's powers are already set forth in the Code of Virginia.</p> <p>LIKELY IMPACT: The regulations will be shorter and not contain unnecessary language.</p>
12VAC5-550-125		<p>This section describes the process by which a parent may receive a Certificate of Birth Resulting in Stillbirth.</p>	<p>CHANGE: The change is to remove the requirement to pay a fee to receive a Certificate pursuant to the section. Multiple changes in style and form are also made.</p> <p>INTENT: The intent is to provide stillbirth certificates free of charge. The requirements for the certificate have been reorganized for clarity and to make the section consistent with the Registrar of Regulations' <i>Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code ("Style Requirements")</i>.</p> <p>RATIONALE: Chapter 171 (2022) removed the authority to charge a fee associated with obtaining a stillbirth certificate for unintended, intrauterine fetal deaths. Also, regulatory language should conform to the <i>Style Requirements</i> to ensure concise, clear, and consistent regulatory language.</p> <p>LIKELY IMPACT: The impact of the change is negligible, as there are very few stillbirth certificates produced each year, and the loss of revenue is minimal. In Virginia, there were approximately 2,800 unintended, intrauterine fetal deaths between 2018 and 2020; which led to only 229 applications for certificates. For those wishing to obtain a certificate, though, they can do so free of charge. The language will also be more readable.</p>
12VAC5-550-130		<p>This section included the form to be used to register a marriage and the items to be included on the form.</p>	<p>CHANGE: The section will be updated to reference the process by which an officer issuing marriage licenses is to report those marriages to the State Registrar of Vital Records, including the form. It will also reference the form required to be used by members of the public to obtain a certified copy of a marriage certificate. The word "items" is also stricken from the section title, as the section no longer lists the items in the form but refers to the form itself, instead.</p> <p>INTENT: The intent is to make the regulations clearer and more reflective of the processes governed by the State Registrar and to reference the required forms to be used. In effect, because the forms no longer require race to be reported, it removes the current requirement which is unenforceable.</p>

			<p>RATIONALE: The rationale is that Chapters 209, 210, and 211 (2020), prompted by the order in a federal court case, <i>Rogers v. Virginia State Registrar, 507 F. Supp. 3d 664 (E.D. Va. 2019)</i>, removed the reporting of race from marriage applications, licenses, and records.</p> <p>LIKELY IMPACT: The regulations will comply with the Code of Virginia.</p>
12VAC5-550-140		This section included the form to be used to register a divorce or annulment and the items to be included on the form.	<p>CHANGE: The section will be updated to reference the process by which a clerk of the court granting decrees of divorce and annulment to the State Registrar of Vital Records, including the form. It will also reference the form required to be used by members of the public to obtain a certified copy of a divorce or annulment certificate. The word “items” is also being stricken from the section title, as the section no longer lists the items in the form but makes reference to the form itself, instead.</p> <p>INTENT: The intent is make the regulations clearer and more reflective of the processes governed by the State Registrar and to reference the required forms to be used. In effect, because the forms no longer require race to be reported, it removes the current requirement which is unenforceable.</p> <p>RATIONALE: The rationale is that Chapters 209, 210, and 211 (2020), prompted by the order in a federal court case, <i>Rogers v. Virginia State Registrar, 507 F. Supp. 3d 664 (E.D. Va. 2019)</i>, removed the reporting of race from divorce and annulment records.</p> <p>LIKELY IMPACT: The regulations will comply with the Code of Virginia.</p>
12VAC5-550-320		This section describes the process by which a person may obtain a new birth certificate to reflect a change in sex and associated name change. The regulations currently require evidence of specific surgical procedures and diagnoses and a court order.	<p>CHANGE: The section still describes the process but refers to the specific form to be used, which is to be completed by a healthcare provider who has provided clinically appropriate treatment. It removes the requirement to submit a court order changing one’s sex. The section maintains a reference to the process by which a person changing the sex on their birth certificate may change their name but specifies the evidence that may be required. The amendment also updates the style and form of the language.</p> <p>INTENT: The intent is to conform the process to the Code of Virginia and clarify the process and form to change one’s sex</p>

			<p>as it appears on a birth certificate. The intent is also to include in the regulations a reference to the evidence requirements the State Registrar’s Office may need to accurately identify the birth certificate corresponding to the person requesting the change of sex. Also, regulatory language should conform to the <i>Style Requirements</i> to ensure concise, clear, and consistent regulatory language.</p> <p>RATIONALE: The rationale is that Chapters 465 and 466 (2020) amended the process to change one’s sex on their birth certificate in the Code of Virginia. The amendment prohibited requirements for evidence or documentation of any medical procedure and required the submission of a specific form to the State Registrar that is completed and signed by a health care provider confirming clinically appropriate treatment for gender transition. Additionally, a court order granting a name change may not contain enough information to accurately identify the person’s birth certificate, as multiple people born in the Commonwealth have the same name. The Office of Vital Records may need to inspect additional information, which the person would have submitted to the Circuit Court to obtain the court order changing their name, to accurately make that identification.</p> <p>LIKELY IMPACT: The regulations will comply with the Code of Virginia and more clearly and accurately reflect the process to change one’s sex and name.</p>
<p>12VAC5-550-440</p>		<p>This section describes the process and requirements to correct or amend a vital record.</p>	<p>CHANGE: The subsections related to amending a birth certificate or marriage, divorce, or annulment record will be updated to make style and form changes. The death certificate amendment procedure will also be updated to allow for changes to be made administratively (i.e., without a court order) within 45 days instead of 30 and beyond 45 days in certain circumstances.</p> <p>INTENT: The intent of the style and form changes is to conform the section to the <i>Style Requirements</i>. The intent of the substantive change is to clarify the process by which a person may amend a death certificate, which includes an additional 15 days to request an administrative amendment.</p> <p>RATIONALE: The rationale is that the death certificate amendment process in the Code of Virginia was changed by Chapters 465 and 466 (2022). Also, regulatory language</p>

			<p>should conform to the <i>Style Requirements</i> to ensure concise, clear, and consistent regulatory language.</p> <p>LIKELY IMPACT: The regulations will comply with the Code of Virginia and members of the public who wish to amend a death certificate will utilize the new process and timelines. Additionally, the regulation will be clearer and more readable.</p>
<p>12VAC5-550-450</p>		<p>This section describes the evidence that a person is required to submit to request an amendment to a vital record.</p>	<p>CHANGE: The requirements related to amending birth and death certificates are separated. There are also minimal style changes made to the first paragraph of subsection A.</p> <p>INTENT: The intent is to clarify the difference between the evidence required to change a birth certificate vs. a death certificate. Also, regulatory language should conform to the <i>Style Requirements</i> to ensure concise, clear, and consistent regulatory language.</p> <p>RATIONALE: The rationale is that the process by which a death certificate can be amended, and subsequently the evidence needed, were changed by Chapters 465 and 466 (2022). The current regulatory requirements do not distinguish between the two types of certificates, though the process for each is now different.</p> <p>LIKELY IMPACT: The regulations will comply with the Code of Virginia and members of the public who wish to amend a death certificate will utilize the new process and timelines. Additionally, the regulation will be clearer and more readable.</p>
<p>12VAC5-550-460</p>		<p>This section describes how the registrar makes requested and authorized amendments to vital records.</p>	<p>CHANGE: The changes are mostly non-substantive and in only style and form. Subsection A will be amended to change the provision that a birth certificate on which a name is amended within seven years will not be considered as an amendment to the vital record– the timeframe will be reduced to one year and considered as an administrative change.</p> <p>INTENT: The intent of the style changes is to conform the regulations to the <i>Style Requirements</i>. The change regarding the timeframe in which a name may be changed without considering a birth certificate to be amended is intended to comply with § 32.1-269 (B) of the Code.</p>

			<p>RATIONALE: Regulatory language should conform to the <i>Style Requirements</i> to ensure concise, clear, and consistent regulatory language. Also, § 32.1-269 (B) requires the Board to “prescribe by regulation the conditions under which omissions or errors on certificates [...] may be corrected within one year after the date of the event without the certificate being marked amended.” The process will be updated to reflect that one-year point instead of seven years.</p> <p>LIKELY IMPACT: Most changes clarify the language, but also include a clarification of the timeline associated with the term “amendment” to now refer to changes made after one year from the date of the vital event. This change is needed to support the other changes to Regulations pertaining to vital records amendments which are necessary due to Chapters 116 and 117 of the 2022 Acts of Assembly.</p>
12VAC5-550-520		<p>A. The fee to be charged by the State Registrar or by the city or county registrar shall be \$10 for each full certification or short-form certification of a vital record, or for a search of the files or records when no copy is made.</p> <p>B. When documents are amended or delayed birth registration is requested, the requester shall be charged an administrative fee of \$10.</p>	<p>CHANGE: The change is to update the fee for a certified copy from \$10 to \$12 unless otherwise directed in the Code. There are also style and form changes made to the section.</p> <p>INTENT: The intent is to conform the regulations to the Appropriation Act, which sets the fee at \$12, and to reference the special circumstances in which no fee is to be charged. The intent is also to conform the language to the <i>Style Requirements</i>.</p> <p>RATIONALE: Item 309 A, Chapter 4 of the 2004 Acts of Assembly, Special Session I initially updated the “standard vital records fee” to \$12. Item 290 A, Chapter 2 of the 2022 Acts of Assembly, Special Session I, includes that language. Also, regulatory language should conform to the <i>Style Requirements</i> to ensure concise, clear, and consistent regulatory language.</p> <p>LIKELY IMPACT: The regulations will conform to the Appropriation Act language.</p>
FORMS (12VAC5-550)		The section listed 17 forms used by the State Registrar of Vital Records.	<p>CHANGE: Forms only used by the Office of Vital Records, which include vital record templates, will be removed. The applications for a Birth Record, Marriage-Divorce Record, Death Record, Stillbirth Certificate, form to change sex designation, and request to amend a birth certificate are all added. Additionally, the report of adoption, acknowledgment of paternity, and affidavit for correction of a record are all updated to reflect the most updated and effective version of the form.</p>

			<p>INTENT: The intent is to only list those forms that are used by the public and to ensure access to the most up-to-date versions of the forms.</p> <p>RATIONALE: The rationale is that forms listed in the section should include access to printable or downloadable versions of the form and vital record/certificate templates should not be publicly accessible. The forms that members of the public need or are required to use should be listed and accessible.</p> <p>LIKELY IMPACT: The public will have access via the regulations in the VAC online to all relevant forms. Also, the section will be more concise with the removal of unnecessary references to other forms.</p>
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Office of Regulatory Management
Economic Review Form

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-550
VAC Chapter title(s)	Board of Health Regulations Governing Vital Records
Action title	Amend Regulations Following Statutory Changes
Date this document prepared	4/12/2023
Regulatory Stage (including Issuance of Guidance Documents)	Fast Track Action

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)

<p>(1) Direct & Indirect Costs & Benefits (Monetized)</p>	<p>There are no monetized costs associated with any of the proposed regulatory changes.</p> <p>There are no monetized benefits associated with the proposed changes to the following sections:</p> <ul style="list-style-type: none"> • 12VAC5-550-5 • 12VAC5-550-20 • 12VAC5-550-30 • 12VAC5-550-50 • 12VAC5-550-60 • 12VAC5-550-130 • 12VAC5-550-140 • 12VAC5-550-9998 (FORMS) • All style and form changes throughout the chapter <p>The monetized benefits associated with the proposed changes are detailed below:</p> <ul style="list-style-type: none"> • The regulatory action will amend the Certificate of birth resulting in a stillbirth regulation (12VAC5-550-125) removing the requirement of a fee to be established for this certificate type. This action is required to conform to Chapter 171 of the 2022 Acts of Assembly. Benefits: Individuals requesting a certificate of birth resulting in a stillbirth will no longer be charged a \$12 fee. From 2018 through 2020, the Office of Vital Records issued 229 of these certificates, equaling an average savings of \$916 per year if fees were not charged during that time period. • The regulatory action will amend the Change of sex (12VAC5-550-320) to update the requirements for changing the sex on a birth certificate to conform to Chapter 466 of the 2020 Acts of Assembly. Benefits: Individuals seeking to change the sex on their birth certificate can now accomplish this through a simplified administrative process that does not require court costs. Legal fees can range widely, so VDH does not have a way to calculate this potential benefit. • The regulatory action will amend the Applications for correction (12VAC5-550-440), Evidence required for corrections or amendments (12VAC5-550-450), and Methods of correcting or altering certificates (12VAC5-550-460) to allow information on a death certificate to be amended with supporting evidence for 45 days after the filing of the death certificate, and to clarify amendment forms and processes to create internal consistency within the Regulations. This action is required to conform to Chapter 117 of the 2022 Acts of Assembly. The change to Section 460 is to conform to § 32.1-269 (B) of the Code of Virginia.
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	Benefits: Individuals seeking to amend a death certificate no longer need to pay court fees to obtain a court order to request an amendment to the decedent’s name, informant’s name, name of spouse, marital status, name of parents, and place of residency when outside of the Commonwealth if an amendment is made within 45 days of filing the death certificate. Legal fees can range widely, so VDH does not have a way to calculate this potential benefit.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$9,160 (over 10 years)
(3) Net Monetized Benefit	\$8,048	
(4) Other Costs & Benefits (Non-Monetized)	<p>There are no non-monetized costs for any of the proposed changes. Non-monetized benefits for the following changes are listed below:</p> <ul style="list-style-type: none"> <p>● The regulatory action will amend Definitions (12VAC5-550-5). Minimal updates clarify the language used in the Regulations to support a clearer understanding of the requirements and information included in 12VAC5-550.</p> <p>Benefits: Individuals will benefit inasmuch as the regulatory language will be clearer and easier to understand.</p> <p>● The regulatory action will repeal 12VAC5 – 550-20, 12VAC5 – 550-30, 12VAC5 – 550-50, 12VAC5 – 550-60 which are not regulatory in nature</p> <p>Benefits: The benefit of this change is to reduce the length of the regulation by removing unnecessary language.</p> <p>● The regulatory action will amend the Marriage return and certificate items (12VAC5-550-130) and Report of divorce or annulment items (12VAC5-550-140), removing the item “race” on marriage and divorce certificates. This action is required to comply with Chapters 209, 210, and 211 of the 2020 Acts of Assembly.</p> <p>Benefits: The benefits of this change are that the regulations will comply with the Code of Virginia.</p> <p>● The regulatory action will amend the Change of sex (12VAC5-550-320) to update the requirements for changing the sex on a birth certificate to conform to Chapter 466 of the 2020 Acts of Assembly.</p> <p>Benefits: The change will conform the regulation to the Code, reducing confusion about the process to change the sex on their birth certificate.</p> <p>● The regulatory action will amend the Applications for correction (12VAC5-550-440), Evidence required for corrections or amendments (12VAC5-550-450), and Methods of correcting or altering certificates (12VAC5-550-460) to allow information on a death certificate to be</p> 	

	<p>amended with supporting evidence for 45 days after the filing of the death certificate, and to clarify amendment forms and processes to create internal consistency within the Regulations. This action is required to conform to Chapter 117 of the 2022 Acts of Assembly. The change to Section 460 is to conform to § 32.1-269 (B) of the Code of Virginia.</p> <p>Benefits: The change will conform the regulation to the Code, reducing confusion about the process to amend a death certificate.</p> <ul style="list-style-type: none"> ● In addition to the substantive changes mentioned above, several style and form changes are also being made to conform the language to the <i>Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code</i>. If these changes were promulgated in their own action, they would be exempt from the requirements of Article 2 of the Administrative Process Act, pursuant to § 2.2-4006 (A)(3): Benefits: The language will conform to the <i>Form and Style Requirements</i> and be clearer and more readable. ● The regulatory action will amend the Fees (12VAC5-550-520) to document the fee charged for a vital record as established by Chapter 534 of the 2013 Acts of Assembly and the 2004 Budget Bill – (Chapter 4). Benefits: Individuals will benefit inasmuch as the Regulatory language will be clearer and easier to understand when it is consistent with the Code. ● The regulatory action will amend the Forms (12VAC5-550-9998) to document and link to forms that are explicitly referenced in these amendments, while removing those forms not referenced in the Regulations, and updating the effective dates. Benefits: Forms will be easier to find.
(5) Information Sources	Report of the number of certificates of birth resulting in stillbirth issued from the Virginia Vital Events and Screening Tracking System (VVESTS) for years 2018 - 2020

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

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Monetized costs and benefits:</p> <p>The changes made in this action are required to conform to Chapters 116, 117, and 171 of the 2022 Acts of Assembly; Chapters 209, 210, 211, 465, and 466 of the 2020 Acts of Assembly; Item 290 (A), Chapter 2, 2022 Acts of Assembly, Special Session I; and § 32.1-269 (B). These changes are non-discretionary.</p> <p>The repeal of sections 20, 30, 50, and 60 is intended to conform the chapter to the definition of a “regulation” in § 2.2-4001 and reflect the intent of 1VAC7-10-40(C), which indicate that the provisions are non-regulatory in nature and should be omitted from the regulation.</p>
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	<ul style="list-style-type: none"> • The “status quo” option would be to just leave the sections in the regulation. There are no costs or benefits associated with that option. <p>The style and form changes are to conform with the <i>Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code</i> and could be considered non-discretionary.</p> <ul style="list-style-type: none"> • The “status quo” option would be to leave the language in its current style and form, for which there are no associated costs or benefits. 	
(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)	There are no non-monetized costs or benefits from maintaining the “status quo” option.	
(5) Information Sources		

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

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Monetized costs & benefits: This regulatory action has no monetized costs or benefits.</p> <p>The changes made in this action are required to conform to Chapters 116, 117, and 171 of the 2022 Acts of Assembly; Chapters 209, 210, 211, 465, and 466 of the 2020 Acts of Assembly; Item 290 (A), Chapter 2, 2022 Acts of Assembly, Special Session I; and § 32.1-269 (B). These changes are non-discretionary and not subject to consideration of alternative approaches.</p> <p>The repeal of sections 20, 30, 50, and 60, along with the style and form changes, make no substantive changes to regulatory requirements associated with the chapter, are non-regulatory, and do not affect the rights or powers of any person or agency. As such, there are no viable alternative approaches to be considered.</p>	
(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)	There are no non-monetized costs or benefits under alternative approach(es) associated with this regulatory action:
(5) Information Sources	

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)	Monetized costs: No monetized costs to local partners are associated with this regulatory action. Monetized benefits: There are no monetized benefits to local partners associated with this regulatory action.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$0
(3) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs or benefits to local partners associated with this regulatory action.	
(4) Assistance		
(5) Information Sources		

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 & Benefits (Monetized)	Monetized costs: There are no costs to families associated with this regulatory action. Monetized benefits: As stated in Table 1a, families who experience a stillbirth within the Commonwealth and require a certificate of birth resulting in a stillbirth will not be required to pay the \$12 administrative fee for the certificate (12VAC5-550-125).	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits

	(a) \$0	(b) \$916/year benefits throughout the entire Commonwealth.
(3) Other Costs & Benefits (Non-Monetized)	<p>Style and form changes made to regulations to conform to the <i>Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code</i> will make the regulatory language clearer, easier to understand, and more readable.</p> <p>Removing forms not referenced in the regulations will make the forms easier to find by family members.</p>	
(4) Information Sources		

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)	<p>Costs: none.</p> <p>Benefits: none.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$0
(3) Other Costs & Benefits (Non-Monetized)	There are no other costs or benefits to small businesses associated with this regulatory action.	
(4) Alternatives		
(5) Information Sources		

Changes to the Number of Regulatory Requirements

For each individual VAC Chapter amended, repealed, or promulgated by this regulatory action, list (a) the initial requirement count, (b) the count of requirements that this regulatory package is adding, (c) the count of requirements that this regulatory package is reducing, (d) the net change in the number of requirements. This count should be based upon the text as written when this stage was presented for executive branch review. Five rows have been provided, add or delete rows as needed. In the last row, indicate the total number for each column.

Table 5: Total Number of Requirements

	Number of Requirements			
Chapter number	Initial Count	Additions	Subtractions	Net Change
12VAC5-550 (only the sections included in this action)	33	13	13	0
TOTAL	33	13	13	0

1 **Project 7299 - Fast-Track**

2 **Department of Health**

3 **Amend Regulations following Periodic Review - Amendments to comply with the Code of**
4 **Virginia.**

5 **12VAC5-550-5. Definitions.**

6 In addition to the words and terms defined in § 32.1-249 of the Code of Virginia, the following
7 words and terms when used in this chapter shall have the following meanings unless the context
8 clearly indicates otherwise:

9 "Board" means the State Board of Health.

10 "Commissioner" means the State Health Commissioner.

11 "Department" means Virginia Department of Health.

12 "Immediate family" means a registrant's mother, father (name must be shown on the
13 certification), sibling, current spouse and adult children.

14 "Informant" means the person providing information to complete the filing of a vital record in
15 order to document a vital event.

16 "Midwife" means a registered nurse who has met the additional requirements of education
17 and examination for licensure as a nurse practitioner in the Commonwealth.

18 "Primary evidence" means valid first-hand documentation established before the registrant's
19 18th birthday, ~~such as~~ including school admission records, physician's records, immunization
20 records, passport, federal census abstracts, baptismal records and insurance applications.

21 "Registrant" means the person whose personal information is primarily registered on a vital
22 record and filed in the systems of vital records.

23 "Registrar" means the State Registrar of Vital Records or a county, city, deputy, or special
24 registrar.

25 "Secondary evidence" means valid documentation established after the registrant's
26 eighteenth birthday ~~such as~~ including marriage records, ~~child's a~~ birth certificate, school records,
27 social security records, driver's records, work permit and employment records. ~~Such evidence~~
28 ~~must be at least five years old.~~

29 **Statutory Authority**

30 §§ 32.1-12 and 32.1-250 of the Code of Virginia.

31 **Historical Notes**

32 Derived from Virginia Register Volume 19, Issue 26, eff. October 8, 2003.

33 **~~12VAC5-550-20. Purpose of chapter. (Repealed.)~~**

34 ~~The board has promulgated this chapter to facilitate the vital record registration activities and~~
35 ~~health statistical services in a manner to ensure the uniform and efficient administration of the~~
36 ~~system. Required certificates, reports, and forms shall be prescribed, where feasible, to include~~
37 ~~data collected nationally for the benefit of all citizens. The protection of individual data from casual~~
38 ~~perusal is essential to the validity of the program as well as a desirable shield of sensitive personal~~
39 ~~information while providing health statistics for the protection of society as a whole.~~

40 **Statutory Authority**

41 § 32.1-273 of the Code of Virginia.

42 **Historical Notes**

43 Derived from VR355-29-100 § 1.2, eff. April 1, 1995.

44 **~~12VAC5-550-30. Administration of chapter. (Repealed.)~~**

45 ~~This chapter is administered by the board, the commissioner, and the State Registrar of Vital~~
46 ~~Records and Health Statistics.~~

47 ~~The State Registrar shall carry out the provisions of Chapter 7 (§ 32.1-249 et seq.) of Title~~
48 ~~32.1 of the Code of Virginia and the regulations of the board.~~

49 **~~Statutory Authority~~**

50 ~~§§ 32.1-12 and 32.1-250 of the Code of Virginia.~~

51 **~~Historical Notes~~**

52 ~~Derived from VR355-29-100 § 1.3, eff. April 1, 1995; amended, Virginia Register Volume 19, Issue~~
53 ~~26, eff. October 8, 2003.~~

54 **~~12VAC5-550-50. Application of Administrative Process Act. (Repealed.)~~**

55 ~~Except where specifically provided otherwise by statute, the provisions of the Virginia~~
56 ~~Administrative Process Act, which is codified as Chapter 1.1:1 of Title 9 of the Code of Virginia,~~
57 ~~shall govern the adoption, amendment, modification, and revision, of this chapter, and the conduct~~
58 ~~of all proceedings hereunder.~~

59 **~~Statutory Authority~~**

60 ~~§ 32.1-273 of the Code of Virginia.~~

61 **~~Historical Notes~~**

62 ~~Derived from VR355-29-100 § 1.6, eff. April 1, 1995.~~

63 **~~12VAC5-550-60. Powers and procedures of chapter not exclusive. (Repealed.)~~**

64 ~~The board reserves the right to authorize any procedure for the enforcement of this chapter~~
65 ~~that is not inconsistent with the provisions set forth herein and the provisions of Chapter 7 of Title~~
66 ~~32.1 of the Code of Virginia.~~

67 **~~Statutory Authority~~**

68 ~~§ 32.1-273 of the Code of Virginia.~~

69 **~~Historical Notes~~**

70 ~~Derived from VR355-29-100 § 1.7, eff. April 1, 1995.~~

71 **~~12VAC5-550-125. Certificate of birth resulting in a stillbirth.~~**

72 ~~In accordance with A. Pursuant to § 32.1-258.1 of the Code of Virginia, a certificate of birth~~
73 ~~resulting in a stillbirth shall be issued upon request from the parent the State Registrar shall, upon~~
74 ~~the request of either individual listed as the parent on a report of fetal death in Virginia, issue a~~
75 ~~Certificate of Birth Resulting in Stillbirth for a an unintended, intrauterine fetal death death~~
76 ~~occurring after a gestational period of 20 weeks or more, gestation and payment of the appropriate~~
77 ~~fee for a vital record. This~~

78 ~~B. The certificate shall contain the following information; name (optional); :~~

79 ~~1. The registrant's name, if one is provided;~~

80 ~~2. The mother's maiden name;~~

81 ~~3. The father's name (if indicated), if indicated;~~

82 ~~4. The date of event the fetal death; and~~

83 ~~5. The hospital of occurrence or location the fetal death occurred.~~

84 ~~When C. If no report of spontaneous fetal death is available to establish the event,~~
85 ~~documentation from the following sources is acceptable: the parent may provide documentation~~
86 ~~from the following sources to establish that an unintended, intrauterine fetal death after a~~
87 ~~gestational period of 20 weeks or more occurred.~~

88 1. The licensed physician or licensed nurse midwife who provided care to the mother;
89 documentation from the

90 2. The medical record maintained at the hospital of occurrence, copy of the report of
91 spontaneous fetal death or documentation from where the fetal death occurred; or

92 3. The funeral service director (if such services were provided). if funeral services were
93 provided.

94 **Statutory Authority**

95 §§ 32.1-12 and 32.1-250 and 32.1-258.1 of the Code of Virginia.

96 **Historical Notes**

97 Derived from Virginia Register Volume 19, Issue 26, eff. October 8, 2003.

98 **12VAC5-550-130. Marriage return and certificate items.**

99 ~~The record of marriage to be used shall be the Marriage Return and Certificate,~~
100 ~~Commonwealth of Virginia, and shall contain the following items: city or county of the court of~~
101 ~~issuance; court clerk's number; for the groom: full name, age, date and place of birth, social~~
102 ~~security number or control number issued by the Department of Motor Vehicles, race, marital~~
103 ~~status if previously married, number of marriage, education, usual residence, the names of~~
104 ~~parents; for the bride: full name, maiden name, age, date and place of birth, social security number~~
105 ~~or control number issued by the Department of Motor Vehicles, race, marital status if previously~~
106 ~~married, number of marriage, education, usual residence, and names of parents; signature of~~
107 ~~clerk of court and date of license; date and place of marriage; whether civil or religious ceremony;~~
108 ~~certification and signature of officiant indicating title, address, and year and court of qualification;~~
109 ~~date received by clerk of court from officiant; and state file number.~~

110 A. The VS3 form, Commonwealth of Virginia - Marriage Return, shall be used to record
111 marriages that occur in the Commonwealth. The form shall be filled out in its entirety.

112 B. An officer issuing marriage licenses shall, on or before the tenth day of each calendar
113 month, forward to the State Registrar a record of each marriage filed with him during the preceding
114 calendar month pursuant to § 32.1-267.

115 C. To request a certified copy of a certificate of marriage, an applicant shall fill out in its
116 entirety, sign, and submit a VS6MD form, Commonwealth of Virginia - Application for Certification
117 of a Marriage and/or Divorce Record, to the registrar.

118 **Statutory Authority**

119 §§ 32.1-12 and 32.1-250 of the Code of Virginia.

120 **Historical Notes**

121 Derived from VR355-29-100 § 3.4, eff. April 1, 1995; amended, Virginia Register Volume 19, Issue
122 26, eff. October 8, 2003.

123 **12VAC5-550-140. Report of divorce or annulment items.**

124 ~~The report of divorce or annulment to be used shall be the Report of Divorce or Annulment,~~
125 ~~Commonwealth of Virginia, and shall contain the following items: city or county of court of~~
126 ~~issuance; for the husband: full name, date and place of birth, social security number or control~~
127 ~~number issued by the Department of Motor Vehicles, education, number of marriage, usual~~
128 ~~residence; for the wife: full maiden name, date and place of birth, social security number or control~~
129 ~~number issued by the Department of Motor Vehicles, education, number of the marriage, usual~~
130 ~~residence; date and place of marriage; identity of plaintiff and to whom divorce granted; number~~
131 ~~and custody of children under 18 in this family; date of separation; date of divorce; legal grounds~~
132 ~~or cause of divorce; signature of attorney or petitioner; certification and signature of clerk of court~~
133 ~~indicating type of decree; court file number; date final order entered; and state file number.~~

134 A. The VS4 form, Commonwealth of Virginia - Report of Divorce or Annulment, shall be used
135 to register divorce or annulment in the Commonwealth. The form shall be filled out in its entirety.

136 B. A clerk of court shall, on or before the tenth day of each calendar month, forward to the
137 State Registrar the report of each final decree of divorce and annulment granted during the
138 preceding calendar month pursuant to § 32.1-268.

139 C. To request a certified copy of a certificate of divorce or annulment, an applicant shall fill out
140 in its entirety, sign, and submit the VS6MD form, Commonwealth of Virginia - Application for
141 Certification of a Marriage and/or Divorce Record, to the registrar.

142 **Statutory Authority**

143 §§ 32.1-12 and 32.1-250 of the Code of Virginia.

144 **Historical Notes**

145 Derived from VR355-29-100 § 3.5, eff. April 1, 1995; amended, Virginia Register Volume 19, Issue
146 26, eff. October 8, 2003.

147 **12VAC5-550-320. Change of sex.**

148 ~~Except as provided in subdivision 3 of 12VAC5-550-450, upon presentation of acceptable~~
149 ~~evidence (preoperative diagnosis, postoperative diagnosis and description of procedure) and a~~
150 ~~notarized affidavit from the physician performing the surgery, a new certificate of birth may be~~
151 ~~prepared by the State Registrar for a person born in this Commonwealth whose sex has been~~
152 ~~changed by surgical gender reassignment procedure. A certified copy of the court order changing~~
153 ~~the name of the registrant as well as designating the sex of the registrant must be in the~~
154 ~~possession of the State Registrar together with a request that a new certificate be prepared.~~

155 A. The State Registrar shall issue a new certificate of birth to a show a change of sex of the
156 registrant upon request of a registrant or the registrant's legal representative and submission of a
157 complete Changing Sex Designation, VS42 Form, which shall be completed by a health care
158 provider from whom the registrant has received treatment stating that the registrant has
159 undergone clinically appropriate treatment for gender transition.

160 B. The State Registrar shall also issue, upon request of a registrant or the registrant's legal
161 representative requesting a change of sex pursuant to this section, a new certificate of birth to
162 show a new name if the registrant or the registrant's legal representative submits (i) a certified
163 copy of a court order changing the registrant's name and (ii) if requested by the State Registrar,
164 other evidence necessary to verify the facts of the registrant's birth.

