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

Call to Order and Welcome	Lee Jones, DMD Nominating Committee Chair
Nomination of Officers	Nominating Committee Members
Adjourn	

State of Board of Health
Agenda
June 13, 2024 – 9:30 a.m.
Norfolk State University

Call to Order	Gary Critzer, Chair
Introductions	Mr. Critzer
Welcoming Remarks	Norfolk and Norfolk State University Leadership
Review of Agenda	Alexandra Jansson, MPP Sr. Policy Analyst
Approval of April 10, 2024 Minutes	Mr. Critzer
Commissioner's Report	Karen Shelton, MD State Health Commissioner
Regulatory Action Update	John Kotyk Legislative and Regulatory Coordinator
Public Comment Period	
Break	
<u>Lunch Presentation</u> Community Health Needs Assessments	Susan Girois, MD, MPH, FACP Director, Norfolk Health District Caitlin S. Pedati MD, MPH, FAAP Director, Virginia Beach Health District

	Felicia Mebane, PhD, MSPH Director of the Center for Public Health Initiatives and Associate Dean at the Joint School of Public Health
<u>Regulatory Action Items</u> Regulations Governing Durable Do Not Resuscitate Orders 12VAC5-66 (Fast Track Amendments)	Rachel Stradling Acting Director Office of Emergency Medical Services
Virginia's Rules and Regulations Governing Cooperative Agreements 12VAC5-221 (Fast Track Amendments)	Kim Beazley Director Office of Licensure and Certification
<u>Non-Regulatory Action Items</u> EMS State Plan: Interim Plan	Ms. Stradling
Electronic Meeting Policy	Ms. Jansson
Report of Nominating Committee	Dr. Jones
Other Business	
Adjourn	

MINUTES FROM APRIL 10, 2024

State Board of Health
April 10, 2024 - 9:00am
Perimeter Center, Boardroom 2

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

Members Absent: Elizabeth Ruffin Harrison; Patricia Kinser, PhD., Vice Chair; Maribel Ramos; and Stacey Swartz, PharmD.

Virginia Department of Health (VDH) Staff Present: Seth Austin, Director, Office of Vital Records; Brianna Bill, VDH Agency Star; Michael Capps, Senior Policy Analyst; Susan Fischer Davis, Chief Deputy Commissioner for Community Health Services; Tiffany Ford, Deputy Commissioner for Administration; Stephanie Gilliam, Deputy Director for Budget, Office of Financial Management; Julie Henderson, Director, Office of Environmental Health Services; Joe Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs; Alexandra Jansson, Senior Policy Analyst; John Kotyk, Legislative and Regulatory Coordinator; VDH Agency Star, Cathy Peppers, Executive Assistant; Maria Reppas, Director, Office of Communications; John Ringer, Director, Public Health Planning and Evaluation; Karen Shelton, State Health Commissioner; and Rachel Stradling, Acting Deputy Commissioner for Population Health and Preparedness.

Other Staff Present: Adam Hade, Assistant Attorney General; Dara Hechter, Health and Human Resources Fellow; Darrell W. Kuntz III, Assistant Attorney General; Robin Kurz, Senior Assistant Attorney General; and Allyson Tysinger, Senior Assistant Attorney General/Section Chief.

Call to Order
Mr. Critzer called the meeting to order at 9:08 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.

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

Approval of December 15, 2023, Minutes
The minutes from the December 15 meeting were reviewed. Dr. Jones made a motion to approve the minutes, seconded by Dr. Vaughters. The motion passed unanimously by voice vote.

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

- Agency Stars

- New VDH Personnel Welcome and Introductions
- Communicable Disease Update
- Workforce Development
- Accreditation Updates
- Naloxone Distribution Program
- Highlight: Maternal Health Roundtable
- Joint Commission on Healthcare (JCHC) Studies
- Joint Legislative and Audit Review Commission (JLARC) Study
- Internship Academy Look Ahead

There was discussion regarding the outreach to targeted groups for communicable diseases, workforce issues and the maternal health roundtable and initiatives.

Regulatory Action Update

Mr. Capps reviewed the summary of all pending VDH regulatory actions.
There are 51 pending actions under development:

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

Since the December 2023 Board Meeting, the Commissioner approved seven regulatory actions on behalf of the Board while the Board was not in session. They were all results of a periodic review:

- *Disease Reporting and Control Regulations (12VAC5-90)* where the recommendation was to amend the regulations to conform the language to the Code of Virginia and the Virginia Registrar of Regulations' *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code ("Style Guide"),* reflect the best available scientific evidence and recommendations, and reduce regulatory burden where possible.
- *Rabies Regulations (12VAC5-105)* where the recommendation was to amend the regulations to conform the language to Chapter 121 of the 2023 Acts of Assembly and to the *Style Guide,* reflect current best practice, and reduce regulatory burden where possible.
- *Virginia Immunization Information System (12VAC5-115)* where the recommendation was to amend the regulations to conform the language to the *Style Guide*, update processes and forms, and reduce regulatory burden where possible.
- *Regulations Governing Cooperative Agreements (12VAC5-221)* where the recommendation was to amend the regulations to conform the language to the *Style Guide,* address public comment, and reduce regulatory burden where possible.
- *Regulations for Alternative Onsite Sewage Systems (12VAC5-613)* where the recommendation was to amend the regulations to conform the language to the *Style Guide,* reflect updates in science and technology, current industry best practices, public feedback, and to reduce regulatory burden where possible.
- *Alternative Discharging Sewage Treatment Regulations for Individual Single-Family*

Dwellings (12VAC5-640) where the recommendation was to retain the regulations as is.
- *Schedule of Civil Penalties (12VAC5-650)* where the recommendation was to retain the regulations as is.

Since the December 2023 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 15 periodic reviews in progress:
- 12 VAC 5-67 Advance Health Care Directive Registry
- 12 VAC 5-125 Regulations for Bedding and Upholstered Furniture Inspection Program
- 12 VAC 5-215 Rules and Regulations Governing Health Data Reporting
- 12 VAC 5-216 Methodology to Measure Efficiency and Productivity of Health Care Institutions
- 12 VAC 5-217 Regulations of the Patient Level Data System
- 12 VAC 5-220 Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations
- 12 VAC 5-371 Regulations for the Licensure for Nursing Facilities
- 12 VAC 5-381 Home Care Organization Regulations
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- 12 VAC 5-407 Regulations for the Submission of Health Maintenance Organization Quality of Care Performance Information
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- 12 VAC 5-520 Regulations Governing the State Dental Scholarship
- 12 VAC 5-545 Guidelines for the Nurse Educator Scholarship
- 12 VAC 5-590 Waterworks Regulations
- 12 VAC 5-620 Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells

Public Comment Period

There were 15 people signed up for the public comment period. 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 10 minutes was made by Dr. Puritz, seconded by Dr. Jeng. The motion was approved by unanimous vote.

Pamela Burnham, Julie Cumming, Tom Jeffries, Doris Knick, Sharon Landrum, and Carol Sargeant spoke regarding the health effects of non-ionizing radiation from Smart Meters. Sheila Furay, Lori Leonard, and Kathy Stevens spoke regarding COVID-19 vaccines. Appreciation and support for the proposed amendments to the Regulations for Summer Camps was expressed during the comment period by Maile Armstrong, Ann Warner, Gareth Kalfas, and Anthony Gomez. Support for the Rainwater Harvesting Regulations was made by Tyrone Jarvis. Human trafficking was commented on by Mary Ottinot, RN, BSN.

Additional written comments can be found at the end of the minutes document.

Travel Preparations

Ms. Jansson shared the process for reimbursement with the Board in preparation for the June 2024 meeting. She shared that the hotel and meeting spaces were still being finalized, but more information would be shared with the Board as it became available.

Mr. Hilbert highlighted the potential agenda which included visiting the Norfolk Vector Control Operations Center and the Virginia Beach Human Resource Center on June 12th and the Board's business meeting on June 13th at Norfolk State University.

There was discussion around what time the educational tours on the 12th would begin and when Board members should arrive.

Fast Track Amendments to Regulations Governing Vital Records 12VAC 5-550

Mr. Austin presented the Fast Track Amendments to the Regulations Governing Vital Records. The amendments update language so that the public and government organizations have better direction concerning the responsibilities and requirements needed to perform their duties.

The amendments should reduce the challenges faced by the public when determining how to register a vital event or request a copy of a vital record, will make the operations of the Office of Vital Records more transparent, and will improve clarity and readability to the regulations by conforming to the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code* published by the Virginia Registrar of Regulations.

There was discussion regarding who owns the records and has access, particularly related to persons who may have protective orders; why certain fields like education are collected, and correcting minor typos.

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

Proposed Amendments to Regulations for Summer Camps 12VAC5-440

Ms. Henderson presented the proposed amendments to the Regulations for Summer Camps. The Board of Health promulgated the Regulations for Summer Camps in or before 1950; there have been no known amendments since the initial promulgation. Since the 1950's there have been substantial changes to camp design, operation, and public health and safety standards. Over the past 70 years, the overnight summer camp industry has evolved, establishing national standards and voluntary certification from accreditation organizations, including the American Camps Association and Boy Scouts of America. Not every overnight summer camp in Virginia is accredited or part of a national organization. Inconsistency in camp operations throughout the Commonwealth and varying levels of participation in accreditation or adherence to national standards supports the need for statewide regulations that establish minimal health and safety provisions for overnight summer camp operations.

The VDH Office of Environmental Health Services and a stakeholder workgroup of over 40 industry representatives, collectively drafted, edited, and recommended the proposed amendments to the Regulations for Summer Camps. As part of the agency's efforts to clarify and

improve the readability and understanding of the Regulations, VDH also addressed the establishment of and consistent use of defined terms and the style and formatting of regulatory content. The goal of the amendments are to collectively establish up-to-date basic health and safety standards for overnight summer camps. In addition, the agency proposes to rename the title of the regulations and definition of a summer camp to "Resident Camp" to reflect the overnight component rather than a seasonal assumption, as some overnight camps operate beyond the summer season. Henceforth the regulations are referred to as the "Regulations for Resident Camps." Further, the effort seeks to amend and clarify the vague regulatory language and content that contributes to inconsistencies in interpretation and the enforcement of the regulation across the Commonwealth.

There was discussion regarding how many people per year go through resident camps and security concerns regarding medical records that may be stored at the camp.

A motion to approve the proposed amendments was made by Dr. Jeng with Dr. Jones seconding. The motion passed by unanimous voice vote.

Final Promulgation for the Rainwater Harvesting System Regulations 12VAC5-635

Ms. Henderson presented the final Rainwater Harvesting System Regulations. These are new regulations to provide standards for the use of rainwater harvesting systems, including systems that collect rainwater for human consumption.

Water used for human consumption in Virginia is currently provided from permitted waterworks and from private wells; both programs are regulated by VDH. However, a demand for another source of water supply exists where public source and groundwater availability is limited. For example, groundwater limitations may occur as (i) a result of natural scarcity or contamination, or (ii) in coastal areas under threat of inundation or saltwater intrusion. In addition, rainwater harvesting is an emerging technology with early adopters having interest in natural resource protection. The Uniform State Building Code relies upon VDH to provide water quality standards, including treatment standards for non-potable applications. The Regulations will allow VDH to provide assurance to building officials that rainwater harvesting systems applicable to both potable and non-potable use are protective of public health.

To ensure systems installed pursuant to the Regulations are protective of human health, and that the Regulations are not unduly burdensome, rainwater harvesting systems are divided into four end tier uses. The highest end tier use – potable water – requires the greatest level of treatment and oversight. The specified end use will determine the minimum design, construction, and ongoing operation and maintenance standards for each system. VDH will require permits to construct and operate a rainwater harvesting system for potable use. Non-potable systems will be documented in a registry but will not be subject to permitting by VDH.

There was discussion regarding regulations pertaining to private well testing.

Dr. Vaughters made a motion to approve the regulations with Dr. Jeng seconding. The motion passed by unanimous voice vote.

Fast Track Amendments to the Food Regulations 12VAC5-421

Ms. Henderson presented the Fast Track Amendments to the Food Regulations to the Board. The Food Regulations establish minimum sanitary standards for the operation of the Commonwealth's food establishments, which include traditional restaurants, mobile food units, temporary food vendors, hospital and nursing facility food service, and school food service. This action is limited to three items: the requirements for who can preside over an informal conference or proceeding, the allowance for the presiding officer to release impounded food after an informal conference, and the removal of a Document Included by Reference which has no corresponding reference in the text of the regulation.

Mr. Daniels made a motion to approve the amendments with Dr. Jeng seconding. The motion passed by unanimous voice vote.

Board of Health Annual Report

Dr. Vanessa Walker-Harris, Director for the Office of Family Health Services, presented the Annual Report to the Board. The Annual Report contains and overview of the Commonwealth's health-related data in these major categories:

- Demographics
- Income
- Housing
- Education
- Access
- Provider Availability
- Food Access
- Immunizations
- Mortality

Additionally, the report discusses data and initiatives related to:

- Heart disease
- Maternal and Infant Mortality
- Cancer
- HIV and Sexually Transmitted Infections
- Suicide
- Substance Use and Drug Overdoses

There was also information shared on the work being done related to increasing access to data for communities.

There was discussion regarding the need for measurable data to be included in the report, initiatives surrounding substance use, veteran suicide, and pediatric workforce.

Dr. Puritz made a motion to approve the Annual Report with Mr. Desjadon seconding. The motion passed by unanimous voice vote.

2024 General Assembly Legislative Update

Ms. Jansson provided the Board with an overview of the recent General Assembly session.

She shared that VDH will have a number of new reports, regulatory actions, and programs. Ms. Jansson highlighted bills in the following areas:

- Maternal Health
- Prescription Drugs
- Hospitals
- Opioid related
- Inherited and Communicable Conditions

Ms. Jansson also highlighted several bills that did not fit into the above categories. The General Assembly will reconvene on April 17 to consider the Governor's recommended amendments and vetoes.

There was discussion around the legislation regarding sickle cell screenings, factors in how lead agencies for bills are determined, and

2024 General Assembly Budget Update

Ms. Gilliam provided the Board with an overview of the VDH budget based on the actions of the 2024 General Assembly Session. Ms. Gilliam noted that the budget was not final and was subject to change following the April 17 reconvened Session. She highlighted changes from the introduced budget by the General Assembly and then further amendments from Governor Youngkin.

Key highlights included overviews of budget amendments by office and pass throughs, amendments for legislation that was vetoed, that the budget would go above $1 billion for the first time, and salary adjustments for staff.

There was discussion around the funding for the Behavioral Health Loan Repayment Program.

Appointment of Nominating Committee

Mr. Critzer appointed Dr. Jones, Ms. Green, and Ms. Harrison to the nominating committee. The nominating committee will meet in June prior to the Board meeting to recommend a slate of officers for the Board.

Other Business

There was no additional business before the Board.

Adjourn

The meeting adjourned at 2:24pm.

The remainder of the document is written comment submitted at the Board meeting. It may not reflect the position or opinions of the Board or members.

VAMFA speech 04102024, VA Board of Health meeting
Lori D. Leonard

Dr. Thorp's Handout and Questions on X, 3 April 2024 @ 1146P.M.

I quote, "The (Virginia) State Board of Health exists…to promote and protect the health of all Virginians". "Improvement of Virginia's public health infrastructure and improvement in the health and well-being of all Virginians" are listed as priority issues of the Board. (Virginia Board of Health website: https://www.vdh.virginia.gov/commissioner/board-of-health/mission-roles-priorities-and-functions/)

I have given you two handouts today. One is a pamphlet about vaccination harms published by the Weston A. Price Foundation. I draw your attention to the other handout now, which is copied from Dr. James Thorp's message on X, April 3, 2024. Dr. Thorp is boarded by the American Board of Obstetrics & Gynecology and has been in practice for over 44 years. He is a maternal-fetal medicine specialist in Illinois.

Dr. Thorp asked questions related to this handout, and Pfizer's Phase 2/3 trial. Two places in Virginia were sites for this trial—The Group for Women, and Tidewater Physicians for Women, both in Norfolk VA.

Refer to your handout as I repeat Dr. Thorp's questions:

- "As a healthcare professional, scientist, researcher, or physician what does this data tell YOU from the Pfizer Phase 2/3 clinical trial?
- If you were a pregnant woman and your Obstetrician showed you this data would you have agreed to take the Covid 19 vaccine in pregnancy?
- Why were the patients in the placebo group subsequently vaccinated?
- Do you think that this clinical trial was adequately powered?
- Why was this submitted 18 months after the vaccine rollout?
- Given the grossly underpowered Pfizer Phase 2/3 clinical trial, had this clinical trial been completed what do you think the results would have shown?"

I ask the Board: what is your response to these questions? Will you continue to ignore what "we" have presented to you over many months? Are you going to put more Virginia babies and moms at risk of deformities, disability, miscarriage, and death? You are responsible for this destruction of human health.

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PAGES

THE LARGEST UNETHICAL MEDICAL EXPERIMENT IN HUMAN HISTORY

Ronald N. Kostoff, Ph.D.

Research Affiliate, School of Public Policy, Georgia Institute of Technology

KEYWORDS

Unethical Research; Electromagnetic Fields; Wireless Radiation; Radiofrequency Radiation; RF; Non-Ionizing Radiation; Mobile Networking Technology; 5G; Adverse Health Effects

ABSTRACT

This monograph describes the largest unethical medical experiment in human history: the implementation and operation of non-ionizing non-visible EMF radiation (hereafter called wireless radiation) infrastructure for communications, surveillance, weaponry, and other applications. It is unethical because it violates the key ethical medical experiment requirement for "informed consent" by the overwhelming majority of the participants.

The monograph provides background on unethical medical research/experimentation, and frames the implementation of wireless radiation within that context. The monograph then identifies a wide spectrum of adverse effects of wireless radiation as reported in the premier biomedical literature for over seven decades. Even though many of these reported adverse effects are extremely severe, the ***true extent of their severity has been grossly underestimated***.

Most of the reported laboratory experiments that produced these effects are not reflective of the real-life environment in which wireless radiation operates. Many experiments do not include pulsing and modulation of the carrier signal, and most do not account for synergistic effects of other toxic stimuli acting in concert with the wireless radiation. These two additions ***greatly exacerbate the severity of the adverse effects from wireless radiation***, and their neglect in current (and past) experimentation results in substantial under-estimation of the breadth and severity of adverse effects to be expected in a real-life situation. This lack of credible safety testing, combined with depriving the public of the opportunity to provide informed consent, contextualizes the wireless radiation infrastructure operation as an unethical medical experiment.

Addition of the nascent fifth generation of mobile networking technology (5G) globally to the existing mobile technology network will contribute further to the largest unethical medical experiment in human history!

This monograph consists of four chapters and eight appendices. Chapter 1 focuses on unethical research, showing how wireless radiation infrastructure implementation fits into the

REFERENCE MATERIAL FROM TOM JEFFRIES' PUBLIC COMMENTS

framework of unethical medical experimentation, and providing many examples of other types of unethical medical experimentation.

Chapter 2 is the main technical chapter, focusing on adverse health effects of wireless radiation. It describes:

- adverse effects from past research, and what additional adverse effects can be expected when 5G is implemented fully
- lack of full consensus among key stakeholders on adverse effects from wireless radiation, and the role played by conflicts-of-interest in this lack of consensus
- the main reason that this unethical medical experiment was allowed to take place:

The Federal government that ***promotes*** accelerated implementation of wireless radiation technology also 1) ***sponsors*** research examining the technology's potential adverse effects and 2) ***regulates*** the technology's potentially adverse impacts on the public. This unethical promotion-sponsorship-regulation conflict-of-interest lays the groundwork for unethical medical experimentation!

Chapter 3 contains the references for the main text, and Chapter 4 contains the eight appendices.

Appendix 1 presents more details about unethical medical experiments, including examples and many references for further study.

Appendix 2 contains a manual taxonomy of a representative adverse EMF effects database; Appendix 3 contains a factor analysis taxonomy of the same database; and, Appendix 4 contains a text clustering taxonomy of the same database. All three taxonomies contain links between the categories in the summary tables and the titles of papers associated with each category.

Appendix 5 shows the ***potential contribution of wireless radiation to the opioid crisis*** and ***potential contribution of wireless radiation to exacerbation of the coronavirus pandemic***.

Appendix 6 shows the ***link between funding source and research outcomes***, and presents many references on the topic of funding source-driven bias.

Appendix 7 describes the under-recognized adverse effects of wireless radiation related to ***medical implants*** (pacemakers, defibrillators, cochlear implants, dental implants, bone pins, etc) and metal appendages (metal jewelry, etc), and potential ***micro/nano***-implant analogues.

Appendix 8 shows ***adverse effects of wireless radiation on automotive vehicle occupants*** (and bystanders), and the under-advertised on-board and external sources of this radiation.

CITATION TO MONOGRAPH

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PREFACE

Humanity is racing along two parallel paths to self-destruction: 1) accelerating irreversible climate change, and 2) rapidly increasing exposure to health and life-threatening mixtures of toxic stimuli. The most ubiquitous constituent of these toxic mixtures is wireless radiation, which is proceeding to blanket humanity and its ecological life support chain.

A small fraction of the population has given informed consent to wireless radiation exposure, gambling (like users of cigarettes, cocaine, fentanyl) that they can escape the severe adverse consequences of exposure. Another small fraction of the population has not given informed consent, but receives harmful second-hand exposure because of the broad-scale transmission of wireless radiation from terrestrial and satellite sources. The vast majority of the population has given ***Mis***-informed Consent to this exposure. This ***mis***-information is supplied by the telecommunications industry, its lobbyists, its government partners, its political enablers, its marketing arm (the mainstream media), and even some academic enablers.

While research over the past seventy+ years has shown hard evidence of severe adverse effects from wireless radiation, the full extent of the damage from existing wireless radiation infrastructure is not known, much less the damage expected from 4G/5G infrastructure being implemented rapidly today. Attempting to identify the full extent of these adverse effects is the global medical experiment being conducted today. The fact that this experiment is being conducted with ***mis***-informed consent makes it an unethical medical experiment. Because of the magnitude of this experiment, it is the *largest unethical medical experiment in human history!*

Chapter 1 of this monograph presents the case for wireless radiation infrastructure implementation without credible safety testing being not only an unethical medical experiment, but the largest in human history. It presents wireless radiation infrastructure implementation in the context of other recent examples of unethical medical experiments, and shows how these others pale in comparison to the projected suffering and lethality from wireless radiation exposure based on even the incomplete biomedical data gathered to date.

Chapter 2 is the main technical chapter in this monograph. It covers a broad scope of adverse health and life-supporting ecological effects from wireless radiation, mainly at communications frequencies. Some of these adverse effects are not well-known to the general public, but they are important nevertheless. While the majority of the chapter is technical, its initial section provides the context for evaluating the biomedical literature results. In particular, it emphasizes the conflicts-of-interest operable in all aspects of the wireless radiation biomedical research process, ranging from the initial health-effects research sponsorship to the final research results dissemination in the premier technical literature and other forums. As Chapter 2 shows, we have known about the adverse health and ecological effects of wireless radiation exposure for seventy+ years, but decision-makers of all stripes have nevertheless chosen to impose this health and life-threatening toxic stimulus on an unsuspecting global populace.

Additionally, there are eight appendices. The copious material contained in the appendices supports the statements made in the main text (Chapters 1 and 2). Three sub-appendices, while grounded in hard evidence, are somewhat more hypothetical than the rest. They include 1) linkages between wireless radiation exposure and exacerbation of the opioid crisis and the coronavirus pandemic, and 2) potentially enhanced heating and temperature increases to thermally-damaging levels from short RF pulses and tissue-imbedded nanoparticles. My purpose in presenting these three more hypothetical sub-appendices is to stimulate more discussion, and especially more research, on the nature and validity of these linkages.

Finally, it is my hope that this monograph receives the widest distribution, especially among those who have 1) been the targets of this decades-long mis-information campaign and 2) given their consent to wireless radiation exposure based upon mis-information. It is this segment of the public whose informed actions could reverse the increasing implementation of wireless radiation infrastructure, and prevent the infliction of even more damage, since the other stakeholders involved in the promotion of wireless radiation infrastructure have shown little desire to protect the public against the known and projected ravages of wireless radiation.

Ronald N. Kostoff, Gainesville, VA, 15 February 2020

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AUTHOR BIO

RONALD KOSTOFF - RESEARCH AFFILIATE - GEORGIA INSTITUTE OF TECHNOLOGY

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EXECUTIVE SUMMARY

ES-1. Overview

We are in the midst of the largest unethical medical experiment in human history. This experiment is the implementation and operation of a global wireless network for communications, surveillance, and other purposes. It is a ***medical experiment*** because we do not know the full extent of the adverse health effects that will result from this wireless network implementation and operation. It is an ***unethical*** medical experiment because it violates the key ethical medical experiment requirement of ***'informed consent'*** from the participants.

Even though the adverse health effects of wireless radiation reported over the past seventy+ years span the range of severity from discomfort to lethality, we do not know the full extent of adverse health effects from this technology because:

Most laboratory experiments aimed at identifying wireless radiation health effects bear no relation to real-life exposures, and are performed under the most benign conditions of

- single stressors (wireless radiation only)
- no pulsing and modulation of the carrier signal
- no synergistic effects of other toxic stimuli acting in concert with the wireless radiation

These experimental deficiencies are compounded by

- lack of access to the global classified literature on adverse health effects from wireless radiation
- lack of knowledge of proprietary basic and advanced studies on adverse health effects from wireless radiation.

The adverse wireless radiation health effects that have been identified already from the incomplete literature openly available are massive in scope and magnitude. They support the conclusion that ***wireless radiation as already implemented is extremely dangerous to human health***. It acts as both a ***promoter/accelerator*** and ***initiator*** of adverse health effects. Addition of the missing elements described above and more wireless radiation infrastructure will exacerbate further the adverse effects from wireless radiation on

- human health directly through contribution to chronic disease and
- human health indirectly through degradation of the food chain ecosystem.

ES-2. Adverse Impacts of Wireless Radiation on the Most Vulnerable Members of Society

In the spirit of the 'unethical' medical experiments described in this monograph,

it is the poor and dispossessed who will suffer the most from wireless radiation exposure.

This is because wireless radiation plays a dual role of ***initiator*** and ***promoter/accelerator*** of serious disease. In its ***promoter/accelerator*** role, it can accelerate the progression of existing serious diseases such as cancer, and/or, through synergy, can produce serious adverse health effects when combined with other toxic stimuli that neither constituent of the combination could produce in isolation.

Many toxic stimuli, such as harsh chemicals, biotoxins, ionizing radiation sources, vibrating machinery, prolonged sitting doing repetitive tasks, high air pollution, etc, are used/experienced by the poorest members of society in their occupations, and many toxic stimuli, such as air pollutants, toxic wastes, etc, are very prevalent in their residential environments. Thus, people who spray pesticides in farm labor or household applications, people who do cleaning with harsh chemicals, people who dispose of hazardous materials, basically, ***people who do the dirty work in our society and live in dirty environments***, are already leading candidates for higher risk of serious diseases. Adding a wireless radiation ***promoter/accelerator*** to their residential and occupational environments will radically increase their chances for developing serious diseases. Closing the 'digital divide' for them will translate to increased suffering and reduced longevity!

ES-3. Role of Conflicts-of-Interest in the Sponsorship, Conduct, and Dissemination of Wireless Radiation Research

The results shown in the literature cannot be separated from the context in which this research has been sponsored, conducted, and disseminated!

In the USA (and in most, if not all, countries), the two major sponsors of wireless radiation health and safety research are the Federal government and the wireless radiation industry, in that order. Both of these organizations have a strong intrinsic conflict-of-interest with respect to wireless radiation.

The Federal government is a strong promoter of wireless radiation infrastructure development and rapid expansion, most recently supporting accelerated implementation of 5G infrastructure.

The Federal government that ***promotes*** accelerated implementation of wireless radiation technology also 1) ***sponsors*** research examining the technology's potential adverse effects and 2) ***regulates*** the technology's potentially adverse impacts on the public. The fact that these development, regulation, and safety functions may be assigned to different Executive Agencies within the Federal government is irrelevant from an independence perspective. ***The separate Executive Agencies in the Federal government are like the tentacles of an Octopus; they operate synchronously under one central command.***

The wireless promoters' main objectives of developing and implementing the technology rapidly are enabled by suppressing knowledge (to the public) of potential adverse effects from the technology's operation. These fundamental conflicts impact the objectivity of the health and safety R&D sponsors and performers. Any ***Federal research sponsor*** of wireless radiation technology safety would be highly conflicted between 1) a desire to satisfy Executive and Legislative objectives of accelerating expansion of wireless radiation technology and implementation and 2) sponsoring objective research focused on identifying and reporting adverse effects of wireless radiation expected under real-life conditions. Likewise, any ***sponsored research performer*** addressing wireless radiation technology safety would be highly conflicted between 1) reporting the actual adverse effects expected under real-life conditions and 2) the desire to satisfy wireless radiation promotional objectives of the research sponsors in order to maintain long-range funding.

ES-4. Adverse Health Effects from Wireless Radiation Exposure.

In aggregate, for the high frequency (radiofrequency-RF) part of the spectrum, expert reviews show that RF radiation below the FCC (Federal Communications Commission) exposure guidelines can result in:

-carcinogenicity (brain tumors/glioma, breast cancer, acoustic neuromas, leukemia, parotid gland tumors),

-genotoxicity (DNA damage, DNA repair inhibition, chromatin structure),

-mutagenicity, teratogenicity,

-neurodegenerative diseases (Alzheimer's Disease, Amyotrophic Lateral Sclerosis),

-neurobehavioral problems, autism,

-reproductive problems, pregnancy outcomes,

-oxidative stress, inflammation, apoptosis, blood-brain barrier disruption,

-pineal gland/melatonin production, sleep disturbance, headache,

-irritability, fatigue, concentration difficulties, depression, dizziness, tinnitus,

-burning and flushed skin, digestive disturbance, tremor, cardiac irregularities, and can

-adversely impact the neural, circulatory, immune, endocrine, and skeletal systems.

The effects range from myriad feelings of discomfort to life-threatening diseases. From this perspective, RF exposure is a highly pervasive cause of disease!

ES-5. Adverse Impacts of Wireless Radiation on the Food Chain

The struggle for survival of human life on Earth is dependent on the logistical food supply chain. At the foundation of this supply chain (before the farmers become involved in harvesting its bounty) are the insects, seeds, flora, trees, etc, that enable the bountiful growth of the myriad potential foods. If the integrity of this foundational logistical supply chain is threatened in any way, then both the animals and plant products we consume become unavailable.

There is a substantial literature on the adverse impacts of wireless radiation on this foundational logistical supply chain. These adverse effects are from the pre-5G wireless radiation exposures, and would include enhanced coupling from the higher frequency harmonics of the RF signal. Many of these supply chain elements (e.g., insects, seeds, larvae, etc) are very small, and we could expect enhanced resonance/energy coupling with the shorter-wavelength 5G radiation when implemented. This indirect impact of wireless radiation may turn out to be at least as (if not more) important as the direct impact of wireless radiation on human survival!

From a broader perspective, most of the laboratory experiment component of the wireless radiation adverse effects literature can be viewed as related to the foundational food supply chain. Much of this research is focused on mice, rats, insects, small birds, small fish, etc. These species tend to be prey of larger animals/fowl/fish, and eventually make their way to the human food table. Any environmental factor that affects the health of these species adversely will eventually impact the humans who are at the end of that chain. In reality, we have accumulated a massive literature describing the adverse impacts of wireless radiation on myriad contributing components to our food supply, and the results do not bode well for our future ability to feed the growing world's population!

ES-6. Adverse Impacts of Wireless Radiation on Medical and Non-Medical Implants

There were two major types of medical implants covered by the database articles showing adverse effects: active implants that produced electrical signals mainly for controlling heart irregularities (e.g., pacemakers, defibrillators) and hearing deficiencies (e.g., cochlear implants), and passive metallic implants for structural support (e.g., dental implants, bone pins, plates, etc). Additionally, there are articles addressing adverse effects from wireless radiation in the vicinity of metallic appendages (e.g., metallic eyeglasses, metallic jewelry, etc).

The external EMF (electromagnetic fields) from microwaves (and other sources) could 1) impact the electrical operation of the active medical implants adversely, 2) increase the Specific Absorption Rate (SAR) values of tissue in the vicinity of the passive implants substantially because of resonance effects, and 3) increase the flow and acidity of saliva in the vicinity of dental structures. While the EMF effects on the cochlear implants could adversely affect auditory capability, EMF effects on the heart-related implants could potentially be life-threatening. The increased SAR values around the passive metal implants could result in increased tissue temperatures, and could adversely impact integration and longevity of the passive metallic implants.

In the mouth, the combination of 1) increased tissue temperatures in proximity to the implant or other orthodontic structures and 2) increased flow rate and acidity of saliva could lead to 3) increased leaching of heavy metals (a known contributor to serious diseases). This also raises the question: what other adverse health effects from the exposure of both the active and passive implants to increasing levels of wireless radiation have not been identified or addressed?

There is a third class of structures whose interaction physics with RF are related to those of the passive implants. These are termed implant analogues, and include myriad exogenous particles (mainly nanoparticles) that penetrate, and imbed in, the skin. The resultant nanoparticle-imbedded tissues have the potential for increased energy absorption from the incoming RF signal, thereby resulting in potentially increased thermal damage over and above the thermal damage resulting from the pulsed high-peak-to-average power of the RF signal. Additionally, more research needs to be done to ascertain the magnitudes of these thermal transients and associated stresses, in order to estimate the levels of enhanced potential damage from RF radiation.

ES-7. Studies in the USSR on Wireless Radiation Health Effects

Much research examining potential adverse effects from wireless radiation, especially in the athermal parameter range, was performed in the USSR as far back as seventy+ years ago. Their results confirm the wide scope of adverse effects reported in recent years and summarized in the present monograph. Unfortunately, their results appear to have had little effect in influencing wireless radiation safety standards in the USA and many other countries.

ES-8. Adverse Effects Expected from Addition of 5G to Existing Communications Networks

The potential 5G adverse health effects derive from the intrinsic nature of the radiation, and how this radiation interacts with tissue and other target structures. 4G networking technology was associated mainly with carrier frequencies in the range of ~1-2.5 GHz (cell phones, WiFi). The wavelength of 1 GHz radiation is 30 cm, and the penetration depth in human tissue is a few centimeters. The highest performance 5G networking technology (millimeter wave) is mainly associated with carrier frequencies at least an order of magnitude above the 4G frequencies, although, as stated in Chapter 2, "ELFs (0–3000Hz) are always present in all telecommunication EMFs in the form of pulsing and modulation". Penetration depths for the high-performance carrier frequency component of 5G radiation (aka high-band) will be on the order of a few millimeters.

For much of the early implementation of 5G, and perhaps later, 5G will be integrated with 4G. Some vendors will start out/have started out with 'low-band' 5G (~600-900 MHz); some will start out with 'mid-band' 5G (~2.5 GHz-4.2 GHz); and some will start out with 'high band' 5G (~24-47 GHz). All these modes are associated with potentially severe adverse health effects, and none have been tested for safety in any credible manner.

At the millimeter carrier wavelengths characteristic of high-band high-performance 5G, one can expect resonance phenomena with small-scale human structures, as well as resonances with insects/insect components, seeds, etc.

The common 'wisdom' being presented in the literature and the broader media is that, if there are adverse impacts resulting from millimeter-wave 5G, the main impacts will be focused on near-surface phenomena, such as skin cancer, cataracts, and other skin conditions, because of shallow RF penetration depths. However, there is evidence that biological responses to millimeter-wave irradiation can be initiated within the skin, and the subsequent systemic signaling in the skin can result in physiological effects on the nervous system, heart, and immune system. There is additional evidence that adverse effects from millimeter-wave radiation can occur in organs and tissue well below the skin surface. This should not be surprising, since there are myriad signaling conduits connecting the skin to deeper structures in the body.

ES-9. Lack of Full Consensus on Wireless Radiation Adverse Effects

Not all studies of wireless radiation have shown adverse effects on health. There are many possibilities to explain this.

1) There could be 'windows' in parameter space where adverse effects occur, and the studies/experiments were conducted outside these 'windows'. Operation outside these windows could show
   - no effects or
   - hormetic effects or
   - therapeutic effects.

   The single stressor studies that constitute most of wireless radiation laboratory health research, and indeed constitute most of the laboratory medical research literature, essentially yield very narrow windows. Adverse effects are identified over very limited parameter ranges, and adverse effects shown by many combinations of stressors are not revealed when these stressors are tested in isolation over the same parametric ranges.

One could conclude that, whether by design or accident, ***the real-world impact of single stressor studies is to conceal, rather than reveal, many of the more serious adverse health effects of wireless radiation***.

The stressor variables to be used for health studies should not be limited to single stressors in isolation, but should include to the extent possible combinations of toxic stimuli stressors, since these combinations reflect more accurately real-life exposures.

2) Research quality could be poor, and adverse effects were overlooked.

3) Or, the research team could have had a preconceived agenda

where finding no adverse effects from wireless radiation was the main objective of the research!

ES-10. Potential Links of Wireless Radiation to Enhancement of Opioid Crisis

The previous findings reported in this Executive Summary are based on hard evidence and have been validated in numerous studies. The present section is based on hard evidence as well, but the link of wireless radiation to the opioid crisis is not as far along in the validation process. It should be viewed as a hypothesis at this point, and serve as a basis for discussion and further research.

It has been shown many times that one impact of wireless radiation (at myriad frequencies) is release of endogenous opioids. This release of endogenous opioids can enable analgesic effects by itself, or can enhance the analgesic effects of exogenous analgesics. This has been demonstrated at pulsed millimeter-wave frequencies, WiFi frequencies, mobile phone frequencies, radiofrequencies, and extremely low frequencies. Additionally, as has been demonstrated by the results of the current monograph, wireless radiation at all the above frequencies has resulted in serious mid-term and especially long-term adverse health effects.

Therefore, wireless radiation exposure, especially at cell phone, WiFi, and millimeter-wave pulsed and modulated frequencies, generates ***1) analgesic and pleasurable short-term effects and 2) serious adverse mid- and long-term effects***. There would be some exceptions for the short-term, such as electrohypersensitivity (EHS) sufferers, who are immediately affected adversely and strongly by wireless radiation exposure.

For most people, the enhanced analgesic short-term effects of the wireless radiation would in effect mask the long-term damage from this radiation.

As time proceeds, the increasing discomfort from the adverse mid-and long-term effects of wireless radiation requires increasingly stronger analgesics to suppress, and the increasing use of exogenous analgesics becomes necessary. This potentially enhanced use of exogenous analgesics could lead to opioid and/or other analgesic addictions.

ES-11. Potential Links of Wireless Radiation to Current Coronavirus Pandemic

The previous findings reported in this Executive Summary are based on hard evidence and have been validated in numerous studies. The present section is based on hard evidence as well, but the link of wireless radiation to the coronavirus pandemic is not as far along in the validation process. It should be viewed as a hypothesis at this point, and serve as a basis for discussion and further research.

There are on the order of 300,000 viruses, many/most of which have zoonotic potential. To develop vaccines for all of these viruses (before an epidemic or pandemic strikes) is unreasonable (based on present technology) because of the sheer numbers involved. To develop vaccines for any specific virus during an epidemic or pandemic (which was the mainstream approach taken for the coronavirus during the SARS pandemic of 2002-2003) is completely unrealistic, because of the lead times required for vaccine development, efficacy testing, credible mid-and long-term safety testing, and implementation.

Those who succumbed during the SARS pandemic had 1) myriad co-morbidities and 2) weakened immune systems unable to neutralize the SARS coronavirus. ***Having a strong immune system that allowed a smooth transition from innate immune system operation to adaptive immune system operation was the one intrinsic defense that worked!*** The SARS experience showed that the best and most realistic approach for defense against any potential viral attack is ***reversing immune-degrading lifestyles*** well before any pandemic or epidemic outbreaks. In that case, the immune system would be sufficiently strong to be able to handle viral exposure on its own without the emergence of serious symptoms, as was the case with those exposed to the SARS coronavirus (with coronavirus antibodies in their serum) who exhibited no (or minimal) symptoms.

This gets to the link between wireless radiation exposure and the latest coronavirus pandemic. To the degree that non-ionizing radiation exposure, superimposed on the myriad toxic stimuli to which many people are exposed by choice or imposition, degrades the operation of the innate and adaptive immune systems, it would increase the likelihood that the immune system could not counteract the exposure to the coronavirus (or any virus) as nature intended. Thus, ***it would contribute to the exacerbation of adverse effects from coronavirus exposure***. The bottom line is that exposures to essentially ALL the exogenous immune-damaging toxic stimuli (including, but not limited to, wireless radiation) need to be removed before resistance to viral exposures of any type can be improved substantially.

ES-12. Adverse Effects of Wireless Radiation in Automotive Sector

The modern automobile is a powerful source of wireless radiation at myriad frequencies, and is subject to external wireless radiation at myriad frequencies as well. The trend has not been to reduce these sources, but rather to add equipment both to the vehicle and to the external environment that will substantially increase the wireless radiation flux associated with the vehicle. The numbers and types of sources are not well-known, even among those experts and laymen concerned about adverse effects from wireless radiation.

An interesting diagram (and narrative) showing radars and other wireless sensors in modern cars can be found at the following link: (http://www.radiationdangers.com/automotive-radiation/automotive-radiation/). I would recommend the reader study that diagram in detail, to better appreciate how ubiquitous are these sources of wireless radiation. Not all the wireless radiation enters the cabin, since some/much is outward-directed, but some/much of it will enter the cabins of other cars on the road.

However, that diagram tells only part of the story. Assume there is a car pool commuting to work from the suburbs of a major city. It is not uncommon (in today's world) for a one-way trip to take from one-two hours, or more. Even in a regular car, or mid-size SUV, there might be four or so passengers. They may be using cell phones, WiFi, or both, thereby adding to the radiation from the automotive-based sensors/transmitters.

There will be cell towers lining the sides of a major highway, thereby increasing the radiation to the occupants substantially. Depending on conditions, there may be substantial air pollution to which the occupants are exposed. Additionally, the prolonged sitting is very dangerous, and is a contributing factor to many serious diseases. If the vehicle is new, there may be substantial out-gassing of toxic chemicals from the interior materials. Combined exposure to the wireless radiation, air pollution and other toxic substances, coupled with prolonged sitting and continual impacts from the car's motions, produces a synergistic effect that substantially exacerbates adverse impacts from any of the constituent components.

Chapter 1 – Unethical Research

1A. Monograph Overview

We are in the midst of the largest unethical medical experiment in human history. This experiment is the implementation and operation of a global wireless network for communications, surveillance, and other purposes. It is a ***medical experiment*** because we do not know the full extent of the adverse health effects that will result from this wireless network implementation and operation. It is an ***unethical*** medical experiment because it violates the key ethical medical experiment requirement of ***'informed consent'*** from the participants.

The current chapter provides 1) some background on the requirements for ethical medical research/experimentation and 2) examples of how those requirements have been violated in the past century. It places wireless radiation implementation and operation in the context of these other examples of unethical medical experiments.

Chapter 2 presents a detailed description of some of the adverse health effects of wireless radiation as reported in the unclassified open literature. Even though the adverse health effects of wireless radiation reported over the past seventy+ years span the range of severity from discomfort to lethality, we do not know the full extent of adverse health effects from this technology because:

Most laboratory experiments aimed at identifying wireless radiation health effects bear no relation to real-life exposures, and are performed under the most benign conditions of

- single stressors (wireless radiation only)
- no pulsing and modulation of the carrier signal
- no synergistic effects of other toxic stimuli acting in concert with the wireless radiation

These experimental deficiencies are compounded by

- lack of access to the global classified literature on adverse health effects from wireless radiation
- lack of knowledge of proprietary basic and advanced studies on adverse health effects from wireless radiation.

As Chapter 2 shows, the adverse wireless radiation health effects that have been identified already from the incomplete literature openly available are massive in scope and magnitude. They support the conclusion that ***wireless radiation as already implemented is extremely dangerous to human health***. It acts as both a ***promoter/accelerator*** and ***initiator*** of adverse health effects. Addition of the missing elements described above and more wireless radiation infrastructure will exacerbate further the adverse effects from wireless radiation on

- human health directly through contribution to chronic disease and
- human health indirectly through degradation of the food chain ecosystem.

Chapter 3 contains the references for the main text.

Chapter 4 contains eight Appendices:

- Appendix 1 contains examples of unethical medical experiments conducted in the last century, mainly (not entirely) in the USA or under USA auspices;
- Appendix 2 contains a manual taxonomy of the adverse health and biomedical effects component of a representative wireless radiation literature, and is derived in part from the taxonomies in Appendices 3 and 4;
- Appendix 3 contains a taxonomy based on factor analysis of the same representative wireless radiation literature;
- Appendix 4 contains a taxonomy based on text clustering of the same representative wireless radiation literature;
- Appendix 5 shows ***potential links between wireless radiation exposure and 1) expansion of the opioid crisis*** and ***2) exacerbation of coronavirus pandemic***;
- Appendix 6 lists references showing ***effects of industry funding on research outcomes*** for myriad (mainly biomedical) research disciplines;
- Appendix 7 overviews the oft-neglected topics of wireless radiation adverse effects on regions containing ***medical implants*** (e.g., pacemakers, defibrillators, cochlear implants, dental implants, bone pins, plates, etc) and appendages (e.g., metal eyeglasses, earrings, metal jewelry, etc), as well as other ***micro/nano*** exogenous implant analogues;
- Appendix 8 describes ***adverse effects of automotive-based wireless radiation***.

1B. Unethical Research

1B1. Broad Definition

There are myriad definitions for 'unethical' research (e.g., http://icahn.mssm.edu/about-us/services-and-resources/faculty-resources/handbooks-and-policies/faculty-handbook/research-environment/research-integrity; https://oprs.usc.edu/training/booklets/; https://history.nih.gov/about/timelines_laws_human.html).

These definitions of 'unethical' research encompass a broad spectrum of actions. Much reporting of 'unethical' medical research in myriad media tends to focus on one aspect only: biomedical experiments performed on subjects who did not give 'informed consent'. The classic example reflects the experiments performed on concentration camp inmates by the Nazi-regime doctors during WWII, and the lesser-known experiments performed by their Japanese counterparts during WWII. These experiments were certainly horrific, but not unique. The test subjects in these experiments were neither ***informed*** about the nature and consequences of these experiments, nor did they give ***consent***.

1B2. Informed Consent

A comprehensive discussion of the importance of 'informed consent' in medical experimentation was presented in a journal Special Issue [Goodwin, 2016]. An excellent overview and rationale for informed consent in human experiments is shown in the following box (obtained from a booklet titled Informed Consent in Human Subjects Research), prepared by the Office for Protection of Research Subjects, University of Southern California (https://oprs.usc.edu/training/booklets/).

> Informed Consent is a voluntary agreement to participate in research. It is not merely a form that is signed but is a process, in which the subject has an understanding of the research and its risks. Informed consent is essential before enrolling a participant and ongoing once enrolled. Informed Consent must be obtained for all types of human subjects' research including; diagnostic, therapeutic, interventional, social and behavioral studies, and for research conducted domestically or abroad. Obtaining consent involves informing the subject about his or her rights, the purpose of the study, the procedures to be undergone, and the potential risks and benefits of participation. Subjects in the study must participate willingly. Vulnerable populations (i.e. prisoners, children, pregnant women, etc.) must receive extra protections. The legal rights of subjects may not be waived and subjects may not be asked to release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

There are three important concepts in this definition: research, informed, and consent.

Research

What is a research experiment? According to myriad Web sources, an experiment is a set of actions undertaken to

- make a discovery or
- test a hypothesis or
- demonstrate a known fact.

The first two of these can be classified as **research** experiments, and the third is a **demonstration** experiment. A further breakdown would be informative. There are ***proactive*** experiments, where established rules and procedures (the scientific approach) are used to plan, conduct, and report the experiment. There are ***reactive*** experiments, where the experiment is secondary to higher priority actions, and consequently is conducted and reported under more constrained conditions. The proactive experiments can be viewed generally as explicit or 'a priori', and the reactive experiments can be viewed generally as implicit or 'a posteriori'.

Where does wireless technology implementation and operation fit in this research experiment categorization? Wireless technology implementation has two major characteristics: development and operation of a technology to achieve targeted technical goals (***explicit***), and conduct of an experiment that may result in serious adverse health impacts (***implicit***). Of interest in the current document is the experiment (***implicit***) component.

Identification of wireless radiation health effects will result from both proactive and reactive experiments. The proactive experiments are (mainly) the thousands of laboratory-based studies (performed to estimate wireless radiation health impacts) that have been reported in the biomedical literature. The reactive experiments are (mainly) those studies that have been done after the previous generations of mobile networking technologies have been implemented (usually epidemiology), and those studies that will be done after 5G is implemented.

Thus, 5G implementation can be viewed mainly as an implicit reactive ***research*** experiment with respect to identifying myriad adverse health effects on the exposed population. It will also have a ***demonstration*** component, confirming thousands of pre-5G research studies that have shown adverse health effects from wireless radiation in 5G and non-5G frequency ranges. Because these studies tend to under-estimate real-life effects of wireless radiation, the full scope of adverse health effects from 5G operation under real-life conditions are currently unknown. Ascertainment of these adverse health effects will require 'a posteriori' reactive research experiments after 5G implementation, under today's 5G implementation scenario. A major concern, especially in the current environment of accelerating 5G implementation, is that serious longer-term latent health effects will be discovered ***only after 5G has been fully implemented***.

Informed

There is much information available in the open literature detailing the adverse health effects of wireless radiation. These adverse effects reflect the role of wireless radiation both as a ***promotor/accelerator and/or initiator*** of myriad biomedical abnormalities and serious diseases. However, the vast public is not informed (or is misinformed) of these adverse health effects by the:

- developers of wireless radiation systems,
- vendors of these systems,
- mainstream media
- government regulators of these systems, and
- Federal, State, and Local politicians who pass laws that accelerate implementation of these systems.

