State of Board of Health
Agenda
March 17, 2016 – 9:00 a.m.
Perimeter Center – Boardroom 2

Call to Order and Welcome	Bruce Edwards, Chair
Pledge of Allegiance	Megan Getter
Introductions	Mr. Edwards
Review of Agenda	Joseph Hilbert Director of Governmental and Regulatory Affairs
Approval of September 17, 2015 Minutes	Mr. Edwards
Approval of December 3, 2015 Minutes	Mr. Edwards
Commissioner's Report	Marissa Levine, MD, MPH, FAAFP State Health Commissioner
Budget Update	Michael McMahon Administration Operations Director
Legislative Update	Mr. Hilbert
Break	
Abortion Facility Licensure Status Report	Erik Bodin, Director Office of Licensure and Certification
Regulatory Action Update	Mr. Hilbert
Public Comment Period	

<u>Board Action Item</u>

Board of Health Annual Report - Virginia's Plan for Well-Being	Mr. Hilbert Lilian Peake, MD, MPH Deputy Commissioner for Population Health

Working Lunch
Lunch Speakers – David Paylor, Director, Virginia Department of Environmental Quality
Dr. Levine
Environmental Quality and Public Health Issues Concerning Coal Ash Storage Facilities in Virginia

<u>Regulatory Action Items</u>

Regulations for the Licensure of Home Care Organizations 12VAC5-381 (Fast track amendments)	Mr. Bodin

Authorized Onsite Soil Evaluator Regulations 12VAC5-615 (Repeal regulations)	Dwayne Roadcap, Acting Director Office of Environmental Health Services
Sewage Handling and Disposal Regulations 12VAC5-610 (Final amendments)	Mr. Roadcap
Virginia Radiation Protection Regulations: Fee Schedule 12VAC5-490 (Proposed amendments)	Steve Harrison, Director Office of Radiological Health
Regulations Governing Durable Do Not Resuscitate Orders 12VAC5-66 (Fast track amendments)	Gary Brown, Director Office of Emergency Medical Services
Regulations Governing Virginia Newborn Screening Services 12VAC5-71 (Final regulations)	Vanessa Walker-Harris, MD, Director Office of Family Health Services
Appointment of Nominating Committee	Mr. Edwards
Member Reports	
Other Business	
Adjourn	

COMMONWEALTH of VIRGINIA
Department of Health
Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER
P O BOX 2448
RICHMOND, VA 23218
TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: January 14, 2016

TO: Virginia State Board of Health

FROM: Erik Bodin
Director, Office of Licensure and Certification

SUBJECT: Fast Track Amendments- Regulations for the Licensure of Home Care Organizations

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Enclosed for your review is a Fast Track action to amend the Regulations for the Licensure of Home Care Organizations (12VAC5-381).

In March of 2015, the Virginia Department of Health (VDH) conducted a periodic review of 12VAC5-381, "Regulations for Licensure of Home Care Organizations." As a result of the review, VDH determined it was necessary to use the regulatory process to amend these regulations. It is necessary to amend these regulations as the regulatory chapter has not been comprehensively revised in over a decade. This regulatory action is necessary to amend the regulations to correct certain provisions which are no longer accurate, clarify certain requirements and insert additional best practices. This regulatory action was created with significant input from relevant stakeholders.

The Board of Health is requested to approve this Fast Track action at its March 2016 meeting. Should the Board of Health approve the Fast Track Action the proposed 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 amendments 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 amendments will become effective.

townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-381
Regulation title(s)	Regulations for the Licensure of Home Care Organizations
Action title	Comprehensive update of the regulatory chapter
Date this document prepared	February 19, 2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

In March of 2015, the Virginia Department of Health (VDH) conducted a periodic review of 12VAC5-381, Regulations for Licensure of Home Care Organizations. As a result of the review, VDH determined it was necessary to use the regulatory process to amend these regulations. It is necessary to amend these regulations as the regulatory chapter has not been comprehensively revised in over a decade. This regulatory action is necessary to amend the regulations to correct certain provisions which are no longer accurate, clarify certain requirements, and insert additional best practices.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

DMAS- means Department of Medical Assistance Services

EDCD – means Elderly or Disabled with Consumer Direction

HCO- means Home Care Organization

OLC- means Office of Licensure and Certification of the Virginia Department of Health

VDH – means Virginia Department of Health

Statement of final agency action

Please 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.

The amendments to the Regulations for Licensure of Home Care Organizations (12VAC5-381) were approved by the State Board of Health on March 17, 2016.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The regulation is promulgated under the authority of §§ 32.1-12 and 32.1-162.12 of Chapter 5 of Title 32.1 of the Code of Virginia (Code). Section 32.1-12 grants the Board of Health the legal authority "to make, adopt, promulgate, and enforce such regulations necessary to carry out the provisions of Title 32.1 of the Code." Section 32.1-162.12 of the Code of Virginia directs the Board to promulgate regulations governing the activities and services provided by home care organizations as may be necessary to protect the public health, safety and welfare. Section 32.1-162.12 of the Code of Virginia directs the Board of Health to promulgate regulations with minimum standards for informed consent contract, the qualifications and supervision of licensed and non-licensed personnel, a complaint procedure for consumers, the provision and coordination of treatment and services provided by the organization, clinical records kept by the organization, utilization and quality control review procedures and arrangements for the continuing evaluation of the quality of care provided. Executive Order 17 (2014) requires that every existing state regulation be reviewed at least once every four years by the promulgating agency. Pursuant to that order VDH conducted a periodic review of 12VAC5-381 in March of 2015. This regulatory action is necessary in order for the regulatory chapter to be in compliance with the general principles of Executive Order 17 (2014), which requires that regulations be clearly written and easily understandable and that regulations shall be designed to achieve their intended objective in the most efficient, and cost effective manner.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

In March of 2015, VDH conducted a periodic review of 12VAC5-381, "Regulations for Licensure of Home Care Organizations." As a result of the review, VDH determined it was necessary to use the regulatory process to amend these regulations. It is necessary to amend these regulations as the regulatory chapter has not been comprehensively revised in over a decade. The regulatory action is essential to protect the health safety and welfare of citizens as 12VAC5-381 is currently out of date and contains several inaccuracies. This proposed regulatory action shall correct any inaccuracies, bring the regulatory action up to date, clarify certain requirements and insert additional best practices.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

The provider community is aware that the current regulations are out of date and in need of correction and update. Further the provider community was consulted in the creation of this regulatory action and has provided input and feedback regarding the proposed amendments. For these reasons, VDH believes the regulatory action will be noncontroversial.

Substance

Please 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.

Definitions – Words which are not used in the regulatory chapter were removed from the definition section. A few corrections were made and a few necessary terms were added such as adverse event, medication management, office and skilled services director.

License – Clarification that all HCOs must also obtain a business license by the State Corporation Commission and that the addition of branch offices requires the reissuance of a license.

Exemption from licensure – Clarification that all agencies must first obtain state licensure and provide services to clients before applying for national accreditation or federal certification.

Location – New section, which requires that HCOs be located in business or commercial zones. The section permits a one year grace period for each HCO to ensure compliance with this section.

License application; initial and renewal – Removal of the pre-licensure consultation language as this service is no longer provided. Clarification of the minimum filing requirements for licensure application.

Compliance appropriate for all types of HCOs- Repeal of this section as it is unnecessary.

Changes to or reissue of a license – Addition of the necessity for reissuance of a license in the event of addition or removal of a branch office or the addition or removal of skilled services.

Fees – Update to the fee structure due to increased costs of the program; Clarification that all fees are nonrefundable.

On-site inspection – Clarification of the requirements of the initial survey; retooling of inspection schedule; clarification of the requirement that the administrator, nursing director or their designated alternate be available at the time of the surveyor's arrival.

Criminal records checks – Minor clarifying language.

Variances – Update of the section; clarification that variances are temporary in nature.

Violation of This Chapter or Applicable Law; Denial, Revocation, or Suspension of License- Update of the section.

Discontinuation of services – Removal of subsections which are repetitive of other sections; minor clarifying language.

Management and administration – Clarification of which changes to an organization require reissuance of a license; clarification of the posting of a license.

Administrator – Clarification of the prerequisites of an administrator and the administrator's responsibilities.

Written policies and procedures – Minor clarifying language including an update required due to legislation.

Financial controls – Addition of the requirement that the organization maintain records of a working budget throughout operations. Removal of the requirement that an independent CPA audit an organization triennially. This change reflects internal VDH OLC policy.

Personnel practices – Minor clarifying language; clarification regarding the documentation requirement of criminal record checks of employees that work in multiple locations.

Indemnity coverage – Minor clarifying language.

Contract services- Minor clarifying language.

Client rights – Addition of the requirement that each HCO have a procedure regarding a client’s opportunity to offer feedback and input regarding services provided by the assigned home care attendants.

Handling complaints received from clients – Minor clarifying language.

Quality improvement – Minor clarifying language.

Drop sites – Addition of the clarifying language that drop sites shall not be separately licensed.

Client record system- Addition of the requirement that informed consent and information regarding medication errors and drugs reactions must be kept within a client's record. Update that notes on the care or services provided by home attendants be incorporated into the client record within fourteen working days.

Home attendants – Update to reflect changes to the Department of Medical Assistance Services Personal Care Aide Training Curriculum.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.

The primary advantages of the regulatory action to the public are increased health and safety protections at home care organizations. The primary disadvantage to the public associated with the regulatory action is some home care organizations may need to change some of their current operating policies and procedures. This may cause a financial impact on these facilities. That financial impact might be passed on to the facilities' patients. VDH does not foresee any additional disadvantages to the public. The primary advantage to the agency and the Commonwealth is the promotion of public health and safety. There are no disadvantages associated with the proposed regulatory action in relation to the agency or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.

There are no requirements in this proposal that exceed federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No locality will be particularly affected by the proposed regulatory action.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please 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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.

Section 32.1-162.12 of the Code of Virginia directs the Board to promulgate regulations governing the activities and services provided by home care organizations as may be necessary to protect the public health, safety and welfare. Section 32.1-162.12 of the Code of Virginia directs the Board of Health to promulgate regulations with minimum standards for informed consent contract, the qualifications and supervision of licensed and non-licensed personnel, a complaint procedure for consumers, the provision and coordination of treatment and services provided by the organization, clinical records kept by the organization, utilization and quality control review procedures and arrangements for the continuing evaluation of the quality of care provided. Executive Order 17 (2014) requires that every existing state regulation be reviewed at least once every four years by the promulgating agency. Pursuant to that order VDH conducted a periodic review of 12VAC5-381 in March of 2015. This regulatory action is necessary in order for the regulatory chapter to be in compliance with the general principles of Executive Order 17 (2014), which requires that regulations be clearly written and easily understandable and that regulations shall be designed to achieve their intended objective in the most efficient, and cost effective manner. The regulations are mandated by law, the review of the regulations is mandated by law and there are no viable alternatives to the proposed regulatory action to achieve the necessary regulatory changes as determined by the regulatory review.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	None
Projected cost of the new regulations or changes to existing regulations on localities.	None
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Licensed home care organizations throughout the Commonwealth, patients served by licensed home care organizations throughout the Commonwealth
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are approximately 1,200 home care organizations within the Commonwealth of Virginia. Approximately 80-85% of home care organizations qualify as small businesses.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the**	VDH believes the projected costs associated with the proposed regulatory changes will be minimal for most HCOs. The projected changes will require minimal additional recordkeeping and other administrative costs. There will be costs associated with the relocation of for those HCOs currently located within residentially zoned areas. Those facilities will be required to relocate.

proposed regulatory changes or new regulations.	
Beneficial impact the regulation is designed to produce.	This regulatory action is designed to promote and ensure the health and safety of patients who receive services from home care organizations.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

Section 32.1-162.12 of the Code of Virginia directs the Board to promulgate regulations governing the activities and services provided by home care organizations as may be necessary to protect the public health, safety and welfare. Section 32.1-162.12 of the Code of Virginia directs the Board of Health to promulgate regulations with minimum standards for informed consent contract, the qualifications and supervision of licensed and non-licensed personnel, a complaint procedure for consumers, the provision and coordination of treatment and services provided by the organization, clinical records kept by the organization, utilization and quality control review procedures and arrangements for the continuing evaluation of the quality of care provided. Executive Order 17 (2014) requires that every existing state regulation be reviewed at least once every four years by the promulgating agency. Pursuant to that order VDH conducted a periodic review of 12VAC5-381 in March of 2015. This regulatory action is necessary in order for the regulatory chapter to be in compliance with the general principles of Executive Order 17 (2014), which requires that regulations be clearly written and easily understandable and that regulations shall be designed to achieve their intended objective in the most efficient, and cost effective manner. The regulations are mandated by law, the review of the regulations is mandated by law and there are no viable alternatives to the proposed regulatory action to achieve the necessary regulatory changes as determined by the regulatory review.

Public participation notice

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.

Periodic review and small business impact review report of findings

If this fast-track is the result of a periodic review/small business impact review, use this form to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates,

or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Commenter	Comment	Agency response
Christy Glynn	Reporting unlicensed HCO aides To my knowledge there is currently no avenue offered to report unlicensed home care aides, also referred to as Personal Care aides (PCA) or Nurse Aides (NAs) that have never tested with the Board of Nursing or other state goverened reporting agency. OLC requires agencies to have a policy for reporting licensed employees, however, home care employees delivering unskilled home care support/companion/custodial services are not required to be state licensed and there should not be such requirement. Should a PCA commit a reportable offense that would be reportable if they were otherwise licensed, who should oversee this level of home care companion reporting?	VDH Office of Licensure and Certification (OLC) regulations have provisions regarding personnel practices (12VAC5-381-200), which include mandated reporting of abuse, neglect, and exploitation, client rights (12VAC5-381-230), which include a provision requiring the facilities policies and procedures ensure each client is free from mental and physical abuse, neglect and property exploitation, and several provisions regarding the handling of complaints (12VAC5-381-30, 12VAC5-381-100, 12VAC5-381-150, 12VAC5-381-180, 12VAC5-381-230, and 12VAC5-381-240). In addition, the regulations require that every home care organization client be provided with information regarding how to contact the State Ombudsman (12VAC5-381-240 (C)(2)). VDH OLC believes these protections address the commenter's concerns.
Christy Glynn, Team Nurse, Inc.	**12VAC5-381-360. Personal Care Services. Clarify LPN role for Supervisory visits** Current wording: ***F. A registered nurse or licensed practical nurse shall be available during all hours that personal care services are being provided.*** ***Comment***.....Would like a clear description/role of the LPN involving supervision of home care cases with personal care aides (PCAs), nurse aides (NAs), certified nurse adies (CNAs) following the (registered nurse) RNs directed Plan of Care (POC). DMAS has outlined supervisory notes somewhat clarifying the LPN role with certain supervisory visits. With Licensure there needs to be clarification regarding the LPN's role with consideration to current DMAS language. This makes it less confusing since both DMAS and Licensure play daily roles with the actual delivery of services for home	VDH OLC believes the amendment to 12VAC5-381-360 (E) provides the clarification that the commenter is looking for. That amendment is provided here for clarity. E. Supervision of ~~services~~ home attendants shall be provided as often as necessary ~~as determined by the client's needs, the assessment of the registered nurse, and~~ according to the organization's written policies not to exceed ~~90~~ 120 days. Such supervision may be provided by a qualified licensed practical nurse.

	care throughout VA. Below is current information for DMAS..... **DEPARTMENT OF MEDICAL ASSISTANCE** Title of Regulation: **12VAC30-120. Waivered Services (amending 12VAC30-120-900, 12VAC30-120-920, 12VAC30-120-925, 12VAC30-120-930; adding 12VAC30-120-905, 12VAC30-120-924, 12VAC30-120-935, 12VAC30-120-945, 12VAC30-120-990, 12VAC30-120-995; repealing 12VAC30-120-910, 12VAC30-120-940 through 12VAC30-120-980).** Statutory Authority: § 32.1-325 of the Code of Virginia; 42 USC § 1396 et seq. Effective Date: February 12, 2015. Specifically: **12VAC30-120-935. Participation standards for specific covered services.** F. Agency-directed personal care services. The personal care provider agency shall hire or contract with and directly supervise a RN who provides ongoing supervision of all personal care aides and LPNs. LPNs may supervise, pursuant to their licenses, personal care aides based upon RN assessment of the waiver individuals' health, safety, and welfare needs. ***Comment***: this is not the complete standard as there is addtional information with the DMAS reg. Thank you for your time with review of my comment. Any clarification or guidance you offer me is greatly appreciated if I have not reviewed all of the OLC HCO regulation to support this comment.	