165 **Statutory Authority**

166 §§ 32.1-12 and 32.1-250 of the Code of Virginia.

167 **Historical Notes**

168 Derived from VR355-29-100 § 9.5, eff. April 1, 1995; amended, Virginia Register Volume 19, Issue
169 26, eff. October 8, 2003.

170 Part XI

171 Correction and Amendment

172 **12VAC5-550-440. Applications for correction.**

173 ~~A. After 30 days from the date of filing, no change or alteration in any birth or death certificate~~
174 ~~on file with the State Registrar or on file in any city or county of this Commonwealth shall be made~~
175 ~~except upon application to the State Registrar.~~

176 ~~1. To change or alter a birth certificate, such application shall be made by the reporting~~
177 ~~source, one of the parents, guardian, or legal representative of the child, or, if the person~~
178 ~~whose certificate is involved is 18 years of age or over, by the person himself.~~

179 ~~2. To change or alter a death certificate, such application shall be made by the surviving~~
180 ~~spouse or the next of kin of the deceased, attending funeral service licensee, or other~~
181 ~~reporting source, such as hospital medical records.~~

182 ~~3. Changes or alterations of the medical certification of cause of death may be requested~~
183 ~~only by the attending physician or by the medical examiner.~~

184 ~~B. Within 30 days from the date of filing, A. The State Registrar may enter missing data or~~
185 ~~corrected information may be entered on a birth or death certificate by the State Registrar or by~~
186 ~~the city or county registrar when the original record is in his possession. If the missing or corrected~~
187 ~~data is obtained at the initiative of the State Registrar within 30 calendar days from the date of~~
188 ~~filing, the State Registrar shall not consider the record to be amended.~~

189 B. The following persons may request an amendment to a birth certificate by filing an
190 application with the State Registrar in the form of a written letter or the Birth Certificate
191 Amendment Request, VS43 Form:

192 1. If the registrant is under 18 years of age, the informant who filed the birth certificate, the
193 registrant's parent, guardian, or legal representative, or

194 2. If the registrant is 18 years of age or over or has been emancipated pursuant to Article
195 15 (§ 16.1-331 et seq.) of Chapter 11 of Title 16.1 of the Code of Virginia, the registrant
196 or the registrant's legal representative.

197 ~~1. Applications for changes or alterations may be made by persons outlined in subdivision~~
198 ~~A 1 or A 2 of this section.~~

199 ~~2. Missing or corrected data may be obtained at the initiative of the city or county registrar~~
200 ~~by personal call, telephone, or query form from the reporting source responsible for filing~~
201 ~~the birth or death certificate. Data so obtained by the registrar shall not be deemed an~~
202 ~~amendment.~~

203 C. The State Registrar shall, upon receipt of an application pursuant to subsection B of this
204 section, advise the person whether the amendment can be made administratively, subject to the
205 evidence requirements of this chapter or if the amendment requires a court order.

206 ~~G. Marriage and D. The registrar may amend a record of marriage, divorce, or annulment~~
207 ~~records on file with the State Registrar may be amended only by upon notification from the clerk~~
208 ~~of court in which the original record is filed. Such The notification to the State Registrar shall~~
209 ~~indicate what which items have been amended on the original record and shall indicate that the~~
210 ~~State Registrar's registrar's copy should shall be amended accordingly. Evidence The court in~~
211 ~~which the original record is filed shall determine the evidence required for amending a record of~~
212 ~~marriage and, divorce, or annulment, records shall be determined by the court in which the original~~
213 ~~record is filed.~~

214 E. A person may request the State Registrar to amend a death certificate by submitting an
215 affidavit and supporting documentary evidence testifying to the corrected information to be
216 amended within 45 days of the filing of the death certificate. The State Registrar shall amend the
217 death certificate to reflect the new information upon receipt of the affidavit and supporting
218 documentary evidence.

219 F. Pursuant to § 32.1-269.1, if more than 45 calendar days have elapsed since the filing of a
220 death certificate, the State Registrar, upon receipt of an affidavit testifying to the corrected
221 information, shall amend the following information to reflect the new information and evidence:

222 1. The spelling of the name of the registrant, registrant's parent or spouse, or the
223 informant;

224 2. The sex, age, race, date of birth, place of birth, citizenship, social security number,
225 education, occupation or kind of business, military status, or date of death of the registrant;

- 226 3. The place of residence of the registrant, if located within Virginia; or
227 4. The name of the institution, county, city, town, street, or place where the death occurred.

228 G. Pursuant to § 32.1-269.1, for death certificate amendments received more than 45 calendar
229 days since the filing of the death certificate, other than correction of the information by the State
230 Registrar pursuant to subdivision F, the surviving spouse or immediate family of the registrant,
231 attending funeral service licensee, or other reporting source may file a petition, along with a sworn
232 affidavit under oath that supports the request, with the circuit court of the county or city in which
233 the registrant resided at the time of his death or the Circuit Court of the City of Richmond
234 requesting an order to amend the death certificate.

235 H. Upon receipt of a certified copy of an order from the clerk of the circuit court of the county
236 or city in which the registrant resided at the time of his death or the Circuit Court of the City of
237 Richmond, the State Registrar shall amend the death certificate in accordance with the order.

238 I. Only the provider who completed the registrant's medical certification pursuant to § 32.1-
239 263 may request a change or amendment to the medical certification of cause of death.

240 **Statutory Authority**

241 §§ 32.1-12 and 32.1-250 , and 32.1-269.1 of the Code of Virginia.

242 **Historical Notes**

243 Derived from VR355-29-100 § 11.1, eff. April 1, 1995; amended, Virginia Register Volume 19,
244 Issue 26, eff. October 8, 2003.

245 **12VAC5-550-450. Evidence required for corrections or amendments.**

246 ~~Every~~ A. A person shall include a correction affidavit and documentary evidence pursuant to
247 this section with an application for a correction or amendment of to amend a birth or death
248 certificate shall be accompanied by appropriate documentary evidence as follows:

249 1. Except as provided in subdivisions 2 and 3 of this section, name changes, other than
250 minor corrections in spelling involving the given names or surname of a registrant, or the
251 given names or surnames of the parents or of a spouse as listed on a certificate, shall
252 require that a certified or attested copy of a court order changing the name be obtained.

253 a. In cases where the mother's married surname is listed instead of her maiden name,
254 a correction can be made administratively with a correction affidavit and copy of her
255 birth record.

256 b. In cases where the given name shown on a birth certificate was not used or known
257 to the registrant and this fact can be proven by the registrant, the birth certificate can
258 be amended administratively with primary evidence showing the name at birth and a
259 correction affidavit.

260 2. Within one year of birth, the given names listed on a birth certificate may be changed
261 by the affidavit of:

262 a. Both parents;

263 b. The mother in the case of a child born out of wedlock;

264 c. The father in the case of the death or incapacity of the mother;

265 d. The mother in the case of the death or incapacity of the father; or

266 e. The guardian or agency having legal custody of the registrant.

267 3. In cases of hermaphroditism or pseudo-hermaphroditism, given names of a registrant
268 may be changed on a birth certificate by affidavit of the parents or guardian as listed in
269 subdivision 2 of this section, or by affidavit of the registrant if 18 years of age or older.
270 Additionally, a statement from a physician must be submitted which certified the birth
271 record of the registrant contains an incorrect designation of sex because of congenital

272 hermaphroditism, pseudo-hermaphroditism, or ambiguous genitalia which has since been
273 medically clarified.

274 4. Except as otherwise provided in the Code of Virginia or this chapter, after one year from
275 the date of birth, any change of name shall be made only by court order, and any second
276 change of name within one year shall be made only by court order.

277 5. Within seven years after birth, given names may be added to a birth certificate where
278 such information has been left blank by use of an affidavit only prepared by the parent,
279 guardian, or legal representative of the child.

280 6. If the date of birth on a birth certificate is to be changed more than one year, a certified
281 copy of a court order changing the date of birth shall be submitted. Evidence to be supplied
282 to the court in support of such change should include a federal census transcript from the
283 Bureau of the Census.

284 7. If the date of birth on a birth certificate is to be changed to one year or less from the
285 date of birth, a federal census transcript from the Bureau of the Census shall be required
286 as documentary evidence.

287 8. If a federal census transcript cannot be obtained, an affidavit shall be obtained which
288 sets forth: the identity of the incorrect record, the incorrect data as it is listed, the correct
289 data as it should be listed, and the documentary evidence supporting the facts. In addition
290 to the affidavit, a document or certified or true copy of such document must be obtained
291 which was written before the registrants' eighth birth date and will establish the identity of
292 the certificate to be altered or corrected and will support the true and correct facts. Any
293 item of a vital record which has been previously corrected may only be changed again by
294 court order.

295 9. All documents, except the affidavit, shall be returned to the applicant after review.

296 B. To amend a death certificate pursuant to 12VAC5-550-440, an applicant shall submit to the
297 State Registrar a certified copy of a court order obtained pursuant to § 32.1-269.1 or a correction
298 affidavit and primary or secondary documentary evidence testifying to the amended information.

299 **Statutory Authority**

300 §§ 32.1-12 and 32.1-250 of the Code of Virginia.

301 **Historical Notes**

302 Derived from VR355-29-100 § 11.2, eff. April 1, 1995; amended, Virginia Register Volume 19,
303 Issue 26, eff. October 8, 2003.

304 **12VAC5-550-460. Methods of correcting or altering certificates.**

305 A. ~~A~~ The State Registrar shall record a new name authorized by court order ~~shall be recorded~~
306 ~~by drawing a single line through the name appearing on the certificate record and inserting the~~
307 ~~new name above it or to the side of it the new name.~~ In addition, there shall be inserted on the
308 ~~certificate~~ the State Registrar shall insert on the record a statement that the name was changed
309 by court order and the date and place of ~~such the court~~ order. ~~The~~ The State Registrar shall also
310 insert the word "Amended" shall be written in the top margin of the certificate record. ~~Certificates~~
311 ~~on which given names are added within seven years after birth or on which given names have~~
312 ~~been changed~~ The State Registrar shall not consider a record as amended if the registrant's name
313 is amended within one year of the vital event that was recorded, or if the name is amended at any
314 time pursuant to subdivision 3 of 12VAC5-550-450 ~~shall not be considered as amended.~~

315 B. ~~In all other cases, corrections or alterations shall be made~~ The State Registrar shall record
316 amendments to other items by drawing a single line through the incorrect item, if listed, and by
317 inserting the correct or missing data immediately above it or to the side of it, or by completing the
318 blank item, ~~as the case may be.~~ In addition, there shall be inserted on the certificate the State

319 Registrar shall insert a statement identifying the affidavit and documentary evidence used as proof
320 of the correct facts amended information and the date the correction amendment was made. If
321 the State Registrar receives the request to amend a record three months have elapsed from after
322 the date of filing, the State Registrar shall insert the word "Amended" shall be written in the top
323 margin of the certificate unless otherwise stated in this chapter.

324 **Statutory Authority**

325 § 32.1-273 of the Code of Virginia.

326 **Historical Notes**

327 Derived from VR355-29-100 § 11.3, eff. April 1, 1995.

328 **12VAC5-550-520. Fees.**

329 A. ~~The fee to be charged by the State Registrar or by the city or county registrar shall be \$10~~
330 ~~, except if otherwise directed in the Code of Virginia, charge a fee of \$12 for each full certification~~
331 ~~or short form certification of a vital record, or for a search of the files or records when no copy is~~
332 ~~made.~~

333 B. ~~When documents are amended or delayed birth registration is requested, the requester~~
334 ~~shall be charged an administrative fee of \$10. The registrar shall charge a fee of \$10 to amend a~~
335 ~~vital record or register a delayed birth registration.~~

336 **Statutory Authority**

337 §§ 32.1-12 and 32.1-250 of the Code of Virginia.

338 **Historical Notes**

339 Derived from VR355-29-100 § 13.2, eff. April 1, 1995; amended, Virginia Register Volume 19,
340 Issue 26, eff. October 8, 2003.

341 FORMS (12VAC5-550)

342 ~~Certificate of Live Birth, VS1 (eff. 1/93).~~

343 ~~Certificate of Death, VS2 (eff. 1/89).~~

344 ~~Certificate of Death (Medical Examiner's Certificate), VS2A (eff. 1/89).~~

345 ~~Marriage Register, VS3 (eff. 1/90).~~

346 ~~Report of Divorce or Annulment, VS4 (eff. 1/90).~~

347 ~~Report of Spontaneous Fetal Death, VS5 (eff. 1/93).~~

348 ~~Report of Induced Termination of Pregnancy, VS5A (eff. 1/90).~~

349 ~~Application for Certification of a Vital Record, VS6 (eff. 7/02).~~

350 ~~Out-of-State Transit Permit, VS10 (eff. 7/85).~~

351 ~~Permit for Disinterment, Transit, and Reinterment, VS11 (eff. 7/85).~~

352 ~~Delayed Certificate of Birth, VS12 (eff. 4/85).~~

353 ~~Marriage Return, VS3 (eff. 10/19).~~

354 ~~Report of Divorce or Annulment, VS4 (eff. 07/20).~~

355 [Birth Record Application VS6B \(eff. 07/2020\).](#)

356 [Marriage-Divorce Record Application VS6MD \(eff. 02/2020\).](#)

357 [Death Record Application VS6D \(eff. 07/2022\).](#)

358 [Stillbirth Application VS6FD \(eff. 07/2022\).](#)

359 ~~Report of Adoption, VS21 (eff. 7/85).~~

360 [Report of Adoption, VS21 \(eff. 07/2012\).](#)

361 ~~Acknowledgement of Paternity, VS22 (eff. 9/93).~~
362 [Acknowledgement of Paternity, VS22 \(eff. 07/2004\).](#)
363 ~~Affidavit for Correction of a Record, VS32 (eff. 1/87).~~
364 [Affidavit for Correction of a Record, VS32 \(eff. 09/2005\).](#)
365 ~~Hospital Monthly Vital Statistics Report, VS33 (eff. 7/89).~~
366 ~~Funeral Director's Monthly Vital Statistics Report, VS33-A (eff. 3/90).~~
367 ~~Court Order Establishing Record of Birth, VS40 (eff. 10/88).~~
368 [Form for Changing Sex Designation, VS42 \(eff. 07/2020\).](#)
369 [Birth Certificate Amendment Request Form, VS43 \(eff. 07/2021\).](#)



COMMONWEALTH of VIRGINIA

Department of Health
P O BOX 2448
RICHMOND, VA 23218

Karen Shelton, MD
State Health Commissioner

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

MEMORANDUM

DATE: April 20, 2023

TO: State Board of Health

FROM: Dwayne Roadcap
Director, Office of Drinking Water

SUBJECT: Proposed Amendments to the Waterworks Operation Fee Regulations (12VAC5-600) Following Periodic Review

Enclosed for your review are amendments to the Waterworks Operation Fee regulations (12VAC5-600) (“Regulations”) following a periodic review.

Code of Virginia § 32.1-171.1.A requires that the State Board of Health “adjust the fee schedule so that the revenues from such fees cover the costs necessary to operate the Waterworks Technical Assistance Program required by this section.” These regulations establish the means by which the Office of Drinking Water (“ODW”) assesses and collects fees from each waterworks for ODW’s Waterworks Technical Assistance Fund (“Fund”). The Fund is intended to support ODW’s technical assistance to waterworks so that they comply with the Safe Drinking Water Act and the Virginia Waterworks Regulations, thereby protecting public health.

ODW has struggled with stagnant revenue streams and increasing costs and overhead. Currently, ODW provides technical assistance to all types of waterworks but not all of them pay a fee. Additionally, fees have not been modified over time to reflect inflationary pressures. The proposed regulations seek to address these issues by applying fees to all types of waterworks and addressing the impact of inflation as appropriate. Without amendments to the Regulations, ODW’s Technical Assistance Program will not be adequately funded and ODW staff will be challenged with making decisions on which waterworks will be provided with technical assistance. This could cause waterworks to receive less or no technical assistance in preventing or resolving water quality and supply issues, such that water-borne illness and health impacts are possible due to insufficient funding.

Upon approval by the Board, the proposed draft amendments to the Regulations will be submitted for executive branch review and, upon approval by the Governor, will be published in the Virginia Register of Regulations with provision for a 60-day public comment period.



townhall.virginia.gov

Proposed Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC5-600
VAC Chapter title(s)	Waterworks Operation Fee
Action title	Amend and Update the Waterworks Operation Fee Regulations
Date this document prepared	April 19, 2023

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 State Board of Health (Board) proposes amendments to the Waterworks Operation Fee ("Regulations") as part of a routine review and update.

Code of Virginia § 32.1-171.1(A) requires that the State Board of Health establish fees to be charged to waterworks owners and "adjust the fee schedule so that the revenues from such fees cover the costs necessary to operate the Waterworks Technical Assistance Program required by this section."

The regulations codify how the Virginia Department of Health (VDH) Office of Drinking Water (ODW) generates revenue from fees charged to the waterworks that are regulated by the ODW under the federal Safe Drinking Water Act (SDWA) and the Virginia *Waterworks Regulations* (12VAC5-590.) The Regulations have not been amended since 2014. Additionally, some portions of the Regulations, such as the fee assessed for nontransient noncommunity waterworks, have not changed since the regulations were adopted in 1993. In addition to modifying the fee for nontransient noncommunity waterworks and

clarifying the method by which operation fees are calculated, the amendments seek to add categories of waterworks, not previously charged a fee, into the Regulations. Specifically, transient noncommunity waterworks and wholesale waterworks are proposed to be added to the list of categories of waterworks that are charged a fee for the technical assistance and compliance oversight provided by ODW.

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.

"APA" means the Administrative Process Act (Code of Virginia § 2.2-4000, et seq.)

"Board" means the State Board of Health

"EPA" means the United States Environmental Protection Agency.

"NTNC" means nontransient noncommunity waterworks.

"ODW" means the Virginia Department of Health – Office of Drinking Water.

"PWSID" means the Public Water System Identification Number.

"SDWA" means the Safe Drinking Water Act.

"TNC" means transient noncommunity waterworks.

"VDH" means the Virginia Department of Health.

Any relevant technical terms are defined in 12VAC5-600-10. *Definitions*, in the Regulations.

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."

The impetus for the change is a periodic review of the chapter completed in 2021, during which the agency determined that the chapter should be amended to reflect these proposed changes.

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 promulgating agency is the State Board of Health.

Code of Virginia § 32.1-12 authorizes the Board to make, adopt, promulgate, and enforce regulations as necessary to carry out Title 32.1 of the Code of Virginia and other laws of the Commonwealth of Virginia administered by the Board, the State Health Commissioner or VDH.

Code of Virginia § 32.1-170(A)(8) authorizes the Board to set forth in its regulations a "[m]ethodology for determining the waterworks operation fee authorized by § 32.1-171.1."

Code of Virginia § 32.1-171.1(A) directs the Board, through regulation, to establish the fee to be charged each waterworks owner, allowing for certain exemptions, and states that “[t]he Board shall adjust the fee schedule so that the revenues from such fees cover the costs necessary to operate the Waterworks. Technical Assistance Program required by this section.” The Technical Assistance Program is supported by regulations of the Board (the Waterworks Regulations, 12VAC5-590) governing waterworks, water supplies, and pure water, and is designed to protect the public health and promote the public welfare and includes criteria and procedures to accomplish these purposes.

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.

1. VDH has primacy from United States Environmental Protection Agency (EPA) for enforcing the SDWA in Virginia. VDH carries out its primacy authority through ODW. The amendments to the Regulations will adjust the existing fee charged to NTNC systems, add a flat fee for wholesale waterworks with under 15 non-waterworks customer accounts, and add a fee for TNC systems. The fee charged to NTNC systems pursuant to the regulations has not changed since 1993. In that time, according to the U.S. Bureau of Labor Statistics, the Consumer Price Index has risen by over 100%. The amendments also clarify that the fees are charged per waterworks based on PWSID, rather than per owner. Some waterworks owners own more than one waterworks, each identified by a separate PWSID. These amendments will generate more revenue needed for ODW to provide technical assistance to waterworks to ensure compliance with federal and state drinking water law and regulations, while distributing the share of fees more broadly across all regulated entities.
2. Since 1996, after the original Regulations were adopted, ODW has been required to regulate all TNCs in the Commonwealth. Regulating TNCs has increased ODW's workload by approximately 1,200 waterworks, or 43%. TNCs tend to be small and require a significant amount of technical assistance. TNCs have not paid any fees to VDH for the technical assistance they receive.
3. Wholesale waterworks is another category of waterworks to which the proposed regulations seek to charge a specific fee. Wholesale waterworks have “wholesale” service connections through which they pipe water to a separate downstream, regulated waterworks that distributes the water to consumers. A wholesale waterworks may also have non-wholesale connections through which water is distributed directly to consumers. A wholesale waterworks typically has a large facility producing large quantities of water through complex treatment. These facilities are regulated under the SDWA and the *Waterworks Regulations*. ODW staff regularly inspects wholesale waterworks and provides direct technical assistance.

As an example, a wholesale waterworks that qualified as a community waterworks and that had three connections, with each being a separate customer account, currently would pay \$9.00 for its waterworks operation fee even though it may produce millions of gallons of drinking water per day (the current operation fee charged to community waterworks is \$3.00 per service connection). A wholesale waterworks that has only wholesale connections (i.e., does not pipe water directly to consumers) currently may not pay any fee even though it may be producing a large amount of drinking water every day. The proposed revision to the regulation institutes a minimum fee for wholesale waterworks with fewer than 15 non-waterworks customer accounts to cover the technical assistance they receive from ODW. Under the proposed amendments to the regulations, wholesale waterworks with 15 or more non-waterworks customer accounts would continue to pay a fee using the methodology applied to community waterworks.

4. The goal of the proposed change is to allow ODW to continue to sufficiently meet the need for technical assistance, while more equitably distributing the fee among the types of waterworks that most need technical assistance. Without adequate funding, ODW will face continued challenges making decisions regarding which waterworks will be provided assistance. With reduced or no technical assistance, some waterworks may not adequately prevent or resolve water quality and supply issues, resulting in an increased risk of water-borne illness and adverse health impacts.
5. Examples of the fee structure from other states:
 - a. Pennsylvania – Pennsylvania’s 2021 Public Water System Compliance Report to the EPA (https://files.dep.state.pa.us/Water/BSDW/DrinkingWaterManagement/PublicDrinkingWater/PA_DEP_2021_Annual_Compliance_Report_Final.pdf) reported 8,273 public water systems, which is significantly more than Virginia. The fee structure it developed in 2019 (<https://files.dep.state.pa.us/Water/BSDW/Chapter109/SDW%20Fees%20Invoice%20Webinar%20Quarter%202.pdf>) was designed to cover a \$7.5 million budget shortfall. All waterworks pay a fee, and fees are charged based on the type of waterworks and the population served by that waterworks. Community waterworks fees start at \$250 for a population of 100 or less to a maximum of \$40,000 for a population of 100,001 or more. NTNCs pay a \$100 fee for a population of 100 or less up to \$1,000 for a population of 3,301 or more. TNCs pay \$50 for a population of 100 or less up to \$500 for a population of 1,001 or more. All other waterworks types pay a fee of either \$1,000 or \$2,500.
 - b. Tennessee – Tennessee’s Division of Water Resources 2021 Annual Compliance Report (https://www.tn.gov/content/dam/tn/environment/water/drinking-water-unit/wr_wq_dw_2021-annual-compliance-report.pdf) reported 770 public water systems (452 community water systems, 290 TNCs, and 28 NTNCs), which is significantly fewer than Virginia. The fee structure in Tennessee’s Public Water Systems Regulations, Chapter 0400-45-01-.32, Fees for Public Water Systems (<https://publications.tnsosfiles.com/rules/0400/0400-45/0400-45-01.20190217.pdf>) charges all public water systems an annual maintenance fee based on the type of water system and the number of connections. Community water system fees start at \$300 for a system with less than 250 connections. Community water systems with over 200,000 connections pay \$105,000 plus \$0.35 per connection for each connection over 200,000. NTNCs are divided into schools and industries. Schools are charged \$250 and industries are charged either \$250 or \$2,000 based on the type of water source (\$250 for ground or \$2,000 for surface). TNCs are divided into churches and “all others,” which includes restaurants, campgrounds, motels, etc. Churches are charged \$100 and all others are charged \$200. Wholesale waterworks with less than 15 service connections are charged \$400 if the system has a ground water source or \$2,000 if the system has a surface water source. State facilities are charged \$250 if the system has a ground water source or \$2,000 if the system has a surface water source.

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 main issues discussed and proposed in the amendments as decided by the regulatory stakeholder group include:

1. The proposed amendments clarify that in applying the \$160,000 statutory cap on waterworks operation fees, the identification of waterworks that is used for calculating the fee owed is based on the PWSID. VDH’s current billing practice, which has focused on the identity of the owner when the owner owns multiple waterworks, has shorted the Waterworks Technical Assistance Fund by an estimated \$177,405 annually. While the proposed amendments clarify the method by which waterworks are identified – focusing on the PWSID – the current regulatory language states that the cap is to be applied on a per waterworks basis. The authority for VDH to increase

- recovery of this amount through a change to its current billing practice exists in the current regulation, and the proposed amendment is intended to clarify the billing practice to be used.
2. The proposed amendments will increase the NTNC annual fee from \$90 to \$120.
 3. The proposed amendments will add an annual fee of \$60 for each TNC system.
 4. ODW currently charges wholesale waterworks as community waterworks, resulting in invoices of less than \$30.00 per year for some of the largest water suppliers in the Commonwealth. Stakeholders initially proposed that wholesale waterworks pay a flat fee of \$2,500.00 annually and ultimately supported that if a wholesale waterworks has 15 or more end-user accounts, then it will pay a fee based on the methodology applied to community waterworks, rather than the \$2,500 flat fee. The 15 end-user cutoff is intended to comply with the essence of stakeholder consensus, which was that wholesale waterworks with a relatively small direct-to-consumer portion of their operations should pay the wholesale waterworks fee rather than the presumably smaller community waterworks fee (because they are more wholesalers than community waterworks). Ultimately, the proposed amendments use the term “non-waterworks customer accounts” rather than “end-user accounts.” “Customer accounts” is an existing defined term in the regulations. Creation of a new defined term – “end-user” – might create confusion. Additionally, the goal being pursued by the stakeholder group through the “end-user” concept is better addressed by framing it as “non-waterworks customer accounts.”
 5. If a waterworks chooses to pay in quarterly installments, their total fee invoice must be greater than \$1,600 under the proposed changes; the current regulations set that threshold amount at \$400.
 6. Other proposed amendments attempt to conform the language between the *Waterworks Regulations* and the *Waterworks Operation Fee* regulations.
 7. Additionally, the proposed amendments make technical corrections to identified statutory authority for certain sections of the regulations as appropriate.

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.

1. The primary advantage of the proposed changes is that increased fees allow ODW to continue to meet its statutory obligation to conduct the Waterworks Technical Assistance Program pursuant to Va. Code § 32.1-171.1 through technical assistance to regulated waterworks. Specifically, ODW will be able to continue to provide assistance to TNCs which serve restaurants, campgrounds, comfort stations, and other Virginia venues that have a transient population. This is in support of required compliance with the SDWA and the Waterworks Regulations. Failure of a TNC to comply with the Waterworks Regulations may impact other licenses held related to the facility served by the TNC system, such as restaurants and campgrounds that are also regulated by VDH. Without additional resources from waterworks operation fees, ODW will not be able to meet its mandate to provide such technical assistance to waterworks, which will especially impact smaller waterworks that rely on these services more than larger systems that have greater resources. Failure to provide the required technical assistance can lead to negative public health impacts for the customers of affected waterworks that depend on ODW’s technical assistance program. The amendments also help the

State Board of Health satisfy its obligation in Va. Code § 32.1-171.1 to “adjust the fee schedule so that the revenues from such fees cover the costs necessary to operate the Waterworks Technical Assistance Program...”

2. Owners of TNCs, NTNCs, and certain wholesale waterworks will be charged greater fees under the proposed regulations. Private citizens may be charged slightly higher rates with the increased fee costs, depending on the degree to which their water purveyor decides to pass on the charges to their customers.
3. The amendments clarify and provide a better framework for the billing process associated with this fee.
4. There will be improved consistency between the Waterworks Regulations, which were amended in 2021, and the Waterworks Operation Fee regulations.

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.

Not Applicable; there are no federal requirements for assessing fees for technical assistance to regulated waterworks in Virginia.

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.

Agencies, Localities and Other Entities Particularly Affected:

Some localities, school boards, other regional organizations, and state agencies that own transient noncommunity and/or nontransient noncommunity waterworks will be affected. As such, those entities would be impacted at most \$60 per year for newly billed transient noncommunity waterworks or \$30 per year for nontransient noncommunity waterworks. No state agencies are expected to be impacted by the change in billing of wholesale waterworks.

Additionally, all transient noncommunity waterworks, all nontransient noncommunity waterworks, and wholesale waterworks with fewer than 15 non-waterworks customer accounts will be particularly affected because of changes to the relevant fee structures.

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

<p><i>For your agency:</i> projected costs, savings, fees, or revenues resulting from the regulatory change, including:</p> <ul style="list-style-type: none"> 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. 	<p>a) Waterworks Technical Assistance Fees make up the revenue referenced below and are directly billed to waterworks. The number of invoices to waterworks will more than double from approximately 1,248 to 2,817 as more waterworks are regulated under existing SDWA and <i>Waterworks Regulations</i> provisions.</p> <p>Expected revenue from FY2023 operation fees is \$4,806,225. The proposed regulatory amendments are estimated to increase annual revenue from operation fees by \$142,947. This does not include any increase in expected revenue by a change in billing practices with respect to application of the \$160,000 cap on fees per waterworks.</p> <p>b) Technical assistance expenditures to waterworks are on-going. For the FY2022 billing cycle, costs to complete invoicing (staff, printing, postage) totaled \$20,318. ODW is expecting these costs to more than double to around \$60,000 per year considering a doubling of the number of invoices and increased cost of staff and materials.</p> <p>Currently, VDH is using a MS Access database, Excel spreadsheets, and mail merge to invoice waterworks. VITA has informed ODW that MS Access does not meet VITA requirements. Consequently, VDH will be required to purchase compliant software that will meet this need. This cost will need to be incurred even if the proposed regulatory amendments do not go into effect. VDH does not have a purchase price on the software as it would require extensive evaluation and staff time. It is anticipated that the software will cost not less than \$150,000 in the first year and then drop off in subsequent years. There will be a one-time expense to purchase billing software, as well as an annual expense for the software license.</p> <p>Additionally, in the first year of using the new billing software there will be increased staff time for training and process development. Expenses in subsequent years will reflect a decrease in staff time with efficiencies and a software</p>
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	<p>licensing fee estimated at 10% of the original cost.</p> <p>c) ODW has been having budget issues. Increased costs without revenue support will exacerbate the budget shortfalls. ODW will have to implement new compliant billing software, so the expenses for the software and licensing will be borne by the agency even if the fees are not adjusted.</p>
<p><i>For other state agencies:</i> projected costs, savings, fees, or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p>	<p>No costs or revenues will be borne by any other state agencies except for those that own a regulated waterworks, such as a state park or a VDOT interstate rest area that operates a TNC waterworks. The maximum impact on these entities individually would be \$60 per year for the proposed fee for TNC systems.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>The proposed amendments will increase revenues for ODW. This will allow ODW to continue providing the same level of technical assistance it historically has provided to waterworks regulated under the SDWA and thereby protect public health.</p>

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.