These stakeholders 1) **do not inform** the public of the demonstrated adverse effects of wireless radiation and, in many cases, 2) **misinform** the public that wireless radiation is safe from a health perspective.

Consent

Many segments of the public **do provide** consent to be exposed to wireless radiation, because of its perceived benefits to them. A small amount of this consent may be informed, and the providers of this consent may be gambling that they can escape the adverse health effects. Most of the consent is probably not informed, since most people will not do the independent research required to gather in the relevant information on adverse health effects, but will rely on the government's and mainstream media's misleading assurances that wireless radiation is safe.

However, other segments of the public **do not provide** consent to be exposed to wireless radiation from these implemented technologies. Unlike other forms of toxic stimuli (e.g., cigarettes, cocaine, alcohol, etc), where exposures may be individual or very local, wireless radiation exposure is very large in extent. With the advent of the latest generation of wireless radiation (5G), there may be 1) small cell towers erected outside of every few houses, with the consequent radiation blanketing the environment, and 2) thousands of satellites blanketing the Earth's surface with wireless radiation. There are Federal laws that essentially prevent opposition to construction and operation of these small cell towers, and prevent opposition to the launching and operation of these satellites. Forcing exposure to this harmful wireless radiation on members of the public who do not provide consent is the cornerstone of wireless radiation implementation and operation being labeled unethical medical experimentation.

Its context differs from some other technologies with serious adverse effects, such as automotive technology and cigarette smoking. For the most part, users of these other technologies have been informed about potential serious consequences, and non-users are impacted minimally (at least today). Those users are able to make a more informed choice.

1B3. Examples of Unethical Medical Experimentation

Many books and articles have been written concerning horrific medical experiments (that were performed in the USA over the past century) without obtaining 'informed consent' from the test subjects. These books describe a wide spectrum of experiments. Individual readers could have different opinions on whether any of the individual experiments reported are more or less 'unethical' than those in the Nazi concentration camps, or whether they are 'unethical' at all. Appendix 1 contains references to books and journal articles that describe some of these experiments (mainly, but not entirely, conducted in the USA or under USA auspices), based on Medline searches and Web sources. Like most research of this type, the conduct of the experiments and the experimental results are not advertised widely. I was not aware of most of these experiments prior to conducting the analysis on under-reporting of adverse events in my 2015 eBook "Pervasive Causes of Disease" [Kostoff, 2015].

The experiments reported in Appendix 1 cover the full spectrum of toxic stimuli, including biological, chemical, and nuclear. These are the three types of toxic stimuli that constitute the core of Weapons of Mass Destruction (WMD). Interestingly, with all of the USA's concern about potential WMD attacks from Russia, China, Iran, and North Korea, we have completely overlooked the ongoing and exponentially increasing WMD attack on the Homeland that has been occurring for at least two decades: 24/7 spewing of harmful wireless radiation in almost every corner of the USA, with far more to come if 5G is implemented!

The copious references identified in Appendix 1 are not the result of an exhaustive search; they were obtained after a very brief survey. There are undoubtedly many other examples (of 'unethical' medical experiments) published already that were missed by the survey. Given the odious nature of these experiments, there are probably far more experiments whose disclosure has not yet seen the light of day. As shown in the tobacco and asbestos examples in section 9C of Kostoff [2015], most of this information comes to light either from 1) whistleblowers or 2) 'discovery' resulting from lawsuits. In addition, some investigators may stumble across evidence of this type of 'unethical' research while doing relatively unrelated types of investigations.

Documentation of many types of 'unethical' medical experiments may:

- not have been done, or
- have been done and destroyed, or
- have been done but distorted to protect the miscreants.

This is why retrospective analysis of this type of 'research', which in many cases relies heavily on the printed word as 'proof', may be highly under-reflective of the full spectrum of what was actually done in these experiments (e.g., Stephen Kinzer's description of the records destroyed by the Head of the CIA's MK-Ultra program https://www.c-span.org/video/?464648-1/poisoner-chief).

While there are many stages of the medical research process that could be subjected to 'unethical' practices (e.g., those outlined in Chapter 9 of Kostoff [2015], including selection of the most important research problems for funding, conducting the research, disseminating the results of the research, etc), conducting the medical research experiments 'unethically' has received the most attention by far. The references in Appendix 1, and additional books and journal and magazine articles on unethical medical research experiments, are testimony to this imbalance.

Books and articles only tell part of the larger story. A more representative reporting on the damage from any type of 'unethical' medical research would reflect the pain, suffering, and premature mortality resulting from the medical research experimentation. A simple estimate of the experiment's damage could be obtained by integrating the number of people affected by the 'unethical' medical experimentation and the degree of damage experienced by each person. This could be viewed as a 'weighted' impact of the adverse effects of the unethical medical experimentation.

In the most widely reported examples of 'unethical' medical research (the medical experiments performed in the Nazi concentration camps during WWII), perhaps a few thousand prisoners were involved; it is difficult to find accurate information for actual numbers of prisoners involved. Further, it is difficult to separate out the 1) many thousands of German citizens subjected to forced sterilization procedures starting in 1933 and 2) many deliberately exterminated in the concentration camps, from 3) those who suffered from the medical experiments in the camps and died as a result of the experiments alone.

In the references in Appendix 1

- some of the 'unethical' medical experiments described involved under a hundred test subjects,
- many of the 'unethical' medical experiments described tended to involve on the order of hundreds of test subjects (who did not provide 'informed consent'), and
- in some rarer cases, perhaps thousands of test subjects were involved.

Many of these experiments, in parallel with the spirit of the Nazi concentration camp experiments, involved people confined in large institutions who were (usually) not told the full story of the nature of the experiments, or, if they were told, either did not 1) understand it or 2) give 'informed consent'. These people were confined in prisons, the military service, mental institutions, children's institutions, etc.

How do the above odious procedures in these references differ conceptually from the recent trend toward government effectively promoting/mandating implementation of wireless radiation infrastructure whose safety has not been demonstrated, but (a fraction of) whose adverse health effects have been widely demonstrated?

Based on what has been reported in the experiments referenced in Appendix 1 (which could in fact be the tip of a much larger unreported iceberg), perhaps on the order of 10,000-30,000 people may have been subjected to 'unethical' medical experiments in the past century (excluding those who unwittingly participated in clinical trials that were "off-shored" to (typically) developing countries with knowingly less stringent test subject protections [Kostoff, 2015, section 9D3]). A few thousand of these test subjects would have died prematurely, and most would have suffered unnecessarily. These, of course, are horrific numbers. Unfortunately, they pale in comparison to what can be expected if wireless radiation infrastructure is expanded domestically and globally to satisfy the requirements of 5G. The following box shows one estimate of potential adverse effects from wireless radiation.

One of the many adverse health effects of wireless radiation is cancer of the brain, especially gliomas. What approximate increases in glioma incidence can be expected from widespread expansion of wireless radiation?

There are different estimates of glioma incidence and trends in glioma incidence. For an approximate estimate, Rasmussen et al [2017] estimates the glioma incidence in the Danish population at about 7/100,000, a figure in line with other national and global estimates. Additionally, Phillips et al [2018] presents evidence of a 100% increase in Glioblastoma Multiforme from 1995-2015, a major component of glioma. Some of this increase may have been due to wireless radiation exposure, since that time period was associated with a major expansion of cell phone and other wireless device use. For approximate estimation purposes, assume the wireless-free glioma incidence to be about 5/100,000.

Hardell et al [2011] showed, in a case-controlled study, that glioma incidence doubled for those who starting using cell phones as adults (>20 years old), were 'heavy' users (>30 minutes per day), and used cell phones for more than ten years. Hardell also showed glioma incidence quadrupled for those who started using cell phones younger than twenty years old, were heavy users, and used cell phones for more than ten years.

If we apply Hardell's conservative doubling estimate to all potential users, then we can expect an increased glioma incidence per year of about 5/100,000. By the time 5G is rolled out, the global population will be at least eight billion. If we assume ¾ of the global population will be cell phone users and/or exposed to cell towers and other sources of wireless radiation, then about six billion people would be the pool for potential glioma victims from wireless radiation. Multiplying 5/100,000 by 6,000,000,000 yields 300,000 new cases of glioma/year.

In one year, the deaths from glioma alone attributed to wireless radiation will swamp all the deaths from all the horrific unethical medical experiments of the twentieth century referenced in Appendix 1!

This number was obtained using the most conservative estimates of Hardell and the incidence data, and it didn't take into account the increase in glioma incidence that would be expected as latency times increase. For smoking, the average latency period between initiation of smoking and lung cancer is between twenty and thirty years, depending on which database was examined. The fact that glioma incidence shows measurable increases after only a ten-year latency period should be most disturbing, and does not bode well for glioma incidences after a twenty, thirty, or forty-year latency!

Again, glioma is but one of the large numbers of adverse health effects potentially resulting from exposure to wireless radiation. Integrating over all the adverse health effects potentially resulting from the wireless radiation experiment would yield numbers of ***experiment-based*** premature deaths and enhanced suffering unparalleled in human history!

Given the magnitude of 5G projected global implementation, the numbers of people that will be exposed to this radiation, the numbers of people expected to suffer myriad adverse effects from this technology, and the lack of credible 'informed consent' from the vast majority of these people, we are well justified in calling global implementation of mobile networking technology **The Largest Unethical Medical Experiment in Human History!**

Finally, in the spirit of the 'unethical' medical experiments referenced in Appendix 1,

it is the poor and dispossessed who will suffer the most from wireless radiation exposure.

This is because wireless radiation plays a dual role of ***initiator*** and ***promoter/accelerator*** of serious disease, as will be shown in the next chapter. In its ***promoter/accelerator*** role, it can accelerate the progression of existing serious diseases such as cancer, and/or, through synergy, can produce serious adverse health effects when combined with other toxic stimuli that neither constituent of the combination could produce in isolation.

Many toxic stimuli, such as harsh chemicals, biotoxins, ionizing radiation sources, vibrating machinery, prolonged sitting doing repetitive tasks, high air pollution, etc, are used/experienced by the poorest members of society in their occupations, and many toxic stimuli, such as air pollutants, toxic wastes, etc, are very prevalent in their residential environments. Thus, people who spray pesticides in farm labor or household applications, people who do cleaning with harsh chemicals, people who dispose of hazardous materials, basically, ***people who do the dirty work in our society and live in dirty environments***, are already leading candidates for higher risk of serious diseases. Adding a wireless radiation ***promoter/accelerator*** to their residential and occupational environments will radically increase their chances for developing serious diseases. Closing the 'digital divide' for them will translate to increased suffering and reduced longevity!

Chapter 2 – Adverse Impacts of Wireless Radiation

2A. Overview

Wireless communications have been expanding globally at an exponential rate. The latest imbedded version of mobile networking technology is called 4G (fourth generation), and the next generation (5G) is in the early implementation stage. Neither 4G nor 5G have been tested for safety in any credible real-life scenarios. The current chapter assesses the medical and biological studies that have been performed and then published in the biomedical literature, and shows why they are deficient relative to identifying adverse health and safety effects.

However, even in the absence of the missing real-life components (which tend to exacerbate the adverse effects of the wireless radiation shown in the biomedical literature), the published literature shows there is much valid reason for concern about potential adverse health effects from both 4G and 5G technology. The studies reported in the literature should be viewed as extremely conservative, underestimating the adverse impacts substantially.

2A1. The Context of Wireless Radiation Health and Safety Research

Before addressing the technical and biological details of wireless radiation health and safety research shown in the published literature, the context in which this literature has been generated will be discussed.

The results shown in the literature cannot be separated from the context in which this research has been sponsored, conducted, and disseminated!

In the USA (and in most, if not all, countries), the two major sponsors of wireless radiation health and safety research are the Federal government and the wireless radiation industry, in that order. Both of these organizations have a strong intrinsic conflict-of-interest with respect to wireless radiation.

2A1a. Intrinsic Federal government wireless radiation conflict-of-interest

The Federal government is a strong **promoter** of wireless radiation infrastructure development and rapid expansion, most recently supporting accelerated implementation of 5G infrastructure. Every

- Congressional evaluation of 5G I have heard (or read),
- Congressperson's statement on 5G I have heard (or read),
- Presidential proclamation on 5G I have heard (or read), and
- FCC proclamation on 5G I have heard (or read),

has unabashedly supported the ***most accelerated implementation of 5G infrastructure***.

The Federal government that ***promotes*** accelerated implementation of wireless radiation technology also 1) ***sponsors*** research examining the technology's potential adverse effects and 2) ***regulates*** the technology's potentially adverse impacts on the public. The fact that these development, regulation, and safety functions may be assigned to different Executive Agencies within the Federal government is irrelevant from an independence perspective. ***The separate Executive Agencies in the Federal government are like the tentacles of an Octopus; they operate synchronously under one central command.***

The wireless promoters' main objectives of developing and implementing the technology rapidly are enabled by suppressing knowledge (to the public) of potential adverse effects from the technology's operation. These fundamental conflicts impact the objectivity of the health and safety R&D sponsors and performers. Any ***Federal research sponsor*** of wireless radiation technology safety would be highly conflicted between 1) a desire to satisfy Executive and Legislative objectives of accelerating expansion of wireless radiation technology and implementation and 2) sponsoring objective research focused on identifying and reporting adverse effects of wireless radiation expected under real-life conditions. Likewise, any ***sponsored research performer*** addressing wireless radiation technology safety would be highly conflicted between 1) reporting the actual adverse effects expected under real-life conditions and 2) the desire to satisfy wireless radiation promotional objectives of the research sponsors in order to maintain long-range funding.

2A1b. Intrinsic wireless radiation industry conflict-of-interest

The wireless radiation industry is obviously a strong promoter of accelerated development and implementation of wireless radiation devices and infrastructure, and is a sponsor of wireless radiation and safety research. ***Trillions of dollars in revenues are potentially at stake in successful promotion and adoption of wireless radiation infrastructure and technology!*** The industry's conflicts with respect to promotion and safety research are similar to those of the Federal government listed above.

The wireless industry's role in suppressing information about the adverse impacts of wireless radiation was described eloquently in a 2018 Nation article (https://www.thenation.com/article/how-big-wireless-made-us-think-that-cell-phones-are-safe-a-special-investigation/). As this exposé shows, studies on health effects were commissioned by the wireless radiation industry in the 1990s under the management of Dr. George Carlo. The adverse effects shown were downgraded and suppressed, in the spirit of similar suppression by the tobacco and fossil energy industries, as stated in the Nation article:

"Carlo's story underscores the need for caution, however, particularly since it evokes eerie parallels with two of the most notorious cases of corporate deception on record: the campaigns by the tobacco and fossil-fuel industries to obscure the dangers of smoking and climate change, respectively. Just as tobacco executives were privately told by their own scientists (in the 1960s) that smoking was deadly, and fossil-fuel executives were privately told by their own scientists (in the 1980s) that burning oil, gas, and coal would cause a "catastrophic" temperature rise, so Carlo's testimony reveals that wireless executives were privately told by their own scientists (in the 1990s) that cell phones could cause cancer and genetic damage.....Like their tobacco and fossil-fuel brethren, wireless executives have chosen not to publicize what their own scientists have said about the risks of their products. On the contrary, the industry—in America, Europe, and Asia—has spent untold millions of dollars in the past 25 years proclaiming that science is on its side, that the critics are quacks, and that consumers have nothing to fear. This, even as the industry has worked behind the scenes—again like its Big Tobacco counterpart—to deliberately addict its customers. Just as cigarette companies added nicotine to hook smokers, so have wireless companies designed cell phones to deliver a jolt of dopamine with each swipe of the screen."

While the wireless radiation industry doesn't play a formal role in regulating the safety aspects of wireless radiation, it plays a strong de facto role. In addition to its lobbying efforts to minimize regulations on wireless radiation exposure levels, it plays a revolving-door role with respect to regulation.

The previous FCC Chairman had been President of the National Cable & Telecommunications Association (NCTA) and CEO of the Cellular Telecommunications & Internet Association (CTIA) before assuming his FCC Chairmanship. In recognition of his work in promoting the wireless industry, he was inducted into the Wireless Hall of Fame in 2003 and in 2009 (https://en.wikipedia.org/wiki/Tom_Wheeler). The present FCC Chairman served as Associate General Counsel at Verizon Communications Inc., where he handled competition matters, regulatory issues, and counseling of business units on broadband initiatives (https://en.wikipedia.org/wiki/Ajit_Pai#cite_note-Bio-2). As is the case with so many other Federal regulatory agencies [Kostoff, 2015-Chapter 9; 2016], the FCC is essentially an agency captured by industry [Alster, 2015]!

So, in the two most recent Administrations, under two supposedly very different Presidents, the FCC Chairmen had been, in different ways, lobbyists for the wireless radiation technology industry. Both were (and are) extremely ardent promoters of the most rapid acceleration of implementation of 5G infrastructure and associated devices and technologies.

2A1c. Relation of wireless radiation health and safety research to sponsors' and performers' conflicts-of-interest

The incentives for ***sponsors*** of wireless radiation health and safety research to fund studies that will help promote accelerated expansion of wireless radiation devices and infrastructure are many and the disincentives are essentially non-existent. Likewise, incentives for ***performers*** of wireless radiation health and safety research to conduct studies that will help promote accelerated expansion of wireless radiation devices and infrastructure are many and the disincentives are few. Because of this unfortunate reality,

EVERY wireless radiation health and safety study/experiment whose results support the wireless radiation promotion objectives of the organization(s) that sponsor these studies must receive the highest level of scrutiny.

There is not a credibility symmetry between studies whose results 1) support the promotional objectives of their sponsors or 2) do not support the promotional objectives of their sponsors. For studies/experiments of equally high research/scientific quality, those studies that do not support the promotional objectives of their sponsors should be assigned relatively higher credibility priority than those that do support the promotional objectives of their sponsors. This should not be interpreted as a lack of absolute credibility for studies that support the promotional objectives of their sponsors. Many may very well be credible, as discussed further in section 2F.

However, research findings opposing the promotional objectives of the sponsors may result in termination of further funding for the project, and adverse career and financial consequences for the performer(s). Conversely, research findings supporting the promotional objectives of the sponsors will most likely lead to continued and enhanced funding for the project, and very positive career and financial impacts for the performer(s). Therefore, high quality research studies whose results could impose serious career and financial risks for their performers should rank higher in the credibility chain.

These conflicts-of-interest of researchers who accept funding from wireless radiation promoters extend well beyond the papers and studies they publish. This category of wireless radiation researchers tends to populate the Advisory Committees that help set the exposure safety studies imposed by government regulatory agencies. Hardell has done a comprehensive evaluation of some of the more influential Advisory Committees [Hardell, 2017], especially ICNIRP and WHO, and has shown clearly the inter-locking linkages among these proxies of the wireless radiation promoters.

Operationally, the wireless radiation regulatory commissions, their advisory committees, their health and safety research sponsors, and some of the researchers sponsored by the wireless radiation promoters, along with the mainstream media, serve as ***the de facto marketing arm of the wireless radiation promoters***, in their attempts to mislead the public into believing wireless radiation under present day exposure limits is safe!

2A1d. Relation of wireless radiation health and safety research to publishers' conflicts-of-interest

Some journal publishers of articles concerning health and safety effects of wireless radiation have similar conflicts of interest. Many journals are not independent from government or industry sponsorship, in whole or in part, directly or indirectly. This conflict-of-interest is addressed further in section 2F. These journals control the review process by which articles are selected for publication, and it is extremely easy for a journal to select articles for publication that will align strongly with the promotional interests of the organizations or people that contribute to their revenue stream. These direct or indirect journal sponsors include:

- Promotional organizations that contribute directly to the journals;
- Promotional organizations that contribute directly to professional societies that sponsor many of the 'leading' journals;
- Individuals who receive funding from industrial or governmental organizations promoting wireless radiation technology and who
  - contribute directly to the journals and/or
  - contribute to professional societies that sponsor many of the 'leading' journals

Anyone who has read thousands of wireless radiation journal article abstracts on health and safety would have little problem in identifying those journals that rarely publish results opposing the promotional objectives of government and industry (see Slesin [2006] for ***allegations*** of possible bias in one journal's publication patterns of microwave-induced genotoxic results). Equally, they would have little problem in identifying those authors or author institutions that even more rarely publish results opposing the promotional objectives of government and industry. If we take into account the credibility asymmetry between studies whose results 1) support the promotional objectives of their sponsors or 2) do not support the promotional objectives of their sponsors, then a much different picture of the wireless radiation health and safety research literature emerges. Many of the so-called conflicting results disappear when credibility weightings are applied, and the true serious adverse effects resulting from this harmful technology are shown in detail. The reader should keep this credibility asymmetry in mind when evaluating the myriad adverse health effects shown in sections 2D and 2E.

2B. Wireless Radiation/Electromagnetic Spectrum

This section overviews the electromagnetic spectrum, and delineates the parts of the spectrum on which this monograph will focus. The electromagnetic spectrum encompasses the entire span of electromagnetic radiation. The spectrum includes: ionizing radiation (gamma rays, x-rays, and the extreme ultraviolet, with wavelengths below ~10^{-7} m and frequencies above ~$3x10^{15}$ Hz); non-ionizing visible radiation (wavelengths from ~$4x10^{-7}$ m to ~$7x10^{-7}$ m and frequencies between ~$4.2x10^{14}$ Hz and ~$7.7x10^{14}$ Hz); non-ionizing non-visible radiation (short wavelength radio waves and microwaves, with wavelengths between ~10^{-3} m and ~10^{5} m and frequencies between ~$3x10^{11}$ to ~$3x10^{3}$ Hz; long wavelengths, ranging between ~10^{5} m and ~10^{8} m and frequencies ranging between $3x10^{3}$ and 3 Hz).

The low frequencies (3 Hz–300 KHz) are used for electrical power line transmission (60 Hz in the U.S.) as well as maritime and submarine navigation and communications. Medium frequencies (300 KHz–900 MHz) are used for AM/FM/TV broadcasts in North America. Lower microwave frequencies (900 MHz–5 GHz) are used for telecommunications such as microwave devices/communications, radio astronomy, mobile/cell phones, and wireless LANs. Higher microwave frequencies (5 GHz– 300GHz) are used for radar and proposed for microwave WiFi, and will be used for 'high-band' 5G communications. Terahertz frequencies (300 GHz–3000 GHz) are used increasingly for imaging to supplement X-rays in some medical and security scanning applications [Kostoff and Lau, 2017; Kostoff, 2019a; Kostoff et al, 2020].

In the study of non-ionizing EMF radiation health effects reported in this monograph, the frequency spectrum ranging from 3 Hz to 300 GHz is covered, with particular emphasis on the high frequency communications component ranging from ~1 GHz to ~300 GHz. A previous review found that pulsed electromagnetic fields applied for relatively short periods of time could sometimes be used for therapeutic purposes, whereas chronic exposure to electromagnetic fields in the power frequency range (~60 Hz) and microwave frequency range (~1 GHz-tens GHz) tended to result in detrimental health effects [Kostoff and Lau, 2013, 2017]. Because of present concerns about the rapid expansion of new communications systems without adequate safety testing, more emphasis will be placed on the communications frequencies in this monograph.

2C. Modern Non-Ionizing EMF Radiation Exposures

In ancient times, sunlight and its lunar reflections provided the bulk of the visible spectrum for human beings (with fire a distant second and lightning a more distant third). Now, many varieties of artificial light (incandescent, fluorescent, and light emitting diode) have replaced the sun as the main supplier of visible radiation during waking hours. Additionally, EMF radiation from other parts of the non-ionizing spectrum has become ubiquitous in daily life, such as from wireless computing and telecommunications. In the last two or three decades, the explosive growth in the cellular telephone industry has placed many residences in metropolitan areas within less than a mile of a cell tower. Future implementation of the next generation of mobile networking technology, 5G, will increase the cell tower geographical densities by an

order of magnitude. Health concerns have been raised about non-ionizing EMF radiation from (1) mobile communication devices, (2) occupational exposure, (3) residential exposure, (4) wireless networks in homes, businesses, and schools, and (5) other non-ionizing EMF radiation sources such as 'smart meters' and 'Internet of Things'.

2D. Demonstrated Biological and Health Effects from Prior Generations of Wireless Networking Technology

2D1. Limitations of Previous Wireless Radiation Health Effects Studies

There have been two major types of studies performed to ascertain biological and health effects of non-ionizing radiation: laboratory and epidemiology. The laboratory tests provide the best scientific understanding of the effects of wireless radiation, but do not reflect the real-life operating environment in which wireless radiation is embedded. There are three main reasons that laboratory tests do not reflect real-life exposure conditions for human beings.

First, the laboratory tests have been performed mainly on animals, especially rats and mice. Because of physiological differences, there have been continual concerns about extrapolating small animal results to human beings. Additionally, while inhaled or ingested substances can be scaled from small animals to human beings relatively straight-forwardly, radiation may be more problematical. For non-ionizing radiation, penetration depth is a function of frequency, tissue, and other parameters, and radiation of a given wavelength could penetrate much deeper into the (small) animal's interior than similar wavelength radiation in humans. Different organs and tissues would be affected, with different power densities.

Second, the typical incoming EMF signal for many/most laboratory tests performed in the past consisted of the single carrier wave frequency; the lower frequency superimposed signal containing the information was not always included. This omission may be important. As Panagopoulos states: "It is important to note that except for the RF/microwave carrier frequency, Extremely Low Frequencies – ELFs (0–3000Hz) are always present in all telecommunication EMFs in the form of pulsing and modulation. There is significant evidence indicating that the effects of telecommunication EMFs on living organisms are mainly due to the included ELFs.... While ~50% of the studies employing simulated exposures do not find any effects, studies employing real-life exposures from commercially available devices display an almost 100% consistency in showing adverse effects". [Panogopoulos, 2019]. These effects may be exacerbated further with 5G: "with every new generation of telecommunication devices.....the amount of information transmitted each moment.....is increased, resulting in higher variability and complexity of the signals with the living cells/ organisms even more unable to adapt [Panogopoulos, 2019]"

Third, these laboratory tests typically involved one stressor (wireless radiation) and were performed under pristine conditions. This contradicts real-life exposures, where humans are exposed to multiple toxic stimuli, in parallel or over time. In perhaps five percent of the wireless radiation studies reported in the literature, a second stressor (mainly biological or chemical toxic stimuli) was added, to ascertain whether additive, synergistic, potentiative, or antagonistic effects were generated by the combination [Kostoff and Lau, 2013, 2017; Juutilainin et al, 2008; Juutilainin et al, 2006].

Combination experiments are extremely important because, when other toxic stimuli are considered in combination with non-ionizing EMF radiation, the synergies tend to enhance the adverse effects of each stimulus in isolation. In other words, combined exposure to 1) toxic stimuli and 2) non-ionizing EMF radiation translates into much lower levels of tolerance for each toxic stimulus in the combination relative to its exposure levels that produce adverse effects in isolation. So, the regulatory exposure limits for non-ionizing EMF radiation when examined in combination with other potentially toxic stimuli should be far lower for safety purposes than those derived from non-ionizing EMF radiation exposures in isolation [Kostoff et al, 2020].

Thus, almost all of the laboratory tests that have been performed are flawed with respect to demonstrating the full adverse impact of the wireless radiation. Either 1) non-inclusion of signal information or 2) using single stressors only 3) tends to underestimate the seriousness of the adverse effects from non-ionizing radiation. Excluding ***both*** of these phenomena from experiments, as was done in the vast majority of cases, tends to amplify this underestimation substantially. Therefore, the results (of adverse effects from wireless radiation exposure) reported in the biomedical literature should be viewed as 1) extremely conservative and 2) the very low 'floor' of the seriousness of the adverse effects, not the 'ceiling'.

The epidemiology studies typically involved human beings who had been subjected to myriad known and unknown stressors prior to (and during) the study. The wireless radiation exposure levels from e.g. the cell tower studies reported in Kostoff and Lau [2017] associated with increased cancer incidence tended to be orders of magnitude lower than e.g. those exposure levels generated in the recent highly-funded NTP studies [Melnick, 2019] and other laboratory studies associated with increased cancer incidence. The inclusion of real-world effects in the cell tower studies most likely accounted for the orders of magnitude wireless radiation exposure level decreases that were associated with the initiation of increased cancer incidence.

Thus, the laboratory tests were conducted under very controlled conditions not reflective of the real-world, while the epidemiology studies were performed in the presence of many stressors, known and unknown, reflective of the real-world. The exposure levels of the epidemiology studies were, for the most part, uncontrolled.

2D2. Adverse Health Effects Identified in Major Review Studies

Many thousands of papers have been published over the past sixty+ years showing adverse effects from wireless radiation applied in isolation or as part of a combination with other toxic stimuli. Extensive reviews of these wireless radiation biological and health effects have been published, including [Belpomme et al, 2018; Desai et al, 2009; Di Ciaula, 2018; Doyon and Johansson, 2017; Havas, 2017; Kaplan et al, 2016; Kostoff and Lau, 2013, 2017; Kostoff et al, 2020; Lerchl et al, 2015; Levitt and Lai, 2010; Miller et al, 2019; Pall, 2016, 2018; Panagopoulos, 2019; Panagopoulos et al, 2015; Russell, 2018; Sage and Burgio, 2018; Van Rongen et al, 2009; Yakymenko et al, 2016; Bioinitiative, 2019].

In aggregate, for the high frequency (radiofrequency-RF) part of the spectrum, these reviews show that RF radiation below the FCC guidelines can result in:

-carcinogenicity (brain tumors/glioma, breast cancer, acoustic neuromas, leukemia, parotid gland tumors),

-genotoxicity (DNA damage, DNA repair inhibition, chromatin structure),

-mutagenicity, teratogenicity,

-neurodegenerative diseases (Alzheimer's Disease, Amyotrophic Lateral Sclerosis),

-neurobehavioral problems, autism,

-reproductive problems, pregnancy outcomes,

-oxidative stress, inflammation, apoptosis, blood-brain barrier disruption,

-pineal gland/melatonin production, sleep disturbance, headache,

-irritability, fatigue, concentration difficulties, depression, dizziness, tinnitus,

-burning and flushed skin, digestive disturbance, tremor, cardiac irregularities, and can

-adversely impact the neural, circulatory, immune, endocrine, and skeletal systems.

The effects range from myriad feelings of discomfort to life-threatening diseases. From this perspective, RF exposure is a highly pervasive cause of disease!

2D3. Adverse Health Effects from Open Literature Analysis

2D3a. Overview

To corroborate the findings from the major review studies of the previous section, an analysis of a representative sample of the wireless radiation adverse health effects literature was performed. A relatively simple query was used to retrieve records related to adverse health effects from wireless radiation. Some filtering was done to remove records that did not identify adverse health effects, but because of extensive use of titles (and sometimes abstracts) that discuss methodologies rather than results, some/many records were retrieved that did not demonstrate adverse health effects.

In all, 5311 records with abstracts were retrieved from Medline (Pubmed), and these records were categorized by three different methods: manual taxonomy; factor analysis taxonomy; text clustering taxonomy. The three methods and their results will be briefly summarized here, and the more detailed results, including category record titles, will be presented in Appendices 2-4.

2D3b. Manual taxonomy results

Based on the factor analysis (section 2D3c) and text clustering (2D3d) results, as well as reading thousands of abstracts from the full database, a manual taxonomy of adverse health effects from wireless radiation was constructed. Appendix 2 presents this taxonomy (Table A2-1), and the titles of the records that were assigned to each category in the taxonomy. The record titles give a better appreciation for the contents of each category than the brief category heading.

This ***manual taxonomy is the most relevant*** (of the three taxonomies presented) to the main objective of identifying and categorizing specific adverse health effects from wireless technology, since it was not dependent on any algorithm to determine adverse effects categories and received a ***higher level of title filtering*** than the other two. Table A2-1 (reproduced in the following) presents the categories in the taxonomy, and a strong condensation of the key phrases 1) used to define the category and 2) link to the record titles shown in Appendix 2. A more detailed manual taxonomy, with orders-of-magnitude more phrases, is shown in Appendix 2.

The adverse effects identified in the manual taxonomy cover those summarized in the comprehensive review analyses described previously, and go well beyond. While all the categories shown are problematical and harmful, the most researched categories with perhaps the most serious adverse effects are ***cancer/tumors, neurodegenerative diseases, reproduction problems, and genotoxicity***. Thus, even confining these results to the non-classified open literature, many of which are based on single stressor experiments that tend to downplay greatly real-life adverse effects, there is more than enough hard evidence that wireless radiation 1) ***can be extremely harmful in real-life environments***, and 2) ***needs to be subjected to orders-of-magnitude harsher exposure limitations*** than is the case today. In Appendix 2, the categories in Table A2-1 are hyperlinked to their respective record title sections.

Table A2-1 – Manual Taxonomy

CATEGORY	KEY PHRASES
Cancer/Tumors	cancer, leukemia, glioma, lymphoma, melanoma, Hodgkin's disease, tumor, acoustic neuroma, meningioma
Neurodegenerative	memory, central nervous system, learning, neurodegenerative, Alzheimer's disease, cognition, amyotrophic lateral sclerosis, dementia, epilepsy, multiple sclerosis, cognitive impairment, seizures, autism
Reproduction	pregnancy, reproductive, sperm, embryos, testicular, fertility, embryo, testosterone, infertility
Genotoxicity	DNA damage, genotoxic, micronuclei, mutagenic, strand breaks, chromatin, mutation, chromosome aberrations,
Cardiovascular	Cardiac, cardiovascular, pacemaker, implanted, Cardiovascular disease, arrhythmia, arterial blood pressure, ventricular fibrillation
Immunity	lymphocytes, immune system, immunity, leukocytes, antibodies, neutrophils, autoimmune, macrophage,
Biomarkers	apoptosis, oxidative stress, Malondialdehyde, reactive oxygen species, superoxide dismutase, lipid peroxidation, inflammation, oxidation, ornithine decarboxylase, barrier permeability, atrophy, C-reactive protein, oxidative damages
Sensory Disorders	auditory, acoustic, hypersensitivity, electromagnetic hypersensitivity, cataract, tinnitus, dermatitis, cataractogenic, pain sensitivity, pain threshold
Discomfort Symptoms	depression, anxiety, headache, dizziness, depressed, vertigo, nausea, low back pain
Congenital Abnormalities	malformations, teratogenic, congenital malformations, cleft palate,
Circadian Rhythym and Melatonin	melatonin, sleep, circadian, insomnia, pineal function
Chronic Conditions	metabolism, glucose, endocrine, cholesterol, Diabetes, calcium homeostasis, obesity

2D3b1. Adverse effects of wireless radiation on food chain

The above taxonomy (and its associated records) focuses on the direct linkage between wireless radiation exposure and biomarkers, symptoms, and diseases. As such, these effects can be viewed as direct effects. Equally important, but usually overlooked in any discussions of adverse effects of wireless radiation, are the indirect effects, especially those on the ecological infrastructure that supports human life.

An analogy to war and conflict may be instructive. When one examines the great wars and battles of human history, especially those that persisted for more than very short periods, the critical role of logistics in determining the outcome becomes obvious. Many wars/battles have been won or lost by the adequacy and timeliness of logistical supplies and support.

The struggle for survival of human life on Earth is similarly dependent on the logistical food supply chain. At the foundation of this supply chain (before the farmers become involved in harvesting its bounty) are the insects, seeds, flora, trees, etc, that enable the bountiful growth of the myriad potential foods. If the integrity of this foundational logistical supply chain is threatened in any way, then both the animals and plant products we consume become unavailable.

There is a substantial literature on the adverse impacts of wireless radiation on this foundational logistical supply chain. These adverse effects are from the pre-5G exposures, and would include enhanced coupling from the higher frequency harmonics. Many of these supply chain elements (e.g., insects, seeds, larvae, etc) are very small, and we could expect enhanced resonance/energy coupling from the shorter-wavelength 5G radiation when implemented. This indirect impact of wireless radiation may turn out to be at least as important (if not more important) as the direct impact of wireless radiation on human survival! At the end of Chapter 3 are a few references showing the harmful effects of wireless radiation on the foundational food supply chain. They are the tip of the iceberg of a much larger literature on adverse effects of wireless radiation on the foundational food supply chain.

From a broader perspective, most of the laboratory experiment component of the wireless radiation adverse effects literature can be viewed as related to the foundational food supply chain. Much of this research is focused on mice, rats, insects, small birds, small fish, etc. These species tend to be prey of larger animals/fowl/fish, and eventually make their way to the human food table. Any environmental factor that affects the health of these species adversely will eventually impacts the humans who are at the end of that chain. In reality, we have accumulated a massive literature describing the adverse impacts of wireless radiation on myriad contributing components to our food supply, and the results do not bode well for our future ability to feed the existing world's population, much less the growing world's population!

2D3b2. Implants and Appendages

The adverse impacts of wireless radiation on myriad medical implants don't get much discussion in the literature, especially passive implants (defined below), and especially with regard to radiofrequency radiation. A number of articles in the database addressed non-organic implants, which are foreign bodies inserted into humans and animals for medical purposes. Non-organic implants addressed in the present database are typically not rejected by the immune system like organic foreign substances (although some adjuvants such as metal could induce autoimmune responses [Loyo et al, 2013]). Non-rejection does not mean they are safe, especially from exposure to wireless radiation.

There were two major types of implants covered by the database articles showing adverse effects: active implants that produced electrical signals mainly for controlling heart irregularities (e.g., pacemakers, defibrillators) and hearing deficiencies (e.g., cochlear implants), and passive metallic implants for structural support (e.g., dental implants, bone pins, plates, etc). Additionally, there are articles addressing adverse effects from wireless radiation in the vicinity of metallic appendages (e.g., metallic eyeglasses, metallic jewelry, etc).

The external EMF from microwaves (and other sources) could 1) impact the electrical operation of the active implants adversely, 2) increase the Specific Absorption Rate (SAR) values of tissue in the vicinity of the passive implants substantially because of resonance effects, and 3) increase the flow and acidity of saliva in the vicinity of dental structures. While the EMF effects on the cochlear implants could adversely affect auditory capability, EMF effects on the heart-related implants could potentially be life-threatening. The increased SAR values around the passive metal implants could result in increased tissue temperatures, and could adversely impact integration and longevity of the passive metallic implants.

In the mouth, the combination of 1) increased tissue temperatures in proximity to the implant or other orthodontic structures and 2) increased flow rate and acidity of saliva could lead to 3) increased leaching of heavy metals. Exposure to heavy metals is a major contributor to myriad chronic diseases [Kostoff, 2015]. The question then becomes: what other adverse health effects from the exposure of both the active and passive implants to increasing levels of wireless radiation have not been identified or addressed?

Appendix 7 addresses this issue of wireless radiation adverse effects related to medical implants and appendages in more detail, and additionally addresses potential wireless radiation adverse effects on tissues imbedded (deliberately or inadvertently) with exogenous-based nanoparticles that effectively act as micro/nano-implants. These nanoparticle-imbedded tissues may have the potential for enhanced energy absorption from the incoming RF signal, and may exhibit potentially harmful thermal transients (over and above the potential thermal transients resulting from the pulsed high peak-to-average power of the RF signal) that would be camouflaged under the wide averaging time periods in the FCC Guidelines.

2D3c. Factor analysis taxonomy results

The 5,311 records in the retrieved and ***partially*** filtered adverse health effects database were imported into the VP software [VP, 2019], and a factor analysis was performed. Thousands of MeSH Headings extracted by the VP software were inspected visually, and those directly applicable to adverse health effects were selected. The software then used these selected MeSH Headings to generate a factor matrix, which identified the main adverse health effects themes of the database. Appendix 3 presents this taxonomy (Table A3-1), and the titles of the records that were assigned to each category in the taxonomy. The titles give a better appreciation for the contents of each category than the brief category heading.

Table A3-1 (reproduced from Appendix 3) follows. It presents the factors/categories in the taxonomy, and the key MeSH Headings used to define the factor/category and link to the record titles shown in Appendix 3. In Appendix 3, the factors in Table A3-1 are hyperlinked to their respective record titles.

Table A3-1 - Factor Analysis Taxonomy

FACTOR THEME	MESH HEADINGS
1 Electromagnetic hypersensitivity and inflammation	C-Reactive Protein, Liver Diseases, Thyroid Diseases, Inflammation, Tonsillitis, Hypersensitivity
2 Coronary artery disease	Plaque, Atherosclerotic, Coronary Artery Disease, Diabetes Mellitus, Carotid Artery Diseases, Inflammation, Hypertension
3A Congenital abnormalities	Cleft Lip, Cleft Palate, Calcification, Physiologic, Congenital Abnormalities
3B Mammary tumors	Fibroadenoma, Adenoma, Mammary Neoplasms, Animal, Mammary Neoplasms, Experimental, Adenocarcinoma
4 Male infertility	Sperm Count, Spermatozoa, Sperm Motility, Semen, Testis, Infertility, Male, Spermatogenesis, Testosterone, Fertility
5 Brain neoplasms	Meningioma, Glioma, Meningeal Neoplasms, Neuroma, Acoustic, Brain Neoplasms, Glioblastoma, Neoplasms, Radiation-Induced, Neuroma, Cranial Nerve Neoplasms, Parotid Neoplasms, Central Nervous System Neoplasms
6 Sensory disorders	Burning Mouth Syndrome, Taste Disorders, Skin Diseases, Mouth Diseases, Dizziness, Vision Disorders, Hypersensitivity, Delayed, Fatigue
7 Breast neoplasms	Carcinoma, Lobular, Carcinoma, Ductal, Breast, Breast Neoplasms, Male, Adenoma
8 Oxidative stress	Oxidative Stress, Malondialdehyde, Glutathione Peroxidase, Lipid Peroxidation, Reactive Oxygen Species, Apoptosis, DNA Damage, Nitric Oxide, Protein Carbonylation
9 Neurodegenerative diseases	Parkinson Disease, Neurodegenerative Diseases, Alzheimer Disease, Amyotrophic Lateral Sclerosis, Motor Neuron Disease, Occupational Diseases, Dementia, Brain Diseases, Dementia, Vascular
10 Cerebrovascular disorders	Cerebrovascular Disorders, Dementia, Migraine Disorders, Tinnitus, Headache, Sleep Wake Disorders, Carotid Artery Diseases, Alzheimer Disease, Dementia, Vascular

11 Congenital abnormalities and glandular-based tumors	Cleft Lip, Cleft Palate, Fibroadenoma, Adenoma, Calcification, Physiologic, Mammary Neoplasms, Animal, Mammary Neoplasms, Experimental, Adenocarcinoma
12 Skin neoplasms	Carcinoma, Basal Cell, Carcinoma, Squamous Cell, Skin Neoplasms, Cocarcinogenesis, Neoplasms, Experimental, Neoplasms, Radiation-Induced, Colonic Neoplasms
13 Leukemia	Leukemia, Myeloid, Acute, Leukemia, Lymphocytic, Chronic, B-Cell, Leukemia, Myelogenous, Chronic, BCR-ABL Positive, Leukemia, Myeloid, Leukemia, Multiple Myeloma, Lymphoma, Leukemia, Radiation-Induced, Acute Disease, Liver Neoplasms, Experimental, Central Nervous System Neoplasms
14 Precancerous conditions	Atrophy, Precancerous Conditions, Hyperplasia, Hypersensitivity, Delayed, Thymus Gland, Capillary Permeability, Lymphoma
15 Circadian Rhythm	Melatonin, Circadian Rhythm, Pineal Gland
16 Eye diseases	Eye Diseases, Cataract, Vision Disorders, Sensation Disorders, Neurotic Disorders, Lens, Crystalline, Corneal Diseases, Edema, Hematologic Diseases
17 Electromagnetic interference in implanted electronic devices	Tachycardia, Ventricular, Ventricular Fibrillation, Death, Sudden, Cardiac, Arrhythmias, Cardiac
18 Liver Neoplasms	Liver Neoplasms, Carcinoma, Hepatocellular, Neoplasm Recurrence, Local, Lymphatic Metastasis
19 Symptoms of discomfort	Headache, Dizziness, Fatigue, Depression, Anxiety, Tremor, Sleep Wake Disorders, Neurotic Disorders, Stress, Psychological, Anxiety Disorders, Nervous System Diseases
20 Neoplasms	Lung Neoplasms, Ovarian Neoplasms, Pituitary Neoplasms, Lymphoma, Prostatic Neoplasms, Colonic Neoplasms, Carcinoma, Breast Neoplasms, Hematologic Neoplasms, Neoplasms, Liver Neoplasms, Cell Transformation, Neoplastic, Nervous System Neoplasms

2D3d. Text clustering taxonomy results

The 5,311 records in the retrieved and ***partially*** filtered adverse health effects database were imported into the CLUTO software [CLUTO, 2019], and a text clustering was performed. Forty-eight lowest level clusters were selected, based on theme resolution desired (average ~100 records per lowest level category). Appendix 4 presents this taxonomy (Table A4-1, Table A4-2), and the titles of the records that were assigned to each lowest-level category in the taxonomy. The titles give a better appreciation for the contents of each category than the brief category theme shown.

Table A4-1 (reproduced from the Appendix) presents the high-level clusters in the taxonomy, and the cluster themes. In Appendix 4, the fourth-level clusters in Table A4-2 (repeated from the fourth level shown in Table A4-1) are hyperlinked to their respective record titles.

Table A4-1 - CLUTO-Based Text Clustering Taxonomy – Top Levels

SECOND LEVEL	FOURTH LEVEL
Cluster 92 (2561) – Adverse effects of wireless radiation at cellular level, including radiation absorption at different frequencies	Cluster 78 (912) - Adverse impacts of wireless radiation, especially on cataracts, cells, and cognitive functions
	Cluster 79 (428) - Microwave radiation absorption at different frequencies
	Cluster 82 (529) - Adverse effects of mobile phone radiation, especially oxidative stress
	Cluster 84 (692) - Genotoxic effects of radiofrequency radiation
Cluster 93 (2750) – Adverse health effects of EMF on humans, especially cancer and neurodegenerative diseases, and on implanted electronic devices	Cluster 81 (673) - Adverse impacts of power-line EMF
	Cluster 85 (540) - Adverse impacts of low-frequency EMF, emphasizing cancer and neurodegenerative diseases
	Cluster 83 (668) – Adverse effects of mobile phone use, especially brain tumors, and brain and neural function
	Cluster 89 (869) - Human health risks from electromagnetic radiation, including adverse effects on implanted electronic devices, and possible protections

Note: Numbers in parentheses reflect numbers of records in cluster

2D3e. Wireless radiation adverse health effects in closed literatures

It should be re-emphasized at this point that almost all of the wireless radiation findings reported above reflect what is published in the open literature. That tends to emphasize basic research, and tends to be produced by academia, with its strong incentives for publication.

There's a much larger world of effort centered around wireless radiation technology and engineering development (for surveillance, communications, and weaponry) performed in organizations that have 1) few incentives to publish and 2) many prohibitions against publication due to classification and/or proprietary issues. Publication of adverse effects of these wireless systems could have severe financial consequences for all the stakeholders involved, and could result in potential military operational constraints as well.

The Federal government and industry who sponsor and many times conduct these advanced wireless radiation technology studies and demonstrations have 1) strong incentives to classify and proprietarize any results detrimental to their promotional activities and 2) no incentives to release results showing serious adverse health effects from wireless radiation to the public!

Consider the example shown in section 2D4 concerning the Zalyubovskaya [1977] reference, derived from Kostoff [2019a]. It shows some 1970s Soviet studies on EMF effects, including millimeter-wave effects, that were classified for 35 years until declassification in 2012. If relatively benign studies like those were classified for 35 years, one can only imagine the more serious studies that remain classified until this day. Or, Soviet studies that were not presented in an open forum because of their sensitivity. Or, USA studies that were performed decades ago (or recently), and remain classified to this day.

Also, consider the following example, which came to light relatively recently.

On 30 October 2019, an article was published suggesting the presence of cancer clusters among military pilots [https://www.mcclatchydc.com/news/nation-world/national/national-security/article236413708.html]. This may be the tip of the iceberg, since there are latency periods preceding the emergence of these cancers. It is unclear how well the health conditions of these pilots are tracked once they leave the service (according to the article), or, more specifically, ***how well the public is informed*** as to how well the health conditions of these pilots are tracked once they leave the service, and, if they are tracked, what the results of this tracking are. If there is tracking, who is funding the tracking, and what is its objectivity?

Severe recruiting consequences would result if it were shown that these serious diseases are in fact associated with exposures to on-board avionics and other stressors unique to the aircraft environment (EMF in combinations with other unique stressors [chemicals, psychological stress, high and low-G forces, etc] that performance aircraft crews face). It would be valuable to get EMF exposure data (***using an independent assessment***) under myriad flight conditions for many different military aircraft, with all the onboard avionics in full operation.

A similar article generated by the same organization addressing RF exposures of military pilots [https://www.mcclatchydc.com/news/nation-world/national/national-security/article237797304.html] complements the information contained in the above example, as shown in the following:

The largest Grumman measurement reported in the article translates to ***300 million microwatts/square meter***! This is thirty times today's FCC general public exposure limit, which itself is three-four orders-of-magnitude above levels shown by the cell tower studies to increase cancer incidence substantially. In parallel, the pilots are also being exposed to myriad other toxic stimuli, including EMF of other frequencies, cosmic radiation, perhaps fuel odors, etc, increasing the possibility of adverse effect synergies.

These may be the tip of the iceberg of RF exposure measurements done in the aircraft cabin, and there is no evidence that these were the highest occurring exposures. These types of exposure measurements rarely, if ever, see the light of day in the open literature, and are not advertised (for obvious purposes) by government-industry.

Additionally, while the gold coating mentioned may have kept a substantial amount of external RF from entering the cabin, it also would have delayed RF (that was internally generated or entered the cabin through non-gold coated non-metallic avenues) from leaving the cockpit, mirroring a hohlraum effect.