Following the amendments proposed in this regulatory action the regulation shall meet the criteria set out in Executive Order 17 (2014). The regulation is mandated by law. The Virginia Department of Health is not aware of any complaints concerning the regulation from the public. Following the amendments proposed in this regulatory action the regulation shall be written as plainly as possible. The regulation does not overlap, duplicate or conflict with federal or state law or regulation. The regulations have been evaluated in the recent periodic review as to whether technology, economic conditions or other factors have changed in the area affected by the regulation; in areas where there are changes the Virginia Department of Health has suggested amendment.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

VDH does not anticipate any impact on the institution of the family and family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
10 – Definitions		The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise: "Activities of daily living" or "ADLs" means bathing, dressing, toileting, transferring, bowel control, bladder control and eating/feeding. A person's degree of independence in performing these activities is part of determining the appropriate level of care and services. A need for assistance exists when the client is unable to complete an activity due	The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise: "Activities of daily living" or "ADLs" means bathing, dressing, toileting, transferring, bowel control, bladder control and eating/feeding. A person's degree of independence in performing these activities is part of determining the appropriate level of care and services. A need for assistance exists when the client is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's functional level is based on the client's need for assistance most or all of the time to perform personal care tasks in order to live independently. "Administer" means the direct application of a controlled

		to cognitive impairment, functional disability, physical health problems, or safety. The client's functional level is based on the client's need for assistance most or all of the time to perform personal care tasks in order to live independently. "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a client by (i) a practitioner or by his authorized agent and under his direction or (ii) the client at the direction and in the presence of the practitioner as defined in § 54.1-3401 of the Code of Virginia. "Administrator" means a person designated in writing by the governing body as having the necessary authority for the day-to-day management of the organization. The administrator must be an employee of the organization. The administrator, the director of nursing, or other clinical director may be the same individual if that individual is dually qualified. "Available at all times during operating hours" means an individual is readily available on the premises or by telecommunications. "Barrier crimes" means certain offenses, specified in § 32.1-162.9:1 of the Code of Virginia, that automatically bar an	substance, whether by injection, inhalation, ingestion or any other means, to the body of a client by (i) a practitioner or by his authorized agent and under his direction or (ii) the client at the direction and in the presence of the practitioner as defined in § 54.1-3401 of the Code of Virginia. "Administrator" means a person designated in writing by the governing body as having the necessary authority for the day-to-day management of the organization. The administrator must be an employee of the organization. The administrator, the director of ~~nursing~~ skilled services, or other clinical director may be the same individual if that individual is dually qualified. "Adverse event" means the result of drug or health care therapy that is neither intended nor expected in normal therapeutic use and that causes significant, sometimes life-threatening conditions or consequence at some future time. Such potential future adverse outcome may require the arrangement for appropriate follow-up surveillance and perhaps other departures from the usual plan of care. "Available at all times during operating hours" means an individual is readily available on the premises or by telecommunications. "Barrier crimes" means certain offenses, specified in § 32.1-162.9:1 of the Code of Virginia, that automatically bar an individual convicted of those offenses from employment with a home care organization. "Blanket fidelity bond" means a bond that provides coverage that protects an organization's losses as a result of employee theft or fraud. "Branch office" means a geographically separate office of the home care organization that performs all or part of the primary functions of the home care

		individual convicted of those offenses from employment with a home care organization. "Blanket fidelity bond" means a bond that provides coverage that protects an organization's losses as a result of employee theft or fraud. "Branch office" means a geographically separate office of the home care organization that performs all or part of the primary functions of the home care organization on a smaller scale. "Chore services" means assistance with nonroutine, heavy home maintenance for persons unable to perform such tasks. Chore services include minor repair work on furniture and appliances; carrying coal, wood and water; chopping wood; removing snow; yard maintenance; and painting. "Client record" means the centralized location for documenting information about the client and the care and services provided to the client by the organization. A client record is a continuous and accurate account of care or services, whether hard copy or electronic, provided to a client, including information that has been dated and signed by the individuals who prescribed or delivered the care or service. "Client's residence" means the place where the individual or client makes his home such as	organization on a smaller scale. "Chore services" means assistance with nonroutine, heavy home maintenance for persons unable to perform such tasks. Chore services include minor repair work on furniture and appliances; carrying coal, wood and water; chopping wood; removing snow; yard maintenance; and painting. "Client record" means the centralized location for documenting information about the client and the care and services provided to the client by the organization. A client record is a continuous and accurate account of care or services, whether hard copy or electronic, provided to a client, including information that has been dated and signed by the individuals who prescribed or delivered the care or service. ~~"Client's residence" means the place where the individual or client makes his home such as his own apartment or house, a relative's home or an assisted living facility, but does not include a hospital, nursing facility or other extended care facility.~~ "Commissioner" means the State Health Commissioner. "Companion services" means assisting persons unable to care for themselves without assistance. Companion services include transportation, meal preparation, shopping, light housekeeping, companionship, and household management. "Contract services" means services provided through agreement with another agency, organization, or individual on behalf of the organization. The agreement specifies the services or personnel to be provided on behalf of the organization and the fees to provide these services or personnel. "Criminal record report" means the statement issued by the Central Criminal Record Exchange, Virginia Department of State Police. "Department" means the Virginia

		his own apartment or house, a relative's home or an assisted living facility, but does not include a hospital, nursing facility or other extended care facility. "Commissioner" means the State Health Commissioner. "Companion services" means assisting persons unable to care for themselves without assistance. Companion services include transportation, meal preparation, shopping, light housekeeping, companionship, and household management. "Contract services" means services provided through agreement with another agency, organization, or individual on behalf of the organization. The agreement specifies the services or personnel to be provided on behalf of the organization and the fees to provide these services or personnel. "Criminal record report" means the statement issued by the Central Criminal Record Exchange, Virginia Department of State Police. "Department" means the Virginia Department of Health. "Discharge or termination summary" means a final written summary filed in a closed client record of the service delivered, goals achieved and final disposition at the time of client's discharge or termination from service. "Dispense" means to deliver a drug to an	Department of Health. ~~"Discharge or termination summary" means a final written summary filed in a closed client record of the service delivered, goals achieved and final disposition at the time of client's discharge or termination from service.~~ "Dispense" means to deliver a drug to an ultimate user by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery. "Drop site" means a location that HCO staff use in the performance of daily tasks such as obtaining supplies, using fax and copy machines, charting notes on care or services provided, and storing client records. These locations may also be called charting stations, workstations, or convenience sites. "Employee" means an individual who has the status of an employee as defined by the U.S. Internal Revenue Service. "Emergency management plan" means a plan developed by the organization to mitigate the damage of potential events that could endanger the organization's ability to function. "Functional limitations" means the level of a client's need for assistance based on an assessment conducted by the supervising nurse. There are three criteria to assessing functional status: (i) the client's impairment level and need for personal assistance, (ii) the client's lack of capacity, and (iii) how the client usually performed the activity over a period of time. If a person is mentally and physically free of impairment, there is not a safety risk to the individual, or the person chooses not to complete an activity due to personal preference or choice, then that person does not need assistance. "Governing body" means the

		ultimate user by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery. "Drop site" means a location that HCO staff use in the performance of daily tasks such as obtaining supplies, using fax and copy machines, charting notes on care or services provided, and storing client records. These locations may also be called charting stations, workstations, or convenience sites. "Employee" means an individual who has the status of an employee as defined by the U.S. Internal Revenue Service. "Functional limitations" means the level of a client's need for assistance based on an assessment conducted by the supervising nurse. There are three criteria to assessing functional status: (i) the client's impairment level and need for personal assistance, (ii) the client's lack of capacity, and (iii) how the client usually performed the activity over a period of time. If a person is mentally and physically free of impairment, there is not a safety risk to the individual, or the person chooses not to complete an activity due to personal preference or choice, then that person does not need assistance. "Governing body" means	individual, group or governmental agency that has legal responsibility and authority over the operation of the home care organization. "Home attendant" means a nonlicensed individual performing ~~skilled,~~ pharmaceutical and personal care services, under the supervision of the appropriate health professional, to a client in the client's residence. Home attendants are also known as ~~certified nurse aides or CNAs,~~ home care aides, home health aides, or personal care aides. "Home care organization" or "HCO" or "organization" means a public or private entity providing an organized program of home health, pharmaceutical or personal care services, according to § ~~32.1-162.1~~ 32.1-162.7 of the Code of Virginia in the residence of a client or individual to maintain the client's health and safety in his home. A home care organization does not include any family members, relatives or friends providing caregiving services to persons who need assistance to remain independent and in their own homes. "Home health agency" means a public or private agency or organization, or part of an agency or organization, that meets the requirements for participation in Medicare under 42 CFR 440.70 (d), by providing skilled nursing services and at least one other therapeutic service, for example, physical, speech, or occupational therapy; medical social services; or home health aide services, and also meets the capitalization requirements under 42 CFR 489.28. "Homemaker services" means assistance to persons with the inability to perform one or more instrumental activities of daily living. Homemaker services may also include assistance with bathing areas the client cannot reach, fastening client's clothing, combing hair, brushing dentures, shaving

		the individual, group or governmental agency that has legal responsibility and authority over the operation of the home care organization. "Home attendant" means a nonlicensed individual performing skilled, pharmaceutical and personal care services, under the supervision of the appropriate health professional, to a client in the client's residence. Home attendants are also known as certified nurse aides or CNAs, home care aides, home health aides, or personal care aides. "Home care organization" or "HCO" means a public or private entity providing an organized program of home health, pharmaceutical or personal care services, according to § 32.1-162.1 of the Code of Virginia in the residence of a client or individual to maintain the client's health and safety in his home. A home care organization does not include any family members, relatives or friends providing caregiving services to persons who need assistance to remain independent and in their own homes. "Home health agency" means a public or private agency or organization, or part of an agency or organization, that meets the requirements for participation in Medicare under 42 CFR 440.70 (d), by providing skilled nursing services and at	with an electric razor, and providing stabilization to a client while walking. Homemaker services do not include feeding, bed baths, transferring, lifting, putting on braces or other supports, cutting nails or shaving with a blade. "Infusion therapy" means the procedures or processes that involve the administration of injectable medications to clients via the intravenous, subcutaneous, epidural, or intrathecal routes. Infusion therapy does not include oral, enteral, or topical medications. "Instrumental activities of daily living" means meal preparation, housekeeping/light housework, shopping for personal items, laundry, or using the telephone. A client's degree of independence in performing these activities is part of determining the appropriate level of care and services. "Licensed practical nurse" means a person who holds a current license issued by the Virginia Board of Nursing or a current multistate licensure privilege to practice nursing in Virginia as a licensed practical nurse. "Licensee" means a licensed home care provider. "Medical plan of care" means a written plan of services, and items needed to treat a client's medical condition, that is prescribed, signed and periodically reviewed by the client's primary care physician. <u>"Medication management" means the monitoring of medications that a patient takes to confirm that he is complying with a medication regimen, while also ensuring the patient is avoiding potentially dangerous drug interactions and other complications.</u> "Nursing services" means client care services, including, but not limited to, the curative, restorative, or preventive aspects of nursing that are performed or supervised by a registered nurse according to a medical plan of care.

		least one other therapeutic service, for example, physical, speech, or occupational therapy; medical social services; or home health aide services, and also meets the capitalization requirements under 42 CFR 489.28. "Homemaker services" means assistance to persons with the inability to perform one or more instrumental activities of daily living. Homemaker services may also include assistance with bathing areas the client cannot reach, fastening client's clothing, combing hair, brushing dentures, shaving with an electric razor, and providing stabilization to a client while walking. Homemaker services do not include feeding, bed baths, transferring, lifting, putting on braces or other supports, cutting nails or shaving with a blade. "Infusion therapy" means the procedures or processes that involve the administration of injectable medications to clients via the intravenous, subcutaneous, epidural, or intrathecal routes. Infusion therapy does not include oral, enteral, or topical medications. "Instrumental activities of daily living" means meal preparation, housekeeping/light housework, shopping for personal items, laundry, or using the telephone. A client's degree of independence in performing these activities is part of	"Office" means a place where business is conducted. A home care organization office is a place where client records, employee personnel files, financial records and the organization's policies and procedures are stored. "OLC" means the Office of Licensure and Certification of the Virginia Department of Health. "Operator" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity that is responsible for the day-to-day administrative management and operation of the organization. ~~"Organization" means a home care organization.~~ "Person" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity that operates a home care organization. "Personal care services" means the provision of nonskilled services, including assistance in the activities of daily living, and may include instrumental activities of daily living, related to the needs of the client, who has or is at risk of an illness, injury or disabling condition. A need for assistance exists when the client is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's functional level is based on the client's need for assistance most or all of the time to perform the tasks of daily living in order to live independently. "Primary care physician" means a physician licensed in Virginia, according to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia, or licensed in an adjacent state and identified by the client as having the primary responsibility in determining the delivery of the client's medical care. The responsibility of physicians contained in this chapter may be

		determining the appropriate level of care and services. "Licensed practical nurse" means a person who holds a current license issued by the Virginia Board of Nursing or a current multistate licensure privilege to practice nursing in Virginia as a licensed practical nurse. "Licensee" means a licensed home care provider. "Medical plan of care" means a written plan of services, and items needed to treat a client's medical condition, that is prescribed, signed and periodically reviewed by the client's primary care physician. "Nursing services" means client care services, including, but not limited to, the curative, restorative, or preventive aspects of nursing that are performed or supervised by a registered nurse according to a medical plan of care. "OLC" means the Office of Licensure and Certification of the Virginia Department of Health. "Operator" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity that is responsible for the day-to-day administrative management and operation of the organization. "Organization" means a home care organization.	implemented by nurse practitioners or physician assistants as assigned by the supervising physician and within the parameters of professional licensing. "Qualified" means meeting current legal requirements of licensure, registration or certification in Virginia or having appropriate training, including competency testing, and experience commensurate with assigned responsibilities. "Quality improvement" means ongoing activities designed to objectively and systematically evaluate the quality of client care and services, pursue opportunities to improve client care and services, and resolve identified problems. Quality improvement is an approach to the ongoing study and improvement of the processes of providing health care services to meet the needs of clients and others. "Registered nurse" means a person who holds a current license issued by the Virginia Board of Nursing or a current multistate licensure privilege to practice nursing in Virginia as a registered nurse. "Service area" means a clearly delineated geographic area in which the organization arranges for the provision of home care services, personal care services, or pharmaceutical services to be available and readily accessible to persons. "Skilled services" means ~~the provision of the home health~~ those services listed in 12VAC5-381-300. "Skilled services director" means a physician or registered nurse who is an employee of the organization and responsible for overseeing the overall direction and management of skilled services. The administrator and the skilled services director may be the same individual if that individual is dually qualified. "Supervision" means the ongoing

		"Person" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity that operates a home care organization. "Personal care services" means the provision of nonskilled services, including assistance in the activities of daily living, and may include instrumental activities of daily living, related to the needs of the client, who has or is at risk of an illness, injury or disabling condition. A need for assistance exists when the client is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's functional level is based on the client's need for assistance most or all of the time to perform the tasks of daily living in order to live independently. "Primary care physician" means a physician licensed in Virginia, according to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia, or licensed in an adjacent state and identified by the client as having the primary responsibility in determining the delivery of the client's medical care. The responsibility of physicians contained in this chapter may be implemented by nurse practitioners or physician assistants as assigned by the supervising physician and within the	process of monitoring the skills, competencies and performance of the individual supervised and providing regular, documented, face-to-face guidance and instruction. "Sworn disclosure statement" means a document disclosing an applicant's criminal convictions and pending criminal charges occurring in Virginia or any other state. "Third-party crime insurance" means insurance coverage that protects an organization's losses as a result of employee theft or fraud. Intent: Removal of unnecessary terms, including those which are not used within the regulatory chapter or the definition is used within the regulatory chapter. Insertion of new terms which will clarify certain provisions of the regulatory chapter. Likely impact: Greater clarity of the regulatory chapter and less burdensome regulations.