<p>Projected costs, savings, fees, or revenues resulting from the regulatory change.</p>	<p>The only impact on localities would be for those that currently own or operate a public waterworks. Most localities are customers of larger waterworks. ODW cannot estimate what portion of the change to the fee would be passed on to the customers. See ORM Economic Impact Form, Table 2.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>See ORM Economic Impact Form, Table 2</p>

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.

<p>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.</p>	<p>Virginia waterworks regulated by the SDWA and the <i>Waterworks Regulations</i> will be affected by this regulatory change, with downstream impacts potentially applying to all customers of public drinking water systems.</p> <p>See ORM Economic Impact Form, Tables 1a, 3 and 4.</p>
<p>Agency's best estimate of the number of such entities that will be affected. Include an estimate</p>	<p>TNCs have not been charged a fee. With the revision of this regulation, approximately 1,251</p>

<p>of the number of small businesses affected. Small business means a business entity, including its affiliates, that:</p> <ul style="list-style-type: none"> 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. 	<p>TNCs will be billed \$60 per year. These represent entities of varying sizes who have a small staff and through-traffic (customers) totaling 25 or more people per day for at least 60 days out of the year. ODW does not collect information on the structure of ownership of these waterworks nor on their gross sales. It is likely that most of these entities have fewer than 500 full-time employees.</p> <p>NTNCs are currently charged \$90 per year. There are approximately 516 NTNC systems. The revision would increase the fee to \$120 per year, an increase of \$30 annually. These represent businesses and some municipal owned waterworks that serve 25 or more of the same people per year (non-residential; typically, employees). ODW does not collect information on the structure of ownership of these waterworks nor on their gross sales. It is likely that most of these entities have fewer than 500 full-time employees.</p>
<p>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:</p> <ul style="list-style-type: none"> 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. 	<p>Other than the increased fee for some waterworks, as described above, the only additional cost should be the time required for TNCs to receive, process, and pay the new annual invoice. Administrative costs for waterworks that have historically received a waterworks operation fee invoice should not change.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The proposed regulatory amendments will allow ODW to provide enhanced technical assistance to affected waterworks.</p>

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.

The main alternative is to take no action, but the Board is unable to fulfill the responsibilities mandated in Code of Virginia § 32.1-171.1(A), which require the Board to “adjust the fee schedule so that the revenues from such fees cover the costs necessary to operate the Waterworks Technical Assistance Program...” ODW has struggled with stagnant revenue streams while costs and overhead are increasing.

Grant funding, general fund monies, and regulant fees have changed very little. A VDH-Department of Planning and Budget 2022 report to the General Assembly reviewed ODW's budget. (See "Review of the Budget and Structure of the Office of Drinking Water as required in Item 296 of the 2022 Appropriation Act," <https://rga.lis.virginia.gov/Published/2022/RD805/PDF>.) The report notes that regulants' fees, among other sources of revenue, have been static for several years, while expenditures are increasing. Inflation from 1992 to 2022 has caused the value of \$1.00 in 1992 to drop to \$0.47 in 2022, such that any increases in NTNC and community waterworks fees have not been able to keep up with increases in costs. (See "Review of the Budget and Structure of the Office of Drinking Water as required in Item 296 of the 2022 Appropriation Act," <https://rga.lis.virginia.gov/Published/2022/RD805/PDF>, pages 12-13). The report identifies a number of possible ways to address ODW's budget strain, including several options that would require direction by the General Assembly such as raising or eliminating the \$160,000 cap on fees and increasing the fee that can be charged per connection from \$3. (See "Review of the Budget and Structure of the Office of Drinking Water as required in Item 296 of the 2022 Appropriation Act," <https://rga.lis.virginia.gov/Published/2022/RD805/PDF>; pages 12-18 in particular.) Further, in 2022, the EPA hired a consulting firm to evaluate ODW's workload and resource needs. As noted in the budget report, the consulting firm's preliminary report notes that ODW needs at least 21 to 46 FTEs and a minimum of \$2.5 million in additional revenue by 2025 to "adequately sustain the drinking water program." (See "Review of the Budget and Structure of the Office of Drinking Water as required in Item 296 of the 2022 Appropriation Act," <https://rga.lis.virginia.gov/Published/2022/RD805/PDF>, page 31.) The final report from the consulting firm states that Virginia's drinking water program needs \$9,412,098 in additional funding. Additionally, ODW currently has seven staff vacancies for which hiring is on hold due to its budget shortfall. Thus, taking no action is not considered viable.

In 2022, the General Assembly provided significant assistance to ODW; however, the waterworks operation fee is intended to cover the costs associated with providing technical assistance services to the waterworks. Currently, only community and NTNC waterworks pay a fee, though ODW provides assistance to all regulated waterworks. Technical assistance costs are higher than the fees collected.

ODW has determined that waterworks that have been paying the waterworks operation fee are essentially subsidizing those waterworks that are not assessed such a fee. This proposed regulatory change will ensure that all waterworks types that get the benefit of technical assistance from ODW are funding that service. The proposed regulatory change also increases certain existing fees to reflect increases in costs that ODW has experienced due to inflation.

See also Table 1c on the ORM Economic Impact form.

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

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.

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1. Not applicable

2. The regulations impose payment deadlines and assess late fees for failure to make timely payment. The amended regulations could adopt a less stringent payment schedule, but doing so would likely impact how quickly waterworks owners pay their fees. A delay in payment of fees would negatively impact the amount of funding for ODW’s Waterworks Technical Assistance Program early in the fiscal year. The amended regulations could elect to not impose any late fees for payment that is not timely. Doing so, however, would remove an incentive for waterworks owners to timely pay their fee and may negatively impact the health of the fund that ODW relies on for the statutorily required Waterworks Technical Assistance Program.
3. Not applicable
4. Not applicable
5. Small waterworks, in the form of TNC systems, which may be small businesses, have been exempt from these regulations and have paid no fees, while receiving technical assistance from ODW. In 2021, TNC systems comprised 44% of all regulated waterworks, and ODW staff provided 17,150 hours of assistance to them. Covering these costs has been accomplished by use of federal funds (which are not sufficient) and the use of State general funds. Fees will help defray costs to these funding sources. Small waterworks are often the beneficiaries of the technical assistance that is provided by ODW thanks to funding provided via the waterworks operation fee. The proposed amendments to the regulations seek to more equitably spread the burden of these fees in comparison to the historical approach. As stated above, it is likely that most TNCs and NTNCs are small businesses.

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

**Periodic Review and
Small Business Impact Review Report of Findings**

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in EO 19 and the ORM procedures, e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable. In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency’s decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

This form is not being used to report a result of periodic review.

1. ODW depends on these funds to run its technical assistance programs. ODW helps protect the public health, safety, and welfare by providing support to waterworks through ODW’s technical assistance program. Code of Virginia § 32.1-171.1(A) requires that the Board establish fees to be charged to waterworks owners and “adjust the fee schedule so that the revenues from such fees cover the costs necessary to operate the Waterworks Technical Assistance Program required by this section.”
2. There have not been any complaints regarding these regulations outside of the stakeholder review process. The comments have been mainly to keep the TNC fee as low as possible. It was also noted that applying the \$160,000 cap on fees based on the waterworks, rather than the identity of the owner, will increase Prince William County Water Authorities’ invoice significantly. Applying the \$160,000 cap per waterworks is already allowed under the current regulations.

3. The regulatory fee structure is uncomplicated as it is clearly written and easily understandable. Additionally, VDH handles much of the work required by the regulations as the agency generates the annual invoices and monitors payment. The regulated community pays the annual fee through either a one-time payment or by quarterly installments. The regulated community also has the ability to request an adjustment to an annual fee by providing updated information on changes to the number of customer accounts.
4. There are no overlaps, nor conflicts, with any other federal or state laws or regulations.
5. The operation fee structure has not changed since 2012, and inflation has eroded ODW's ability to provide the regulated community with technical assistance. While the proposed regulatory change includes a new fee for TNC systems, these waterworks must be able to provide the public and their employees with safe, clean drinking water, and they rely on ODW for technical assistance to do so. These fees will allow ODW to continue to assist these waterworks in their efforts. Any economic impact on small business is expected to be minor. A small business that owns a TNC system will be assessed an annual fee of \$60, while a small business that owns a NTNC system will see its annual fee increase by \$30.

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency's response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

Comme nter	Comment	Agency response
<p>Sarah Holland</p> <p>Chief Executive Officer, Virginia Health Catalyst</p>	<p>Dear Mr. Roadcap,</p> <p>I write to you on behalf of Virginia Health Catalyst (Catalyst) staff, board, and partners. Catalyst is a statewide advocacy nonprofit committed to ensuring all Virginians have equitable access to safe, trusted, affordable, fluoridated drinking water – and that it's Virginian's beverage of choice.</p> <p>Thank you for the opportunity to provide comment on the Notice of Intended Regulatory Action to consider amending 12VAC5-600, Waterworks Operation Fee. Catalyst supports the prioritization of equity and environmental justice in any amendments to be made.</p> <p>Communities of color, rural populations, and low-wealth individuals experience more barriers to accessing clean water than privileged communities.</p> <p>Black, Hispanic and Native American residents are more likely to live in environmentally disadvantaged neighborhoods, with exposure to water that violates quality standards. (1)</p> <p>Black and Hispanic children and adults are two to three times more likely to report not drinking their tap water than members of white households. In 2017-2018, roughly 3 out of 10 Black adults and children and nearly 4 of 10 Hispanic adults and children didn't drink their tap water. (2)</p>	<p>Equity was a primary consideration during the discussions on modifications to these regulations. Some water systems are not paying an equitable fee based on the level of technical assistance provided by the Virginia Department of Health – Office of Drinking Water. These proposed modifications attempt to spread the costs of compliance and technical assistance programs among the water systems more equitably.</p> <p>Since these regulations only apply to a fee for technical assistance, there is no direct environmental justice issues related to these regulations. Indirectly, the VDH – ODW can better provide technical assistance to address environmental justice with</p>

	<p>Small and rural community water systems are more likely to serve marginalized communities and face unique challenges compared with large and urban systems, and are found to have more compliance violations than urban systems. (3)</p> <p>In order for all Virginians to have equitable access to safe, affordable, trusted drinking water, equity must remain a priority and emphasis in all of our work. Catalyst is currently convening a taskforce (Water Equity Taskforce) comprised of water stakeholders from across the commonwealth to develop recommendations to improve equitable access to water, and we are pleased to partner with the Office of Drinking Water staff in this effort. We commend the Office of Drinking Water staff for their hard work to keep Virginia’s water safe, and to appropriately assess the needs of communities by prioritizing a better understanding of equity and environmental injustice.</p> <p>If you have any questions, please do not hesitate to contact me at sholland@vahealthcatalyst.org.</p> <p>Thank you,</p> <p>Sarah Holland</p> <p>Chief Executive Officer, Virginia Health Catalyst</p> <p>Jill Baumgartner, Judith Rodriguez, Frans Berkhout, Yvonne Doyle, Majid Ezzati, George Owuso, Zahidul Quayyum, Bethlehem Solomon, Meghan Winters, Gary Adamkiewicz, Brian E. Robinson, Synthesizing the links between secure housing tenure and health for more equitable cities, Wellcome Open Research, 10.12688/wellcomeopenres.17244.1, 7, (18), (2022).</p> <p>Rosinger, A. Y., Patel, A. I., & Weaks, F. (2021). Examining recent trends in the racial disparity gap in tap water consumption: Nhanes 2011–2018. Public Health Nutrition, 1–7. https://doi.org/10.1017/s1368980021002603</p> <p>Marcillo, C. E. & Krometis, L. A. H. Small towns, big challenges: does rurality influence Safe Drinking Water Act compliance? AWWA Water Sci. 1, e1120 (2019).</p>	<p>more equitable fees paid by all regulated water systems.</p>
<p>Waterworks Advisory Committee – Fee Regulations Subgroup</p>	<p>See minutes of 5/12/2022 meeting on Town Hall: https://townhall.virginia.gov/L/GetFile.cfm?File=Meeting\58\35143\Minutes_VDH_35143_v1.pdf.</p>	<p>Comments consolidated into the proposed revised regulations.</p>

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.

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, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of 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:
 Barry E. Matthews
 109 Governor Street, 6th Floor
 Richmond, Virginia 23219
 804 477-5171 or barry.matthews@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.

A public hearing will not be held following the publication of this stage of this regulatory action.

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 the existing VAC Chapter(s) and the proposed regulation. If the 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
10	N/A	Sets forth definitions.	Change: Adds the following new definitions: consecutive waterworks, noncommunity waterworks, non-payment, person, Public Water System Identification Number, transient noncommunity waterworks, and wholesale waterworks. Revised the following existing definitions: customer

			<p>account, nontransient noncommunity waterworks, service connection, and waterworks.</p> <p>Intent: Provide definitions for terms as necessary to aid in the understanding of the substantive requirements of the regulations as proposed to be amended. Additionally, when defined terms are also defined in the Waterworks Regulations, 12VAC5-590, ensure that the definitions are identical.</p> <p>Rationale: These changes provide consistency between the two sets of regulations that govern drinking water in Virginia. Additional definitions were added for terms as needed to provide clarity.</p> <p>Likely Impact: Provides clarity.</p>
20	N/A	<p>Establishes that the fee schedule is based on the number of customer accounts for a community waterworks and is based on status as a NTNC for NTNC systems. Establishes a cap of \$160,000 per year per waterworks on the fee owed by a waterworks owner.</p>	<p>Change: Adds that the fee schedule for a TNC is based on its status as a TNC. Adds that the fee schedule for a wholesale waterworks is based on it being classified as a wholesale waterworks. Clarifies that the \$160,000 cap is applied per the PWSID, which is assigned to each waterworks.</p> <p>Intent: To explain generally how fees are applied to NTNCs and wholesale waterworks, which are subject to fees under the proposed regulation. Provide clarity as to the application of the \$160,000 fee cap.</p> <p>Rationale: Explain in a central location the general method by which fees are calculated and the fee cap applied, while later sections provide more detail.</p> <p>Likely impact: Provides clarity.</p>
30	Repealed	<p>States that the APA applies to this chapter.</p>	<p>Change: Repeal.</p> <p>Intent: To remove unnecessary language.</p> <p>Rationale: The APA applies under operation of statute whether or not the regulation states that it applies.</p>

			Likely Impact: To streamline the regulation.
40	N/A	Clarifies that the Commissioner may enforce this chapter through any lawful means, including revocation.	<p>Changes: Minor stylistic edit.</p> <p>Intent: To improve readability.</p> <p>Rationale: Make the regulation easier to read.</p> <p>Likely Impact: Improves the readability of the section.</p>
50	N/A	Currently requires a community waterworks owner to pay an annual assessed fee of \$3 for each customer account, describes how and when payment is to be made, and describes how the number of customer accounts will be determined.	<p>Change: Clarifies that invoicing is to be based on a community waterworks' PSWID, which is specific to each waterworks. The number of customer accounts for community waterworks is determined based on the highest number of customer accounts in the 12 months preceding July 1. The language relating to payment methodology clarifies the dates by which payment must be made and modifies when a community waterworks owner can pay in quarterly installments rather than a yearly lump sum by increasing the threshold amount under which a waterworks may pay in quarterly installments (from when the fee is more than \$400 to when the fee is more than \$1,600).</p> <p>Intent: To provide clarity on the payment methodology, including how to determine the number of customer accounts, and increase the threshold amount for a community waterworks to be able to submit fees quarterly in order to limit the administrative costs associated with managing quarterly installments.</p> <p>Rationale: Clarification is needed on how a community waterworks is identified, and the number of customer accounts is calculated, when assessing the annual fee. Additionally, the increase to the threshold amount for quarterly payments reduces ODW's administrative and billing costs associated with those waterworks that take advantage of a low threshold for quarterly installments.</p>

			<p>Likely impact: Provides clarity on how the fee is calculated and reduces agency costs.</p>
N/A	55	N/A	<p>Change: Establishes a \$2,500 annual fee for wholesale waterworks systems with fewer than 15 customer accounts that are non-waterworks. Wholesale waterworks with 15 or more customer accounts that are non-waterworks will be treated as community waterworks and subject to the fee established in 12VAC5-600-50.</p> <p>Intent: Replace and clarify the language in 12VAC5-600-90, which would be repealed, and adopt a fee for wholesale waterworks.</p> <p>Rationale: Wholesale waterworks that are community waterworks have previously paid an annual fee based on their number of customer accounts, which may be very few even though such waterworks may produce very large amounts of water. Historically, these systems have requested and benefited from the technical assistance provided by ODW. This change differentiates between wholesale waterworks with less than 15 non-waterworks customer accounts, which would now pay \$2,500 annually, and wholesale waterworks with 15 or more non-waterworks customer accounts, which will be assessed a fee as a community waterworks as specified in 12VAC5-600-50.</p> <p>Likely impact: Some wholesale waterworks will see a fee increase. Improved clarity of the regulatory language.</p>
60	N/A	Establishes an annual fee of \$90 for each NTNC system and describes how and when payment is to be made.	<p>Change: Increases the annual fee for each NTNC system by \$30 and clarifies that invoicing is to be based on a waterworks' PSWID, which is specific to each waterworks. The language also changes the date by which payment is due from November 1 of each year to August 1.</p> <p>Intent: The fee is increased in recognition of the funding needs of the technical assistance program. The</p>

			<p>date change helps to ensure that technical assistance funding is available beginning early in the fiscal year.</p> <p>Rationale: The fee for NTNC systems has not changed since 1993, and these systems are heavy users of technical assistance services. In 2021, NTNC systems comprised 38% of all regulated waterworks, and this class of systems used 14,250 hours of ODW time for technical assistance services. This minimal fee increase is necessary to appropriately fund the technical assistance program. The addition of the PWSID is to provide clarity and to be consistent with the same change for community waterworks.</p> <p>Likely impact: Minimal increase in the fee paid by NTNCs and provides clarity.</p>
N/A	65	N/A	<p>Change: Establishes a \$60 annual fee and the payment requirements for TNC systems.</p> <p>Intent: To have TNC systems share the burden of funding ODW’s technical assistance activities.</p> <p>Rationale: Historically, these systems have been the heaviest users of technical assistance services, significantly more than other system types, without having to share in the burden of supporting the technical services they benefit from. In 2021, this system class comprised 44% of all regulated waterworks and used 17,150 hours of ODW staff time for technical services.</p> <p>Likely impact: A minimal annual cost to these systems.</p>
70	N/A	Requires VDH to send each waterworks owner a payment form/data verification notice by July 1 while noting that the waterworks owner is not relieved of its duties if the owner does not receive such a form.	<p>Change: Rather than referencing a “payment form/data verification notice” generically, specifically identifies the “Waterworks Operation Fee – Invoice/Data Verification Notice,” which is identified as a form at the end of the chapter.</p>

			<p>Intent: Provide clarification and a direct reference to the cited form.</p> <p>Rationale: A direct reference to the applicable form is preferable to a generic reference to a form.</p> <p>Likely impact: Improve clarity.</p>
80	N/A	Establishes that the fees are nonrefundable but are credited to a new owner of the same waterworks.	<p>Change: Adds citation to new sections of the regulations, 12VAC5-600-55 and 12VAC5-600-65, as they include new fees for wholesale waterworks and transient noncommunity systems.</p> <p>Intent: To clarify that the new fees will be treated the same in 12VAC5-600-80 as the existing fees.</p> <p>Rationale: All classes of waterworks should be treated equally, and this language change is necessary to achieve this.</p> <p>Likely impact: Improve clarity and establish uniformity as to fees not being refundable.</p>
90	55	Provides an exemption from the community waterworks fee under 12VAC5-600-50 for customer accounts through which water is sold or delivered to another waterworks.	<p>Change: Repealed and replaced by 12VAC5-600-55 of this chapter.</p> <p>Intent: To repeal this section.</p> <p>Rationale: With the promulgation of 12VAC5-600-55, this section was no longer needed and was not accurate.</p> <p>Likely impact: Removes an unnecessary and inaccurate section of the regulations in light of the addition of 12VAC5-600-55.</p>
100	N/A	Provides the address where payments are to be made and to whom the payment is to be made.	<p>Change: Adds language that assesses a convenience fee for credit card payments, clarifies the type of payment that has to be mailed to ODW, and removes ODW's mailing address.</p> <p>Intent: Clarify how electronic payments and non-electronic payments are to be made.</p> <p>Rationale: The additional language will shift the financial burden of credit card-type payments from ODW to the waterworks, who benefit from the ease</p>

			<p>of this type of payment. With the increase in the use of electronic payments, clarification was needed on how non-electronic payments needed to be made. VDH's mailing address is included on the fee invoice that each owner receives, so the address was removed from this section as both unnecessary and redundant. Additionally, agency addresses are not generally included in regulations so as to avoid having to amend the regulation if the agency's address changes.</p> <p>Likely impact: Nominal increase in costs to waterworks that choose to pay using a credit card.</p>
110	N/A	<p>Establishes that operation fees that are not timely paid are subject to interest, administrative charges, and late penalty fees pursuant to § 2.2-4805 of the Code of Virginia.</p>	<p>Change: Adds non-monetary impacts for a waterworks owner's nonpayment of the required fee.</p> <p>Intent: To encourage waterworks owners to pay operation fees.</p> <p>Rationale: Provides additional incentives for owners to pay the waterworks operation fee. The current regulation does not provide a process under which VDH could reduce or refuse to provide funding and technical assistance services to an owner who fails to pay the required fee. This addition to the regulation will further encourage owners to pay the required fee in order to continue to receive future funding and/or technical assistance or be required to provide documentation to remain in compliance. This change will also be more equitable, in that owners that pay their fees will have access to all of the benefits and services ODW provides, whereas owners that do not pay risk losing such access.</p> <p>Likely impact: A reduction in the number of owners that fail to pay their annual operation fees.</p>
Forms	N/A	<p>Two forms currently available.</p>	<p>Change: The two existing forms were consolidated into one form and the version date updated.</p>

			<p>Intent: Streamline the billing process and reduce costs.</p> <p>Rationale: Two forms are not needed. The two existing forms were so similar that they could easily be combined making the fee billing process more efficient and less costly.</p> <p>Likely impact: Greater efficiency resulting in reduced costs in billing operation fees and lower operation costs in administering the Waterworks Technical Assistance Fund.</p>
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Virginia Department of Health - Office of Drinking Water
Economic Review Form

March 2023

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5-600
VAC Chapter title(s)	Waterworks Operation Fee
Action title	Amend and Update the Waterworks Operation Fee Regulations
Date this document prepared	April 20, 2023
Regulatory Stage (including Issuance of Guidance Documents)	Proposed (Action 5867 / Stage 9465)

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)	Direct Costs: Costs to the Virginia Department of Health’s Office of Drinking Water (ODW) relating to changing the Waterworks Operation Fee: \$40,000 <ul style="list-style-type: none"> • The number of invoices to waterworks will more than double from 1,248 to 2,817.
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- For the billing cycle 2022, costs to complete invoicing (staff, printing, postage) totaled \$20,318. ODW is expecting these costs to more than double to around \$60,000 per year considering a doubling of the number of invoices and increased cost of staff and materials. Further, in the first year of using the new billing software there will be increased staff time for training and process development.
- Increased costs for invoicing of approximately \$40,000 for a new total of approximately \$60,000.

In addition to the increased fees expected to be assessed to waterworks owners under the proposed regulatory amendment, which are discussed below as direct benefits to ODW, the proposed regulatory amendments include authority for the Virginia Department of Health (VDH) to assess a convenience fee, at the prevailing credit vendor convenience rate fee, to waterworks paying their fee by credit card. The exact cost of this to the regulated community would depend on the number of waterworks that choose to pay by credit card and the amount of the prevailing credit vendor convenience rate fee.

Additional costs to VDH related to issuance of operation fee invoices that will be incurred regardless of whether the Waterworks Operation Fee regulations are amended include:

- Currently, VDH is using a MS Access database, Excel spreadsheets, and mail merge to invoice waterworks. This appears to not meet VITA requirements. Consequently, VDH will be required to purchase compliant software that will meet this need. VDH does not have a purchase price on the software as it would require extensive evaluation and staff time. It is anticipated that the software will cost not less than \$150,000 in the first year and then drop off in subsequent years.
- Expenses in subsequent years will reflect a decrease in staff time with efficiencies and a software licensing fee estimated at 10% of the original cost.
- Total first-year cost for additional software is estimated at \$150,000. This amount is not reflected in costs due to this proposed regulatory action because these costs will be incurred regardless of whether this regulatory action is undertaken.
- Total cost in subsequent years for additional invoicing and software is estimated at \$15,000. This amount is not reflected in costs due to this proposed regulatory action because these costs will be incurred regardless of whether this regulatory action is undertaken.

Indirect Costs: \$0

	<ul style="list-style-type: none"> Indirect costs for staff time are accounted for in the expenses above, estimating the number of hours required. <p>Direct Benefits to ODW: \$142,947</p> <ul style="list-style-type: none"> ODW estimates that the waterworks operation fee will generate additional annual revenue due to the proposed regulatory change in the amount of \$142,947. This benefit to ODW will be paid by the regulated community on account of the additional fees that would be assessed under the proposed amendment to the regulations. <p>Indirect Benefits: \$0</p> <ul style="list-style-type: none"> There are no monetizable indirect benefits associated with this change. 	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) Year 1: \$40,000 Year 2+: \$40,000	(b) Year 1: \$142,947 Year 2+: \$142,947
(3) Net Monetized Benefit	Year 1: \$102,947 Year 2+: \$102,947	
(4) Other Costs & Benefits (Non-Monetized)	<p>Costs:</p> <p>(1) Waterworks owners may elect to pass on additional costs for the waterworks operation fee to their customers.</p> <p>Benefits:</p> <p>(1) The proposed amendments will allow ODW to continue providing substantial technical assistance to waterworks regulated under the Safe Drinking Water Act in order to protect public health.</p> <p>(2) The existing fee structure has not been materially modified since 2012, and the fee paid by nontransient noncommunity waterworks has not been modified since the regulation was adopted in 1993. Transient noncommunity waterworks, which comprised 44% of all regulated waterworks in 2021, have been receiving non-compliance technical assistance services from the Office of Drinking Water (17,150 ODW staff hours valued at around \$1.07 million in 2021) but have not been paying a technical assistance fee, unlike the community and nontransient noncommunity waterworks in the state. Assessing a fee to transient noncommunity waterworks will ensure that no one</p>	

	<p>classification of waterworks is fully subsidizing assistance to other classifications of waterworks.</p> <p>(3) A portion of the revenues from this regulatory change will be used to purchase billing software that meets state requirements. The current billing process uses local copies of Access databases and Excel spreadsheets, is inefficient, and does not integrate with VDH financial software. Billing software will integrate with standard financial systems and will allow for improved budgeting and tracking of receivables. The software is necessary regardless of any regulatory amendment.</p>
(5) Information Sources	<p>Billing data from VDH-Shared Business Services for FY2022</p> <p>2022 list of all regulated community, nontransient noncommunity, and transient noncommunity waterworks including Public Water System Identification Number, owner information, numbers of reported service connections, waterworks type, water source. This was pulled from the Safe Drinking Water Information System, which is the electronic information management system developed by the U.S. Environmental Protection Agency for states to manage information for regulated waterworks.</p>

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

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Direct Costs: \$0</p> <ul style="list-style-type: none"> Without the regulatory changes, no additional costs will be incurred on account of the status quo being maintained. However, ODW will still have to bear the costs associated with upgrading noncompliant billing software as described in Table 1a. <p>Indirect Costs: \$0</p> <ul style="list-style-type: none"> There are no indirect costs incurred as a result of not changing the regulation. ODW will bear costs associated with upgrading noncompliant billing software as described elsewhere, and indirect costs for staff time related thereto are accounted for in the prior discussion of this expense, estimating the number of hours required. <p>Direct Benefits: \$0</p> <ul style="list-style-type: none"> There are no new direct benefits associated with maintaining the status quo. <p>Indirect Benefits: \$0</p> <ul style="list-style-type: none"> There are no indirect benefits to maintaining the status quo. Maintaining the status quo will perpetuate the provision of free
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	services to transient noncommunity waterworks and subsidized services to all other regulated waterworks.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) Year 1: \$0 Year 2+: \$0	(b) Year 1: \$0 Year 2+: \$0
(3) Net Monetized Benefit	Year 1: \$0 Year 2+: \$0	
(4) Other Costs & Benefits (Non-Monetized)	Non-monetizable costs of maintaining the status quo include negatively impacting ODW’s ability to continue to sufficiently meet the need for technical assistance to waterworks, while not more equitably distributing the fee among the types of waterworks that most need technical assistance. Without adequate funding, ODW will remain challenged with making decisions on which waterworks will be provided assistance. If these choices cause waterworks to receive less or no technical assistance in preventing or resolving water quality and supply issues, water-borne illness and health impacts are possible.	
(5) Information Sources	Same as Table 1a above.	

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

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>There are no viable regulatory alternatives to fee increases as contained in these proposed regulations. Code of Virginia § 32.1-171.1.A requires that the State Board of Health “adjust the fee schedule so that the revenues from such fees cover the costs necessary to operate the Waterworks Technical Assistance Program required by this section.” Consequently, the Board is required to assess a fee and adjust it appropriately.</p> <p>In 2022, the Virginia Department of Health and the Department of Planning and Budget published a “Review of the Budget and Structure of the Office of Drinking Water as required in Item 296 of the 2022 Appropriation Act.” Among the possibilities discussed is applying the \$160,000 cap on fees on a per waterworks basis, rather than a per owner basis. Applying the cap on a per waterworks basis is consistent with the current Waterworks Operation Fee regulations. ODW intends to pursue this approach and no regulatory change is required for ODW to do so. Accounting for this increased revenue stream was included in developing the proposed amendments to the regulations. The budget report, however, does not present a change in how the fee cap is applied as</p>
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	<p>being a one-stop solution to ODW’s budgetary issues when it comes to fees collected. The budget report discusses several other possible options to address ODW’s budget issues, which include options that would require direction from the General Assembly. (https://rga.lis.virginia.gov/Published/2022/RD805/PDF; see pages 12-18 in particular.) These options include:</p> <ul style="list-style-type: none"> • Increasing the \$160,000 cap. • Removing the \$160,000 cap, which would result in an estimated annual revenue increase of approximately \$1.93 million. • Increasing the fee per connection, which is currently set at \$3 maximum, by \$1 to \$3 with or without the removal of the \$160,000 cap. For example, an increase from \$3 to \$5.13 would result in an increase in annual revenue of almost \$765,000. <p>Direct Costs: an estimated seven waterworks would pay higher fees totaling an estimated \$177,405 if the cap on fees is applied on a per waterworks basis, rather than a per owner basis. Additional costs to the regulated community from options set forth in the budget report are dependent upon direction from the General Assembly.</p> <p>Indirect Costs: dependent upon direction from the General Assembly.</p> <p>Direct Benefits: additional possible sources of revenue from fees as addressed in the budget report are dependent upon direction from the General Assembly. Application of the cap on fees on a per waterworks basis would result in benefits to ODW equal to the additional costs to the regulated community.</p> <p>Indirect Benefits: dependent upon direction from the General Assembly.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$177,405 incurred by the regulated community without further change in statute or regulation.	(b) Unknown to the extent options other than changing how ODW applies the fee cap require direction from the General Assembly. Only changing how ODW applies the fee cap would result in a benefit of \$177,405 to ODW on account of the increase in fees.
(3) Net Monetized Benefit	Unknown to the extent that options other than changing how ODW applies the fee cap require direction from the General Assembly. As for changing the application of the fee cap by itself, it would result in direct benefits to ODW as the recipient of the fee payment that are equal to the increase in fees paid due to the change.	