This cockpit problem reflects a disturbing trend. The military services became network-centric decades ago. They are almost completely dependent on wireless communications and wireless detection/surveillance for all their operations. If they were to allow their labs and contractors to report the possible damage from the levels of exposures happening in the field and at their facilities, potentially resulting in much lower wireless radiation exposure limits, they would be forced to eliminate many decades of so-called advances in their weaponry and operations. It could also impact their recruitment efforts adversely. No different in kind from their civilian counterparts, although the military may be operating at higher exposure levels because of their ultra-high-performance requirements.

So, while the adverse health effects of wireless radiation listed above in the monograph are very serious in their own right, they may be just the tip of the iceberg of the totality of adverse health effects that have actually been demonstrated if the non-published or classified studies had been taken into account.

2D4. Adverse Wireless Radiation Health Effects from Former USSR Literature Analysis

2D4a. Overview

The Former Soviet Union/USSR was a major player in biomedical research on health effects of non-ionizing radiation (both adverse and therapeutic) since at least the 1950s, and perhaps well before. Some/much of the work was published in the Soviet open literature, and available in Russian. Some/much of it was translated by USA intelligence agencies, and later declassified. Some may still be classified. The major difference between the USA and Soviet research on adverse effects of wireless radiation appears to be emphasis on thermal (USA) vs athermal (Soviet) effects. This difference is reflected in the different wireless radiation exposure limits imposed by each government.

2D4b. Glaser and Dodge review of East European radiofrequency literature

Glaser and Dodge addressed this issue within a comprehensive review of East European radiofrequency and microwave radiation literature [Glaser and Dodge, 1976], as follows:

THERMAL VS ATHERMAL EFFECTS – USA-USSR

"The most significant difference between East and West relative to biological mechanisms of effects of microwaves concerns the question of thermogenic versus nonthermogenic (or athermal) effects.....The traditional Soviet and East European view from the earliest publications of bio-studies has been that microwave and radio frequency fields can functionally, and even morphologically in some cases, alter the organism at field flux or power densities below those which cause measureable heating in tissues or biological substrates. Thus, reversible changes in behavior, physiological function, and microstructures are frequently reported at power densities of microwatts per square centimeter (muW/cm2), well below the Western world's "safe" exposure level of 10 milliwatts per square centimeter (10 mW/cm2).....In contrast, the prevailing Western view, particularly in the United States, is that the effects of microwave and radio frequency fields are attributable only to the heating mechanism of those fields which are generally encountered at power densities in excess of 10 mW/cm2.....

The disparity between Eastern and Western views in this respect finds its most eloquent expression in daily occupational exposure standards for microwaves. In the Soviet Union and some East European countries, the standard for an occupational exposure day is 0.01 mW/cm2.....In the United States and some Western European countries, the value for continuous exposure is 10 mW/cm2.

Prior to 1953, it was believed that 100 mW/cm2 was the lowest level at which significant biological damage would occur.....Thus, 10 mW/cm2 is approximately one tenth the level calculated to cause significant heating in human tissues, and agrees with physiologic and metabollc calculations . Intermediate standards between these values are practiced by some European countries....."

This conclusion, presented 43 years ago in print, is particularly disheartening. Despite all the evidence of adverse athermal effects of wireless radiation that was generated prior to 1976 (especially in the USSR, but in the USA as well), and the voluminous evidence (of adverse athermal effects of wireless radiation) that has been reported from global research since 1976, the USA government (along with many others) has refused to recognize the credibility of these athermal wireless radiation effects in the setting of regulatory exposure standards.

2D4c. Glaser review of global radiofrequency literature circa 1972

What was the state of the open literature on adverse health effects of wireless radiation in the 1970s, including what was known about Soviet and East European research? One partial answer can be gleaned from a very comprehensive review of the global radiofrequency and microwave biomedical effects literature published as a DTIC report in 1972 [Glaser, 1972]. The abstract of this report states in part:

> "More than 2300 references on the biological responses to radio frequency and microwave radiation, published up to April 1972, are included in this bibliography of the world literature. Particular attention has been paid to the effects on man on non-ionizing radiation at these frequencies. The citations are arranged alphabetically by author, and contain as much information as possible so as to assure effective retrieval of the original documents. ***Soviet and East European literature is included in detail***. An outline of the effects which have been attributed to radio frequency and microwave radiation is included as Chapter 1."

The effects mentioned in the last sentence have been converted to a more readable form by Dr. Magda Havas on her outstanding Web site (describing decades of global research on wireless radiation health effects) [Havas, 2019]. As stated on her Web site, Dr. Havas has obtained hard copies of Dr. Glaser's references from Dr. Glaser, and is in the process of scanning them and making them available to a wider audience. Dr. Havas' summary of the effects mentioned in the last sentence of the box above is repeated in the following table:

CATEGORY	ADVERSE EFFECTS
A. Heating of Organs* [Applications: Diathermy, Electrosurgery, Electrocoagulation, Electrodesiccation, Electrotomy]	This includes heating of the whole body or part of the body like the skin, bone and bone marrow, lens of the eye with cataracts and damage to the cornea; genitalia causing tubular degeneration of testicles; brains and sinuses; metal implants causing burns near hip pins etc. These effects are reversible except for damage to the eye.

B. Changes in Physiologic Function	This includes contraction of striated muscles; altered diameter of blood vessels (increased vascular elasticity), dilation; changes in oxidative processes in tissues and organs; liver enlargement; altered sensitivity to drugs; decreased spermatogenesis leading to decreased fertility and to sterility; altered sex ratio of births in favor of girls; altered menstrual activity; altered fetal development; decreased lactation in nursing mothers; reduction in diuresis resulting in sodium excretion via urine output; altered renal function; changes in conditioned reflexes; decreased electrical resistance of skin; changes in the structure of skin receptors; altered rate of blood flow; altered biocurrents in cerebral cortex in animals; changes in the rate of clearance of tagged ions from tissues; reversible structural changes in the cerebral cortex and diencephalon; changes in electrocardiographs; altered sensitivity to light, sound, and olfactory stimuli; functional and pathological changes in the eyes; myocardial necrosis; hemorrhage in lungs, liver, gut and brain and generalized degeneration of body tissue at fatal levels of radiation; loss of anatomical parts; death; dehydration; altered rate of tissue calcification.
C. Central Nervous System Effects	This includes headaches; insomnia; restlessness (daytime and during sleep); changes in brain wave activity (EEG); cranial nerve disorders; pyramidal tract lesions; disorders of conditioned reflexes; vagomimetic and sympathomimetic action of the heart; seizure and convulsions.
D. Autonomic Nervous System Effects	Altered heart rhythm; fatigue, structural alterations in synapses of the vagus nerve; stimulation of the parasympathetic nervous system leading to Bradycardia and inhibition of the sympathetic nervous system.
E. Peripheral Nervous System Effects	Effects on locomotor nerves.
F. Psychological Disorders	Symptoms include neurasthenia (general bad feeling); depression; impotence; anxiety; lack of concentration; hypochondria; dizziness; hallucinations; sleepiness or insomnia; irritability; decreased appetite; loss of memory; scalp sensations; fatigue; chest pain, tremors.
G. Behavioral Changes in Animals Studies	Effects include changes in reflexive, operant, avoidance and discrimination behaviors
H. Blood Disorders	Effects include changes in blood and bone marrow; increased phagocytic and bactericidal functions; increased rate of hemolysis (shorter lifespan of cells); increased blood sedimentation rate;

	decreased erythrocytes; increased blood glucose concentrations; altered blood histamine content; changes in lipids and cholesterol; changes in Gamma Globulin and total protein concentration; changes in number of eosinophils; decrease in albumin/globulin ratio; altered hemopoiesis (rate of blood corpuscles formation); leukopenia (increased number of white blood cells and leukocytosis; reticulocytosis (increase in immature red blood cells).
I. Vascular Disorders	This includes thrombosis and hypertension.
J. Enzyme and Other Biochemical Changes (in vitro)	Changes in the activity of cholinesterase (also in vivo); phosphatase; transaminase; amylase, carboxydismutase; denaturation of proteins; inactivation of fungi, viruses, and bacteria; killed tissue cultures; alterated rate of cell division; increased concentration of RNA in lymphocytes and decreased concentration of RNA in brain, liver and spleen; changes in pyruvic acid, lactic acid and creatinine excretions; changes in concentration of glycogen in liver (hyperglycemia); altered concentrationsof 17-ketosteroids in urine.
K. Metabolic Disorders	Effects include glycosuria (sugar in urne); increase in urinary phenols; altered processing of metabolic enzymes; altered carbohydrate metabolism.
L. Gastro-Intestinal Disorders	Effects include anorexia; epigastric pan; constipation; altered secretion of stomach digestive juices.
M. Endocrine Gland Changes	Effects include altered functioning of pituitary gland, thyroid gland (hyper-thyroidism and enlarged thyroid, increased uptake of radioactive iodine), and adrenal cortex; decreased corticosteroids in blood; decreased glucocorticoidal activity; hypogonadism (with decreased production of testosterone).
N. Histological Changes	Changes in tubular epithelium of testicles and gross changes.
O. Genetic and Chromosomal Changes	Effects include chromosomal aberrations (shortening, pseudochiasm, diploid structures, amitotic divisions, bridging, "stickiness"; irregularities in chromosomal envelope); mutations; mongolism; somatic alterations (not involving nucleus or chromosomes); neoplastic diseases (tumors).
P. Pearl Chain Effect	This refers to intracellular orientation of subcellular particles and orientation of cellular and other (non-biologic particles, i.e. mini magnetics) affecting orientation of animals, birds, and fish in electromagnetic fields.
Q. Miscellaneous Effects	These include sparking between dental fillings; metallic taste in mouth; changes in optical activity of colloidal solutions; treatment for

	syphilis, poliomyelitis, skin diseases; loss and brittleness of hair; sensations of buzzing, vibrations, pulsations, and tickling about head and ears; copious perspiration, salivation, and protrusion of tongue; changes in the operation of implanted cardiac pacemakers; changes in circadian rhythms.

Thus, much was known about the adverse health effects of both thermal and athermal high-frequency wireless radiation even in the early 1970s (Glaser's review did not address lower frequency radiation effects, although we now know these lower frequency effects could be equally damaging as those from high frequency), but this long-standing knowledge has not translated into adequate protections for the public from wireless radiation, both in the USA and the rest of the world.

2D4d. Joint Publications Research Service translations of East European research

Another avenue of insight into Soviet and East European research in the 1970s era was provided by the Joint Publications Research Service (JPRS). A description of this organization follows [https://guides.library.harvard.edu/jprs]:

> The United States Joint Publications Research Service is a government agency which translates foreign language books, newspapers, journals, unclassified foreign documents and research reports. Approximately 80% of the documents translated are serial publications. JPRS is the largest single producer of English language translations in the world. More than 80,000 reports have been issued since 1957, and currently JPRS produces over 300,000 pages of translations per year.
>
> **In its early years JPRS concentrated heavily on scientific and technical material from communist countries. Gradually coverage has broadened to include more non-scientific materials.**

2D4d1. Maritime occupational radiofrequency exposures in USSR

One of the Soviet technical books translated by the JPRS is listed on Dr. Havas' Web site [https://magdahavas.com/pick-of-the-week-15-russian-translations-on-biological-effects-of-magnetic-fields-and-radio-frequency-radiation/]. This book [Kulikovskaya, 1970] is important because it shows the levels of wireless radiation to which Soviets in some occupations were exposed fifty years ago, numbers that many wireless radiation proponent countries do not readily advertise. Whether these exposures are greater or less today is unclear; powers may be higher, but shielding may be better.

In the introductory section of Chapter IV (Biological Effect of Radio Waves – p.70), the following statement is made:

"Foreign researchers are giving basic attention to the effect of electromagnetic radio waves beginning with the thermal effect, that is, heating the animate organism by the field energy.

The research performed in our country, in contrast to foreign research, is based on a complex of dynamic studies of the reactions of the organism to the effect of low irradiation intensities, and, especially, in the superhighfrequency range, recognition of the cumulative biological effect in the case of chronic explosure to low power flux densities."

This quoted statement confirms the statement of Glaser and Dodge in section 2D4b above. Since the bulk of the references in Kulikovskaya's book are from the 1950s and 1960s, one can surmise that *a decision was made by the Western powers (especially the USA, who led the Western powers at that time) seventy years ago to downplay the adverse effects of athermal wireless radiation, and promote the false concept that only the thermal effects of wireless radiation are responsible for biomedical damage*. The decision-makers from the Western powers recognized seventy years ago that *wide-ranging wireless communications and surveillance were not possible if biologically protective exposure limits were promulgated.* Through countless Administrations and Legislatures since the days of President Eisenhower, all USA (and most foreign) decision-makers have presented a consistent and unified front promoting increased exposure to wireless radiation at the expense of the health of the nation's citizens!

The following table shows examples (from Kulikovskaya [1970]) of maximum levels of exposure to wireless radiation for Soviet citizens working in the marine environment. The maximum electric field exposure levels exceed the Soviet regulatory limits at that time (which were up to an order-of-magnitude lower than the USA regulatory limits) by up to two orders-of-magnitude!

To place these numbers in perspective, the Building Biologists' recommendations for safe long-term exposure limits in these frequency ranges is less than one volt per meter (https://mdsafetech.org/conversion-and-exposure-limits-emr-emf/). Thus, the reported exposures exceed safe levels by two-three orders of magnitude.

The research was performed at the Laboratory of Physical Factors of the State Scientific Research Insitute of Labor Hygiene and Professional Diseases. The exposure levels reported are what the Soviet government was willing to release to the public. Whether they were the most severe exposures experienced by members of the civilian and military fleets remains unknown. In terms of personnel recruitment for these jobs, it was/is not in the government's (Soviet or otherwise, including USA) best interests to release to the public exposure levels that would show these jobs to be highly dangerous to health. The book attempts to make the point that most exposures experienced by maritime personnel are much lower than the maximum, probably to assuage the public. The results are disturbing nevertheless, and should be viewed as the 'floor' of exposures to be expected relative to measurements made by an 1) ***independent objective group*** 2) ***on location during operations*** 3) ***without having given advanced notice***!

REGION	FREQ RANGE MHz	MAX EXPOS V/m	EXP LIMIT V/m
Electromagnetic Fields Near Tube Generators for High-Frequency Heating of Metals (P.23)	.06-.8	1,000+	20
Electromagnetic Waves Near Tube Generators for High-Frequency Heating of Dielectrics (P.26)	10-30	500+	20
Electromagnetic Fields in the Radio Rooms of Ships (P. 29)	.3-23		
Passenger Ships (P. 32)	.4-.8	2,000	20
Ships of the Tanker Fleet (P. 36)	.4-.8	2,000	20
Dry Cargo Ships (P. 37)	.4-.8	1,600	20
Ships of the Auxiliary Fleet (P. 40)	.4-.8	420	20
Electromagnetic Fields of Radio Communications Antennas on the Decks and Superstructures of Ships (P. 44)	.3-3	880	20
"In conclusion, it can be stated that the highest intensity of an electric field up to hundreds and sometimes ***thousands and more volts per meter*** occurs near the antenna drops and metal masses on the top bridges and decks during operation of a medium wave radio. Here, the magnetic component of the field can reach ***ten and even fifteen amps/meter***." P. 52)			
Superhigh Frequency Electromagnetic Fields of Radar Antennas on the Decks of Ships (P. 52)	3,000-15,000		
"Studies of the conditions of irradiation of the deck crew with superhigh-frequency fields performed on ships for various purposes show that when the radar antennas are installed on columns 1.2-2.5 meters above the deck of the top bridge, the power flux density can be hundreds and sometimes ***thousands of microwatts per square centimeter***." (P. 54)			
Some Adverse Health Effects of Marine Radio Operators (P. 80) "The conditions of labor of marine radio operators are least favorable….. a relatively large number of people with various diseases appear among radio operators. Thus, out of 215 radio operators, 50 had chronic diseases (23.2 percent).....The primary disruption of the state of health of ship radio operators is damage to the organs of sight.....Among the diseases of the cardiovascular system occurring in ship radio operators, hypertonic disease. myocardial distrophy and disruption of the blood circulation in the brain play the leading role. All radio operators suffering from diseases of the cardiovascular system are young (from 30 to 35 years old) with five to 10 years of service. Among the diseases of the nervous system encountered in them, functional disorders of the central nervous system, vegetative neurosis, and neurasthenic syndrome are noted.....Thus, it is possible to consider it established that the largest number of people with health impairments occur among ship radio operators as compared to other marine professions."			

2D4d2. Biomedical effects of millimeter-wave exposures in some USSR research

Additionally, consider the following USSR reference [Zalyubovskaya, 1977] translated by the JPRS and published as a classified document in 1977.

SYSTEMIC ADVERSE EFFECTS FROM MILLIMETER-WAVE RADIATION

This is one of many translations of articles produced in the Former Soviet Union on wireless radiation (also, see reviews of Soviet research on this topic by McRee [1979, 1980], Glazer and Dodge [1976], Kositsky et al [2001]). On p. 57 of the pdf link, the article by Zalyubovskaya addresses biological effects of millimeter radiowaves. Zalyubovskaya ran experiments using power fluxes of 10,000,000 microwatts/square meter (the FCC guideline limit for the general public today), and frequencies on the order of 60 GHz. Not only was skin impacted adversely, but also heart, liver, kidney, spleen tissue as well, and blood and bone marrow properties. These results reinforce the conclusion of Russell (see section 2E) that systemic results may occur from millimeter-wave radiation. And, to re-emphasize, for Zalyubovskaya's experiments, the incoming signal was unmodulated carrier frequency only, and the experiment was single stressor only. Thus, the expected real-world results (when human beings are impacted, the signals are pulsed and modulated, and there is exposure to many toxic stimuli) would be far more serious and would be initiated at lower (perhaps much lower) power fluxes.

The Zalyubovskaya paper was published in 1977. What national security concerns caused it (and the other papers in the linked pdf reference) to be classified in the first place, and then kept classified for 35 years until declassification in 2012? What other papers on this topic with similar findings were published in the USSR (and the USA) at that time, or even earlier, and how many such papers never saw the light of day in the USSR (and the USA) at that time? It appears that we have known about the potentially damaging effects of millimeter-wave radiation on the skin (and other major systems in the body) for well over forty years, yet the discourse today only revolves around the possibility of modest potential effects on the skin and perhaps cataracts from millimeter-wave radiation.

2D4d3. Health effects from millimeter-wave exposures in Russian and Ukrainian literature

The review by Kositsky referenced in section 2D4d2 [Kositsky et al, 2001] appears to be based on 1) open literature publication of 2) wireless radiation biological effects 3) by Russian and Ukrainian researchers, covering the publication time period of 1968-2000. It appears to be quite comprehensive, and addresses both wireless radiation 1) adverse health effects and 2) therapeutics. It covers millimeter-wave frequencies almost exclusively. Some important takeaways from the Kositsky review are shown in the following box.

BIOLOGICAL EFFECTS FROM MILLIMETER-WAVE RADIATION

"there is a large probability of harmful effects from incidental generalized exposure, as confirmed in experiments on animals"

"Since living organisms have evolved under conditions of low natural background EHF EMR, they lack a ready-made mechanism of evolutionary adaptation to heightened levels of radiation resulting from technogenic factors"

"The results of clinical research showed that prolonged contact with EMF in the SHF band can lead to development of diseases, the clinical profile of which is determined above all by changes in the functional condition of the nervous and cardiovascular systems"

"Under EFD of 60 μW/cm2, disturbance of female cycles; reduction in fertility, number and weight of offspring; increase in postnatal deaths of the rat pups by a factor of 2.5; and dystrophic changes in the reproductive organs of the animals were noted"

"The results obtained give evidence that a single exposure to low-intensity EHF EMR without modulation, and with modulation at low frequencies of 5-10 Hz, induce opposite effects in red bone marrow (RBM). In the former case, we have pronounced stimulation of proliferative processes in the RBM, which are reversible. In the latter case—progressive depression of the process of blood production, right down to the formation of hypo- and aplastic conditions in the RBM on the sixth day of observation."

"biological effects of millimeter waves (BEF MMW):…They do not depend on the intensity of EMR, starting from the threshold to noticeable heating of tissue…..Irreversible BEF occur only during prolonged or cyclical exposure…..During amplitude or frequency modulation of MMW, bioeffects are maintained or strengthened as the power of exposure is significantly reduced…..The body "remembers" the effect of EMR for a relatively long time……In some cases, EMR influences sensitivity to other factors (chemicals, ionizing radiation, etc.), and the effects may persist through time."

"In epidemiological studies of the population of Ukraine, a connection was established between leukemia in children and cancer in adults, and exposure to EMF at industrial frequencies."

"Specific injuries under radiowave exposure are development of cataracts, instability in leukocyte make-up of peripheral blood, and vegeto-vascular disorder"

"the likelihood of cancer was three times greater under SHF exposure"

"It can be proposed that the current increase in electromagnetic pollution of the environment exceeds human adaptational capacities"

"The danger of mobile telephones consists of the fact that in addition to direct effects on the brain, the whole body is irradiated via the biologically active points of the concha of the ear"

"Observed higher resonance frequencies of a living cell coincide with frequencies of radiation of communications satellites. The power densities and duration of irradiation created by these satellites will significantly exceed…..the energetic doses inducing changes in living cells…… there will be a likelihood of changes (including negative changes) in the genetic apparatus of living cells during prolonged exposure to low-energy electromagnetic radiation from communications satellites"

"Combination with other deleterious factors: ionizing radiation, toxic substances, geomagnetic anomalies and stress significantly increase the effects of HF EMR."

"Occurrence of a narcotic-type dependency (by stimulating production of endorphins) is possible under regular irradiation with HF EMR."

"in animals irradiated with EMF, the nature of the infectious process changes—the course of the infectious process is aggravated"

"Absorption of EMF in biologically active points is many times more effective than in other parts of the skin, and this energy influences the internal organs and the body as a whole through the system of Chinese meridians."

In summary, these excerpts show that

- adverse effects can be initiated with very low doses of EMR,
- millimeter-wave radiation can impact regions below the skin, and
- adverse effects may be exacerbated when the EMR is combined with other toxic stimuli.

Given Kositsky's statement in section 2D4 about the potential of a narcotic-type dependency from exposure to EMR through stimulating production of endorphins, could EMR be effectively serving as one of the gateway 'drugs' to the increased opioid use we observe today? Appendix 5 addresses the potential impact of wireless radiation exposure on the opioid crisis, and shows that wireless radiation could indeed be a contributing factor to the overuse of opioids we are seeing today!

and industry (and academia in some cases) in concealing harm of toxic substances (whose continued use is of importance to one or both organizations). These examples, and many others in the large USA government-industry candidate pool from which they were selected, show that

government-industry collusion to suppress adverse effects from technologies is endemic across technologies; ***it is not an aberration, but may be closer to the norm for technologies that are sensitive commercially, militarily, and politically.***

A comprehensive article in The New Yorker magazine (https://www.newyorker.com/magazine/2014/02/10/a-valuable-reputation?verso=true) details the travails that Prof. Tyrone Hays had to endure from industry in his quest to show that the herbicide Atrazine contributes to severe adverse effects. While the European Union banned the use of Atrazine almost two decades ago, the EPA has allowed its use to continue in the USA.

Finally, Appendix 6 lists study references showing effects of industry funding on research outcomes for myriad research disciplines (mainly within biomedical). What these references don't show (for the most part) is how industry convinced the regulators to incorporate the results of these studies in setting the lax regulations we see in practice today [e.g., Kostoff, 2018a]. Given that the sponsor and performer incentives of those studies are no different from the sponsor-performer incentives of wireless radiation health effects studies, there is little reason for expecting less concealment of adverse effects in the wireless radiation studies. Given the magnitude of revenues at stake for wireless radiation technology implementation, there is much reason for expecting more concealment and/or neutralization of adverse effects in the wireless radiation studies!

2F3. Interpreting Wireless Radiation Health Study Findings

Wireless radiation can play two roles as a contributor to adverse health effects: **initiator** and/or **promoter/accelerator**. The **initiator** role is reflected by single stressor studies (EMF alone) that show adverse health effects. The **promoter/accelerator** role is reflected by 1) combination studies that show no adverse effects from any of the constituents when tested in isolation, but show adverse effects (synergies) when tested in combination or 2) accelerating emergence of serious diseases. There can also be **initiator and promoter/accelerator** roles shown by combination studies, where each constituent tested in isolation shows a modest adverse effect, but the combination shows a much larger (i.e., synergistic) effect [Kostoff and Lau, 2013, 2017; Kostoff et al, 2018; Kostoff, 2018b].

So, if a study shows an adverse health effect from wireless radiation, and if it passes the criteria for high quality research, then that specific adverse effect for the parameter range shown could be accepted as credible. If a study shows no adverse health effects from wireless radiation in a single stressor experiment, the study MAY reflect no **initiator** role ***in the parameter window selected***, if the study is deemed to be of high research quality. However, such an experiment

offers little insight as to the **promoter/accelerator** role of the wireless radiation *in the parameter range selected.* The same would hold true for no adverse effects shown in combination experiments; there is no reason to believe that, even if wireless radiation serves as a promoter/accelerator for some combinations, it would therefore serve as a promoter/accelerator for all combinations.

In summary, the adverse effects of wireless radiation that result from credible high-quality studies published in the biomedical literature form the 'floor' for total adverse impacts of this wireless radiation. Given the insights of synergies from toxic stimuli combination studies evidenced in [Kostoff and Lau, 2013, 2017, Kostoff et al, 2018b, Juutiliin, 2006, 2008], many more adverse impacts from wireless radiation can be expected if the parameter range of single stressor studies is expanded and the numbers of combination studies are greatly expanded.

Further, there is little doubt that the biological effects of wireless radiation studies that have been classified (by the organization promoting the expansion of this technology, the Federal government, for alleged 'national security' purposes) show substantially more harmful effects from this technology in real-life situations.

Even the Gold Standard for research credibility – **independent replication of research results** – is questionable in politically, commercially, and militarily sensitive areas like wireless radiation safety. Suppose there are two research groups (funded by the same government agency) who both arrive at the same conclusion that just coincidentally coincides with what the government sponsor wanted. Would this be considered independent? Or, these two research groups received funding from different agencies of the same government. Would that be considered independent? Or, these two research groups received funding from two different governments that both had the same accelerated development objectives for the technology of interest. Review articles tend to treat these types of cases as independent, and don't make the distinction as long as the validation doesn't arise from within the performer group/organization.

Given the broad support exhibited today by the USA Federal government, military, and industry for the rapid implementation of 5G (and, indeed, the governments of most, if not all, the major developed countries globally), all these organizations must present a united front in declaring 5G (and previous generations of mobile networking technology) to be safe. If one government lab, or one highly-funded performer, were to perform a credible real-life simulation of wireless radiation effects and show the potential damage that might result, then the government's and industry's current fast-track effort to ***implement 5G before the full extent of the damage becomes known*** would be derailed.

It is unrealistic that any government would allow this to happen!

Even reporting of conflict-of-interest in wireless radiation research papers or evaluation panels leaves much to be desired. Currently, potential research performer conflicts of interest are identified by listing of funding sources in the published papers, or other formal documented evidence of conflicts of interest. However, there are many potential conflicts of interest that may not be as formal, but could be at least as influential as the formal conflicts in determining the outcome of the research or proposal. To ascertain these other less formal conflicts of interest would require vetting:

1) any elements of the researchers'/evaluators' investment portfolio that would profit from operation and expansion of the mobile telecommunications network, including impacts on related industries;

2) any elements of their present business endeavors that would profit from operation and expansion of this network, including impacts on related industries;

3) any elements of present or future pensions that would profit from operation and expansion of this network, including impacts on related industries;

4) any proposals or future employment offers in the pipeline or being considered that would profit from operation and expansion of this network, including impacts on related industries;

5) any other conflicts of interest by which they could profit from operation and expansion of the mobile telecommunications network, including impacts on related industries.

2G. Conclusions

Wireless radiation offers the promise of improved 1) remote sensing, 2) communications and data transfer, and 3) connectivity. Unfortunately, there is a large body of data from laboratory and epidemiological studies showing that previous generations of wireless networking technology have significant adverse health impacts. Much of this data was obtained under conditions not reflective of the real-world. When real-world considerations are added, such as 1) including the information content of signals along with the carrier frequencies, and 2) including other toxic stimuli in combination with the wireless radiation, ***the adverse effects are increased substantially***. Superimposing 5G mobile networking technology on an imbedded toxic wireless radiation environment (4G, 3G, etc) will exacerbate the myriad adverse health effects already shown to exist. Far more research and testing of potential 5G health effects is required before further rollout can be justified. Without this additional testing and demonstrated safety of potential 5G health effects, we will be even further along in **The Largest Unethical Medical Experiment in Human History!**

Chapter 4 – Appendices

Appendix 1 – Unethical Medical Experiments

A1-A. Overview

The biomedical literature reflects much good research. However, the world today is also awash in unethical medical experiments. There are two major types. The first type is classical unethical medical experiments, where test subjects are explicitly/proactively selected for experiments on biological effects of drugs or potentially harmful substances, and participate in these experiments without having given 'informed consent'. The second type may be far more prevalent. Here, potentially harmful substances are introduced into commercial, military, or other government practice without adequate demonstration of safety. Then, test subjects are implicitly/reactively selected 'a posteriori' to participate in these de facto experiments, again without having given informed consent. These latter studies are usually epidemiological studies.

In parallel with the burgeoning conduct of unethical medical experiments is production of a literature that addresses the ethics of, and in many cases bemoans the prevalence and conduct of, these myriad unethical medical experiments. The experiments and the accompanying ethics literature form a symbiosis, where the literature feeds off the experiments, and the experiments spawn an additional literature. It is not clear how much, if any, impact the ethics literature has had/does have/will have on the conduct of the unethical medical experiments, especially those unethical medical experiments of the second type defined above.

Appendix 1A provides a few examples of mainly classical unethical medical experiments, and Appendix 1B provides a few references that reflect the medical experiment ethics literature.

Appendix 1A – Unethical Medical Experiments - Examples

This Sub-Appendix provides examples of unethical medical experiments, conducted mainly 1) over the last 100 years and 2) within the USA or under its auspices. The list is not exhaustive, since an abbreviated search approach was used, covering both Medline and the Web. Some of the more useful Web sources of information are shown in the following table:

https://en.wikipedia.org/wiki/Unethical_human_experimentation;
https://en.wikipedia.org/wiki/Human_subject_research;
https://en.wikipedia.org/wiki/Unethical_human_experimentation_in_the_United_States;
https://en.wikipedia.org/wiki/Medical_torture;
https://abuse.wikia.org/wiki/Unethical_human_experimentation_in_the_United_States;
https://www.amazon.com/s?k=human+experimentation&i=stripbooks&page=2&qclid=Cj0KCQiA89zvBRDoARIsAOIePbBy8acwX6tfMZcGkZyi_UTov1I7_PxcFYDAgDWiAgHVc7anOyx57slaAgtNEALw_wcB&hvadid=241915884190&hvdev=c&hvlocphy=9007578&hvnetw=g&hvpos=2o1&hvqmt=b&hvrand=12610529676369552698hvtargid=kwd-1053626641&hydadcr=22561_10346245&qid=1576539483&ref=sr_pg_2;
https://www.bibliotecapleyades.net/ciencia/ciencia_industryweapons173.htm.

It should be noted that information of this type is not easy to obtain. The research performers and their sponsors are not motivated to reveal such odious experiments to any oversight organizations, and therefore tend to conceal these experiments to the largest extent possible. There are three main routes by which this information eventually gets to the public: whistle-blowers; discovery in legal lawsuits; inadvertent access by researchers examining other topics. While we don't know the extent of these types of experiments that have not been reported, it is probably a good assumption that there are huge numbers.

Following are some of the books and journal/magazine articles that describe these experiments. It is by no means a complete list, and the interested reader would be well-advised to read the articles with the Web links provided in the box.

Examples of Unethical Medical Experiments

Albarelli H.P, Kaye JS. The Hidden Tragedy of the CIA's Experiments on Children. 11 August 2010. Truthout.

Annas, George J.; Grodin, Michael A. The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation. 1995. Oxford University Press. ISBN 978-0-19-510106-5.

Anon. History of the Human Subjects Protection System. Institutional Review Board Guidebook. Office for Human Research Protections. 1993. Archived from the original on 2013-02-18. Retrieved 2011-06-03.

ABOUT THE AUTHOR

Ronald Neil Kostoff received a Ph. D. in Aerospace and Mechanical Sciences from Princeton University in 1967. He has worked for Bell Laboratories, Department of Energy, Office of Naval Research, and MITRE Corp. He invented the Wake Shield for producing high vacuum in low orbit, and used in manned space missions for research and development. He has published over 200 peer-reviewed articles, served as Guest Editor of four journal Special Issues since 1994, obtained two text mining system patents, and presently is a Research Affiliate at Georgia Institute of Technology.

He has published on numerous medical topics in the peer-reviewed literature, including:

- potential treatments for
    - Multiple Sclerosis,
    - Parkinson's Disease,
    - Raynaud's Phenomenon,
    - Cataracts,
    - SARS,
    - Vitreous Restoration,
    - Peripheral Neuropathy/Peripheral Arterial Disease
    - Alzheimer's Disease, and
    - Chronic Kidney Disease;
- potential causes of Chronic Kidney Disease;
- potential causes of Alzheimer's Disease;
- potential causes of Peripheral Neuropathy/Peripheral Arterial Disease
- potential impacts of Electromagnetic Fields on health; and
- synergistic effects of toxic stimuli combinations.

His recent publications in toxicology have shown that regulatory exposure limits to toxic stimuli are, on average, orders of magnitude too high compared to exposures shown to cause damage in the biomedical literature, and are not protecting the public from harmful substances.

He is listed in:

- Who's Who in America, 60th Edition (2006),
- Who's Who in Science and Engineering, 9th Edition (2006), and
- 2000 Outstanding Intellectuals of the 21st Century, 4th Edition, (2006).

VIRGINIA MEDICAL
VAMFA.org
FREEDOM ALLIANCE

The Honorable Governor Glenn Youngkin
Governor, The Commonwealth of Virginia
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Karen Shelton, MD
State Health Commissioner
Virginia Department of Health
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The Honorable Jason Miyares
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Secretary John Littel
Secretary of Health
Commonwealth of Virginia
1111 E. Broad St.
4th Floor
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William Harp, MD
Board of Medicine
9960 Mayland Dr., Suite 300
Richmond, VA 23233

March 25, 2024

Dear Governor Youngkin, Dr. Shelton, Honorable Jason Miyares, Secretary Littel and Dr. Harp:

I am writing to you, as the president of the Virginia Medical Freedom Alliance, to request that the Virginia Department of Health (VDH) formally retract its 10/28/2021 email and send a letter to all healthcare practitioners and pharmacists throughout the Commonwealth removing any prohibition against the use of ivermectin and hydroxychloroquine in the treatment of Covid-19. Further, we are asking that any ads, social media posts or documents discouraging the use of ivermectin and hydroxychloroquine in the treatment of Covid-19 be removed from its website and literature.

Following the recent court decision in United States District Court of the Southern District of Texas Galveston Division, Mary Talley Bowden, Plaintiff v. U.S. Department of Health and Human Services, et al., Defendants, Case No. 3:22-cv-184, the FDA retired its Consumer Update entitled, *Why You Should Not Use Ivermectin to Treat or Prevent Covid-19.* Further, they will delete and not republish Twitter, LinkedIN, and Facebook posts that read, "You are not a horse, You are not a cow. Seriously, y'all. Stop it."; Instagram posts, "You are not a horse. Stop it with the #ivermectin. It's not authorized for treating #Covid."; Twitter post that reads, "Hold your horses, y'all. Ivermectin may be trending, but it still isn't authorized or approved to treat

Covid-19" and all social media posts on FDA accounts that link to *Why You Should Not Use Ivermectin to Treat or Prevent Covid-19.*

In light of the decision, the members of the Virginia Medical Freedom Alliance, are again respectfully requesting that the Virginia Department of Health retract in full it's emailed statements of October 28, 2021 in which then Commissioner Norman Oliver stated,

"VDH strongly discourages the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial. Ivermectin is approved by FDA for human use to treat infections caused by internal and external parasites. It is not approved to prevent or treat Covid-19 or any other viral illness. Ivermectin is also available to treat certain veterinary conditions; medications formulated or intended for use in animals shouldn't be used by humans.

In addition, we urge physicians, other prescribers, and pharmacists-trusted healthcare professionals in their communities- to warn patients against the use of ivermectin outside of FDA-approved indications and guidance, whether intended for use in humans or animals, as well as purchasing ivermectin from online stores. Veterinary forms of this medications are highly concentrated for large animals and pose a significant toxicity risk for humans. Use of ivermectin for the preventions and treatment of Covid-19 has been demonstrated to be harmful to patients."

The impact of the October 28, 2021 letter from the Virginia Department of Health had a devastating effect on physicians and patients throughout the Commonwealth of Virginia. This letter was threatening to both physicians and pharmacists. Many physicians who had been **actively providing early treatment** to patients diagnosed with Covid-19 were blocked by pharmacies that would no longer fill their prescriptions following the email.

The letter from the VDH prevented doctors from prescribing ivermectin to patients diagnosed with Covid-19. This delayed early treatment caused increased hospitalization and death throughout the Commonwealth. Repeatedly patients were told to "go home and return when you cannot breathe, there is nothing we can do." Never, in my worst nightmares did I imagine that those in control would take such a callous position.

I, like so many other physicians, was watching data from around the world. I learned of the vitamin supplement regimes by the end of March and the beginning of April of 2020. Despite the readily availability of this information, leaders in public health were silent and deaf to those treating Covid-19 and those in functional medicine and alternative medicine. Studies from Uttar Pradesh in India, Mexico City and other cities around the world demonstrated the clear safety and efficacy of ivermectin but were dismissed by our healthcare officials.

When a crisis is present, all options must be on the table and each evaluated for safety and efficacy. Allowing doctors to be doctors is most beneficial to the patient. However, the VDH repeated the CDC and FDA non-binding advice, rather than grounding its decisions and fiduciary responsibility on direct evidence by consulting with physicians around the Commonwealth who treated thousands of patients with repurposed medications and nutraceuticals.

The Commonwealth blocked patient access to life saving treatments. This prohibition continues to this day. Almost all commercial, big chain pharmacies across the state will not fill a prescription for ivermectin if the the diagnosis is Covid-19. Further, some pharmacists threatened to report physicians who prescribed ivermectin.

This prohibition resulted in the exponential increase in the cost of ivermectin. Patients initially were able to pay $20 or less for a prescription. Rapidly, a single course of ivermectin to treat Covid-19 became several hundred dollars and for some patients closer to a thousand dollars.

Ivermectin is a drug that has been on the market for over 40 years. Its development won the Nobel Prize in Medicine. Ivermectin is over the counter in most of the world and further has a demonstrated safety profile that supersedes many drugs currently over-the-counter, i.e.) acetaminophen, in the United States. There is no evidence of liver, kidney, lung or heart toxicity. The cost of a 12 mg pill is approximately 33 cents. However, the cost of hospitalization and disability because of delayed treatment cost and continues to costs the taxpayer billions of dollars. More importantly, thousands of people in Virginia lost their lives.

The letter from the VDH sited no medical evidence or study to document harm to patients. The VDH did not seek the advice from physicians throughout the Commonwealth of Virginia who were prescribing ivermectin and hydroxychloroquine as early treatment and treatment for Covid-19. The VDH went further than the FDA scare tactics and sent a strong prohibitive message.

The VDH continues to decline consultation with leading experts in the treatment of Covid-19 and those injured by the "safe and effective" gene therapy while and hospitals throughout the Commonwealth continue to use Remdesivir, a known renal toxic drug.

We have a team of physicians and healthcare providers that would be happy to meet with you to attest to the safety and efficacy of ivermectin. We also have thousands of patients whose voices need to be heard about how ivermectin saved their lives and the lives of their family members. You should also hear the stories of people, who sacrificed their own lives to give their ivermectin to another.

These are the real stories of the pandemic. These are the stories of why the United States of America had the highest mortality rate in the world from Covid-19.

It is time to allow doctors to be doctors and pharmacists to be pharmacists and work to prevent another patient from needlessly dying from Covid-19.

Thus, I again ask that the VDH send a letter to all healthcare practitioners throughout the state to remove any prohibition to the use of ivermectin and hydroxychloroquine in the treatment of Covid-19.

Further, we would be most grateful to have you meet with our team of physicians so that we can learn from each other and our patients.

Respectfully,

Sheila M. Furey, MD
President, Virginia Medical Freedom Alliance
drfurey@protonmail.com

Attachements: VDH letters of March 25, 2020, October 28, 2021

VDH VIRGINIA DEPARTMENT OF HEALTH
To protect the health and promote the well-being of all people in Virginia

COVID-19 UPDATE FOR VIRGINIA

COMMONWEALTH of VIRGINIA
Department of Health

M. NORMAN OLIVER, MD, MA
STATE HEALTH COMMISSIONER

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RICHMOND, VA 23218

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1-800-828-1120

COVID-19 Update for Virginia

October 28, 2021

Dear Colleague:

Thank you for your continued partnership in responding to the COVID-19 pandemic. Please visit the Virginia Department of Health (VDH) website for current clinical and public health guidance, epidemiologic data, and other information. Updates on the following topics are included in this correspondence:

- **CDC Expands Eligibility for COVID-19 Booster Doses for Certain Recipients of Moderna and Johnson & Johnson COVID-19 Vaccines and Allows for Heterologous Booster Doses**
- **Update on Pfizer COVID-19 Vaccines for Children Aged 5 to 11 Years**
- **VDH Webinar on Understanding COVID-19 Vaccine: What the Evidence Tells Us**
- **VDH Statement on the Use of Ivermectin for the Prevention or Treatment of COVID-19**

CDC Expands Eligibility for COVID-19 Booster Doses for Certain Recipients of Moderna and Johnson & Johnson COVID-19 Vaccines and Allows for Heterologous Booster Doses

On October 21, the Centers for Disease Control and Prevention's (CDC) Director Dr. Rochelle Walensky endorsed the recommendations of the Advisory Committee on Immunization Practices (ACIP) to expand eligibility for COVID-19 booster shots. Booster doses are now available to certain recipients of the Moderna and Johnson & Johnson (J&J)/Janssen primary series, and heterologous (or "mix and match") booster doses are allowed. Booster doses of Pfizer vaccine were already authorized for certain recipients of the Pfizer primary series. On October 20, the U.S. Food and Drug Administration (FDA) amended emergency use authorizations (EUAs) for Pfizer, Moderna, and J&J vaccines. Updated FDA fact sheets for healthcare providers (Pfizer, Moderna, J&J) and recipients and caregivers (Pfizer, Moderna, J&J) are also available.

A booster shot of COVID-19 vaccine is recommended **at least six months** after the completion of an mRNA vaccine primary series (Moderna or Pfizer) for certain populations. These people **should** receive a booster:

- People aged 65 years and older
- People aged ≥ 18 years who live in long-term care settings
- People aged 50 to 64 years with an underlying medical condition

In addition, these people **may** also benefit from a booster based on their individual benefits and risks:

- People aged 18 to 49 years with an underlying medical condition
- People aged 18 to 64 years who work or live in high-risk settings

Moderna sent a letter to vaccine providers to alert them of prescribing information for booster doses. Importantly, the booster dose of Moderna COVID-19 vaccine is 50 micrograms (μg) in 0.25 mL, which is **half the dose of the primary series vaccine**. Although the dose sizes for the booster and primary series are

different, the product used for both purposes is the same. The dose for the Pfizer booster is the same as the primary series vaccine (0.3 mL).

Additionally, all individuals aged ≥ 18 years who received a J&J primary series **should** receive a single COVID-19 vaccine booster dose **at least two months** after the J&J primary dose. The dose and the product for the J&J booster is the same as the initial dose (0.5 mL).

CDC recommendations now allow for heterologous (or "mix and match") booster doses. Individuals who are eligible to receive a COVID-19 booster dose may choose which vaccine product they would like to receive as a booster and discuss which product is most appropriate for them with their healthcare provider. If a heterologous booster dose is administered, the interval between the primary series and the booster dose should be based on the vaccine that was used in the primary series. The booster dose size and volume are the same regardless of whether the patient is receiving a homologous (same as primary series) or heterologous (different from primary series) booster.

An individual risk benefit assessment can be used to help determine which booster dose is most appropriate for a particular patient, including the risks of the different available vaccines. The potential risks of an mRNA booster dose include the rare risk of myocarditis or pericarditis. The risk of these conditions is highest among males aged ≤ 30 years based on data from mRNA primary vaccine series. Additionally, the potential risk of the J&J vaccine include the rare conditions of Guillain-Barré Syndrome (GBS) and thrombosis with thrombocytopenia (TTS). Based on data after receipt of the J&J primary dose, the risk of GBS is highest among males aged 50 to 64 years, and the risk of TTS is highest among females aged 18 to 49 years. Vaccine providers should ensure women aged 18 to 49 years are aware of the increased risk for TTS and of the availability of mRNA vaccines. Individuals who had TTS following their initial J&J vaccine should not receive a J&J booster dose. More guidance is available in CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines.

Moderately and severely immunocompromised people who are aged ≥ 18 years and received a two-dose mRNA vaccine and an additional primary mRNA dose **may** receive a COVID-19 booster dose (i.e., Pfizer, Moderna, or J&J) at least six months after their additional primary dose. Immunocompromised individuals who are aged ≥ 18 years and received the J&J vaccine at least two months ago **should** receive a booster dose of COVID-19 vaccine. If these individuals receive a Moderna booster dose, they should receive the 50 µg in 0.25 mL booster dose (half dose).

As a reminder, COVID-19 booster doses may be given at the same time, or anytime before or after other vaccines, **including the flu shot**. This is especially important now that we are in the flu season. Help keep your patients from falling behind on their recommended vaccines by coadministering them with COVID-19 booster doses or primary series. People seeking a booster dose should be permitted to self-attest to their eligibility.

If your patients are uncertain of which vaccines they received in the past, they can look up their COVID-19 vaccination record at www.vaccinate.virginia.gov. If they have difficulty looking up their record, they can contact 877-VAX-IN-VA (877-823-4628). Please also encourage your patients to enroll in CDC's v-safe after vaccination health checker℠ and complete health check-ins after COVID-19 vaccination. V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after COVID-19 vaccination.

Update on Pfizer COVID-19 Vaccines for Children Aged 5 to 11 Years

On October 26, FDA's Vaccines and Related Biological Products Advisory Committee recommended the extension of Pfizer's COVID-19 vaccine EUA for children aged 5 to 11 years. There are still multiple steps that must occur at the federal level before providers can begin administering vaccines to this population. Next, the FDA must decide whether to formally amend the EUA. If amended, CDC's ACIP will meet and vote on recommendations for Pfizer vaccine for 5 to 11 year olds, and finally the CDC Director will determine official CDC recommendations.

There are some important differences between Pfizer's vaccine for children aged 5 to 11 years and the vaccine for people aged 12 years and older. The dose size for Pfizer vaccine for 5 to 11 year olds is 10 micrograms (mcg) / 0.2 mL, which is **a third of the dose size for Pfizer recipients aged 12 years or older**. Although the active ingredients in the Pfizer COVID-19 vaccine for 5 to 11 year olds are the same as those in the vaccine authorized for people aged 12 years and older, the product configurations and vials are different. Vaccine providers will be required to use the Pfizer product for 5 to 11 year olds if vaccination is authorized and recommended for this age group.

If FDA amends the Pfizer EUA, available supplies of the vaccine for 5 to 11 year olds will be prepositioned with vaccine providers; however, providers are not able to begin administering these vaccines until the CDC Director provides official recommendations. Initial supplies may be very limited. VDH expects that over the next few months all children in Virginia will have access to the vaccine, but there may not be enough for everyone to get them in the first few weeks.

VDH Webinar on Understanding COVID-19 Vaccine: What the Evidence Tells Us

VDH will host a Webinar on Understanding COVID-19 Vaccine: What the Evidence Tells Us on November 3 from 6:00 pm to 7:00 pm. This is a free event that has been approved for Continuing Medical Education (CME) credit / Continuing Education (CE) credit for physicians, nurses, and pharmacists. This webinar is open to all healthcare professionals and all healthcare staff. Information to access the webinar and descriptions of the panelists are available here Please share this with members of your professional organizations.

VDH Statement on the Use of Ivermectin for the Prevention or Treatment of COVID-19

VDH strongly discourages the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial. Ivermectin is approved by FDA for human use to treat infections caused by internal and external parasites. It is not approved to prevent or treat COVID-19, or any other viral infection.

Ivermectin is also available to treat certain veterinary conditions; medications formulated or intended for use in animals should not be used by humans.

In addition, we urge physicians, other prescribers, and pharmacists—trusted healthcare professionals in their communities—to warn patients against the use of ivermectin outside of FDA-approved indications and guidance, whether intended for use in humans or animals, as well as purchasing ivermectin from online stores. Veterinary forms of this medication are highly concentrated for large animals and pose a significant toxicity risk for humans. Use of ivermectin for the prevention and treatment of COVID-19 has been demonstrated to be harmful to patients.

Thank you again for your continued partnership as we respond to the COVID-19 pandemic.

Sincerely,

M. Norman Oliver, M.D., M.A.
State Health Commissioner

TREATMENT OF COVID-19

COMMONWEALTH of VIRGINIA
Department of Health
P O BOX 2448
RICHMOND, VA 23218

M. Norman Oliver, MD, MA
State Health Commissioner

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

Treatment of COVID-19

March 25, 2020

Dear Colleague:

In the most recent days, there has been a surge in demand of potential treatments for COVID-19 for drugs commonly used to treat malaria, lupus, rheumatoid arthritis, HIV, bacterial infections and other conditions. This is leading to an inadequate medication supply for patients already taking these medications for chronic conditions and hospitalized COVID-19 patients being treated with these medications under facility-specific treatment protocols while studies are ongoing.