		parameters of professional licensing. "Qualified" means meeting current legal requirements of licensure, registration or certification in Virginia or having appropriate training, including competency testing, and experience commensurate with assigned responsibilities. "Quality improvement" means ongoing activities designed to objectively and systematically evaluate the quality of client care and services, pursue opportunities to improve client care and services, and resolve identified problems. Quality improvement is an approach to the ongoing study and improvement of the processes of providing health care services to meet the needs of clients and others. "Registered nurse" means a person who holds a current license issued by the Virginia Board of Nursing or a current multistate licensure privilege to practice nursing in Virginia as a registered nurse. "Service area" means a clearly delineated geographic area in which the organization arranges for the provision of home care services, personal care services, or pharmaceutical services to be available and readily accessible to persons. "Skilled services" means the provision of the home health services	

		listed in12VAC5-381-300. "Supervision" means the ongoing process of monitoring the skills, competencies and performance of the individual supervised and providing regular, documented, face-to-face guidance and instruction. "Sworn disclosure statement" means a document disclosing an applicant's criminal convictions and pending criminal charges occurring in Virginia or any other state. "Third-party crime insurance" means insurance coverage that protects an organization's losses as a result of employee theft or fraud.	
20 – License		A. A license to operate a home care organization is issued to a person. However, no license shall be issued to a person who has been sanctioned pursuant to 42 USC § 1320a-7b. Persons planning to seek federal certification or national accreditation pursuant to § 32.1-162.8 of the Code of Virginia must first obtain state licensure. B. The commissioner shall issue or renew a license to establish or operate a home care organization if the commissioner finds that the home care organization is in compliance with the law and this regulation. C. The commissioner may issue a license to a home care organization authorizing the licensee	A. A license to operate a home care organization is issued to a person by the department. Such license shall be in addition to any business license required by the State Corporate Commission or by any Virginia locality. ~~However, no~~ No license shall be issued to a person who has been sanctioned pursuant to 42 USC § 1320a-7b. Persons planning to seek federal certification or national accreditation pursuant to § 32.1-162.8 of the Code of Virginia must first obtain state licensure. B. The commissioner shall issue or renew a license to establish or operate a home care organization if the commissioner finds that the home care organization is in compliance with the law and this regulation. C. The commissioner may issue a license to a ~~home care organization~~ person authorizing the licensee to provide services at one or more branch offices serving portions of the total geographic area

		to provide services at one or more branch offices serving portions of the total geographic area served by the licensee, provided each branch office operates under the supervision and administrative control of the licensee. The address of each branch office at which services are provided by the licensee shall be included on any license issued to the licensee. D. Every home care organization shall be designated by an appropriate name. The name shall not be changed without first notifying the OLC. E. Licenses shall not be transferred or assigned. F. Any person establishing, conducting, maintaining, or operating a home care organization without a license shall be guilty of a Class 6 felony according to §32.1-162.15 of the Code of Virginia.	served by the licensee, provided each branch office operates under the supervision and administrative control of the licensee. The address of each branch office at which services are provided by the licensee shall be included on any license issued to the licensee. <u>The addition of a branch office shall require a survey of the new branch location and the reissuance of the organization's license.</u> D. Every home care organization shall be designated by an appropriate name. The name shall not be changed without first notifying the OLC. E. Licenses shall not be transferred or assigned. F. Any person establishing, conducting, maintaining, or operating a home care organization without a license shall be guilty of a Class 6 felony according to § 32.1-162.15 of the Code of Virginia. <u>G. Any person establishing, conducting, maintaining, or operating a home care organization shall obtain the required business license(s) from the State Corporation Commission and if required by any Virginia locality.</u> Intent: Clarification that each home care organization requires a business license by the State Corporation Commission in addition to the license acquired by the Virginia Department of Health. Clarification that the addition of branch offices requires reissuance of a license. Likely impact: Greater clarity of the regulations.
30 – Exemption from licensure		A. This chapter is not applicable to those individuals and home care organizations listed in § 32.1-162.8 of the Code of Virginia. Organizations planning to seek federal certification as a home	A. This chapter is not applicable to those individuals and home care organizations listed in § 32.1-162.8 of the Code of Virginia. ~~Organizations planning to seek federal certification as a home health agency or national accreditation must first obtain state licensure and provide services to~~

		health agency or national accreditation must first obtain state licensure and provide services to clients before applying for national accreditation or federal certification. In addition, this chapter is not applicable to those providers of only homemaker, chore or companion services as defined in 12VAC5-381-10. B. A licensed organization requesting exemption must file a written request and pay the required fee stated in 12VAC5-381-70 D. C. The home care organization shall be notified in writing if the exemption from licensure has been granted. The basis for the exemption approval will be stated and the organization will be advised to contact the OLC to request licensure should it no longer meet the requirement for exemption. D. Exempted organizations are subject to complaint investigations in keeping with state law.	~~clients before applying for national accreditation or federal certification.~~ In addition, this chapter is not applicable to those providers of only homemaker, chore or companion services as defined in 12VAC5-381-10. B. Organizations planning to seek federal certification as a home health agency or national accreditation must first obtain state licensure and provide services to clients before applying for national accreditation or federal certification. Upon receiving national accreditation or federal certification an organization may be exempted from maintaining a state license. A licensed organization requesting this exemption must file a written request and pay the required fee stated in 12VAC5-381-70 (D). C. The home care organization shall be notified in writing if the exemption from licensure listed in 12VAC5-381-30 (B) has been granted. The basis for the exemption ~~approval~~ decision will be stated and the organization ~~will~~shall be advised to contact the OLC to request licensure should it no longer meet the requirement for exemption. D. ~~Exempted organizations~~ Organizations exempted from licensure under 12VAC5-381-30 (B) are subject to complaint investigations in keeping with state law. Should a complaint investigation prove an exempted organization's noncompliance with state regulations, the OLC shall notify the authority responsible for the organization's accreditation or certification. Intent: Clarify the requirements of licensure exemption in the case of federal certification. Likely impact: Greater clarity of the regulations.

35 – Location		N/A	The offices of a home care organization shall be located in a building that is zoned for business or commercial use. Offices shall not be located in residentially zoned areas. Entities licensed as of the effective date of this section with offices located within residentially zoned areas shall have one year to come into compliance with this section. Intent: Some home care organizations are currently operated out of personal residences. This creates a number of concerns regarding the safety of patient records and accessibility of the office for patients or family members. Provision of a one year grace period to come into compliance with this new requirement. Likely impact: Greater safety of patient records and providing greater accessibility to patients. Some facilities may be required to relocate.
40 – License application; initial and renewal.		A. The OLC provides prelicensure consultation and technical assistance regarding the licensure process. The purpose of such consultation is to explain the regulation and the survey process. Prelicensure consultations are arranged after a completed initial application is on file with the OLC. B. Licensure applications are obtained from the OLC. The OLC shall consider an application complete when all requested information and the appropriate fee, stated in 12VAC5-381-70, is submitted. If the OLC finds the application incomplete, the applicant will be notified in writing.	A. ~~The OLC provides prelicensure consultation and technical assistance regarding the licensure process. The purpose of such consultation is to explain the regulation and the survey process. Prelicensure consultations are arranged after a completed initial application is on file with the OLC.~~ Licensure applications can be found on the OLC's website. B. ~~Licensure applications are obtained from the OLC. The OLC shall consider an application complete when all requested information and the appropriate fee, stated in 12VAC5-381-70, is submitted. If the OLC finds the application incomplete, the applicant will be notified in writing.~~ Applicants for initial licensure must at a minimum file the following documentation in order for an application to be considered complete:

		C. The activities and services of each applicant and licensee shall be subject to an inspection by the OLC to determine if the organization is in compliance with the provisions of this chapter and state law. D. A completed application for initial licensure must be submitted at least 60 days prior to the organization's planned opening date to allow the OLC time to process the application. An incomplete application shall become inactive six months after it is received by the OLC. Applicants must then reapply for licensure with a completed application and application fee. An application for a license may be withdrawn at any time. E. Licenses are renewed annually. The OLC shall make renewal applications available at least 60 days prior to the expiration date of the current license. F. It is the home care organization's responsibility to complete and return a renewal application to assure timely processing. Should a current license expire before a new license is issued, the current license shall remain in effect provided a complete and accurate application was filed on time.	1. An application obtained from the OLC; 2. The initial licensure fee of $600; 3. The required business license(s) from the State Corporation Commission or by any Virginia locality; 4. A list of the governing body members and organizing documents; 5. Evidence of the administrator's qualifications; 6. Evidence of indemnity coverage; 7. The organization's client rights policies and procedures; 8. Job descriptions of the administrator, nursing director and financial manager; 9. A copy of the organization's business plan, and working budget; and 10. Evidence of the financial controls required by 12VAC5-381-190. The OLC reserves the right to request additional documentation before considering an initial licensure application complete. C. The activities and services of each applicant and licensee shall be subject to an inspection by the OLC to determine if the organization is in compliance with the provisions of this chapter and state law. Applicants for initial licensure shall be notified of the time and date of the initial survey. D. A completed application for initial licensure must be submitted at least 60 days prior to the organization's planned opening date to allow the OLC time to process the application. If the OLC finds the application incomplete, the applicant shall be notified in writing. An incomplete application shall become inactive ~~six months~~ 30 days after ~~it is received by the OLC~~the OLC's written notification. Applicants with an inactive application must ~~then~~ reapply for

			licensure with a completed application and application fee. An application for a license may be withdrawn at any time. E. ~~Licenses are renewed annually. The OLC shall make~~ Annual renewal applications ~~available~~ shall be submitted by the organization at least 60 days prior to the expiration date of the current license. F. Providers failing to submit an acceptable plan of correction as required in 12VAC5-381-80 shall not be eligible for license renewal. Failure to submit a plan of correction shall be grounds for denial, suspension, or revocation of the facility's license in accordance with in 12VAC5-381-130. ~~F~~G. It is the home care organization's responsibility to complete and return a renewal application to assure timely processing. Should a current license expire before a new license is issued, the current license shall remain in effect provided a complete and accurate application was filed on time. Intent: Removal of the language regarding prelicensure consultation as VDH OLC no longer has the resources to provide this service. Clarification of the necessary minimum filing requirements in order for an application to be considered complete. Clarification that providers who have not provided an acceptable plan of correction are not eligible for license renewal. Likely impact: Greater clarity of the regulations.
50 – Compliance Appropriate for All Types of Hcos.		All organizations shall be in compliance with Part I (12VAC5-381-10 et seq.) and Part II (12VAC5-381-150 et seq.) of this chapter. In addition, organizations shall be in compliance with Part III (12VAC5-381-300 et	~~**12VAC5-381-50. Compliance appropriate for all types of HCOs.** **(Repealed.)**~~ ~~All organizations shall be in compliance with Part I (12VAC5-381-10 et seq.) and Part II (12VAC5-381-150 et seq.) of this chapter. In addition, organizations shall be in compliance with Part III~~

		seq.), Part IV (12VAC5-381-350), or Part V (12VAC5-381-360 et seq.) of this chapter as applicable to the services provided by the organization.	~~(12VAC5-381-300 et seq.), Part IV (12VAC5-381-350), or Part V (12VAC5-381-360 et seq.) of this chapter as applicable to the services provided by the organization.~~ Intent: Repeal an unnecessary section. Likely impact: Less burdensome regulations.
60 – Changes to or Reissue of a License		A. It is the responsibility of the organization's governing body to maintain a current and accurate license. Licenses that are misplaced or lost must be replaced. B. An organization shall give written notification 30 working days in advance of any proposed changes that may require the reissuance of a license. Notices shall be sent to the attention of the director of the OLC. The following changes require the reissuance of a license and payment of a fee: 1. Operator; 2. Organization name; or 3. Address. C. The OLC will evaluate written information about any planned changes in operation that affect the terms of the license or the continuing eligibility for a license. A licensing representative may inspect the organization during the process of evaluating a proposed change. D. The organization will be notified in writing whether a new application is needed.	A. It is the responsibility of the organization's governing body to maintain a current and accurate license. Licenses that are misplaced or lost must be ~~replaced~~reissued. B. An organization shall give written notification 30 working days ~~in advance of any proposed changes~~ prior to changes that ~~may~~ require the reissuance of a license. Notices shall be sent to the attention of the director of the OLC. The following changes require the reissuance of a license and payment of a fee: 1. Operator; 2. Organization name; ~~or~~ 3. Address~~.~~; 4. Addition or removal of a branch office; or 5. Addition or removal of skilled services. C. The OLC ~~will~~ shall evaluate written information about any planned changes in operation that affect the terms of the license or the continuing eligibility for a license. A licensing representative may inspect the organization during the process of evaluating a proposed change. D. The organization ~~will~~ shall be notified in writing whether a new application is needed. Intent: Clarify that when a facility adds or removes branch offices or skilled services the facility's license must be reissued. Likely impact: Greater clarity of the

			regulations.
70- Fees		A. The OLC shall collect a fee of $500 for each initial and renewal license application. Fees shall accompany the licensure application and are not refundable. B. An additional late fee of $50 shall be collected for an organization's failure to file a renewal application by the date specified. C. A processing fee of $250 shall be collected for each reissuance or replacement of a license and shall accompany the written request for reissuance or replacement. D. A one time processing fee of $75 for exemption from licensure shall accompany the written exemption request.	A. The OLC shall collect a fee of ~~$500~~ $600 for each initial and renewal license application. Fees shall accompany the licensure application ~~and are not refundable~~. B. An additional late fee of ~~$50~~ $100 shall be collected for an organization's failure to file a renewal application by the date specified. C. A processing fee of ~~$250~~$300 shall be collected for each reissuance or replacement of a license and shall accompany the written request for reissuance or replacement. D. A one-time processing fee of ~~$75~~ $125 for exemption from licensure shall accompany the written exemption request. E. All fees shall be nonrefundable. Intent: Amend the fees to more accurately reflect the cost of the licensure program. Clarify that fees are nonrefundable. Likely impact: Slight financial impact on the facilities.
80- On-site inspections.		A. An OLC representative shall make periodic unannounced on-site inspections of each home care organization as necessary but not less often than biennially. The organization shall be responsible for correcting any deficiencies found during any on-site inspection. Compliance with all standards will be determined by the OLC according to applicable law. B. The home care organization shall make available to the OLC's representative any necessary records and shall allow access to	A. Applicants for initial licensure shall be notified of the time and date of the initial survey. Failure to be fully prepared may result in the cancellation of the initial survey. In the event of the cancellation of the initial survey, the applicant shall wait 120 days before reapplying for an initial license. An applicant reapplying for licensure shall be required to submit all elements in 12VAC5-381-40 (B). ~~A.~~ B. An OLC representative shall make periodic unannounced on-site inspections of each home care organization as necessary but not less often than ~~biennially~~triennially. The organization shall be responsible for correcting any deficiencies found during any on-site inspection. Compliance with all standards ~~will~~shall be determined by the OLC according to applicable law.

		interview the agents, employees, contractors, and any person under the organization's control, direction or supervision. C. After the on-site inspection, the OLC's representative shall discuss the findings of the inspection with the administrator or his designee. D. The administrator shall submit, within 15 working days of receipt of the inspection report, an acceptable plan for correcting any deficiencies found. The plan of correction shall contain: 1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action; 2. The expected correction date; 3. A description of the measures implemented to prevent a recurrence of the violation; and 4. The signature of the person responsible for the validity of the report. E. The administrator will be notified whenever any item in the plan of correction is determined to be unacceptable. F. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained. G. Completion of corrective actions shall not exceed 45 working days from the last day of the inspection.	~~B.~~ C. The home care organization shall make available to the OLC's representative any necessary records and shall allow access to interview the agents, employees, contractors, and any person under the organization's control, direction or supervision. D. If the OLC's representative arrives on the premises to conduct a survey and the administrator, the nursing director, or a person authorized to give access to client records is not available on the premises, such person or the designated alternate shall be available on the premises within one hour of the surveyor's arrival. A list of current clients shall be provided to the surveyor within two hours of arrival, if requested. Failure to be available shall be grounds for penalties in accordance with § 32.1-27 of the Code of Virginia and denial, suspension, or revocation of the facility's license in accordance with 12VAC5-381-130. ~~C.~~ E. After the on-site inspection, the OLC's representative shall discuss the findings of the inspection with the administrator or his designee. ~~D.~~ F. The administrator shall submit, within 15 working days of receipt of the inspection report, an acceptable plan for correcting any deficiencies found. The plan of correction shall contain: 1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action; 2. The expected correction date; 3. A description of the measures implemented to prevent a recurrence of the violation; and 4. The signature of the person responsible for the validity of the report. ~~E.~~ G. The administrator will be notified whenever any item in the plan of correction is determined to be unacceptable.