(4) Other Costs & Benefits (Non-Monetized)	Additional funding from modifying the method by which ODW applies the \$160,000 fee cap would increase ODW’s ability to provide technical assistance services, even if modifying how the cap is applied is not indicated in the budget report as being a complete solution for the budget issue by itself.
(5) Information Sources	The Virginia Department of Health and the Department of Planning and Budget “Review of the Budget and Structure of the Office of Drinking Water as required in Item 296 of the 2022 Appropriation Act.”

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)	<p>Direct Costs: local partners that own waterworks would experience direct costs based on the number and classification of waterworks they own. The additional cost could be up to \$2,500 for each wholesale waterworks with fewer than 15 end-user accounts owned by a local partner, an additional \$60 for each TNC waterworks owned by a local partner, and an additional \$30 for each NTNC waterworks owned by a local partner.</p> <p>Additionally, if a local partner chooses to pay its invoice by credit card it will be assessed a convenience fee at the prevailing credit vendor convenience rate fee. The exact cost of this to the regulated community as a whole would depend on the number of local partners that own waterworks that choose to pay by credit card and the amount of the prevailing credit vendor convenience rate fee.</p> <p>Indirect costs: administrative costs for processing the invoice, likely minimal, for each waterworks that was not previously subject to a fee now having to pay a fee.</p> <p>Direct benefits: none.</p> <p>Indirect benefits: none.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) Unknown – see above for general discussion as the per owner costs would vary based on the type of waterworks.	(b) \$0

(3) Other Costs & Benefits (Non-Monetized)	If the technical assistance program is adequately funded, then all waterworks can continue receiving these necessary services from ODW.
(4) Assistance	None.
(5) Information Sources	Staff input.

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 & Benefits (Monetized)	<p>Direct Costs: Families that are customers of a wholesale waterworks may be affected by the pass-through of the additional costs to the end user. The waterworks owner currently has authority to adjust water rates to ensure water expenses are borne by the customer. It is likely that any amount that the waterworks might decide to pass on to the customer will be minimal.</p> <p>Families that go to businesses that have a regulated waterworks (transient noncommunity waterworks) might be affected by the regulation in that the owner of the business may choose to pass the additional business expenses on to the customer. Owners of businesses that own a nontransient noncommunity waterworks may do likewise. This would likely be a minor increase since the maximum fee to transient noncommunity waterworks will be \$60 per year, and the fee for nontransient noncommunity waterworks would increase by \$30 under the proposed amendment to the regulations. For purposes of this Form, VDH has assumed that all monetizable costs will be borne by the waterworks.</p> <p>Indirect Costs: none.</p> <p>Direct Benefits: none.</p> <p>Indirect Benefits: none.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0 (see explanation above)	(b) \$0 (see explanation above)

(3) Other Costs & Benefits (Non-Monetized)	ODW would be able to continue providing technical assistance, with resulting health benefits, to waterworks that provide potable water to families and other entities. A lack of technical assistance to waterworks can result in a negative impact on the health of families and others.
(4) Information Sources	Staff input.

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)	<p>Direct Costs: Transient noncommunity waterworks are typically small businesses. The amount of the proposed fee (\$60/year) would be borne by the business. They would have the option to pass that cost on to their customer.</p> <p>Likewise, the fee for wholesale waterworks with less than 15 end-user accounts would now be \$2,500 and nontransient noncommunity waterworks would see an increase of \$30 in their annual fee.</p> <p>Additionally, if a small business that owns a waterworks chooses to pay its invoice by credit card it will be assessed a convenience fee at the prevailing credit vendor convenience rate fee. The exact cost of this would depend on the number of such waterworks that choose to pay by credit card and the amount of the prevailing credit vendor convenience rate fee.</p> <p>Many of these waterworks have small businesses as part of their larger customer base. They would have the option to pass along the cost to their entire customer base. They currently have authority to do this with other expenses through rate adjustments. Waterworks owners are not expected to pass along any fee increase to small businesses in an amount that is greater than any fee passed along to other customers.</p> <p>Indirect Costs: administrative costs for processing the invoice, likely minimal, for each waterworks that was not previously subject to a fee now having to pay a fee.</p> <p>Direct Benefits: none.</p> <p>Indirect Benefits: none.</p>
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(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) See box (1) above for the fee increases on a per waterworks basis. It is unknown what quantity of such waterworks are considered to be owned by “small businesses.”	(b) \$0
(3) Other Costs & Benefits (Non-Monetized)	Non-monetized benefits to small businesses include that this fee will support technical assistance through the Office of Drinking Water to these waterworks in support of their compliance with the Safe Drinking Water Act and the Virginia <i>Waterworks Regulations</i> . Consistent compliance with these regulations will support their other business functions through provision of safe drinking water to staff and customers. ODW would be able to continue to provide the level of technical assistance that waterworks have used and enjoyed in the past.	
(4) Alternatives	Maintaining the status quo would reduce the small financial burden on certain waterworks but could have unintended regulatory consequences if a waterworks is unable to stay in compliance with regulations.	
(5) Information Sources	Staff input.	

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	Initial Count	Additions	Subtractions	Net Change
12VAC5-600-55	N/A	3	N/A	+3
12VAC5-600-65	N/A	2	N/A	+2
12VAC5-600-100	1	1	0	+1
12VAC5-600-120	N/A	4	N/A	+4

Cost Reductions or Increases (if applicable)

VAC Section(s) Involved	Description of Regulatory Requirement	Initial Cost	New Cost	Overall Cost Savings/Increases
12VAC5-600-55	Fee for wholesale waterworks	Annual fee of \$3 per customer account	\$2,500 annual flat fee if the waterworks has fewer than 15 end-user accounts	Up to \$2,500 additional cost for each wholesale waterworks with fewer than 15 end-user accounts. This is expected to result in a total fee increase of approximately \$52,407 to wholesale waterworks as a whole.
12VAC5-600-60	Fee for nontransient noncommunity waterworks	\$90 annual fee per nontransient noncommunity waterworks	\$120 annual fee per nontransient noncommunity waterworks	\$30 annual fee increase per nontransient noncommunity waterworks. This is expected to result in a total fee increase of approximately \$15,480 to nontransient noncommunity waterworks as a whole.
12VAC5-600-65	Fee for transient noncommunity waterworks	\$0 – this is a new cost	\$60 annual fee per transient noncommunity waterworks; Estimated \$40,000 annual cost to agency related to additional invoices.	\$60 annual fee per transient noncommunity waterworks. This is expected to result in a total fee increase of approximately \$75,060 to transient noncommunity waterworks as a whole. These fees would be paid to the agency, which

				is expected to incur approximately \$40,000 in additional costs related to additional invoices.
12VAC5-600-100	Convenience fee charged for use of a credit card to pay fee	\$0 – this is a new cost	Charged at prevailing credit card vendor convenience fee rate.	Depends on the credit card vendor convenience fee rate and how many waterworks choose to pay by credit card.

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
12VAC5-600-50	Increases the fee threshold to be able to pay on a quarterly basis, as opposed to a lump sum, from over \$400 to over \$1,600.	Under the proposed regulatory amendments, waterworks must pay the assessed fee in a lump sum by August 1 if the fee is \$1,600 or less. Under the current regulation, a waterworks could pay in quarterly installments, with the first quarter payment due on August 1, if the fee was more than \$400.
12VAC5-600-60	Moves the date by which nontransient noncommunity waterworks must pay their waterworks operation fee from November 1 to August 1.	The proposed regulatory amendment gives owners of nontransient noncommunity waterworks three fewer months to pay the fee.
12VAC5-600-120	Adds a new section stating actions that VDH may take for non-payment of the waterworks operation fee that is in addition to seeking recovery of that fee. The options include limiting technical assistance to a waterworks to the state's legal requirement, limiting access to financial assistance, collecting	Provides for the possibility of non-monetary penalties that the agency can impose on a waterworks that fails to pay its waterworks operation fee.

	financial records of the waterworks, and requiring the waterworks to submit a Waterworks Business Operation Plan.	
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1 **Project 7059 - NOIRA**

2 **Department of Health**

3 **Amend and Update the Waterworks Operation Fee Regulations**

4 **12VAC5-600-10. Definitions.**

5 As used in this chapter, unless otherwise defined, words and terms are the same as those in
6 § 32.1-167 of the Code of Virginia or in 12VAC5-590-10 (Waterworks Regulations) and shall have
7 the following meanings unless the context clearly indicates otherwise:

8 "Board" means the State Board of Health.

9 "Commissioner" means the State Health Commissioner who is the executive officer of the
10 State Board of Health.

11 "Community waterworks" means a waterworks that serves at least 15 service connections
12 used by year-round residents or regularly serves at least 25 year-round residents.

13 "Consecutive waterworks" means a waterworks that receives some or all of its finished water
14 from one or more waterworks. Consecutive waterworks may provide additional treatment to
15 finished water. Delivery may be through a direct connection or through the distribution system of
16 one or more consecutive waterworks.

17 "Customer account" means (i) a metered or unmetered potable water service connection to
18 the customer that is billed in any way by the waterworks owner or (ii) where any community
19 waterworks sends no billing, the customer accounts shall be defined as equal to the population
20 served divided by ~~four~~ 2.8.

21 "Department" means the Virginia Department of Health.

22 "Due" means received or postmarked by the stated date.

23 "Fiscal year" means the year from July 1 to June 30.

24 "Noncommunity waterworks" means a waterworks that is not a community waterworks but
25 operates at least 60 days out of the year.

26 "Non-payment" means any fee owed to the Virginia Department of Health's Waterworks
27 Technical Assistance Fund that is 60 days or greater past due.

28 "Nontransient noncommunity waterworks" or "NTNC" means a waterworks that is not a
29 community waterworks and that regularly serves at least 25 of the same persons over six months
30 out of the year. When used in the context of an NTNC, "regularly serves" means four or more
31 hours per day, for four or more days per week, for 26 or more weeks per year.

32 "Owner" means an individual, group of individuals, partnership, firm, association, institution,
33 corporation, governmental entity, or the federal government that supplies or proposes to supply
34 water to any person within this Commonwealth from or by means of any waterworks.

35 "Person" means any individual, corporation, partnership, association, cooperative, limited
36 liability company, trust, joint venture, government, political subdivision, or any other legal or
37 commercial entity and any successor, representative, agent, or instrumentality thereof.

38 "Public Water System Identification Number" or "PWSID" means a unique identifying number
39 used by the Virginia Department of Health that is specific to each waterworks.

40 "Service connection" means the point of delivery of finished water from a waterworks to a
41 customer's consumer's building service line water system, fire protection system, irrigation
42 system, and to all other points where finished water is delivered through the distribution
43 to a consumer. Generally, the service connection occurs at the water meter, or at the distribution
44 main if no water meter is installed, or in the case of an owner of both the waterworks and the

45 building supplied, the point of entry into the building. Service connections may be permanent,
46 temporary, or emergency, as follows:

- 47 1. ~~If a meter is installed, the service connection is the downstream side of the meter;~~
- 48 2. ~~If a meter is not installed, the service connection is the point of connection to the~~
49 ~~waterworks; or~~
- 50 3. ~~When the waterworks owner is also the building owner, the service connection is the~~
51 ~~entry point to the building.~~

52 "Transient noncommunity waterworks" or "TNC" means a noncommunity waterworks that is
53 not a nontransient noncommunity waterworks (NTNC). A TNC serves at least 25 persons daily
54 for at least 60 days out of the year.

55 "Waterworks" means a system that serves piped water for human consumption to at least 15
56 service connections or 25 or more individuals for at least 60 days out of the year. "Waterworks"
57 includes all structures, equipment and appurtenances used in the storage, collection, purification,
58 treatment and distribution of pure potable water except the piping and fixtures inside the building
59 where such water is delivered.

60 "Wholesale waterworks" means a waterworks that treats source water as necessary to
61 produce potable water and then delivers some or all of that potable water to another waterworks.
62 Delivery may be through a direct connection or through the distribution system or one or more
63 consecutive waterworks.

64 **Statutory Authority**

65 §§ 32.1-12 and 32.1-170 of the Code of Virginia.

66 **Historical Notes**

67 Derived from VR 355-18-014 § 1.1, eff. July 1, 1993; amended, Virginia Register Volume 29,
68 Issue 4, eff. November 22, 2012; Volume 31, Issue 1, eff. October 10, 2014.

69 **~~12VAC5-600-20. Purpose of the regulation Operation fee requirement; fee cap.~~**

70 ~~The regulation establishes a waterworks operation fee schedule where the number of~~
71 ~~customer accounts of a community waterworks is the basis for assessing charges to the~~
72 ~~community waterworks. The fee schedule for nontransient noncommunity waterworks is based~~
73 ~~on the waterworks being classified as a nontransient noncommunity waterworks. A waterworks~~
74 ~~owner shall pay the waterworks operation fee according to the appropriate fee schedule, based~~
75 ~~on the waterworks' classification as a community waterworks, nontransient noncommunity~~
76 ~~waterworks, transient noncommunity waterworks, or wholesale waterworks pursuant to this~~
77 ~~chapter. No owner shall pay a waterworks operation fee pursuant to this chapter of more than~~
78 ~~\$160,000 per year per waterworks Public Water System Identification Number, nor is it the intent~~
79 ~~that an owner be charged this fee on water transferred to another waterworks.~~

80 **Statutory Authority**

81 §§ 32.1-12 and 32.1-170 of the Code of Virginia.

82 **Historical Notes**

83 Derived from VR 355-18-014 § 2.1, eff. July 1, 1993; amended, Virginia Register Volume 29,
84 Issue 4, eff. November 22, 2012.

85 **~~12VAC5-600-30. Compliance with the Administrative Process Act. (Repealed.)~~**

86 ~~The provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia)~~
87 ~~shall govern the promulgation and administration of this chapter.~~

88 **Statutory Authority**

89 ~~§§ 32.1-12 and 32.1-170 of the Code of Virginia.~~

90 **Historical Notes**

91 Derived from VR 355-18-014 § 2.2, eff. July 1, 1993; amended, Virginia Register Volume 29,
92 Issue 4, eff. November 22, 2012.

93 **12VAC5-600-40. Powers and procedure of regulation not exclusive.**

94 The commissioner may enforce this chapter through any means lawfully available including,
95 but not limited to, the revocation of the waterworks operation permit (~~see pursuant to~~ § 32.1-174
96 of the Code of Virginia).

97 **Statutory Authority**

98 §§ 32.1-12 and 32.1-170 and ~~32.1-171.4~~ of the Code of Virginia.

99 **Historical Notes**

100 Derived from VR 355-18-014 § 2.3, eff. July 1, 1993.

101 **12VAC5-600-50. Community waterworks operation fee.**

102 A. ~~An annual waterworks operation fee, not to exceed \$160,000, shall be charged as of July~~
103 ~~1 of each fiscal year to the owner of each community waterworks in an amount as follows:~~

104 For each fiscal year: ~~the number of customer accounts multiplied by no more than \$3.00, the~~
105 ~~department shall assess the owner of each community waterworks an annual waterworks~~
106 ~~operation fee, not to exceed \$160,000 per PWSID. The department shall calculate the fee by~~
107 ~~multiplying the number of customer accounts for each community waterworks, as identified by the~~
108 ~~waterworks' PWSID, by no more than \$3.00. For purposes of performing this calculation, the fee~~
109 ~~shall be based on the highest number of customer accounts for the waterworks in the 12 months~~
110 ~~preceding July 1.~~

111 B. ~~The owner shall pay the assessed fee shall be paid to the department and be due as~~
112 ~~follows:~~

113 1. If the fee established in subsection A of this section is ~~\$400~~ \$1,600 or less, the owner
114 shall pay the fee shall be due in a lump sum ~~on~~ no later than August 1;

115 2. If the fee established in subsection A of this section is more than ~~\$400~~ \$1,600, the
116 owner shall pay the fee shall be due in a lump sum or in equal quarterly installments each
117 year as follows:

118 a. No earlier than July 1 and no later than August 1—The lump sum or first quarterly
119 installment.

120 b. No later than November 1—The second quarterly installment.

121 c. No later than February 1—The third quarterly installment.

122 d. No later than May 1—The fourth quarterly installment.

123 C. ~~Data verification.~~ The number of customer accounts ~~will~~ shall be based on the best
124 available data stored in department databases for a maximum period of ~~six~~ 12 months prior to ~~the~~
125 ~~close of business on June 30~~ July 1. ~~each~~ Every year, ~~as provided by the owner or chief~~
126 ~~administrative officer of the waterworks shall provide updated data to the department. This Data~~
127 ~~verification shall be provided to the department by the owner of for each community waterworks~~
128 ~~at the address specified in 12VAC5-600-100 and is due by~~ no later than August 1 of each year
129 with the appropriate payment.

130 **Statutory Authority**

131 §§ 32.1-12 and 32.1-170 of the Code of Virginia.

132 **Historical Notes**

133 Derived from VR 355-18-014 § 3.1, eff. July 1, 1993; amended, Virginia Register Volume 15,
134 Issue 20, eff. July 21, 1999; Virginia Register Volume 29, Issue 4, eff. November 22, 2012.

135 **12VAC5-600-55. Wholesale waterworks.**

136 A. For each fiscal year, the department shall assess the owner of each wholesale waterworks
137 that has fewer than 15 customer accounts with non-waterworks an annual waterworks operation
138 fee in the amount of \$2,500 per PWSID. The department shall consider a wholesale waterworks
139 that has 15 or more customer accounts with non-waterworks as a community waterworks only for
140 purposes of determining the fee to be assessed under this chapter and shall assess an annual
141 waterworks operation fee pursuant to 12VAC5-600-50.

142 B. For a wholesale waterworks that has fewer than 15 customer accounts with non-
143 waterworks, the owner shall pay the assessed fee to the department no later than August 1 of
144 each year. For a wholesale waterworks that has 15 or more customer accounts with non-
145 waterworks, the owner shall pay the assessed fee to the department in accordance with the
146 schedule set forth in 12VAC5-600-50.

147 **Statutory Authority**

148 §§ 32.1-12 and 32.1-170 and 32.1-171.1 of the Code of Virginia.

149 **12VAC5-600-60. Nontransient noncommunity (NTNC) waterworks operation fee.**

150 ~~A. An annual waterworks operation fee shall be charged as of July 1 of each fiscal year to the~~
151 ~~owner of each NTNC waterworks. For each fiscal year, an amount of no more than \$90 per NTNC~~
152 ~~waterworks shall be assessed. the department shall assess the owner of each NTNC an annual~~
153 ~~waterworks operation fee in the amount of \$120 per PWSID.~~

154 B. The owner shall pay the assessed fee shall be due to the department every November 1
155 no later than August 1 of each year.

156 **Statutory Authority**

157 §§ 32.1-12 and 32.1-170 and 32.1-171.1 of the Code of Virginia.

158 **Historical Notes**

159 Derived from VR 355-18-014 § 3.2, eff. July 1, 1993; amended, Virginia Register Volume 15,
160 Issue 20, eff. July 21, 1999; Volume 29, Issue 4, eff. November 22, 2012.

161 **12VAC5-600-65. Transient noncommunity (TNC) waterworks operation fee.**

162 A. For each fiscal year, the department shall assess the owner of each TNC an annual
163 waterworks operation fee in the amount of \$60 per PWSID.

164 B. The owner shall pay the assessed fee to the department no later than August 1 of each
165 year.

166 **Statutory Authority**

167 §§ 32.1-12 and 32.1-170 and 32.1-171.1 of the Code of Virginia.

168 **12VAC5-600-70. Notice.**

169 ~~The department will shall send to each waterworks owner a payment form/data verification~~
170 ~~notice as prescribed by the department Waterworks Operation Fee - Invoice/Data Verification~~
171 ~~Notice on or before July 1 of each year. Failure to receive this the notice does shall not relieve~~
172 ~~the owner of the responsibility of the owner from providing to provide payments or data~~
173 ~~verification.~~

174 **Statutory Authority**

175 §§ 32.1-12 and 32.1-170 of the Code of Virginia.

176 **Historical Notes**

177 Derived from VR 355-18-014 § 3.3, eff. July 1, 1993; amended, Virginia Register Volume 29,
178 Issue 4, eff. November 22, 2012.

179 **12VAC5-600-80. Refundability.**

180 The fees established in 12VAC5-600-50 and, 12VAC5-600-55, 12VAC5-600-60, and
181 12VAC5-600-65 are nonrefundable but are credited to any new owner of the same waterworks.

182 **Statutory Authority**

183 §§ 32.1-12 and 32.1-170 and 32.1-171.1 of the Code of Virginia.

184 **Historical Notes**

185 Derived from VR 355-18-014 § 3.4, eff. July 1, 1993.

186 **12VAC5-600-90. Exemptions (Repealed).**

187 ~~(Repealed.)Customer accounts through which water is sold or delivered to another~~
188 ~~waterworks are exempted from the fee calculated in 12VAC5-600-50.~~

189 **Statutory Authority**

190 ~~§§ 32.1-12 and 32.1-170 and 32.1-171.1 of the Code of Virginia.~~

191 **Historical Notes**

192 Derived from VR 355-18-014 § 3.5, eff. July 1, 1993.

193 **12VAC5-600-100. Payments.**

194 The department shall charge a convenience fee, at the prevailing credit vendor convenience
195 fee rate, for use of a credit card form of payment. Payments An owner shall make a non-electronic
196 payment are to be made payable to: VDH - Waterworks Technical Assistance Fund , and sent to:

197 Virginia Department of Health
198 Office of Drinking Water
199 Madison Building, 6th Floor
200 409 Governor Street, Room 622
201 Richmond, Virginia 23219

202 **Statutory Authority**

203 §§ 32.1-12 and 32.1-170 of the Code of Virginia.

204 **Historical Notes**

205 Derived from VR 355-18-014 § 3.6, eff. July 1, 1993; amended, Virginia Register Volume 29,
206 Issue 4, eff. November 22, 2012.

207 **12VAC5-600-110. Late fees and , administrative charges , and non-payment**
208 **considerations.**

209 In addition to the powers in 12VAC5-600-40, ~~operation :~~

210 1. Operation fees not received or postmarked by the due date shall be subject to interest,
211 administrative charges, and late penalty fees in accordance with § 2.2-4805 of the Code
212 of Virginia.

213 2. The department may take any or all of the following actions in response to an owner's
214 non-payment of fees due pursuant to this chapter:

- 215 a. Limit the technical assistance provided to a waterworks to the state's legal
216 requirements pursuant to the Safe Drinking Water Act;
217 b. Limit or restrict any waterworks' access to loans, grants, or services provided by the
218 department;
219 c. Collect financial records regarding the operations of the waterworks; and
220 d. Require the submission of a Waterworks Business Operation Plan.

221 **Statutory Authority**

222 §§ 32.1-12 and 32.1-170 of the Code of Virginia.

223 **Historical Notes**

224 Derived from VR 355-18-014 § 3.7, eff. July 1, 1993; amended, Virginia Register Volume 29,
225 Issue 4, eff. November 22, 2012.

226 FORMS (12VAC5-600)

227 ~~[Waterworks Operation Fee - Invoice/Data Verification Notice - less than \\$400 \(rev. 8/14\)](#)~~

228 ~~[Waterworks Operation Fee - Invoice/Data Verification Notice - \\$400 or more \(rev. 8/14 8/22\)](#)~~



COMMONWEALTH of VIRGINIA

Department of Health
P O BOX 2448
RICHMOND, VA 23218

Karen Shelton, MD
State Health Commissioner

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

MEMORANDUM

DATE: April 24, 2023

TO: State Board of Health

FROM: Suresh Soundararajan
Office Director, Office of Information Management

SUBJECT: Fast Track Action - Regulations of the Patient Level Data System – Amend Regulation to Update Data Element Reporting and Conform to Item 307 (D1) of Chapter 552 of the 2021 Acts of Assembly Special Session I

Enclosed for your review and approval are the proposed amendments to 12VAC5-217-20, Regulations of the Patient Level Data System.

Chapter 552 of the 2021 Acts of Assembly Special Session I Item 307(D1) required inpatient hospitals to report the admission source of any individuals meeting the criteria for voluntary or involuntary psychiatric commitment to the State Board of Health. This statutory mandate was met through the use of an emergency action that created the “Legal Status” field. The State Board of Health promulgated emergency regulations to implement the requirements effective January 17, 2022. The Virginia Department of Health proposes to amend the regulations by amending the regulatory language to make the emergency regulations permanent and also updating the regulatory language to reflect current inpatient data reporting requirements.

The State Board of Health is requested to approve the Fast Track Action. Should the State Board of Health approve the Fast Track Action, the amendments will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. 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)	12-VAC5-217-20
VAC Chapter title(s)	Regulations of the Patient Level Data System
Action title	Amend Regulation to Update Data Element Reporting and Conform to Item 307 (D1) of Chapter 552 of the 2021 Acts of Assembly Special Session I
Date this document prepared	April 24, 2023

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 State Board of Health (“Board”) proposes to amend 12VAC5-217-20, Regulations of the Patient Level Data System by permanently adopting the emergency regulation promulgated in January 2022 and updating the language to reflect current inpatient data reporting practices. Item 307 (D1) of Chapter 552 of the 2021 Acts of Assembly Special Session I (“2021 Appropriation Act”) requires inpatient hospitals to report to the Board the admission source of any individuals meeting the criteria for voluntary or involuntary psychiatric commitment. To conform to this mandate, the emergency regulation was promulgated effective January 17, 2022. To make this regulation permanent, the Board proposes to adopt the emergency language through this Fast-Track action.

Additional amendments are proposed to conform the regulations to reflect the data reporting elements currently submitted by inpatient hospitals to Virginia Health Information (VHI). Non-regulatory language is

also being removed from 12VAC5-217-20 to conform to the *Form and Style Requirements* set forth by the Virginia Registrar of Regulations.

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.

DBHDS – Department of Behavioral Health and Developmental Services

VHI – Virginia Health Information

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.

Item 307(D1) of the 2021 Appropriation Act requires inpatient hospitals to report the admission source of any individuals meeting the criteria for voluntary or involuntary psychiatric commitment. Item 307(D2) required the Department of Health to promulgate regulations within 280 days from enactment of Chapter 552 of 2021 Special Session I. An emergency regulatory action was used to meet that legislatively mandated deadline. A six-month extension was granted by the Governor, and the emergency regulation will expire January 15, 2024. The requirement in the 2021 Appropriation Act is also found in Item 299 C1 of Chapter 2 of the 2022 Acts of Assembly, Special Session I (2022 Appropriation Act.) To conform to the Acts of Assembly mandate, the Board is proposing to make the regulatory language permanent using this Fast-Track action.

Non-substantive changes are being made to conform the language to the Registrar of Regulation's *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

The rulemaking is expected to be noncontroversial because it is being utilized to conform the regulation to the legislative mandates and the existing data elements currently submitted by the inpatient hospitals in Virginia. Regulated entities are already submitting the data elements being added to the regulatory text because they are required by federal rules or because the data elements are part of the Uniform Billing Form, which is the standard claim form that hospitals use for all data related to hospital admissions and would be collected even if the Board did not require reporting of the data elements to VHI.

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 Code of Virginia § 32.1-12 gives the Board the responsibility to make, adopt, promulgate, and enforce regulations. Virginia Code § 32.1- 276.6(A) requires the Board to establish and administer an integrated system for collection and analysis of data which is used by consumers, employers, providers, purchasers of health care and state government. Section 32.1-276.6(B) of the Code of Virginia requires that every inpatient hospital shall submit to the Board patient level data containing the elements set forth in the regulations.

Item 307 (D1) of the 2021 Appropriations Act and Item 299 (C1) of the 2022 Appropriation Act require inpatient hospitals to report the admission source of any individuals meeting the criteria for voluntary or involuntary psychiatric commitment as outlined in §§ 16.1-338, 16.1-339, 16.1-340.1, 16.1-345, 37.2-805, 37.2-809, or 37.2-904 of the Code of Virginia to the State Board of Health through the creation of the "Legal Status" field. The Board shall collect and share any and all data regarding the admission source of individuals admitted to inpatient hospitals as a psychiatric patient, pursuant to Virginia Code § 32.1-276.6, with the Department of Behavioral Health and Developmental Services (DBHDS).

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 justification for the regulatory change is that the regulation should incorporate all legislative mandates and existing data reporting requirements in order to be clear and understandable for regulated entities. The regulatory change is essential to protect the health, safety, or welfare of citizens because the current regulation does not reflect current data elements submitted by inpatient hospitals or the mandates set forth by the Acts of Assembly, therefore burdening the regulated community. The goals of the regulatory change are to make the mandates incorporated by the Acts of Assembly permanent before the expiration of the emergency extension deadline, and to conform the Regulations to reflect current data reporting elements submitted. The problems it is intended to solve is the understandability and clarity of the regulations, as well as the impending expiration deadline for the emergency regulation and the language within it. Amending the regulation to include the language mandated by the Acts of Assembly, updated data elements, and technical changes for form and style will ensure that the language from the emergency regulation is permanently adopted, that data elements reflect current industry practices, and that the regulation is clear and uniform.

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.

12VAC5-217-20. Reporting Requirements for patient level data elements

A new legal status field was added through the emergency language to include the provision of information required by Item 307(D1) of the 2021 Appropriation Act. This change adds codes for the

“legal status” of voluntary or involuntary psychiatric admissions. During the review of the emergency language, changes were proposed to it in order to conform the language to the Form and Style requirements.

During that review of the emergency language, the data element table is proposed to be replaced with a new table consisting of all data elements currently submitted by inpatient hospitals to VHI, as well as removal of non-regulatory references to the Uniform Billing Form and Manual.

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 are removal of non-regulatory language, addition of legislative mandates that had previously had not been incorporated into the regulations, and the addition of data elements currently submitted by inpatient hospitals. The primary advantages to VDH and the Commonwealth are increased clarity of the minimum requirements for the reporting requirements of inpatient hospitals of patient level data elements, hopefully reducing the staff time associated with reviewing incorrect or incomplete submissions, as well as the time associated with having those entities resubmit their data submissions. There are no disadvantages to the public or the Commonwealth. The new proposed data elements located in the data elements table and the “legal status” of admission are already submitted by hospital systems, therefore no additional regulatory burdens will result in this change to the regulation. VDH is not aware of any pertinent matters of interest to the regulated community, government officials, or the public.

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.

There are no regulatory requirements that exceed applicable federal requirements in this action.

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

There are no other state agencies that will be affected by this action.

Localities Particularly Affected

There are no localities that will be affected by this action.

Other Entities Particularly Affected

Other entities that could be affected by this proposed change are inpatient hospitals that submit patient data. However, all inpatient hospitals already submit each proposed data element, so amending the regulation will result in increased clarity of submission requirements, not an additional regulatory burden faced by the inpatient hospitals.

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

<p><i>For your agency:</i> 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</p>	<p>For VDH, the projected cost savings for updating the regulation are associated with complete and correct data submissions to VHI/VDH from inpatient hospitals. Submissions that are complete and correct take less time by a contracted vendor to review, and facilities will not have to take time to submit again, saving money for both the agency and hospitals.</p>
<p><i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p>	<p>There are no known projected savings, fees, or revenues resulting from the regulatory change.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>These amendments will conform the regulations to current practice and therefore will not have an economic impact on any state agencies. Amending the regulation to reflect current practice will increase clarity among the regulants and potentially decrease the number or incorrect, or incomplete data submissions received by VDH and VHI. Amending the regulation to adhere to the legislative mandate ensures the regulations stay in compliance, benefiting all agencies who utilize the regulatory chapter.</p>

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.	There are no projected costs, savings, fees, or revenues resulting from the regulatory change.
Benefits the regulatory change is designed to produce.	These amendments will conform the regulations to current practice and therefore will not have an economic impact on affected entities. Removing non-regulatory language will increase the clarity and understandability of the Regulation. Amending the regulation to adhere to the legislative mandate ensures the regulations stay in compliance.