There are currently no antiviral drugs approved by the U.S. Food and Drug Administration (FDA) to treat COVID-19. Some *in-vitro* or *in-vivo* studies suggest potential therapeutic activity of some agents against related coronaviruses, but there are no available data from observational studies or randomized controlled trials in humans for the CDC to support recommending any investigational therapeutics for patients with confirmed or suspected COVID-19 at this time.

The Virginia Department of Health in consultation with the Virginia Department of Health Professions recommends the following:

- Prescriptions for chloroquine, hydroxychloroquine, mefloquine and azithromycin should be restricted in the outpatient setting and should require a diagnosis "consistent with the evidence for its use."
- Community pharmacists should use professional judgement to determine whether a prescription is valid and that there is a bona fide practitioner-patient relationship prior to dispensing.
- Prioritize treatment for continuation of existing medication therapy, inpatient settings, and other indications where there is not an alternative therapy.
- Advise against hoarding these medications or stockpiling.

There is currently no available data from randomized clinical trials to inform clinical use. Refer to the CDC for more information on therapeutic options for COVID-19. (https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html).

Sincerely,

M. Norman Oliver, MD, MA
State Health Commissioner

Virginians are dealing with a mandate to receive "Smart utility meters". The industry is claiming that analog utility meter software is out of date. This has been proven a lie by other states that have decided to allow analog meters to remain. Those meters have worked well for 20+ years without additional fees for consumers.

This is part of the "Great Reset" agenda for spying on people in their own homes (government sanctioned data collection), frying them with erratic microwave pulses that are known to cause biological harm, ultimately coercing, and controlling behavior, and curbing energy usage at their will while charging consumers astronomical fees.

The SCC which regulates Utilities in VA, held a hearing about rate charges for Dominion's opt-out policy, among other things. I'm providing you all with copies of the highlights regarding opt-out charges. **What you should find suspicious is, that while under oath, Dominion representatives were unable to provide levels of radiation that consumers are receiving.** (scc.virginia.gov/DocketSearch#caseDetails/144136)

You should also **pay close attention** to the fact that **the hearing examiner recommended medical opt-out options**. He was flooded with testimonies of health problems and concerns from across our beautiful state. They also reported concerns of intrusion of privacy rights, fire hazards, and exorbitant price increases.
All of which I believe I've spoken to you about before, but difficult to fit in with a 2-minute timer.

What we need now are 3 things:

#1) We the people need to look at the New Hampshire Commission Report**.** Your work has already been done by their state's Department of Health to examine the concerns of 5G wireless radiation. I will email you each a copy of this so you can see their results for yourself. (390 pages)
(http://www.gencourt.state.nh.us/statstudcomm/committees/1474/reports/5G%20final%20report.pdf)
It would behoove you to get an RF meter so you can see these invisible threats for yourself.
#2) We need you to recognize that you are in an important position to protect humanity - Including, and especially our children, who are NOT vectors for disease, as one of the BOH members stated publicly in the past. We are ALL made in His image. We have GOD given rights to protect our lives, health, and property that shall not be infringed upon.
*I'm aware that No amount of evidence can ever convince people whose minds are closed and think they know everything. Please humble yourselves, get educated on this topic, and prove that you truly care about Virginians' health. Listen to the EMF Hazards 2024 Summit**.** It's free because they recognize the importance of educating us on this danger, but it is an invaluable source of excellent research by world renowned experts. https://emfhazards.com
3) **We want YOU to contact our AG, Lt. Governor & Governor and tell them that smart meters are a serious health concern, and that analog meters should remain or be reinstalled for all requesting consumers at no charge. The ADA protects individuals harmed by microwave frequencies for clear reasons. There are over 7 decades of suppressed research on this subject.**
We know that "Mandates are a tool of bullies, criminals, and dictators who can't persuade on the merits." This was best said by lawyer Aaron Siri. We the people of VA know that we cannot comply our way to Freedom.

WE WILL NOT COMPLY, and we expect that all elected officials will respect our rights as smart consumers to say NO THANK YOU. No state or utility regulatory entity is allowed to use extortion to coerce us. We will protect our own family's health, personal private data, pocketbooks, and our homes. We will not pay more to not be injured in our own homes with a product we never asked for, regardless of the funding given to our legislators to approve and push these "smart" meters. **This should be across the board for all utility companies.**
We expect the SCC to allow farmers, families, and business owners to keep their analog meters should they choose to do so. Forgiveness should be made for those who are behind on their bills as well. ALL of God's people's lives matter.
Thank you, as you serve us, the public and speak on our behalf, we look forward to hearing back from you!

EMF
MEDICAL CONFERENCE 2021

A Virtual Conference

Prevention, Diagnosis, and Treatment of EMF Associated Illness

January 28 to 31, 2021

EMFConference2021.com

Watch the entire conference on Vimeo: https://vimeo.com/showcase/10624511

Watch the entire conference on Youtube: https://www.youtube.com/playlist?list=PL4rlYraNQvqCEibq4niZui4HuBHMwBuZG

Note: in each video, you can select Transcripts, and Settings to increase or slow the playback speed.

Pre-Conference Course: Electrosmog and Electrotherapeutics 101

(Formerly 4 CME/CE credits)

Magda Havas, PhD, Professor Emeritus, Trent University, Conference Co-Chair

1: The Big Picture: Bio-Geo-Electro Magnetics (29:06) Watch on Vimeo or Youtube
2: Radio Frequencies, Microwaves & 5G (34:33) Watch on Vimeo or Youtube
3: Extremely Low Frequency Electromagnetic Fields (34:52) Watch on Vimeo or Youtube
4. Questions & Answers #1 with Dr. Havas (48:24) Watch on Vimeo or Youtube
5. Dirty Electricity (34:56) Watch on Vimeo or Youtube
6. Ground Current Pollution (40:27) Watch on Vimeo or Youtube
7. Electrotherapeutics: Frequency, Light & Electro-Therapy (25:26) Watch on Vimeo or Youtube
8. Questions & Answers #2 with Dr. Havas (57:51) Watch on Vimeo or Youtube

EMF Medical Conference 2021: Prevention, Diagnosis, and Treatment of EMF Associated Illness

(Formerly 20.5 CME/CE credits)

9. Welcome and Introductions, Hillel Baldwin, MD, Neurosurgeon, Conference Co-Chair (06:37) Watch on Vimeo or Youtube

Session 1: Radio Frequency Radiation Research

10: From Toxins to Towers: A Primer on the Science of Wireless Health Effects, Cindy Russell MD, Executive Director, Physicians for Safe Technology (49:02) Watch on Vimeo or Youtube

11: U.S. National Toxicology Program Studies on Cell Phone Radiation, Ronald Melnick, PhD, Former Senior Toxicologist - U.S. National Toxicology Program, NIEHS/NIH (26:33) Watch on Vimeo or Youtube

12: Radiofrequency Radiation Research, Moderator Devra L. Davis, PhD, MPH, Founding President, Environmental Health Trust, USA (10:33) Watch on Vimeo or Youtube

13: Results of Carcinogenicity Bioassay on Rats Exposed to Mobile Phone Radiofrequency Radiation, Fiorella Belpoggi, PhD, Scientific Director, The Ramazzini Institute, Italy (15:21) Watch on Vimeo or Youtube

14: Oxidative Mechanisms of Health Effects of Low Intensity Radiofrequency/ Microwave Radiation, Igor Yakymenko, PhD, DrSc, Professor of Environmental Science, Department of Environmental Safety National University of Food Technologies, Ukraine (27:32) Watch on Vimeo or Youtube

15: Rebuttal of Some of the Arguments that Most Present RFR Exposure Guidelines are Adequate to Protect the Public, Henry Lai, PhD, Professor Emeritus of Bioengineering, University of Washington (USA), Editor Emeritus, Electromagnetic Biology and Medicine (16:22) Watch on Vimeo or Youtube

16: Session 1: Panel Discussion/Q&A (30:26) Watch on Vimeo or Youtube

17: Epidemiological, Clinical and Toxicological Evidence of RF-EMF on Reproduction, Devra L. Davis, PhD, MPH, Founding President, Environmental Health Trust, USA (30:52) Watch on Vimeo or Youtube

18: Neurological Effects of Nonionizing Electromagnetic Fields, Henry Lai, PhD, Professor Emeritus of Bioengineering, University of Washington (USA), Editor Emeritus, Electromagnetic Biology and Medicine (17:57) Watch on Vimeo or Youtube

19: EMF and Biological Health Effects Panel Discussion, Q&A (8:20) Watch on Vimeo or Youtube

Session 2: EMF Biological and Health Effects

20: Brain Cancer and EMR … Is There a Link? Charles Teo, AM, MBBS, FRACS, Neurosurgeon (Australia) - Founder, Cure Brain Cancer Foundation (35:19) Watch on Vimeo or Youtube

21: Panel Discussion: Brain Cancer and EMR, Dr. Teo, Dr. Davis, Dr. Lai, Dr. Baldwin, Dr. Havas (23:03) Watch on Vimeo or Youtube

22: Functional Brain Scans of Patients Exposed to Neurotoxic Chemicals and/or EMF, Gunnar Heuser, MD, PhD (30:43) Watch on Vimeo or Youtube

23: Diplomats' Mystery Illness: Pulsed Radiofrequency/ Microwave Radiation, Beatrice Alexandra Golomb, MD, PhD (46:06) Watch on Vimeo or Youtube

24: Session 2: Q&A, Dr. Goldberg, Dr. Golomb (17:45) Watch on Vimeo or Youtube

25: Session 2: Panel Discussion, Dr. Havas, Dr. Golomb, Dr. Davis, Dr. Baldwin, Dr. Lai, Dr. Heuser (30:29) Watch on Vimeo or Youtube

Session 3, Part 1: Prevention, Differential Diagnosis and Treatment

26: Differential Diagnosis of Complex Cases, Elizabeth Seymour, MD, MS, BS, FAAFP (35:50) Watch on Vimeo or Youtube

27: Prevention, Diagnosis & Treatment of EMF Associated Illness (with focus on mobile phones and 5G) New Aspects on International Policies & Actions for Public Health, Piero Lercher, MD (19:25) Watch on Vimeo or Youtube

28: Clinical Observations and Recommended Practice Guidelines for the Management of EHS Patients, Riina Bray, MD BASo, MSc, MCFP, MHSc (25:31) Watch on Vimeo or Youtube

29: EMF Sensitivity Treatment Modalities, Stephanie McCarter, MD (29:49) Watch on Vimeo or Youtube

30: Session 3, Part 1 Panel Discussion/Q&A, Dr. Baldwin, Dr. Seymour, Dr. Lercher, Dr. Bray, Dr. McCarter (31:37) Watch on Vimeo or Youtube

Session 3, Part 2: Prevention, Differential Diagnosis and Treatment

31: Prevention, Diagnosis, and Management of Electromagnetic Hypersensitivity (EHS), Erica Mallery-Blythe, MD, BSBM (57:35) Watch on Vimeo or Youtube

32: Electromagnetic Fields in Cancer Therapy, Joseph R. Salvatore, MD (37:21) Watch on Vimeo or Youtube

33: Evidence-based Tools for Developing a Discriminating Eye for Dietary Supplement Quality - Focus on EMF Mitigation, Christopher D'Adamo, PhD (55:32) Watch on Vimeo or Youtube

34: How to Create a Low EMF Building, Peter Sierck, CIEC, REA, EMRS, RFSO (1:02:43) Watch on Vimeo or Youtube

35: Session 3 - Part 2: Panel Discussion Q&A, Dr. Mattson, Dr. Goldberg, Dr. Salvatore, Dr. Mallery-Blythe, Dr. D'Adamo, Dr. Seymour, Dr. Lercher, Dr. Bray, Dr. McCarter, Mr. Sierck (1:02:39) Watch on Vimeo or Youtube

Session 3, Part 3: Prevention, Differential Diagnosis and Treatment

36: Brain on Fire: How Biotoxins Cause Brain Inflammation, Mary Ackerley, MD, MD(H), ABIHM (30:07) Watch on Vimeo or Youtube

37: Indoor Mold Illness: Pathophysiology, Diagnosis and Treatment. Review of the Basics, Keith Berndston, MD (26:56) Watch on Vimeo or Youtube

38: How to Advocate for Persons Who Have Electromagnetic Hypersensitivity, Canadian Campaigns, Sheena Symington, B.Sc., M.A. (22:35) Watch on Vimeo or Youtube

39: Bacterial Effects of EMF Exposure, Sharon Goldberg, MD (20:01) Watch on Vimeo or Youtube

40: A Chicken in Every Pot, a Fiber in Every Home, Paul Héroux, PhD (47:16) Watch on Vimeo or Youtube

41: Challenges and Benefits of EMFs in Energy Medicine, Karl Maret MD, M.Eng (30:18) Watch on Vimeo or Youtube

42: Session 3, Part 3 Panel Discussion/Q&A, Dr. Mallery-Blythe, Dr. Havas, Dr. Ackerley, Dr. Goldberg, Dr. Héroux, Dr. Maret, Ms. Symington (27:00) Watch on Vimeo or Youtube

Session 4, Part 1: Public Health Implications & Public Policy Review

43: Public Health Implications and Public Policy Review, Anthony B. Miller, MD, FRCP, FRCP (C), FFPH, FACE (24:04) Watch on Vimeo or Youtube

44: Glow Kids – How Screen Addiction is Hijacking Our Kids – And How to Break the Trance, Nicholas Kardaras, PhD, LCSW (33:28) Watch on Vimeo or Youtube

45: Overcoming the Dam of Denial, Mary Anne Tierney, RN, MPH, EMRS (16:30) Watch on Vimeo or Youtube

46: Role Play, Mary Anne Tierney, RN, MPH and Cece Doucette, MTPW (9:44) Watch on Vimeo or Youtube

Say NO To SMART Meters

VIRGINIA MEDICAL FREEDOM ALLIANCE
VAMFA.org

Unexplained Illness? It could be your Smart Meter!

- While we are exposed to wireless radiation from many sources, smart meters send high pulsed erratic signals that our bodies are unable to modulate. Some people are affected immediately and severely. Long-term, nearly everyone will be affected because smart meters effect our cells and hormones. Some of the health problems people experience immediately or soon after installation of smart meter are: • Heart Arrhythmias •Hypertension • Neurological Injury • Cognitive Loss • Diabetes • Cancer • Mood Disturbances • High Blood Pressure • Rashes • Nosebleeds (esp. children) • Vision Problems (blurred, dry eye) • Fatigue • Anxiety • Insomnia •We are living beings therefore all are affected by this. Babies are affected sooner within the womb and outside of the womb than adults. The effects of smart meters are cumulative. Just because you can't feel it doesn't mean it's not affecting you. You can't feel radon, either.

People who have experienced injury from the smart meters need our support now.

Who should control your Health & Your home? A corporation or you?

Smart Meters: *SMART is an acronym for Self-Monitoring, Analysis & Reporting Technology Smart Meters;*

- Will increase your electric rates (peak pricing). Has your utility bill gone up?
- The electromagnetic radiation (EMR) emitted whenever smart meters wirelessly transmit or receive data signals cause severe health problems for many people.
- Allows the utilities to *remotely* monitor & shut off the power, gas or water at their discretion not yours, to your smart appliances at will (via "Energy Star" smart-chipping). ***Dominion has already shut power off to residents.***
- Allows the utilities to sell your usage data to third parties without your knowledge or consent (Walmart & Green button download my data). According to the utilities themselves, the data is worth more than the electricity they sell you because it reveals your private personal behavior in your own home.
- Causes home electrical fires, appliance short-outs, flickering lights. (dirty electricity).

Your Money, Your Health, and Your Property are at Risk -Take action details are on the back side

LEARN MORE & JOIN US:

We need as many residents as possible to attend the next Chesterfield County Board of Supervisors meeting to speak up and encourage the Board to adopt a Resolution to allow consumers to keep their analog meters that have worked for centuries!

Wednesday, April 24th, 2024, at 6:00 PM
Wednesday, May 15, 2024 at 6 p.m.
Public Meeting Room, Inside the Police Station
10001 Iron Bridge Road
Chesterfield, VA 23832

Contact: Doris Knick county resident to see the Resolution and get the "smart" meter flyer to learn more: healersporch@yahoo.com

Sign up to give public comment: Email hallsj@chesterfield.gov must email before 5pm night before and choose afternoon or evening session. (3 minutes)

If you cannot attend in person, you can help by:

- **Calling the following Board Members and/or email them to tell them to support the Resolution to allow consumers to keep their analog meters that have worked for centuries, put smart meters on the agenda and allow Doris to present about Smart Meters:**

* Bonus if you could call these "public servants" of Doris Knick + Julie Cummings

James Holland (Chair)	(804)768-7528	hollandj@chesterfield.gov
Mark S. Miller (Vice Chair)	(804)7748-1200	MillerMark@chesterfield.gov
Jim Ingle	(804)768-7398	IngleJ@chesterfield.gov
Jessica Schneider	(804)768-7396	schneiderjes@chesterfield.gov
Kevin Carroll	(804)748-1200	carrollkevin@chesterfield.gov

Thank you for your help!

Sign our Petition to AG Miyares to encourage him to **Intervene, Investigate, and Protect Consumer Rights regarding "SMART" Meters: https://citizengo.org/en-us/signit/211649**

VAMFA.org

COMMONWEALTH OF VIRGINIA
STATE CORPORATION COMMISSION

APPLICATION OF

VIRGINIA ELECTRIC AND POWER COMPANY **CASE NO. PUR-2023-00101**

For a 2023 biennial review of the rates, terms and conditions for the provision of generation, distribution and transmission services pursuant to § 56-585.1 A of the Code of Virginia

REPORT OF ALEXANDER F. SKIRPAN, JR., CHIEF HEARING EXAMINER

January 17, 2024

The Company and Staff generally agree, Dominion Energy had a ROE of 9.04 percent for the earnings test period of 2021 and 2022. Based on the earnings test result, the Company is not required to provide any bill credits, and may defer approximately $46 million of severe weather event costs from 2021 and 2022, for future recovery. Nonetheless, I question whether Subsection A8 permits such a deferral in this case.

As for going-forward rates, legislation passed in 2023 prohibits an increase in overall rates in this proceeding unless the Company requires an increase of $350 million or more. Overall rates can be reduced. Dominion Energy initially calculated a required overall increase of $25.560 million for Rate Year 2024, and $51.241 million for Rate Year 2025. On rebuttal, the Company revised its calculated required revenue increase to $61 million for Rate Year 2024 and $105 million for Rate Year 2025. Because these amounts are less than $350 million, Dominion Energy seeks no increase in overall base rates. In its direct case, Consumer Counsel recommended overall base rate reductions of $105.744 million for Rate Year 2024, and a reduction of $135.674 million for Rate Year 2025. Staff's testimony supports an overall base rate reduction of $72.400 million for Rate Year 2024, and a reduction of $62.749 million for Rate Year 2025.[1]

In addition, several cost allocation and rate design issues were raised in this proceeding.

Dominion Energy, Staff, Consumer Counsel, Appalachian Voices, DCC, Navy, Google, Kroger, Committee, and Walmart filed a Stipulation that resolved all issues in this proceeding. The Stipulation is not opposed by any of the other parties to this case.

To support the Commission's discretion in deciding this case, the Discussion section of this report will address 14 revenue requirements, and 11 cost allocation and rate design issues and will make findings on those issues without regard to the Stipulation offered. After addressing issues without regard to the Stipulation, I provide an analysis of the Stipulation.

---

[1] Under Staff's recommendation, if overall base rates are reduced by $72.400 million for Rate Year 2024, then the overall base rate change for Rate Year 2025 would be an increase of $9.651 million (*i.e.*, $62.749 million minus $72.400 million).

Ultimately, I recommend that the Commission adopt the Stipulation with recommend modifications.

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HISTORY OF THE CASE

On July 3, 2023, Virginia Electric and Power Company ("Dominion Energy" or "Company") filed an application ("Application") with the State Corporation Commission ("Commission"), pursuant to § 56-585.1 A of the Code of Virginia ("Code") for a biennial review of the Company's rates, terms, and conditions for the provision of generation, distribution, and transmission services.

The Application states during the 2023 Session, the Virginia General Assembly enacted Chapter 775 (HB 1770) of the 2023 Virginia Acts of Assembly ("Legislation").[2] The Legislation, in part, amended Code § 56-585.1, and became effective on July 1, 2023. As stated in the Application, the Legislation, *inter alia*, has modified the review process for Dominion Energy's base rates. Significantly, the Legislation returned the Commonwealth's incumbent electric utilities to more frequent, biennial reviews of base rates; required Dominion Energy to combine certain existing rate adjustment clauses that have a combined annual revenue requirement of at least $350 million as of July 1, 2023, with its base rates; established that prospective base rates will be set based solely on the forward-looking cost of service; directed Dominion Energy's authorized return on equity ("ROE") be set at 9.70 percent in the present proceeding; and stated the Company must take reasonable efforts to maintain an equity component of total capitalization of 52.1 percent through the end of 2024.

Concurrent with its Application, the Company filed its Motion for Entry of a Protective Order. A Hearing Examiner's Protective Ruling was entered on July 21, 2023.

On July 20, 2023, the Commission issued its Order for Notice and Hearing in which, among other things, the Commission: (i) scheduled a telephonic hearing for November 20, 2023, at 10 a.m. to receive the testimony of public witnesses; (ii) scheduled an in-person public hearing for November 28, 2023, at 10 a.m.; (iii) directed the Company to provide notice to the public; (iv) provided interested persons an opportunity to comment on the Company's Application; and (v) appointed a Hearing Examiner to conduct all further proceedings in this matter on behalf of the Commission and directed the Hearing Examiner to file a final report on or before January 18, 2024.

On July 19, 2023, the Office of the Attorney General's Division of Consumer Counsel ("Consumer Counsel") filed its notice of participation. On July 26, 2023, the Department of the Navy on behalf of the Federal Executive Agencies ("Navy") filed its notice of participation. On July 27, 2023, the Virginia Committee for Fair Utility Rates ("Committee") filed its notice of participation. On July 31, 2023, the Apartment and Office Building Association of Metropolitan Washington ("AOBA") filed its notice of participation. On August 1, 2023, Appalachian Voices filed its notice of participation. Also on August 1, 2023, the Virginia Poverty Law Center ("VPLC") filed its notice of participation. On August 17, 2023, Walmart Inc. ("Walmart") filed its notice of participation. On August 23, 2023, the Data Center Coalition ("DCC") filed its notice of participation. On September 13, 2023, Google LLC ("Google") filed its notice of participation. On September 14, 2023, Kroger Limited Partnership I and Harris Teeter, LLC

[2] *See also* Senate Bill 1265, 2023 Va. Act ch. 757.

(collectively, "Kroger") filed their notice of participation. On September 15, 2023, Microsoft Corporation ("Microsoft") filed its notice of participation. On September 18, 2023, Direct Energy Business, LLC and Direct Energy Services, LLC (collectively, "Direct Energy") filed their notice of participation.

On July 20, 2023, Dominion Energy filed corrected filing schedules.

During the proceeding, 135 public comments were filed concerning Dominion Energy's Application. The largest number of comments, 190[3], focused on the introduction of advanced metering infrastructure ("AMI"), raising health, safety, privacy, and concerns for the loss of legal

[3] Comments related to AMI Meters/Opt-Out Program were filed by the following: Mary Parisi; Kandi Armentrout; Ann Rigdon; Mark Bowser; Roger Woitte; Vicki and Lonnie Binkerd; Kathleen Forsythe; Nancy Lasik; Daniel Lasik; Larry Lu; Frederick P. Falcone; (sent in 2 comments); William Denk; Sheila Resseger; Marie Tromburg; Margarita Shostak; Ashleigh Magee; Eric and Susan Smith; Antun Radencic; Tamara Dreier; Carol Ofiesh; Leigh Bloomfield; Judy Rainbow; Shawn Brinkley; Eric White; Linda Richardson; India Drew; Kathleen and Michael Horner; Deanna Losen; Helen Bramow; Nicole Saur; Michael Reardon; Patricia Miles; Shannon Spiers; Kristen Blankinship; AnneMarie Freedman; Doris Knick; Neil Goodman; Wirawan Purwanto; David White; Cyndi Willard; Olivia Degenkolb; Laith Shevalier; Michael Hilbert; Charles Frohman; Nan Cooper; Joshua Hilbert; Nancy Jett; Lina Basyuk; Christopher Smith; Amy Neale; Craig Speed; David Zacharias; John Cruickshank; Karin Smith; Robert Birch; Brandi Vaidya; Megan Clevenger; Hugh Owen; Thomas Cooper; Steven Thompson; Alexis Tompkins; Katrina Holden; Ilona Brandt; Christine Renner; Shari Fryer; Heather Sanchez; Rose Ellen Ray; Michael Willoughby; Julia Lewis; Audrey Walters; Marianne Mazzatenta; Becky Stemper; Jerry Teplitz; Mikhala Majeau; Amber Condry; Susan Breeden; Carl Doll; Elizabeth Balcar; Connie Youngman; Ingrid Hartsook; Sandy Freeman; Scott Schafer; Mark Scott; Mel Cassell; Margaret Markham; Danielle Gucwa; Brent Holmes; Kim Hobaugh; Mary Sullivan; Grace Hilbert; Monica Weadon; Marilyn Edewaard; Brenda Watkins; Jackie Lombardo; Mr. and Mrs. Michael Lukacs; Elizabeth Finch; Bruce Lipscomb; Shelly Dotson; Phillip George; Rebecca Oshiro; Mary Mann; Wayne Steltz; Anita Bernier; Karen German; Sherry Reynolds; Linda Loffredo; Kathy Blum; Sally Bastian; Joye Wagner; Kevin Carter; James Thomas; Erica Teichert; Sandra Cuddy; Janis Wise; Roberta Bittle; Dianna Howard; Bryan Adkins; Christiann Rogers; Shannon Somogyi; Lee Vail; Anica Ham; Eric Overmyer; Donna Clarner; Henry McCleary; Julie Zackrisson; Debora Warner; John Knutsen; TC Anthony; Mickael Benita; Camtu Nguyen; Marshall Overstreet; Katherine Phillips; Lisa Edwards; Stephen Connally; Alla Benita; Anna Kinworthy; Cary Nunnally; Jill King; Mitchell Turner; Dawn Mitchell; Chris Goodwin; Lauren Mora; Twila Stoltzfus (two comments); Tom Esposito; Mark Scott; Alec Snetkov; Elena Buchanan; Megan Brown; William Worsley; Sara Gerloff; Sheé Lee Rock; Pamela Burnham; Barbara Cruickshank; Allison Andrews; Mary Hanson; Jennifer Yane; Douglas Briskman; Jenny DeMarco; Holly Rhode; Kimberly Richardson; Christina Navarrete; Dean Sprigg; Josh Shaw; Robert Wright; Megan Ellis; Kate Carbonelli; Matthew Corso; Raymond Hensley; Nancy Orr; Gail Culbreath; Denise Dodds; Kelly Edwards; Suzanne Fisher; E. R. Higgins; Jean Phillips; Jason and Suzanne Smart; Mary Bauer; Caroline Kennedy; Lori Leonard; Mindy Andes; Valerie Pegues-Johnson; Jane Pyrak; Marquelia Elvira; Irina Zabello; and Sean Coleman.

and natural rights. The Commission received 39[4] comments urging the Commission to adopt tariff language to provide safeguards and clarity for disconnections. In addition, the Commission received 6[5] comments in opposition to a rate increase, 1[6] comment on the rate design for Rate Schedule 10, 1[7] comment on poor tree maintenance practices, and 1[8] comment reporting an inoperative link.

On July 31, 2023, by Virginia counsel, AOBA filed its Motion for Admission *Pro Hac Vice* of Frann G. Francis, Esquire, to practice before the Commission in this proceeding. Frann Francis, Esquire, was admitted *pro hac vice* in a Hearing Examiner's Ruling dated August 18, 2023. Also on July 31, 2023, by Virginia counsel, AOBA filed its Motion for Admission *Pro Hac Vice* of Excetral K. Caldwell, Esquire, to practice before the Commission in this proceeding. Excetral K. Caldwell, Esquire, was admitted *pro hac vice* in a Hearing Examiner's Ruling dated September 5, 2023.

On August 21, 2023, Dominion Energy filed corrected filing schedules.

On August 25, 2023, Dominion Energy filed its Proof of Notice and Service as directed by ordering paragraphs (7) through (9) of the Commission's Order for Notice and Hearing.[9]

On October 2, 2023, Dominion Energy filed a Motion for Additional Protective Treatment for Extraordinarily Sensitive Information. A Hearing Examiner's Protective Ruling Providing Additional Protective Treatment for Extraordinarily Sensitive Contract & Prices Information and RFP & RFI Results was entered on October 11, 2023.

On October 4, 2023, Dominion Energy filed a Motion for Additional Protective Treatment for Extraordinarily Sensitive Information. A Hearing Examiner's Protective Ruling

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[4] Comments related to Dominion Energy's disconnection policy were received from: Teresa Stanley; Harriet Flynn; Anita Ward; Brook Smith; Edward Savage; Kelly Hart; Jeanine Underwood; Shannon Ragan; Steven Vogel; Susan Perry; Anne Berk; Elizabeth Lumsden; William Thomas; Lydia Moyer; Barbara Spitz; Peter Van Acker; Diana Boeke; Andrew Russell; Vickie Garton-Gundling; Dennis Warren; Jennie Waering; Anne McKeithen; Lisa Fues; Ned Wulin; Jennifer Bailey; Frances Schutz; Allya Henry; Melinda Lewis; Elisabeth Chaves, Climate Equity Policy Fellow, Virginia Organizing; Tyneshia Griffin, Environmental Policy Analyst, New Virginia Majority; Victoria Higgins, Virginia Director, Chesapeake Climate Action Network; Benjamin Hoyne, Virginia Interfaith Power & Light; Kendl Kobbervig, Clean Virginia; Majesta-Doré Legnini, Health Justice Fellow, Legal Aid Justice Center; Joy Loving, Climate Alliance of the Valley; Albert Orr; Chet Hepburn; and Virginia Pannabecker.

[5] Comments in opposition to a rate increase were filed by: Joshua Lovett; Tessa Easter; David Tucker; Melissa Kern; Terrance Finazzo; and Mary Hanley.

[6] A comment concerning the rate design on Rate Schedule 10 was filed by Brian Coughlan, Utility Management Services, Inc.

[7] A comment regarding poor tree maintenance practices was filed by Theresa Quiggins.

[8] A comment reporting an inoperative link was filed by Michael Aldrich.

[9] Exhibit No. 3 (Proof of Notice and Service).

Providing Additional Protective Treatment for Extraordinarily Sensitive Customer Names was entered on October 12, 2023.

On October 10, 2023, AOBA, Consumer Counsel, Navy, Direct Energy, Walmart, Committee, and VPLC filed their direct testimony and exhibits.

Also on October 10, 2023, Kroger, by Virginia counsel, filed an Application to Practice *Pro Hac Vice* of Kurt J. Boehm and Jody Kyler Cohn. Kroger's Application was granted in a Hearing Examiner's Ruling dated November 1, 2023.

On October 17, 2023, VPLC filed corrections to its direct testimony.

On October 23, 2023, Staff filed its direct testimony and exhibits.

On November 1, 2023, Walmart, by Virginia counsel, filed a Motion for Admission of Attorney *Pro Hac Vice* of Steven W. Lee. Walmart's motion was granted by a Hearing Examiner's Ruling dated November 6, 2023.

On November 6, 2023, Dominion Energy filed its rebuttal testimony and exhibits.

On November 14, 2023, a Proposed Stipulation and Recommendation ("Stipulation") was filed by Dominion Energy, Staff, Consumer Counsel, Appalachian Voices, DCC, Navy, Google, Kroger, Committee, and Walmart ("Stipulating Participants"). The Stipulation resolved all issues raised in this proceeding. The Stipulation was unopposed during the hearing.

On November 20, 2023, the telephonic public witness hearing was convened. Thirty-six witnesses presented testimony during the hearing. Joseph K. Reid, III, Esquire, Elaine S. Ryan, Esquire, Timothy Patterson, Esquire, and Brianna M. Jackson, Esquire, of McGuireWoods, LLP, and Lisa Crabtree, Esquire, of Dominion Services, appeared on behalf of Dominion Energy. William Cleveland, Esquire, and Josephus Allmond, Esquire, of the Southern Environmental Law Center, appeared on behalf of Appalachian Voices. Carrie H. Grundmann, Esquire of Spilman, Thomas & Battle, PLLC, appeared on behalf of Walmart. Christian F. Tucker, Esquire, of Christian & Barton, LLP, appeared on behalf of the Committee. Brian R. Greene, Esquire, of Greene Hurlocker, PLC, appeared on behalf of Direct Energy and Microsoft. Cody T. Murphey, Esquire, of Eckert Seamans Cherin & Mellot, LLC, appeared on behalf of DCC. Angelina S. Lee, Esquire, and Jason Cross, Esquire, of the Department of the Navy, appeared on behalf of the Navy. William T. Reisinger, Esquire, of Reisinger Gooch, PLC, appeared on behalf of VPLC. C. Meade Browder, Jr., Senior Assistant Attorney General, John E. Farmer, Jr., Assistant Attorney General, R. Scott Herbert, Assistant Attorney General, and Carew S. Bartley, Assistant Attorney General, appeared on behalf of Consumer Counsel. Frederick D. Ochsenhirt, Esquire, Arlen Bolstad, Esquire, William Harrison, IV, Esquire, K. Beth Clowers, Esquire, and Simeon Brown, Esquire, appeared on behalf of Staff.

On November 21, 2023, Kroger and Google requested to be excused from the hearing scheduled for November 28, 2023. Kroger and Google were excused as a preliminary matter during the November 28th hearing.[10]

On November 27, 2023, Staff filed its supplemental testimony.

On November 27, 2023, Dominion Energy filed the background and qualifications of Franklin M. Hinckle, Jr.

On November 28, 2023, the evidentiary hearing was convened as scheduled in the Commission's courtroom. Joseph K. Reid, III, Esquire, Elaine S. Ryan, Esquire, Timothy Patterson, Esquire, and Brianna M. Jackson, Esquire, of McGuireWoods, LLP, and Lisa Crabtree, Esquire, of Dominion Services, appeared on behalf of Dominion Energy. Josephus Allmond, Esquire, of the Southern Environmental Law Center, appeared on behalf of Appalachian Voices. Carrie H. Grundmann, Esquire of Spilman, Thomas & Battle, PLLC, appeared on behalf of Walmart. Timothy G. McCormick, Esquire, and Christian F. Tucker, Esquire, of Christian & Barton, LLP, appeared on behalf of the Committee. Brian R. Greene, Esquire, of Greene Hurlocker, PLC, appeared on behalf of Direct Energy and Microsoft. Cody T. Murphey, Esquire, of Eckert Seamans Cherin & Mellot, LLC, appeared on behalf of DCC. Angelina S. Lee, Esquire, of the Department of the Navy, appeared on behalf of the Navy. William T. Reisinger, Esquire, of Reisinger Gooch, PLC, appeared on behalf of VPLC. Excetral K. Caldwell, Esquire, of AOBA, appeared on behalf of AOBA. C. Meade Browder, Jr., Senior Assistant Attorney General, John E. Farmer, Jr., Assistant Attorney General, and R. Scott Herbert, Assistant Attorney General, appeared on behalf of Consumer Counsel. Frederick D. Ochsenhirt, Esquire, Arlen Bolstad, Esquire, K. Beth Clowers, Esquire; and William H. Harrison, Esquire, appeared on behalf of Staff. Two additional public witnesses appeared during this hearing.

SUMMARY OF THE RECORD

In its Application, Dominion Energy, stated this proceeding presents three principal issues: (i) a review of the Company's cost of service and earnings for the historical periods 2021 and 2022 ("Biennial Review Period"); (ii) whether the Company's rates for generation and distribution services ("Base Rates") should change or remain the same for upcoming rate periods ending on December 31, 2024, and December 31, 2025 (collectively "Upcoming Rate Periods"); and (iii) any proposed changes to the Company's cost allocation and rate design, tariff offerings, or terms and conditions of service.[11]

For the first principal issue, Dominion Energy asserted its actual ROE for the Biennial Review Period was 9.04 percent for its generation and distribution services.[12] This was within the range, and below the midpoint of its authorized return band of 8.65 percent to 10.05

[10] Tr. at 165.
[11] Exhibit No. 4 (Application), at 2.
[12] *Id.* at 5.

Cost Allocation and Rate Design Issues

The issues to be addressed in this section include: (i) AMI Opt-Out Policy; (ii) functional realignment and revenue rebalancing; (iii) allocation methodology; (iv) basic customer charge; (v) GADC; (vi) service disconnections and payment plans; (vii) C$M; (viii) Rate Schedule 1 blocking; (ix) Rate Schedule 10; (x) EV tariff; and (xi) other tariff changes and Terms and Conditions.

(i) AMI Opt-Out Policy

Company witness Miller presented Dominion Energy's proposed changes to its AMI Opt-Out policy.[1522] Mr. Miller explained the Company's current policy is to allow Rate Schedule 1 customers to avoid AMI meter installation, if the customer's account is in good standing and the customer does not participate in net metering.[1523] He testified to opt-out, a customer is required to return forms that acknowledge the election to opt-out of the AMI meter without cost, which he contended is an interim solution until Dominion Energy has a Commission-approved opt-out policy.[1524] Mr. Miller recommended adoption of a monthly fee of $10.35 for customers who either agree to the Company's new AMI Opt-Out Policy or otherwise refuse installation of an AMI meter.[1525] He confirmed, if approved, customers whom have opted out of having an AMI meter will be mailed a letter informing the customer of the new policy and that the new monthly fee will be charged to their account effective January 1, 2025, unless the customer elects to have an AMI meter installed.[1526]

Staff witness Ricketts reported the proposed monthly fee represents only part of Dominion Energy's estimated $31.04 per month cost of continued manual meter reading for an opt-out customer.[1527] She stated the Company "will continue to gather and refine information supporting its monthly opt-out charge and would propose additional increases to the charge, if supported, as part of the Company's next two Biennial Review cases."[1528] Ms. Ricketts advised that if the proposed AMI Opt-Out Policy is adopted, current opt-out customers would be given the choice of having an AMI meter installed at no charge, or having the monthly fee of $10.35 applied on a going-forward basis, beginning January 1, 2025.[1529] She estimated a bill impact of approximately $0.03 per month for all residential customers using 1,000 kWh per month for the Company to continue to read meters for customers who opt-out, even with the monthly charge of $10.35.[1530] Ms. Ricketts confirmed Dominion Energy has not included any administrative costs in its estimated $31.04 per month cost to continue manual meter reading for opt-out

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[1522] Exhibit No. 10 (Miller Direct), at 33.
[1523] *Id.*
[1524] *Id.*
[1525] *Id.* at 34.
[1526] *Id.* at 35.
[1527] Exhibit No. 41 (Ricketts Direct), at 6.
[1528] *Id.* at 7 (footnote omitted).
[1529] *Id.* at 7-8.
[1530] *Id.* at 9.

customers.[1531] She recommended "that the Commission direct the Company to identify the actual administrative costs incurred during 2024 and 2025 in the next biennial review proceeding."[1532]

Staff witness Ricketts did not generally oppose the Company's proposed AMI Opt-Out Policy and did not take a position on the appropriate AMI opt-out cost.[1533] Nonetheless, Ms. Ricketts maintained the Commission could require more or less payments from the AMI opt-out customers.[1534]

Staff witness Ricketts raised several concerns regarding Dominion Energy's proposed changes to the AMI Opt-Out language in Section X.I. of the Terms and Conditions.[1535] For Section X.I.2, relating to the waiver of the monthly opt-out fee when conditions prevent the Company from physically reading the meter, Ms. Ricketts recommended the inclusion of language that specifies the applicable conditions under which the Company may waive such fees.[1536] Regarding Section X.I.6, Ms. Ricketts recommended inclusion of a definition of "Opt-Out Customers" as "Customers served under Residential Service – Schedule 1 that request to opt-out of receiving a smart meter and have a non-communicating digital meter installed by the Company as an alternative."[1537] For Section X.I.1.b.ii and Section X.I.1.b.iii, Ms. Ricketts recommended these sections clarify that the "last 12 months" stated therein refers to the "last 12 months as of the date of the customer's opt-out request."[1538] Regarding Section X.I.4, Ms. Ricketts recommended that instead of providing opt-out customers with a non-communicating digital meter as promptly as working conditions permit, the tariff should also provide such installation will be made in "no later than 30-days."[1539] Regarding Section X.I.6, Ms. Ricketts recommended the following revisions:

> In addition to opt-out Customers, the Company ~~reserves the right to~~ *will* charge the monthly Non-Communicating Meter Service Charge of $10.35 when the Customer refuses the installation of a smart meter and does not comply with the smart meter opt-out process.[1540]

On rebuttal Company witness Miller noted Staff witness Ricketts did not oppose the implementation of the policy; but recommended that in the next biennial the Company identify the actual administrative costs associated with AMI opt-out incurred during 2024 and 2025.[1541]

[1531] *Id.* at 9-10.
[1532] *Id.* at 10.
[1533] *Id.*
[1534] *Id.* at 11.
[1535] *Id.* at 15.
[1536] *Id.*
[1537] *Id.* at 16.
[1538] *Id.* at 17 (emphasis omitted).
[1539] *Id.* at 17-18.
[1540] *Id.* at 19.
[1541] Exhibit No. 50 (Miller Rebuttal), at 42.

Mr. Miller advised that "isolating costs attributable solely to AMI opt-out activities is not possible."[1542]

For the proposed language used in Section X.I.4 of the Terms and Conditions, Company witness Miller proposed the following language to address possible supply chain issues:[1543]

> Once the Company receives a complete Non-Communicating Meter Option Enrollment Form, the Company shall install the non-communicating digital meter as promptly as working conditions permit, but no later than 30-days from receipt of the signed Non-Communicating Meter Option Enrollment Form, provided that applicable equipment is available.

For the proposed AMI opt-out charge, Company witness Miller affirmed, in this case, the Company believes any charge up to $31.04 would be reasonably supported by the facts of the case.[1544]

AMI meters and Dominion Energy's proposed monthly charge were vehemently opposed by many of those filing public comments and providing public witness testimony. Opposition to AMI meters was based on health, safety, privacy, and the loss of legal and natural rights. Issues concerning the AMI meters and the proposed monthly charge addressed by public witnesses generally involved: (1) problems related to the lack of notice during the installation process; problems experienced by witnesses who attempted to opt-out; surveillance and the information collected by smart meters (and maybe digital opt-out meters), along with the use or sale of such information; when the Company will use AMI meters to disconnect customers; whether the opt-out meters are truly noncommunicating meters; health concerns and issues experienced by customers; and the fairness of the proposed $10.35 per month charge.

During the hearing, Company witness Hinckle provided Dominion Energy's response to several of these issues. Mr. Hinckle testified when the Company plans to deploy AMI meters, customers are sent a postcard at least 10 days in advance to announce the installation of the AMI meter, its benefits, that the customer will experience a brief power outage, and is provided an 800 number for customers with questions to call.[1545] He stated when the meter exchange occurs, the technician knocks on the door to explain the purpose of his or her visit, and provides a telephone contact for those who wish to opt-out.[1546]

Mr. Hinckle explained, if a customer decided to participate in Dominion Energy's opt-out program, he/she would call the Company's contact center and speak with a specially trained agent.[1547] He confirmed the opt-out customer would be sent an enrollment package, along with

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[1542] *Id.*
[1543] *Id.* at 43.
[1544] *Id.* at 44.
[1545] Hinckle, Tr. at 320-21.
[1546] *Id.* at 321.
[1547] *Id.* at 332.

an opt-out consent form.[1548] Mr. Hinckle testified after at least 45 days, if the Company has not received the opt-out consent form, a second communication is mailed to the customer.[1549] Mr. Hinckle stated, if there is no response after the second communication, a third communication will be sent with a schedule of when the Company will install an AMI meter.[1550] Nonetheless, Mr. Hinckle asserted:

> At any time through that process if – or when the customer returns the consent form, the Company then schedules the installation of the noncommunicating digital meter. And that typically is installed within a three-week period.[1551]

Mr. Hinckle affirmed the opt-out meters, though digital, are noncommunicating as they are without network interface controller cards.[1552] He stated for customers who believe their opt-out meters are communicating, Dominion Energy "is more than willing to work with the customer and investigate and coordinate an independent third-party testing."[1553]

Mr. Hinckle explained analog meters are becoming obsolete and are no longer supported by the Company.[1554] He emphasized meter equipment is owned and operated by Dominion Energy, and for that reason, customers may not provide their own analog meters.[1555]

Mr. Hinckle addressed the radio frequency levels, and confirmed the AMI meters are fully in compliance with the Federal Communications Commission ("FCC") safety standards.[1556] However, he was unable to provide testimony on EMF levels associated with AMI meters.[1557]

Regarding the information captured by AMI meters, Mr. Hinckle advised AMI meters record usage particular to the meter and the meter is identified by code in the Company's billing system.[1558] He explained one of the advantages of AMI meters is customers can set up an online account with the Company and sign up for usage alerts "to quickly detect if an appliance, such as a heat pump or an electric water heater is not operating properly."[1559] Mr. Hinckle stated to his knowledge, an AMI meter cannot control which appliance or circuits may be used.[1560] He also affirmed Dominion Energy does not sell any of the information gathered by AMI meters to third

[1548] *Id.*
[1549] *Id.*
[1550] *Id.* at 332-33.
[1551] *Id.* at 333.
[1552] *Id.* at 321-22.
[1553] *Id.* at 322-23.
[1554] *Id.* at 323.
[1555] *Id.* at 323-24.
[1556] *Id.* at 324.
[1557] *Id.* at 325.
[1558] *Id.* at 326.
[1559] *Id.* at 326.
[1560] *Id.* at 328.

parties, and will only provide information to third parties engaged by the Company to provide analysis of its distribution or transmission network.[1561]

Mr. Hinckle testified AMI meters do not use electricity in order to operate.[1562]

The AMI issues in this proceeding are: (1) customer information; (2) AMI Opt-Out Program monthly fees; and (3) AMI Opt-Out Program specifics.

(1) Customer Information

One of the most prevalent themes of the public witness testimonies and public comments concerning AMI meters is a lack of communication between Dominion Energy and its customers. Many of the public witnesses and commentors claimed to have no notice that AMI meters were being installed or struggled with the opt-out process.[1563]

A lack of information creates conditions conducive to mistrust or fear regarding what information is collected by AMI meters, how that information is used, and even the benefits to be derived from use of AMI meters.[1564] Opt-out customers should be given assurances their digital opt-out meters do not communicate, and that the Company is willing to work with customers and

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[1561] *Id.* at 329.

[1562] *Id.* at 330.

[1563] *See*: Damarco, Tr. at 17; Stall, Tr. at 29; Lyons, Tr. at 41-42 (describes her unsuccessful efforts to opt-out or receive opt-out form in the mail); Royals-Tracey, Tr. at 47 (smart meter was forced on her home without notice or consent); H. Hentzen, Tr. at 90; D. Hentzen, Tr. at 95 (stated: "that was very underhanded in how they swept in, changed the meters, and the people really had no say-so."); J. Howard, Tr. at 99; Leonard, Tr. at 102 ("A smart meter was installed on my home without my knowledge and without my consent."); Liunes, Tr. at 111; J. Jackson, Tr. 125: R. Jackson, Tr. at 127; Davies, Tr. at 144 (troubles with opt-out program); C. Howard, Tr. at 152.

[1564] *See*: Damarco, Tr. at 18-19 (did not trust non-communicating meters); Stall, Tr. at 30 ("we know that these smart meters are controlling everything in a smart home."); G. Hilbert, Tr. at 68; M. Hilbert, Tr. at 72 (smart meters raise "substantial concerns about privacy, fairness, health, equity, and individual liberties."); Clarke, Tr. at 75; H. Hentzen, Tr. at 91 (questioned the need for a smart meter); D. Hentzen, Tr. at 94 (smart meter are installed "to surveil us, surveil the usage, and then have the ability to stop our power . . . ."); Picente, Tr. at 96 (concern for radiation, surveillance, and the Company's ability to shut off power at any time); J. Howard, Tr. at 99 (causing higher electric bills); Leonard, Tr. at 104 (questioned the use of smart meters for surveillance and the selling of data to third parties); Baker, Tr. at 115; Pendergraft, Tr. at 117 (expressed a lack of understanding about smart meters and the Company's ability to remotely disconnect customers); DeWeese, Tr. at 121-22 (questioned claimed meter reading savings because he has an analog meter and has not seen a meter reader in over 20 years); J. Jackson, Tr. at 125 (surveillance by smart meter and opt-out meters); R. Jackson, Tr. at 127; D. Machen, Tr. at 136; J. Cumming, Tr. at 140; Davies, Tr. at 145; Frohman, Tr. at 149-50 (dangerous spying device that increases costs by an average of 10 percent); C. Howard, Tr. at 152 (lack of information provided by the Company); Delgado, Tr. at 175.

investigate and coordinate independent third-party testing. Moreover, a lack of information may contribute to some of the health concerns presented by the public witnesses and commentors. For example, I am unaware of any information being presented on the level of EMF emitted by an AMI meter, and how that level of EMF compares to other sources of EMF likely to be found in a residence, such as a microwave oven, hair dryer, WiFi router, or cell phone.