			~~F.~~ H. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained. ~~G.~~ I. Completion of corrective actions shall not exceed 45 working days from the ~~last day of the inspection~~date the inspection report is received by the administrator as demonstrated by certified mail. Intent: Clarify the requirements of initial surveys. Clarify the repercussions should a facility be unprepared for an inspection. Clarify that inspections shall occur triennially. Likely impact: Greater clarity of the regulations. VDH OLC no longer has the resources to conduct inspections on a biennial basis therefore VDH is amending the regulation to reflect that inspections will occur on a triennial basis.
100 – Complaint investigations conducted by the OLC		A. The OLC has the responsibility to investigate any complaints regarding alleged violations of this chapter and applicable law. B. Complaints may be received in writing or orally and may be anonymous. C. When the investigation is complete, the licensee and the complainant, if known, will be notified of the findings of the investigation. D. As applicable, the administrator shall submit, within 15 working days of receipt of the complaint report, an acceptable plan of correction for any deficiencies found during a complaint investigation. The plan of correction shall contain:	A. The OLC has the responsibility to investigate any complaints regarding alleged violations of this chapter and applicable law. B. Complaints may be received in writing or orally and may be anonymous. C. When the investigation is complete, the licensee and the complainant, if known, will be notified of the findings of the investigation. D. As applicable, the administrator shall submit, within 15 working days of receipt of the complaint report, an acceptable plan of correction for any deficiencies found during a complaint investigation. The plan of correction shall contain: 1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action; 2. The expected correction date; 3. A description of the measures implemented to prevent a recurrence of the violation; and

		1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action; 2. The expected correction date; 3. A description of the measures implemented to prevent a recurrence of the violation; and 4. The signature of the person responsible for the validity of the report. E. The administrator will be notified in writing whenever any item in the plan of correction is determined to be unacceptable. F. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.	4. The signature of the person responsible for the validity of the report. E. The administrator ~~will~~ shall be notified ~~in writing~~ whenever any item in the plan of correction is determined to be unacceptable. F. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained. Intent: Slight technical amendment. Likely impact: None
110- Criminal Records Checks.		A. Section 32.1-162.9:1 of the Code of Virginia requires home care providers, as defined in § 32.1-162.7 of the Code of Virginia, to obtain a criminal record report on applicants for compensated employment from the Virginia Department of State Police. Section 32.1-162.9:1 of the Code of Virginia also requires that all applicants for employment in home care organizations provide a sworn disclosure statement regarding their criminal history. B. The criminal record report shall be obtained	A. Section 32.1-162.9:1 of the Code of Virginia requires home care providers, as defined in § 32.1-162.7 of the Code of Virginia, to obtain a criminal record report on applicants for compensated employment from the Virginia Department of State Police. ~~Section 32.1-162.9:1 of the Code of Virginia also requires that all~~ All applicants for employment in home care organizations shall provide a sworn disclosure statement regarding their past and pending criminal history. The sworn disclosure statement shall be stored with the criminal record report within the employee's personnel file. B. The criminal record report shall be obtained within 30 days of employment. It shall be the responsibility of the organization to ensure that its employees have not been convicted of any of the barrier

		within 30 days of employment. It shall be the responsibility of the organization to ensure that its employees have not been convicted of any of the barrier crimes listed in § 32.1-162.9:1 of the Code of Virginia. C. The organization shall not accept a criminal record report dated more than 90 days prior to the date of employment. D. Only the original criminal record report shall be accepted. An exception is permitted for organizations using temporary staffing agencies for the provision of substitute staff. The organization shall obtain a letter from the temporary staffing agency containing the following information: 1. The name of the substitute staffing person; 2. The date of employment by the temporary staffing agency; and 3. A statement verifying that the criminal record report has been obtained within 30 days of employment, is on file at the temporary staffing agency, and does not contain any barrier crimes listed in § 32.1-162.9:1 of the Code of Virginia. E. No employee shall be permitted to work in a position that involves direct contact with a patient until an original criminal record report has been received by the home care organization or temporary staffing agency, unless such	crimes listed in § 32.1-162.9:1 of the Code of Virginia. C. The organization shall not accept a criminal record report dated more than 90 days prior to the date of employment. D. Only the original criminal record report shall be accepted. An exception is permitted for organizations using temporary staffing agencies for the provision of substitute staff. The organization shall obtain a letter from the temporary staffing agency containing the following information: 1. The name of the substitute staffing person; 2. The date of employment by the temporary staffing agency; and 3. A signed statement verifying that the criminal record report has been obtained within 30 days of employment, is on file at the temporary staffing agency, and does not contain any barrier crimes listed in § 32.1-162.9:1 of the Code of Virginia. E. No employee shall be permitted to work in a position that involves direct contact with a patient until an original criminal record report has been received by the home care organization or temporary staffing agency, unless such person works under the direct supervision of another employee for whom a background check has been completed in accordance with subsection B of this section. F. A criminal record report remains valid as long as the employee remains in continuous service with the same organization. G. A new criminal record report and sworn statement shall be required when an individual terminates employment at one home care organization and begins work at another home care organization. The following exceptions are permitted: 1. When an employee transfers

		person works under the direct supervision of another employee for whom a background check has been completed in accordance with subsection B of this section. F. A criminal record report remains valid as long as the employee remains in continuous service with the same organization. G. A new criminal record report and sworn statement shall be required when an individual terminates employment at one home care organization and begins work at another home care organization. The following exceptions are permitted: 1. When an employee transfers within 30 days to an organization owned and operated by the same entity. The employee's file shall contain a statement that the original criminal record report has been transferred or forwarded to the new work location. 2. When an individual takes a leave of absence, the criminal record report and sworn statement will remain valid as long as the period of separation does not exceed six consecutive months. If six consecutive months have passed, a new criminal record report and sworn disclosure statement are required. H. A sworn disclosure statement shall be completed by all applicants for employment. The sworn	within 30 days to an organization owned and operated by the same entity. The employee's file shall contain a statement that the original criminal record report has been transferred or forwarded to the new work location. 2. When an individual takes a leave of absence, the criminal record report and sworn statement will remain valid as long as the period of separation does not exceed six consecutive months. If six consecutive months have passed, a new criminal record report and sworn disclosure statement are required. ~~H. A sworn disclosure statement shall be completed by all applicants for employment. The sworn disclosure statement shall be attached to and filed with the criminal record report.~~ ~~I~~H. Any applicant denied employment because of convictions appearing on his criminal record report shall be provided a copy of the report by the hiring organization. ~~J~~I. All criminal record reports and sworn disclosure statements shall be confidential and maintained in locked files accessible only to the administrator or designee. ~~K~~J. Further dissemination of the criminal record report and sworn disclosure statement information is prohibited other than to the commissioner's representative or a federal or state authority or court as may be required to comply with an express requirement of law for such further dissemination. Intent: Slight technical amendments and rearrangement of the section. Likely impact: None.

		disclosure statement shall be attached to and filed with the criminal record report. I. Any applicant denied employment because of convictions appearing on his criminal record report shall be provided a copy of the report by the hiring organization. J. All criminal record reports shall be confidential and maintained in locked files accessible only to the administrator or designee. K. Further dissemination of the criminal record report and sworn disclosure statement information is prohibited other than to the commissioner's representative or a federal or state authority or court as may be required to comply with an express requirement of law for such further dissemination.	
120-Variances		A. The OLC can authorize variances only to its own licensing regulations, not to regulations of another agency or to any requirements in federal, state, or local laws. B. A home care organization may request a variance to a particular regulation or requirement contained in this chapter when the standard or requirement poses a special hardship and when a variance to it would not endanger the safety or well-being of clients. The request for a variance must describe how compliance with the current regulation is economically	~~A. The OLC can authorize variances only to its own licensing regulations, not to regulations of another agency or to any requirements in federal, state, or local laws.~~ ~~B. A home care organization may request a variance to a particular regulation or requirement contained in this chapter when the standard or requirement poses a special hardship and when a variance to it would not endanger the safety or well-being of clients. The request for a variance must describe how compliance with the current regulation is economically burdensome and constitutes a special hardship to the home care organization and to the clients it serves. When applicable, the request should include proposed alternatives to meet the purpose of the requirements that will ensure the~~

		burdensome and constitutes a special hardship to the home care organization and to the clients it serves. When applicable, the request should include proposed alternatives to meet the purpose of the requirements that will ensure the protection and well-being of clients. At no time shall a variance approved for one individual be extended to general applicability. The home care organization may at any time withdraw a request for a variance. C. The OLC shall have the authority to waive, either temporarily or permanently, the enforcement of one or more of these regulations provided safety, client care and services are not adversely affected. D. The OLC may rescind or modify a variance if (i) conditions change; (ii) additional information becomes known that alters the basis for the original decision; (iii) the organization fails to meet any conditions attached to the variance; or (iv) results of the variance jeopardize the safety, comfort, or well-being of clients. E. Consideration of a variance is initiated when a written request is submitted to the Director, OLC. The OLC shall notify the home care organization in writing of the receipt of the request for a variance. The OLC may attach conditions to a variance to protect the safety and well-being of	~~protection and well-being of clients. At no time shall a variance approved for one individual be extended to general applicability. The home care organization may at any time withdraw a request for a variance.~~ ~~C. The OLC shall have the authority to waive, either temporarily or permanently, the enforcement of one or more of these regulations provided safety, client care and services are not adversely affected.~~ ~~D. The OLC may rescind or modify a variance if (i) conditions change; (ii) additional information becomes known that alters the basis for the original decision; (iii) the organization fails to meet any conditions attached to the variance; or (iv) results of the variance jeopardize the safety, comfort, or well-being of clients.~~ ~~E. Consideration of a variance is initiated when a written request is submitted to the Director, OLC. The OLC shall notify the home care organization in writing of the receipt of the request for a variance. The OLC may attach conditions to a variance to protect the safety and well-being of the client.~~ ~~F. The licensee shall be notified in writing if the requested variance is denied.~~ ~~G. If a variance is denied, expires, or is rescinded, routine enforcement of the regulation or portion of the regulation shall be resumed.~~ ~~H. The home care organization shall develop procedures for monitoring the implementation of any approved variances to assure the ongoing collection of any data relevant to the variance and the presentation of any later report concerning the variance as requested by the OLC.~~ A. The commissioner may authorize a temporary variance only to a specific provision of this chapter. In no event shall a temporary variance exceed the term of the license. A home care organization may request a temporary variance to a

		the client. F. The licensee shall be notified in writing if the requested variance is denied. G. If a variance is denied, expires, or is rescinded, routine enforcement of the regulation or portion of the regulation shall be resumed. H. The home care organization shall develop procedures for monitoring the implementation of any approved variances to assure the ongoing collection of any data relevant to the variance and the presentation of any later report concerning the variance as requested by the OLC.	particular standard or requirement contained in a particular provision of this chapter when the standard or requirement poses an impractical hardship unique to the home care organization and when a temporary variance to it would not endanger the safety or well-being of patients. The request for a temporary variance shall describe how compliance with the current standard or requirement constitutes an impractical hardship unique to the home care organization. The request should include proposed alternatives, if any to meet the purpose of the standard or requirement that will ensure the protection and well-being of patients. At no time shall a temporary variance be extended to general applicability. The home care organization may withdraw a request for a temporary variance at any time. B. The commissioner may rescind or modify a temporary variance if: (i) conditions change; (ii) additional information becomes known that alters the basis for the original decision; (iii) the home care organization fails to meet any conditions attached to the temporary variance; or (iv) results of the temporary variance jeopardize the safety or well-being of patients. C. Consideration of a temporary variance is initiated when a written request is submitted to the commissioner or his designee. The commissioner or his designee shall notify the home care organization in writing of the receipt of the request for a temporary variance. The licensee shall be notified in writing of the commissioner's decision on the temporary variance request. If granted, the commissioner may attach conditions to a temporary variance to protect the safety and well-being of patients. D. If a temporary variance is denied, expires or is rescinded, routine enforcement of the standard or requirement to which the temporary

			variance was granted shall be resumed. Intent: Restructuring of the section to reflect best practices and changes in administrative practices. Likely impact: Greater clarity of the regulations.
130- ~~Revocation or suspension of a license~~ Violation of this chapter or applicable law; denial, revocation, or suspension of license.		A. The commissioner is authorized to revoke or suspend any license if the licensee fails to comply with the provisions of Article 7.1 (§ 32.1-162.7 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia or the regulations of the board. B. If a license is revoked, the commissioner may issue a new license when the conditions upon which revocation was based have been corrected and compliance with all provisions of the law and this chapter has been achieved. C. When a license is revoked or suspended, the organization shall cease operations. If the organization continues to operate after its license has been revoked or suspended, the commissioner may request the Office of the Attorney General to petition the circuit court of the jurisdiction in which the home care organization is located for an injunction to cause such home care organization to cease operations. D. Suspension of a license shall in all cases be for an indefinite time. The suspension may be lifted and rights under the license fully or	~~A. The commissioner is authorized to revoke or suspend any license if the licensee fails to comply with the provisions of Article 7.1 (§ 32.1-162.7 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia or the regulations of the board.~~ ~~B. If a license is revoked, the commissioner may issue a new license when the conditions upon which revocation was based have been corrected and compliance with all provisions of the law and this chapter has been achieved.~~ ~~C. When a license is revoked or suspended, the organization shall cease operations. If the organization continues to operate after its license has been revoked or suspended, the commissioner may request the Office of the Attorney General to petition the circuit court of the jurisdiction in which the home care organization is located for an injunction to cause such home care organization to cease operations.~~ ~~D. Suspension of a license shall in all cases be for an indefinite time. The suspension may be lifted and rights under the license fully or partially restored at such time as the commissioner determines that the rights of the licensee appear to so require and the interests of the public will not be jeopardized by resumption of operation.~~ A. When the department determines that a home care organization is (i) in violation of any provision of Article 7.1 (§ 32.1-162.7 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia or of any applicable regulation, or (ii) is permitting, aiding, or abetting the commission of any illegal act in the home care organization, the department may

		partially restored at such time as the commissioner determines that the rights of the licensee appear to so require and the interests of the public will not be jeopardized by resumption of operation.	deny, suspend, or revoke the license to operate a home care organization in accordance with § 32.1-162.13 of the Code of Virginia. B. If a license is revoked as herein provided, a new license may be issued by the commissioner after satisfactory evidence is submitted to him that the conditions upon which revocation was based have been corrected and after proper inspection has been made and compliance with all provision of Article 7.1 of Chapter 5 of Title 32.1 of the Code of Virginia and applicable state and federal law and regulations hereunder has been obtained. C. Suspension of a license shall in all cases be for an indefinite time. The commissioner may restore a suspended license when he determines that the conditions upon which suspension was based have been corrected and that the interests of the public will not be jeopardized by resumption of operation. No additional fee shall be required for restoring such a license. D. The home care organization has the right to contest the denial revocation, or suspension of a license in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia). E. Whenever a license is revoked or suspended and the organization continues to operate, the Commissioner shall request the Office of the Attorney General to petition the circuit court of the jurisdiction in which the home care organization is located for an injunction to cause such home care organization to cease providing services for the purpose of patient protection. F. The Commissioner or his designee shall notify the Department of Medical Assistance Services whenever any license is revoked, suspended, or expired.