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.	Entities likely to be affected are inpatient hospitals in Virginia.
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.	There are 102 hospitals that submitted patient level data to VHI in Q3 of 2022, none of which qualify as small businesses. Therefore, no small businesses will be affected by the proposed changes.
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.	Inpatient hospitals are likely to experience a decrease in time spent towards data submission due to clearer element requirements. Hospitals will not have to resubmit their data more than once, saving time for the staff who prepare and submit the data. In FY2022, Inpatient hospitals were invoiced \$22,614 due to incorrect or incomplete data reports. The proposed changes will address discrepancies in the regulation and make it clearer, which may help reduce the cost of correction for those data submissions currently faced by inpatient hospitals.
Benefits the regulatory change is designed to produce.	These amendments will conform the regulations to current practice and therefore will not have an economic impact on affected entities. Removing non-regulatory language will increase the clarity and understandability of the Regulation. Amending the regulation to adhere to the legislative mandate ensures the regulations stay in compliance.

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.

No alternative was considered because the General Assembly requires the Board to adopt regulations governing the reporting requirements for patient level data, and amending the regulation is the least burdensome, least intrusive, and less costly method to accomplish the purpose of this action. Amending the regulation to meet the Form and Style Requirements allows for the regulation to be more uniform and easier to understand.

The only alternative to amending the regulations by updating the data elements submitted by inpatient hospitals is the status quo, however, the status quo option does not accurately reflect in the regulations the data that inpatient hospitals submit.

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.

The Board is required to regulate the reporting requirements for patient level data elements pursuant to § 32.1-276.6 of the Code of Virginia. This regulatory action is the least burdensome method to conform the Regulations of the Patient Level Data System (12VAC5-217-20) to the statute. The proposed amendments are the least stringent method to ensure that the regulations accurately reflect current data submission elements and conform to the legislative mandates. The removal of non-regulatory language allows for regulants to comply with regulatory requirements without reading through unnecessary regulatory text or a separate document (i.e., The Uniform Billing Manual) to understand the reporting requirements.

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 Board 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: Townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Dr. Kindall Bundy, Policy Analyst, Virginia Department of Health, Office of Information Management, 109 Governor Street, 4th Floor, Richmond VA 23219; email: kindallbundy@vdh.virginia.gov; fax: (804) 229-0517. 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
217-20 (Emergency Regulation Language)	N/A		<p>Change: Patient legal status has been added to the table of data elements submitted by inpatient hospitals.</p> <p>Intent: The intent of these changes is to conform to Chapter 552 of 2021 Special Session I Item 307(D1).</p> <p>Rationale: The patient-level discharge data submitted to VHI currently includes the patient's legal status due to the addition of this element through the previous emergency action.</p> <p>Likely Impact: The legal status field will be permanently adopted to the Regulation, allowing for better clarity among regulants and ensuring the</p>

			<p>Board is in compliance with the legislative mandates set forth by the Acts of Assembly.</p>
<p>217-20</p>	<p>N/A</p>	<p>The regulatory text contains references to the Uniform Billing Form and Uniform Billing Manual. Additionally, for required elements not in the Uniform Billing Form, the text contains instructions to comply with the table's instructions for format of submitted data.</p>	<p>Change: References to the Uniform Billing Form (UB) are removed</p> <p>Intent: The intent of these changes is to conform to the form and style guidelines and remove non-regulatory language.</p> <p>Rationale: Removing non-regulatory language improves clarity of the regulation and conforms to the form and style guidelines. It appears that it was previously the Board's intent that the language served to incorporate the UB by reference to ensure that the data elements on the form and the instructions for submission of those elements. The regulation used to reference specific versions of the UB and contained cross-references between the listed data elements and their UB counterparts. The purpose of removing specific versions and instead referencing the "latest publication of the Uniform Billing Manual..." was to "prevent the regulations from becoming outdated when changes are made to the billing forms," as stated in the Agency Background Document of the regulatory action effective February 1, 2016. At the time that action was submitted for publication, 1VAC7-10 had not yet been promulgated; the Final exempt action which created the chapter was published in the following issue of the <i>Register</i> and went into effect January 1, 2016, subsequently prohibiting the adoption of prospective changes to an incorporated document. It is still the Board's intent to require submission of the data elements contained in the UB, along with the additional elements otherwise required by state law or federal law or regulation. Pursuant to 1VAC7-10-140 and 1VAC7-10-160, the Board may not reference the "latest publication" of the UB, and thus would be required to pursue a regulatory action each time the UB is updated to add data elements. Because the Board is also requiring data elements beyond those included in the UB, it is most efficient to</p>

			<p>list all required data elements in the table in Section 20, which similarly require a regulatory action to update. This way, all requirements are listed in one place and the Board complies with the Virginia Code Commission's regulations.</p> <p>Likely Impact: The likely impact of this change is better clarity among the regulants.</p>
217-20		<p>Current data elements listed in the stricken table:</p> <ul style="list-style-type: none"> • Hospital identifier • Attending physician identifier • Other physician identifier • Payor identifier • Employer identifier • Patient identifier (SSN) • Patient sex • Race code • Date of birth • Street address, city of county, and zip code • Employment status code • Patient status • Birth weight • Admission type • Admission source • Admission date • Admission hour • Admission diagnosis code • Discharge date • Principal diagnosis code • External cause of injury code • Co-morbid conditions existing but not treated • Principal procedure code and date • Revenue code • Total charges 	<p>Change: Data elements listed in the new table (new elements bolded, emergency regulation language italicized):</p> <ol style="list-style-type: none"> 1. Provider Number 2. Provider National Provider Identifier (NPI) 3. Patient Control Number Part of the UB. This is how the hospitals identify specific medical records when they need to be re-accessed for any reason. Both VHI and hospitals find reporting this valuable. 4. Discharge Date 5. Patient Zip Code 6. Patient Date of Birth 7. Patient Sex 8. Admission Date and Hour 9. Admission Type 10. Admission Source 11. Patient Discharge Status 12. Medical Record Number Similarly to the Patient Control Number, this value is a submission associated with the UB and helps hospitals identify specific medical records. 13. Revenue Center Code 14. Revenue Center Units 15. Revenue Center Charges 16. Total Charges 17. Payor Identifier 18. Patient Relationship to Insured A This used to be in the Virginia Administrative Code but was removed for some reason in 2016. The agency background document submitted does not address the reason for the removal in the 2016. This value is part of how the "Payor Identifier" is reported.

			<p>19. Patient Social Security Number (SSN) 20. Employment Status Code 21. Employer Identifier 22. Principal Diagnosis Code 23. Other Diagnosis Code 24. Admitting Diagnosis Code 25. External Cause of Injury 26. Principal Procedure Code 27. Principal Procedure Date 28. Other Procedure Code 29. Other Procedure Dates 30. Attending Physician 31. Operating Physician 32. Other Physician/Provider 33. Infant Birth Weight 34. Patient Race 35. Patient Street Address 36. Patient City or County 37. Patient Legal Status Added to conform to the 2021 Appropriation Act.</p> <p>Intent: The intent of these changes is to add data elements that are already submitted by inpatient hospitals to VHI.</p> <p>Rationale: Inpatient hospitals already submit this data to VHI.</p> <p>Likely Impact: The likely impact of this change is better clarity of the regulations and better understanding of the data element reporting requirements by the regulated community.</p>

If the regulatory change is replacing an **emergency regulation**, and the proposed regulation is identical to the emergency regulation, complete Table 1 and/or Table 2, as described above.

If the regulatory change is replacing an **emergency regulation**, but changes have been made since the emergency regulation became effective, also complete Table 3 to describe the changes made since the emergency regulation.

Table 3: Changes to the Emergency Regulation

Emergency chapter-section number	New chapter-section number, if applicable	Current <u>emergency</u> requirement	Change, intent, rationale, and likely impact of new or changed requirements since emergency stage
217-20	N/A	The current emergency requirement adds the Legal Status field to the reporting requirements.	Change: The emergency regulation language was updated with non-substantive changes

			<p>Intent: The intent of this change is to conform to the Form and Style Guidelines</p> <p>Rationale: Conforming to the Form and Style Guidelines allows for better clarity among the regulants and allows for consistency in the Regulations</p> <p>Likely Impact: The likely impact of this change is better clarity among the regulants.</p>
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Office of Regulatory Management
Economic Review Form

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5-217-20
VAC Chapter title(s)	Reporting Requirements for Patient Level Data Elements
Action title	Amend Regulation to Update Data Element Reporting and Conform to Item 307 (D1) of Chapter 552 of the 2021 Acts of Assembly Special Session I
Date this document prepared	April 24, 2023
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)

<p>(1) Direct & Indirect Costs & Benefits (Monetized)</p>	<p>The regulatory action will amend 12VAC5-217-20 by making updates clarify language used in the regulations, to make corrections to outdated citations, update the inpatient data elements, and enhance the clarity of the regulations to achieve improvements that will be reasonable, prudent, and will not impose an unnecessary burden on the Virginia Department of Health and the public.</p> <p>Direct Costs: There are no monetized direct costs associated with this change.</p> <p>Indirect Costs: There are no monetized indirect costs associated with this change.</p> <p>Direct Benefits: Inpatient hospitals are likely to experience a decrease in time spent towards data submission due to clearer element requirements. Hospitals will not have to resubmit their data more than once, saving time for the staff who prepare and submit the data. In FY2022, Inpatient hospitals were invoiced \$22,614 due to incorrect or incomplete data reports. The proposed changes will address discrepancies in the regulation and make it clearer, which may help reduce the cost of correction for those data submissions currently faced by inpatient hospitals.</p> <p>Indirect Benefit: There are no monetized indirect benefits associated with this change.</p> <p>The regulatory action will conform the provisions (12VAC5-217-20) to the requirements in Chapter 552 Item 307(D1) of the 2021 Acts of Assembly Special Session I.</p> <p>Direct Costs: There are no monetized direct costs associated with this change.</p> <p>Indirect Costs: There are no monetized indirect costs associated with this change.</p> <p>Direct Benefits: There are no monetized direct benefits associated with this change.</p> <p>Indirect Benefit: There are no monetized indirect benefits associated with this change.</p>
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(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$22,614
(3) Net Monetized Benefit	+\$22,614	
(4) Other Costs & Benefits (Non-Monetized)	Direct Benefits: The benefit is simplifying the current regulations to be less burdensome by clarifying the language used within it. This action also seeks to make the emergency regulation permanent, which ensures the Board stays in compliance with the Acts of Assembly mandate.	
(5) Information Sources		

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

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Direct Costs: There are no monetized direct costs associated with no change.</p> <p>Indirect Costs: There are no monetized indirect costs associated with no change.</p> <p>Direct Benefits: There are no monetized direct benefits associated with no change.</p> <p>Indirect Benefit: There are no monetized indirect benefits associated with no change.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a)	(b)
(3) Net Monetized Benefit		
(4) Other Costs & Benefits (Non-Monetized)	<p>Direct Cost: The direct cost of making no changes to the regulation is that the emergency regulations would expire, leaving the Board out of compliance with the Acts of Assembly mandate. Another cost of making no changes is that the regulations would not conform to the Form and Style Guide, leaving the regulations confusing and not uniform with the rest of Virginia’s regulatory chapters.</p> <p>Benefits: There are no direct or indirect benefits to leaving the regulation as is.</p>	

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

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>There are no alternatives available for this regulation, as the Board is mandated to adopt the emergency regulatory language. The updates reflect the current data elements already submitted by inpatient hospitals and the style guide changes are necessary for the administration of this regulation, so no alternative was considered besides the Status Quo option.</p> <p>Direct Costs: There are no monetized direct costs associated with this change.</p> <p>Indirect Costs: There are no monetized indirect costs associated with this change.</p> <p>Direct Benefits: There are no monetized direct benefits associated with this change.</p> <p>Indirect Benefit: There are no monetized indirect benefits associated with this change.</p>	
(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)	There are no non-monetized costs or benefits associated with an alternative.	
(5) Information Sources		

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)	<p>Direct Costs: There are no monetized direct costs for local partners associated with this change.</p> <p>Indirect Costs: There are no monetized indirect costs for local partners associated with this change.</p> <p>Direct Benefits: There are no monetized direct benefits for local partners associated with this change.</p> <p>Indirect Benefit: There are no monetized indirect benefits for local partners associated with this change.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$0
(3) Other Costs & Benefits (Non-Monetized)	The benefit to local partners is clarity of the data reporting elements collected by VHI to be distributed and shared. Inpatient data is shared with other state agencies and local partners, so clarifying the regulations for inpatient level data benefits those entities.	
(4) Assistance	There is no assistance required for local partners as a result of the proposed changes.	
(5) Information Sources		

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 & Benefits (Monetized)	Families will not experience any costs or benefits of this regulatory change, as the regulation applies to inpatient hospitals.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$0

(3) Other Costs & Benefits (Non-Monetized)	N/A
(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)	There are 102 hospitals that submitted patient level data to VHI in Q3 of 2022, none of which qualify as a small business. Therefore, no small businesses will be affected by the proposed changes.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$0
(3) Other Costs & Benefits (Non-Monetized)	N/A	
(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	Initial Count	Additions	Subtractions	Net Change
12VAC5-217-20	30	+7	0	+7

1 **Project 6605 - Other Action**

2 **Department of Health**

3 **Amend Regulation to conform to Chapter 552 Item 307(D1) of the 2021 Acts of Assembly**
4 **Special Session I**

5 **12VAC5-217-20. Reporting requirements for patient level data elements.**

6 Every ~~Each~~ inpatient hospital shall submit, in an electronic data format, a complete filing of
7 each patient level data element listed in the table in this section for each hospital inpatient,
8 including a separate record for each infant, if applicable. ~~Most of these data elements are currently~~
9 ~~collected from a Uniform Billing Form located in the latest publication of the Uniform Billing Manual~~
10 ~~prepared by the National Uniform Billing Committee. The Uniform Billing Form and the Uniform~~
11 ~~Billing Manual are located on the National Uniform Billing Committee's website at www.nubc.org.~~
12 ~~The Uniform Billing Manual provides a detailed field description and any special instruction~~
13 ~~pertaining to that element. An asterisk (*) indicates when the required data element is either not~~
14 ~~on the billing form or in the Uniform Billing Manual. The instructions provided under that particular~~
15 ~~data element should then be followed. Inpatient hospitals that submit patient level data directly to~~
16 ~~the board or the nonprofit organization shall submit it in an electronic data format.~~

Data Element
1. Hospital identifier.* Enter the six-digit Medicare provider number or a number assigned by the board or its designee.
2. Attending physician identifier. Enter the nationally assigned physician identification number, either the Uniform Physician Identification Number (UPIN) or National Provider Identifier (NPI) as approved by the board for the physician assigned as the attending physician for an inpatient.
3. Other physician identifier. Enter the nationally assigned physician identification number, either the Uniform Physician Identification Number (UPIN) or National Provider Identifier (NPI) as approved by the board for the physician identified as the operating physician for the principal procedure reported.
4. Payor identifier.
5. Employer identifier.
6. Patient identifier.* Enter the nine-digit social security number of the patient. If a social security number has not been assigned, leave blank. The nine-digit social security number is not required for patients under four years of age.
7a. Patient sex.
7b. Race code.* If an inpatient hospital collects information regarding the choices listed below, the appropriate one-digit code reflecting the race of

the patient should be entered. If a hospital only collects information for categories 0, 1, or 2, then the appropriate code should be entered from these three selections.

0 = White

1 = Black

2 = Other

3 = Asian

4 = American Indian

5 = White Hispanic

6 = Black Hispanic

7c. Date of birth.

7d. Street address, city or county, and zip code.

7e. Employment status code.

7f. Patient status (i.e., discharge).
Inpatient codes only.

7g. Birth weight (for infants).*
Enter the birth weight of newborns in grams.

8a. Admission type.

8b. Admission source.

8c. Admission date.

8d. Admission hour.

8e. Admission diagnosis code.

9a. Discharge date.
Only enter date of discharge.

10. Principal diagnosis code.
Enter secondary diagnoses (up to eight).
In addition, include diagnoses recorded in the comments section for DX6-DX9.

11. External cause of injury code (E-code).
Record all external cause of injury codes in secondary diagnoses position after recording all treated secondary diagnoses.

12. Co-morbid conditions existing but not treated.

13. Principal procedure code and date.
Enter other procedures and dates (up to five). In addition, include procedures recorded in the comments section for PX4-PX6.

~~14. Revenue code (up to 23).
Units of service (up to 23).
Units of service charges (up to 23).~~

~~15. Total charges (by revenue code category or by HCPCS code).
(R.C. Code 001 is for total charges. See page 47-1.)~~

<u>Data Element</u>
<u>1. Provider Number</u> <u>Enter the Medicare Provider Number</u>
<u>2. Provider NPI</u>
<u>3. Patient Control Number</u>
<u>4. Discharge Date</u> <u>Discharge/ Statement Covers Period Through Date in MMDDYYYY format</u>
<u>5. Patient Zip Code</u> <u>Zip Code of Patient Address</u>
<u>6. Patient Date of Birth</u> <u>Date in MMDDYYYY format</u>
<u>7. Patient Sex</u> <u>M, F, or U</u>
<u>8. Admission Date and Hour</u> <u>Date in MMDDYYYY format, hour of admission in military time</u>
<u>9. Admission Type</u>
<u>10. Admission Source</u>
<u>11. Patient Discharge Status</u>
<u>12. Medical Record Number</u>
<u>13. Revenue Center Code (up to 22)</u>
<u>14. Revenue Center Units (up to 22)</u>
<u>15. Revenue Center Charges (up to 22)</u> <u>Dollars and cents with an implied decimal</u>
<u>16. Total Charges</u> <u>Dollars and cents with an implied decimal. If greater than \$999,999.99, then use 99999999</u>
<u>17. Payor Identifier (up to 3)</u> <u>Enter the Board of Health approved payor designation which will be the nationally assigned payor ID, its successor, or English description of the payor</u>
<u>18. Patient Relationship to Insured A</u>

19. Patient Social Security Number (SSN)

Enter the nine-digit social security number of the patient. If a social security number has not been assigned leave blank. The nine-digit social security number is not required for patients under four years of age

20. Employment Status Code

Use the following codes

1 = Employed Full Time

2 = Employed Part Time

3 = Not Employed

4 = Self-employed

5 = Retired

6 = On Active Military Duty

9 = Unknown

21. Employer Identifier

Enter the federally approved EIN, or employer name

22. Principal Diagnosis Code

Codes set ICD-10 or their successors, omit decimal; eighth character is the Present On Admission value (Y, N, U, W or 1)

23. Other Diagnosis Code (up to 17)

Codes set ICD-10 or their successors, omit decimal; eighth character is the Present On Admission value (Y, N, U, W or 1)

24. Admitting Diagnosis Code

Codes set ICD-10 or their successors, omit decimal, eighth character is the Present On Admission value (Y, N, U, W or 1)

25. External Cause of Injury Code (up to 3)

Codes set ICD-10 or their successors, omit decimal; eighth character is the Present On Admission value (Y, N, U, W or 1)

26. Principal Procedure Code

Codes set ICD-10 or their successors, omit decimal

27. Principal Procedure Date

Date in MMDDYY format

28. Other Procedure Codes (up to 5)

Codes set ICD-10 or their successors, omit decimal

29. Other Procedure Dates (up to 5)

Date in MMDDYY format

30. Attending Physician

Physician's Individual NPI

31. Operating Physician

Physician's Individual NPI

32. Other Physician Provider (up to 2)

Physician's Individual NPI

33. Infant Birth Weight (in grams)

34. Patient Race

Use the following codes:

0 = White

1 = Black

2 = Other, specified

3 = Asian

4 = American Indian

5 = Hispanic - White

6 = Hispanic - Black

9 = Unknown, not recorded

35. Patient Street Address

Enter the valid patient's residence street number and street name. Do not include PO Box numbers

36. Patient City or County

Enter the valid patient's complete City or County of residence

37. Patient Legal Status

Enter the legal status of a psychiatric admission:

1 = § 16.1-338 Parental admission of minors younger than 14 and nonobjecting minors 14 years of age or older

2 = § 16.1-339 Parental admission of objecting minor 14 years of age or older

3 = § 16.1-340.1 Involuntary temporary detention order of a minor

4 = § 16.1-345 Involuntary commitment of a minor

5 = § 37.2-805 Voluntary admission of an adult

6 = § 37.2-809 Involuntary temporary detention order of an adult

7 = § 37.2-904 Sexually violent predator



COMMONWEALTH of VIRGINIA

Karen Shelton, MD
State Health Commissioner

Department of Health
P O BOX 2448
RICHMOND, VA 23218

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

MEMORANDUM

DATE: May 11, 2023

TO: State Board of Health

FROM: Rebekah E. Allen, JD
Senior Policy Analyst, Office of Licensure and Certification

SUBJECT: Exempt Final Action – Regulations for the Licensure of Hospitals in Virginia – Amend Regulation after Enactment of Chapter 417 of the 2023 Acts of Assembly

Enclosed for your review is an Exempt Final action to amend the Regulations for the Licensure of Hospitals in Virginia (12VAC5-410-10 *et seq.*) to reflect the requirements of Chapter 417 of the 2023 Acts of Assembly.

Chapter 417 of the 2023 Acts of Assembly directs the State Board of Health to amend its regulations to require hospitals with emergency departments “to establish a security plan...using standards established by the International Association for Healthcare Security and Safety or other industry standard” and that is “based on the results of a security risk assessment of each emergency department location” and “include the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times as indicated to be necessary and appropriate by the security risk assessment.” Chapter 417 further enumerates what identified risks that hospitals must consider when developing security plans and training requirements for security personnel. Chapter 417 authorizes the State Health Commissioner to “provide a waiver from the requirement that at least one off-duty law-enforcement officer or trained security personnel be present at all times in the emergency department if the hospital demonstrates that a different level of security is necessary and appropriate for any of its emergency departments based upon findings in the security risk assessment.”

The second enactment clause of Chapter 417 exempts this regulatory action from the Administrative Process Act (§ 2.2-4000 *et seq.* of the Code of Virginia), provided that the State Board of Health gives an opportunity for public comment prior to adoption. A general notice with the proposed regulatory action was published on April 10, 2023 in *The Virginia Register of*

Regulations; this general notice had a 30-day public comment period during which three were comments were received.

The State Board of Health is requested to approve the Exempt Final Action. Should the State Board of Health approve the Exempt Final Action, the amendments will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. 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. There will be no additional public comment period following publication. Thirty days after publication, the regulation will become effective.



townhall.virginia.gov

Exempt Action: Final Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-410-10 <i>et seq.</i>
VAC Chapter title(s)	Regulations for the Licensure of Hospitals in Virginia
Action title	Amend Regulation after Enactment of Chapter 417 of the 2023 Acts of Assembly
Final agency action date	
Date this document prepared	May 11, 2023

This information is required for executive branch review pursuant to 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. In addition, this information is required by the Virginia Registrar of Regulations pursuant to the Virginia Register Act (§ 2.2-4100 *et seq.* of the Code of Virginia). Regulations must conform to 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.

Chapter 417 of the 2023 Acts of Assembly requires the State Board of Health to amend its hospital regulations to require hospitals with emergency departments “to establish a security plan...using standards established by the International Association for Healthcare Security and Safety or other industry standard” and that is “based on the results of a security risk assessment of each emergency department location of the hospital.” This security plan must “include the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times as indicated to be necessary and appropriate by the security risk assessment.” Chapter 417 further enumerates what identified risks that hospitals must consider when developing security plans and training requirements for security personnel. Chapter 417 authorizes the State Health Commissioner to “provide a waiver from the requirement that at least one off-duty law-enforcement officer or trained security personnel be present at all times in the emergency department if the hospital demonstrates that a different level of security is

necessary and appropriate for any of its emergency departments based upon findings in the security risk assessment.”

The second enactment clause of Chapter 417 exempts this regulatory action from the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), provided that the State Board of Health gives an opportunity for public comment prior to adoption. The State Board of Health published a general notice in *The Virginia Register of Regulations* on April 10, 2023 containing the proposed regulatory text; this general notice had a 30-day public comment period during which three comments were received. On June 15, 2023, the State Board of Health convened one of its quarterly meetings, during which a public comment period was held prior to adoption to this regulatory action; 3 comments were received regarding this regulatory action during the meeting.

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, internal staff review, 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.”

The mandate for this change is found in Chapter 417 of the 2023 Acts of the Assembly.

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.

Supplemental Information for Exempt Action: Final Regulation

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-410-10 <i>et seq.</i>
VAC Chapter title(s)	Regulations for the Licensure of Hospitals in Virginia
Action title	Amend Regulation after Enactment of Chapter 417 of the 2023 Acts of Assembly
Final agency action date	
Date this document prepared	May 16, 2023

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage and provide the agency’s response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

The “Exempt Action: Final Regulation Agency Background Document” does not have a section devoted to public comment as those actions typically do not require an opportunity for public comment prior to adoption. Since this opportunity was required for this action and public comment was received, a summary of the comments received and response to those comments have been prepared as a courtesy to the public.

Commenter	Comment	Agency response
Aimee Perron Seibert, Virginia College of Emergency Physicians (VACEP)	<p>VACEP supports the draft regulations as written and urges the State Board of Health (Board) to adopt them, including the process outlined for waivers in the draft.</p> <p>VACEP worked in conjunction with the Virginia Nurses Association and the Medical Society of Virginia (MSV) to negotiate the compromise with the Virginia Hospital & Healthcare Association (VHHA) on Chapter 417 of the 2023 Acts of Assembly that passed both houses of the General Assembly unanimously. VACEP believes Chapter 417 allowed for the requested flexibility by hospitals for the varying needs of different</p>	<p>The agency notes the support of VACEP for the regulations as drafted. The agency also notes the additional information regarding the threat of violence in emergency departments and the work that stakeholders engaged in during the 2023 Regular Session to reach a compromise regarding the mandates in Chapter 417 of the 2023 Acts of Assembly. The agency further notes VACEP’s opposition to the comments provided by VHHA.</p>

Agency Supplemental Information

	<p>communities by including a waiver option.</p> <p>VACEP firmly and wholeheartedly disagrees with the VHHA's interpretation of Chapter 417 contained in VHHA's public comment on the draft regulations. VACEP believes it was very clear from numerous discussions, including with the patron Senator Favola, that the security risk assessment would guide the creation of a security plan, but that it was never the intent--nor does VACEP believe it to be the plain reading of the law—to permit hospitals to (1) never need security in their emergency departments (EDs) or (2) exempt them from obtaining a waiver from the 24/7/365 security personnel requirement if there was a different need shown by the security risk assessment.</p> <p>VACEP states the clear purpose of the waiver was to acknowledge that some EDs might need security on one or two shifts a day, rather than the entire day. VACEP disagrees vehemently with the notion that an ED has no need for any security personnel to be present, and points to national trends and anecdotal evidence from its members about feeling unsafe in their EDs and about the violence they experience not being taken seriously.</p> <p>VACEP encourages the State Board of Health to focus on the purpose of the bill to ensure safe workplaces for doctors and nurses and safe places for patients to be cared for who are experiencing life threatening emergencies.</p>	
<p>Clark Barrineau, Medical Society of Virginia (MSV)</p>	<p>MSV supports the draft regulations as written and urges the State Board of Health (Board) to adopt them, including the process outlined for waivers in the draft. MSV believes the draft regulations align with the legislative intent of Chapter 417 of the 2023 Acts of</p>	<p>The agency notes the support of MSV for the regulations as drafted. The agency also notes the additional information regarding the threat of violence against healthcare providers and the work that stakeholders engaged in during the 2023 Regular Session to reach a compromise regarding the mandates in Chapter 417 of the 2023 Acts of</p>

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	<p>Assembly—which MSV believes is to make hospitals and emergency rooms more secure.</p> <p>MSV expresses regret and surprise at the public comments offered by the Virginia Hospital & Healthcare Association (VHHA) as VHHA was an active stakeholder in conversations regarding Chapter 417 throughout the 2023 General Assembly session. MSV shares that VHHA expressed no public opposition to the final version of Chapter 417, despite having opportunity to do so in subcommittees and committees in both the House of Delegates and Senate.</p> <p>MSV believes VHHA's newly expressed concern about the 24/7/365 security presence requirement is already assuaged by the legislative compromise of the waiver that VHHA agreed to with the bill patron, Senator Favola. MSV points out that Chapter 417 gives the State Health Commissioner (Commissioner) the ability to provide a waiver from that requirement, and the draft amendments for 12VAC5-410-10 <i>et seq.</i> give the Commissioner appropriate oversight to follow that provision.</p> <p>MSV asserts that any effort to water down the intent of Chapter 417 places patients and healthcare providers in jeopardy. MSV pointed to VHHA's proposed changes for the drafted L.5.c that would prevent the Commissioner from rescinding or modifying a waiver unless the Commissioner could prove the <i>absence</i> of a security guard led to one or more incidents that jeopardized the health or safety of patients, employees, contractors, or the public. MSV contends that VHHA's suggestion amounts to requiring the Commissioner to prove a negative, with the sole intent of keeping the standard for security in Virginia's hospitals low.</p>	<p>Assembly. The agency further notes MSV's opposition to the comments provided by VHHA.</p>
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	<p>MSV provides several statistics from the Bureau of Labor Statistics about the growing rate of injuries from violent attacks against medical professionals over the last decade and the rate of workplace violence for healthcare providers compared to other industries. MSV also referenced the 2022 Tulsa hospital shooting where a disgruntled patient killed a surgeon, physician, receptionist, and visitor. MSV asserts that this data and types of tragedies were the impetus of Chapter 417 and weakening Chapter's 417 intent is irresponsible.</p>	
<p>R. Brent Rawlings, Virginia Hospital & Healthcare Association (VHHA)</p>	<p>VHHA does not support the draft regulations as written and provided suggested changes in its public comment, along with more general comments about the draft regulation. VHHA specifically opposes any requirement for 24/7/365 security presence in emergency departments (EDs)</p> <p>VHHA asserts that federal regulations and accreditation standards do not require or assume the need for security personnel to be always present in the hospital or any given department. VHHA states that it and its members have concerns with mandating the 24/7/365 presence of at least one off-duty law-enforcement officer or trained security personnel at every ED, as many hospitals have determined that this requirement is not appropriate or necessary at some EDs.</p> <p>VHHA points to the 24/7/365 requirement as presenting significant cost and workforce concerns because the cost of off-duty law enforcement officers has escalated, and the additional demands placed on police has reduced the availability of officers for off-duty assignments. VHHA contends that private security firms are subject to the same workforce</p>	<p>The agency notes that VHHA does not the regulations as drafted. The agency support also notes the alternative interpretation of Chapter 417 of the 2023 Acts of Assembly offered by VHHA and the impact of that interpretation on the draft regulations. The agency further notes VHHA's specific suggested changes, which are addressed in greater detail below.</p>