Another area of controversy fueled, in part, by a lack of information is the Company's proposed monthly opt-out charge.[1565] Many public witnesses and commentors found it unfair that they paid to have their meters read for years, only to have Dominion Energy propose an additional monthly charge exclusively for opt-out customers related to the cost of reading their meters. I am not aware of any attempt by the Company to explain to its opt-out customers that the cost of meter reading has been eliminated from the Company's cost of service to the extent it has deployed AMI meters. It was only through discovery and information developed throughout the course of this case that the Company calculated the cost of reading opt-out customer meters was $31.04 per month, or approximately three times their proposed monthly charge of $10.35. It was also developed during this proceeding is that the Company plans to increase the monthly opt-out charge to reflect the full cost of reading opt-out customer meters over the next two biennial reviews.

Therefore, I find Dominion Energy should be directed to undertake measures to provide information to its opt-out customers both directly by mail and on its website concerning:

- The process for opting out or changing an opt-out election;
- Information collected by AMI meters and how that information is used;
- Customer benefits of AMI meters;
- Why digital opt-out meters cannot communicate, and the Company's willingness to work with customers and investigate and coordinate independent third-party testing;
- The level of EMF emitted by an AMI meter, and how that level of EMF compares to other sources of EMF likely to be found in a residence, such as a microwave oven, hair dryer, WiFi router, or cell phone;
- The elimination or significant reduction of meter reading costs in the cost of service for residential customers related to the deployment of AMI meters; and

[1565] Bauer, Tr. at 24; Lanza, Tr. at 76-77 (unnecessary charge, customers could send pictures of the meter); H. Hentzen, Tr. at 90-91; Picente, Tr. at 96; Leonard, Tr. at 104; DeWeese, Tr. at 122 ("a tax to punish those who do not accept the politically motivated claim of human caused climate change."); J. Jackson, Tr. at 125 (unacceptable to be required to pay a monthly fee to prevent being injured in her own home); D. Machen, Tr. at 137; J. Cummings, Tr. at 140 (customers suffering with electronic hypersensitivity should not be charged for attempting to protect themselves); Davies, Tr. at 144 (fees are discrimination); Frohman, Tr. at 150 (charges are insult to injury); Delgado, Tr. at 175 (meter reading was done before without charging extra).

- Dominion Energy's estimated total monthly cost of reading an opt-out customer's meter and the Company's proposed phase-in of such a charge.

(2) AMI Opt-Out Program Monthly Fees

As described above, Company witness Miller recommended adoption of a monthly fee of $10.35, effective January 1, 2025, for customers who either agree to the Company's new AMI Opt-Out Policy or otherwise refuse installation of an AMI meter.[1566] In addition, Mr. Miller maintained the total cost associated with reading the meters of opt-out customers is $31.04 per month.[1567] Staff witness Ricketts affirmed that "Staff does not take a position on the appropriate AMI opt-out cost at this time."[1568] As also described above, public witnesses and commentors opposed the institution of a monthly fee for opt-out customers.

Whether the Commission adopts the Company's proposed $10.35 monthly fee for opt-out customers depends upon the weight given to the underlying facts and circumstances presented in the current record. On the one hand, manually reading the noncommunicating meters of opt-out customers is an identifiable cost of providing service to customers who have exercised their right to choose. While the Company maintains the cost associated with manually reading the meters of opt-out customers is $31.04 per month, they also indicate they will continue to gather additional data to determine the full costs of providing manual meter reading for opt-out customers in future proceedings.[1569] Thus, I find the proposed monthly fee of $10.35 runs little, if any, risk of exceeding the actual cost of manually reading the meters of opt-out customers.

On the other hand, Staff did not take a position on the appropriate AMI opt-out cost. Consequently, the Commission is asked to make this decision without the benefit of an independent Staff evaluation or recommendation regarding the Company's cost of manually reading the meters of opt-out customers. It may also be premature to institute a charge for AMI opt-out customers prior to communications directed in the prior section. Furthermore, based on public witness testimony and commentors, additional inquiry should be made into the possibility and workings of a medical waiver of the AMI opt-out fees for the few AMI opt-out customers who suffer from electro-hypersensitivity.[1570]

[1566] Exhibit No. 10 (Miller Direct), at 34-35.
[1567] Exhibit No. 50 (Miller Rebuttal), at 43-44.
[1568] Exhibit No. 41 (Ricketts Direct), at 10.
[1569] *Id.* at 11.
[1570] *See*, G. Hilbert, Tr. at 65-70. Among other things, Ms. Hilbert testified:

> Although I didn't let them install one on my home, I am being affected by my neighbors' meters. As a result, I have to currently occupy only a small square footage of my basement where the RFR is lowest. I am unable to care for my family, and I can't even cook a meal in my own kitchen, because it is one of the worst affected areas in my home. *Id.* at 66.

I find at a minimum, whether or not the proposed monthly charge of $10.35 is approved in this proceeding, for Dominion Energy's next biennial review, the Commission should direct: (a) the Company to present its determination of the cost of manually reading the noncommunicating meters of opt-out customers; (b) the Company to address the possibility and working of a medical waiver of the AMI opt-out fees; and (c) Staff to evaluate and make recommended findings regarding the cost of manually reading the noncommunicating meters of opt-out customers. Based on the record of this proceeding, I find the Company's proposed monthly charge for AMI opt-out customers is premature and should not be implemented in this proceeding.

(3) AMI Opt-Out Program Specifics

As discussed above, Staff witness Ricketts made several recommendations to the Terms and Conditions of Dominion Energy's AMI Opt-Out Program. Company witness Miller accepted many of these recommendations, but objected to recommendations to: (a) identify the actual administrative costs associated with AMI opt-out in the next biennial review proceeding due to the impossibility of isolating costs such as call center activities, meter servicing, other metering program administration and reporting/analysis, and meter shop or warehouse activities, from functions outside of the AMI Opt-Out Program; and (b) Staff's proposed language for Section X.I.4 for a 30-day timeline for installing a noncommunicating meter, without the additional language: "provided that applicable equipment is available."[1571]

I find where the Staff and Company agreed on the Terms and Conditions of Dominion Energy's AMI Opt-Out Program, the record supports the adoption of such language by the Commission. As for the differences, while it may not be possible to isolate actual administrative costs associated with AMI opt-out, it may be possible for the Company to develop a reasonable allocation of such costs to the AMI Opt-Out Program. Therefore, I find Dominion Energy should present an optional allocation of administrative costs to the AMI Opt-Out Program. I also find the Company's qualifying for Section X.I.4 language of "provided that applicable equipment is available" should be adopted.

(ii) Functional Realignment and Revenue Rebalancing

In his direct testimony, Company witness Haynes stated Dominion Energy's proposed revenue neutral change for the 2025 rate period will increase base distribution revenue by $67,761,000, and reduce base generation revenue by $67,761,000.[1572] Mr. Haynes provided the following table displaying seven customer classes and each class's existing functional rates of return and functional rate of return indices (class rate of return/jurisdictional rate of return):[1573]

[1571] Exhibit No. 50 (Miller Rebuttal), at 42-43.
[1572] Exhibit No. 9 (Haynes Direct), at 17.
[1573] *Id.* at 20.

Consumer Counsel. For example, overall revenue requirements ranged from the Company's calculated required increases of $61 million for Rate Year 2024 and $105 million for Rate Year 2025, to Consumer Counsel's recommended required decreases of $106 million for Rate Year 2024 and $136 million for Rate Year 2025.[1795] All of this is part of the record. And while I find, absent the Legislation's $350 million threshold limitation to rate increases for this case, the record supports an increase $3.6 million for Rate Year 2025. The Commission may accept or reject any of the recommendations or findings made in this report. I also note there are a few revenue requirement issues that could significantly change results. Consequently, with only one or two changes to my recommendations, the Commission could arrive at a significantly different revenue requirement outcome.

Accepting the Stipulation with modifications is my overall recommendation to the Commission. More specifically, I recommend the Commission adopt the Stipulation subject to the modifications outlined in the differences section above and the findings below. These recommended modifications pertain mostly to the administration of future or other proceedings, have limited financial impact, and are in the public interest. However, based on the Commission's review of the record and the comments of Staff and the parties, the Commission certainly has the discretion to accept or reject any of my recommended modifications as they are not offered as a package. Nor is the Commission limited to my recommended modifications. Based on its review of the record, the Commission may adopt other/additional modifications.

FINDINGS AND RECOMMENDATIONS

Based on the evidence received in this case and in the absence of the Stipulation, I find:

1. The earnings test results of 9.04 percent ROE should be accepted;

2. The actual end-of-test period capital structure, which produces an overall cost of capital of 6.952 percent with an equity ratio of 50.333 percent is reasonable, and is required by Subsection 11A, and should be used for all going-forward rates;

3. As directed by the Legislation, the authorized ROE is 9.70 percent;

4. The Commission lacks sufficient record to determine the reasonableness of the Company's updated budgeted distribution capital expenditures, which should not be included in the revenue requirement calculation in this case. The Commission should establish a policy for biennial reviews that significant updates to an application filed less than a month before the scheduled date for Respondents to file their direct testimony and exhibits will not be considered or included in the final revenue requirement determination, and Staff should be directed to fully vet and analyze all timely updates filed by the applicant;

5. Based on § 56-585.5 B 2 of the Code, it is in the public interest to reflect a 2045 retirement date for Dominion Energy's carbon emitting generating units. However, the

[1795] Exhibit No. 58.

base rates in this proceeding, as well as the rates associated with Rider GV and Rider BW should be based on the retirement assumption in the Company's depreciation study. The incremental cost of reflecting a 2045 retirement for Dominion Energy's carbon emitting units in compliance with the VCEA should be collected through Rider CE;

6. Based on the requirements of the VCEA, the Company's forecasted sales savings are reasonable for Rate Year 2024 and Rate Year 2025. However, the determination of a reasonable level of forecasted savings extending at least two years into the future should be a determination made in a DSM/EE proceeding that can then be used in future biennial review proceedings;

7. Based on the approval of investments in the Company's VO program, the Company's forecasts are more likely than Staff and Consumer Counsel's forecasts of no savings; therefore, no adjustments to the Company's DSM/EE or VO revenue reduction forecasts should be made in this proceeding;

8. If the Commission adopts the Company, Staff, and Consumer Counsel's interpretation of Subsection A8, the amortization of the Subsection A8 assets should be over a two-year period beginning on January 1, 2023, and the Company should not be permitted to earn a return on its Subsection A8 regulatory assets;

9. If the Commission adopts my interpretation of Subsection A8, there are no Subsection A8 assets to be amortized;

10. Dominion Energy has provided adequate detail to support its adjustment to Rate Year 2024 and Rate Year 2025 non-NUG capacity expense;

11. The Company failed to show the December 2022 credit for ancillary service margins is non-recurring and Staff's use of an 18-month average reflects such large settlements appear infrequent, but could reoccur;

12. The Company's forecasted F&H planned outage expenses should be accepted over the use of an adjustment based on a three-year average that contains COVID-19 years 2020 and 2021;

13. Staff has supported its adjustment to other power delivery O&M based on the most recent Virginia contract extension;

14. Because a three-year average including COVID-19 years 2020 and 2021 is unreliable for forecasting O&M expense factors for Rate Year 2024 or Rate Year 2025, Consumer Counsel witness Smith's adjustments for payroll and benefits expense based on actual test year 2022 O&M expense factors should be accepted;

15. Based on the Commission's long-standing treatment of stock-based compensation, Consumer Counsel witness Smith's proposed adjustment should be rejected;

16. Dominion Energy has adequately explained and supported the reasonableness and prudence of its adjustments for PJM administrative fees for Rate Year 2024 and Rate Year 2025;

17. Staff's GT Plan benefits adjustment should be accepted, with the amount of the adjustment modified to reflect the corrections made by Dominion Energy in its rebuttal testimony;

18. The Commission should direct the Company to implement the internal controls and recommendations of Staff witness Myers concerning charitable contributions and lobbying costs;

19. The total generation and distribution revenue requirement for Rate Year 2024 is a reduction of $20.558 million;

20. The total generation and distribution revenue requirement for Rate Year 2025 is an increase of $3.607 million. Because this increase is less than $350 million, based on the Legislation, Dominion Energy is not permitted to increase its overall base rates from 2022 levels in this proceeding. Consequently, the rate reduction for Rate Year 2024 would be reversed for Rate Year 2025 to restore rates to levels comparable to 2022;

21. Dominion Energy should be directed to undertake measures to provide information to its opt-out customers both directly by mail and on its website concerning: the process for opting out or changing an opt-out election; information collected by AMI meters and how that information is used; customer benefits of AMI meters; why digital opt-out meters cannot communicate, and the Company's willingness to work with customers and investigate and coordinate independent third-party testing; the level of EMF emitted by an AMI meter, and how that level of EMF compares to other sources of EMF likely to be found in a residence, such as a microwave oven, hair dryer, WiFi router, or cell phone; the elimination or significant reduction of meter reading costs in the cost of service for residential customers related to the deployment of AMI meters; and the Company's estimated total monthly cost of reading an opt-out customer's meter and the Company's proposed phase-in of such a charge;

22. The Company should be directed to present, in its next Biennial Review, its determination of the cost of manually reading the noncommunicating meters of opt-out customers;

23. The Company should be directed to evaluate the possibility and workings of a medical waiver of any future AMI opt-out fees;

24. Based on the record of this proceeding, the Company's proposed monthly charge for AMI opt-out customers is premature and should not be implemented at this time;

25. Dominion Energy should present an optional allocation of administrative costs associated with the AMI Opt-Out Program;

26. The Company's proposal to include "provided that applicable equipment is available" should be included in Section X.I.4 of its tariff;

27. The required change in generation revenues for Rate Year 2025 is a reduction of $65.819 million and the required change in distribution revenues for Rate Year 2025 is an increase of $69.423 million. Because these results are similar to the change in functional revenues in Dominion Energy's Application of $67.761 million, I find the revenue neutral revenue rebalancing from generation to distribution effective January 1, 2025, should be $67.761 million as proposed in Dominion Energy's Application, as further corrected in the Company's rebuttal testimony;

28. In the event the Commission determines there should be a revenue decrease in this case, the Commission should adopt the recommendation of Staff witness G. Watkins that the incremental differences between Dominion Energy's and the Commission's determined overall changes in distribution and generation revenues be assigned pro-ratably based on the Company's proposed class revenue changes;

29. The Commission should approve continued use of the A&E method. However, as demonstrated by the testimony of Staff witness G. Watkins, there are alternatives to the A&E method that should continue to be developed and considered by the Commission to ensure that COSSs accurately reflect cost causation;

30. There should be no change in the residential fixed monthly customer charge of $7.58 per month;

31. There should be no change in the customer charges for rate schedules 1G, 1S, and 1T;

32. A customer charge of $12.85 should be adopted for rate schedule 5C;

33. The customer charges for rate schedules other than the residential rate schedules and for rate schedule 5C should be set as proposed by Dominion Energy;

34. The Commission should accept Dominion Energy's proposed reductions to GADC; and direct the Company to present in its next biennial review gradual options for eliminating the GADC from applicable rate schedules, including a full elimination option; and to present customer bill analyses associated with these options;

35. The tariff language for nonpayment disconnections adopted for Appalachian Power Company should also be adopted for Dominion Energy;

36. No change to Dominion Energy's Terms and Conditions related to payment plan options should be made in this proceeding; and the Commission should direct the parties to further develop and address this issue in Dominion Energy's next biennial review proceeding;

37. Dominion Energy's proposed C$M changes to Part Q of Section XXII, as amended in the Rebuttal Testimony of Company witness Reilly to include the insertion of "in distribution assets" into three places within Part Q of Section XXII should be adopted;

38. No change in the general rate design or blocking of Rate Schedule 1 for either distribution or generation services should be adopted in this case; and Staff and the parties should be directed to present and support alternative rate designs and blocking proposals for the residential rate schedules in the Company's next biennial review;

39. Dominion Energy's proposed revision to Rate Schedule 10 to make eligibility similar to the eligibility for standard service rate schedules in Schedules GS-3 and GS-4 should be approved by the Commission;

40. The one-year contract provisions of Rate Schedule 10 should be retained. However, if the one-year contract is retained, the Commission should direct Dominion Energy to provide: (i) a renewal notice 90 days before the customer's contract term expires; and (ii) notify customers in a tariff provision that if they choose service under Schedule 10, they will be precluded from shopping for competitive energy alternatives;

41. Customers on Rate Schedule 10 should continue to be prohibited from participating in PJM's demand response programs;

42. The Commission should direct the Company, Walmart and interested stakeholders to develop a new EV rate design to present for approval in Dominion Energy's next biennial review proceeding; and

43. The Company's proposed other tariff changes and Terms and Conditions, as corrected, and as addressed in section xi in the above discussion should be adopted by the Commission.

Nonetheless, the Stipulating Participants have offered a Stipulation that is unopposed by all of the non-Stipulating Participants. Based on the record of this proceeding, I find the Commission should approve the Stipulation subject to the following modifications:

1. Paragraph 2 should be eliminated;

2. The Commission should establish a policy for biennial reviews that significant updates to an application filed less than a month before the scheduled date for Respondents to file their direct testimony and exhibits will not be considered or included in the final revenue requirement determination, and Staff should be directed to fully vet and analyze all timely updates filed by the applicant;

3. The Commission should direct, in future DSM/EE proceedings, a determination of a reasonable level of forecasted savings extending at least two years into the future be made for use in future biennial review proceedings;

4. Paragraph 5 of the Stipulation should be modified to reflect use of the actual end-of-period capital structure with an overall weighted average cost of capital of 6.952 percent;

5. Paragraph 6 of the Stipulation should be modified to provide that based on § 56-585.5 B 2 of the Code, it is in the public interest to reflect a 2045 retirement date for Dominion Energy's carbon emitting generating units. However, the base rates in this proceeding, as well as the rates associated with Rider GV and Rider BW should be based on the retirement assumption in the Company's depreciation study, with the incremental cost of reflecting a 2045 retirement for Dominion Energy's carbon emitting units in compliance with the VCEA collected through Rider CE;

6. Paragraph 10 of the Stipulation should be modified to add the following exception to the final sentence of the paragraph: "except for the customer charge for rate schedule 5C, which will be $12.85 based on the testimony of Staff witness G. Watkins."

7. Paragraph 11 of the Stipulation should be modified to reflect: (a) the proposed monthly charge for AMI opt-out customers will not be adopted in this proceeding; (b) the Company will undertake measures to provide information to its opt-out customers, including warning opt-out customers of the Company's estimated total monthly cost of reading an opt-out customer's meter and the Company's proposed phase-in of such a charge; and (c) the Company will present its evaluation of a medical waiver in its next biennial review proceeding; and

8. Paragraph 13 of the Stipulation should be modified to reflect that the Company will incorporate the same tariff language for nonpayment disconnections as recently adopted for Appalachian Power Company.

Accordingly, **I RECOMMEND** the Commission enter an order that:

1. ***ADOPTS*** the findings set forth above;

2. ***APPROVES*** the Stipulation as modified; and

3. ***DISMISSES*** this case from the Commission's docket of active cases.

COMMENTS

The parties are advised that, pursuant to Rule 5 VAC 5-20-120 C of the Commission's Rules of Practice and Procedure ("Rules")[1796] and § 12.1-31 of the Code, any comments to this Report must be filed on or before February 1, 2024. To promote administrative efficiency, the parties are encouraged to file electronically in accordance with Rule 5 VAC 5-20-140 of the Commission's Rules. If not filed electronically, an original and fifteen (15) copies must be submitted in writing to the Clerk of the Commission, c/o Document Control Center, P.O. Box

[1796] 5 VAC 5-20-10 *et seq.*

2118, Richmond, Virginia 23218. Any party filing such comments shall attach a certificate to the foot of such document certifying that copies have been served by electronic mail to all counsel of record and any such party not represented by counsel.

Respectfully submitted,

Alexander F. Skirpan, Jr.
Chief Hearing Examiner

The Commission's Document Control Center is requested to send a copy of the above Report to all persons on the official Service List in this matter. The Service List is available from the Clerk of the State Corporation Commission, c/o Document Control Center, 1300 East Main Street, Tyler Building, First Floor, Richmond, Virginia 23219.

Virginia State Corporation Commission
eFiling CASE Document Cover Sheet

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Case Number (if already assigned)	PUR-2023-00101
Case Name (if known)	Application of Virginia Electric and Power Company for a 2023 biennial review of the rates, terms and conditions for the provision of generation, distribution and transmission services pursuant to § 56-585.1 A of the Code of Virginia
Document Type	REEX
Document Description Summary	Comments of Virginia Electric and Power Company on the January 17, 2024 Report of Alexander F. Skirpan, Jr., Chief Hearing Examiner
Total Number of Pages	54
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COMMONWEALTH OF VIRGINIA

STATE CORPORATION COMMISSION

AT RICHMOND, FEBRUARY 28, 2024

APPLICATION OF

VIRGINIA ELECTRIC AND POWER COMPANY

CASE NO. PUR-2023-00101

For a 2023 biennial review of the rates, terms and conditions for the provision of generation, distribution and transmission services pursuant to § 56-585.1 A of the Code of Virginia

FINAL ORDER

On July 3, 2023, Virginia Electric and Power Company ("Dominion" or "Company") filed an application ("Application") with the State Corporation Commission ("Commission"), pursuant to § 56-585.1 A of the Code of Virginia ("Code"), for a biennial review of the Company's rates, terms, and conditions for the provision of generation, distribution, and transmission services.

The Application states that during its 2023 Session, the Virginia General Assembly enacted Chapter 775 (HB 1770) of the 2023 Virginia Acts of Assembly ("Legislation").[1] The Legislation, in part, amended Code § 56-585.1 and became effective on July 1, 2023. As stated in the Application, the Legislation, *inter alia*, has modified the review process for Dominion's base rates.[2] Significantly, the Legislation returned the Commonwealth's incumbent electric utilities to more frequent, biennial reviews of base rates; required Dominion to combine certain existing rate adjustment clauses that have a combined annual revenue requirement of at least $350 million as of July 1, 2023, with its base rates; established that prospective base rates will be

[1] *See also* Senate Bill 1265, 2023 Va. Acts ch. 757.

[2] *See* 2023 Va. Acts ch. 775; Ex. 4 (Application) at 1.

set based solely on the forward-looking cost of service; directed that Dominion's authorized rate of return on equity ("ROE") be set at 9.70% in the present proceeding; and stated that the Company must take reasonable efforts to maintain an equity component of total capitalization of 52.1% through the end of 2024.[3]

On July 20, 2023, the Commission issued an Order for Notice and Hearing that, among other things, directed Dominion to provide public notice of its Application; scheduled a telephonic hearing on November 20, 2023, to receive the testimony of public witnesses; scheduled a public evidentiary hearing for November 28, 2023, to receive evidence on the Company's Application; provided interested persons an opportunity to comment on the Company's Application or to participate as respondents in this proceeding; directed Commission Staff ("Staff") to investigate the Application and file testimony and exhibits containing its findings and recommendations thereon; and appointed a Hearing Examiner to conduct all further proceedings in this matter on behalf of the Commission, including filing a final report with proposed findings and recommendations.

Notices of participation were filed by the following: Walmart Inc. ("Walmart"); the Department of the Navy, on behalf of all Federal Executive Agencies ("Navy"); the Virginia Committee for Fair Utility Rates ("Committee"); the Apartment and Office Building Association of Metropolitan Washington ("AOBA"); Appalachian Voices; Virginia Poverty Law Center ("VPLC"); Data Center Coalition ("DCC"); Google LLC ("Google"); Kroger Limited Partnership I and Harris Teeter, LLC (collectively, "Kroger"); Microsoft Corporation ("Microsoft"); Direct Energy Business, LLC and Direct Energy Services, LLC (collectively,

[3] *See* 2023 Va. Acts ch. 775; Ex. 4 (Application) at 1-2.

"Direct Energy"); and the Office of the Attorney General's Division of Consumer Counsel ("Consumer Counsel").

On October 10, 2023, the Navy, the Committee, AOBA, VPLC,[4] Walmart, Direct Energy, and Consumer Counsel filed testimony. On October 23, 2023, Staff filed testimony. On November 6, 2023, Dominion filed rebuttal testimony. Further, numerous public comments were filed in the docket.

On November 14, 2023, Dominion, Staff, Consumer Counsel, Appalachian Voices, DCC, the Navy, Google, Kroger, the Committee, and Walmart filed a Proposed Stipulation and Recommendation ("Stipulation"), which resolved all outstanding issues raised in this proceeding. AOBA, Direct Energy, Microsoft, and VPLC did not join in, but did not oppose, the Stipulation.

On November 15, 2023, the Chief Hearing Examiner issued a ruling that, among other things, retained the scheduled hearings to provide all participants the opportunity to develop a full record in this proceeding. On November 20, 2023, the telephonic public witness hearing was convened. Thirty-six witnesses presented testimony during the hearing. On November 28, 2023, the evidentiary hearing was convened. Two additional public witnesses provided testimony during the evidentiary hearing.

On January 17, 2024, the Report of Alexander F. Skirpan, Jr., Chief Hearing Examiner ("Report") was filed. In the Report, the Chief Hearing Examiner recommended that the Commission approve the Stipulation subject to certain modifications.[5] The Chief Hearing Examiner also made 43 recommended findings for the Commission's consideration, should the

[4] On October 17, 2023, VPLC filed corrected testimony.

[5] Report at 245.

Stipulation not be adopted.[6] The Chief Hearing Examiner recommended that the Commission enter an order that adopts the findings in the Report; approves the Stipulation as modified in the Report; and dismisses the case from the Commission's docket.[7]

Comments on the Report were filed by Dominion, AOBA, Appalachian Voices, the Committee, Consumer Counsel, DCC, Direct Energy, Google, Kroger, Microsoft, the Navy, VPLC, Walmart, and Staff.

NOW THE COMMISSION, upon consideration of this matter, is of the opinion and finds as follows.

The Commission has thoroughly considered and evaluated the evidence and arguments in the record of this proceeding.[8] That consideration included the particular issues associated with, and specifically addressed by, the terms of the proposed Stipulation. That consideration also included the thoughtful and detailed analysis of the numerous complex issues in the proceeding as presented in the Chief Hearing Examiner's approximately 250-page Report in this matter.[9]

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[6] *Id.* at 241-245.

[7] *Id.* at 246.

[8] *See also Board of Supervisors of Loudoun County v. State Corp. Comm'n*, 292 Va. 444, 454 n.10 (2016) ("We note that even in the absence of this representation by the Commission, pursuant to our governing standard of review, the Commission's decision comes to us with a presumption that it considered all of the evidence of record.") (citation omitted).

[9] As characterized by Staff, "the Chief Hearing Examiner, in his Report, developed a robust and carefully considered record for the Commission." Staff's Comments on the Chief Hearing Examiner's Report at 14. Indeed, the Commission rejects Direct Energy's denunciation that "[t]here was no valid reason" for the Chief Hearing Examiner to "issu[e] findings on the merits of the contested issues in addition to issuing findings on whether the Stipulation should be approved." Direct Energy's Comments and Exceptions to the Chief Hearing Examiner' Report at 8. To the contrary, and as recognized by Dominion: "The Company appreciates the Chief Hearing Examiner's meticulous development of the record in this case" and "fully respects the Commission's obligation and authority to decide the issues in this case consistent with its statutory charge." Dominion's Comments on the Chief Hearing Examiner's Report at 2, 7.

The Commission hereby approves and adopts the Stipulation. The Commission finds that, taken as a whole, the Stipulation is in the public interest and represents a reasonable resolution of the issues presented in this proceeding. In addition, and consistent with the provisions of the Stipulation, any factual or legal matters attendant to the Stipulation and the Commission's approval thereof shall have no precedential effect.[10]

Finally, the Commission has also taken note of the Chief Hearing Examiner's procedural recommendations for future biennial review and DSM/EE proceedings.[11] While not part of the Stipulation or the Commission's adoption thereof, the Commission appreciates the concerns raised in the Report and finds that such matters may be appropriately addressed in relevant future proceedings.

Accordingly, IT IS ORDERED THAT:

(1) The Stipulation is approved and adopted by the Commission.

(2) The Company's Application is approved as modified by the Stipulation as set forth herein.

(3) The Company shall forthwith file revised tariffs and terms and conditions of service and supporting workpapers with the Clerk of the Commission and with the Commission's Divisions of Public Utility Regulation and Utility Accounting and Finance, as necessary to comply with the Stipulation and this Final Order. The stipulated one-time credit, based on electric supply usage billed in January through June 2024 in the aggregate amount of $15 million shall be applied to customer bills by September 30, 2024. The Clerk of the Commission shall

[10] Ex. 2 (Stipulation) at 7.

[11] Report at 245.

retain such filing for public inspection in person and on the Commission's website: scc.Virginia.gov/pages/Case-Information.

(4) For approved tariff changes effective January 1, 2025, the Company shall file revised tariffs and terms and conditions of service and supporting workpapers with the Clerk of the Commission and with the Commission's Divisions of Public Utility Regulation and Utility Accounting and Finance, at least forty-five (45) days in advance of such effective date. The Clerk of the Commission shall retain such filing for public inspection in person and on the Commission's website: scc.virginia.gov/pages/Case-Information.

(5) The cost of the one-time credit in the aggregate amount of $15 million shall be included in the 2024 earnings test.

(6) Within sixty (60) days of completing the credits to customers' bills ordered herein, the Company shall file with the Commission's Divisions of Public Utility Regulation and Utility Accounting and Finance a report verifying that all credits have been completed.

(7) The Stipulation, and this Final Order approving the Company's Application as modified by the Stipulation, shall have no precedential effect.

(8) This case is dismissed.

Commissioner James C. Dimitri participated in this matter.

A COPY hereof shall be sent electronically by the Clerk of the Commission to all persons on the official Service List in this matter. The Service List is available from the Clerk of the Commission.

Paragraph (10) reflects a compromise among the Stipulating Parties, and in this instance, disrupting this negotiated result would result in direct increases to customer bills.

G. AMI Opt Out Charge

Concerning the Company's Advanced Metering Infrastructure ("AMI") program, the Report recommends that:

> Paragraph 11 of the Stipulation should be modified to reflect: (a) the proposed monthly charge for AMI opt-out customers will not be adopted in this proceeding; (b) the Company will undertake measures to provide information to its opt-out customers, including warning opt-out customers of the Company's estimated total monthly cost of reading an opt-out customer's meter and the Company's proposed phase-in of such a charge; and (c) the Company will present its evaluation of a medical waiver in its next biennial review proceeding.

The Company maintains that the issue of an AMI opt-out charge is ripe for determination in this proceeding and its proposed opt-out policy, incorporating the Staff revisions adopted by the Company on rebuttal, is reasonable. The Company respects the views of customers on this issue and respects their ability to opt-out of AMI participation. But it should be acknowledged that the public witnesses testifying with respect to AMI concerns in this proceeding reflect an infinitesimally small percentage of the over two million customers with a deployed AMI meter. To further condition the AMI deployment process or the cost recovery associated with opt-out customers will not resolve the debate, but it will perpetuate a cost shift to participating customers. The agreement of the Stipulating Parties reflected in Paragraph (11) is fully supported by the record evidence and should be adopted without modification.

The issue of establishing an appropriate AMI opt out fee and policy was raised in the Company's 2021 triennial review, Case No. PUR-2021-00058, and ultimately deferred to a

future proceeding. The 2021 triennial review stipulation adopted by the Commission provided that:

> The Company's AMI opt-out policy shall not be adopted. The Company will further evaluate the impact of this policy, including necessary opt-out fee adjustments located in Section X of the Terms and Conditions and any potential alternative metering options, and present that evaluation in the next triennial review proceeding or another appropriate proceeding.[41]

In accordance with the 2021 triennial review stipulation, Company Witness Robert E. Miller presented the Company's proposed AMI opt-out charge and updated opt-out policy in the instant case. In support of the AMI opt-out charge, Mr. Miller testified that:

> When a customer opts out of smart meter installation or requests to replace their existing smart meter with a noncommunicating meter, the Company must expend additional resources both initially and on an ongoing basis. Up front, there are administrative expenses associated with a customer's initial decision to opt out of smart meter installation, such as program administration and reporting, customer communications and account management, work order generation and scheduling, inventory management and shipping. The Company must also exchange the customer's existing meter for an opt-out meter and send someone to manually read the non-communicating meter on a monthly basis.[42]

While the evidence shows that a fully supported opt-out charge would be $31.04 per month,[43] the Company proposed a stepped approach in implementing the opt out fee and recommends a monthly opt-out fee of $10.35.[44] Staff did not oppose the Company's proposal, noting that while some costs would still be borne by non-opt out customers, "currently, *all* costs associated with opting out of smart meter installation are socialized across all residential customers because *all* costs are currently recovered through base rates."[45]

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[41] *2021 triennial review*, Ex. 3 ¶ (8) (Proposed Stipulation and Recommendation).
[42] Ex. 10 (Miller Direct) at 33.
[43] Ex. 50 (Miller Rebuttal) at 43.
[44] Ex. 10 (Miller Direct) at 34.
[45] Ex. 41 (Ricketts) at 11.

The Report emphasizes that many of the public comments filed in the case expressed opposition to AMI meters and complained about a lack of information.[46] During the evidentiary hearing, Company Witness Frank Hinckle explained in detail the process for communicating with customers about AMI deployment and alternative options.[47] The Company acknowledges the concerns raised by the public comments and testimony. Respectfully, though, it is important to put these concerns in context. To date, the Company has deployed approximately 2 million AMI meters.[48] The number of public witnesses expressing concerns about AMI meters, which included 33 live witnesses and 190 written comments, represents only a tiny fraction of these customers—approximately 0.0001115%. The decision to deploy these meters is not at issue in this case, and it is likely that there will always be a number of customers who dislike this technology. Therefore, while these customer concerns are important to the Company, they do not necessarily weigh on the precise issues before the Commission in this case and are not a basis to modify the Stipulation.

In sum, the Company's AMI opt-out policy and fee were thoroughly litigated in this proceeding and the issues are ripe for Commission determination. The evidence shows that non-opt-out customers are currently subsidizing the costs of opt-out customers, and further delay in implementing an opt-out fee will only perpetuate this subsidization.

H. Service Disconnection Tariff Language

The Report's final proposed modification concerns the Company's tariff provisions related to service disconnections. The Stipulation provides that "[t]he Company shall formally

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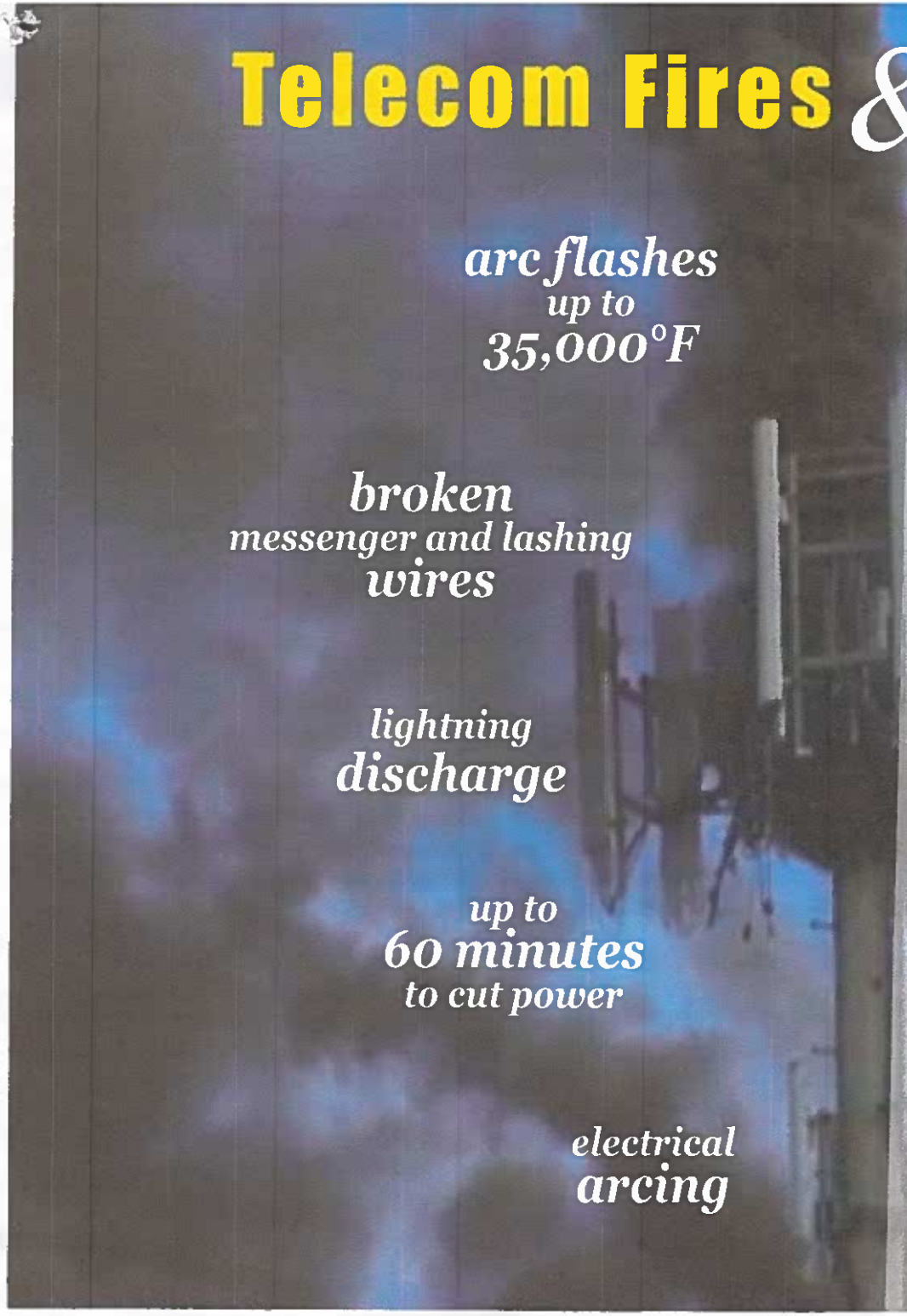
[46] Report at 200-205.
[47] Tr. 319:22-324:4 (Hinckle).
[48] *See Petition of Virginia Electric and Power Company, For approval of a plan for electric distribution grid transformation projects pursuant to § 56-585.1 A 6 of the Code of Virginia,* Case No. PUR-2023-00051, Ex. 1 to the Petition at 19 (Mar. 31, 2023)

Telecom Fires & Federal Wireless Bills



Few would dispute that an electrical device failure can cause a fire. Yet what eludes those promoting more than 50 federal wireless bills is that **each cell tower is an electrical device.** Cell towers and their related telecommunications equipment can cause devastating fires. Worse, these fires can not be extinguished through conventional means.

Except to protect the perimeter, firefighters can do nothing to extinguish the fire until the **utility cuts the power — which can take up to 60 minutes.**[1] In fact, anyone putting water on a cell tower fire before the electricity is cut may be electrocuted.[2,3] Imagine a cell tower fire in a neighborhood or next to a school amidst a high wind event. The time it takes to cut power does not change — no matter the risk to people and property.

Legislators supporting these bills are overlooking that cell towers should NOT be placed near homes, day care centers, or schools for this simple reason — **people need time to escape.**

Here are **just a few examples** of telecommunications-initiated fires in the last 15 years.

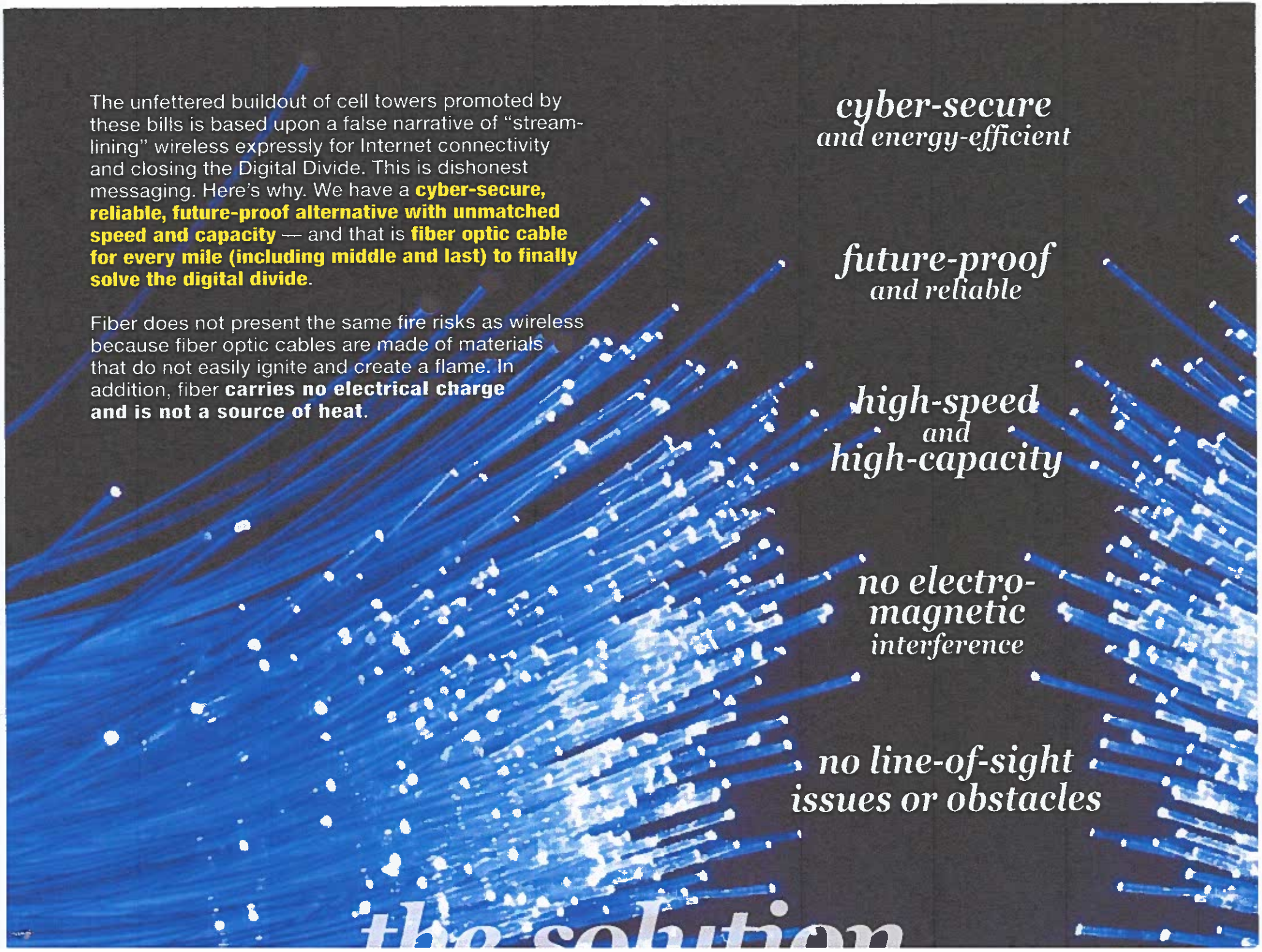
- **Four major fires in Southern California 2007–2020** were caused (or contributed to) by telecom equipment. Collectively, these fires killed 5 people, injured dozens of others (including firefighters), and led to well more than $6 billion in damages:
    - Guejito Fire (2007) in San Diego (which merged into the Witch Creek Fire)
    - Malibu Canyon Fire (2007)
    - Woolsey Fire (2018)
    - Silverado Fire in Irvine (2020)
- The **2007 Malibu Canyon Fire** started when SCE utility poles overloaded with telecom equipment snapped in the wind. The California Public Utilities Commission (CPUC) found that AT&T, NextG (now Crown Castle), Southern California Edison (SCE), Sprint (now T-Mobile), and Verizon were contributorily negligent and then impeded the investigation of the fire.[4]
- The **Woolsey Fire started on November 8, 2018.** It burned nearly 100,000 acres of land, caused three fatalities, and prompted the evacuation of more than 295,000 people — and caused more than $6 billion in damages.[5] SCE's own telecommunications company played a major role in the inferno. The Safety and Enforcement Division (SED) found that SCE conducted a May 2018 telecommunications inspection and found a broken SCE telecom messenger wire and a broken lashing wire. SCE did not assign an urgent level to the repair — a fatal error. Six months later, the broken equipment was energized, and the Woolsey inferno ignited.[6]
- A **March 2021 Chula Vista, California fire** was caused by an AT&T cell tower that was partially concealed in a light fixture around a track at Otay Ranch High School. The tower burst into flames at 7:30 PM on a Tuesday evening. The Fire Incident Report was obtained through a CPRA request. The area of origin was within the equipment; the heat source was "electrical arcing." When the fire department arrived, the 100-ft pole appeared to have an internal fire that traveled up the pole to the cell phone equipment and stadium lighting at the top of the pole. Firefighters maintained a safe distance until they could verify all power supply to the pole had been secured. As they were waiting for the representative from SDG&E to arrive to confirm the power had been cut, the heat of the fire due to arcing caused the steel pole to become molten plasma. It collapsed onto the bleachers near the football field, burning the track, and destroying the bleachers.[7] Temperatures of an arc flash can reach as much 35,000 °F — three times the estimated temperature of the sun's surface.[8]
- In **June 2023, the First Congregational Church in Spencer, Massachusetts** burned to the ground as a result of lightning hitting a Verizon tower in the church steeple. There is an increased incidence of lightning strikes where cell towers are located. Lightning mitigation systems are not always required and even when included as part of construction, they do not guarantee a cell tower can escape a direct lightning incident. In spite of swift response by six area fire departments, the church (originally built in 1743) was completely destroyed by the rapidly moving inferno. The stated cause of the fire was "lightning discharge."[9]

The US Congress has witnessed an unprecedented avalanche of telecom-written wireless bills. These **bills grant telecom maximum control by preempting local zoning laws, taking away state and municipal rights to oversee placement — and most of all — safety**. Collectively, these bills override the 1996 Telecommunications Act, a volume of amendments to the Constitution, the National Historic Preservation Act (NHPA), and the National Environmental Policy Act.

These bills **pretend to preserve local governments' enforcement of local building codes** — yet here's the catch. So long as those codes are not inconsistent with FCC regulations. **The FCC can overrule local safety requirements** — a form of preemption. Code enforcement, a purely state function under existing safety codes, has a route to appeal that stays at the state level. These bills would **federalize safety codes** — jeopardizing community authority at the local level where local issues are best known. If the carriers want less stringent fire and building codes, they merely lobby the FCC Commissioners to change the rules so **telecom** once again **gets to police telecom** when it comes to fire safety. The carriers bolster their bottom line while local jurisdictions and citizens are silenced and pay the price in safety and health.

When we stop evaluating how wireless technology impacts the environment in its entirety — *from our front yards and school yards to our national parks* — we cease to evaluate the **risk each cell tower carries with it — FIRE**.

If legislators, local officials, agencies, and citizens fail to express strong opposition to these bills, the unstoppable proliferation of cell towers would be such risky business, it would be no different than striking a match in the middle of a bone-dry forest just to see if there is a fire.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Telecom's market power has been allowed to dictate deeply-rooted overcharging of consumers — funds adding up to billions per state that must be recovered. This massive corruption continues unabated because Congress has never investigated telecom's cross-subsidies resulting in more fraud and waste, more cell towers, greater fire risk, and increased radiation.

Telecom greed fuels industry's betrayal of a commitment to a promised buildout to bring fiber optic to/through our schools, businesses, and homes — every home (not just the privileged). These profits then reward and drive telecom's agenda via a **false narrative** that more wireless will solve a Digital Divide — *even though* **wireless has already failed to deliver**.

To **combat** telecom's usual **wireless "fix"** for broadband access, in 2022, the National Telecommunications and Information Administration (NTIA) issued the first federal government proposal that seeks to promote infrastructure policies focused on the public interest. The NTIA stated that fiber-to-the-premises is the preferred technology platform for meeting coverage goals. The **future of Internet access is fiber**.

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Environmental injustice abounds. There's a giant macro tower in Brenda's underprivileged neighborhood's community garden. Residents can no longer grow fresh vegetables for the entire neighborhood since a major carrier took over garden property more than 5 years ago. Everywhere in her East LA neighborhood, one sees cell towers. Yet none of this infrastructure connected residents to the Internet despite an extremely expensive service price. Ultimately, fiber gave reliable capacity and speed at a lower price.

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Telecom's promises are empty. For 30 years, telecom has been introducing bills and getting them passed under the guise of *"closing the Digital Divide."* **None of the bills before Congress mandate that telecoms connect underprivileged neighborhoods to the Internet.** Federal programs putting a priority on fiber to the premises (FTTP) this past year finally connected Brenda's neighborhood. **Only fiber is future-proof** — with no harms or added fire risk to Brenda's family.

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Study NCT04754594 To Evaluate the Safety, Tolerability, and Immunogenicity of BNT162b2 Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older Submitted Date: July 14, 2023 (v21) (Pfizer Phase 2/3 Trial)

(Section 19. Secondary Outcome) Infants with Major Congenital Anomalies & Developmental Delays from Birth Through 6 Months of Life	Infants in "Vaccine" (BNT162b 30 ug) Group	Infants in Placebo Group
Number of Infants in Each Group	156	159
Congenital Anomalies and Developmental Delays	8/156 (5.1%)	2/159 (1.3%)
Relative Risk (95% Confidence Interval)	4.1 (0.9-20), p = 0.078	

https://classic.clinicaltrials.gov/ct2/history/NCT04754594?V_21&embedded=true

James A Thorp MD on X @jathorpMFM

Say NO To SMART Meters

DANGER!