			Intent: Restructuring of the section to reflect best practices and changes in administrative practices. Likely impact: Greater clarity of the regulations.
140- ~~Return of a license~~ Discontinuation of services		A. Circumstances under which a license must be returned include, but are not limited to (i) transfer of ownership and (ii) discontinuation of services. B. The licensee shall notify its clients and the OLC, in writing, 30 days before discontinuing services. C. If the organization is no longer operational, or the license has been suspended or revoked, the license shall be returned to the OLC within five working days. The licensee shall notify its clients and the OLC where all home care records will be located.	~~A. Circumstances under which a license must be returned include, but are not limited to (i) transfer of ownership and (ii) discontinuation of services.~~ ~~B. The licensee shall notify its clients and the OLC, in writing, 30 days before discontinuing services.~~ ~~C.~~ If the organization ~~is no longer operational~~discontinues services, or the license has been suspended or revoked, the license shall be returned to the OLC within five working days. The ~~licensee~~organization shall notify its clients and the OLC where all patient home care records will be located. Intent: Restructuring of the section to reflect best practices and changes in administrative practices. Likely impact: Greater clarity of the regulations.
150- Management and administration		A. No person shall establish or operate a home care organization, as defined in § 32.1-162.7 of the Code of Virginia, without having obtained a license. B. The organization must comply with: 1. This chapter (12VAC5-381); 2. Other applicable federal, state or local laws and regulations; and 3. The organization's own policies and procedures. C. The organization shall submit or make available reports and information necessary to establish compliance with this chapter and applicable law.	A. No person shall establish or operate a home care organization, as defined in § 32.1-162.7 of the Code of Virginia, without having obtained a license. B. The organization ~~must~~shall comply with: 1. This chapter (12VAC5-381); 2. Other applicable federal, state or local laws and regulations; and 3. The organization's own policies and procedures. C. The organization shall submit or make available reports and information necessary to establish compliance with this chapter and applicable law. D. The organization shall permit representatives from the OLC to conduct inspections to: 1. Verify application information; 2. Determine compliance with

		D. The organization shall permit representatives from the OLC to conduct inspections to: 1. Verify application information; 2. Determine compliance with this chapter; 3. Review necessary records and documents; and 4. Investigate complaints. E. The organization shall notify the OLC 30 days in advance of changes affecting the organization, including the: 1. Service area; 2. Mailing address of the organization; 3. Ownership; 4. Services provided; 5. Operator; 6. Administrator; 7. Organization name; and 8. Closure of the organization. F. The current license from the department shall be posted for public inspection. G. Service providers or community affiliates under contract with the organization must comply with the organization's policies and this chapter. H. The organization shall not use any advertising that contains false, misleading or deceptive statements or claims, or false or misleading disclosures of fees and payment for services. I. The organization shall have regular posted business hours and be fully operational during such business hours. In addition, the organization shall provide or arrange	this chapter; 3. Review necessary records and documents; and 4. Investigate complaints. E. The organization shall notify the OLC 30 days in advance of changes affecting the organization, including the: 1. ~~Service area;~~ Operator; 2. ~~Mailing address of the organization;~~ Organization name; 3. ~~Ownership;~~ Physical or mailing address; 4. Branch offices; 4~~5~~. Services provided; ~~5. Operator;~~ 6. Service area ~~6. Administrator;~~ 7. Ownership ~~7. Organization name~~ 8. Administration; and ~~8.~~ 9. Closure of the organization. Changes to E (1) – E (5) shall require reissuance of the organization's license pursuant to 12VAC5-381-60. F. The current license from the department shall be posted for public inspection, in a conspicuous place to which members of the public have ready access. Posting of the license on the organization's website shall meet this requirement. G. Service providers or community affiliates under contract with the organization must comply with the organization's policies and this chapter. H. The organization shall not use any advertising that contains false, misleading or deceptive statements or claims, or false or misleading disclosures of fees and payment for services. I. The organization shall have regular posted business hours and be fully operational during such business hours. In addition, the organization shall provide or arrange for services to their clients on an on-call basis 24 hours a day, seven days a week. J. The organization shall accept a

		for services to their clients on an on-call basis 24 hours a day, seven days a week. J. The organization shall accept a client only when the organization can adequately meet that client's needs in the client's place of residence. K. The organization must have a prepared plan for emergency operations in case of inclement weather or natural disaster to include contacting and providing essential care to clients, coordinating with community agencies to assist as needed, and maintaining a current list of clients who would require specialized assistance. L. The organization shall encourage and facilitate the availability of flu shots for its staff and clients.	client only when the organization can adequately meet that client's needs in the client's place of residence. K. The organization must have a prepared plan for emergency operations in case of inclement weather or natural disaster to include contacting and providing essential care to clients, coordinating with community agencies to assist as needed, and maintaining a current list of clients who would require specialized assistance. L. The organization shall encourage and facilitate the availability of flu shots for its staff and clients. Intent: Minor restructuring to clarify which changes require a reissuance of the organization's license. Clarification regarding posting of a license. Likely impact: Greater clarity of the regulations.
170- Administrator		A. The governing body shall appoint as administrator an individual who has evidence of at least one year of training and experience in direct health care service delivery with at least one year within the last five years of supervisory or administrative management experience in home health care or a related health program. B. The administrator shall be responsible for the day-to-day management of the organization, including but not limited to: 1. Organizing and supervising the administrative function of the organization;	~~The governing body shall appoint as administrator an individual who has evidence of at least one year of training and experience in direct health care service delivery with at least one year within the last five years of supervisory or administrative management experience in home health care or a related health program.~~ The governing body shall appoint an administrator who has experience within the last five years with health care administration or management. Preference shall be given to applicants who are licensed health care professionals. B. The administrator shall be responsible for the day-to-day management of the organization, including but not limited to: 1. Organizing and supervising the administrative function of the organization;

		2. Maintaining an ongoing liaison with the governing body, the professional personnel and staff; 3. Employing qualified personnel and ensuring adequate staff orientation, training, education and evaluation; 4. Ensuring the accuracy of public information materials and activities; 5. Implementing an effective budgeting and accounting system; 6. Maintaining compliance with applicable laws and regulations and implementing corrective action in response to reports of organization committees and regulatory agencies; 7. Arranging and negotiating services provided through contractual agreement; and 8. Implementing the policies and procedures approved by the governing body. C. The individual designated to perform the duties of the administrator when the administrator is absent from the organization shall be able to perform the duties of the administrator as identified in subsection B of this section. D. The administrator or his designee shall be available at all times during operating hours and for emergency situations.	2. Maintaining an ongoing liaison with the governing body, the professional personnel and staff; 3. Employing qualified personnel and ensuring adequate staff orientation, training, education and evaluation; 4. Ensuring the accuracy of public information materials and activities; 5. Implementing an effective budgeting and accounting system; 6. Maintaining compliance with applicable laws and regulations and implementing corrective action in response to reports of organization committees and regulatory agencies; 7. Arranging and negotiating services provided through contractual agreement; and 8. ~~Implementing the policies and procedures approved by the governing body.~~ Ensuring the development, implementation and enforcement of all policies and procedures. C. ~~The individual designated to perform the duties of the administrator when the administrator is absent from the organization shall be able to perform the duties of the administrator as identified in subsection B of this section.~~ The organization shall designate an individual to perform the duties of the administrator when the administrator is absent. D. The administrator or his designee shall be available at all times during operating hours and for emergency situations. Intent: Clarification of the necessary prerequisites of an administrator. Likely impact: Greater clarification of the regulations.
180- Written policies and procedures		A. The organization shall implement written policies and procedures approved by the	A. The organization shall implement written policies and procedures approved by the governing body.

		governing body. B. All policies and procedures shall be reviewed at least annually, with recommended changes submitted to the governing body for approval, as necessary. C. Administrative and operational policies and procedures shall include, but are not limited to: 1. Administrative records; 2. Admission and discharge or termination from service criteria; 3. Informed consent; 4. Advance directives, including Durable Do Not Resuscitate Orders; 5. Client rights; 6. Contract services; 7. Medication management, if applicable; 8. Quality improvement; 9. Mandated reporting of abuse, neglect and exploitation pursuant to § 63.2-1606of the Code of Virginia; 10. Communicable and reportable diseases; 11. Client records, including confidentiality; 12. Record retention, including termination of services; 13. Supervision and delivery of services; 14. Emergency and on-call services; 15. Infection control; 16. Handling consumer complaints; 17. Telemonitoring; and 18. Approved variances. D. Financial policies and procedures shall include, but are not limited to: 1. Admission agreements; 2. Data collection and verification of services	B. All policies and procedures shall be reviewed at least annually, with recommended changes submitted to the governing body for approval, as necessary. C. Administrative and operational policies and procedures shall include, but are not limited to: 1. Administrative records; 2. Admission and discharge or termination from service criteria; 3. Informed consent; 4. ~~Advance~~ Providing information regarding advance directives, including Durable Do Not Resuscitate Orders; 5. Client rights; 6. Contract services; 7. Medication management, if applicable; 8. Quality improvement; 9. Mandated reporting of abuse, neglect and exploitation pursuant to § 63.2-1606 of the Code of Virginia; 10. Communicable and reportable diseases; 11. Client records, including confidentiality; 12. Record retention, including termination of services; 13. Supervision and delivery of services; 14. Emergency and on-call services; 15. Infection control; 16. Handling consumer complaints; 17. Telemonitoring; ~~and~~ 18. Approved variances~~.~~ ; and 19. An emergency management plan. D. Financial policies and procedures shall include, but are not limited to: 1. Admission agreements; 2. Data collection and verification of services delivered; 3. Methods of billing for services by the organization and by

		delivered; 3. Methods of billing for services by the organization and by contractors; 4. Client notification of changes in fees and charges; 5. Correction of billing errors and refund policy; and 6. Collection of delinquent client accounts. E. Personnel policies and procedures shall include, but are not limited to a: 1. Written job description that specifies authority, responsibility, and qualifications for each job classification; 2. Process for maintaining an accurate, complete and current personnel record for each employee; 3. Process for verifying current professional licensing or certification and training of employees or independent contractors; 4. Process for annually evaluating employee performance and competency; 5. Process for verifying that contractors and their employees meet the personnel qualifications of the organization; 6. Process for obtaining a criminal background check and maintaining a drug-free workplace pursuant to § 32.1-162.9:1 of the Code of Virginia; and 7. Process for reporting licensed and certified medical personnel for violations of their licensing or certification to the appropriate board	contractors; 4. Client notification of changes in fees and charges; 5. Correction of billing errors and refund policy; and 6. Collection of delinquent client accounts. E. Personnel policies and procedures shall include, but are not limited to a: 1. Written job description that specifies authority, responsibility, and qualifications for each job classification; 2. Standards of conduct, which shall include corrective action that may be taken to address violations of the standards, and a method for enforcing the standards while an employee is in a client's residence; ~~2.~~ 3. Process for maintaining an accurate, complete and current personnel record for each employee; ~~3~~. 4. Process for verifying current professional licensing or certification and training of employees or independent contractors; ~~4~~5. Process for annually evaluating employee performance and competency; ~~5~~6. Process for verifying that contractors and their employees meet the personnel qualifications of the organization; ~~6~~7. Process for obtaining a criminal background check and maintaining a drug-free workplace pursuant to § 32.1-162.9:1 of the Code of Virginia; and ~~7~~8. Process for reporting licensed and certified medical personnel for violations of their licensing or certification to the ~~appropriate board within the Department of Health Professions.~~ Director of the Office of Licensure and Certification at the Department of Health as required by § 54.1-

		within the Department of Health Professions. F. Admission and discharge or termination from service policies and procedures shall include, but are not limited to: 1. Criteria for accepting clients for services offered; 2. The process for obtaining a plan of care or service; 3. Criteria for determining discharge or termination from each service and referral to other agencies or community services; and 4. Process for notifying clients of intent to discharge/terminate or refer, including: a. Oral and written notice and explanation of the reason for discharge/termination or referral; b. The name, address, telephone number and contact name at the referral organization; and c. Documentation in the client record of the referral or notice. G. Policies shall be made available for review, upon request, to clients and their designated representatives. H. Policies and procedures shall be readily available for staff use at all times.	2400.6. F. Admission and discharge or termination from service policies and procedures shall include, but are not limited to: 1. Criteria for accepting clients for services offered; 2. The process for obtaining a plan of care or service; 3. Criteria for determining discharge or termination from each service and referral to other agencies or community services; and 4. Process for notifying clients of intent to discharge/terminate or refer, including: a. Oral and written notice and explanation of the reason for discharge/termination or referral; b. The name, address, telephone number and contact name at the referral organization; and c. Documentation in the client record of the referral or notice. G. Policies shall be made available for review, upon request, to clients and their ~~designated~~ representatives. H. Policies and procedures shall be readily available for staff use at all times. Intent: Minor clarifying amendments. Addition of the necessity of a Standards of Conduct, and a minor amendment necessary because of legislative changes, which will require reporting to the Director of the OLC. Likely impact: Greater safety of patients due to the addition of standards of conduct. Greater clarity of the regulations.
190- Financial controls		A. Every applicant for an initial license to establish or operate a home care organization shall include as part of his application a detailed operating budget	A. Every applicant for an initial license to establish or operate a home care organization shall include as part of his application a detailed operating budget showing projected operating expenses for

		showing projected operating expenses for the three-month period after a license to operate has been issued. Further, every applicant for an initial license to establish or operate a home care organization shall include as part of his application proof of initial reserve operating funds in the amount sufficient to ensure operation of the home care organization for the three-month period after a license to operate has been issued. Such funds may include: 1. Cash; 2. Cash equivalents that are readily convertible to known amounts of cash and that present insignificant risk of change in value; 3. Borrowed funds that are immediately available to the applicant; or 4. A line of credit that is immediately available to the applicant. Proof of funds sufficient to meet these requirements shall include a current balance sheet demonstrating the availability of funds, a letter from the officer of the bank or other financial institution where the funds are held, or a letter of credit from a lender demonstrating the current availability of and amount of a line of credit. B. The organization shall document financial resources to operate based on a working budget showing projected revenue and expenses.	the three-month period after a license to operate has been issued. Further, every applicant for an initial license to establish or operate a home care organization shall include as part of his application proof of initial reserve operating funds in the amount sufficient to ensure operation of the home care organization for the three-month period after a license to operate has been issued. Such funds may include: 1. Cash; 2. Cash equivalents that are readily convertible to known amounts of cash and that present insignificant risk of change in value; 3. Borrowed funds that are immediately available to the applicant; or 4. A line of credit that is immediately available to the applicant. Proof of funds sufficient to meet these requirements shall include a current balance sheet demonstrating the availability of funds, a letter from the officer of the bank or other financial institution where the funds are held, or a letter of credit from a lender demonstrating the current availability of and amount of a line of credit. B. The organization shall document financial resources to operate based on a working budget showing projected revenue and expenses. The organization shall maintain records of financial resources and a working budget throughout operations and shall make these records available to any OLC representative conducting an on-site inspection in accordance with 12VAC5-381-80. C. All financial records shall be kept according to generally accepted accounting principles (GAAP). ~~D. All financial records shall be audited at least triennially by an independent certified public~~