Agency Supplemental Information

	<p>challenges that make recruitment and retention difficult and more costly.</p> <p>VHHA's specific suggestions are as follows:</p> <p><i>(i) 12VAC5-410-280.I.1 and J.2 – Other Industry Standards</i></p> <p>VHHA disagrees with this regulation and suggests that individual hospitals should be provided with the flexibility to determine the industry standard to apply in its organization. VHHA contends that the requirement for each hospital to request permission from OLC to use a different standard is administratively burdensome and not required by statute. VHHA proposes that OLC could develop a list of acceptable industry standards that are the same or similar based upon input from hospitals to include in its guidance that could be updated from time to time as new standards are developed and identified.</p> <p>VHHA proposed the following language at I.1 “Is developed using standard established by the Healthcare Security Industry Guidelines 13th Edition (International Association for Healthcare Security and Safety), or other standard identified by the Department.” VHHA further proposes eliminating J.2 entirely.</p> <p><i>(ii) 12VAC5-410-280.I.3 – Security Personnel Requirement</i></p> <p>VHHA opposes the requirement to have 24/7/365 security presence in EDs and proffers an alternative interpretation of Chapter 417 of the 2023 Acts of Assembly. VHHA contends that hospitals should be permitted to operate without 24/7/365 ED security presence without any waiver from the State Health Commissioner (Commissioner) if the risk assessment conducted by the</p>	<p><i>(i) 12VAC5-410-280.I.1 and J.2 – Other Industry Standards</i></p> <p>The agency notes VHHA’s suggestion. Guidance documents are created by agencies to provide interpretation or implementation of the law but cannot be used to impose regulatory requirements on the public. Further, the Virginia Code Commission in 1VAC7-10-140(A) authorizes the incorporation by reference of all or any part of a publication or document, with the incorporated text “becom[ing] the text of the regulation and an enforceable part of the regulation.” In the absence of known alternative standards that can be incorporated by reference into the regulatory text and knowing the limitations of guidance documents, the agency included a process in the draft regulations by which a hospital may request to use a different standard. If one or more alternative standards are commonly requested by hospitals, the agency will revisit 12VAC5-410-280.I.1 in the future to explicitly incorporate those alternative standards into the regulation and eliminate the need for further individual hospital requests.</p> <p><i>(ii) 12VAC5-410-280.I.3 – Security Personnel Requirement</i></p> <p>The agency notes VHHA’s comment regarding its interpretation of the ED security presence requirement. The Commissioner’s waiver authority is for “the requirement that at least one off-duty law-enforcement officer or trained security personnel be present at all times in the emergency department.” A hospital bears the burden of proving “a different level of security is necessary and appropriate for any of its emergency departments based upon findings in the</p>
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Agency Supplemental Information

<p>hospital conclude 24/7/365 security is not necessary. VHHA contends that a waiver from the Commissioner would only be needed if the risk assessment did conclude 24/7/365 security was necessary if a hospital demonstrates it could take other measures to ensure ED security.</p> <p>VHHA suggests the reference to subsection K should be changed to subsection L.</p> <p><i>(iii) 12VAC5-410-280.L – Waiver Process</i></p> <p>L.1: VHHA opposes with the requirement that a copy of the security risk assessment must have been “reviewed and approved by the governing body or its designee” because VHHA contends that security risk assessments or documents of this nature are a function of day-to-day management and would constitute an additional regulatory burden not required by statute and inconsistent with existing business practices. VHHA proposes eliminating “that has been reviewed and approved by the governing body or its designee” and corresponding changes should be made to subsection L.3.b below.</p> <p>VHHA would support including in the regulation at L.1 a requirement that the hospital specify the rationale for the request for waiver, supported by the results of the security risk assessment and information on any alternative measures or mitigating strategies proposed to address the subject or intent of the regulatory requirement requested to be waived.</p> <p>L.2: VHHA proposes it should be revised to state that “The commissioner shall grant a waiver pursuant to this section, and shall specify . . .” because VHHA interprets this to mean that the Commissioner is required to grant a waiver where the hospital</p>	<p>security risk assessment”, i.e., something other than 24/7/365 ED security presence is necessary per the security risk assessment. It would be nonsensical for the Commissioner to have the authority to waive a 24/7/365 ED security presence requirement if Chapter 417 did not contain any such requirement.</p> <p>The agency notes VHHA’s comment about the subsection cross-reference and has corrected this.</p> <p><i>(iii) 12VAC5-410-280.L – Waiver Process</i></p> <p>L.1: The agency notes VHHA’s suggestions. The agency would highlight that the draft regulations provide for review and approval of the security plan by “the governing body <i>or its designee</i>” (emphasis added) so that a hospital’s governing body has the flexibility to designate someone else to carry out this function. All general hospitals in Virginia are certified by the Centers for Medicare and Medicaid Services (CMS), which has extensive emergency preparedness requirements that call for both risks assessments and the involvement of facility leadership in the review and update/approval of these assessments and plans. The draft regulation gives hospitals the flexibility—if it wishes to utilize it—to align staff responsibilities so that the state and federal risk assessments may be reviewed and approved/updated by the same person(s). Alternatively, the hospital’s leadership can designate someone else in “day-to-day management” if the hospital determines that to be more appropriate.</p> <p>The agency notes that the intent of the regulation is to identify the minimum information a waiver request must have, and a hospital is not limited in the information it wishes to provide to the Commissioner in evaluating a waiver request. It has been the agency’s experience that requesters of variances (which are functionally the same as a waiver) nearly always supplement the minimum information required by regulation with additional information they believe will support their request and that mandating further regulatory burden is not needed for most requesters.</p>
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Agency Supplemental Information

	<p>demonstrates that a different level of security is necessary and appropriate for any of its emergency departments based upon findings in the security risk assessment. VHHA further proposes that L.2 should be further revised to state: “The commissioner shall grant a waiver pursuant to this subsection upon receipt of information and rationale demonstrating that a different level of security is necessary and appropriate for the emergency department.” This would continue to provide the Commissioner with the authority to require additional information from the hospital as determined appropriate to demonstrate that a different level of security is necessary and appropriate for the emergency department prior to granting a waiver.</p> <p>L.3: VHHA proposes that notice of a changed security risk assessment should only be required where such change impacts when and how many off-duty-law-enforcement officers or trained security personnel should be present at the emergency department. This could be accomplished by eliminating the word “and” in the first instance in L.3.</p> <p>L.5.a: VHHA opposes permitting the Commissioner to modify or rescind a waiver if the security risk assessment changes. There could be changes to the security risk assessment that would have no bearing on the determination of whether at least one off-duty law-enforcement officer or trained security personnel be present at all times in the emergency department. The underlying concern, that there is a change to a security risk assessment that indicates that a different level of security may now be necessary and appropriate, is already captured by L.5.b “Additional</p>	<p>L.2: The agency notes VHHA’s suggestion. The agency does not disagree with VHHA that the waiver must be given if the hospital makes the requisite demonstration, which is already addressed in subsection L. The authority to request additional information to evaluate a hospital’s requested waiver is already address in L.4.</p> <p>L.3: The agency notes VHHA’s suggestion and has removed the “and” in the first instance of L.3.</p> <p>L.5.a: The agency notes VHHA’s suggestion and has revised L.5.a and L.5.b into a single subdivision and added clarity regarding what security risk assessment changes are of pertinent interest.</p> <p>L.5.c: The agency notes VHHA’s suggestion. This language is similar to variance language used for other medical care facility licensing programs administered by the Virginia Department of Health and the State Health Commissioner. These concerns about subjectivity and ambiguity have not manifested for variances, which are functionally the same as a waiver.</p> <p>L.6: The agency notes VHHA’s suggestion. The agency does not have the regulatory authority to exempt public documents from release if those documents are not already exempt from disclosure pursuant to the Freedom of Information Act (FOIA). As FOIA may be amended in the future, the phrase “to the extent those records are exempt from disclosure” is needed to keep the draft regulation aligned with the statutes.</p>
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	<p>information becomes known with alters the basis for the original decision” so VHHA proposes that L.5.a be eliminated.</p> <p>L.5.c: VHHA opposes giving the Commissioner the authority to modify or rescind a waiver where “results of the waiver jeopardize the health or safety of patients, employees, contractors, or the public” because of concerns regarding subjectivity and ambiguity. VHHA proposes the text be revised to read “The commissioner can demonstrate that the waiver directly results in jeopardizing the health or safety of patients, employees, contractors, or the public.”</p> <p>L.6: VHHA agrees that all information that a hospital discloses pursuant to this subsection pertaining to waiver should not be released to the public. VHHA suggests eliminating the language “to the extent those records are exempt from disclosure.”</p>	
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Office of Regulatory Management
Economic Review Form

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-410-10 <i>et seq.</i>
VAC Chapter title(s)	Regulations for the Licensure of Hospitals in Virginia
Action title	Amend Regulation after Enactment of Chapter 417 of the 2023 Acts of Assembly
Date this document prepared	May 11, 2023
Regulatory Stage (including Issuance of Guidance Documents)	Exempt

Cost Benefit Analysis

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

<p>(1) Direct & Indirect Costs & Benefits (Monetized)</p>	<p>Direct Costs (monetized):</p> <ul style="list-style-type: none"> • Cost of developing and updating a security plan: <ul style="list-style-type: none"> ○ VDH has a record of 113 emergency departments in the Commonwealth. ○ Per International Association of Professional Security Consultants, security consulting fees typically range from \$100 to \$500 per hour, with an average rate of around \$200 per hour. ○ Assuming a consultant is hired for 20 hours at \$200 per hour to create a security plan because the hospital does not have an emergency department security plan that meets the minimum standards, the cost of developing a security plan would be at least \$4,000 per hospital emergency department. ○ Assuming a consultant is hired for 10 hours at \$200 per hour to update a security plan in two years' time, the cost of developing a security plan would be at least \$2,000 per hospital emergency department. ○ Total cost is estimated to not exceed \$452,000 in Year 0 and \$226,000 in Years 2 and 4. • Cost of implementing security measures: <ul style="list-style-type: none"> ○ The hospital may need to purchase security equipment, such as cameras, alarms, and access control systems, to
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	<p>secure the emergency department. The cost of such equipment may depend on the size of the emergency department and the level of security required.</p> <ul style="list-style-type: none"> ○ Assuming the hospital needs to install cameras, alarms, and access control systems, the total cost of equipment and installation is estimated to be \$100,000. ○ VDH does not have data to indicate how many hospitals, if any, would need to install such equipment. ○ Total cost is unknown. <ul style="list-style-type: none"> ● Personnel cost for security personnel 24/7: <ul style="list-style-type: none"> ○ Per the average hourly wage information from the Bureau of Labor Statistics (BLS) May 2021 data in general medical and surgical hospitals (NAICS 622100) for Police and Sheriff’s Patrol Officers (Code 30-3051) and the fringe benefits from the September 2022 BLS for the South Atlantic area, an off-duty law enforcement officer would cost \$29.35 hour. ○ Per the average hourly wage information from the Bureau of Labor Statistics (BLS) May 2021 data in general medical and surgical hospitals (NAICS 622100) for Security Guards (Code 33-9032) and the fringe benefits from the September 2022 BLS for the South Atlantic area, a trained security personnel could cost \$19.90 per hour. ○ Given 168 hours in a week, 52 weeks in a year, and assuming there is one off-duty law enforcement officer present 24/7, a hospital that only employs off-duty law enforcement officers would incur an annual cost of \$256,402. ○ Given 168 hours in a week, 52 weeks in a year, and assuming there is one trained security personnel present 24/7, a hospital that only employs trained security personnel would incur an annual cost of \$173,846. ○ VDH does not have data to indicate which type of security personnel a hospital will choose (off-duty law enforcement versus trained security personnel), how many security personnel are needed (either per shift or per week) for sufficient 24/7 coverage at a given emergency department beyond what a hospital has already incurred costs for, whether a hospital will employ or contract security personnel, whether a hospital will secure a waiver from the 24/7 coverage requirement, and what the reduced amount of security a hospital may have under a waiver. ○ Based on the median between the annual salary costs of off-duty law enforcement officers and trained security personnel costs described above and not discounting the
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	<p>value based on the lack of data VDH described above, total cost is estimated to be \$24,309,012 annually.</p> <p>Indirect Costs (monetized): VDH is not aware of any monetized indirect costs at this time.</p> <p>Direct Benefits (monetized):</p> <ul style="list-style-type: none"> • Reduction in the number of violent incidents: <ul style="list-style-type: none"> ○ According to BLS, the rate of nonfatal occupational injuries and illnesses in hospitals was 6.1 per 100 full-time workers in 2021. ○ Assuming two-thirds of these injuries are due to violent incidents in the emergency department and assuming that emergency departments have an average of 100 full-time workers, then the hospital can expect to save around $4.07 \times 100 = 407$ hours of lost work time due to injuries prevented by the security plan. ○ Assuming an average hourly wage of \$30 for hospital workers, this would result in a benefit of \$7,950 per year per emergency department. ○ Total benefit is estimated to be \$1,379,730 annually. <p>Indirect Benefits (monetized): VDH is not aware of any monetized indirect benefits at this time.</p>
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(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$115,533,826	(b) \$6,508,322

(3) Net Monetized Benefit	-\$109,025,504
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(4) Other Costs & Benefits (Non-Monetized)	<p>Other Costs (non-monetized):</p> <ul style="list-style-type: none"> • Staff training costs that may need to be incurred to ensure that all employees are familiar with the new security plan and understand their roles in implementing it. • Potential hiring of additional administrative staff to manage the implementation and maintenance of the security plan, which could result in increased personnel costs. • Increased wait times could result from implementation of the security plan. • Reduced flexibility from operational or facility design that could limit its ability to respond to changing patient needs or emergency situations, potentially leading to reduced efficiency and increased costs.
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	<p>Other Benefits (non-monetized):</p> <ul style="list-style-type: none"> • Improved safety and security for patients, staff, and visitors in the emergency department. • Improved staff morale and job satisfaction, which can lead to improved retention rates and reduced costs associated with recruitment and training. • Increased patient satisfaction and retention. • Reduced risk of violence or other security incidents in the emergency department. • Increased staff preparedness and training to handle security incidents, potentially reducing the severity of the incident and minimizing the impact on patients, staff, and visitors. • Improved reputation and trust among patients and the community. • Improved public perception of the healthcare system as a whole. • Reduced liability and legal costs associated with security incidents, if a hospital is able to demonstrate that it had taken reasonable measures to prevent a security incident. • Increased efficiency from a well-designed security plan can reduce the amount of time and resources spent on security-related issues that could lead to cost savings.
(5) Information Sources	<p>Bureau of Labor Statistics; International Association of Professional Security Consultants; Division of Acute Care Services, Office of Licensure and Certification.</p> <p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p>

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

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Direct Costs (monetized):</p> <ul style="list-style-type: none"> • Cost of establish a training protocol for emergency department personnel: <ul style="list-style-type: none"> ○ VDH has a record of 113 emergency departments in the Commonwealth. ○ Per International Association of Professional Security Consultants, security consulting fees typically range from \$100 to \$500 per hour, with an average rate of around \$200 per hour. ○ Developing the training materials could cost anywhere from \$500 to \$5,000, depending on the amount and
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	<p>complexity of the content, the format of the materials, and the level of customization required.</p> <ul style="list-style-type: none"> ○ The cost of delivering the training will depend on the chosen method. In-person training could cost \$1,000 to \$5,000, depending on the location, number of participants, and duration of the training. Online training could cost \$500 to \$2,000, depending on the platform used and the level of interactivity required. ○ Overall, the total cost of developing a training protocol for emergency department security personnel could range from \$2,500 to \$20,000, depending on the factors mentioned above. ○ Total cost (based on median value) is estimated to be \$1,271,250 in Year 0, which was 2019. ○ Total cost of the ongoing delivery of training (based on median value) is estimated to be \$226,000 starting Year 1 (2020) and every year thereafter. <p>Indirect Costs (monetized): VDH is not aware of any monetized indirect costs at this time.</p> <p>Direct Benefits (monetized): VDH is not aware of any monetized direct benefits at this time.</p> <p>Indirect Benefits (monetized): VDH is not aware of any monetized indirect benefits at this time.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$2,111,314	(b) \$0
(3) Net Monetized Benefit	-\$2,111,314	
(4) Other Costs & Benefits (Non-Monetized)	<p>Other Costs (non-monetized): VDH is not aware of any non-monetized costs at this time.</p> <p>Other Benefits (non-monetized):</p> <ul style="list-style-type: none"> ● Improved safety and security for patients, staff, and visitors in the emergency department. ● Increased staff preparedness and training to handle security incidents, potentially reducing the severity of the incident and minimizing the impact on patients, staff, and visitors. 	

(5) Information Sources	<p>Bureau of Labor Statistics; International Association of Professional Security Consultants; Division of Acute Care Services, Office of Licensure and Certification.</p> <p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p>
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Table 1c: Costs and Benefits under Alternative Approach(es)

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>The majority of the proposed regulatory action is non-discretionary and also generate the bulk of the costs and benefits of the action.</p> <p>Direct Costs (monetized):</p> <ul style="list-style-type: none"> • Cost of developing a security plan with no requirement to update periodically: <ul style="list-style-type: none"> ○ VDH has a record of 113 emergency departments in the Commonwealth. ○ Per International Association of Professional Security Consultants, security consulting fees typically range from \$100 to \$500 per hour, with an average rate of around \$200 per hour. ○ Assuming a consultant is hired for 20 hours at \$200 per hour to create a security plan because the hospital does not have an emergency department security plan that meets the minimum standards, the cost of developing a security plan would be at least \$4,000 per hospital emergency department. ○ Total cost is estimated to not exceed \$452,000 in Year 0. • Cost of implementing security measures: <ul style="list-style-type: none"> ○ The hospital may need to purchase security equipment, such as cameras, alarms, and access control systems, to secure the emergency department. The cost of such equipment may depend on the size of the emergency department and the level of security required. ○ Assuming the hospital needs to install cameras, alarms, and access control systems, the total cost of equipment and installation is estimated to be \$100,000. ○ VDH does not have data to indicate how many hospitals, if any, would need to install such equipment. ○ Total cost is unknown. • Personnel cost for security personnel 24/7: <ul style="list-style-type: none"> ○ Per the average hourly wage information from the Bureau of Labor Statistics (BLS) May 2021 data in general medical and surgical hospitals (NAICS 622100) for Police and Sheriff’s Patrol Officers (Code 30-3051) and the
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fringe benefits from the September 2022 BLS for the South Atlantic area, an off-duty law enforcement officer would cost \$29.35 hour

- Per the average hourly wage information from the Bureau of Labor Statistics (BLS) May 2021 data in general medical and surgical hospitals (NAICS 622100) for Security Guards (Code 33-9032) and the fringe benefits from the September 2022 BLS for the South Atlantic area, a trained security personnel could cost \$19.90 per hour.
- Given 168 hours in a week, 52 weeks in a year, and assuming there is one off-duty law enforcement officer present 24/7, a hospital that only employs off-duty law enforcement officers would incur an annual cost of \$256,402.
- Given 168 hours in a week, 52 weeks in a year, and assuming there is one trained security personnel present 24/7, a hospital that only employs trained security personnel would incur an annual cost of \$173,846.
- VDH does not have data to indicate which type of security personnel a hospital will choose (off-duty law enforcement versus trained security personnel), how many security personnel are needed (either per shift or per week) for sufficient 24/7 coverage at a given emergency department beyond what a hospital has already incurred costs for, whether a hospital will employ or contract security personnel, whether a hospital will secure a waiver from the 24/7 coverage requirement, and what the reduced amount of security a hospital may have under a waiver.
- Based on the median between the salary costs described above and not discounting the value based on the lack of data VDH described above, total cost is estimated to be \$24,309,012 annually.

Indirect Costs (monetized): VDH is not aware of any monetized indirect costs at this time.

Direct Benefits (monetized):

- Reduction in the number of violent incidents:
 - According to BLS, the rate of nonfatal occupational injuries and illnesses in hospitals was 6.1 per 100 full-time workers in 2021.
 - Assuming two-thirds of these injuries are due to violent incidents in the emergency department and assuming that emergency departments have an average of 100 full-time workers, then the hospital can expect to save around 4.07

	<p>x 100 = 407 hours of lost work time due to injuries prevented by the security plan.</p> <ul style="list-style-type: none"> ○ Assuming an average hourly wage of \$30 for hospital workers, this would result in a benefit of \$7,950 per year per emergency department. ○ Total benefit is estimated to be \$1,379,730 annually. <p>Indirect Benefits (monetized): VDH is not aware of any monetized indirect benefits at this time.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$115,120,002	(b) \$6,508,322
(3) Net Monetized Benefit	-\$108,611,679	
(4) Other Costs & Benefits (Non-Monetized)	<p>Other Costs (non-monetized):</p> <ul style="list-style-type: none"> • Staff training costs that may need to be incurred to ensure that all employees are familiar with the new security plan and understand their roles in implementing it. • Potential hiring of additional administrative staff to manage the implementation of the security plan, which could result in increased personnel costs. • Increased wait times could result from implementation of the security plan. • Reduced flexibility from operational or facility design that could limit its ability to respond to changing patient needs or emergency situations, potentially leading to reduced efficiency and increased costs. <p>Other Benefits (non-monetized):</p> <ul style="list-style-type: none"> • Improved safety and security for patients, staff, and visitors in the emergency department, though this may be reduced without periodic updates to the security plan. • Improved staff morale and job satisfaction, which can lead to improved retention rates and reduced costs associated with recruitment and training, though this may be reduced without periodic updates to the security plan. • Increased patient satisfaction and retention, though this may be reduced without periodic updates to the security plan. • Reduced risk of violence or other security incidents in the emergency department, though this may be reduced without periodic updates to the security plan. 	

	<ul style="list-style-type: none"> • Increased staff preparedness and training to handle security incidents, potentially reducing the severity of the incident and minimizing the impact on patients, staff, and visitors, though this may be reduced without periodic updates to the security plan. • Improved reputation and trust among patients and the community, though this may be reduced without periodic updates to the security plan. • Improved public perception of the healthcare system as a whole, though this may be reduced without periodic updates to the security plan. • Reduced liability and legal costs associated with security incidents, if a hospital is able to demonstrate that it had taken reasonable measures to prevent a security incident, though this may be reduced without periodic updates to the security plan. • Increased efficiency from a well-designed security plan can reduce the amount of time and resources spent on security-related issues that could lead to cost savings, , though this may be reduced without periodic updates to the security plan.
(5) Information Sources	<p>Bureau of Labor Statistics; International Association of Professional Security Consultants; Division of Acute Care Services, Office of Licensure and Certification.</p> <p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p>

Impact on Local Partners

Table 2: Impact on Local Partners

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>To the best of the agency’s knowledge, only one hospital would be considered a local partner and it has one emergency department.</p> <p>Direct Costs (monetized):</p> <ul style="list-style-type: none"> • Cost of developing and updating a security plan: <ul style="list-style-type: none"> ○ VDH has a record of 113 emergency departments in the Commonwealth. ○ Per International Association of Professional Security Consultants, security consulting fees typically range from \$100 to \$500 per hour, with an average rate of around \$200 per hour. ○ Assuming a consultant is hired for 20 hours at \$200 per hour to create a security plan because the hospital does not have an emergency department security plan that
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	<p>meets the minimum standards, the cost of developing a security plan would be at least \$4,000 per hospital emergency department.</p> <ul style="list-style-type: none"> ○ Assuming a consultant is hired for 10 hours at \$200 per hour to update a security plan in two years' time, the cost of developing a security plan would be at least \$2,000 per hospital emergency department. ○ Total cost is estimated to not exceed \$4,000 in Year 0 and \$2,000 in Years 2 and 4. <ul style="list-style-type: none"> ● Cost of implementing security measures: <ul style="list-style-type: none"> ○ The hospital may need to purchase security equipment, such as cameras, alarms, and access control systems, to secure the emergency department. The cost of such equipment may depend on the size of the emergency department and the level of security required. ○ Assuming the hospital needs to install cameras, alarms, and access control systems, the total cost of equipment and installation is estimated to be \$100,000. ○ VDH does not have data to indicate how many hospitals, if any, would need to install such equipment. ○ Total cost is unknown. ● Personnel cost for security personnel 24/7: <ul style="list-style-type: none"> ○ Per the average hourly wage information from the Bureau of Labor Statistics (BLS) May 2021 data in general medical and surgical hospitals (NAICS 622100) for Police and Sheriff's Patrol Officers (Code 30-3051) and the fringe benefits from the September 2022 BLS for the South Atlantic area, an off-duty law enforcement officer would cost \$29.35 hour ○ Per the average hourly wage information from the Bureau of Labor Statistics (BLS) May 2021 data in general medical and surgical hospitals (NAICS 622100) for Security Guards (Code 33-9032) and the fringe benefits from the September 2022 BLS for the South Atlantic area, a trained security personnel could cost \$19.90 per hour. ○ Given 168 hours in a week, 52 weeks in a year, and assuming there is one off-duty law enforcement officer present 24/7, a hospital that only employs off-duty law enforcement officers would incur an annual cost of \$256,402. ○ Given 168 hours in a week, 52 weeks in a year, and assuming there is one trained security personnel present 24/7, a hospital that only employs trained security personnel would incur an annual cost of \$173,846. ○ VDH does not have data to indicate which type of security personnel a hospital will choose (off-duty law
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	<p>enforcement versus trained security personnel), how many security personnel are needed (either per shift or per week) for sufficient 24/7 coverage at a given emergency department beyond what a hospital has already incurred costs for, whether a hospital will employ or contract security personnel, whether a hospital will secure a waiver from the 24/7 coverage requirement, and what the reduced amount of security a hospital may have under a waiver.</p> <ul style="list-style-type: none"> ○ Based on the median between the salary costs described above and not discounting the value based on the lack of data VDH described above, total cost is estimated to be \$215,124 annually. <p>Indirect Costs (monetized): VDH is not aware of any monetized indirect costs at this time.</p> <p>Direct Benefits (monetized):</p> <ul style="list-style-type: none"> ● Reduction in the number of violent incidents: <ul style="list-style-type: none"> ○ According to BLS, the rate of nonfatal occupational injuries and illnesses in hospitals was 6.1 per 100 full-time workers in 2021. ○ Assuming two-thirds of these injuries are due to violent incidents in the emergency department and assuming that emergency departments have an average of 100 full-time workers, then the hospital can expect to save around $4.07 \times 100 = 407$ hours of lost work time due to injuries prevented by the security plan. ○ Assuming an average hourly wage of \$30 for hospital workers, this would result in a benefit of \$7,950 per year per emergency department. ○ Total benefit is estimated to be \$7,950 annually. <p>Indirect Benefits (monetized): VDH is not aware of any monetized indirect benefits at this time.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$1,083,620	(b) \$37,501
(3) Other Costs & Benefits (Non-Monetized)	<p>Other Costs (non-monetized):</p> <ul style="list-style-type: none"> ● Staff training costs that may need to be incurred to ensure that all employees are familiar with the new security plan and understand their roles in implementing it. 	

	<ul style="list-style-type: none"> • Potential hiring of additional administrative staff to manage the implementation and maintenance of the security plan, which could result in increased personnel costs. • Increased wait times could result from implementation of the security plan. • Reduced flexibility from operational or facility design that could limit its ability to respond to changing patient needs or emergency situations, potentially leading to reduced efficiency and increased costs. <p>Other Benefits (non-monetized):</p> <ul style="list-style-type: none"> • Improved safety and security for patients, staff, and visitors in the emergency department. • Improved staff morale and job satisfaction, which can lead to improved retention rates and reduced costs associated with recruitment and training. • Increased patient satisfaction and retention. • Reduced risk of violence or other security incidents in the emergency department. • Increased staff preparedness and training to handle security incidents, potentially reducing the severity of the incident and minimizing the impact on patients, staff, and visitors. • Improved reputation and trust among patients and the community. • Improved public perception of the healthcare system as a whole. • Reduced liability and legal costs associated with security incidents, if a hospital is able to demonstrate that it had taken reasonable measures to prevent a security incident. <p>Increased efficiency from a well-designed security plan can reduce the amount of time and resources spent on security-related issues that could lead to cost savings.</p>
(4) Assistance	None.
(5) Information Sources	<p>Bureau of Labor Statistics; International Association of Professional Security Consultants; Division of Acute Care Services, Office of Licensure and Certification.</p> <p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p>

Impacts on Families

Table 3: Impact on Families

(1) Direct & Indirect Costs & Benefits (Monetized)	The regulatory requirements proposed by these changes are imposed on hospitals with one or more emergency departments, not imposed families. Therefore, VDH is not aware of any direct monetized costs, indirect monetized costs, direct monetized benefits, and indirect monetized benefits for families.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$0
(3) Other Costs & Benefits (Non-Monetized)	VDH is not aware of any other non-monetized costs and benefits for families.	
(4) Information Sources	Division of Acute Care Services, Office of Licensure and Certification. VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.	

Impacts on Small Businesses

Table 4: Impact on Small Businesses

(1) Direct & Indirect Costs & Benefits (Monetized)	VDH is not aware of any direct monetized costs, indirect monetized costs, direct monetized benefits, and indirect monetized benefits for small businesses because to the best of the agency’s knowledge, no hospital with an emergency department meets the definition of a small business.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$0
(3) Other Costs & Benefits (Non-Monetized)	VDH is not aware of any other non-monetized costs or non-monetized benefits for small businesses because to the best of the agency’s knowledge, no hospital with an emergency department meets the definition of a small business.	
(4) Alternatives	To the best of the agency’s knowledge, no hospital with an emergency department meets the definition of a small business.	

<p>(5) Information Sources</p>	<p>Division of Acute Care Services, Office of Licensure and Certification.</p> <p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p>
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Changes to Number of Regulatory Requirements

Table 5: Total Number of Requirements

	Number of Requirements			
Chapter number	Initial Count	Additions	Subtractions	Net Change
410	4216	758	0	758
TOTAL				

1 **Project 7156 - Exempt Final**

2 **Department of Health**

3 **Amend Regulation after Enactment of Chapter 417 of the 2023 Acts of Assembly**
4 **12VAC5-410-280. Emergency service.**

5 A. Hospitals with an emergency department/service shall have 24-hour staff coverage and
6 shall have at least one physician on call at all times. Hospitals without emergency service shall
7 have written policies governing the handling of emergencies.

8 B. No less than one registered nurse shall be assigned to the emergency service on each
9 shift. Such assignment need not be exclusive of other duties, but must have priority over all other
10 assignments.

11 C. Those hospitals that provide ambulance services shall comply with Article 2.1 (§ 32.1-111.1
12 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia and 12VAC5-31.

13 D. The hospital shall provide equipment, drugs, supplies, and ancillary services
14 commensurate with the scope of anticipated needs, including radiology and laboratory services
15 and facilities for handling and administering of blood and blood products. Emergency drugs and
16 equipment shall remain accessible in the emergency department at all times.

17 E. Current roster of medical staff members on emergency call, including alternates and
18 medical specialists or consultants shall be posted in the emergency department.

19 F. Hospitals shall make special training available, as required, for emergency department
20 personnel.

21 G. Toxicology reference material and poison antidote information shall be available along with
22 telephone numbers of the nearest poison control centers.

23 H. Each emergency department shall post notice of the existence of a human trafficking
24 hotline to alert possible witnesses or victims of human trafficking to the availability of a means to
25 gain assistance or report crimes. This notice shall be in a place readily visible and accessible to
26 the public, such as the patient admitting area or public or patient restrooms. The notice shall meet
27 the requirements of § 40.1-11.3 C of the Code of Virginia.