VIRGINIA MEDICAL
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FREEDOM ALLIANCE

VAMFA Stop Wireless Radiation Harms Team
Doris Knick -Team Lead
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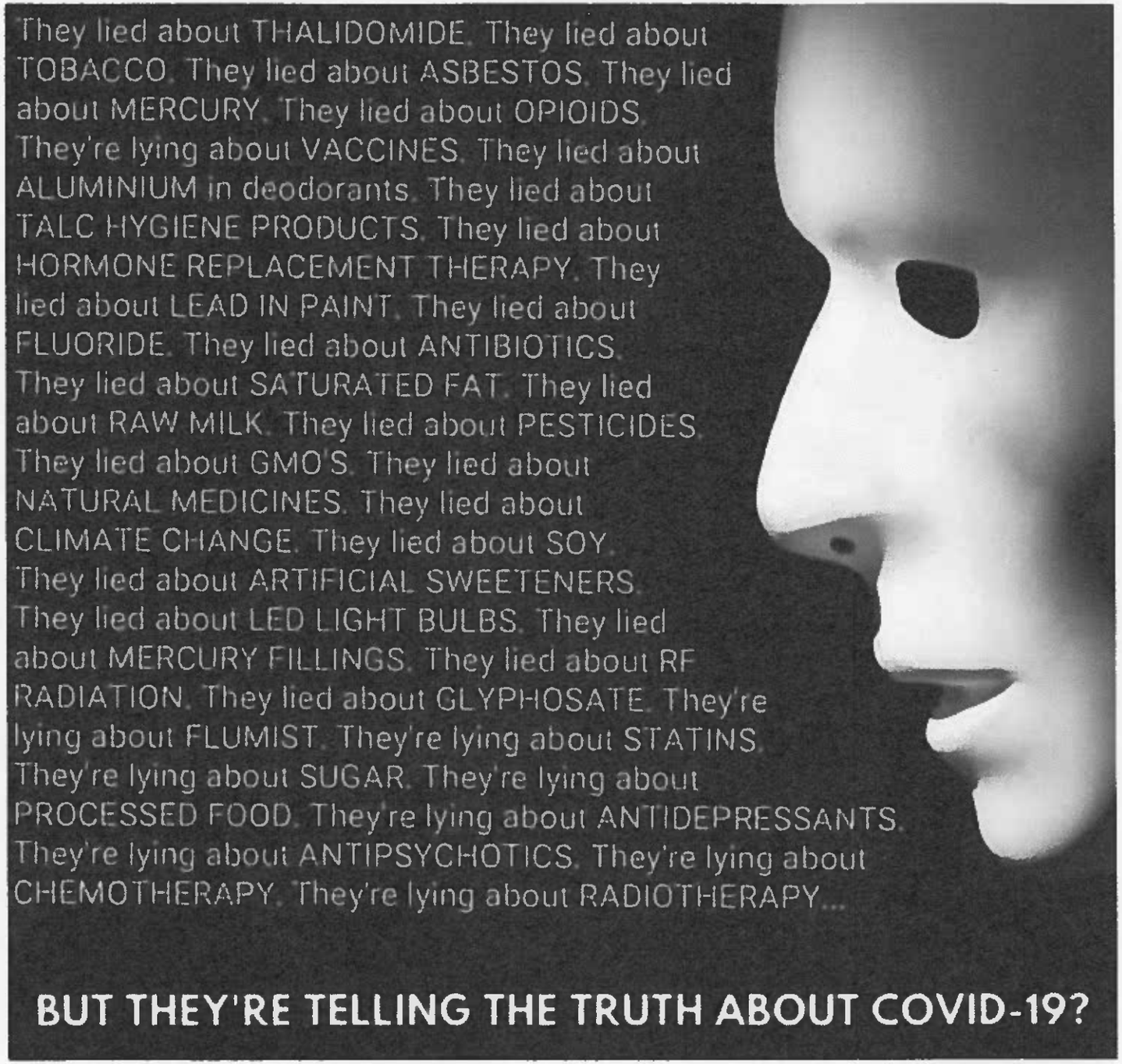
gettr.com/user/VAMEDFREEDOM
https://vamfa.org/emr-and-smart-meters/


They lied about THALIDOMIDE. They lied about TOBACCO. They lied about ASBESTOS. They lied about MERCURY. They lied about OPIOIDS. They're lying about VACCINES. They lied about ALUMINIUM in deodorants. They lied about TALC HYGIENE PRODUCTS. They lied about HORMONE REPLACEMENT THERAPY. They lied about LEAD IN PAINT. They lied about FLUORIDE. They lied about ANTIBIOTICS. They lied about SATURATED FAT. They lied about RAW MILK. They lied about PESTICIDES. They lied about GMO'S. They lied about NATURAL MEDICINES. They lied about CLIMATE CHANGE. They lied about SOY. They lied about ARTIFICIAL SWEETENERS. They lied about LED LIGHT BULBS. They lied about MERCURY FILLINGS. They lied about RF RADIATION. They lied about GLYPHOSATE. They're lying about FLUMIST. They're lying about STATINS. They're lying about SUGAR. They're lying about PROCESSED FOOD. They're lying about ANTIDEPRESSANTS. They're lying about ANTIPSYCHOTICS. They're lying about CHEMOTHERAPY. They're lying about RADIOTHERAPY...
BUT THEY'RE TELLING THE TRUTH ABOUT COVID-19?

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, livewurst, 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 intregity 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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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-existant 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.

From: Virginia Medical Freedom Alliance
To: VBH quarterly meeting, April 10, 2024

The "Hot Zone" with Dr. Peter McCullough and John Leake, April 6 2024

Pfizerer just quietly (with zero media coverage) released the results of an obligatory post-marketing study of the effects of its COVID-19 vaccine on pregnant women (Study NCT04754594)

The study evaluated the Safety, Tolerability, and Immunogenicity of their vaccine BNT162b2 Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older

Submitted Date: July 14, 2023).

As Steve Kirsch observed in a recent, thorough analysis, this study has contained numerous, highly suspicious elements from its beginning.

It began with Pfizer's laughable claim that it could NOT recruit a statistically significant number of unvaccinated pregnant women to serve as the control group because it was virtually impossible to find pregnant women who did not wish to receive the experimental COVID-19 vaccine as soon as possible.

Though the trial sample size was small and consisted of (156 infants of mothers who received the shot and 159 infants of mothers who received placebo), the results showed a 4X higher rate of congenital defects in the group who received the shot.

Because there has been ZERO media coverage of these results, Pfizer has not been obliged to address this extremely alarming fact.

If the company is pressed, it will undoubtedly claim that the sample size is not statistically significant because it was just too darn hard to recruit pregnant women who did not wish to receive the shot ASAP.

https://clinicaltrials.gov/study/NCT04754594?tab=results

"John Leake from Courageous Discourse with Dr Peter McCullough"<petermccuIloughmd@substack.com

Commissioner's Report

Dr. Karen Shelton
State Health Commissioner

Outline

Agency Stars

Communicable Diseases

Health Director Meeting

Hurricane and Extreme Heat Preparedness

EMS Update

Ballad Update

Administrative Ecosystem Update

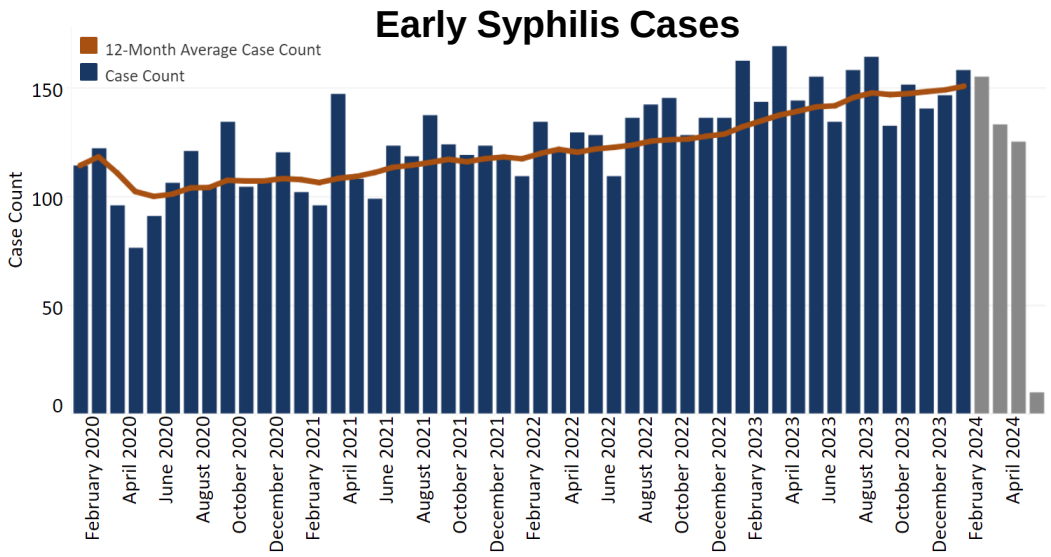
Language Access

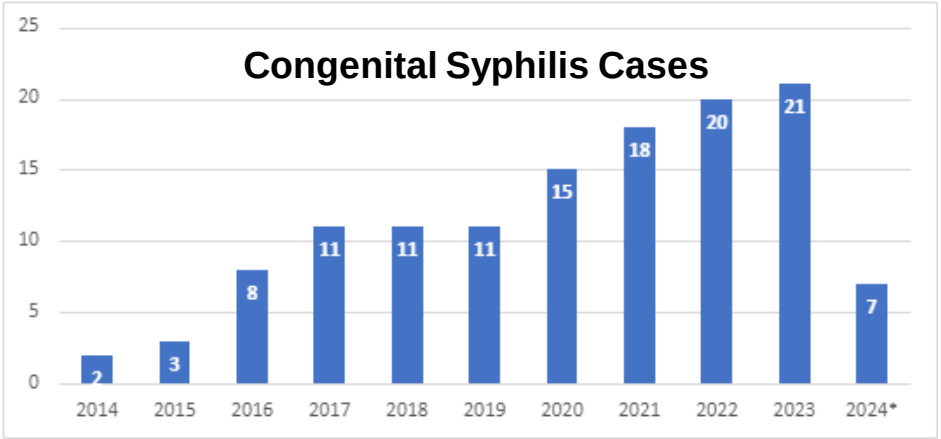
Agency Stars

Harry Bennett

Paul Brumund, MHA, VCA

Sexually Transmitted Infections Update





Data Updates

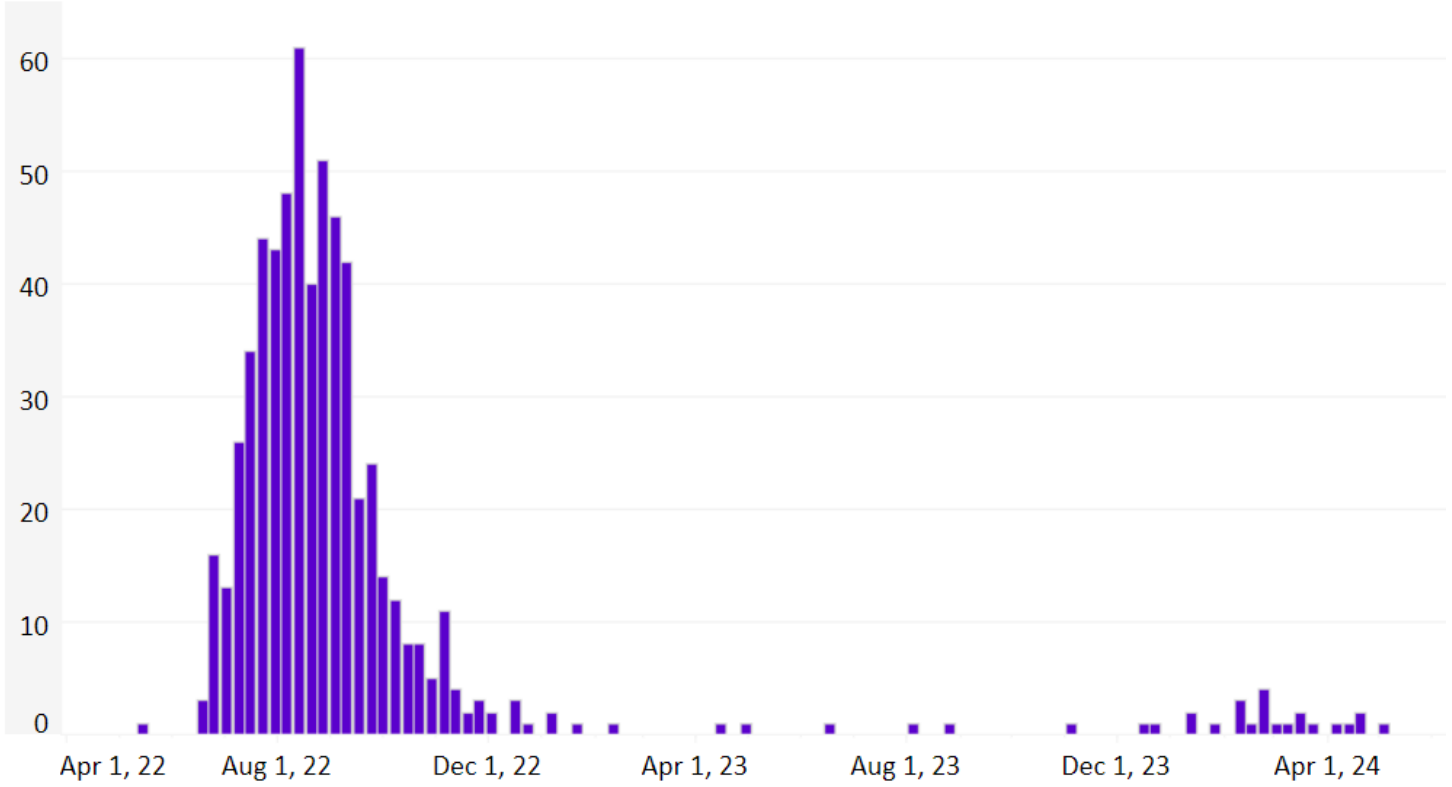
- Incidence of syphilis in CY2024 remains high
  - 2.6% higher counts of early syphilis Jan-Feb 2024 vs 2023
  - 23.8% higher counts of late syphilis Jan-Feb 2024 vs 2023
- Cases among women still high
- 10% of early syphilis cases in CY2023 were associated with substance use; 11% so far in CY2024
- 7 congenital syphilis cases so far in 2024

Program Updates

- Regional syphilis meetings ongoing- Central and Eastern kickoffs, Southwest planned for June
- Continued efforts to train DIS to collect blood specimens in the field
- Ongoing collaboration between VDH and DMAS

Mpox Update

Cases in Virginia, May 2022 – May 2024



Cases	**599**
Hospitalizations	**35**
Deaths	**2**

Mpox Data in Virginia (as of May 14, 2024)

Cases in Virginia by Age and Sex

Age Group	Cases (%)
0-9 Years	0 (0)
10-14 Years	1 (0.2)
15-19 Years	16 (2.7)
20-29 Years	213 (35.6)
30-39 Years	241 (40.2)
40-49 Years	89 (14.9)
50-59 Years	33 (5.5)
60-69 Years	4 (0.7)
70+ Years	2 (0.3)
Sex	**Cases (%)**
Female	34 (5.7)
Male	565 (94.3)

HPAI A(H5N1) in Dairy Cattle

- Since March 2024, dairy cattle in nine states reported affected
- In April 2024, VDH program level ICS structure implemented for HPAI preparedness.
  - Close coordination among VDH, DCLS, VDACS, VDEM and DWR.
- Recent clinician letter requested a low threshold for testing patients with relevant symptoms and exposure history.
- VDH, in partnership with VDEM, is offering a one-time distribution of personal protective equipment (PPE) to help protect workers from possible H5N1 bird flu infection.
- To date, there have been no reported H5N1 bird flu infections in cattle or people in Virginia.

Source: https://www.aphis.usda.gov/livestock-poultry-disease/avian/avian-influenza/hpai-detections/livestock
www.vdh.virginia.gov/hpai

Meningococcal Disease Update

- Twelve cases of meningococcal disease have been reported across four health planning regions since January 30. This is above baseline incidence and generates concern of increased transmission among vulnerable populations. Four cases have been fatal.
    - Five cases are associated with the statewide outbreak of *Neisseria meningitidis* serogroup Y that was first identified in June 2022 in eastern Virginia.
        - CDC released a health advisory on March 28 alerting jurisdictions to a nationwide increase in meningococcal disease linked to this strain (ST-1466). In Virginia, and across the US, cases are disproportionately occurring in people ages 30–60 years, Black or African American people, and people with HIV.
    - Two cases are caused by a strain of *N. meningitidis* that is resistant to ciprofloxacin and penicillin. This strain has only been detected in residents of/travelers to the DC metro area.

- **VDH Response**:
    - VDH expanded our vaccination strategy in April to increase access to MenACWY vaccine for persons at increased risk for meningococcal disease (e.g., people with HIV).
    - VDH also released a clinician letter on April 11th to raise provider awareness of the ongoing outbreak and provide testing and prophylaxis guidance in response to the detection of antibiotic-resistant N. meningitidis in northern Virginia.

Pertussis outbreaks

- VDH is reporting an increase in pertussis outbreaks.
  - 3 outbreaks and 3 clusters have been reported this year in a variety of settings, including: 2 high schools, 2 universities, 1 religious community, and 1 home.
  - Number of cases range from 2-21 people (median 4 cases)
- This increase in pertussis activity indicates a return to pre-pandemic levels. Prior to the COVID-19 pandemic, Virginia averaged 9 pertussis outbreaks per year.

- **VDH Response**:
  - Local health department staff are distributing pertussis test kits to health care providers to support timely testing at Virginia's state laboratory.
  - Providers are advised to maintain a high index of suspicion for pertussis.
  - VDH is updating the pertussis outbreak investigation guidance in the Disease Control Manual.

Tickborne Disease Update

- Lyme Disease Awareness Month
  - Social media messages
  - Outreach and education through cooperative extension programs and Virginia DCR
  - Tick surveillance
- Alpha-gal Syndrome
  - House Bill 93 enrolled by the 2024 General Assembly
  - Vector-borne Program preparing for surveillance

Health Director Meeting

- ~90 meeting attendees including VDH District Directors, Office Directors, central office Community Health Services staff, and Office of the Commissioner staff
- Meeting topics and highlights
  - Maternal Health
  - Enabling VDH to Harness the Power of Data
  - Syphilis Prevention: A Call to Action
  - Response to the Overdose and Substance Use Disorder Crisis
  - The Current State of VDH Nursing
  - Kepone to Blue Zone
  - Visioning the Future of Public Health

Hurricane and Extreme Heat Preparedness

Ongoing interagency collaboration with the Virginia Department of Social Services (VDSS), Virginia Department of Emergency Management (VDEM), and other Virginia Emergency Support Team (VEST) agencies in advance of hurricane season

Planning, Training and Exercising

- Disaster Shelter Training Courses
  - Health and Medical Fundamentals
  - Environmental Health
  - Nursing
- Regional Tabletop Exercises
- VDH Mass Care Plan
- Virginia Emergency Support Team Exercise (VESTEX)

Public Information and Education

Public Health Surveillance

New CDC and NWS Heat and Health Initiative:

- The HeatRisk Forecast Tool, designed for public health audiences, provides a seven-day heat forecast nationwide
- The HeatRisk Dashboard informs the public on how best to protect themselves when outdoor temperatures are high and could impact their health
- New CDC clinical guidance helps clinicians keep at-risk individuals safe when temperatures rise

EMS Update

- As VDH prepares for the next phase of transition, the Workforce Engagement & Development team is completing a comprehensive program of 1-2-1's and group meetings.
- Rachel Stradling is operating as the Interim Director while we search for a permanent Director. We had over 70 applications, and are in the first stages of narrowing the candidate pool.
- Fitch & Associates are completing their Stakeholder engagement work, and analysis all the data they have collected over the last 5 months. We hope to have their full report of recommendations in early July so that we can continue the forward momentum.

Active Supervision of Cooperative Agreement with Ballad Health

What is a Cooperative Agreement?

- Federal anti-trust concerns generally prevent the merger of hospitals and health systems such that a monopoly on the provision of hospital services is created.

- The use of Cooperative Agreement, also known as Certificate of Public Advantage (COPA), provides some insulation from Federal antitrust action by replacing the business constraints of the marketplace with state active supervision of the cooperative agreement, assuring that the benefits of the cooperative agreement outweigh its disadvantages.

- The Commissioner is solely responsible for determining what constitutes active supervision.

- Failure to actively supervise the Cooperative Agreement to assure, on an ongoing basis, that the benefits of the cooperative agreement outweigh the disadvantages of the loss of competition invites possible intervention by the Federal Trade Commission (FTC).

Ballad Update

Active Supervision

- Primary responsibility for the Commonwealth's ongoing active supervision efforts is assigned to the Cooperative Agreement section of the Division of Certificate of Public Need in the Office of Licensure and Certification (OLC).

- The primary team includes:
  - Two full-time positions dedicated solely to cooperative agreement functions,
  - A "Monitor," located in southwest Virginia,
    - Works closely with counterpart Monitors from Tennessee and the Southwest Virginia Health Authority,
  - An analyst based in Richmond,
  - Both positions report to the Director of the Division of COPN.

- The Deputy Commissioner for Governmental and Regulatory Affairs is the Commissioner's point person for ensuring active supervision of the Cooperative Agreement.

Ballad Update

Current Topics

- Ballad is quickly reaching the $308 Million spending obligations on five of the six required plans.
- News articles have emphasized Ballad's shortfall in Charity Care and long Emergency Department Wait Times.
- Payor Contract Negotiations
- Reconvening Cooperative Agreement Technical Advisory Panel (TAP) to reinvigorate metric reporting requirements with Population Health and access/accessibility metrics in mind.
- Considering Changes to the CA to align with TN COPA and bring the document up-to-date.
- Virginia & Tennessee Health Commissioners are meeting monthly to keep informed and maintain alignment between the states.

Ballad Update

Regulatory Update

- Regulations, 12VAC5-221 Regulations Governing Cooperative Agreements
  - Promulgated in 2017 and last amended in 2018
  - Periodic review conducted and completed in April 2024
    - Fast Track action has been initiated as a result of the periodic review
  - The amendments in the Fast Track action address:
    - The results of the 2024 periodic review
    - Public comment received during the periodic review
    - Updates to conform the regulation to the Virginia Registrar of Regulation's *Form, Style, and Procedure Manual for Publication of Virginia Regulations*

Administrative Ecosystem Update

- IT Service Management – Sustainment, Operations and Maintenance
- Travel Management System – COVRAMP/ECOS Process, software identified
- SPCC Bank of America Reconciliation – Implemented
- Grants Management System – Project Started, finishing up Discovery Phase, expected Phase 1 implementation in Fall 2024
- Employee Experience Portal for HR using ServiceNow – Kick off May 23, 2024
- CyberSecurity Incident and Risk Management using ServiceNow - Sustainment, Operations and Maintenance
- CyberSecurity Identity Access Management Assessment – Completed
- Process Automation – Ongoing, Sustainment, Operations and Maintenance
- Finance Systems – Planning and expecting work to start right after FY 24 closing
- Procurement and General Services – Discovery Phase and work to begin first quarter of FY 25

Language Access

Interpreter Training for Bilingual VDH Staff

- 74 staff enrolled from 14 districts and 4 central offices
- Primarily Spanish, but also Arabic, Haitian Creole and Ukrainian
- More than 30 additional training slots still available

Translation of Critical, Frequently Used Agency Documents

- 30 documents have been translated into 8 languages and posted to Translation Library
- More than 30 additional translation requests are being reviewed

Language Access

Implementation of New Statewide Contract with OMNIA Partners

- 8 separate vendors are part of this contract
- Offer a variety of translation and interpretation services
- Specific information concerning each vendor is being provided to districts and offices

Assessment by Office of Secretary of Health and Human Resources

- Initiated in January 2024
- Consultants are reviewing topics including digital platforms, informational resources, translation of forms and notices, interpretation services and staff interaction with residents
- VDH has participated in several interviews and provided documents and survey responses; a final report is expected

Questions?

REGULATORY ACTION UPDATE

State Board of Health
Regulatory Action Update
June 13, 2024

Overview of Pending Regulatory Actions:

There are 52 pending actions under development:

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

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

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

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

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

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

Regulatory Actions Taken by the Commissioner on Behalf of the Board pursuant to § 32.1-20 of the Code of Virginia since the April 10, 2024 Board Meeting while the Board was not in Session:

Approved a Notice of Intended Regulatory Action (NOIRA) for the Sewage Handling and Disposal Regulations (12VAC5-610)

- This action is being initiated a result of a recent periodic review. Amendments will address changes to the industry and related best practices since the last comprehensive update to the Regulations more than 20 years ago, clarify existing requirements, and consider public comment and regulatory reduction where possible.

Non-Regulatory Actions Taken by the Commissioner on Behalf of the Board since the April 10, 2024 Board Meeting while the Board was not in Session:

None

Periodic Review of Regulations

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

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

VDH has 16 periodic reviews in progress:

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

12 VAC 5-620	Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells	Intend to issue result after current action becomes effective.

Executive Branch Review Activity Completed since the December 15, 2023 Board Meeting:

The Office of the Attorney General certified:

- Fast Track Action for the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations (12VAC5-220)
- Fast Track Action for the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations (12VAC5-220)
- Proposed Amendments to the Regulations for Summer Camps (12VAC5-440)
- Final Rainwater Harvesting Systems Regulations (12VAC5-635)
- Fast Track Action for the Food Regulations (12VAC5-421)

The Department of Planning and Budget completed the review of:

- Fast Track Action for the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations (12VAC5-220)
- NOIRA for the Sewage Handling and Disposal Regulations (12VAC5-610)
- Final Rainwater Harvesting Systems Regulations (12VAC5-635)

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

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

The Office of Regulatory Management completed the review of:

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

The Governor approved:

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

PUBLIC COMMENT

Public Comment Period

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

LUNCH PRESENTATION: COMMUNITY HEALTH NEEDS ASSESSMENTS

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

Rachel Stradling

Acting Director

Office of Emergency Medical Services

COMMONWEALTH of VIRGINIA

Department of Health

Karen Shelton, MD
State Health Commissioner

P O BOX 2448
RICHMOND, VA 23218

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

MEMORANDUM

DATE: 05/15/2024

TO: Virginia State Board of Health

FROM: Rachel Stradling, Acting Director - Office of Emergency Medical Services

SUBJECT: Fast Track Action – Regulations Governing Durable Do Not Resuscitate Orders – Amend Following Periodic Review

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Enclosed for your review are Fast Track amendments to the Regulations Governing Durable Do Not Resuscitate (DNR) Orders (12VAC5-66 *et seq.).*

A Periodic Review was conducted pursuant to Executive Order 14 (as amended July 16, 2018), during which the Virginia Department of Health (VDH) identified the need to amend the existing Regulations Governing Durable DRN Orders. These Fast Track amendments seek to improve clarity throughout the chapter by (i) removing unnecessary, duplicative, or outdated language, (ii) revising existing language to provide clarity and maintain consistency with the Code of Virginia and the Virginia Administrative Code, (iii) updating the regulatory structure of the chapter to better conform with the Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.

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, unless objections are filed.

townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-66
VAC Chapter title(s)	Regulations Governing Durable Do Not Resuscitate Orders
Action title	Amend DNR Regulations Following Periodic Review
Date this document prepared	5/15/2024

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) is proposing Fast Track amendments to the Regulations Governing Durable Do Not Resuscitate Orders (12VAC5-66). These amendments seek to provide necessary updates to these regulations to better reflect current standards and practices, legal authority, and form and style requirements.

A Periodic Review of 12VAC5-66 resulted in the determination that regulatory action is appropriate for this chapter primarily to modernize 12VAC5-66 and conform the chapter with the Form and Style Requirements of the Virginia Register of Regulations and the Virginia Administrative Code. Additional substantive changes, including the removal of unenforceable provisions, which exceed the Board's statutory authority, related to how physicians issue Durable DNR Orders were identified and are addressed by these Fast Track amendments. Further, the amendments aim to streamline the regulatory language to provide clarity and ease

of reading, and to reduce the regulatory burden on citizens of the Commonwealth in accordance with Executive Order 19 (2022).

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.

All acronyms utilized in this document are included in the "Definitions" section of the regulations (12VAC5-66-10).

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.

This regulatory action is recommended to implement the results of a periodic review of 12VAC5-66, conducted pursuant to Executive Order 19 (2022) and § 2.2-4017 of the Code of Virginia.

The action is expected to be noncontroversial and therefore, appropriate for the fast-track process as it will ensure that emergency medical services providers can efficiently access and understand the regulations governing Durable DNR Orders.

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.

1. Promulgating Agency: State Board of Health (Board)
2. Authority:
    a. Section 32.1-12 of the Code of Virginia authorizes the Board to "make, adopt, promulgate and enforce such regulations…as may be necessary to carry out the

provisions of this title and other laws of the Commonwealth administered by it, the Commissioner or the Department."

b. Section 32.1-111.4 of the Code of Virginia requires the Board to "prescribe by regulation…[p]rocedures…to authorize qualified emergency medical services personnel to follow Do Not Resuscitate Orders pursuant to § 54.1-2897.1."
c. Section 32.1-111.5 of the Code of Virginia requires the Board to "prescribe by regulation…qualifications necessary for authorization to follow Do Not Resuscitate Orders pursuant to § 54.1-2897.1.

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

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.

This regulatory action repeals 12VAC5-66-20 and 12VAC5-66-30.

This action amends 12VAC5-66-10, 12VAC5-66-40, 12VAC5-66-50, 12VAC5-66-60, 12VAC5-66-70, and 12VAC5-66-80.

1. Terminology Updates: The amendments introduce more precise and expanded terminology, including:
    a. Adding definitions of "CPR", "EMS personnel" and "Health care personnel"
    b. Removing outdated or irrelevant terms for "Agent" and "Qualified Emergency Services personnel" and "Qualified health care personnel"
    c. Expanding the definitions of "Durable DNR Order" and "Qualified health care facility" to provide better clarity and consistency throughout the chapter.
2. Structural Modifications: The structure of the chapter has been improved for better clarity and organization. It includes more relevant section titles and removes outdated style and form conventions. These changes will improve clarity to providers and citizens of the Commonwealth.
3. Content Removal: These amendments repeal a section related to Issuance of Durable Do Not Resuscitate Orders as the Board lacks statutory authority for those provisions. Section 54.1-2897.1 of the Code of Virginia governs the issuance of Durable DNR Orders by physicians.

4. Procedural Clarifications: The amendments provide clarification on the execution and revocation of DNR orders, including thorough instructions on how these orders should be documented, maintained, and verified, especially by EMS personnel. These procedural clarifications codify standard, existing practices.

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.

Primary Advantage: The changes are designed to enhance the clarity, comprehensiveness, and application of the regulations governing Durable Do Not Resuscitate orders. By updating terminology, ensuring compliance with the Code of Virginia, refining procedural details, and improving the clarity and readability of the chapter, the revisions will benefit health care providers, patients, and citizens of the Commonwealth.

Disadvantage**:** There are no disadvantages associated with the changes.

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 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 state agency will be affected.

Localities Particularly Affected

No localities will be particularly affected.

Other Entities Particularly Affected

EMS agencies and providers will have clearer, more readable regulations regarding Durable DNR Orders.

Economic Impact

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

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There are no projected costs, savings, fees, or revenues to the Virginia Department of Health expected as a result of this change.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no projected costs, savings, fees, or revenues to other state agencies expected as a result of this change.
For all agencies: Benefits the regulatory change is designed to produce.	The regulatory change ensures that the language is consistent with *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

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.	See ORM Economic Impact form.
Benefits the regulatory change is designed to produce.	See ORM Economic Impact form.

Impact on Other Entities

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

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be	See ORM Economic Impact form.

affected, include a specific statement to that effect.	
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.	See ORM Economic Impact form.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	See ORM Economic Impact form.
Benefits the regulatory change is designed to produce.	See ORM Economic Impact form.

Alternatives to Regulation

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

No viable alternatives to this regulatory change have been identified. These amendments seek to update 12VAC5-66 to provide clarity, consistency, and ensure compliance with the Code of Virginia while reducing the regulatory burden on citizens of the Commonwealth.

Maintaining the status quo by not amending 12VAC5-66 may result in the noncompliance with the regulations as written.

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. Non-substantive changes are made for the purpose of clarity, readability, and transparency, but do not change compliance or reporting requirements. These amendments contain few substantive changes. Those substantive changes that are proposed remove duplicative requirements and align the regulations with the Code of Virginia. The proposed changes 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 also indicate the nature of, and reason for, your objection to using this process.

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

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email, or fax to:

R. D. Passmore, NRP, TS-C
Director - Regulation & Compliance Enforcement Division
Office of Emergency Medical Services
Virginia Department of Health
1041 Technology Park Dr,
Glen Allen VA 23059
Tel: 804-888-9131
Email: Ron.Passmore@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
12VAC5-66-10		This section contains no requirements and lists relevant definitions for the chapter.	**Change:** Amending, adding, or removing definitions for words and terms used in the chapter. 1. Removing “Agent” as it is not used in this Chapter. 2. Adding “CPR”– extracted from “Durable Do Not Resuscitate Order…” definition. 3. Amending "Durable Do Not Resuscitate Order" or "Durable DNR Order" by removing the phrases “...or forms…” and “As the terms 'advance directive' and 'Durable Do Not Resuscitate Order' are used in this article.” Instead, the term “for the purpose of this chapter” is used, as this phrasing clarifies that the definitions, rules, or provisions that follow are specifically intended to apply within the context of this particular chapter of the regulations. Physician orders for life sustaining treatment (POLST) is introduced. 4. Amending “Emergency medical services agency" or "EMS agency " by referring to the Code of Virginia. 5. Amending “Emergency Medical Services" or "EMS" by referring to the Code of Virginia. 6. Adding “health care personnel” – which is the result of removing the word “qualified” from all references on the chapter.

			7. Amending the definition of "Incapable of making an informed decision" by referring to the Code of Virginia. 8. Amending “Office of EMS" or "OEMS" by removing the phrase “Virginia Office of Emergency Medical Services is a state office located….” 9. Amending “Other Do Not Resuscitate Order" or "Other DNR Order” by adding the following terminology “physician orders for life sustaining treatment (POLST) form.” 10. Amending “Person authorized to consent on the patient's behalf” by removing “parents” and adding “other legal guardian…” 11. Repealing “qualified emergency medical services personnel” 12. Amending “qualified health care facility” to articulate Department of Behavioral Health and Services via acronym since it is the second time is used. Expanding health care facility to include continuing care retirement community registered with the State Corporation Commission. 13. Repealing “qualified health care personnel” *14.* Making additional modifications to align with the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.* **Intent:** The intent is to improve the clarity, completeness, and usability of the rules that govern Durable Do Not Resuscitate orders. Additionally, the changes seek to conform to the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*. The adjustments will ensure that emergency

			medical services providers can efficiently access and understand the regulations governing DNRs**.** **Rationale:** Pursuant to 1VAC7-10-40, the Registrar may omit from publication and the Code Commission may omit from the Virginia Administrative Code (VAC) provisions which are non-regulatory in nature, such as defined words that are not used in the regulatory text. Furthermore, proper style and format, grammatical correctness, and consistency of language are required to conform to the journalistic style of the Virginia Register of Regulations. **Likely Impact**: The likely impact is that the chapter will be more readable.
12VAC5-66-20		The section contains no requirements and makes references to statutory authority for the regulations.	**Change:** Repealing 12VAC5-66-20. **Intent:** The intent is to remove unnecessary sections. **Rationale:** The rationale of the change is that authority sections are non-regulatory in nature and should not be included in regulations. Pursuant to 1VAC7-10-40, the Registrar may omit from publication and the Code Commission may omit from the Virginia Administrative Code (VAC) provisions which are non-regulatory in nature. The Code itself confers authority to regulate and each section of the VAC identifies the statutory authority, so the section is unnecessary. Removing unnecessary language contributes to the targeted 25% reduction in regulatory requirements in accordance with Executive Order 19 (2022). **Likely Impact**: The likely impact is that the chapter will be more readable.

12VAC5-66-30		The section contains no requirements and makes references to the purpose of the regulations.	**Change:** Repealing 12VAC5-66-30. **Intent:** The intent is to remove unnecessary sections. **Rationale:** The rationale of the change is that the current language is non-regulatory. The Registrar, pursuant to 1VAC7-10-40 (C), has the authority to remove purpose statements from regulations, and as such, they should not be included in regulations. Removing unnecessary language contributes to the targeted 25% reduction in regulatory requirements in accordance with Executive Order 19 (2022). **Likely Impact**: The likely impact is that the chapter will be more readable.
12VAC5-66-40		This section describes the Durable Do Not Resuscitate (DNR) Order Form, including its contents and effective period, as well as information regarding the validity of a DNR Order and its acceptable photocopies.	**Change:** 1. Amending section catchline to "General Requirements" since most of the requirements are not related to "Forms." The logical arrangement of the section better communicates the meaning of the regulation. 2. Amending the subsection catchlines to ensure concise drafting of the regulations. 3. Amending subsection related to "Availability of the Durable DNR Order Form" by adding "legible photocopy of the Durable DNR Order form, POST form, or POLST form…." The "POLST" (Physician Orders for Life-Sustaining Treatment) concept expands on the previous Durable DNR Order forms. 4. Removing nonregulatory language regarding the general availability of forms and their distribution while conforming with the *Form and Style Requirements for the Virginia*

			Register of Regulations and Virginia Administrative Code. a. Example: i. Removing sub. 6 because this is not a requirement on the regulant - it is a suggestion. ii. Removing sub. 7 because it is an unnecessary requirement. This is current practice, and can remain, but it does not need to be a regulatory requirement. **Intent:** The intent is to create changes that reflect a broader and more detailed approach to DNR orders. Finaly, the changes also seek to conform to the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*. **Rationale:** The rationale is that proper style and format, grammatical correctness, and consistency of language are required to conform to the journalistic style of the Virginia Register of Regulations. Such adherence facilitates providers in achieving enhanced clarity and organization within their work. Removing unnecessary language inapplicable to regulants contributes to the targeted 25% reduction in regulatory requirements in accordance with Executive Order 19 (2022). **Likely Impact:** The likely impact is that the chapter will be more readable.

12VAC5-66-50		This section describes authorized Alternate Durable DNR Jewelry, including its design and identifiability, who may purchase and sell it, and what information is required for purchase.	**Change:** 1. Removing redundant language, such as references to the Board's inherent authorization of DNR and the clarification that Alternate Durable DNR Jewelry qualifies as a Durable DNR Order, as already stated in 12VAC5-66. 2. Introducing new text specifying that only the patient with a Durable DNR Order or their authorized representative can purchase Alternate Durable DNR jewelry, and they must present the Durable DNR Order to an approved vendor. The jewelry must include "Do Not Resuscitate," the patient's full legal name, the physician's name and phone number, and the Virginia Durable DNR Order issuance date. 3. Adding the word "Order" for consistency. 4. Conforming with the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*. **Intent:** The intent is to conform to the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*. **Rationale:** The rationale is that proper style and format, grammatical correctness, and consistency of language are required to conform to the journalistic style of the Virginia Register of Regulations. Removing redundant language enhances clarity and contributes to the targeted 25% reduction in regulatory requirements in accordance with Executive Order 19 (2022).

			Likely Impact: The likely impact is that the chapter will be more readable.
12VAC5-66-60		This section describes applicability of the chapter to Other DNR Orders. It provides guidelines on the use of DNR Orders in various health care settings.	**Change:** 1. Removing the word "qualified" before "health care personnel" 2. Removing "when," "any," or "currently" 3. Conforming to *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code* in an effort to deliver clarity and precision. **Intent:** By following the *Form and Style Requirements for the Virginia Register of Regulations and the Virginia Administrative Code*, the updates enhance clarity, precision, and effectiveness in their implementation and enforcement. **Rationale:** The rationale is that proper style and format, grammatical correctness, and consistency of language are required to conform to the journalistic style of the Virginia Register of Regulations. **Likely Impact:** The likely impact is that the regulations will be more readable.
12VAC5-66-70		This section describes the process for issuance of Durable DNR Orders.	**Change:** Repealing 12VAC5-66-70 because certain of its provisions exceed the Board's statutory authority and other provisions in this section are redundant and therefore unnecessary **Intent:** The intent is to conform the regulations to the Board's statutory authority, and to eliminate nonregulatory text.

			Rationale: The Board should not exceed its statutory authority and removing duplicative language enhances clarity and contributes to the 25% reduction in regulatory requirements in accordance with Executive Order 19 (2022). **Likely Impact:** The likely impact is that the chapter will be more readable.
12VAC5-66-80.		This section describes implementation procedures for Durable DNR Orders.	**Change:** 1. Removing unenforceable language related to compliance with general procedures and ensure that the content is accurately stated or incorporated by reference in the regulations. 2. The section has been revised for improved style and structure. Regarding patient verification, the requirement for a driver's license has been removed, now specifying the need for identification with a photograph, signature, etc. Conditional terms have been updated from "when" to "if". Non-relevant regulatory text related to documenting care in medical records has been removed. Furthermore, amendments have been made to align with the *Form and Style Requirements for the Virginia Register of Regulations and the Virginia Administrative Code*, while also eliminating nonregulatory language found verbatim in the Code of Virginia or similar sections within this chapter. **Intent:** The intent is to conform to the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code* and enhance overall clarity.

			Rationale: The rationale is that proper style and format, grammatical correctness, and consistency of language are required to conform to the journalistic style of the Virginia Register of Regulations. Removing redundant language enhances clarity and contributes to the targeted 25% reduction in regulatory requirements in accordance with Executive Order 19 (2022). **Likely Impact:** The likely impact is that the chapter will be more readable.

Office of Regulatory Management

Economic Review Form

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5-66
VAC Chapter title(s)	Regulations Governing Durable Do Not Resuscitate Orders
Action title	Amend Durable DNR Regulations Following Periodic Review
Date this document prepared	May 15, 2024
Regulatory Stage (including Issuance of Guidance Documents)	Fast-Track

Cost Benefit Analysis

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

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

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

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

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: • There are no direct monetized costs associated with this regulatory action. Direct Benefits: • There are no direct monetized benefits associated with this change. Indirect Costs: • There are no indirect monetized costs associated with this change. Indirect Benefits: • The Office of EMS is required to supply physicians or licensed health care facilities with physical copies of the Durable DNR Order Form upon request. To manage the printing and distribution of these forms, the Office of EMS is authorized to procure a vendor and charge a nominal fee to cover printing and shipping costs. However, to date, such requests have not been made. • The proposed changes may indirectly benefit the Office of EMS because expenses from printing and distribution of forms would not be required by regulation.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Net Monetized Benefit	There is no net monetized benefit.	
(4) Other Costs & Benefits (Non-Monetized)	No other non-monetized costs or benefits identified	
(5) Information Sources	Periodic review of existing regulations	

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

(1) Direct & Indirect Costs &	Direct Costs:

Benefits (Monetized)	• There are no direct monetized costs as a result of maintaining the status quo. Direct Benefits: • There are no direct monetized benefits as a result of maintaining the status quo. Indirect Costs: • The Office of EMS is required to supply physicians or licensed health care facilities with physical copies of the Durable DNR Order Form upon request. To manage the printing and distribution of these forms, the Office of EMS is authorized to procure a vendor and charge a nominal fee to cover printing and shipping costs. If the requests are made, it may result in additional costs to the Office of EMS from expenses associated with printing and distribution of forms. Indirect Benefits: $0 • There are no indirect monetized benefits as a result of maintaining the status quo.

(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 new non-monetizable costs or benefits associated with maintaining the status quo.
(5) Information Sources	Periodic review of existing regulations and information from Table 1a above.

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

(1) Direct & Indirect Costs & Benefits (Monetized)	There are no alternatives available for this regulation. Direct Costs: There are no monetized direct costs associated with this change. Direct Benefits: There are no monetized direct benefits associated with this change.

	Indirect Costs: There are no monetized indirect costs associated with this change. Indirect Benefits: There are no monetized indirect benefits associated with this change.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Net Monetized Benefit		
(4) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs or benefits associated with an alternative.	
(5) Information Sources	VDH Office of Emergency Medical Services	

Impact on Local Partners

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

Table 2: Impact on Local Partners

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: • There are no direct monetized costs to local partners associated with this regulatory action. Direct Benefits: • There are no direct monetized benefits to local partners associated with this regulatory action. Indirect Costs: • There are no indirect monetized costs to local partners associated with this regulatory action. Indirect Benefits: • There are no indirect 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)	No other non-monetized costs or benefits have been identified.	
(4) Assistance	No assistance required.	
(5) Information Sources	Periodic review of existing regulations.	

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)	Direct Costs: • There are no direct costs to families associated with this regulatory action. Direct Benefits: • There are no direct benefits to families associated with this regulatory action. Indirect Costs: • There are no indirect costs to families associated with this regulatory action. Indirect Benefits: • There are no indirect benefits to families 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)	No other non-monetized costs or benefits identified
(4) Information Sources	Periodic review of existing regulations

Impacts on Small Businesses

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

Table 4: Impact on Small Businesses

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: • There are no direct monetized costs to small businesses associated with this regulatory action. Indirect Costs: • There are no indirect monetized costs to small businesses associated with this regulatory action. Direct Benefits: • There are no direct monetized benefits to small businesses associated with this regulatory action. Indirect Benefits: • There are no indirect monetized benefits to small businesses 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)	No other non-monetized costs or benefits identified	
(4) Alternatives	No alternative approaches to the required periodic review identified	
(5) Information Sources	Periodic review of existing regulations	

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

Key:
Please use the following coding if change is mandatory or discretionary and whether it affects externally regulated parties or only the agency itself:
(M/A): Mandatory requirements mandated by federal and/or state statute affecting the agency itself
(D/A): Discretionary requirements affecting agency itself
(M/R): Mandatory requirements mandated by federal and/or state statute affecting external parties, including other agencies
(D/R): Discretionary requirements affecting external parties, including other agencies

VAC Section(s) Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
12VAC5-66-10	**(M/A):**	**0**	0	0	0
	(D/A):	**0**	0	0	0
	(M/R):	**0**	0	0	0
	(D/R):	**0**	0	0	0
12VAC5-66-20	**(M/A):**	**0**	0	0	0
	(D/A):	**0**	0	0	0
	(M/R):	**0**	0	0	0
	(D/R):	**0**	0	0	0
12VAC5-66-30	**(M/A):**	**0**	0	0	0
	(D/A):	**0**	0	0	0
	(M/R):	**0**	0	0	0
	(D/R):	**0**	0	0	0
12VAC5-66-40	**(M/A):**	**0**	0	0	0
	(D/A):	**5**	0	3	-3
	(M/R):	**0**	0	0	0
	(D/R):	**3**	1	0	+1
12VAC5-66-50	**(M/A):**	**0**	0	0	0
	(D/A):	**2**	0	0	0
	(M/R):	**0**	0	0	0
	(D/R):	**3**	0	1	-1

12VAC5-66-60	**(M/A):**	**0**	0	0	0
	(D/A):	**0**	0		0
	(M/R):	**0**	0	0	0
	(D/R):	**0**	1	0	+1
12VAC5-66-70	**(M/A):**	**0**	0	0	0
	(D/A):	**0**	0		0
	(M/R):	**0**	0	0	0
	(D/R):	**10**	0	10	-10
12VAC5-66-80	**(M/A):**	**0**	0	0	0
	(D/A):	**0**	0		0
	(M/R):	**5**	0	5	0
	(D/R):	**14**	0	1	-1
				Grand Total of Changes in Requirements:	**(M/A): 0**
					(D/A): -3
					(M/R): 0
					(D/R): -10

Cost Reductions or Increases (if applicable) NOT APPLICABLE

VAC Section(s) Involved*	Description of Regulatory Requirement	Initial Cost	New Cost	Overall Cost Savings/Increases

Other Decreases or Increases in Regulatory Stringency (if applicable) NOT APPLICABLE

VAC Section(s) Involved*	Description of Regulatory Change	Overview of How It Reduces or Increases Regulatory Burden

Length of Guidance Documents (only applicable if guidance document is being revised) NOT APPLICABLE

Title of Guidance Document	Original Word Count	New Word Count	Net Change in Word Count

*If the agency is modifying a guidance document that has regulatory requirements, it should report any change in requirements in the appropriate chart(s).

Project 7311 - Fast-Track

Department of Health

Amend Durable DNR Regulations Following Periodic Review 2022

~~Part I~~

~~Definitions~~

12VAC5-66-10. Definitions.

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

~~"Agent" means an adult appointed by the declarant under an advance directive, executed or made in accordance with the provisions of § 54.1-2983 of the Code of Virginia to make health care decisions for him.~~

"Alternate Durable DNR jewelry" means a Durable DNR bracelet or necklace issued by a vendor approved by the Virginia Office of Emergency Medical Services. ~~A Durable DNR Order must be obtained by the patient, from a physician, to obtain Alternate Durable DNR jewelry.~~

"Board" means the State Board of Health.

"Cardiac arrest" means the cessation of a functional heartbeat.

"Commissioner" means the State Health Commissioner.

"CPR" or cardiopulmonary resuscitation shall include cardiac compression, endotracheal intubation and other advanced airway management devices that pass beyond the oral pharynx, artificial ventilation, defibrillation, administration of cardiac resuscitative medications, and related procedures.

"Durable Do Not Resuscitate Order" or "Durable DNR Order" means a written ~~physician's~~ order issued pursuant to § 54.1-2987.1 of the Code of Virginia, in a Durable Do Not Resuscitate Order form ~~or forms~~ authorized by the board , to withhold cardiopulmonary resuscitation from an individual in the event of cardiac or respiratory arrest. ~~For purposes of this chapter, cardiopulmonary resuscitation shall include cardiac compression, endotracheal intubation and other advanced airway management, artificial ventilation, defibrillation, administration of cardiac resuscitative medications, and related procedures. As the terms "advance directive" and "Durable Do Not Resuscitate Order" are used in this article,~~ For the purposes of this chapter, a Durable Do Not Resuscitate Order or ~~other~~ Other DNR Order ~~is not and~~ shall not be construed as an advance directive. When used in ~~these regulations~~ this chapter , the term "Durable DNR Order" shall include any authorized Alternate Durable DNR jewelry issued in conjunction with an original Durable DNR Order. "Durable DNR Order" shall also include a physician order for scope of treatment (POST) or physician orders for life sustaining treatment (POLST) form. Durable DNR ~~orders~~ Order Forms, including POST or POLST forms, shall be ~~completed~~ filled out and signed by a ~~licensed practitioner~~ physician and signed by the patient or patient's authorized representative.