		C. All financial records shall be kept according to generally accepted accounting principles (GAAP). D. All financial records shall be audited at least triennially by an independent certified public accountant (CPA) or audited as otherwise provided by law. E. The organization shall have documented financial controls to minimize risk of theft or embezzlement.	~~accountant (CPA), or audited as otherwise provided by law.~~ ~~E~~D. The organization shall have documented financial controls to minimize risk of theft or embezzlement. Intent: Part D has proven ineffective in practice. Therefore the language in Part B was developed with stakeholders in order to attempt to the same ends. To ensure that accurate up to date records are kept at all times. Likely impact: Increased financial security of facilities; which may reduce facility closures and thus lead to greater patient safety.
200- Personnel practices		A. Personnel management and employment practices shall comply with applicable state and federal laws and regulations. B. The organization shall design and implement a staffing plan that reflects the types of services offered and shall provide qualified staff in sufficient numbers to meet the assessed needs of all clients. C. Employees and contractors shall be licensed or certified as required by the Department of Health Professions. D. The organization shall design and implement a mechanism to verify professional credentials. E. Any person who assumes the responsibilities of any staff position or positions shall meet the minimum qualifications for that position or positions. F. The organization shall obtain the required sworn statement and criminal record check for	A. Personnel management and employment practices shall comply with applicable state and federal laws and regulations. B. The organization shall design and implement a staffing plan that reflects the types of services offered and shall provide qualified staff in sufficient numbers to meet the assessed needs of all clients. C. Employees and contractors shall be licensed or certified as required by the Department of Health Professions. D. The organization shall design and implement a mechanism to verify professional credentials. E. Any person who assumes the responsibilities of any staff position or positions shall meet the minimum qualifications for that position or positions. F. The organization shall obtain the required sworn statement and criminal record check for each compensated employee as specified in § 32.1-162.9:1 of the Code of Virginia. G. Each employee position shall have a written job description that includes: 1. Job title; 2. Duties and responsibilities required of the position; 3. Job title of the immediate

		each compensated employee as specified in § 32.1-162.9:1 of the Code of Virginia. G. Each employee position shall have a written job description that includes: 1. Job title; 2. Duties and responsibilities required of the position; 3. Job title of the immediate supervisor; and 4. Minimum knowledge, skills, and abilities or professional qualifications required for entry level. H. Employees shall have access to their current position description. There shall be a mechanism for advising employees of changes to their job responsibilities. I. New employees and contract individuals shall be oriented commensurate with their function or job-specific responsibilities. Orientation shall include: 1. Objectives and philosophy of the organization; 2. Confidentiality; 3. Client rights; 4. Mandated reporting of abuse, neglect, and exploitation; 5. Applicable personnel policies; 6. Emergency preparedness procedures; 7. Infection control practices and measures; 8. Cultural awareness; and 9. Applicable laws, regulations, and other policies and procedures that apply to specific positions, specific duties	supervisor; and 4. Minimum knowledge, skills, and abilities or professional qualifications required for entry level. H. Employees shall have access to their current position description. There shall be a mechanism for advising employees of changes to their job responsibilities. I. New employees and contract individuals shall be oriented commensurate with their function or job-specific responsibilities. Orientation shall include but is not limited to: 1. Objectives and philosophy of the organization; 2. All of the organization's policies and procedures; ~~2~~3. Confidentiality; ~~3~~4. Client rights; ~~4~~5. Mandated reporting of abuse, neglect, and exploitation; ~~5. Applicable personnel policies;~~ ~~6. Emergency preparedness procedures;~~ ~~7~~6. Infection control practices and measures; ~~8~~7. Cultural awareness; and ~~9~~8. Applicable laws, regulations, and other policies and procedures that apply to specific positions, specific duties and responsibilities. J. The organization shall develop and implement a policy for evaluating employee performance. K. Individual staff development needs and plans shall be a part of the performance evaluation. L. The organization shall provide opportunities for and record participation in staff development activities designed to enable staff to perform the responsibilities of their positions. M. All individuals who enter a client's home for or on behalf of the organization shall be readily identifiable by employee nametag,

		and responsibilities. J. The organization shall develop and implement a policy for evaluating employee performance. K. Individual staff development needs and plans shall be a part of the performance evaluation. L. The organization shall provide opportunities for and record participation in staff development activities designed to enable staff to perform the responsibilities of their positions. M. All individuals who enter a client's home for or on behalf of the organization shall be readily identifiable by employee nametag, uniform or other visible means. N. The organization shall maintain an organized system to manage and protect the confidentiality of personnel files and records. O. Employee personnel records, whether hard copy or electronic, shall include: 1. Identifying information; 2. Education and training history; 3. Employment history; 4. Results of the verification of applicable professional licenses or certificates; 5. Results of reasonable efforts to secure job-related references and reasonable verification of employment history; 6. Results of performance evaluations; 7. A record of disciplinary actions taken by the organization, if any;	uniform or other visible means. N. The organization shall maintain an organized system to manage and protect the confidentiality of personnel files and records. O. Employee personnel records, whether hard copy or electronic, shall include: 1. Identifying information; 2. Education and training history; 3. Employment history; 4. Results of the verification of applicable professional licenses or certificates; 5. Results of reasonable efforts to secure job-related references and reasonable verification of employment history; 6. Results of performance evaluations; 7. A record of disciplinary actions taken by the organization, if any; 8. A record of adverse action by any licensing bodies and organizations, if any; 9. A record of participation in staff development activities, including orientation; and 10. The criminal record check and sworn affidavit. <u>For employees that work in multiple locations, the original criminal record check shall reside in their employee record located in the central office and the organization shall provide proof of this documentation to any OLC representative conducting an inspection in accordance with 12VAC5-381-80.</u> P. All positive results from drug testing shall be reported to the health regulatory boards responsible for licensing, certifying, or registering the person to practice, if any, pursuant to § 32.1-162.9:1 of the Code of Virginia. Q. Each employee personnel record shall be retained in its entirety for a minimum of three years after termination of employment. R. Personnel record information

		8. A record of adverse action by any licensing bodies and organizations, if any; 9. A record of participation in staff development activities, including orientation; and 10. The criminal record check and sworn affidavit. P. All positive results from drug testing shall be reported to the health regulatory boards responsible for licensing, certifying, or registering the person to practice, if any, pursuant to § 32.1-162.9:1 of the Code of Virginia. Q. Each employee personnel record shall be retained in its entirety for a minimum of three years after termination of employment. R. Personnel record information shall be safeguarded against loss and unauthorized use. S. Employee health-related information shall be maintained separately within the employee's personnel file.	shall be safeguarded against loss and unauthorized use. S. Employee health-related information shall be maintained separately ~~within the~~ from the remainder of the employee's personnel file. Intent: Simplifying and clarifying language and clarification regarding criminal record checks of employees who work in multiple locations. Likely impact: Greater clarity of the regulations.
210 – Indemnity coverage		A. The governing body shall ensure the organization and its contractors have appropriate indemnity coverage to compensate clients for injuries and losses resulting from services provided. B. The organization shall purchase and maintain the following types and minimum amounts of indemnity coverage at all times: 1. Malpractice insurance consistent with § 8.01-581.15 of the Code of Virginia; 2. General liability	A. The governing body shall ensure the organization and its contractors have appropriate indemnity coverage to compensate clients for injuries and losses resulting from services provided. B. The organization shall purchase and maintain the following types and minimum amounts of indemnity coverage at all times: 1. Malpractice insurance ~~consistent~~which complies with § 8.01-581.15 of the Code of Virginia; 2. General liability insurance covering personal property damages, bodily injuries, product liability, and libel and slander of at least $1 million comprehensive general liability per occurrence; and

		insurance covering personal property damages, bodily injuries, product liability, and libel and slander of at least $1 million comprehensive general liability per occurrence; and 3. Third-party crime insurance or a blanket fidelity bond of $50,000 minimum.	3. Third-party crime insurance or a blanket fidelity bond of $50,000 minimum. Intent: Minor correction Impact: Greater clarity of the regulations
220- Contract Services		A. There shall be a written agreement for the provision of services not provided by employees of the organization. B. The written agreement shall include, but is not limited to: 1. The services to be furnished by each party to the contract; 2. The contractor's responsibility for participating in developing plans of care or service; 3. The manner in which services will be controlled, coordinated, and evaluated by the primary home care organization; 4. The procedures for submitting notes on the care or services provided, scheduling of visits, and periodic client evaluation; 5. The process for payment for services furnished under the contract; and 6. Adequate liability insurance and third-party crime insurance or a blanket fidelity bond. C. The organization shall have a written plan for provision of care or services when a contractor is unable to deliver services. D. The contractor shall	A. There shall be a written agreement for the provision of services not provided by employees of the organization. B. The written agreement shall include, but is not limited to: 1. The services to be furnished by each party to the contract; 2. The contractor's responsibility for participating in developing plans of care or service; 3. The manner in which services will be controlled, coordinated, and evaluated by the primary home care organization; 4. The procedures for submitting notes on the care or services provided, scheduling of visits, and periodic client evaluation; 5. The process for payment for services furnished under the contract; and 6. Adequate liability insurance and third-party crime insurance or a blanket fidelity bond~~.~~ as required by 12VAC5-381-210 (B). C. The organization shall have a written plan for provision of care or services when a contractor is unable to deliver services. D. The contractor shall conform to applicable organizational policies and procedures as specified in the contract, including the required sworn disclosure statement and criminal record check. Intent: Minor clarifying language Likely impact: Greater clarity of the regulations

		conform to applicable organizational policies and procedures as specified in the contract, including the required sworn disclosure statement and criminal record check.	
230- Client rights		A. The organization shall establish and implement written policies and procedures regarding the rights of clients. B. Client rights shall be reviewed with clients or client designees upon admission to the organization. The review shall be documented in the client's record. C. Written procedures to implement the policies shall ensure that each client is: 1. Treated with courtesy, consideration and respect and is assured the right of privacy; 2. Assured confidential treatment of his medical and financial records as provided by law; 3. Free from mental and physical abuse, neglect, and property exploitation; 4. Assured the right to participate in the planning of the client's home care, including the right to refuse services; 5. Served by individuals who are properly trained and competent to perform their duties; 6. Assured the right to voice grievances and complaints related to organizational services without fear of reprisal; 7. Advised, before care is initiated, of the extent to which payment for the home care organization services may be expected from federal or	A. The organization shall establish and implement written policies and procedures regarding the rights of clients. B. Client rights shall be reviewed with clients or client designees upon admission to the organization. The review shall be documented in the client's record. C. Written procedures to implement the policies shall ensure that each client is <u>at a minimum</u>: 1. Treated with courtesy, consideration and respect and is assured the right of privacy; 2. Assured confidential treatment of his medical and financial records as provided by law; 3. Free from mental and physical abuse, neglect, and property exploitation; 4. Assured the right to participate in the planning of the client's home care, including the right to refuse services; 5. Served by individuals who are properly trained and competent to perform their duties; 6. Assured the right to voice grievances and complaints related to organizational services without fear of reprisal; 7. Advised, before care is initiated, of the extent to which payment for the home care organization services may be expected from federal or state programs, and the extent to which payment may be required from the client; 8. Advised orally and in writing of any changes in fees for services that are the client's responsibility. The home care organization shall advise the client of these changes as soon as possible, but no later than 30 calendar days from the date the home care

		state programs, and the extent to which payment may be required from the client; 8. Advised orally and in writing of any changes in fees for services that are the client's responsibility. The home care organization shall advise the client of these changes as soon as possible, but no later than 30 calendar days from the date the home care organization became aware of the change; 9. Provided with advance directive information prior to start of services; and 10. Given at least five days written notice when the organization determines to terminate services. D. Before care is initiated, the home care organization shall inform the client, orally and in writing, of: 1. The nature and frequency of services to be delivered and the purpose of the service; 2. Any anticipated effects of treatment, as applicable: 3. A schedule of fees and charges for services; 4. The method of billing and payment for services, including the: a. Services to be billed to third party payers; b. Extent to which payment may be expected from third party payers known to the home care organization; and c. Charges for services that will not be covered by third party payers; 5. The charges that the	organization became aware of the change; 9. Provided with advance directive information prior to start of services; ~~and~~ 10. Given at least five days written notice when the organization determines to terminate services~~.~~; and 11. Afforded an opportunity to offer feedback and input regarding the services provided by the assigned home care attendant or attendants. The organization shall clearly inform its clients that such feedback and input is voluntary, may be anonymous, and any information provided shall not affect the client's care. D. Before care is initiated, the home care organization shall inform the client, orally and in writing, of: 1. The nature and frequency of services to be delivered and the purpose of the service; 2. Any anticipated effects of treatment, as applicable: 3. A schedule of fees and charges for services; 4. The method of billing and payment for services, including the: a. Services to be billed to third party payers; b. Extent to which payment may be expected from third party payers known to the home care organization; and c. Charges for services that will not be covered by third party payers; 5. The charges that the individual may have to pay; 6. The requirements of notice for cancellation or reduction in services by the organization and the client; and 7. The refund policies of the organization. Intent: Provide patients an opportunity to offer feedback to the facility. Likely impact: Greater patient satisfaction.

		individual may have to pay; 6. The requirements of notice for cancellation or reduction in services by the organization and the client; and 7. The refund policies of the organization.	
240- Handling Complaints Received from Clients		A. The organization shall establish and maintain complaint handling procedures that specify the: 1. System for logging receipt, investigation and resolution of complaints; and 2. Format of the written record of the findings of each complaint investigated. B. The organization shall designate staff responsible for complaint resolution, including: 1. Complaint intake, including acknowledgment of complaints; 2. Investigation of the complaint; 3. Review of the investigation of findings and resolution for the complaint; and 4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint. C. The client or his designee shall be given a copy of the complaint procedures at the time of admission to service. The organization shall provide each client or his designee with the name, mailing address, and telephone number of the: 1. Organization contact person; 2. State Ombudsman; and	A. The organization shall establish and maintain complaint handling procedures that specify the: 1. System for logging receipt, investigation and resolution of complaints; and 2. Format of the written record of the findings of each complaint investigated. B. The organization shall designate staff responsible for complaint resolution, including: 1. Complaint intake, including acknowledgment of complaints; 2. Investigation of the complaint; 3. Review of the investigation of findings and resolution for the complaint; and 4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint. C. The client or his ~~designee~~representative shall be given a copy of the complaint procedures at the time of admission to service and at the time of any changes to the organization's complaint procedures. The organization shall provide each client or his ~~designee~~representative with the name, mailing address, and telephone number of the: 1. ~~Organization~~ Organization's complaint contact person; 2. State Ombudsman; and 3. Complaint Unit of the OLC. D. The organization shall maintain documentation of all complaints received and the status of each complaint from date of receipt through its final resolution. Records shall be maintained from the date of

		3. Complaint Unit of the OLC. D. The organization shall maintain documentation of all complaints received and the status of each complaint from date of receipt through its final resolution. Records shall be maintained from the date of last inspection and for no less than three years.	last inspection and for no less than three years. Intent: Minor clarifying language Likely impact: Greater clarity of the regulations.
250-Quality Improvement		A. The organization shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The findings shall be used to correct identified problems and revise policies and practices, as necessary. Exclusive concentration on administrative or cost-of-care issues does not fulfill this requirement. B. The following data shall be evaluated to identify unacceptable or unexpected trends or occurrences: 1. Staffing patterns and performance to assure adequacy and appropriateness of services delivered; 2. Supervision appropriate to the level of service; 3. On-call responses; 4. Client records for appropriateness of services provided; 5. Client satisfaction; 6. Complaint resolution; 7. Infections; 8. Staff concerns regarding client care; and	A. The organization shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The findings shall be used to correct identified problems and revise policies and practices, as necessary. Exclusive concentration on administrative or cost-of-care issues does not fulfill this requirement. B. The following data shall be evaluated to identify unacceptable or unexpected trends or occurrences: 1. Staffing patterns and performance to assure adequacy and appropriateness of services delivered; 2. Supervision appropriate to the level of service; 3. Any medication errors; ~~3~~4. On-call responses; ~~4~~5. Client records for appropriateness of services provided; ~~5~~6. Client satisfaction; ~~6~~7. Complaint resolution; ~~7~~8. Infections; ~~8~~9. Staff concerns regarding client care; and ~~9~~10. Provision of services appropriate to the clients' needs. C. A quality improvement committee responsible for the oversight and supervision of the program, shall

		9. Provision of services appropriate to the clients' needs. C. A quality improvement committee responsible for the oversight and supervision of the program, shall consist of: 1. The director of skilled services or organization's register nurse as appropriate for the type of services provided; 2. A member of the administrative staff; 3. Representatives from each of the services provided by the organization, including contracted services; and 4. An individual with demonstrated ability to represent the rights and concerns of clients. The individual may be a member of the organization's staff, a client, or a client's family member. In selecting members of this committee, consideration shall be given to a candidate's abilities and sensitivity to issues relating to quality of care and services provided to clients. D. Measures shall be implemented to resolve important problems or concerns that have been identified. Health care practitioners, as applicable, and administrative staff shall participate in the resolution of the problems or concerns that are identified. E. Results of the quality improvement program shall be reported annually to the governing body and the administrator and	consist of: 1. The director of skilled services or organization's register nurse as appropriate for the type of services provided; 2. A member of the administrative staff; 3. Representatives from each of the services provided by the organization, including contracted services; and 4. An individual with demonstrated ability to represent the rights and concerns of clients. The individual may be a member of the organization's staff, a client, or a client's ~~family member~~representative. In selecting members of this committee, consideration shall be given to a candidate's abilities and sensitivity to issues relating to quality of care and services provided to clients. D. Measures shall be implemented to resolve important problems or concerns that have been identified. Health care practitioners, as applicable, and administrative staff shall participate in the resolution of the problems or concerns that are identified. E. Results of the quality improvement program shall be reported annually to the governing body and the administrator and available in the organization. The report shall be acted upon by the governing body and the organization. All corrective actions shall be documented. Intent: Minor clarifying language Likely impact: Greater clarity of the regulations.