28 I. Every hospital with an emergency department shall establish ~~protocols to ensure that~~
29 ~~security personnel of the emergency department receive training appropriate to the populations~~
30 ~~served by the emergency department. This training may include training based on a trauma-~~
31 ~~informed approach in identifying and safely addressing situations involving patients or other~~
32 ~~persons who pose a risk of harm to themselves or others due to mental illness or substance abuse~~
33 ~~or who are experiencing a mental health crisis. a security plan for each emergency department~~
34 that:

35 1. Is developed using standards established in the Healthcare Security Industry
36 Guidelines, 13th Edition (International Association for Healthcare Security and Safety);

37 2. Is based on:

38 a. The results of a security risk assessment of each emergency department location
39 of the hospital; and

40 b. Risks for the emergency department identified in consultation with the emergency
41 department medical director and nurse director, including:

42 (1) Trauma level designation;

43 (2) Overall patient volume;

44 (3) Volume of psychiatric and forensic patients;

- 45 (4) Incidents of violence against staff;
46 (5) Level of injuries sustained from such violence; and
47 (6) Prevalence of crime in the community.
- 48 3. Includes the presence of one or more off-duty law-enforcement officers or trained
49 security personnel in the emergency department at all times, except as provided in
50 subsection L of this section, and as indicated to be necessary and appropriate by the
51 security risk assessment; and
- 52 4. Outlines training requirements for security personnel in:
- 53 a. The potential use of and response to weapons;
54 b. Defensive tactics;
55 c. De-escalation techniques;
56 d. Appropriate physical restraint and seclusion techniques;
57 e. Crisis intervention;
58 f. Trauma-informed approaches; and
59 g. Safely addressing situations involving patients, family members, or other persons
60 who pose a risk of harm to themselves or others due to mental illness or substance
61 abuse or who are experiencing a mental health crisis.
- 62 J. The hospital may:
- 63 1. Accept from its security personnel the satisfactory completion of the Department of
64 Criminal Justice Services minimum training standards for auxiliary police officers as
65 required by § 15.2-1731 of the Code of Virginia in lieu of the training prescribed by
66 subdivision I 4 of this section; and
- 67 2. Request to use industry standards other than those specified in subdivision I 1 of this
68 section by submitting a written request for alternative industry standards to the OLC that:
- 69 a. Specifies the title, edition if applicable, and author of the alternative industry
70 standards; and
71 b. Provides an explanation of how the alternative industry standards are substantially
72 similar to those specified in subdivision I 1 of this section.
- 73 K. Every hospital with an emergency department shall update its security plan, including its
74 security risk assessment, for each emergency department location of the hospital as often as
75 necessary but not to exceed 2 years.
- 76 L. The commissioner shall provide a waiver from the requirement that at least one off-duty
77 law-enforcement officer or trained security personnel be present at all times in the emergency
78 department if the hospital demonstrates that a different level of security is necessary and
79 appropriate for any of its emergency departments based upon findings in the security risk
80 assessment.
- 81 1. A hospital shall submit a written request for a waiver pursuant to this subsection and
82 shall:
- 83 a. Specify the location of the emergency department for which the waiver is requested;
84 b. Provide a dated copy of the security risk assessment performed for the specified
85 emergency department that has been reviewed and approved by the governing body
86 or its designee; and
87 c. Indicate the requested duration of the waiver.
- 88 2. The commissioner shall specify in any waiver granted pursuant to this subsection:
- 89 a. The location of the emergency department for which the waiver is granted;

- b. The level of security to be provided at the specified emergency department location;
- c. The effective date of the waiver; and
- d. The duration of the waiver, which may not exceed two years from the date of issuance.

3. A hospital granted a waiver pursuant to this subsection shall:

a. Notify the commissioner in writing no less than 30 calendar days after its security risk assessment changes if such change impacts when how many off-duty law-enforcement officers or trained security personnel should be present at the emergency department for which a waiver was granted;

b. Provide a dated copy of the changed security risk assessment performed for the specified emergency department that has been reviewed and approved by the governing body or its designee; and

c. Indicate whether the hospital is:

(1) Requesting a modification to its existing waiver; or

(2) Surrendering its existing waiver.

4. The commissioner may request additional information from the hospital in evaluating the requested waiver.

5. The commissioner may modify or rescind a waiver granted pursuant to this subsection if:

a. Additional information becomes known that alters the basis for the original decision, including if the security risk assessment changes regarding how many off-duty law-enforcement officers or trained security personnel should be present at the emergency department for which a waiver was granted; or

b. Results of the waiver jeopardize the health or safety of patients, employees, contractors, and the public.

6. Pursuant to the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia), the Department of Health:

a. May not release to the public information that a hospital discloses pursuant to this subsection, the waiver request, and the response to the waiver to the extent those records are exempt from disclosure; and

b. Shall notify the Secretary of Public Safety and Homeland Security of any request for records specified in subdivision L 6 a of this section, the person making such request, and the Department of Health's response to the request.

J. M. Each hospital with an emergency department shall establish a protocol for treatment of individuals experiencing a substance use-related emergency to include the completion of appropriate assessments or screenings to identify medical interventions necessary for the treatment of the individual in the emergency department. The protocol may also include a process for patients who are discharged directly from the emergency department for the recommendation of follow-up care following discharge for any identified substance use disorder, depression, or mental health disorder, as appropriate, that may include:

1. Instructions for distribution of naloxone;

2. Referrals to peer recovery specialists and community-based providers of behavioral health services; or

3. Referrals for pharmacotherapy for treatment of drug or alcohol dependence or mental health diagnoses.

Statutory Authority

136 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

137 **Historical Notes**

138 Derived from VR355-33-500 § 2.12, eff. July 28, 1993; amended, Virginia Register Volume 11,
139 Issue 8, eff. April 1, 1995; Volume 22, Issue 8, eff. January 25, 2006; Volume 35, Issue 4, eff.
140 November 14, 2018; Volume 36, Issue 23, eff. August 6, 2020.

141 **Documents Incorporated by Reference (12VAC5-410)**

142 Guidelines for Design and Construction of Hospitals, 2018 Edition, Facility Guidelines
143 Institute, Washington D.C., <http://www.fgiguideines.org>

144 Guidelines for Design and Construction of Outpatient Facilities, 2018 Edition, Facility
145 Guidelines Institute, Washington, D.C., <https://fgiguideines.org>

146 Healthcare Security Industry Guidelines, International Association for Healthcare Security and
147 Safety, 13th Edition, <https://www.iahss.org/>

COST BENEFIT ANALYSIS WORKSHEET

December 2022

Discount Rate:	3%
Time horizon:	4 years

Notes:

1. Year 0 represents the current fiscal year.
2. In the green cells, insert the expected costs and benefits for your analysis. Insert zero (0) for years where no costs or benefits are expected.
3. DO NOT CHANGE THE DISCOUNT RATE unless you wish to use a different rate; if so, please make a note of this on the Economic Impact form and provide a rationale.
4. If you need to add additional rows, please contact ORM first.

Estimated Dollar Amounts						
Year	Preferred Option (Table 1a)		No Action (Table 1b)		Alternative (Table 1c)	
	Cost	Benefit	Cost	Benefit	Cost	Benefit
0	24,761,012	1,379,730	1,271,250	0	24,761,012	1,379,730
1	24,309,012	1,379,730	226,000	0	24,309,012	1,379,730
2	24,535,012	1,379,730	226,000	0	24,309,012	1,379,730
3	24,309,012	1,379,730	226,000	0	24,309,012	1,379,730
4	24,535,012	1,379,730	226,000	0	24,309,012	1,379,730
TOTAL	122,449,060	6,898,650	2,175,250	0	121,997,060	6,898,650

Present Value						
Year	Preferred Option (Table 1a)		No Action (Table 1b)		Alternative (Table 1c)	
	Cost	Benefit	Cost	Benefit	Cost	Benefit
0	24,761,012	1,379,730	1,271,250	0	24,761,012	1,379,730
1	23,600,983	1,339,544	219,417	0	23,600,983	1,339,544
2	23,126,602	1,300,528	213,027	0	22,913,575	1,300,528
3	22,246,190	1,262,648	206,822	0	22,246,190	1,262,648
4	21,799,040	1,225,872	200,798	0	21,598,242	1,225,872
TOTAL	115,533,826	6,508,322	2,111,314	0	115,120,002	6,508,322

	Preferred Option (Table 1a)	No Action (Table 1b)	Alternative (Table 1c)
Net Benefit	-109,025,504	-2,111,314	-108,611,679

VIRGINIA
REGULATORY TOWN HALL

Agency

Virginia Department of Health

Board

State Board of Health

3 comments

All comments for this forum**[Back to List of Comments](#)****Commenter:** R. Brent Rawlings on behalf of Virginia Hospital & Healthcare Association

5/9/23 5:27 pm

VHHA Public Comment on Draft Amendments for 12VAC5-410-10 et seq. to Implement SB 827

May 9, 2023

Ms. Rebekah E. Allen, J.D.
Senior Policy Analyst
Virginia Department of Health
Office of Licensure and Certification
9960 Mayland Drive, Suite 401
Henrico, Virginia 23233

RE: Public Comment on Draft Amendments for 12VAC5-410-10 et seq. to Implement SB 827 from 2023 Regular Session

Dear Ms. Allen,

On behalf of the Virginia Hospital & Healthcare Association (VHHA) and its hospital and health system members across the Commonwealth, please accept these comments submitted in response to the notice of public comment on draft amendments for 12VAC5-410-10 et seq. to implement SB 827 from the 2023 Regular Session. SB 827 pertains generally to hospital emergency department security requirements.

The safety and security of patients, staff, and the public is of paramount concern for hospitals. In the current environment, there is a clear need to take appropriate measures to ensure the physical security of hospitals, and emergency departments in particular, but the decision to embed security personnel in healthcare settings is one that requires careful consideration of a number of factors including level of risk, legal and regulatory limitations, and community response.

For example, applicable federal regulations at 42 C.F.R. § 482.13 are designed to place some limitations on use of security staff and recognize the distinction between the role of hospital staff in ensuring security and law enforcement. In interpreting this regulation, the Centers for Medicare and Medicaid Services (CMS) provides that security staff may carry weapons as allowed by hospital policy, and state and federal law. *However, the use of weapons by security staff is considered a law enforcement action, not a health care intervention.* If a weapon is used by security or law enforcement personnel on a person in a hospital (patient, staff, or visitor) to protect people or hospital property from harm, CMS expects the situation to be handled as a criminal activity and for the perpetrator to be placed in the custody of local law enforcement.

Federal regulations and accreditation standards applied to hospitals do not require or assume the need for security personnel to be present in the hospital or any given department at all times. An assessment of risk is

the most reliable indicator of the need for security personnel in hospital settings. The risk factors that are considered include size of the facility, security call volumes, area crime statistics, high risk areas (e.g., emergency department, trauma center, psychiatric unit), clinical staffing levels, visitor traffic level, and emergency department visit levels. Because the level of risk varies widely, security staffing levels likewise can vary dramatically from hospital to hospital and from location to location. Security personnel duties can range from full-time posts at a single location to patrol and response across multiple locations. The presence of security personnel is often also limited to certain periods of the day when there is a higher level of risk or activity.

VHHA and its member hospitals and health systems continue to have concerns with mandating the presence of at least one off-duty law-enforcement officer or trained security personnel at every emergency department location at all times. Many hospitals have determined that this requirement is not appropriate or necessary at some emergency department locations based upon factors described above – level of risk, legal and regulatory limitations, and community response.

While requiring at least one off-duty law-enforcement officer or trained security personnel at every emergency department location at all times as a precautionary measure may appear reasonable regardless of competing factors, this presents significant cost and workforce concerns that must also be taken into consideration. Industry experts note that the cost of off-duty law enforcement officers has escalated and, as we have seen here in Virginia, the additional demands placed on many police departments has reduced the availability of officers for off-duty assignments. Similarly, private security firms are subject to the same workforce challenges applied to all industries making recruitment and retention difficult and more costly.

It is also important to note that the physical presence of security personnel is just one component of security. For example, hospitals are required by federal regulations and accrediting bodies to maintain all-hazards security plans, train staff on emergency preparedness and response, violence prevention and de-escalation techniques, and employ robust physical security systems and access control measures. All of these components should be taken into account when evaluating what level of security is appropriate and necessary at any given facility.

Accordingly, any state regulation pertaining to emergency department security must provide flexibility for hospitals to develop and implement security plans, especially as it pertains to any requirement to maintain the presence of an off-duty law-enforcement officer or trained security personnel in the hospital or in the emergency department. Any such determination should be informed by each hospital's security plan and security risk assessment.

SB 827 requires every hospital with an emergency department to establish a security plan for the emergency department. The security plan must be developed using standards established by the International Association for Healthcare Security and Safety (IAHSS) or other industry standard and be based on the results of a security risk assessment of each emergency department location of the hospital. The security plan must include the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times, *as indicated to be necessary and appropriate by the security risk assessment*. VHHA interprets this to mean that where the security risk assessment indicates that the presence of at least one trained security personnel is *not* necessary and appropriate, a different security standard could be applied. Furthermore, this would not require any waiver by the Commissioner of Health.

SB 827 provides for a waiver to be granted by the Commissioner of Health from the requirement that at least one off-duty law-enforcement officer or trained security personnel be present at all times in the emergency department. VHHA interprets this to mean that even where the security risk assessment indicates the need for at least one off-duty law-enforcement officer or trained security personnel to be present at all times, the Commissioner shall grant a waiver where the hospital demonstrates that a different level of security is necessary and appropriate for such emergency department. For example, where there are other measures taken to ensure the security of the facility in combination with some other level or frequency of off-duty law-enforcement officer or trained security personnel presence.

Accordingly, VHHA submits that any regulations should incorporate these flexibilities established in SB 827 pertaining to the presence of off-duty law-enforcement officers or trained security personnel. Any regulation

that limits these flexibilities or has the effect of mandating for any emergency department the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times would be problematic for the reasons stated and would be opposed by VHHA.

As it pertains to the draft regulations in particular, VHHA provides the following additional comments:

12VAC5-410-280.I.1 and J.2 – Other Industry Standards

SB 827 provides that the “security plan shall be developed using standards established by the International Association for Healthcare Security and Safety or other industry standard.” 12VAC5-410-280.I.1 as drafted appears to grant the OLC with the authority to determine what other industry standard may be used in his sole discretion. VHHA disagrees with this regulation. Individual hospitals should be provided with the flexibility to determine the industry standard to apply in its organization. Furthermore, the requirement for each hospital to request permission from OLC to use a different standard is administratively burdensome and not required by statute.

VHHA submits that as an alternative, OLC could develop a list of acceptable industry standards that are the same or similar based upon input from hospitals to include in its guidance that could be updated from time to time as new standards are developed and identified. For purpose of the regulation at I.1 it would be sufficient to state “Is developed using standard established by the Healthcare Security Industry Guidelines 13th Edition (International Association for Healthcare Security and Safety), or other standard identified by the Department.” This would provide notice to hospitals of all acceptable industry standards without requiring individual approval and additional regulatory burden. OLC would also retain the ability to assess whether a standard is substantially similar, without creating the additional administrative burden of responding to and managing individual hospital requests.

Along with the proposed alternative above, VHHA submits that the regulation at J.2 pertaining to requests to use other industry standards should be eliminated.

12VAC5-410-280.I.3 – Security Personnel Requirement

As discussed above, VHHA interprets 12VAC5-410-280.I.3 to mean that where the security risk assessment indicates that the presence of at least one trained security personnel is *not* necessary and appropriate, a different security standard could be applied, without the requirement for any waiver by the Commissioner of Health. The OLC would retain the ability to inspect security plans and risk assessments to confirm that the presence of at least one trained security personnel is not necessary and appropriate as indicated by the security risk assessment.

We also note that it appears the reference to subsection K (pertaining to security plan updates) should be changed to subsection L (pertaining to waivers).

12VAC5-410-280.L – Waiver Process

VHHA disagrees with the requirement at L.1.B that a copy of the security risk assessment, or any security risk assessment, must have been “reviewed and approved by the governing body or its designee.” Security risk assessments or documents of this nature are a function of day-to-day management and are not required to be reviewed or approved by the governing body. This would constitute an additional regulatory burden not required by statute and inconsistent with existing business practices. Accordingly, VHHA submits that the words “that has been reviewed and approved by the governing body or its designee” should be eliminated. Corresponding changes should be made to subsection L.3.b below.

VHHA would support including in the regulation at L.1 a requirement that the hospital specify the rationale for the request for waiver, supported by the results of the security risk assessment and

information on any alternative measures or mitigating strategies proposed to address the subject or intent of the regulatory requirement requested to be waived.

VHHA submits that L.2 should be revised to state that “The commissioner *shall* grant a waiver pursuant to this section, and shall specify . . .” SB 827 expressly states that “The commissioner *shall* provide a waiver from the requirement that at least one off-duty law-enforcement officer or trained security personnel be present at all times in the emergency department if the hospital demonstrates that a different level of security is necessary and appropriate for any of its emergency departments based upon findings in the security risk assessment.” VHHA interprets this to mean that the Commissioner is *required* to grant a waiver where the hospital demonstrates that a different level of security is necessary and appropriate for any of its emergency departments based upon findings in the security risk assessment. In order to ensure that the regulation is implemented consistent with the language and intent of the statute, L.2 should be further revised to state: “The commissioner shall grant a waiver pursuant to this subsection upon receipt of information and rationale demonstrating that a different level of security is necessary and appropriate for the emergency department.” This would continue to provide the Commissioner with the authority to require additional information from the hospital as determined appropriate to demonstrate that a different level of security is necessary and appropriate for the emergency department prior to granting a waiver.

L.3 requires a hospital that has been granted a waiver to notify the Commissioner any time its security risk assessment changes. VHHA submits that notice should only be required where such change impacts when and how many off-duty-law-enforcement officers or trained security personnel should be present at the emergency department. This could be accomplished by eliminating the word “and” in the first instance in L.3.

VHHA disagrees with the provision at L.5.a permitting the Commissioner to modify or rescind a waiver if the security risk assessment changes. There could be changes to the security risk assessment that would have no bearing on the determination of whether at least one off-duty law-enforcement officer or trained security personnel be present at all times in the emergency department. The underlying concern, that there is a change to a security risk assessment that indicates that a different level of security may now be necessary and appropriate, is already captured by L.5.b “Additional information becomes known with alters the basis for the original decision.” Accordingly, VHHA submits that L.5.a should be eliminated.

VHHA also disagrees with the provision at L.5.c giving the Commissioner the authority to modify or rescind a waiver where “results of the waiver jeopardize the health or safety of patients, employees, contractors, or the public.” We are concerned that this is very subjective and ambiguous. As an alternative, VHHA submits that this subsection be revised to state “The commissioner can demonstrate that the waiver directly results in jeopardizing the health or safety of patients, employees, contractors, or the public.”

Lastly, with respect to L.6, VHHA agrees that all information that a hospital discloses pursuant to this subsection pertaining to waiver should not be released to the public. Information regarding security plans and security risk assessments is highly sensitive information and could jeopardize the security of the hospital. Accordingly, VHHA submits that the language “to the extent those records are exempt from disclosure” should be deleted.

In conclusion, VHHA is encouraged that SB 827 and these regulations will help to promote even greater uniformity in security planning by hospitals across the Commonwealth and result in further improvement by our hospitals in their efforts to provide the safest environment possible for their patients, staff, and the public. At the same time, it is important that the implementing regulations provide needed flexibility for different levels of risk at various emergency departments across the Commonwealth and avoid imposing unnecessary regulatory burden on hospitals.

Thank you for your consideration of these comments. Please let us know if we can provide you with any further information on this matter.

Sincerely,
/s/
R. Brent Rawlings
Senior Vice President and General Counsel

cc: Ms. Julie M. Dime, Vice President of Government Affairs
CommentID: 216937

Commenter: Clark Barrineau

5/10/23 10:58 pm

Medical Society of Virginia Comment Regarding Draft Amendments for 12VAC5-410-10 et seq.

Medical Society of Virginia (MSV) Comment Regarding Draft Amendments for 12VAC5-410-10 et seq. to Implement SB 827

May 10, 2023

Ms. Rebekah E. Allen, J.D.
Senior Policy Analyst
Virginia Department of Health
Office of Licensure and Certification
9960 Mayland Drive, Suite 401
Henrico, Virginia 23233

RE: Comment on Draft Amendments for 12VAC5-410-10 et seq. to Implement SB 827 from 2023 Regular Session

Dear Ms. Allen,

The Medical Society of Virginia (MSV) strongly supports efforts to assure the safety and wellness of Virginia's healthcare providers. According to the Bureau of Labor Statistics, healthcare providers are 5 times more likely to experience workplace violence than employees in other industries. As representatives of Virginia's physicians, the MSV knows the threat of violence in the workplace is a significant contributor to physician burnout and exhaustion.

SB 827 represents an ongoing effort by the General Assembly to help make the Commonwealth the best place to give and receive care. The MSV supports the drafted regulations, and we thank the Department of Health for their diligent work. As written, these regulations align with the legislative intent of SB 827—which is to make hospitals and emergency rooms more secure.

Regrettably, we were surprised to read the public comment from our colleagues at the Virginia Hospital and Healthcare Association (VHHA). VHHA was an active stakeholder in conversations regarding SB 827 throughout the 2023 General Assembly session. VHHA expressed no public opposition to the final version of SB 827, despite having ample opportunity to do so in subcommittees and committees in both the House and Senate.

VHHA's newly expressed concern around SB 827's requirement of "the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times" is already assuaged by the legislative compromise VHHA agreed to three months ago with the bill patron, Senator Favola. SB 827 gives the Commissioner the ability to provide a waiver from the requirement, and the draft amendments for 12VAC5-410-10 et seq. give the Commissioner appropriate oversight to follow that provision. As such, the MSV supports the waiver amendment language as drafted by VDH and rejects VHHA's efforts to avoid this important process.

Any effort to water down the intent of SB 827 is an effort to jeopardize patients and healthcare providers. For example, VHHA's comment regarding L.5.c would make the Commonwealth less safe. As written, the draft amendments give the Commissioner the authority to modify or rescind a waiver where "results of the waiver jeopardize the health or safety of patients, employees, contractors, or the public." This is reasonable. If there is a fight or shooting in an ER, one would hope all security decisions in a hospital would be reconsidered. VHHA's suggestion—that "the commissioner can demonstrate that the waiver directly results in jeopardizing the health or safety of patients, employees, contractors, or the public"—must be rejected. This language is a needless legal hurdle placing the burden of proof on the Commissioner and the Commonwealth. Were VHHA's suggestion adopted, the Commissioner would have to be able to prove the absence of a security guard led to (for example) a shooting in an ER. VHHA's suggestion is proving a negative, with the sole intent of keeping the standard for security in Virginia's hospitals low.

We must address the problem of violence in our healthcare system now. According to the Bureau of Labor Statistics, the rate of injuries from violent attacks against medical professionals grew by 63% from 2011 to 2020. In 2022, the country was shocked by an act of gun violence in Tulsa, Oklahoma when a disgruntled patient returned to St. Francis Health System and killed a surgeon, physician, receptionist, and visitor. Tragedies like those in Oklahoma are what sparked SB 827 and weakening SB 827's intent while these tragedies and statistics continue to accumulate is irresponsible.

As such, the MSV asks VDH to adopt the regulations as drafted. Please let us know any questions. We look forward to seeing this important legislation implemented this summer.

Sincerely,

Clark Barrineau
Assistant Vice President of Government Affairs and Public Policy
Medical Society of Virginia
CommentID: **216978**

Commenter: Aimee Perron Seibert, VA College of Emergency Physicians

5/10/23 11:26 pm

VACEP Public Comment on 12VAC5-410-10 et seq Draft Regulations for the Implementation of SB 827

Rebekah E. Allen, JD
Senior Policy Analyst
VA Department of Health
9960 Mayland Drive
Suite 401
Henrico, VA 23233

RE: VACEP Public Comment on 12VAC5-410-10 et seq Draft Regulations for the Implementation of SB 827

Dear Ms. Allen:

On behalf of the Virginia College of Emergency Physicians (VACEP), we are writing to support the draft regulations as presented by VDH. The need and urgency for this legislation and accompanying regulations cannot be understated. An August 2022 survey of emergency physicians from the American College of Emergency Physicians (ACEP) shows that violence in ERs is increasing dramatically. Instances of patient and family member violence on emergency physicians and nurses not only harm the caregivers, but also impacts the care that can be provided to others waiting for lifesaving care.

During the 2023 legislative session, VACEP worked in conjunction with the VA Nurses Association and the Medical Society of VA to negotiate the compromise with the VA Hospital and Healthcare Association (VHHA) that passed both houses of the General Assembly unanimously. As in most instances of compromise, both sides didn't get exactly the outcome they wanted, but we believe the final bill allowed for the requested flexibility by hospitals for the varying needs of different communities by including a waiver option.

It is therefore with great surprise and disappointment that we have to firmly and wholeheartedly disagree with the VHHA's subsequent "interpretation" of the language in the bill in their posted public comment. It was very clear from our numerous discussions, including with the patron Senator Favola, that the security risk assessment would certainly guide the creation of a security plan. However, it was never the intent- nor do we believe the plain reading of the law- that would lead to hospitals: 1.) Not needing *any* security in their ER ever or; 2). that if there was a different need shown other than security present in the ER 365 days a year, seven days a week and 24 hours a day, that they would be exempt from even having to apply for a waiver from that legal requirement.

The clear purpose of the waiver was to acknowledge that some emergency departments might need security on one or two shifts a day, not the entire day. We disagree vehemently with the notion that there are ERs in the Commonwealth that have no need for any security personnel to be present in the emergency department. Not only are we backed up by national trends, but we hear stories every day from our members about not feeling safe in their ERs and about the violence they experience not being taken seriously. These emergency physicians work tirelessly in already difficult conditions, lately with patients boarded up and down their hallways, and they deserve to be supported and protected by their hospitals, as outlined in SB 827, which was supported by the legislature and signed by the Governor.

We urge VDH to adopt the regulations as drafted, including the process outlined for waivers, and we look forward to working with our nursing colleagues and with hospital administrators across Virginia to complete timely security risk assessments and draft security plans together, as directed by law.

We should not lose sight of the purpose of this bill- ensuring safe workplaces for doctors and nurses and safe places for patients to be cared for who are experiencing life threatening emergencies. Cases of verbal assaults, serious threats of violence, hitting, slapping, spitting, kicking, and punching are becoming more and more common every day in ERs. Legislators passed SB827 expecting hospitals to provide the necessary trained security to ensure safety- we hope you will adopt the regulations as drafted because they reflect the legislation and the underlying legislative intent of the parties involved.

If you have any additional questions or concerns, do not hesitate to reach out.

CommentID: 216981

VIRGINIA ACTS OF ASSEMBLY -- 2023 SESSION

CHAPTER 417

An Act to amend and reenact § 32.1-127 of the Code of Virginia, relating to hospital emergency departments; required security and training; regulations.

[S 827]

Approved March 23, 2023

Be it enacted by the General Assembly of Virginia:

1. That § 32.1-127 of the Code of Virginia is amended and reenacted as follows:

§ 32.1-127. Regulations.

A. The regulations promulgated by the Board to carry out the provisions of this article shall be in substantial conformity to the standards of health, hygiene, sanitation, construction and safety as established and recognized by medical and health care professionals and by specialists in matters of public health and safety, including health and safety standards established under provisions of Title XVIII and Title XIX of the Social Security Act, and to the provisions of Article 2 (§ 32.1-138 et seq.).