"Emergency ~~Medical Services~~ medical services " or "EMS" ~~means the services rendered by an agency licensed by the Virginia Office of Emergency Medical Services, an equivalent agency licensed by another state or a similar agency of the federal government when operating within this Commonwealth.~~ shall have the same meaning as in § 32.1-111.1 of the Code of Virginia.

"Emergency medical services agency" or "EMS agency" ~~means any agency, licensed to engage in the business, service, or regular activity, whether or not for profit, of transporting or~~

~~rendering immediate medical care to such persons who are sick, injured, wounded, or otherwise incapacitated or helpless.~~ shall have the same meaning as in § 32.1-111.1 of the Code of Virginia.

"Emergency medical services personnel" or "EMS personnel" shall have the same meaning as in § 32.1-111.1 of the Code of Virginia.

"Health care personnel" means any qualified emergency medical services personnel and any licensed health care practitioner functioning in any facility, program, or organization operated or licensed by the State Board of Health, the Department of Social Services, or the Department of Behavioral Health and Developmental Services (DBHDS) or operated, licensed, or owned by another state agency, or a continuing care retirement community registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2.

"Incapable of making an informed decision"~~ means the inability of an adult patient, because of mental illness, intellectual disability, or any other mental or physical disorder that precludes communication or impairs judgment, to make an informed decision about providing, withholding, or withdrawing a specific medical treatment or course of treatment because he is unable to understand the nature, extent, or probable consequences of the proposed medical decision, or to make a rational evaluation of the risks and benefits of alternatives to that decision. For purposes of this article, persons who are deaf or dysphasic or have other communication disorders but who are otherwise mentally competent and able to communicate by means other than speech, shall not be considered incapable of making an informed decision. The determination that the patient is "incapable of making an informed decision" shall be made in accordance with § 54.1-2983.2 of the Code of Virginia.~~ shall have the same meaning as in § 54.1-2982 of the Code of Virginia.

"Office of EMS" or "OEMS" means the Virginia Office of Emergency Medical Services ~~. The Virginia Office of Emergency Medical Services is a state office located~~ within the Virginia Department of Health (VDH).

"Other Do Not Resuscitate Order" or "Other DNR Order" means a written physician's order not to resuscitate a patient in the event of cardiac or respiratory arrest on a form other than the authorized state standardized Durable DNR Order Form , POST Form, or POLST Form under policies and procedures of the health care facility to which the individual who is the subject of the order has been admitted.

"Person authorized to consent on the patient's behalf" means any person authorized by law to consent on behalf of the patient incapable of making an informed decision or, in the case of a minor child, the parent or ~~parents~~ other legal guardian having custody of the child, ~~or the child's legal guardian or as otherwise provided by law.~~

"Physician" means a person licensed to practice medicine in the Commonwealth of Virginia or in the jurisdiction where the treatment is to be rendered or withheld.

~~"Qualified emergency medical services personnel" means personnel certified to practice as defined by § 32.1-111.1 of the Code of Virginia when acting within the scope of their certification.~~

"Qualified health care facility" means a facility, program, or organization operated or licensed by the State Board of Health, the Department of Social Services , or ~~the Department of Behavioral Health and Developmental Services (DBHDS)~~ or operated, licensed, or owned by another state agency, or a continuing care retirement community registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia.

~~"Qualified health care personnel" means any qualified emergency medical services personnel and any licensed health care provider or practitioner functioning in any facility, program, or organization operated or licensed by the State Board of Health or by DBHDS or operated, licensed, or owned by another state agency.~~

"Respiratory arrest" means cessation of breathing.

~~Part II~~

~~Purpose and Applicability~~

12VAC5-66-20. ~~Authority for regulation.~~ (Repealed.)

~~Section 54.1-2987.1 of the Code of Virginia vests authority for the regulation of Durable DNR Orders in the State Board of Health and directs the board to prescribe by regulation the procedures, including the requirements for forms to authorize qualified health care personnel to follow Durable DNR Orders. All EMS DNR Orders and all Durable Do Not Resuscitate Orders issued or in effect between July 1, 1999, and March 27, 2002, are to be considered valid Durable DNR Orders and shall remain valid until revoked.~~

12VAC5-66-30. ~~Purpose of regulations.~~ (Repealed.)

~~The board has promulgated these regulations in order to carry out the intent of Virginia law that a person shall have the opportunity to execute a Durable DNR Order that comports with his wishes.~~

~~Part III~~

~~Requirements and Provisions~~

12VAC5-66-40. ~~The Durable Do Not Resuscitate Order Form.~~ General Requirements.

A. The Durable DNR Order Form shall be a standardized document ~~as~~ approved by the board and consistent with ~~these regulations. The~~ this chapter, including the following requirements ~~and provisions shall apply to the approved Durable DNR Order Form.~~ :

B. ~~Content of the Form –~~ A Durable DNR Order Form shall contain, from a physician with whom the patient has a bona fide physician/patient relationship, a do not resuscitate determination, signature and the date of issue, the signature of the patient or, if applicable, the person authorized to consent on the patient's behalf.

~~2.~~ C. ~~Effective Period for a Signed Durable DNR Order –~~ A signed Durable DNR Order shall remain valid until revoked in accordance with § 54.1-2987.1 of the Code of Virginia ~~and 12VAC5-66-80 E~~ or until rescinded, in accordance with accepted medical practice, by the provider who issued the Durable Do Not Resuscitate Order.

~~3.~~ D. ~~Durable DNR Order Form~~ A Durable DNR Order ~~or Alternate Durable DNR jewelry that complies with 12VAC5-66-50~~ shall be valid for the purposes of withholding or withdrawing cardiopulmonary resuscitation by ~~qualified~~ health care personnel in the event of cardiac or respiratory arrest.

~~4.~~ E. ~~Availability of the Durable DNR Order Form. The~~ An original or a legible photocopy of the Durable DNR Order Form, POST Form, or POLST Form ~~that complies with this section or Alternate Durable DNR jewelry that complies with 12VAC5-66-50~~ shall be ~~maintained and~~ readily available to ~~qualified~~ health care personnel at the patient's current location. ~~or residence.~~

~~5. Qualified health care personnel may honor a legible photocopy of a Durable DNR Form or Other Durable DNR Order as if it were an original.~~

~~6. A patient who is traveling outside his home or between health care facilities should have an original or photocopied Durable DNR Order, Other Durable DNR Order, or Alternate Durable DNR jewelry accompany him.~~

~~7.~~ F. ~~Distribution of Durable DNR Order Forms - The authorized Virginia Durable DNR Order Form shall be a standardized form available for download via the Internet from the Office of Emergency~~

~~Medical Services website. The downloadable form will contain directions for completing the form and three identical Durable DNR Order Forms: one original form to be kept by the patient, the second to be placed in the patient's permanent medical record, and the third to be used by the patient for requesting Alternate Durable DNR jewelry.~~ Three identical Durable DNR Order Forms shall be filled out and distributed as follows:

1. Copy one - to be kept by patient.

2. Copy two - to be kept in the patient's permanent record.

3. Copy three - to be used to order Alternate Durable DNR jewelry.

~~8. Hard copies of the Durable DNR Order Form shall also be made available to physicians or licensed health care facilities by the Office of EMS. The Office of EMS may utilize a vendor to print and distribute the Durable DNR Order Form and a nominal fee may be charged in an amount necessary to cover printing and shipping fees.~~

G. A Durable DNR Order or Other DNR Order may only be revoked in accordance with § 54.1-2987.1 D.

12VAC5-66-50. Authorized ~~alternate~~ Alternate Durable DNR jewelry.

~~The board authorizes the use of Alternate Durable DNR jewelry in conjunction with the issuance of a Durable DNR Order. These Alternate Durable DNR jewelry items shall be uniquely-designed and uniquely-identifiable bracelets and necklaces that are available only from a vendor approved by the Virginia Department of Health, Office of EMS. The Alternate Durable DNR jewelry must be purchased from the approved vendor by the person to whom a Durable DNR Order Form applies, or the person authorized to consent on the patient's behalf. An original Durable DNR Order Form must be obtained from a physician and provided to the vendor in order to receive Alternate Durable DNR jewelry. Such a necklace or bracelet may be utilized either to validate the Durable DNR Order Form or in place of an original Durable DNR Order Form in the event that the original order is not readily available at the site where the person to whom the order applies is found. In order to be honored by qualified health care personnel in place of the standard Durable DNR Order Form, the Alternate Durable DNR jewelry must contain the minimum information approved by the State Board of Health in 12VAC5-66-60.~~

A. A person may use Alternate Durable DNR jewelry.

B. Only the patient to whom a Durable DNR Order applies, or the person authorized to consent on the patient’s behalf, may purchase Alternate Durable DNR jewelry.

C. The patient to whom a Durable DNR Order applies, or the person authorized to consent on the patient's behalf shall present a Durable DNR Order Form to the approved vendor to purchase approved Alternate Durable DNR jewelry.

D. The Alternate Durable DNR jewelry shall display the following information:

1. The following words: Do Not Resuscitate;

2. The patient's full legal name;

3. The physician's name and phone number; and

4. The Virginia Durable DNR Order issuance date.

12VAC5-66-60. Other DNR Orders.

A. Nothing in these regulations shall be construed to preclude licensed health care practitioners from following any Other Do Not Resuscitate Order in accordance with the applicable policies and procedures of the health care facility in which they practice.

B. ~~Qualified health~~ Health care personnel ~~are authorized to~~ shall honor ~~any~~ an Other Do Not Resuscitate ~~(DNR)~~ Order as if it were a Durable Do Not Resuscitate Order ~~when~~ if the Other DNR Order includes the information required in 12VAC5-66-40 and the patient is ~~currently~~ admitted to ~~a hospital or other~~ or in transit from a qualified health care facility ~~or is in transit from a qualified health care facility provided that such order includes the same information as listed in subdivision 1 of 12VAC5-66-40~~, except that an Other DNR Order shall not be required to include the signature of the patient or a person authorized to consent for the patient on the order itself.

C. Nothing in ~~these regulations~~ this chapter shall prohibit ~~qualified~~ health care personnel from following ~~any~~ a direct verbal order issued by a licensed physician not to resuscitate a patient in cardiac or respiratory arrest when ~~such~~ the physician is physically present.

~~Part IV~~

~~Implementation Procedures~~

~~12VAC5-66-70. Issuance of a Durable DNR Order.~~ (Repealed.)

~~A. A Durable DNR Order may be issued to a patient by a physician, with whom the patient has established a bona fide physician/patient relationship, as defined by the Board of Medicine in their current guidelines, only with the consent of the patient or, if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the person authorized to consent on the patient's behalf.~~

~~B. The use of the authorized Durable DNR Order Form is encouraged to provide uniformity throughout the health care continuum.~~

~~C. The authorized Durable DNR Order can be honored by qualified health care personnel in any setting.~~

~~D. Qualified health care personnel are authorized to honor only a Durable DNR Order on an authorized form or Alternate DNR jewelry, except as provided in 12VAC5-66-60 of these regulations.~~

~~E. Prior to issuing a Durable DNR Order, the physician shall explain to the patient or the person authorized to consent on the patient's behalf, the alternatives available for response in the event of cardiac or respiratory arrest. If the option of a Durable DNR Order is agreed upon, the physician shall have the following responsibilities:~~

~~1. Explain the circumstances under which qualified health care personnel may follow a Durable DNR Order.~~

~~2. Explain how to and who may revoke the Durable DNR Order.~~

~~3. Document the patient's full legal name.~~

~~4. Document the execution date of the Durable DNR Order.~~

~~5. Obtain the signature of the patient or the person authorized to consent on the patient's behalf on all three forms: the patient's copy, medical record copy, and the copy used for obtaining Alternate DNR jewelry.~~

~~6. Make sure that the issuing physician's name is clearly printed and the form is signed.~~

~~7. Record the contact telephone number for the issuing physician.~~

~~8. Issue the original Durable DNR Order Form, and the patient and Alternate DNR jewelry copies to the patient and maintain the medical record copy in the patient's medical file.~~

~~F. The person to whom a Durable DNR Order applies or the person authorized to consent on the patient's behalf must present the following information to the approved vendor in order to purchase and be issued an approved Alternate Durable DNR necklace or bracelet. The necklace or bracelet must contain the following information:~~

~~1. The following words: Do Not Resuscitate;~~

~~2. The patient's full legal name;~~

~~3. The physician's name and phone number; and~~

~~4. The Virginia Durable DNR issuance date.~~

12VAC5-66-80. Durable DNR Order implementation procedures.

A. ~~Qualified health~~ Health care personnel shall ~~comply with the following general procedures and published Virginia Durable DNR Order Implementation Protocols~~ follow the procedures in this section when caring for a patient who is in cardiac or respiratory arrest and who ~~is known or suspected to~~ may have a Durable DNR Order in effect.

B. ~~Initial assessment and intervention. Perform~~ Health care personnel shall initiate routine patient assessment and resuscitation or intervention until a valid Durable DNR Order ~~, Alternate DNR jewelry,~~ or Other DNR Order can be confirmed ~~, as follows:~~ .

~~1. Determine the presence of a Durable DNR Order, approved Alternate Durable DNR jewelry, ; or Other DNR Order.~~

~~2. If the patient is within a qualified health care facility or in transit between qualified health care facilities, any qualified health care personnel may honor an Other DNR Order as set forth in 12VAC5-66-60.~~

~~3. Determine that the Durable DNR form or Alternate DNR jewelry is not altered.~~

~~4. Verify, through driver's license or other identification with a photograph and signature or by positive identification by a family member or other person who knows the patient , . that the patient in question is the one for whom the Durable DNR Order, Alternate DNR jewelry, or Other DNR Order was issued.~~

~~5. If the Durable DNR Order, Alternate DNR jewelry, or Other DNR Order is intact, unaltered, and verified as issued for the patient, qualified health care personnel may consider it valid.~~

C. Health care personnel may withhold or terminate resuscitation efforts only when:

1. An intact, unaltered original or photocopy of the Durable DNR Order Form, POST Form, or POLST Form, approved Alternate Durable DNR jewelry or Other DNR Order is located; and

2. The patient for whom the Durable DNR Order or Other DNR Order was issued is verified by identification with a photograph and signature or by positive identification by a family member or other person who knows the patient.

D. If the Durable DNR Order or Other DNR Order is intact, unaltered, and verified as issued for the patient, health care personnel may consider it valid.

~~C.~~ E. ~~Resuscitative measures to be withheld of withdrawn.~~ In the event of cardiac or respiratory arrest of a patient with a valid Durable DNR Order~~, Alternate Durable DNR jewelry,~~ or Other DNR Order ~~under the criteria set forth in subsection B of this section, qualified~~ health care personnel shall withhold or withdraw cardiopulmonary resuscitation (CPR) unless otherwise directed by a physician physically present at the ~~patient~~ patient's location. ~~CPR shall include:~~

~~1. Cardiac compression;~~

~~2. Artificial ventilation;~~

~~3. Defibrillation;~~

~~4. Endotracheal Intubation or other advanced airway management, including supra-glottic devices such as the LMA, or other airway devices that pass beyond the oral pharynx, such as the Combi Tube, PTL etc.; or~~

~~5. Administration of related procedures or cardiac resuscitation medications as prescribed by the patient's physician or medical protocols.~~

~~D. Procedures to provide comfort care or to alleviate pain. In order to provide comfort care or to alleviate pain for a patient with a valid Durable DNR Order of any type or Other DNR Order the following interventions may be provided, depending on the needs of the particular patient:~~

F. Health care personnel may provide the following interventions to a patient with a valid Durable DNR Order or Other DNR Order to provide comfort care or to alleviate pain.

1. Airway management, including positioning, nasal or pharyngeal airway placement;

2. Suctioning;

3. Supplemental oxygen delivery devices;

4. Pain medications or intravenous fluids;

5. Bleeding control;

6. Patient positioning; or

7. Other therapies deemed necessary to provide comfort care or to alleviate pain.

~~E. Revocation.~~

~~1. If a patient is able to, and does, express to a health care provider or practitioner the desire to be resuscitated in the event of cardiac or respiratory arrest, such expression shall revoke the provider's or practitioner's authority to follow a Durable DNR Order or Other DNR Order. In no case shall any person other than the patient have authority to revoke a Durable DNR Order or Other DNR Order executed upon the request of and with the consent of the patient himself.~~

~~If the patient is a minor or is otherwise incapable of making an informed decision and the Durable DNR Order or Other DNR Order was issued upon the request and with the consent of the person authorized to consent on the patient's behalf, then the expression by said person to a health care provider or practitioner of the desire that the patient be resuscitated shall so revoke the provider's or practitioner's authority to follow a Durable DNR Order or Other DNR Order.~~

~~2. The expression of such desire to be resuscitated prior to cardiac or respiratory arrest shall constitute revocation of the order; however, a new order may be issued upon consent of the patient or the person authorized to consent on the patient's behalf.~~

~~3. The provisions of this section shall not authorize any qualified emergency medical services personnel or licensed health care provider or practitioner who is attending the patient at the time of cardiac or respiratory arrest to provide, continue, withhold or withdraw treatment if such provider or practitioner knows that taking such action is protested by the patient incapable of making an informed decision. No person shall authorize providing, continuing, withholding or withdrawing treatment pursuant to this section that such person knows, or upon reasonable inquiry ought to know, is contrary to the religious beliefs or basic values of a patient incapable of making an informed decision or the wishes of such patient fairly expressed when the patient was capable of making an informed decision.~~

~~F.~~ G. ~~Documentation. When~~ If following a Durable DNR Order or Other DNR Order for a particular patient admitted to a qualified health care facility, ~~qualified~~ health care personnel shall document care rendered or withheld as required by facility policies and procedures. ~~When~~ If following a Durable DNR Order or Other DNR Order for a particular patient who is not admitted to a qualified health care facility or who is in transit from a health care facility, ~~qualified~~ health care personnel shall document in the patient's medical record the care rendered or withheld in the following manner:

~~1. Use standard patient care reporting documents (i.e. patient chart, pre-hospital patient care report).~~

~~2.~~ 1. Describe assessment of the patient's cardiac or respiratory arrest status ~~.~~ ;

~~3.~~ 2. Document which identification (e.g., Durable DNR Order Form, Alternate Durable DNR jewelry, ~~or~~ Other DNR Order , or alternate form of identification) was used to confirm Durable DNR status and that it was intact, not altered, ~~not canceled or~~ and not ~~officially~~ revoked~~.~~ ; and

~~4.~~ 3. Record the name of the patient's physician who issued the Durable DNR Order~~,~~ or Other DNR Order.

~~5. If the patient is being transported, keep the Durable DNR Order, Alternate Durable DNR jewelry, or Other DNR Order with the patient.~~

~~G. General considerations. The following general principles shall apply to implementation of all Durable DNR Orders.~~

~~1. If there is misunderstanding with family members or others present at the patient's location or if there are other concerns about following the Durable DNR Order or Other DNR Order, contact the patient's physician or EMS medical control for guidance.~~

~~2. If there is any question about the validity of a Durable DNR Order, resuscitative measures should be administered until the validity of the Durable DNR Order or Other DNR Order is established.~~

H. If the patient is being transported, the Durable DNR Order or Other DNR Order shall remain with the patient.

I. If the patient's family or others present at the patient's location contest the Durable DNR Order or Other DNR Order, EMS personnel shall contact the patient's physician or EMS medical control for guidance.

J. If there is any question about the validity of a Durable DNR Order or Other DNR Order, resuscitative measures shall be administered until the validity of the Durable DNR Order or Other DNR Order is confirmed.

Virginia's Rules and Regulations Governing Cooperative Agreements 12VAC5-221 Fast Track Amendments

Kim Beazley
Director
Office of Licensure and Certification

COMMONWEALTH of VIRGINIA

Department of Health

Karen Shelton, MD
State Health Commissioner

P O BOX 2448
RICHMOND, VA 23218

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

MEMORANDUM

DATE: April 24, 2024

TO: State Board of Health

FROM: Kimberly F. Beazley
Director, Office of Licensure and Certification

SUBJECT: Fast Track Action – Regulations Governing Cooperative Agreements – Amend Regulation following the 2024 Periodic Review.

Enclosed for your review are fast track amendments to the Regulations Governing Cooperative Agreements (12VAC5-221-10 *et seq.*).

The intent of this regulatory action is to amend the chapter governing cooperative agreements to address the public comment received during the 2024 periodic review of the regulation, to align the requirements with statutory authority, and to conform the regulations to the Virginia Registrar of Regulation's *Form, Style, and Procedure Manual for Publication of Virginia Regulations*. Amendments to the chapter will allow the regulation to be more easily understood by regulated entities and clarify and reduce regulatory requirements for both the Virginia Department of Health and the regulants.

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 VAC 5-221
VAC Chapter title(s)	Regulations Governing Cooperative Agreements
Action title	Amend Regulation following the 2024 Periodic Review
Date this document prepared	

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 intent of this regulatory action is to amend the chapter governing cooperative agreements to update the chapter to address the public comment received during the 2024 periodic review of the regulation and to conform the regulations to the Virginia Registrar of Regulation's *Form, Style, and Procedure Manual for Publication of Virginia Regulations*. Amendments to the chapter will allow the regulation to be more easily understood by regulated entities and clarify and reduce regulatory requirements for both the department and the regulants.

Acronyms and Definitions

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

"Board" means the State Board of Health.

"Commissioner" means the State Health Commissioner.

"OLC" means the VDH Office of Licensure and Certification.

"Style Guide" means the *Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

"TAP" means the Technical Advisory Panel.

"VDH" means the Virginia Department of Health.

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.

Enter statement here

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.

Executive Order 19 (2022) requires state regulations to undergo a periodic review every 4 years. This regulatory action is intended to implement the Board's decision in the chapter's most recent periodic review.

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 Board is granted responsibility pursuant to § 32.1-12 of the Code of Virginia to make, adopt, promulgate, and enforce such regulations as may be necessary to carry out the provisions of Title 32.1 of the Code of Virginia. Clause 2 of Chapter 741 of the 2015 Acts of Assembly required the Board to promulgate regulations that address (i) the review of applications for proposed collaborative agreements, (ii) the process by which applications for proposed collaborative agreements shall be approved or denied, (iii) post-approval monitoring, and (iv) a schedule establishing the amount of the annual fee.

Section 15.2-5384.1 of the Code of Virginia sets forth the requirements governing the review and monitoring of cooperative agreements by the Commissioner.

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 Board is granted responsibility pursuant to § 32.1-12 of the Code of Virginia to make, adopt, promulgate, and enforce such regulations as may be necessary to carry out the provisions of Title 32.1 of the Code of Virginia.

The regulation is necessary for the protection of public health, safety, and welfare because it governs cooperative agreements between health systems that create healthcare monopolies and the active supervision of those agreements. Without oversight of these agreements, citizens in those areas covered by the cooperative agreement would be unprotected against abuse of the monopoly's powers, such as price gouging and the reduction or removal of resources.

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

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.

12VAC5-221-10. Definitions.
The following definitions were updated to cross-reference the Code of Virginia:
- "Authority"
- "Cooperative Agreement"
- "Hospital"
- "Participating locality"

The definition of "Commissioner" was updated to include provisions for the Commissioner to designate certain regulatory duties to a chosen designee. The definition for "Plan of separation" was removed and moved to 12VAC5-221-110. A definition for "TAP" was added to the text.

12VAC5-221-20. Separate applications.
This section was repealed.

12VAC5-221-30. Application submission.
The provisions of 12VAC5-221-20 were added as subsection A and re-written for clarity. A provision was added as subsection E to prohibit the Commissioner from reviewing an application if the authority issues a denial.

12VAC5-221-40. Fee Schedule.
This section was repealed for clarity and redispersed into latter sections.

12VAC5-221-50. Public hearing.
The requirements placed on the authority were repealed from this section due to lack of statutory authority. A provision was added to allow the Commissioner to hold a public hearing.

12VAC5-221-60. Submission of public comment.

The allotted time for a member of the public to submit public comment regarding an application for an authorization letter was extended from 14 days to 30 days.

12VAC5-221-65. Reimbursement.
New section. Provisions of 12VAC5-221-40 moved to this section. Added a 7-day notice requirement on the Commissioner prior to contracting with experts or consultants. Added an allotted 7 days for the parties to offer possible alternatives to the Commissioner regarding the experts or consultants.

12VAC5-221-70. Commissioner's request for information.
Added a provision to allow the Commissioner to designate the department to request and receive supplemental information. Removed the list of elements the Commissioner is required to request.

12VAC5-221-80. Commissioner's review.
Repealed the required factors for consideration by the Commissioner and instead cross-referenced the Code. Repealed subsection I to be moved to a latter section.

12VAC5-221-90. Action on an application.
Added the provision to allow the Commissioner's time for review to toll until all requested additional information is received. Repealed the provisions regarding conditioning and moved those requirements to a new section.

12VAC5-221-95. Conditions.
New section. Moved the authority for the Commissioner to condition the authorization letter and changed that authority to require the Commissioner to place conditions on the authorization letter.

12VAC5-221-100. Ongoing supervision.
Moved the definition for "plan of separation" to this section. Amended to allow the Commissioner to designate a representative from the department to request and receive additional information from the applicants. Added the language from a previous section regarding the Commissioner's selection of measures for reviewing the benefits of the Cooperative Agreement. Added language to require the Commissioner to notify applicants within 45 days whether or not the additional information satisfies the Commissioner's request. Added language to require the plan of separation be submitted if any updates are made by the parties.

12VAC5-221-110. Annual reporting.
Removed the requirement for the parties to annually submit their plans of separation. Removed the required $20,000 annual fee. Added the reimbursement language from 12VAC5-221-65.

12VAC5-221-115. Onsite inspection.
New section. Moved the onsite inspection requirements from 12VAC5-221-100 and added the authority for the Commissioner to designate the department to conduct onsite inspections.

12VAC5-221-140. Voluntary termination of cooperative agreement.
Amended the notice filing requirement to require the parties to submit notice to the Commissioner instead of the department. Amended the requirement for the parties to return the cooperative agreement to the department and instead to the Commissioner.

12VAC5-221-150. Official records.
Removed non-regulatory language.

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 of the regulatory changes to the public are that the regulation will be more easily understood and clear. There are no disadvantages to the public related to the regulatory changes. The primary advantages of the regulatory change to the agency are that the regulation will be more easily understood and clear, and that the changes will allow for more streamlined processes relating to this regulation. The primary disadvantage of the regulatory changes is that VDH will experience a temporary reduction in fee revenue due to the removal of the $20,000 annual filing fee. There are no other pertinent matter of interest related to these regulatory changes.

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 changes that exceed 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

There are no other state agencies affected by this regulatory action.

Localities Particularly Affected

The Southwest Virginia Health Authority.

Other Entities Particularly Affected

Ballad Health.

Economic Impact

Consistent with § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact,

specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	The removal of the $20,000 annual fee will lead to a temporary reduction in revenue; however, the parties are required to reimburse the Commissioner for all expenses related to the supervision and oversight of the cooperative agreement, meaning those temporary reductions will be recovered.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no projected costs, savings, fees, or revenues for other state agencies as a result of the regulatory changes.
For all agencies: Benefits the regulatory change is designed to produce.	The benefits of the regulatory changes are that the regulations will be more easily understandable and the reduction in regulatory stringency will allow for a more streamlined process for both VDH and the regulants.

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 for localities as a result of this regulatory change.
Benefits the regulatory change is designed to produce.	The benefit of the regulatory changes is that the regulations will be more easily understandable.

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.	Ballad Health does not qualify as a small business.
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.	Please refer to the above statement.
All projected costs for affected individuals, businesses, or other entities resulting from the	Please refer to table 1a on the Economic Review Form (ERF).

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.	
Benefits the regulatory change is designed to produce.	Please refer to table 1a on the Economic Review Form (ERF).

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 required the Board to adopt regulations governing cooperative agreements. Because updates are needed to the style, structure, and content of the regulation, amending the regulation is the least burdensome method to accomplish the essential purpose of this regulatory change.

Regulatory Flexibility Analysis

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

There is a continued need for the regulation as there is a current cooperative agreement in Virginia, and the Board is mandated to actively supervise cooperative agreements. Ballad Health, the hospital system involved in the current cooperative agreement does not qualify as a small business, and VDH is not aware of any entities that could enter into a cooperative agreement and qualify as a small business.

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: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Allyson Flinn, Policy Analyst, Virginia Department of Health, Office of Licensure and Certification, 9960 Mayland Drive, Suite 401, Henrico, VA 23233; email: regulatorycomments@vdh.virginia.gov; fax: (804) 527-4502. 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
-10		Definitions section	**Change:** The following definitions were updated to cross-reference the Code of Virginia: - "Authority" - "Cooperative Agreement" - "Hospital" - "Participating locality" The definition of "Commissioner" was updated to include provisions for the Commissioner to designate certain regulatory duties to a chosen designee. The definition for "Plan of separation"

			was removed and moved to 12VAC5-221-110. A definition for "TAP" was added to the text. **Intent:** The intent of these changes were to cross-reference the Code of Virginia and ensure conformity with the style guide. **Rationale:** The rationale for these changes is that the cross-references and updates will increase the clarity and understandability of the section for the regulants. **Likely impact:** Increased understandability of the regulation.
-20		Outlines the applicability of the application for an authorization letter	**Change:** Repealed **Intent:** The intent of these changes are to condense the application requirements into one section. **Rationale:** The rationale for repealing is section is to increase the clarity and readability of the regulation. **Likely impact:** Increased readability of the regulation.
-30		Directs interested parties on how to apply for an authorization letter	**Change:** The provisions of 12VAC5-221-20 were added as subsection A and re-written for clarity. A provision was added as subsection E to prohibit the Commissioner from reviewing an application if the authority issues a denial. **Intent:** The intent of these changes are to condense the application requirements into one section and to make clear what the Commissioner's role is if the authority issues a denial. **Rationale:** The rationale of this change is to increase the readability of the regulation and understandability. **Likely impact:** Increased readability and understandability of the regulation.
-40		Outlines the fee schedule and the reimbursement for an application and the supervision of a cooperative agreement	**Change:** Repealed **Intent:** The intent of repealing this section was to redistribute the requirements into the applicable sections.

			Rationale: The rationale of this change is to increase the readability of the regulation. **Likely impact:** Increased readability and understandability of the regulation.
-50		Details the authority's requirements relating to public hearings for applications	**Change:** The requirements placed on the authority were repealed from this section due to lack of statutory authority. A provision was added to allow the Commissioner to hold a public hearing. **Intent:** The intent of the changes are to remove any requirements that are not statutorily supported and to grant authority to the Commissioner to hold a public hearing. **Rationale:** The rationale of this change is to ensure the regulation complies with the Code, and that the authorities granted to the Commissioner are clearly written. **Likely impact:** The regulation will be clearer.
-60		Allows the public to submit public comments within 14 days of the authority's adoption of its recommendation on an application	**Change:** The allotted time for a member of the public to submit public comment regarding an application for an authorization letter was extended from 14 days to 30 days. **Intent:** The intent of the change is to allow more time for members of the public to submit public comments to the Commissioner. **Rationale:** The rationale of this change is that extending the timeline for submission will allow more members of the public to be an active participant in the review of applications. **Likely impact:** More members of the public will submit public comments to the Commissioner.
-65		New section	**Change:** New section. Provisions of 12VAC5-221-40 moved to this section. Added a 7-day notice requirement on the Commissioner prior to contracting with experts or consultants. Added an allotted 7 days for the parties to offer possible alternatives to the Commissioner regarding the experts or consultants.

			Intent: The intent of this change is to ensure the regulation is easily understandable by organizing similar requirements together. **Rationale:** The rationale of this change is to increase the understandability of the regulation to ensure adherence with the requirements. **Likely impact:** The regulation will be clearer.
-70		Outlines the submission requirements for applicants	**Change:** Added a provision to allow the Commissioner to designate the department to request and receive supplemental information. Removed the list of elements the Commissioner is required to request. **Intent:** The intent of the change is to remove unnecessary regulatory requirements. **Rationale:** The rationale for this change is that the removal of unnecessary requirements will make the regulation clearer. **Likely impact:** The regulation will be clearer.
-80		Details the application review process for the Commissioner	**Change:** Repealed the required factors for consideration by the Commissioner and instead cross-referenced the Code. Repealed subsection I to be moved to a latter section. **Intent:** The intent of this change is to group similar regulatory requirements together. **Rationale:** The rationale of this change is that the regulation will be more clear if like-regulatory requirement are grouped together. **Likely impact:** The regulation will be clearer.
-90		Set the Commissioner's review timeline for the review of an application and the optional conditions	**Change:** Added the provision to allow the Commissioner's time for review to toll until all requested additional information is received. Repealed the provisions regarding conditioning and moved those requirements to a new section. **Intent:** The intent of the regulatory changes is to allow the Commissioner to

			have the necessary time to review an application if additional information has been requested, and to make the regulation clearer by grouping like-regulatory requirements together. **Rationale:** The rationale of this change is that the regulation will be clearer if like-regulatory requirements are grouped together, and that the Commissioner will have sufficient review time if the Commissioner is able to toll while awaiting the submission of additional information. **Likely impact:** The regulation will be clearer.
-95		New section	**Change:** New section. Moved the authority for the Commissioner to condition the authorization letter and changed that authority to require the Commissioner to place conditions on the authorization letter. **Intent:** The intent of the regulatory change is to make the conditions easier to find within the regulation. **Rationale:** The rationale of this change is that making the regulation easier to read will increase the understandability of the section. **Likely impact:** The regulation will be clearer.
-100		Details the Commissioner's responsibilities for the active supervision of a cooperative agreement	**Change:** Moved the definition for "plan of separation" to this section. Amended to allow the Commissioner to designate a representative from the department to request and receive additional information from the applicants. Added the language from a previous section regarding the Commissioner's selection of measures for reviewing the benefits of the Cooperative Agreement. Added language to require the Commissioner to notify applicants within 45 days whether or not the additional information satisfies the Commissioner's request. Added language to require the plan of separation be submitted if any updates are made by the parties. **Intent:** The intent of these changes are to:

			• Make the regulation clearer by grouping like-regulatory requirements together; • Ensure for timely review of information and documents submitted by the parties; and • Update the plan of separation requirements to allow for submission only when changes occur. **Rationale:** The rationale of these changes is that the regulation will be easier to read and will increase the understandability of this section and will allow for timely review of information and documents submitted for review. **Likely impact:** The regulation will be clearer, and the review of materials will be timelier.
-110		Contains the requirements for the parties in the creation and submission of their annual report	**Change:** Removed the requirement for the parties to annually submit their plans of separation. Removed the required $20,000 annual fee. Added the reimbursement language from 12VAC5-221-65. **Intent:** The intent of the regulatory changes are to conform with the statutory requirements and to group all like-regulatory requirements together. **Rationale:** The rationale of these changes is that the regulation will be clearer, and the language will be in compliance with the statute. **Likely impact:** The regulation will be clearer and more easily understandable.
-115		New section	**Change:** New section. Moved the onsite inspection requirements from 12VAC5-221-100 and added the authority for the Commissioner to designate the department to conduct onsite inspections. **Intent:** The intent of the regulatory change is to make the on-site inspection requirements easier to find within the regulation. **Rationale:** The rationale of this change is that making the regulation easier to read will increase the understandability of the section.

			Likely impact: The regulation will be clearer.
-120		Details the requirements for the TAP's membership and activities.	**Change:** Updated to conform with the style guidelines. **Intent:** The intent of this change is to conform the language with the style guidelines. **Rationale:** The rationale of this change is that conforming with the style guide will make the regulations uniform and more easily readable. **Likely impact:** The regulation will be uniform and easier to read.
-130		Contains the Commissioner's enforcement options for non-compliance.	**Change:** Updated to conform with the style guidelines. **Intent:** The intent of this change is to conform the language with the style guidelines. **Rationale:** The rationale of this change is that conforming with the style guide will make the regulations uniform and more easily readable. **Likely impact:** The regulation will be uniform and easier to read.
-140		Sets the requirements for the voluntary termination of a cooperative agreement.	**Change:** Amended the notice filing requirement to require the parties to submit notice to the Commissioner instead of the department. Amended the requirement for the parties to return the cooperative agreement to the department and instead to the Commissioner. **Intent:** The intent of the changes are to adhere with the statutory language in the Code. **Rationale:** The rationale of these changes is that the regulation will be clearer, and the language will be in compliance with the statute. **Likely impact:** The regulation will be compliant with the statute.
-150		Details the requirements for the Commissioner and the department and any official records regarding the cooperative agreement.	**Change:** Removed all non-regulatory language. **Intent:** The intent of the change is to adhere with the style guide.

			Rationale: The rationale of this change is that conforming with the style guide will make the regulations uniform and more easily readable. **Likely impact:** The regulation will be uniform and easier to read.

Office of Regulatory Management

Economic Review Form

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5-221
VAC Chapter title(s)	Regulations Governing Cooperative Agreements
Action title	Amend Regulation following the 2024 Periodic Review
Date this document prepared	May 1, 2024
Regulatory Stage (including Issuance of Guidance Documents)	Fast Track

Cost Benefit Analysis

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

(1) Direct & Indirect Costs & Benefits (Monetized)	• **Removal of the required list of submission elements the State Health Commissioner (Commissioner) is required to request from an applicant** Direct Benefits: The parties may not have to produce as many documents in their application, which may produce a cost savings for those parties. This cost savings cannot be determined due to the variability in the cost of the preparation of documents. There are no monetized indirect benefits, or direct or indirect costs associated with this regulatory change. • **Add language to require the Commissioner to notify applicants within 45 days whether the additional information satisfies the Commissioner's request** Direct Benefits: Adding timelines to the Commissioner's review allows for the parties to adhere to any business timelines associated with their monetary contributions outlined within the authorization letter and order. While this monetary benefit cannot be quantified, it is assumed that the addition of a review timeline will result in some kind of monetary benefit for the parties. Indirect benefits: The review timelines may allow the parties to adhere to any business timelines associated with their monetary contributions outlined within the authorization letter and order,

which may result in communities within the localities the cooperative agreement operates in receiving necessary funding in a timely manner. While this indirect monetary benefit cannot be quantified, it is assumed that the addition of review timelines would yield a positive monetary result for the local communities.

There are no monetized direct or indirect costs associated with this regulatory change.

- **Amend the language to require a plan of separation only be required for submission in the case of any updates to that plan**
  Direct Monetary Benefit: Removal of the annual submission requirement would eliminate any additional costs for the parties associated with the creation, certification, and the review by the Commissioner of the plan of separation.

  There are no monetized indirect benefits, or direct or indirect costs associated with this regulatory change.

- **Removed the $20,000 annual filing fee**
  Direct Costs: The removal of the $20,000 annual filing fee will temporarily result in a loss of revenue for VDH; however, this temporary loss will be recovered once the Commissioner is reimbursed for all expenditures relating to the supervision and oversight of the Cooperative Agreement.

  Direct Benefits: The removal of the $20,000 filing fee will ensure any parties subject to the cooperative agreement are only responsible for reimbursing the Commissioner for the associated costs for the supervision and oversight of the cooperative agreement.

  There are no indirect monetized costs or benefits associated with this regulatory change.

There are no monetized direct or indirect costs or benefits associated with the following regulatory requirements:

- **Extended the public comment period from 14 days to 30 days**
- **Added a 7-day notice requirement for the Commissioner to notify the parties prior to contracting experts or consultants**
- **Added a 7-day timeline for the parties to offer alternatives to the Commissioner regarding the experts or consultants**
- **Requires the Commissioner to place conditions on authorization letters for cooperative agreements**

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $94,342
(3) Net Monetized Benefit	$94,342	
(4) Other Costs & Benefits (Non-Monetized)	• **Extended the public comment period from 14 days to 30 days** Non-Monetized Benefits: Extending the time period for public comment by 16 days allows the public more time to submit a comment for consideration to the Commissioner. • **Added a 7-day notice requirement for the Commissioner to notify the parties prior to contracting experts or consultants** Non-Monetized Benefits: A clarified timeline for notice will allow for greater understanding of the regulation. • **Added a 7-day timeline for the parties to offer alternatives to the Commissioner regarding the experts or consultants** Non-Monetized Benefits: A clarified timeline for notice will allow for greater understanding of the regulation. • **Requires the Commissioner to place conditions on authorization letters for cooperative agreements** Non-Monetized Benefits: Requiring the Commissioner to place conditions on authorization letters ensure that the residents of the localities the parties operate within are protected from any disadvantages associated with healthcare monopolies. There are no associated Non-Monetized Costs associated with the regulatory changes.	
(5) Information Sources	VDH OLC Cooperative Agreement Program	

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

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: • There are no new costs associated with maintaining the status quo. Direct Benefits: • There are no new benefits associated with maintaining the status quo.

	Indirect Costs: $0 • There are no new monetizable indirect costs associated with maintaining the status quo. Indirect Benefits: $0 • There are no new monetizable indirect benefits associated with maintaining the status quo.

(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 other non-monetized costs or benefits associated with the status quo.
(5) Information Sources	VDH OLC Cooperative Agreement Program

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

(1) Direct & Indirect Costs & Benefits (Monetized)	The alternative approach offered for this regulatory action contains the requests made by Ballad Health during the periodic review comment period. The requests are as follows: • **Allow the parties to conduct their own initial investigation for non-compliance with the cooperative agreement** There are no direct or indirect monetized costs or benefits associated with this regulatory requirement. • **Require the Commissioner to review submitted plans: 30 days after receipt to request additional information, and 60 days after all information is received to accept, decline, or propose modifications** Direct Benefits: Adding timelines to the Commissioner's review allows for the parties to adhere to any business timelines associated with their monetary contributions outlined within the authorization letter and order. While this monetary benefit cannot be quantified, it is assumed that the addition of a review timeline will result in some kind of monetary benefit for the parties. Indirect benefits: The review timelines may allow the parties to adhere to any business timelines associated with their monetary

	contributions outlined within the authorization letter and order, which may result in communities within the localities the cooperative agreement operates in receiving necessary funding in a timely manner. While this indirect monetary benefit cannot be quantified, it is assumed that the addition of review timelines would yield a positive monetary result for the local communities. Direct cost: The review timelines may require an unattainable turn-around requirement for the Commissioner and the department, and therefore would require VDH to hire additional staff to assist in reviewing the submitted materials and information. VDH estimates that an additional Health Care Compliance Specialist II would be required to adhere to the alternative review timelines; using the third quarter percentile salary, the cost of an additional Health Care Compliance Specialist II is $107,573 (including all salary and fringe costs). There are no indirect costs associated with this regulatory requirement. • **Remove the requirement for the plan of separation to be submitted annually with a certification from an independent organization, and instead only require submission with certification if a significant change has been made to the plan** Direct Monetary Benefit: Removal of the annual submission requirement would eliminate any additional costs for the parties associated with the creation, certification, and the review by the Commissioner of the plan of separation. There are no indirect benefits, or direct or indirect costs associated with this regulatory requirement. • **Remove the submission requirements for the annual report and instead direct the parties to submit all documents and information required for submission by the letter authorizing the cooperative agreement** While removing the submission requirements from the regulations may result in a temporary decrease in costs for the parties due to them no longer needing to prepare these items, the Commissioner has the authority to request any additional documents deemed necessary for proper oversight and supervision of the cooperative agreement; therefore, any item deleted from the list still may be requested by the Commissioner. Due to this authority, this requirement does not have any associated direct or indirect monetary costs or benefits.

	• **Allow the annual audit to be performed by the parties' Chief Executive Officer and Chief Financial Officer** Direct Monetary Benefits: Removing the requirement for the annual audit to be certified by a third party will result in cost savings for the parties, as they would no longer be required to obtain that certification; however, this benefit cannot be quantified as the cost of financial audits is extremely variable. There are no indirect benefits, or direct or indirect costs associated with this regulatory requirement. • **Remove the requirements for the technical advisory panel (TAP) to meet annually and provide the Commissioner with ongoing input on the evolution and development of new measures and achievement of commitments by the parties** There are no indirect or direct monetized costs or benefits associated with this regulatory requirement. Due to the numerous costs and disadvantages of this alternative identified, VDH ultimately chose not to pursue every alternative offered; however, some aspects of the alternatives were adjusted and included as a proposed regulatory change in the primary option.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $507,432	(b) $0
(3) Net Monetized Benefit	$507,432	

(4) Other Costs & Benefits (Non-Monetized)	• **Allow the parties to conduct their own initial investigation for non-compliance with the cooperative agreement** Allowing the parties to conduct their own initial investigation of non-compliance with the cooperative agreement, substituting VDH's oversight and any investigations of non-compliance that occur, may jeopardize the health and safety of the parties' patients, as there is no way for VDH to ensure that the parties' provide sufficient training on investigations to their staff; VDH staff who investigate complaints of non-compliance have been undergone rigorous training regarding investigations of medical care facilities. • **Remove the requirement for the plan of separation to be submitted annually with a certification from an independent organization, and instead only require submission with certification if a significant change has been made to the plan**

	Removing the submission of the plan of separation except when a significant change has been made is a difficult distinction to make, as the parties and the Commissioner may disagree on the significance of a change. Without a third-party opinion about the significance of a change, important changes that jeopardize the parties' ability to separate with minimal health and safety implications for the patients they serve may go unnoticed. • **Remove the requirements for the TAP to meet annually and provide the Commissioner with ongoing input on the evolution and development of new measures and achievement of commitments by the parties** The TAP is comprised of numerous stakeholders and constituents within the localities where the parties operate; removing the requirement for the TAP to meet annually and provide ongoing input removes an integral piece of the active monitoring created to ensure the benefits of the cooperative agreement continue to outweigh the disadvantages of monopoly power.
(5) Information Sources	VDH OLC Cooperative Agreement Program

Impact on Local Partners

Table 2: Impact on Local Partners

(1) Direct & Indirect Costs & Benefits (Monetized)	The Southwest Virginia Health Authority will not be affected by direct or indirect monetized costs and benefits of the regulatory change as they are not subject to the requirements contained in this regulatory chapter.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	Non-monetized Costs & Benefits: There are no non-monetized costs or benefits associated with these regulatory changes for local partners.	
(4) Assistance	There is no assistance needed by local partners in order to adhere to the proposed regulatory changes within this action.	
(5) Information Sources	VDH OLC Cooperative Agreement Program	

Impacts on Families

Table 3: Impact on Families

(1) Direct & Indirect Costs & Benefits (Monetized)	Families will not be affected by direct or indirect monetized costs and benefits of the regulatory change as they are not subject to the requirements contained in this regulatory chapter and thus will incur no direct cost or benefit.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	Non-monetized Costs: There are no non-monetized costs associated with this regulatory chapter. Non-monetized Benefits: These regulatory changes help protect the consumers in southwest Virginia, including families, by clarifying VDH's role in actively supervising the monopolistic activities of Ballad Health to ensure the facilities within this entity are not taking advantage of their monopoly on the healthcare and services offered in that area.	
(4) Information Sources	VDH OLC Cooperative Agreement Program	

Impacts on Small Businesses

Table 4: Impact on Small Businesses

(1) Direct & Indirect Costs & Benefits (Monetized)	Small businesses will not be affected by direct or indirect monetized costs and benefits of the regulatory change as they are not subject to the requirements contained in this regulatory chapter and thus will incur no direct cost or benefit.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	Non-monetized Costs & Benefits: There are no non-monetized costs or benefits associated with these regulatory changes for small businesses.	
(4) Alternatives	Small businesses are not subject to the requirements contained in this regulatory chapter and thus there is no alternative to consider.	
(5) Information Sources	VDH OLC Cooperative Agreement Program	

Changes to Number of Regulatory Requirements

Table 5: Regulatory Reduction

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

Change in Regulatory Requirements

VAC Section(s) Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
12VAC5-221-20	**(M/A):**				
	(D/A):				
	(M/R):	**1**		-1	-1
	(D/R):	**2**		-2	-2
12VAC5-221-30	**(M/A):**				
	(D/A):				
	(M/R):	**6**	+1		+1
	(D/R):	**1**	+3		+3
12VAC5-221-40	**(M/A):**	**10**		-10	-10
	(D/A):	**1**		-1	-1
	(M/R):	**3**		-3	-3
	(D/R):	**4**		-4	-4
12VAC5-221-50	**(M/A):**	**5**	+1	-4	-3
	(D/A):				
	(M/R):				
	(D/R):				
12VAC5-221-60	**(M/A):**				
	(D/A):				
	(M/R):				
	(D/R):	**2**	+1	-1	0
12VAC5-221-65	**(M/A):**		+10		+10
	(D/A):		+1		+1
	(M/R):		+3		+3
	(D/R):		+4		+4
12VAC5-221-70	**(M/A):**				
	(D/A):				
	(M/R):				
	(D/R):	**62**	+1	-60	-59
12VAC5-221-80	**(M/A):**	**12**		-4	-4
	(D/A):				
	(M/R):				
	(D/R):	**25**		-13	-13

12VAC5-221-90	**(M/A):**				
	(D/A):	**0**	+1		+1
	(M/R):				
	(D/R):				
12VAC5-221-95	**(M/A):**		+1		+1
	(D/A):				
	(M/R):				
	(D/R):				
12VAC5-221-100	**(M/A):**	**11**	+2	-5	-3
	(D/A):	**6**	+7		+7
	(M/R):				
	(D/R):		+2		+2
12VAC5-221-110	**(M/A):**				
	(D/A):				
	(M/R):	**21**	+13		+13
	(D/R):	**8**		-4	-4
12VAC5-221-115	**(M/A):**		+1		+1
	(D/A):		+4		+4
	(M/R):				
	(D/R):		+1		+1
12VAC5-221-120	**(M/A):**				
	(D/A):	**43**		-1	-1
	(M/R):				
	(D/R):				
12VAC5-221-140	**(M/A):**				
	(D/A):				
	(M/R):				
	(D/R):	**3**		-1	-1
12VAC5-221-150	**(M/A):**				
	(D/A):	**3**		-3	-3
	(M/R):				
	(D/R):				
				Grand Total of Changes in Requirements:	**(M/A): -8**
					(D/A): +8
					(M/R): +13
					(D/R): -73

Cost Reductions or Increases (if applicable)

VAC Section(s) Involved*	Description of Regulatory Requirement	Initial Cost	New Cost	Overall Cost Savings/Increases
12VAC5-221-110	$20,000 annual filing fee	$20,000	$0	Annual savings of $20,000

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
12VAC5-221-60	Extended the public comment submission period from 14 days to 30 days.	Decreases stringency by allowing the public more time to submit public comments.
12VAC5-221-70	Removed the list of submission requirements from the required submission elements.	Decreases stringency by removing regulatory requirements.
12VAC5-221-100	Added review timelines to the Commissioner's review of supplemental information.	Decreases stringency through the addition of review timelines, allowing the regulants to have a clear understanding of how long a review of information will take.