		available in the organization. The report shall be acted upon by the governing body and the organization. All corrective actions shall be documented.	
270- Drop sites		A. The organization may operate one or more drop sites for the convenience of staff providing direct client care or service. However, such sites shall not: 1. Have staff assigned; 2. Accept referrals; or 3. Be advertised as part of the organization. B. Any client records located at the site shall be safeguarded against loss or unauthorized use. Only authorized personnel shall have access to client records as specified by state and federal law. It shall be the responsibility of the organization to assure that records maintained at the site are readily available for inspection staff. C. Operation of a drop site as a business office shall constitute a separate organization and shall require licensure. D. Drop sites shall be subject to inspection at any time.	A. The organization may operate one or more drop sites for the convenience of staff providing direct client care or service. However, such sites shall not: 1. Have staff assigned; 2. Accept referrals; or 3. Be advertised as part of the organization. B. Any client records located at the site shall be safeguarded against loss or unauthorized use. Only authorized personnel shall have access to client records as specified by state and federal law. It shall be the responsibility of the organization to assure that records maintained at the site are readily available for inspection staff. C. ~~Operation of a drop site as a business office~~ Any location that does not meet the elements of subsection A shall constitute a separate organization and shall require licensure. Drop sites shall not be separately licensed. Should OLC discover a drop site which is separately licensed the organization shall be required to surrender the license of the drop site to the OLC. D. Drop sites shall be subject to inspection at any time. Intent: Clarification that drop sites shall not be licensed as there has been confusion throughout the regulated community regarding this issue. Likely impact: Greater clarity of the regulations. More effective regulations.
280-Client record system		A. The organization shall maintain an organized client record system according to accepted standards of practice.	A. The organization shall maintain an organized client record system according to accepted standards of practice. Written policies and procedures shall specify retention,

		Written policies and procedures shall specify retention, reproduction, access, storage, content, and completion of the record. B. The client record information shall be safeguarded against loss or unauthorized use. C. Client records shall be confidential. Only authorized personnel shall have access as specified by state and federal law. D. Provisions shall be made for the safe storage of the original record and for accurate and legible reproductions of the original. E. Policies shall specify arrangements for retention and protection of records if the organization discontinues operation and shall provide for notification to the OLC and the client of the location of the records. F. An accurate and complete client record shall be maintained for each client receiving services and shall include, but shall not be limited to: 1. Client identifying information; 2. Identification of the primary care physician; 3. Admitting information, including a client history; 4. Information on the composition of the client's household, including individuals to be instructed in assisting the client; 5. An initial assessment of client needs to develop a plan of care or services; 6. A plan of care or	reproduction, access, storage, content, and completion of the record. B. The client record information shall be safeguarded against loss or unauthorized use. C. Client records shall be confidential. Only authorized personnel shall have access as specified by state and federal law. D. Provisions shall be made for the safe storage of the original record and for accurate and legible reproductions of the original. E. Policies shall specify arrangements for retention and protection of records if the organization discontinues operation and shall provide for notification to the OLC and the client of the location of the records. F. An accurate and complete client record shall be maintained for each client receiving services and shall include, but shall not be limited to: 1. Client identifying information; <u>2. A copy of informed consent forms signed by the client, or the client's representative;</u> <u>3. A copy of the consent to release of confidential information signed by the client or the client's representative;</u> ~~2~~<u>4</u>. Identification of the primary care physician; ~~3~~<u>5</u>. Admitting information, including a client history; ~~4~~<u>6</u>. Information on the composition of the client's household, including individuals to be instructed in assisting the client; ~~5~~<u>7</u>. An initial assessment of client needs to develop a plan of care or services; ~~6~~<u>8</u>. A plan of care or service that includes the type and frequency of each service to be delivered either by organization personnel or contract services; ~~7~~<u>9</u>. Documentation of client rights review; ~~and~~

		service that includes the type and frequency of each service to be delivered either by organization personnel or contract services; 7. Documentation of client rights review; and 8. A discharge or termination of service summary. In addition, client records for skilled and pharmaceutical services shall include: 9. Documentation and results of all medical tests ordered by the physician or other health care professional and performed by the organization's staff; 10. A medical plan of care including appropriate assessment and pain management; 11. Medication sheets that include the name, dosage, frequency of administration, possible side effects, route of administration, date started, and date changed or discontinued for each medication administered; and 12. Copies of all summary reports sent to the primary care physician. G. Signed and dated notes on the care or services provided by each individual delivering service shall be written on the day the service is delivered and incorporated in the client record within seven working days. H. Entries in the client record shall be current, legible, dated and authenticated by the person making the entry. Errors shall be corrected	~~8~~10. A discharge or termination of service summary~~.~~; and ~~In addition, client records for skilled and pharmaceutical services shall include:~~ ~~9~~11. Documentation and results of all medical tests ordered by the physician or other health care professional and performed by the organization's staff; ~~10~~12. A medical plan of care including appropriate assessment and pain management; ~~11~~13. Medication sheets that include the name, dosage, frequency of administration, possible side effects, route of administration, date started, and date changed or discontinued for each medication administered; ~~and~~ 14. Any medication errors and drug reactions; and ~~12~~15. Copies of all summary reports sent to the primary care physician. G. Signed and dated notes on the care or services provided by each individual delivering service shall be ~~written~~documented on the day the service is delivered and incorporated in the client record within ~~seven~~fourteen working days. H. Entries in the client record shall be current, legible, dated and authenticated in writing or by electronic signature by the person making the entry. Errors shall be corrected by striking through and initialing. I. Originals or reproductions of individual client records shall be maintained in their entirety for a minimum of five years following discharge or date of last contact unless otherwise specified by state or federal requirements. Records of minors shall be kept for at least five years after the minor reaches 18 years of age. Intent: Clarity regarding required

		by striking through and initialing. I. Originals or reproductions of individual client records shall be maintained in their entirety for a minimum of five years following discharge or date of last contact unless otherwise specified by state or federal requirements. Records of minors shall be kept for at least five years after the minor reaches 18 years of age.	documentation, specifically in relation to consent forms and medication errors and drug reactions. Likely impact: Greater clarity of the regulations.
290 – Home attendants		Home attendants shall be able to speak, read and write English and shall meet one of the following qualifications: 1. Have satisfactorily completed a nursing education program preparing for registered nurse licensure or practical nurse licensure; 2. Have satisfactorily completed a nurse aide education program approved by the Virginia Board of Nursing; 3. Have certification as a nurse aide issued by the Virginia Board of Nursing; 4. Be successfully enrolled in a nursing education program preparing for registered nurse or practical nurse licensure and have currently completed at least one nursing course that includes clinical experience involving direct client care; 5. Have satisfactorily passed a competency evaluation program that meets the criteria of 42 CFR 484.36 (b). Home attendants of personal care services need only be evaluated on the	Home attendants shall be able to speak, read and write English and shall meet one of the following qualifications: 1. Have satisfactorily completed a nursing education program preparing for registered nurse licensure or practical nurse licensure; 2. Have satisfactorily completed a nurse aide education program approved by the Virginia Board of Nursing; 3. Have certification as a nurse aide issued by the Virginia Board of Nursing; 4. Be successfully enrolled in a nursing education program preparing for registered nurse or practical nurse licensure and have currently completed at least one nursing course that includes clinical experience involving direct client care; 5. Have satisfactorily passed a competency evaluation program that meets the criteria of 42 CFR 484.36 (b). Home attendants of personal care services need only be evaluated on the tasks in 42 CFR 484.36 (b) as those tasks relate to the personal care services to be provided; or 6. Have satisfactorily completed ~~training using the "Personal Care Aide Training Curriculum," 2003 edition, of the~~

		tasks in 42 CFR 484.36 (b) as those tasks relate to the personal care services to be provided; or 6. Have satisfactorily completed training using the "Personal Care Aide Training Curriculum," 2003 edition, of the Department of Medical Assistance Services. However, this training is permissible for home attendants of personal care services only.	~~Department of Medical Assistance Services. However, this training is permissible for home attendants of personal care services only.~~ a 40 hour training program in compliance with the Department of Medical Assistance Services (DMAS) Elderly or Disabled with Consumer Direction (EDCD) Waiver Regulations (12VAC30-120) and the EDCD Waiver Provider Manual. Intent: Update for correctness. As the Training Curriculum currently referenced in the regulations no longer exists. Likely impact: Greater clarity of the regulations.
295- Discharge planning		N/A	A. There shall be an organized discharge planning process that includes an evaluation of the client's capacity for self-care and the availability of community services to meet the needs of the client. B. A registered nurse or qualified social worker shall develop or supervise the development of the discharge plan if the client's evaluation indicates a need for a discharge plan. 1. The organization shall arrange for the implementation of the discharge plan. 2. The organization shall transfer or refer clients to appropriate facilities, agencies or services, as needed for follow-up. C. The organization shall reassess its discharge planning process on an on-going basis. The reassessment shall include a review of discharge plans, as well as a review of patients who were discharged without plans, to ensure that the process is responsive to discharge needs. Intent: Previously the requirements of discharge planning were not within the regulations. This is a best practice that should be a part of any patient's medical record and

			therefore has been added here. Likely impact: Better patient care and more complete regulations.
300- Skilled services		A. The organization shall provide a program of home health services that shall include one or more of the following: 1. Nursing services; 2. Physical therapy services; 3. Occupational therapy services; 4. Speech therapy services; 5. Respiratory therapy services; or 6. Medical social services. B. All skilled services delivered shall be prescribed in a medical plan of care that contains at least the following information: 1. Diagnosis and prognosis; 2. Functional limitations; 3. Orders for all skilled services, including: (i) specific procedures, (ii) treatment modalities, and (iii) frequency and duration of the services ordered; 4. Orders for medications, when applicable; and 5. Orders for special dietary or nutritional needs, when applicable. The medical plan of care shall be approved and signed by the client's primary care physician. C. Verbal orders shall be documented within 24 consecutive hours in the client's record by the health care professional receiving the order and shall be countersigned by the prescribing person. D. The primary care physician shall be	A. The organization shall provide a program of home health services that shall include one or more of the following: 1. Nursing services; 2. Physical therapy services; 3. Occupational therapy services; or 4. Speech therapy services~~;~~ . ~~5. Respiratory therapy services; or~~ ~~6. Medical social services.~~ B. All skilled services delivered shall be prescribed in a medical plan of care that contains at least the following information: 1. Diagnosis and prognosis; 2. Functional limitations; 3. Orders for all skilled services, including: (i) specific procedures, (ii) treatment modalities, and (iii) frequency and duration of the services ordered; 4. Orders for medications, when applicable; and 5. Orders for special dietary or nutritional needs, when applicable. The medical plan of care shall be approved and signed by the client's primary care physician. C. Verbal orders shall be documented within 24 consecutive hours in the client's record by the health care professional receiving the order and shall be countersigned by the prescribing person. D. The primary care physician shall be notified immediately of any changes in the client's condition that indicates a need to alter the medical plan of care. E. The medical plan of care shall be reviewed, approved, and signed by the primary care physician at least every 60 days. F. There shall be a ~~director of~~ skilled

		notified immediately of any changes in the client's condition that indicates a need to alter the medical plan of care. E. The medical plan of care shall be reviewed, approved, and signed by the primary care physician at least every 60 days. F. There shall be a director of skilled services, who shall be a physician licensed by the Virginia Board of Medicine or a registered nurse, responsible for the overall direction and management of skilled services including the availability of services, the quality of services and appropriate staffing. The individual shall have the appropriate experience for the scope of services provided by the organization. G. The organization shall develop and implement policies and procedures for the handling of drugs and biologicals, including procurement, storage, administration, self-administration, and disposal of drugs and shall allow clients to procure their medications from a pharmacy of their choice. H. All prescription drugs shall be prescribed and properly dispensed to clients according to the provisions of Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for prescription drugs authorized by § 54.1-	services <u>director</u>, who shall be a <u>licensed</u> physician ~~licensed by the Virginia Board of Medicine~~ or a registered nurse, responsible for the overall direction and management of skilled services including the availability of services, the quality of services and appropriate staffing. The individual shall have the appropriate experience for the scope of services provided by the organization. G. The organization shall develop and implement policies and procedures for the handling of drugs and biologicals, including procurement, storage, administration, self-administration, and disposal of drugs and shall allow clients to procure their medications from a pharmacy of their choice <u>as required by 12VAC5-381-180</u>. H. All prescription drugs shall be prescribed and properly dispensed to clients according to the provisions of Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for prescription drugs authorized by § 54.1-3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushes for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol. <u>I. The organization shall have a policy and procedure to prevent the occurrence of pressure sores or decubitis ulcers.</u> Intent: Removal of respiratory therapy services and medical social services from the Skilled services section as these services are not provided by any home care organizations currently licensed. Slight correcting language and the addition of a prevention program. Likely impact: Greater clarity of the regulations; better patient safety.

		3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushes for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol.	
320- Therapy services		A. Physical therapy, occupational therapy, speech therapy, or respiratory therapy services shall be provided according to the medical plan of care by or under the direction of an appropriately qualified therapist currently licensed in Virginia and may include, but are not limited to: 1. Assessing client needs or admission for service as appropriate; 2. Implementing a medical plan of care and revising as necessary; 3. Initiating appropriate preventive, therapeutic, and rehabilitative techniques according to the medical plan of care; 4. Educating the client and family regarding treatment modalities and use of equipment and devices; 5. Providing consultation to other health care professionals; 6. Communicating with the physician and other health care professionals regarding changes in the client's needs; 7. Supervising therapy assistants and home attendants as appropriate; and 8. Preparing clinical notes. B. Therapy assistants may be used to provide	A. Physical therapy, occupational therapy, speech therapy, or respiratory therapy services shall be provided according to the medical plan of care by or under the direction of an appropriately qualified therapist currently licensed in Virginia and may include, but are not limited to: 1. Assessing client needs or admission for service as appropriate; 2. Implementing a medical plan of care and revising as necessary; 3. Initiating appropriate preventive, therapeutic, and rehabilitative techniques according to the medical plan of care; 4. Educating the client and ~~family~~ the client's representative regarding treatment modalities and use of equipment and devices; 5. Providing consultation to other health care professionals; 6. Communicating with the physician and other health care professionals regarding changes in the client's needs; 7. Supervising therapy assistants and home attendants as appropriate; and 8. Preparing clinical notes. B. Therapy assistants may be used to provide therapy services. 1. The occupational therapy assistant shall be currently certified by the National Board for Certification in Occupational Therapy and shall practice under

		therapy services. 1. The occupational therapy assistant shall be currently certified by the National Board for Certification in Occupational Therapy and shall practice under the supervision of a licensed occupational therapist. 2. The physical therapy assistant shall be currently licensed by the Virginia Board of Physical Therapy and shall practice under the supervision of a licensed physical therapist. C. Duties of therapy assistants shall be within their scope of practice and may include, but are not limited to: 1. Performing services planned, delegated, and supervised by the appropriately licensed therapist; and 2. Preparing clinical notes. D. Supervision of services shall be provided as often as necessary as determined by the client's needs, the assessment of the licensed therapist, and the organization's written policies not to exceed 90 days.	the supervision of a licensed occupational therapist. 2. The physical therapy assistant shall be currently licensed by the Virginia Board of Physical Therapy and shall practice under the supervision of a licensed physical therapist. C. Duties of therapy assistants shall be within their scope of practice and may include, but are not limited to: 1. Performing services planned, delegated, and supervised by the appropriately licensed therapist; and 2. Preparing clinical notes. D. Supervision of services shall be provided as often as necessary as determined by the client's needs, the assessment of the licensed therapist, and the organization's written policies not to exceed 90 days. Intent: Minor correction Likely impact: Greater clarity of the regulations.
340- Medical social services		A. Medical social services shall be provided according to the medical plan of care by or under the direction of a qualified social worker who holds, at a minimum, a bachelor's degree with major studies in social work, sociology, or psychology from a four-year college or university accredited by the Council on Social Work Education and has	A. Medical social services shall be provided according to the medical plan of care by or under the direction of a qualified social worker who holds, at a minimum, a bachelor's degree with major studies in social work, sociology, or psychology from a four-year college or university accredited by the Council on Social Work Education and has at least two years experience in case work or counseling in a health care or social services delivery system. The