B. Such regulations:

1. Shall include minimum standards for (i) the construction and maintenance of hospitals, nursing homes and certified nursing facilities to ensure the environmental protection and the life safety of its patients, employees, and the public; (ii) the operation, staffing and equipping of hospitals, nursing homes and certified nursing facilities; (iii) qualifications and training of staff of hospitals, nursing homes and certified nursing facilities, except those professionals licensed or certified by the Department of Health Professions; (iv) conditions under which a hospital or nursing home may provide medical and nursing services to patients in their places of residence; and (v) policies related to infection prevention, disaster preparedness, and facility security of hospitals, nursing homes, and certified nursing facilities;

2. Shall provide that at least one physician who is licensed to practice medicine in this Commonwealth shall be on call at all times, though not necessarily physically present on the premises, at each hospital which operates or holds itself out as operating an emergency service;

3. May classify hospitals and nursing homes by type of specialty or service and may provide for licensing hospitals and nursing homes by bed capacity and by type of specialty or service;

4. Shall also require that each hospital establish a protocol for organ donation, in compliance with federal law and the regulations of the Centers for Medicare and Medicaid Services (CMS), particularly 42 C.F.R. § 482.45. Each hospital shall have an agreement with an organ procurement organization designated in CMS regulations for routine contact, whereby the provider's designated organ procurement organization certified by CMS (i) is notified in a timely manner of all deaths or imminent deaths of patients in the hospital and (ii) is authorized to determine the suitability of the decedent or patient for organ donation and, in the absence of a similar arrangement with any eye bank or tissue bank in Virginia certified by the Eye Bank Association of America or the American Association of Tissue Banks, the suitability for tissue and eye donation. The hospital shall also have an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage, and distribution of tissues and eyes to ensure that all usable tissues and eyes are obtained from potential donors and to avoid interference with organ procurement. The protocol shall ensure that the hospital collaborates with the designated organ procurement organization to inform the family of each potential donor of the option to donate organs, tissues, or eyes or to decline to donate. The individual making contact with the family shall have completed a course in the methodology for approaching potential donor families and requesting organ or tissue donation that (a) is offered or approved by the organ procurement organization and designed in conjunction with the tissue and eye bank community and (b) encourages discretion and sensitivity according to the specific circumstances, views, and beliefs of the relevant family. In addition, the hospital shall work cooperatively with the designated organ procurement organization in educating the staff responsible for contacting the organ procurement organization's personnel on donation issues, the proper review of death records to improve identification of potential donors, and the proper procedures for maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes takes place. This process shall be followed, without exception, unless the family of the relevant decedent or patient has expressed opposition to organ donation, the chief administrative officer of the hospital or his designee knows of such opposition, and no donor card or other relevant document, such as an advance directive, can be found;

5. Shall require that each hospital that provides obstetrical services establish a protocol for admission or transfer of any pregnant woman who presents herself while in labor;

6. Shall also require that each licensed hospital develop and implement a protocol requiring written discharge plans for identified, substance-abusing, postpartum women and their infants. The protocol shall require that the discharge plan be discussed with the patient and that appropriate referrals for the mother

and the infant be made and documented. Appropriate referrals may include, but need not be limited to, treatment services, comprehensive early intervention services for infants and toddlers with disabilities and their families pursuant to Part H of the Individuals with Disabilities Education Act, 20 U.S.C. § 1471 et seq., and family-oriented prevention services. The discharge planning process shall involve, to the extent possible, the other parent of the infant and any members of the patient's extended family who may participate in the follow-up care for the mother and the infant. Immediately upon identification, pursuant to § 54.1-2403.1, of any substance-abusing, postpartum woman, the hospital shall notify, subject to federal law restrictions, the community services board of the jurisdiction in which the woman resides to appoint a discharge plan manager. The community services board shall implement and manage the discharge plan;

7. Shall require that each nursing home and certified nursing facility fully disclose to the applicant for admission the home's or facility's admissions policies, including any preferences given;

8. Shall require that each licensed hospital establish a protocol relating to the rights and responsibilities of patients which shall include a process reasonably designed to inform patients of such rights and responsibilities. Such rights and responsibilities of patients, a copy of which shall be given to patients on admission, shall be consistent with applicable federal law and regulations of the Centers for Medicare and Medicaid Services;

9. Shall establish standards and maintain a process for designation of levels or categories of care in neonatal services according to an applicable national or state-developed evaluation system. Such standards may be differentiated for various levels or categories of care and may include, but need not be limited to, requirements for staffing credentials, staff/patient ratios, equipment, and medical protocols;

10. Shall require that each nursing home and certified nursing facility train all employees who are mandated to report adult abuse, neglect, or exploitation pursuant to § 63.2-1606 on such reporting procedures and the consequences for failing to make a required report;

11. Shall permit hospital personnel, as designated in medical staff bylaws, rules and regulations, or hospital policies and procedures, to accept emergency telephone and other verbal orders for medication or treatment for hospital patients from physicians, and other persons lawfully authorized by state statute to give patient orders, subject to a requirement that such verbal order be signed, within a reasonable period of time not to exceed 72 hours as specified in the hospital's medical staff bylaws, rules and regulations or hospital policies and procedures, by the person giving the order, or, when such person is not available within the period of time specified, co-signed by another physician or other person authorized to give the order;

12. Shall require, unless the vaccination is medically contraindicated or the resident declines the offer of the vaccination, that each certified nursing facility and nursing home provide or arrange for the administration to its residents of (i) an annual vaccination against influenza and (ii) a pneumococcal vaccination, in accordance with the most recent recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention;

13. Shall require that each nursing home and certified nursing facility register with the Department of State Police to receive notice of the registration, reregistration, or verification of registration information of any person required to register with the Sex Offender and Crimes Against Minors Registry pursuant to Chapter 9 (§ 9.1-900 et seq.) of Title 9.1 within the same or a contiguous zip code area in which the home or facility is located, pursuant to § 9.1-914;

14. Shall require that each nursing home and certified nursing facility ascertain, prior to admission, whether a potential patient is required to register with the Sex Offender and Crimes Against Minors Registry pursuant to Chapter 9 (§ 9.1-900 et seq.) of Title 9.1, if the home or facility anticipates the potential patient will have a length of stay greater than three days or in fact stays longer than three days;

15. Shall require that each licensed hospital include in its visitation policy a provision allowing each adult patient to receive visits from any individual from whom the patient desires to receive visits, subject to other restrictions contained in the visitation policy including, but not limited to, those related to the patient's medical condition and the number of visitors permitted in the patient's room simultaneously;

16. Shall require that each nursing home and certified nursing facility shall, upon the request of the facility's family council, send notices and information about the family council mutually developed by the family council and the administration of the nursing home or certified nursing facility, and provided to the facility for such purpose, to the listed responsible party or a contact person of the resident's choice up to six times per year. Such notices may be included together with a monthly billing statement or other regular communication. Notices and information shall also be posted in a designated location within the nursing home or certified nursing facility. No family member of a resident or other resident representative shall be restricted from participating in meetings in the facility with the families or resident representatives of other residents in the facility;

17. Shall require that each nursing home and certified nursing facility maintain liability insurance coverage in a minimum amount of \$1 million, and professional liability coverage in an amount at least equal to the recovery limit set forth in § 8.01-581.15, to compensate patients or individuals for injuries

and losses resulting from the negligent or criminal acts of the facility. Failure to maintain such minimum insurance shall result in revocation of the facility's license;

18. Shall require each hospital that provides obstetrical services to establish policies to follow when a stillbirth, as defined in § 32.1-69.1, occurs that meet the guidelines pertaining to counseling patients and their families and other aspects of managing stillbirths as may be specified by the Board in its regulations;

19. Shall require each nursing home to provide a full refund of any unexpended patient funds on deposit with the facility following the discharge or death of a patient, other than entrance-related fees paid to a continuing care provider as defined in § 38.2-4900, within 30 days of a written request for such funds by the discharged patient or, in the case of the death of a patient, the person administering the person's estate in accordance with the Virginia Small Estates Act (§ 64.2-600 et seq.);

20. Shall require that each hospital that provides inpatient psychiatric services establish a protocol that requires, for any refusal to admit (i) a medically stable patient referred to its psychiatric unit, direct verbal communication between the on-call physician in the psychiatric unit and the referring physician, if requested by such referring physician, and prohibits on-call physicians or other hospital staff from refusing a request for such direct verbal communication by a referring physician and (ii) a patient for whom there is a question regarding the medical stability or medical appropriateness of admission for inpatient psychiatric services due to a situation involving results of a toxicology screening, the on-call physician in the psychiatric unit to which the patient is sought to be transferred to participate in direct verbal communication, either in person or via telephone, with a clinical toxicologist or other person who is a Certified Specialist in Poison Information employed by a poison control center that is accredited by the American Association of Poison Control Centers to review the results of the toxicology screen and determine whether a medical reason for refusing admission to the psychiatric unit related to the results of the toxicology screen exists, if requested by the referring physician;

21. Shall require that each hospital that is equipped to provide life-sustaining treatment shall develop a policy governing determination of the medical and ethical appropriateness of proposed medical care, which shall include (i) a process for obtaining a second opinion regarding the medical and ethical appropriateness of proposed medical care in cases in which a physician has determined proposed care to be medically or ethically inappropriate; (ii) provisions for review of the determination that proposed medical care is medically or ethically inappropriate by an interdisciplinary medical review committee and a determination by the interdisciplinary medical review committee regarding the medical and ethical appropriateness of the proposed health care; and (iii) requirements for a written explanation of the decision reached by the interdisciplinary medical review committee, which shall be included in the patient's medical record. Such policy shall ensure that the patient, his agent, or the person authorized to make medical decisions pursuant to § 54.1-2986 (a) are informed of the patient's right to obtain his medical record and to obtain an independent medical opinion and (b) afforded reasonable opportunity to participate in the medical review committee meeting. Nothing in such policy shall prevent the patient, his agent, or the person authorized to make medical decisions pursuant to § 54.1-2986 from obtaining legal counsel to represent the patient or from seeking other remedies available at law, including seeking court review, provided that the patient, his agent, or the person authorized to make medical decisions pursuant to § 54.1-2986, or legal counsel provides written notice to the chief executive officer of the hospital within 14 days of the date on which the physician's determination that proposed medical treatment is medically or ethically inappropriate is documented in the patient's medical record;

22. Shall require every hospital with an emergency department to establish protocols to ensure that security personnel of the emergency department, if any, receive training appropriate to the populations served by the emergency department, which may include training based on a trauma-informed approach in identifying and safely addressing situations involving patients or other persons who pose a risk of harm to themselves or others due to mental illness or substance abuse or who are experiencing a mental health crisis to establish a security plan. Such security plan shall be developed using standards established by the International Association for Healthcare Security and Safety or other industry standard and shall be based on the results of a security risk assessment of each emergency department location of the hospital and shall include the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times as indicated to be necessary and appropriate by the security risk assessment. Such security plan shall be based on identified risks for the emergency department, including trauma level designation, overall volume, volume of psychiatric and forensic patients, incidents of violence against staff, and level of injuries sustained from such violence, and prevalence of crime in the community, in consultation with the emergency department medical director and nurse director. The security plan shall also outline training requirements for security personnel in the potential use of and response to weapons, defensive tactics, de-escalation techniques, appropriate physical restraint and seclusion techniques, crisis intervention, and trauma-informed approaches. Such training shall also include instruction on safely addressing situations involving patients, family members, or other persons who pose a risk of harm to themselves or others due to mental illness or substance abuse or who are experiencing a mental health crisis. Such training requirements may be satisfied through completion of the Department of Criminal Justice Services

minimum training standards for auxiliary police officers as required by § 15.2-1731. The Commissioner shall provide a waiver from the requirement that at least one off-duty law-enforcement officer or trained security personnel be present at all times in the emergency department if the hospital demonstrates that a different level of security is necessary and appropriate for any of its emergency departments based upon findings in the security risk assessment;

23. Shall require that each hospital establish a protocol requiring that, before a health care provider arranges for air medical transportation services for a patient who does not have an emergency medical condition as defined in 42 U.S.C. § 1395dd(e)(1), the hospital shall provide the patient or his authorized representative with written or electronic notice that the patient (i) may have a choice of transportation by an air medical transportation provider or medically appropriate ground transportation by an emergency medical services provider and (ii) will be responsible for charges incurred for such transportation in the event that the provider is not a contracted network provider of the patient's health insurance carrier or such charges are not otherwise covered in full or in part by the patient's health insurance plan;

24. Shall establish an exemption from the requirement to obtain a license to add temporary beds in an existing hospital or nursing home, including beds located in a temporary structure or satellite location operated by the hospital or nursing home, provided that the ability remains to safely staff services across the existing hospital or nursing home, (i) for a period of no more than the duration of the Commissioner's determination plus 30 days when the Commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds or (ii) for a period of no more than the duration of the emergency order entered pursuant to § 32.1-13 or 32.1-20 plus 30 days when the Board, pursuant to § 32.1-13, or the Commissioner, pursuant to § 32.1-20, has entered an emergency order for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health;

25. Shall establish protocols to ensure that any patient scheduled to receive an elective surgical procedure for which the patient can reasonably be expected to require outpatient physical therapy as a follow-up treatment after discharge is informed that he (i) is expected to require outpatient physical therapy as a follow-up treatment and (ii) will be required to select a physical therapy provider prior to being discharged from the hospital;

26. Shall permit nursing home staff members who are authorized to possess, distribute, or administer medications to residents to store, dispense, or administer cannabis oil to a resident who has been issued a valid written certification for the use of cannabis oil in accordance with subsection B of § 54.1-3408.3 and has registered with the Board of Pharmacy;

27. Shall require each hospital with an emergency department to establish a protocol for the treatment and discharge of individuals experiencing a substance use-related emergency, which shall include provisions for (i) appropriate screening and assessment of individuals experiencing substance use-related emergencies to identify medical interventions necessary for the treatment of the individual in the emergency department and (ii) recommendations for follow-up care following discharge for any patient identified as having a substance use disorder, depression, or mental health disorder, as appropriate, which may include, for patients who have been treated for substance use-related emergencies, including opioid overdose, or other high-risk patients, (a) the dispensing of naloxone or other opioid antagonist used for overdose reversal pursuant to subsection X of § 54.1-3408 at discharge or (b) issuance of a prescription for and information about accessing naloxone or other opioid antagonist used for overdose reversal, including information about accessing naloxone or other opioid antagonist used for overdose reversal at a community pharmacy, including any outpatient pharmacy operated by the hospital, or through a community organization or pharmacy that may dispense naloxone or other opioid antagonist used for overdose reversal without a prescription pursuant to a statewide standing order. Such protocols may also provide for referrals of individuals experiencing a substance use-related emergency to peer recovery specialists and community-based providers of behavioral health services, or to providers of pharmacotherapy for the treatment of drug or alcohol dependence or mental health diagnoses;

28. During a public health emergency related to COVID-19, shall require each nursing home and certified nursing facility to establish a protocol to allow each patient to receive visits, consistent with guidance from the Centers for Disease Control and Prevention and as directed by the Centers for Medicare and Medicaid Services and the Board. Such protocol shall include provisions describing (i) the conditions, including conditions related to the presence of COVID-19 in the nursing home, certified nursing facility, and community, under which in-person visits will be allowed and under which in-person visits will not be allowed and visits will be required to be virtual; (ii) the requirements with which in-person visitors will be required to comply to protect the health and safety of the patients and staff of the nursing home or certified nursing facility; (iii) the types of technology, including interactive audio or video technology, and the staff support necessary to ensure visits are provided as required by this subdivision; and (iv) the steps the nursing home or certified nursing facility will take in the event of a technology failure, service interruption, or documented emergency that prevents visits from occurring as required by this subdivision. Such protocol shall also include (a) a statement of the frequency with which visits, including virtual and in-person, where appropriate, will be allowed, which shall be at least

once every 10 calendar days for each patient; (b) a provision authorizing a patient or the patient's personal representative to waive or limit visitation, provided that such waiver or limitation is included in the patient's health record; and (c) a requirement that each nursing home and certified nursing facility publish on its website or communicate to each patient or the patient's authorized representative, in writing or via electronic means, the nursing home's or certified nursing facility's plan for providing visits to patients as required by this subdivision;

29. Shall require each hospital, nursing home, and certified nursing facility to establish and implement policies to ensure the permissible access to and use of an intelligent personal assistant provided by a patient, in accordance with such regulations, while receiving inpatient services. Such policies shall ensure protection of health information in accordance with the requirements of the federal Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. § 1320d et seq., as amended. For the purposes of this subdivision, "intelligent personal assistant" means a combination of an electronic device and a specialized software application designed to assist users with basic tasks using a combination of natural language processing and artificial intelligence, including such combinations known as "digital assistants" or "virtual assistants";

30. During a declared public health emergency related to a communicable disease of public health threat, shall require each hospital, nursing home, and certified nursing facility to establish a protocol to allow patients to receive visits from a rabbi, priest, minister, or clergy of any religious denomination or sect consistent with guidance from the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services and subject to compliance with any executive order, order of public health, Department guidance, or any other applicable federal or state guidance having the effect of limiting visitation. Such protocol may restrict the frequency and duration of visits and may require visits to be conducted virtually using interactive audio or video technology. Any such protocol may require the person visiting a patient pursuant to this subdivision to comply with all reasonable requirements of the hospital, nursing home, or certified nursing facility adopted to protect the health and safety of the person, patients, and staff of the hospital, nursing home, or certified nursing facility; and

31. Shall require that every hospital that makes health records, as defined in § 32.1-127.1:03, of patients who are minors available to such patients through a secure website shall make such health records available to such patient's parent or guardian through such secure website, unless the hospital cannot make such health record available in a manner that prevents disclosure of information, the disclosure of which has been denied pursuant to subsection F of § 32.1-127.1:03 or for which consent required in accordance with subsection E of § 54.1-2969 has not been provided.

C. Upon obtaining the appropriate license, if applicable, licensed hospitals, nursing homes, and certified nursing facilities may operate adult day care centers.

D. All facilities licensed by the Board pursuant to this article which provide treatment or care for hemophiliacs and, in the course of such treatment, stock clotting factors, shall maintain records of all lot numbers or other unique identifiers for such clotting factors in order that, in the event the lot is found to be contaminated with an infectious agent, those hemophiliacs who have received units of this contaminated clotting factor may be apprised of this contamination. Facilities which have identified a lot that is known to be contaminated shall notify the recipient's attending physician and request that he notify the recipient of the contamination. If the physician is unavailable, the facility shall notify by mail, return receipt requested, each recipient who received treatment from a known contaminated lot at the individual's last known address.

E. Hospitals in the Commonwealth may enter into agreements with the Department of Health for the provision to uninsured patients of naloxone or other opioid antagonists used for overdose reversal.

2. That the promulgation of regulations pursuant to this act shall be exempt from the requirements of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), except that the State Board of Health shall provide an opportunity for public comment prior to adoption.

STATE BOARD OF HEALTH BYLAWS

ARTICLE I. APPLICABILITY

Section 1. General.

The Board of Health has the authority to adopt bylaws pursuant to Va. Code § 32.1-7. The provisions of these Bylaws are applicable to all proceedings of the State Board of Health ("Board") to the extent that the same are not otherwise governed by the requirements set forth in the Code of Virginia or by Executive Order. Whenever the provisions and authorizations of these Bylaws are in conflict with the provisions and authorizations mandated by the Code of Virginia or by Executive Order, the latter shall control.

Section 2. Authority and Limitations.

The Board is constituted under Va. Code §§ 32.1-5, *et seq.* and 2.2-2100 as a "Policy Board." As a "Policy" board pursuant to Va. Code § 2.2-2100, the Board is specifically charged with the duties and responsibilities set forth in the basic law governing the actions of the Board, as generally established in Title 32.1, as well as in such other Titles of the Code of Virginia. As set forth in and consistent with the basic law, the Board may promulgate public policies or regulations, set rates, distribute federal funds, and adjudicate regulatory or statutory violations.

Section 3. Members

The Board shall consist of residents of the Commonwealth appointed by the Governor for terms of four years each in accordance with Va. Code § 32.1-5. A vacancy other than by expiration of term shall be filled by the Governor for the unexpired term. No person shall be eligible to serve more than two full consecutive four year terms.

Section 4. Representation.

When the Board is requested to appear before the General Assembly, or any legislative or study committees, the Board shall be represented by the State Health Commissioner ("Commissioner") or his designee or by duly designated member(s) who are nominated by the Chair and when practicable, confirmed by the Board.

Individual members of the Board may provide comments to the media, social media, local, state, or federal officials, or members of the public. Any comments made shall be identified as the member's personal views and not the position of the Board unless the member has been authorized by the Board to express its official position.

Section 5. Orientation.

All new members appointed to the Board shall receive an orientation from the Virginia Department of Health (Department) that includes information about the roles and responsibilities of the Board; the committee structure and Bylaws of the Board; the roles and responsibilities of the Department; an overview of the Virginia regulatory process; and the Virginia Freedom of Information Act.

ARTICLE II. MEETINGS

Section 1. Regular Meetings.

Regular meetings of the Board shall be held at least on a quarterly basis at such time and place as the Board may determine, provided, however, that at least one meeting shall be held in the City of Richmond. No business requiring a vote or final decision of the Board may be conducted in the absence of a quorum, as defined under Va. Code § 32.1-8.

Section 2. Annual Meetings.

The regular meeting held in the second quarter of the calendar year shall be designated as an annual meeting. Elections shall be held at the Annual Meeting.

Section 3. Committee Meetings.

The Executive Committee, the establishment and constitution of which are hereinafter set forth, and such other Committees as the Board or Chair may designate, pursuant to Article IV, Section 3 of these Bylaws, may convene at such times as may be established by each committee; provided, however, that all such meetings are open to the public and comply with the notice requirements set forth in Va. Code § 2.2-3707 of the Virginia Freedom of Information Act, Va. Code § 2.2-3700 *et seq.*

Section 4. Special Meetings.

The Chair or any three members of the Board may call a special meeting for a specific purpose or purposes. No business shall be transacted at such special meeting except that expressly set out in the notice of the special meeting.

Section 5. Notice of Meeting.

Public notice of meetings shall be provided in accordance with the requirements of the Freedom of Information Act, Va. Code § 2.2-3700 *et seq.*

Section 6. Quorum.

A quorum of the Board for transaction of any lawful business shall be that established by Va. Code § 32.1-8.

Section 7. Conduct of Meetings.

The Chair shall preside over all meetings of the Board, except that, in the absence or disability of the Chair, the Vice Chair shall preside. The Commissioner, the executive officer of the Board pursuant to Va. Code § 32.1-18, shall serve as Secretary or, with the approval of the Board, shall name his designee to serve as Secretary, as specified by Va. Code § 32.1-9. The Secretary or Secretary-designees shall provide staff support, record all minutes of the meetings, and record in a minute book all resolutions adopted and all transactions occurring at the meeting. The then current edition of Robert's Rules of Order shall govern the conduct of all meetings of the Board when not in conflict with statutory requirements set forth in the Code of Virginia or Executive Orders. Pursuant to Va. Code § 2.2-3710, the Board shall not vote by written or secret ballot. All voting shall be accomplished by voice vote, show of hands, or roll-call vote.

Section 8. Closed Session.

Prior to meeting in a closed session, the Board must vote affirmatively to do so and must announce the purpose of the session. This purpose shall consist of one or more of the purposes for which a closed session is permitted in accordance with the Virginia Freedom of Information Act, Va. Code § 2.2-3700, *et seq.* Minutes may be taken during a closed session but are not required. Such minutes shall not be subject to mandatory public disclosure.

Section 9. Official Records.

All official records of the Board shall be kept on file at the Department and shall be open to inspection as required by law. All files shall be kept in accordance with the applicable Records Retention and Disposition Schedule maintained by the Library of Virginia in accordance with the Virginia Public Records Act, Va. Code § 42.1-76, *et seq.*

ARTICLE III. OFFICERS

Section 1. Number and Title.

The officers of this Board shall be as follows:

1. Chair
2. Vice Chair
3. Secretary, who shall be the Commissioner or, with the approval of the Board, his designee, as prescribed by Va. Code § 32.1-9

Section 2. Duties.

The duties of the officers shall be those usually incident to the respective office and such other special duties as may, from time to time, be specified by the Board. Officers shall be elected annually and shall assume their duties at the close of the meeting at which they are elected.

Section 3. Vacancies.

Vacancies in the position of Chair or Vice Chair shall be filled for the remainder of the term by voice vote, show of hands, or roll-call vote of the Board at its next full meeting following the departure or resignation of the former incumbent.

ARTICLE IV. COMMITTEES

Section 1. Executive Committee.

The Executive Committee of the Board shall be composed of the Chair, the Vice Chair, and two non-officer members of the Board, who shall be elected by the Board. . At each year's Annual Meeting, the Board shall elect the two non-officer members of the Executive Committee from the Board's membership for the coming year. Those elected shall assume their duties at the close of

the meeting at which they are elected. The Chair of the Board shall also serve as Chair of the Executive Committee.

Section 2. Duties.

The Executive Committee shall undertake all such responsibilities as are required or requested by the Board, and, to the extent the Board may officially delegate certain duties to the Executive Committee, all such delegated duties when the full Board is not in session. All actions taken on delegated duties shall be described in full report to the Board at the next successive full Board meeting for review, approval or disapproval, or ratification by the Board, as appropriate

Section 3. Other Committees.

The Board or Chair, as its or his discretion, may appoint such other committees of its members as it may deem advisable and may designate the responsibilities of any such committees.

Section 4. Vacancies.

Vacancies arising on the Executive Committee or any other committee established by the Board or Chair may be filled for the unexpired term by the Board at its next full meeting.

ARTICLE V. ELECTIONS

Section 1. Nominations.

Nominations for Chair, Vice Chair, and two Executive Committee members may be made by a nominating committee appointed by the Chair or the Board for that purpose. Additional nominations may be received by voice from the floor.

Section 2. Voting.

Elections of officers and Executive Committee members must be conducted in open session of at least a quorum of the Board by voice vote, show of hands, or roll-call vote, as required by Va. Code § 2.2-3710. Election to office or Executive Committee membership shall be determined by a simple majority of those present and voting.

ARTICLE VI. AMENDMENTS TO THE BYLAWS

The Board shall review and amend the Bylaws as necessary. At a minimum, the Board shall review its Bylaws every four years. The Bylaws of the Board may be amended at any regular meeting of the Board at which at least a quorum is present by an affirmative vote of two-thirds of the Board membership present and voting, provided that the amendment has been submitted in writing at the previous regular meeting.

These Bylaws are effective on March 7, 2019, and until subsequently amended.

Faye O. Prichard, Chair
State Board of Health

Revised March 2019

Revised March 2012

Virginia State Board of Health Membership Roster – July 2022

Name/Address	Affiliation/Contact	Term Expires
Gary P. Critzer, NRP, CCEMTP Chair 250 S Wayne Avenue, Suite 301 Waynesboro, Virginia 22980	EMS (540) 942-6698 Email: critzerqp@ci.waynesboro.va.us	30-June-2025
Michael Desjadon 560 Hodges Draft Lane West Augusta, Virginia 24485	Corporate Purchaser of Health Care Email: mike@mdvirginia.com	30-June-2026
Melissa L Green 5100 Jackson River Road Hot Springs, Virginia 24445	Nursing Home Industry (404) 520-4841 Email: Melissa.Green@NevaSeniorCare.com	30-June-2025
Elizabeth Ruffin Harrison 1100 Coggins Point Road N. Prince George, Virginia 23860	Consumer (804) 337-2578 Email: lisaruffinharrison@gmail.com	30-June-2025
Anna Jeng, ScD Executive Committee 1147 Surrey Crescent Norfolk, Virginia 23508	Public Environmental Health (504) 430-3571 Email: hjeng@odu.edu	30-June-2025
Lee R. Jones, DMD Carilion Clinic Dental Care 4348 Electric Road Roanoke, Virginia 24018	Virginia Dental Association (540) 776-0222 Email: lrjones@carilionclinic.org	30-June-2026
Patricia Anne Kinser, PhD, WHNP-BC, RN 1100 East Leigh Street Richmond, Virginia 23298	Virginia Nurses Association Email: kinserpa.boh@gmail.com	30-June-2025
Wendy Klein, MD, MACP Vice Chair 1010 N Thompson Street Richmond, Virginia 23230	Medical Society of Virginia Email: wklein@healthbrigade.org	30-June-2023
The Honorable Patricia O’Bannon P.O. Box 90775 Henrico, Virginia 23273	Local Government (804) 501-4208 Email: tuckahoe@henrico.us	30-June-2026
Holly S. Puritz, MD, FACOG The Group for Women 880 Kempsville Road, Suite 2200 Norfolk, Virginia 23502	Medical Society of Virginia (757) 466-6350 Email: h.puritz@tgfw.com	30-June-2024
Maribel E. Ramos 7509 Digby Green Alexandria, Virginia 22315	Consumer Email: ramosmvaboh@gmail.com	30-June-2025
Jim Shuler, DVM Executive Committee 3000 Wakefield Drive Blacksburg, Virginia 24060	Virginia Veterinary Medical Association Email: deljshuler@aol.com	30-June-2023
Stacey Swartz, PharmD 2204 Mt. Vernon Avenue Alexandria, Virginia 22301	Virginia Pharmacists Association (703) 836-1700 Email: stacey.swartz@gmail.com	30-June-2024
Ann B. R. Vaughters, MD 3829 Gaskins Road Richmond, Virginia 23233	Managed Care Health Insurance Plans Email: abrvmdba@gmail.com	30-June-2026
Mary Margaret Whipple 4200 Innslake Drive, Suite 203 Glen Allen, Virginia 23060	Hospital Industry (804) 366-1050 Email: mmwhipple@erols.com	30-June-2024

Virginia State Board of Health Public Participation Policy

The Board of Health (Board) encourages public participation in the performance of its duties and responsibilities. To assure that public comment submitted to the Board is properly processed and to assure that all Board actions are made in compliance with the Administrative Process Act, the Board hereby adopts this Public Participation Policy.

A. Public Comments at Board of Health Meetings

These procedures establish the times for the public to provide appropriate comment to the Board for its consideration. In light of these established procedures, the Board accepts public comment on regulatory actions, as well as general comments, at Board meetings.

The Board schedules a public comment period at the beginning of each regular meeting to provide an opportunity for citizens to address the Board. Anyone wishing to speak to the Board during this time should, at the beginning of the Board meeting, indicate his or her desire on the sign-in sheet. Presentations during the Public Forum shall not exceed two minutes per person. The public comment period shall be no more than twenty minutes.

The Board reserves the right to alter the time limitations set forth above without notice and to ensure that comments presented at the meeting conform to this policy.

B. Public Comment submitted to the Board of Health outside of Board of Health Meetings

1. Any member of the public may submit comments concerning pending non-emergency, non-exempt regulatory actions to the Virginia Regulatory Town Hall at www.townhall.virginia.gov.
2. In accordance with the provisions of the Board's Public Participation Guidelines governing public comment (12VAC5-11-50), any member of the public may submit written comments concerning pending non-emergency, non-exempt regulatory actions directly to the Board of Health, care of the Department of Health:
 - in writing to 109 Governor Street, Richmond Virginia 23219,
 - by fax at 804-864-7022, or
 - via email at healthcommissioner@vdh.virginia.gov.

The Board of Health shall accept public comments in writing after the publication of a regulatory action in the Virginia Register of Regulations as follows:

- i. For a minimum of 30 calendar days following the publication of the notice of intended regulatory action.

- ii. For a minimum of 60 calendar days following the publication of a proposed regulation.
- iii. For a minimum of 30 calendar days following the publication of a repropoed regulation.
- iv. For a minimum of 30 calendar days following the publication of a final adopted regulation.
- v. For a minimum of 30 calendar days following the publication of a fast-track regulation.
- vi. For a minimum of 21 calendar days following the publication of a notice of periodic review.
- vii. Not later than 21 calendar days following the publication of a petition for rulemaking.

The Board of Health may determine if any of the comment periods listed in this subsection shall be extended.

3. Whenever a Board member receives written or verbal comment pertaining to the Department of Health's programs or personnel, such as comments or complaints about the implementation of specific health programs, or actions of agency staff, he or she should decline to make a substantive response and should refer the comment to the [Commissioner/ or other agency designee] for appropriate review and handling. A Board member may, in the alternative, inform the author of the public comment that it should be directed to the appropriate agency staff. Comments received through the Town Hall or the above-specified methods will be summarized for the Board and considered by the Board when making a decision on regulatory action.

Adopted October 23, 2003
Revised December 14, 2012

Overview of Robert's Rules of Order

Following presentation by staff of each regulatory action item, the Chair will ask for a motion to adopt the regulatory action item. Upon receiving a second, the Chair will ask if there is any discussion concerning the motion. At that point, the regulatory action item will then be in the proper posture to be discussed and considered by the Board. It will also be in the proper posture at that point for any Board member to offer amendments to regulatory language.

Each Board member who wishes to participate in the discussion of any of the regulatory action items needs to first be recognized by the Chair prior to speaking. If you wish to be recognized, simply raise your hand. The Chair has the discretion to ask a member the purpose for which they wish to be recognized and if, in the Chair's opinion, such purpose is not germane to the current discussion, could cause confusion, or interfere with the efficient and orderly operation of the Board, the Chair may choose to delay recognition of the member until after the current discussion or item before the Board is completed.

If any Board member wishes to offer an amendment to any regulatory action items, the amendment needs to be offered in the form of a motion. In making that motion, the member needs to state to the Board the language change or changes that they are proposing to the regulatory text. If that motion receives a second from another Board member, the Board will discuss and subsequently vote on the motion.

If, upon hearing the proposed PRIMARY amendment, another Board member desires to further amend that amendment, that member must make a SECONDARY AMENDMENT in the form of a motion, which also must receive a second.

Upon receiving a second, the Board will discuss, and then vote on the SECONDARY AMENDMENT prior to voting on the PRIMARY amendment. If the amendment(s) is(are) adopted, they will be added to the main motion and the Board will move on to the next amendment and repeat the process. Please note that a secondary amendment that is worded such that it completely negates the primary amendment's meaning can get confusing, but if it is adopted, it will be attached to the main motion directly.

According to Robert's Rules, there can only be one secondary amendment offered. There can be no "amendment to the amendment to the amendment".

Board members may provide VDH with written copies of proposed amendments prior to the Board meeting, which will be included in the back of the Board notebooks. Board members may also bring written copies of proposed amendments with them to the meeting which will be photocopied by VDH staff and distributed to the Board prior to consideration. If any Board member wishes to make amendments but has not yet reduced them to writing, VDH will be able to type the proposed amendment into the computer and the proposed amendment language will be displayed on the screen for the Board's consideration prior to voting on the motion. The Chair will ask VDH staff to read the draft amendment aloud. Once the member is satisfied that the amendment has been correctly stated, the Chair will ask the member to offer the amendment in the form of a motion.

The Board must vote on any individual amendments and on the regulatory action as a whole. Votes can be taken via a voice vote with a simultaneous show of hands or a roll call vote. All votes are recorded as part of the official Board meeting minutes.

Robert's Rules provides that any member can make a motion to "call the previous question", or "call for the question". If that motion is seconded, it is not debatable; hence the Board will proceed with the vote on the motion to call the question. If it is agreed to by two-thirds majority of the members, discussion of the pending motion (for example, an amendment that is under consideration) will end and the Board will immediately vote on the motion. If the motion to call the previous question does not receive a two-thirds majority of the votes cast, the discussion will continue.

Finally, please note that under Robert's Rules, a motion must receive a majority vote among the members present and voting in order to be approved. If a motion receives a tie vote, the motion is rejected and does not pass.