Project 7854 – Fast Track

Department of Health

Chapter 221 Amendments Resulting from Periodic Review 2024

Part I

Definitions

12VAC5-221-10. Definitions.

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

"Applicant" means a party to a proposed cooperative agreement ~~who~~ that submits an application to the authority pursuant to § 15.2-5384.1 of the Code of Virginia.

"Application" means the written materials submitted by applicants ~~to the authority and the department~~ in accordance with § 15.2-5384.1 of the Code of Virginia.

"Attorney General" means the Attorney General for the Commonwealth of Virginia.

"Authority" ~~means the political subdivision organized and operated pursuant to Chapter 53.1 (§ 15.2-5368 et seq.) of Title 15.2 of the Code of Virginia, or if such authority is abolished, the board, body, authority, department, or officer succeeding to the principal functions thereof or to whom the powers given by Chapter 53.1 of Title 15.2 of the Code of Virginia are given by law.~~ has the same meaning as ascribed to the term in § 15.2-5369 of the Code of Virginia.

"Commissioner" means the State Health Commissioner ~~.~~ or his designee as may be designated in this chapter.

"Cooperative agreement" ~~means an agreement among two or more hospitals for the sharing, allocation, consolidation by merger or other combination of assets, or referral of patients, personnel, instructional programs, support services, and facilities or medical, diagnostic, or laboratory facilities or procedures or other services traditionally offered by hospitals.~~ has the same meaning as ascribed to the term in § 15.2-5369 of the Code of Virginia.

"Day" ~~or "days"~~ means calendar ~~days~~ day .

"Department" means the Virginia Department of Health.

"Hospital" ~~includes any health center and health provider under common ownership with the hospital and means any and all providers of dental, medical, and mental health services, including all related facilities and approaches thereto and appurtenances thereof. Dental, medical, and mental health facilities includes any and all facilities suitable for providing hospital, dental, medical, and mental health care, including any and all structures, buildings, improvements, additions, extensions, replacements, appurtenances, lands, rights in lands, franchises, machinery, equipment, furnishing, landscaping, approaches, roadways, and other facilities necessary or desirable in connection therewith or incidental thereto (including hospitals; nursing homes; assisted living facilities; continuing care facilities; self-care facilities; mental health facilities; wellness and health maintenance centers; medical office facilities; clinics; outpatient surgical centers; alcohol, substance abuse, and drug treatment centers; dental care clinics; laboratories; research facilities; sanitariums; hospices; facilities for the residence or care of the elderly, the handicapped, or the chronically ill; residential facilities for nurses, interns, and physicians; and any other kind of facility for the diagnosis, treatment, rehabilitation, prevention, or palliation of any human illness, injury, disorder, or disability) together with all related and supporting facilities and equipment necessary and desirable in connection therewith or incidental thereto, or equipment alone, including kitchen, laundry, laboratory, wellness, pharmaceutical,~~

~~administrative, communications, computer and recreational facilities and equipment, storage space, mobile medical facilities, vehicles, and other equipment necessary or desirable for the transportation of medical equipment or the transportation of patients. Dental, medical, and mental health facilities also includes facilities for graduate-level instruction in medicine or dentistry and clinics appurtenant thereto offering free or reduced rate dental, medical, or mental health services to the public.~~ has the same meaning as ascribed to the term in § 15.2-5369 of the Code of Virginia.

"Letter and order authorizing cooperative agreement" or "authorization letter" means a document that is issued by the commissioner approving a cooperative agreement.

"Measure" means some number of factors or benchmarks, which may be binary, a range, or continuous factors.

"Participating locality" ~~means any county or city in the LENOWISCO or Cumberland Plateau Planning District Commissions and the Counties of Smyth and Washington and the City of Bristol with respect to which an authority may be organized and in which it is contemplated that the authority will function.~~ has the same meaning as ascribed to the term in § 15.2-5369 of the Code of Virginia.

"Party" means a hospital entering into a cooperative agreement.

"Plan of separation" means ~~the~~ a written proposal submitted with an application to return the parties to a preconsolidation state, which includes a plan for separation of any combined assets, offering, provision, operation, planning, funding, pricing, contracting, utilization review or management of health services or any combined sharing, allocation, or referral of patients, personnel, employee benefits, instructional programs, support services and facilities or medical, diagnostic or laboratory facilities or procedures or other services traditionally offered by hospitals, including any parent or subsidiary at the time the consolidation occurs or thereafter.

"Primary service area" or "PSA" means the geographic area from which a hospital draws 75% of its patients as measured by the residential zip code of each patient.

"Secondary service area" or "SSA" means the geographic area from which a hospital draws an additional 15% of its patients, as measured by the residential zip code of each patient.

"TAP" means the technical advisory panel.

12VAC5-221-20. ~~Separate applications.~~ (Repealed.)

~~A party shall submit an application for a letter authorizing cooperative agreement for each cooperative agreement the party is applying to enter into. This provision applies even in the event that the parties have an existing letter authorizing cooperative agreement issued by the commissioner. An amendment to a cooperative agreement shall require submission of a new application.~~

Part II

Application

12VAC5-221-30. Application submission.

~~A. Parties within any participating locality may submit an application for a letter authorizing cooperative agreement to the authority. Information regarding the requirements of an application for a letter authorizing cooperative agreement submitted to the authority should be obtained through the authority.~~

A. For each cooperative agreement that the parties within a participating locality intend to enter, the parties shall submit an application requesting an authorization letter to the authority. This provision shall apply even in the event that the parties have an existing authorization letter issued by the commissioner.

B. ~~At the time of submission to the authority,~~ The parties shall submit a copy of the application and any additional requested information simultaneously to: ~~submit a copy of the application to the commissioner and the Attorney General.~~

1. The authority;

2. The commissioner; and

3. The Attorney General.

C. ~~If the authority requires the applicant to submit additional information before determining that the application is complete, the parties shall simultaneously submit a copy of the additional information to the authority, the commissioner, and the Attorney General.~~

~~D.~~ If the applicants believe the materials submitted contain proprietary information that is required to remain confidential, ~~such information must be clearly identified and the applicants shall submit duplicate applications, one with full information for the commissioner's use and one redacted application available for release to the public. Proprietary information that is clearly identified by the applicants will be kept confidential by the department pursuant to subdivision 3 of § 2.2-3705.6 of the Code of Virginia.~~ the applicants shall:

1. Clearly identify the information; and

2. Submit duplicate applications, one with full information for the commissioner's use and one redacted application available for release to the public.

D. The commissioner and the department shall keep proprietary information that is clearly identified by the applicants confidential pursuant to subdivision 3 of § 2.2-3705.6 of the Code of Virginia.

E. Upon receipt of the authority's recommendation to approve an application for a cooperative agreement, the Commissioner shall begin review.

12VAC5-221-40. ~~Fee schedule.~~ (Repealed.)

~~A. Fees shall be remitted only by certified check, cashier's check, bank money order, or other methods approved by the department. Fees shall be made payable to the department.~~

~~B. The application fee shall be $50,000 and shall be due to the department upon its receipt of a recommendation for approval from the authority.~~

~~C. If the commissioner should determine after review of the application that the actual cost incurred by the department is less than $50,000, the applicant shall be reimbursed the amount that is greater than the actual cost. If the commissioner should determine that the actual cost incurred by the department is greater than $50,000, the applicant shall pay any additional amounts due as instructed by the department.~~

~~D. The commissioner shall be reimbursed from applicants seeking approval of a cooperative agreement for all reasonable and actual costs incurred by the commissioner in the commissioner's review of the application, including costs of experts and consultants retained by the commissioner. The commissioner shall incur only those costs necessary to adequately review the application as determined in the commissioner's sole discretion. The commissioner shall maintain detailed records of all costs incurred for which reimbursement is sought.~~

~~E. The commissioner shall determine the activities needed to actively supervise an approved cooperative agreement and may incur only those expenses necessary for such supervision as determined in the commissioner's sole discretion. The commissioner shall be entitled to reimbursement from the parties for all reasonable and actual costs incurred by the commissioner in the supervision of an approved cooperative agreement, including costs of experts and consultants retained by the commissioner. Prior to contracting with experts or consultants, the commissioner shall provide reasonable notice to the parties describing the proposed scope of work and anticipated costs of such experts and consultants. The parties shall be given a~~

~~reasonable time period to provide to the commissioner possible alternatives to the use of such experts and consultants. The commissioner shall consider information submitted by the parties in determining whether to retain an expert or consultant.~~

~~F. The commissioner shall maintain detailed records of all costs incurred for which the commissioner seeks reimbursement from the parties. The commissioner shall provide the parties a written quarterly report detailing all costs incurred by the commissioner related to the supervision of the cooperative agreement for which the commissioner seeks reimbursement. This report shall be provided to the parties within 30 days of the end of each quarter. Within 30 days of receipt of a request for reimbursement, the parties shall make payment to the department.~~

12VAC5-221-50. Public hearing.

A. ~~The authority shall, in conjunction with the commissioner, schedule a public hearing for each completed application submitted. The hearing shall be held no later than 45 days after the receipt of a complete application by the authority.~~

~~B. The authority will publish and issue notice of the hearing in accordance with subsection C of § 15.2-5384.1 of the Code of Virginia.~~ In addition to the hearing held in accordance with subsection C of § 15.2-5384.1 of the Code of Virginia, the commissioner may hold a public hearing for each application submitted.

~~C.~~ B. The public hearing shall be open to the public in accordance with the provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia).

~~D. The public hearing shall be recorded by the Virginia Department of Health.~~

12VAC5-221-60. ~~Public comment to the commissioner~~ Submission of public comment.

~~The~~ A. A member of the public may submit written ~~comments~~ comment regarding ~~the~~ an application to the commissioner. ~~To ensure consideration by the commissioner, written comments must be received no later than 14 days after the authority adopts its recommendation on the application.~~

B. The commissioner may not consider written comment from a member of the public submitted more than 30 days after the authority's recommendation has been made on an application.

12VAC5-221-65. Reimbursement.

A. For each application recommended for approval by the authority, a review deposit of $50,000 shall be paid by the applicants to the department.

B. The review deposit shall be:

1. Remitted only by certified check, cashier's check, bank money order, or other methods approved by the commissioner;

2. Made payable to the department; and

3. Due to the department upon the commissioner's receipt of a recommendation for approval from the authority.

C. If the commissioner determines after review of the application that the actual cost incurred by the department is less than $50,000, the department shall reimburse the applicant the amount that is greater than the actual cost.

D. If the commissioner determines that the actual cost incurred by the department is greater than $50,000, the applicant shall pay any additional amount to be:

1. Remitted only by certified check, cashier's check, bank money order, or other methods approved by the commissioner;

2. Made payable to the department; and

3. Due to the department 30 days after receipt of a request for payment from the commissioner.

E. The commissioner shall:

1. Incur only those costs necessary to adequately review the application as determined in the commissioner's sole discretion; and

2. Maintain detailed records of all costs incurred for which reimbursement is sought.

F. An applicant seeking approval of a cooperative agreement shall reimburse the commissioner for all reasonable and actual costs incurred by the commissioner in the commissioner's review of the application, including costs of experts and consultants retained by the commissioner.

G. The applicants shall make payment to the department within 30 days of receipt of a request for reimbursement.

H. Prior to contracting with experts or consultants, the commissioner shall provide 7 days' notice to the applicants describing the proposed scope of work and anticipated costs of those experts and consultants.

I. The applicants shall have 7 days from the date of receipt of the commissioner's notice pursuant to subsection J of this section to provide to the commissioner possible alternatives to the use of those experts and consultants.

J. The commissioner shall consider information submitted by the applicants in determining whether to retain an expert or consultant.

K. All reimbursement requests by the commissioner shall be subject to the provisions of § 2.2-4805 of the Code of Virginia.

12VAC5-221-70. Commissioner's request for information.

A. Upon receipt of the authority's recommendation for approval, the commissioner ~~and department~~ may request supplemental information from the applicants.

B. To the extent the information is not present within the application, the commissioner shall request the following information:

1. ~~A report or reports used for public information and education about the proposed cooperative agreement prior to the parties' submission of the application. The applicants shall document the efforts used to disseminate the report or reports. The report or reports shall include:~~

~~a. A description of the proposed primary service area (PSA) and secondary service areas (SSA) and the services and facilities to be included in the cooperative agreement;~~

~~b. A description of how health services will change if the letter authorizing cooperative agreement is issued;~~

~~c. A description of improvements in patient access to health care including prevention services for all categories of payers and advantages patients will experience across the entire service area regarding costs, availability, and accessibility upon implementation of the cooperative agreement or findings from studies conducted by hospitals and other external entities, including health economists, and clinical services and population health experts, that describe how implementation of the proposed cooperative agreement will be effective with respect to resource allocation implications; efficient with respect to fostering cost containment, including eliminating duplicative services; and equitable with respect to maintaining quality and competition in health services within the service area and assuring patient access to and choice of insurers and providers within the health care system;~~

d. A description of any plans by the parties regarding existing or planned facilities that will impact access for patients to the services currently offered by the parties at their respective facilities, including expansions, closures, reductions in capacity, consolidation, and reduction or elimination of any services;

e. A description of the findings from community or population health assessments for the service areas regarding major health issues, trends, and health disparities, including comparisons to measures for the state and similar regional areas, and a description of how the health of the population will change if the letter authorizing cooperative agreement is issued; and

f. A description of the impact on the health professions workforce, including long-term employment, wage levels, retirement, benefits, recruitment, and retention of health professionals.

2. A record of community stakeholder and consumer views of the proposed cooperative agreement collected through a public participatory process including meetings and correspondence. Transcripts or minutes of any meetings held during the public participatory process shall be included in the report.

3. A summary of the nature of the proposed cooperative agreement between the parties.

4. A signed copy of the cooperative agreement and a copy of the following:

a. A description of any consideration passing to any party, individual, or entity under the cooperative agreement, including the amount, nature, source, and recipient;

b. A detailed description of any merger, lease, operating or management contract, change of control or other acquisition or change, direct or indirect, in ownership of any party or of the assets of any party to the cooperative agreement;

c. A list of all services and products and of all hospitals and other service locations that are a subject of the cooperative agreement, including those not located or provided within the boundaries of the Commonwealth of Virginia, and including hospitals or other inpatient facilities, insurance products, physician practices, pharmacies, accountable care organizations, psychiatric facilities, nursing homes, physical therapy and rehabilitation units, home care agencies, wellness centers or services, surgical centers or services, dialysis centers or services, cancer centers or services, imaging centers or services, support services, and any other product, facility, or service; and

d. A description of each party's contribution of capital, equipment, labor, services, or other contribution of value to the transaction.

5. A detailed description of the current and proposed PSA and SSA for the parties, including the PSA and SSA of each party's hospitals, not limited to the boundaries of the Commonwealth of Virginia. If the proposed PSA and SSA differ from the service areas where the parties have conducted business over the five years preceding the application, a description of how and why the proposed PSA or SSA differs and why changes are proposed.

6. A description of the prior history of dealings between the parties for the last five years, including their relationship as competitors and any prior joint ventures, affiliations, or other collaborative agreements between the parties.

7. Documents sufficient to show the financial performance of each party to the transaction for each of the preceding five fiscal years, including tax returns, debt, bond rating, and debt service; and copies of offering materials, subsequent filings such as continuing disclosure agreements and material event disclosures, and financial statements prepared by external certified public accountants, including management reports.

8. A copy of the current annual budget and budgets for the last five years for each party to the cooperative agreement. The budgets shall be in sufficient detail so as to determine the fiscal impact of the cooperative agreement on each party. The budgets shall be prepared in conformity with generally accepted accounting principles and all assumptions used shall be documented.

9. Projected budgets, including projected costs, revenues, profit margins, and operating ratios, of each party for each year for a period of five years after a letter authorizing cooperative agreement is issued. The budgets shall be prepared in conformity with generally accepted accounting principles and all assumptions used shall be documented.

10. A detailed explanation of the projected effects, including expected change in volume, price, and revenue as a result of the cooperative agreement, including:

a. Identification of all insurance contracts and payer agreements in place at the time of the application and a description of pending or anticipated changes that would require or enable the parties to amend their current insurance and payer agreements;

b. A description of how pricing for provider insurance contracts are calculated and the financial advantages accruing to insurers, insured consumers, and the parties to the cooperative agreement if the letter authorizing cooperative agreement is issued, including changes in percentage of risk-bearing contracts; and

c. Identification of existing and future business plans, reports, studies, or other documents of each party that:

(1) Discuss each party's projected performance in the market, business strategies, capital investment plans, competitive analyses, and financial projections, including any documents prepared in anticipation of the cooperative agreement; and

(2) Identify plans that will be altered, eliminated, or combined under the cooperative agreement.

11. A copy of the following policies under the proposed cooperative agreement:

a. A policy that assures no restrictions to Medicare or Medicaid patients;

b. Policies for free or reduced fee care for the uninsured and indigent;

c. Policies for bad debt write-off; and

d. Policies that require the parties to the cooperative agreement to maintain or exceed the existing level of charitable programs and services.

12. A description of the plan to systematically integrate health care and preventive health services among the parties to the cooperative agreement in the proposed geographic service area that addresses the following:

a. A streamlined management structure, including a description of a single board of directors, centralized leadership, and operating structure;

b. Alignment of the care delivery decisions of the system with the interests of the community;

c. Clinical standardization;

d. Alignment of the cultural identities of the parties to the cooperative agreement;

e. Any planned expansions, closures, reductions in capacity, consolidation, and reduction or elimination of any services;

f. Any plan for integration regarding health professions workforce development and the recruitment and retention of health professionals; and

g. Any plan for implementation of innovative or value-based payment models.

13. A description of the plan, including economic metrics, that details anticipated efficiencies in operating costs and shared services that can be gained only through the cooperative agreement, including:

a. Proposed use of any cost saving to reduce prices borne by insurers and consumers;

b. Proposed use of cost savings to fund low-cost or no-cost services designed to achieve long-term population health improvements; and

c. Other proposed uses of savings to benefit advancement of health and quality of care and outcomes.

14. A description of the market and the competitive dynamics for health care services in the parties' respective service areas, including at a minimum:

a. The identity of any nonparty hospital located in the PSA and SSA and any nonparty hospital outside of the PSA and SSA that also serves patients in the parties' PSA and SSA;

b. Estimates of the share of hospital services furnished by each of the parties and any nonparty hospitals;

c. Identification of whether any services or products of the proposed cooperative agreement are currently being offered or capable of being offered by any nonparty hospitals in the PSA and SSA and a description of how the proposed cooperative agreement will not exclude such nonparty hospitals from continued competitive and independent operation in the PSA and SSA;

d. A listing of the physicians employed by or under contract with each of the parties' hospitals in the PSA and SSA, including their specialties and office locations;

e. The identity of any potential entrants in the parties' PSA and SSA and the basis for any belief that such entry is likely within the two calendar years immediately following the date of the letter authorizing cooperative agreement is issued by the department; and

f. A list of each party's top 10 commercial insurance payers by revenue within the PSA and SSA.

15. A detailed description of each of the benefits that the parties propose will be achieved through the cooperative agreement. For each benefit include:

a. A description specifically describing how the parties intend to achieve the benefit;

b. A description of what the parties have done in the past with respect to achieving or attempting to achieve the benefits independently or through collaboration and how this may change if the cooperative agreement is granted;

c. An explanation of why the benefit can only be achieved through a cooperative agreement and not through other less restrictive arrangements; and

d. A description of how the parties propose that the commissioner measure and monitor achievement of the proposed benefit, including:

(1) Proposed measures and suggested baseline values with rationale for each measure to be considered by the commissioner in developing a plan to monitor achievement of the benefit;

(2) The current and projected levels and the trajectory for each measure that would be achieved over the next five years under the cooperative agreement;

(3) The projected levels for each measure in five years in the absence of the cooperative agreement; and

(4) A plan for how the requisite data for assessing the benefit will be obtained.

~~16. A description of any potential adverse impact of the proposed cooperative agreement on (i) population health or (ii) quality, availability, cost, or price of health care services to patients or payers.~~

~~17. A description of any commitments the parties are willing to make to address any potential adverse impacts resulting from the cooperative agreement. Each such commitment shall at a minimum include:~~

~~a. The parties' proposed benchmarks and metrics to measure achievement of the proposed commitments;~~

~~b. The parties' proposed plan to obtain and analyze data to evaluate the extent to which the commitments have been met, including how data shall be obtained from entities other than the parties; and~~

~~c. The parties' proposed consequences if they do not meet a commitment.~~

~~18. A plan of separation. The parties shall provide~~ A plan of separation with an independent opinion from a qualified organization verifying the plan of separation can be operationally implemented without undue disruption to essential health services provided by the parties.

~~19. A statement regarding the requirements for any certificate or certificates of public need resulting from the cooperative agreement.~~

~~20. A detailed description of the total cost to the parties resulting from the application for the cooperative agreement. Cost estimates should include costs for consultant, legal, and professional services; capital costs; financing costs; and management costs. The description should identify costs associated with the implementation of the cooperative agreement, including documentation of the availability of necessary funds. The description should identify which costs will be borne by each party.~~

~~21. An explanation of the reasons for the exclusion of any information set forth in this section. If the parties exclude an item because it is not applicable to the proposed cooperative agreement, an explanation of why the item is not applicable shall be provided.~~

~~22. A timetable for implementing all components of the proposed cooperative agreement and contact information for the person or persons authorized to receive notices, reports, and communications with respect to the letter authorizing cooperative agreement.~~

~~23. Records, reports, and documentation to support the information submitted pursuant to this section, including any additional supplemental information requested by the commissioner.~~

C. The commissioner may designate the department to request and to receive supplemental information from the applicants.

~~C.~~ D. All supplemental information submitted to the commissioner shall be accompanied by a verified statement signed by the chairperson of the board of directors and chief executive officer of each party~~;~~ , or if one or more party is an individual, signed by the individual attesting to the accuracy and completeness of the enclosed information.

12VAC5-221-80. Commissioner's review.

A. When reviewing an application, ~~The~~ the commissioner shall consult with ~~the Attorney General when reviewing an application.~~ :

1. The Attorney General; and

2. All other affected agencies of the Commonwealth when reviewing an application.

B. When reviewing an application, ~~The~~ the commissioner may ~~consult with the Federal Trade Commission when reviewing an application.~~ :

1. Consult with the Federal Trade Commission; and

2. Consult and coordinate with other affected jurisdictions.

C. ~~The commissioner may consult and coordinate with other affected jurisdictions when reviewing an application.~~

~~D. The commissioner shall consult with all other affected agencies of the Commonwealth when reviewing an application.~~

~~E.~~ During review of an application, ~~The~~ the commissioner ~~in his review~~ shall examine ~~the record developed by the authority, the authority's recommendation for approval, and any additional information received from the parties. In addition, the commissioner may consider any other data, information, or advice available to him.~~ :

1. The record developed by the authority;

2. The authority's recommendation for approval;

3. Any additional information received from the parties; and

4. Any other data and information available.

~~F.~~ D. The commissioner ~~shall~~ may not render a decision on ~~the~~ an application until all requested supplemental information ~~requested has been~~ is received.

~~G.~~ E. The commissioner shall consider the ~~following~~ factors ~~when conducting a review of an application:~~

~~1. Advantages.~~

~~a. Enhancement of the quality of hospital and hospital-related care, including mental health services and treatment of substance abuse, provided to citizens served by the authority, resulting in improved patient satisfaction;~~

~~b. Enhancement of population health status consistent with the regional health goals established by the authority;~~

~~c. Preservation of hospital facilities in geographical proximity to the communities traditionally served by those facilities to ensure access to care;~~

~~d. Gains in the cost-efficiency of services provided by the hospitals involved;~~

~~e. Improvements in the utilization of hospital resources and equipment;~~

~~f. Avoidance of duplication of hospital resources;~~

~~g. Participation in the state Medicaid program; and~~

~~h. Total cost of care.~~

~~2. Disadvantages.~~

~~a. The extent of any likely adverse impact of the proposed cooperative agreement on the ability of health maintenance organizations, preferred provider organizations, managed health care organizations, or other health care payers to negotiate reasonable payment and service arrangements with hospitals, physicians, allied health care professionals, or other health care providers;~~

~~b. The extent of any reduction in competition among physicians, allied health care professionals, other health care providers, or other persons furnishing goods or services to, or in competition with, hospitals that is likely to result directly or indirectly from the proposed cooperative agreement;~~

~~c. The extent of any likely adverse impact on patients in the quality, availability, and price of health care services; and~~

~~d. The availability of arrangements that are less restrictive to competition and achieve the same benefits or a more favorable balance of benefits over disadvantages~~

~~attributable to any reduction in competition likely to result from the proposed cooperative agreement.~~ the authority is required to consider pursuant to subdivision E of § 15.2-5384.1 of the Code of Virginia when reviewing an application.

~~H.~~ F. The commissioner shall approve the application if he finds by a preponderance of the evidence that the benefits likely to result from the proposed cooperative agreement outweigh the disadvantages likely to result from a reduction in competition from the proposed cooperative agreement.

~~I. In the selection and application of the measures for reviewing the proposed benefits of the cooperative agreement, as well as during the monitoring and active supervision of any approved cooperative agreement, the commissioner shall:~~

~~1. Draw from consensus health and health care metrics, such as those being developed pursuant to the Virginia state innovation model development initiative and state population health improvement plan, to ensure the validity and consistency of the measure;~~

~~2. Use historical actual experience in the region to establish baseline performance and evaluate progress over time;~~

~~3. Consider recommendations on the measures and goals from the technical advisory panel appointed pursuant to 12VAC5-221-120; and~~

~~4. Allow for flexibility, to the extent quantifiable goals or targets are specified, should environmental factors that are outside the control of the parties change significantly.~~

12VAC5-221-90. Action on an application.

A. The commissioner shall issue ~~his~~ a decision in writing within 45 days of receipt of the authority's recommendation. However, if the commissioner has requested supplemental information from the applicants, the commissioner shall have an additional 15 days, following receipt of the supplemental information, to issue a decision.

B. At the request of the applicants, the commissioner may delay ~~issue of his~~ the issuance of a decision to provide additional time to review the record.

C. ~~The commissioner may condition approval of the letter authorizing cooperative agreement upon the applicants' commitment to achieving the improvements in population health, access to health care services, quality, and cost efficiencies identified by the applicants in support of their application. Such conditions may include:~~

~~1. A cap on the negotiated case-mix adjusted revenue per discharge by payer by product. The method for calculating such a case-mix shall be published on the Virginia Department of Health's Office of Licensure and Certification's website in a guidance document. The department may rely on third-party auditors to assist in determining the method for determining such caps, such caps' levels, and a plan for monitoring compliance;~~

~~2. A commitment to return a portion of the cost savings and efficiencies gained through the cooperative agreement to residents in the participating localities through specific proposed mechanisms;~~

~~3. An agreement that the parties shall not prevent or discourage health plans from directing or incentivizing patients to choose certain providers; the parties shall not have any contractual clauses or provisions that prevent health plans from directing or incentivizing patients;~~

~~4. An agreement that the parties shall not engage in the tying of sales of the health system's services with the health plan's purchase of other services from the health system;~~

~~5. An agreement that the parties shall not restrict a health plan's ability to make available to its health plan enrollees cost, quality, efficiency, and performance information to aid enrollees in evaluating and selecting providers in the health plan; and~~

~~6. A commitment that the parties shall not refuse to include certain provisions in contracts with health plans that have been utilized in health plan contracts in other parts of the Commonwealth in order to promote value-based health care, including bundled payments, pay for performance, utilization management, and other processes that reward improvements in quality and efficiency.~~

~~D.~~ The commissioner's decision to approve or deny an application shall constitute a case decision pursuant to the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

12VAC5-221-95. Conditions.

A. The commissioner may condition the approval of the authorization letter on the applicants' commitment to achieving improvements to population health, access to health care services, quality, and cost effectiveness identified by the applicants in support of their application. The conditions may include:

1. A cap on the negotiated case-mix adjusted revenue per discharge by payer by product;

2. A commitment to return a portion of the cost savings and efficiencies gained through the cooperative agreement to residents in the participating localities through specific proposed mechanisms;

3. An agreement that the parties may not prevent or discourage health plans from directing or incentivizing patients to chose certain providers;

4. An agreement that the parties may not have any contractual clauses or provisions that prevent health plans from directing or incentivizing patients;

5. An agreement that the parties may not engage in the typing of sales of the health system's services with the health plan' purchase of other services from the health system;

6. An agreement that the parties may not restrict a health plan's ability to make available to its health plan enrollees cost, quality, efficiency, and performance information to aid enrollees in evaluating and selecting providers in the health plan; and

7. A commitment that the parties may not refuse to include certain provisions in contracts with health plans that have been utilized in health plan contracts in other parts of the Commonwealth in order to promote value-based health care, including bundled payments, pay for performance, utilization management, and other processes that reward improvements in quality and efficiency.

Part III

Monitoring

12VAC5-221-100. Ongoing and active supervision.

A. The commissioner shall maintain active and continuing supervision of the parties in accordance with the terms under this section and to ensure compliance with the cooperative agreement and the letter authorizing cooperative agreement.

B. A party who receives an authorization letter shall submit any information that is requested by the commissioner for ongoing monitoring and supervision. The commissioner may designate the department to request and to receive additional information from the parties.

C. In the selection of the measures for reviewing the proposed benefits of the cooperative agreement and during the monitoring and active supervision of any approved cooperative agreement, the commissioner shall:

1. Draw from consensus health and health care metrics, such as those being developed pursuant to the state health improvement plan to ensure validity and consistency of the measure;

2. Use historical actual experience in the region to establish baseline performance and evaluate progress over time;

3. Consider recommendations on the measures and goals from the TAP appointed pursuant to 12VAC5-221-120; and

4. Allow for flexibility, to the extent quantifiable goals and targets are specified, should environmental factors that are outside the control of the parties change significantly.

~~B. Any party who receives a letter authorizing cooperative agreement shall submit any additional information that is requested by the department to establish benchmarks for ongoing monitoring and supervision. The department's request may include (i) information on patient satisfaction, (ii) information on employee satisfaction, (iii) a charge master, (iv) information reflecting the contracted rates negotiated with nonphysician providers, (v) information reflecting the noncontracted rates negotiated with allied health professionals, and (vi) information reflecting the noncontracted rates negotiated with other providers.~~

~~C.~~ D. The ~~department~~ commissioner shall establish benchmarks and quantitative measures that will be used to evaluate the proposed and continuing benefits of the cooperative agreement. ~~1.~~ The quantitative measures shall include measures of the ~~cognizable~~ identifiable benefits from the cooperative agreement in at least the following categories:

~~a.~~ 1. Population health;

~~b.~~ 2. Access to health services;

~~c.~~ 3. Economic;

~~d.~~ 4. Patient safety

~~e.~~ 5. Patient satisfaction ; and

6. Health outcomes

~~f. Other cognizable benefits~~ .

~~2. Each category may be comprised of measures for subcategories.~~

~~3. The technical advisory panel and the parties to the cooperative agreement may make recommendations for the creation and evaluation of quantitative measures, but the department shall have the exclusive authority to add, modify, accept, or reject recommendations when creating or interpreting the quantitative measures.~~

E. The TAP and the parties of the cooperative agreement may make recommendations for the creation and evaluation of quantitative measures, but the commissioner shall have the exclusive authority to add, modify, accept, or reject recommendations when creating or interpreting the quantitative measures.

~~D. A department representative may make periodic unannounced onsite inspections of the parties' facilities as necessary. If the department finds, after inspection, noncompliance with any provision of this chapter, any applicable state regulations, or the elements of the cooperative agreement or the letter authorizing cooperative agreement, the commissioner shall begin enforcement procedures in accordance with 12VAC5-221-130.~~

~~E. The parties shall make available to the department representative requested records and shall allow access to interview the agents, employees, contractors, and any other person under control, direction, or supervision of the parties.~~

~~F. Complaints received by the department with regard to noncompliance with the cooperative agreement or the letter authorizing cooperative agreement shall be investigated. When the investigation is complete, the parties and the complainant, if known, shall be notified of the findings of the investigation.~~

F. Upon receipt of any requested additional information submitted pursuant to subsection B of this section, the commissioner shall notify the parties within 45 days regarding whether the additional information satisfies the commissioner's request.

G. The parties shall:

1. Report any update to the parties' plan of separation; and

2. Submit the updated plan of separation to the commissioner within 30 days of that update with an independent opinion from a qualified organization that states the plan of separation may be operationally implemented without undue disruption to essential health services provided by the parties.

~~G.~~ H. The commissioner may ~~develop other mechanisms of monitoring the parties to determine compliance with the cooperative agreement and whether compliance continues to meet the requirements of § 15.2-5384.1 of the Code of Virginia. The commissioner may modify the mechanisms of monitoring the parties upon notice to the parties.~~ :

1. Develop other mechanisms of monitoring the parties to determine compliance with the cooperative agreement and whether compliance continues to meet the requirements of § 15.2-5384.1 of the Code of Virginia; and

2. Modify the mechanisms of monitoring the parties upon notice to the parties.

12VAC5-221-110. Annual reporting.

A. The parties shall report annually to the commissioner on the extent of the benefits realized and compliance with any terms and conditions placed on their letter authorizing cooperative agreement. The report shall:

1. Describe the activities conducted pursuant to the cooperative agreement;

2. Include any actions taken in furtherance of commitments made by the parties or terms imposed by the commissioner as a condition for approval of the cooperative agreement;

3. Include information related to changes in price, cost, quality, access to care, and population health improvement;

4. Include actual costs, revenues, profit margins, and operating costs;

5. Include a charge master;

6. Include information reflecting the contracted rates negotiated with nonphysician providers, allied health professionals, and others;

7. Include any measures requested by the department based on the recommendations of the technical advisory panel appointed pursuant to 12VAC5-221-120; and

8. Include the current status of the quantitative measures established under subsection C of 12VAC5-221-100 and the information requested by the department for benchmarks established in subsection B of 12VAC5-221-100.

B. ~~The parties shall be required to update the parties' plan of separation annually and submit the updated plan of separation to the department. The parties shall provide an independent opinion from a qualified organization that states the plan of separation may be operationally implemented without undue disruption to essential health services provided by the parties.~~

~~C.~~ The commissioner may require the parties to supplement the annual report with additional information to the extent necessary to ensure compliance with the cooperative agreement and the letter authorizing cooperative agreement.

~~D.~~ C. All annual reports submitted pursuant to this section shall be certified audited by a third-party auditor.

~~E. The fee due with the filing of the annual report shall be $20,000. If the commissioner should determine that the actual cost incurred by the department is greater than $20,000, the parties~~

~~shall pay any additional amounts due as instructed by the department. The annual filing fee shall not exceed $75,000.~~

D. The parties shall reimburse the commissioner for all costs and expenses deemed necessary by the commissioner regarding the ongoing and active supervision of the cooperative agreement, including costs of experts and consultants retained by the commissioner.

E. The parties shall:

1. Remit payment only by certified check, cashier's check, bank money order, or other methods approved by the commissioner;

2. Make all payments payable to the department; and

3. Submit payment to the department 30 days after the receipt of a request for reimbursement from the commissioner.

F. The commissioner shall:

1. Maintain detailed records of all costs incurred for which reimbursement is sought;

2. Incur only those expenses necessary to actively supervise the cooperative agreement as determined in the commissioner's sole discretion; and

3. Provide the parties a written quarterly report detailing all costs incurred by the commissioner related to the supervision of the cooperative agreement for which the commissioner seeks reimbursement within 30 days of the end of each quarter.

G. Prior to contracting with experts or consultants, the commissioner shall provide 7 days' notice to the parties describing the proposed scope of work and anticipated costs of those experts and consultants.

H. The parties shall have 7 days from the date of receipt of the commissioner's notice pursuant to subsection I of this section to provide to the commissioner possible alternatives to the use of those experts or consultants.

I. The commissioner shall consider information submitted by the parties in determining whether to retain an expert or consultant.

J. All reimbursement requests by the commissioner shall be subject to the provisions of § 2.2-4805 of the Code of Virginia.

~~F.~~ K. The commissioner shall annually issue a written decision and the basis for the decision ~~on an annual basis~~ as to whether the benefits of the cooperative agreement continue to outweigh the disadvantages attributable to a reduction in competition that have resulted from the cooperative agreement.

12VAC5-221-115. Onsite inspection.

A. The commissioner may make periodic unannounced onsite inspections of the parties' facilities as necessary.

B. The commissioner may designate the department to conduct onsite inspections or investigations of the parties' facilities.

C. The parties shall make available to the commissioner requested records and shall allow access to interview the agents, employees, contractors, and any other person under control, direction, or supervision of the parties.

D. The commissioner shall investigate complaints received regarding noncompliance with the cooperative agreement or the authorization letter.

E. When the investigation is complete, the commissioner shall notify the parties and the complainant, if known, of the findings of the investigation.

12VAC5-221-120. Technical advisory panel.

A. The commissioner shall appoint a ~~technical advisory panel~~ TAP to provide ~~(i) initial recommendations to the commissioner as to the quality, cost, and access measures and benchmarks to be considered to objectively track the benefits and disadvantages of a cooperative agreement and (ii) ongoing input to the commissioner on the evolution of these and other new measures and the progress of the parties with respect to achievement of commitments with respect to these measures.~~ :

1. Initial recommendations to the commissioner as to the quality, cost, and access measures and benchmarks to be considered to objectively track the benefits and disadvantages of a cooperative agreement; and

2. Ongoing input to the commissioner on the evolution of these and other new measures and the progress of the parties with respect to achievement of commitments with respect to these measures.

B. The ~~technical advisory panel~~ TAP shall consist of:

1. A representative of the Commissioner ~~of Health~~ who shall serve as chair of the ~~panel~~ TAP;

2. The chief medical or quality officer or officers of the parties;

3. A chief medical or quality officer of a hospital or health system from other state market areas with no affiliation with the parties;

4. A chief medical or quality officer of a health plan that has subscribers in the affected area;

5. Experts in the area of health quality measurement and performance;

6. A consumer and employer representative from the affected area;

7. A representative from the Bureau of Insurance of the State Corporation Commission;

8. The chief financial officer or officers of the parties;

9. A chief financial officer of a hospital or health system from other state market areas with no affiliation with the parties; and

10. A chief financial officer of a health plan that has subscribers in the affected area.

C. ~~The technical advisory panel shall meet at least on an annual basis.~~

~~D.~~ The ~~technical advisory panel~~ TAP shall ~~identify evidence-based cost, quality, and access measures in areas, including population health, patient safety, health outcomes, patient satisfaction, access to care, and any other areas identified by the panel. The panel shall also make recommendations regarding how to best report performance on quality metrics.~~ :

1. Meet at least on an annual basis;

2. Identify evidence-based cost, quality, and access measures in areas, including population health, patient safety, health outcomes, patient satisfaction, access to care, and any other areas identified by the TAP; and

3. Make recommendations regarding how to best report performance on quality metrics.

~~E. The technical advisory panel meetings shall be staffed by the Virginia Department of Health Office of Licensure and Certification.~~

12VAC5-221-130. Enforcement procedures.

A. If the commissioner has reason to believe that compliance with a cooperative agreement no longer meets the requirements of § 15.2-5384.1 of the Code of Virginia or this chapter, the commissioner shall initiate a proceeding pursuant to § 2.2-4019 of the Code of Virginia to determine whether compliance with the cooperative agreement no longer meets ~~the~~ those requirements ~~of § 15.2-5384.1 of the Code of Virginia or this chapter~~.

B. ~~In the course of such a~~ During the proceeding, the commissioner ~~is authorized to~~ may seek reasonable modifications to a letter authorizing cooperative agreement~~. Such modifications shall be~~ with the consent of the parties.

C. The commissioner may revoke a letter authorizing cooperative agreement upon ~~a~~ finding that:

1. The parties are not complying with the terms or conditions of the cooperative agreement or the letter authorizing cooperative agreement;

2. The cooperative agreement is not in substantial compliance with the terms of the parties' application or the letter authorizing cooperative agreement;

3. The benefits resulting from the cooperative agreement no longer outweigh the disadvantages attributable to the reduction in competition resulting from the cooperative agreement;

4. The commissioner's approval was obtained as a result of intentional material misrepresentation to the commissioner or as the result of coercion, threats, or intimidation toward any party to the cooperative agreement; or

5. The parties have failed to pay any required fee ~~required by the department or the authority~~.

D. The proceeding initiated by the commissioner under this section, and any judicial review thereof, shall be held in accordance with and governed by the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

12VAC5-221-140. Voluntary termination of cooperative agreement.

A. ~~Any~~ A party shall file notice ~~with the department~~ in writing to the commissioner ~~within~~ no later than 30 days after terminating its participation in a cooperative agreement. ~~The notice shall be sent in writing to the attention of the director of the department's Office of Licensure and Certification.~~

B. In the event of a termination of a cooperative agreement, the parties shall return the ~~letter authorizing cooperative agreement~~ authorization letter to the ~~department's Office of Licensure and Certification~~ commissioner.

12VAC5-221-150. Official records.

~~A. The commissioner shall maintain on file all cooperative agreements that the commissioner has approved.~~

~~B. All records collected pursuant to this chapter shall be maintained in accordance with the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia) and the Library of Virginia's record management program (§ 42.1-85 of the Code of Virginia).~~

~~C. All approved cooperative agreements and letters authorizing cooperative agreement shall be published on the Virginia Department of Health Office of Licensure and Certification website.~~

~~D. All reports collected pursuant to 12VAC5-221-110 shall be published on the Virginia Department of Health Office of Licensure and Certification website.~~

~~E. The commissioner shall make public his annual determination of compliance with a letter authorizing the cooperative agreement.~~

The department shall make available on its website:

1. All authorization letters of the approved cooperative agreements;

2. All reports collected pursuant to 12VAC5-221-110; and

3. The commissioner's annual determination of compliance with the authorization letter.

EMS State Plan: Interim Plan

Rachel Stradling
Acting Director
Office of Emergency Medical Services

Virginia Department of Health, Office of EMS (OEMS)
Interim Strategic Plan Draft

Mission

Support the essential functions of public health through a coordinated, people centered Emergency Medical Care system for the Commonwealth of Virginia.

Vision

Support a comprehensive, efficient, and resilient Emergency Medical Care System within the Commonwealth of Virginia that is focused on the core public health mission.

Goals

1. Ensure the Office of EMS is properly positioned to support the essential public health functions of Virginia's emergency care system.
    a. The Office of EMS will focus on essential functions such as EMS training, Certification and Regulation, and Trauma System administration, to ensure that the needs of Agencies, Providers, Councils, and other stakeholders are met
    b. Administer Return to Locality, Rescue Squad Assistance Fund, Trauma Fund, and other Code mandated programs in an efficient, timely, and accountable fashion
    c. Create an actionable plan to ensure that the Office of EMS can meet its mission into the future in a fiscally responsible way.
2. Create a new strategic and operational plan based on engagement with multiple sectors and community partners to support the mission of the Office of EMS.
    a. Work with members of the EMS Advisory board, EMS Agencies, EMS Council leaders, and other EMS stakeholders and community partners to create a Strategic and Operational plan for FY2025 and beyond that is built on the core public health mission of the Office of EMS.
    b. Keep accountability to the EMS community front of mind as we institute the proper financial controls and processes to ensure programs and Code required functions are properly aligned with available resources
3. Maintain and build a competent, engaged, and valued workforce.
    a. Focus on activities and processes that promote increased retention and engagement with OEMS staff
    b. Realign leadership structure of OEMS to create better focus on functions, increased communication, and higher levels of accountability from leadership and staff.
    c. Provide for transparency in decision-making as appropriate to staff of OEMS and stakeholders in the EMS community

Electronic Meeting Policy: Updates from 2024 General Assembly Session

Alexandra Jansson, MPP
Staff, State Board of Health

TITLE: Procedures for Electronic Participation in Board of Health Meetings and All-Virtual Meetings

EFFECTIVE DATE: 7/1/24

AUTHORITY: § 2.2-3708.3 of the Code of Virginia

DEFINITIONS:

The following definitions shall apply to the words used in this policy unless otherwise noted:

"Participate electronically" means participating in an in-person meeting through electronic communication from a location that is not the location advertised in the public meeting notice.

"Electronic communication" means the use of technology having electrical, digital, magnetic, wireless, optical, electromagnetic, or similar capabilities to transmit or receive information.

"In-person meeting" refers to a meeting that has not been approved as an all-virtual meeting pursuant to this policy. All in-person meetings must have a quorum assembled in one physical location.

"All-virtual meeting" refers to a meeting that has been approved as an all-virtual meeting pursuant to this policy. During an all-virtual meeting, all members, staff, and the public may participate through electronic communication. No more than two members may be assembled in one physical location that is not open to the public.

PARTICIPATING ELECTRONICALLY DURING IN-PERSON MEETINGS:

Process for making requests

Each individual member shall request approval to participate electronically from the Board of Health (Board) Chair, and Board staff. Each request shall state a specific reason for electronic participation. Electronic participation is limited to the following reasons:

1. A member is unable to attend the meeting because of a temporary or permanent disability or other medical condition that prevents their ability to physically attend such meeting,
2. A medical condition of a family member of a member requires the member to provide care that prevents their physical attendance,
3. A member's principal residence is more than 60 miles from the location of the meeting, or
4. A member is unable to attend due to an emergency or personal matter – the specific nature of which shall be shared with the Chair and staff.

If a member is requesting to participate electronically pursuant to reasons 1, 2, or 3, they must make their request 10 business days before the meeting. The Chair may make exceptions to this rule in his or her discretion.

If a member is requesting to participate electronically pursuant to reason 4, they may make their request up to 24 hours before the scheduled start time of the meeting. The Chair may make exceptions to this rule in his or her discretion.

Other requirements

Whenever an individual member is to participate electronically, the following conditions must be present:

1. A quorum of the Board must be physically assembled at the primary or central meeting location.
2. There must be arrangements for the voice of the remote participant to be heard by all persons at the primary or central meeting location.

If a member is participating electronically, the minutes shall reflect which of the four reasons the member has given. Members participating virtually due to caregiver duties (reason 2) are considered present for the physical quorum.

If a member is participating electronically pursuant to reason 4 (above), the minutes shall also include the specific nature of the personal matter cited by the member. Furthermore, such electronic participation by any one member is limited to by law to two of the Board's meetings or 25% of the meetings per year, whichever is greater. There is no limit to the number of times a member may participate electronically due to other allowable reasons.

Automatic approval; vote required if challenged

Individual electronic participation from a remote location shall be approved unless such participation would violate this policy or the provisions of the Virginia Freedom of Information Act. If a member's participation from a remote location is challenged by one or more members, then the Board shall vote whether to allow such participation and the results of such vote shall be recorded in the minutes with specificity.

If a member is approved to participate electronically the meeting minutes shall reflect the remote location from which the member participated; however, the remote location need not be open to the public and may be identified by a general description.

ALL-VIRTUAL MEETINGS:

The Board of Health may convene all-virtual meetings in accordance with the Virginia Freedom of Information Act. An indication of whether a meeting will be in-person or all-virtual will be included in the meeting notice. The type of meeting will not be changed once the notice is published unless the Board provides a new notice in accordance with the Virginia Freedom of Information Act.

At the third regular meeting of the calendar year, the Board shall discuss potential dates for all-virtual meetings during the following calendar year based on the planned work load of the Board and the schedules of the members. The members may then, by consensus, suggest two meetings that may be held as all-virtual meetings.

At least 15 business days prior to any regular or special meeting, the Chair of the Board shall confirm with staff whether a meeting will be an in-person meeting or an all-virtual meeting. Staff will then communicate the type of meeting to the other members and the public. There is a strong

preference to follow the suggested schedule created each calendar year. However, the Chair may, to the extent allowed by law, change a scheduled in- person meeting to an all-virtual meeting in extenuating circumstances. The Chair may also change a scheduled all-virtual meeting to an in-person meeting at the request of other members and/or Board staff.

The Board may not convene an all-virtual public meeting (i) more than two times per calendar year or 50 percent of its meetings held per calendar year rounded up to the next whole number, whichever is greater, or (ii) consecutively with another all-virtual public meeting.

During all-virtual public meetings, members will be considered absent for portions of the meeting where their video or audio connection fail or are disconnected.

CLARIFICATIONS:

The limits on electronic participation from a remote location due to emergencies or personal matters (reason 4) are separate from the limits on all-virtual meetings and will be counted separately. If a member's request to participate electronically is disapproved, said member may still continue to monitor the meeting from the remote location, but may not participate and may not be counted as present for the meeting.

Three or more members may be gathered in one location during an all-virtual meeting so long as that location is open to the public.

The Board shall review and certify this policy annually by recorded vote.