		at least two years experience in case work or counseling in a health care or social services delivery system. The organization shall have one year from January 1, 2006, to ensure the designated individual meets the qualifications of this standard. B. The duties of a social worker may include, but are not limited to: 1. Assessing the client's psychological status; 2. Implementing a medical plan of care and revising, as necessary; 3. Providing social work services including (i) short-term individual counseling, (ii) community resource planning, and (iii) crisis intervention; 4. Providing consultation with the primary care physician and other health care professionals regarding changes in the client's needs; 5. Preparing notes on the care or services provided; and 6. Participating in discharge planning.	organization shall maintain documentation of the social worker's qualifications. ~~The organization shall have one year from January 1, 2006, to ensure the designated individual meets the qualifications of this standard.~~ B. The duties of a social worker may include, but are not limited to: 1. Assessing the client's psychological status; 2. Implementing a medical plan of care and revising, as necessary; 3. Providing social work services including (i) short-term individual counseling, (ii) community resource planning, and (iii) crisis intervention; 4. Providing consultation with the primary care physician and other health care professionals regarding changes in the client's needs; 5. Preparing notes on the care or services provided; and 6. Participating in discharge planning. Intent: Minor clarifying language. Removal of dated language. Likely impact: Greater clarity of the regulations.
350- ~~Pharmacy services~~ Medication administration		A. All prescription drugs shall be prescribed and properly dispensed to the client according to the provisions of the Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for prescription drugs authorized by § 54.1-3408 of the Drug Control Act, such as epinephrine for emergency	A. All prescription drugs shall be prescribed and properly dispensed to the client according to the provisions of the Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for prescription drugs authorized by § 54.1-3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushes for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol. B. Home attendants may administer

		administration, normal saline and heparin flushes for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol. B. Home attendants may administer normally self-administered drugs as allowed by § 54.1-3408 of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia). Any other drug shall be administered only by a licensed nurse or physician assistant. C. The organization shall develop written policies and procedures for the administration of home infusion therapy medications that include, but are not limited to: 1. Developing a plan of care or service; 2. Initiation of medication administration based on a prescriber's order and monitoring of the client for response to the treatment and any adverse reactions or side effects; 3. Assessment of any factors related to the home environment that may affect the prescriber's decisions for initiating, modifying, or discontinuing medications; 4. Communication with the prescriber concerning assessment of the client's response to therapy, any other client specific needs, and any significant change in the client's condition; 5. Communication with the client's provider pharmacy concerning	normally self-administered drugs as allowed by § 54.1-3408 of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia). Any other drug shall be administered only by a licensed nurse or physician assistant. C. The organization shall develop written policies and procedures for the administration of home infusion therapy medications that include, but are not limited to: 1. Developing a plan of care or service; 2. Initiation of medication administration based on a prescriber's order and monitoring of the client for response to the treatment and any adverse reactions or side effects; 3. Assessment of any factors related to the home environment that may affect the prescriber's decisions for initiating, modifying, or discontinuing medications; 4. Communication with the prescriber concerning assessment of the client's response to therapy, any other client specific needs, and any significant change in the client's condition; 5. Communication with the client's provider pharmacy concerning problems or needed changes in a client's medication; 6. Maintaining a complete and accurate record of medications prescribed, medication administration data, client assessments, any laboratory tests ordered to monitor response to drug therapy and results, and communications with the prescriber and pharmacy provider; 7. Educating or instructing the client, family members, or other caregivers involved in the administration of infusion therapy in the proper storage of medication, in the proper handling of supplies and equipment, in any applicable safety precautions, in recognizing

		problems or needed changes in a client's medication; 6. Maintaining a complete and accurate record of medications prescribed, medication administration data, client assessments, any laboratory tests ordered to monitor response to drug therapy and results, and communications with the prescriber and pharmacy provider; 7. Educating or instructing the client, family members, or other caregivers involved in the administration of infusion therapy in the proper storage of medication, in the proper handling of supplies and equipment, in any applicable safety precautions, in recognizing potential problems with the client, and actions to take in an emergency; and 8. Initial and retraining of all organization staff providing infusion therapy. D. The organization shall employ a registered nurse, who has completed training in infusion therapy, and has the knowledge, skills, and competencies to safely administer infusion therapy, to supervise medication administration by staff. This person shall be responsible for ensuring compliance with applicable laws and regulations, adherence to the policies and procedures related to administration of medications, and conducting periodic	potential problems with the client, and actions to take in an emergency; and 8. Initial and retraining of all organization staff providing infusion therapy. D. The organization shall employ a registered nurse, who has completed training in infusion therapy, and has the knowledge, skills, and competencies to safely administer infusion therapy, to supervise medication administration by staff. This person shall be responsible for ensuring compliance with applicable laws and regulations, adherence to the policies and procedures related to administration of medications, and conducting periodic assessments of staff competency in performing infusion therapy. Intent: Renamed the section to more accurately reflect the content of the section. Likely impact: Greater clarity of the regulations.

		assessments of staff competency in performing infusion therapy.	
355- Discharge Termination		N/A	A. There shall be a discharge or termination summary which will provide a final written summary filed in a client record of the services delivered and final disposition at the time of the client's discharge or termination from service. B. A registered nurse or qualified social worker shall develop or supervise the development of the discharge termination. Intent: New section. Previously the term discharge summary was defined but not utilized within the regulatory chapter. This section takes the elements of the definition and puts them into regulation. Likely impact: Greater clarity of the regulations. Greater patient protection.
360-Personal care services		A. An organization may provide personal care services in support of the client's health and safety in his home. The organization shall designate a registered nurse responsible for the supervision of personal care services. B. The personal care services shall include: 1. Assistance with the activities of daily living. A need for assistance exists when the client is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's functional level is based on the client's need for assistance most or all of the time to perform the tasks of daily living in order to live independently; 2. Administration of normally self-administered drugs as	A. An organization may provide personal care services in support of the client's health and safety in his home. The organization shall designate a registered nurse responsible for the ~~supervision~~coordination of personal care services. B. The personal care services shall include: 1. Assistance with the activities of daily living. A need for assistance exists when the client is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's functional level is based on the client's need for assistance most or all of the time to perform the tasks of daily living in order to live independently; 2. Administration of normally self-administered drugs as allowed in § 54.1-3408 of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia); 3. Taking and recording vital

		allowed in § 54.1-3408of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia); 3. Taking and recording vital signs, if specified in the plan of service; 4. Recording and reporting to the supervisor any changes regarding the client's condition, behavior or appearance; and 5. Documenting the services delivered in the client's record. Personal care services may also include the instrumental activities of daily living related to the needs of the client. C. Such services shall be delivered based on a written plan of services developed by a registered nurse, in collaboration with the client and client's family. The plan shall include at least the following: 1. Assessment of the client's needs; 2. Functional limitations of the client; 3. Activities permitted; 4. Special dietary needs; 5. Specific personal care services to be performed; and 6. Frequency of service. D. The plan shall be retained in the client's record. Copies of the plan shall be provided to the client receiving services and reviewed with the assigned home attendant prior to delivering services. E. Supervision of services shall be provided as often as necessary as determined by the client's needs, the	signs, if specified in the plan of service; 4. Recording and reporting to the supervisor any changes regarding the client's condition, behavior or appearance; and 5. Documenting the services delivered in the client's record. Personal care services may also include the instrumental activities of daily living related to the needs of the client. C. Such services shall be delivered based on a written plan of services developed by a registered nurse, ~~in collaboration~~ with the active participation of the client and client's ~~family~~representative. The plan shall include at least the following: 1. Assessment of the client's needs; 2. Functional limitations of the client; 3. Activities permitted; 4. Special dietary needs; 5. Specific personal care services to be performed; and 6. Frequency of service. D. The plan shall be retained in the client's record. Copies of the plan shall be provided to the client receiving services and reviewed with the assigned home attendant prior to delivering services. E. Supervision of ~~services~~ home attendants shall be provided as often as necessary ~~as determined by the client's needs, the assessment of the registered nurse, and~~ according to the organization's written policies not to exceed ~~90~~ 120 days. Such supervision may be provided by a qualified licensed practical nurse. F. A registered nurse or licensed practical nurse shall be available during all hours that personal care services are being provided. G. Home attendants providing personal care services shall receive at least 12 hours annually of

		assessment of the registered nurse, and the organization's written policies not to exceed 90 days. F. A registered nurse or licensed practical nurse shall be available during all hours that personal care services are being provided. G. Home attendants providing personal care services shall receive at least 12 hours annually of inservice training and education. Inservice training may be in conjunction with on-site supervision.	inservice training and education. Inservice training may be in conjunction with on-site supervision. Intent: Minor clarifying language; integration of a policy document into the regulations. Likely impact: Greater clarity and accuracy of the regulations.

If an existing regulation or regulations (or parts thereof) are being repealed and replaced by one or more new regulations, please use the following chart:

Current chapter-section number	Proposed new chapter-section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements

N/A

If a new regulation is being promulgated, that is not replacing an existing regulation, please use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements

N/A

If the proposed regulation is intended to replace an emergency regulation, and the proposed regulation is identical to the emergency regulation, please choose and fill out the appropriate chart template from the choices above. In this case “current section number” or “current chapter-section number” would refer to the **pre**-emergency regulation.

If the proposed regulation is intended to replace an emergency regulation, and the proposed regulation includes changes since the emergency regulation, please create two charts: 1) a chart describing changes from the **pre-emergency** regulation to the proposed regulation as described in the paragraph above, and 2) a chart describing changes from the **emergency** regulation to the proposed regulation. For the second chart please use the following title: “Changes from the Emergency Regulation.” In this case “current section number” or “current chapter-section number” would refer to the **emergency** regulation.

Project 4306 - none

DEPARTMENT OF HEALTH

Chapter 381 Update Regualtions following Periodic Review

Part I

Definitions and General Information

12VAC5-381-10. Definitions.

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

"Activities of daily living" or "ADLs" means bathing, dressing, toileting, transferring, bowel control, bladder control and eating/feeding. A person's degree of independence in performing these activities is part of determining the appropriate level of care and services. A need for assistance exists when the client is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's functional level is based on the client's need for assistance most or all of the time to perform personal care tasks in order to live independently.

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a client by (i) a practitioner or by his authorized agent and under his direction or (ii) the client at the direction and in the presence of the practitioner as defined in § 54.1-3401 of the Code of Virginia.

"Administrator" means a person designated in writing by the governing body as having the necessary authority for the day-to-day management of the organization. The administrator must be an employee of the organization. The administrator, the director of ~~nursing~~ skilled services, or other clinical director may be the same individual if that individual is dually qualified.

"Adverse event" means the result of drug or health care therapy that is neither intended nor expected in normal therapeutic use and that causes significant, sometimes life-threatening conditions or consequence at some future time. Such potential future adverse outcome may require the arrangement for appropriate follow-up surveillance and perhaps other departures from the usual plan of care.

"Available at all times during operating hours" means an individual is readily available on the premises or by telecommunications.

"Barrier crimes" means certain offenses, specified in § 32.1-162.9:1 of the Code of Virginia, that automatically bar an individual convicted of those offenses from employment with a home care organization.

"Blanket fidelity bond" means a bond that provides coverage that protects an organization's losses as a result of employee theft or fraud.

"Branch office" means a geographically separate office of the home care organization that performs all or part of the primary functions of the home care organization on a smaller scale.

"Chore services" means assistance with nonroutine, heavy home maintenance for persons unable to perform such tasks. Chore services include minor repair work on furniture and appliances; carrying coal, wood and water; chopping wood; removing snow; yard maintenance; and painting.

"Client record" means the centralized location for documenting information about the client and the care and services provided to the client by the organization. A client record is a continuous and accurate account of care or services, whether hard copy or electronic, provided to a client, including information that has been dated and signed by the individuals who prescribed or delivered the care or service.

~~"Client's residence" means the place where the individual or client makes his home such as his own apartment or house, a relative's home or an assisted living facility, but does not include a hospital, nursing facility or other extended care facility.~~

"Commissioner" means the State Health Commissioner.

"Companion services" means assisting persons unable to care for themselves without assistance. Companion services include transportation, meal preparation, shopping, light housekeeping, companionship, and household management.

"Contract services" means services provided through agreement with another agency, organization, or individual on behalf of the organization. The agreement specifies the services or personnel to be provided on behalf of the organization and the fees to provide these services or personnel.

"Criminal record report" means the statement issued by the Central Criminal Record Exchange, Virginia Department of State Police.

"Department" means the Virginia Department of Health.

~~"Discharge or termination summary" means a final written summary filed in a closed client record of the service delivered, goals achieved and final disposition at the time of client's discharge or termination from service.~~

"Dispense" means to deliver a drug to an ultimate user by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

"Drop site" means a location that HCO staff use in the performance of daily tasks such as obtaining supplies, using fax and copy machines, charting notes on care or services provided, and storing client records. These locations may also be called charting stations, workstations, or convenience sites.

"Employee" means an individual who has the status of an employee as defined by the U.S. Internal Revenue Service.

"Emergency management plan" means a plan developed by the organization to mitigate the damage of potential events that could endanger the organization's ability to function.

"Functional limitations" means the level of a client's need for assistance based on an assessment conducted by the supervising nurse. There are three criteria to assessing functional status: (i) the client's impairment level and need for personal assistance, (ii) the client's lack of capacity, and (iii) how the client usually performed the activity over a period of time. If a person is mentally and physically free of impairment, there is not a safety risk to the individual, or the person chooses not to complete an activity due to personal preference or choice, then that person does not need assistance.

"Governing body" means the individual, group or governmental agency that has legal responsibility and authority over the operation of the home care organization.

"Home attendant" means a nonlicensed individual performing ~~skilled,~~ pharmaceutical and personal care services, under the supervision of the appropriate health professional, to a client in the client's residence. Home attendants are also known as ~~certified nurse aides or CNAs,~~ home care aides, home health aides, or personal care aides.

"Home care organization" or "HCO" or "organization" means a public or private entity providing an organized program of home health, pharmaceutical or personal care services, according to § ~~32.1-162.1~~ 32.1-162.7 of the Code of Virginia in the residence of a client or individual to maintain the client's health and safety in his home. A home care organization does not include any family members, relatives or friends providing caregiving services to persons who need assistance to remain independent and in their own homes.

"Home health agency" means a public or private agency or organization, or part of an agency or organization, that meets the requirements for participation in Medicare under 42 CFR 440.70 (d), by providing skilled nursing services and at least one other therapeutic service, for example, physical, speech, or occupational therapy; medical social services; or home health aide services, and also meets the capitalization requirements under 42 CFR 489.28.

"Homemaker services" means assistance to persons with the inability to perform one or more instrumental activities of daily living. Homemaker services may also include assistance with bathing areas the client cannot reach, fastening client's clothing, combing hair, brushing dentures, shaving with an electric razor, and providing stabilization to a client while walking. Homemaker services do not include feeding, bed baths, transferring, lifting, putting on braces or other supports, cutting nails or shaving with a blade.

"Infusion therapy" means the procedures or processes that involve the administration of injectable medications to clients via the intravenous, subcutaneous, epidural, or intrathecal routes. Infusion therapy does not include oral, enteral, or topical medications.

"Instrumental activities of daily living" means meal preparation, housekeeping/light housework, shopping for personal items, laundry, or using the telephone. A client's degree of independence in performing these activities is part of determining the appropriate level of care and services.

"Licensed practical nurse" means a person who holds a current license issued by the Virginia Board of Nursing or a current multistate licensure privilege to practice nursing in Virginia as a licensed practical nurse.

"Licensee" means a licensed home care provider.

"Medical plan of care" means a written plan of services, and items needed to treat a client's medical condition, that is prescribed, signed and periodically reviewed by the client's primary care physician.

"Medication management" means the monitoring of medications that a patient takes to confirm that he is complying with a medication regimen, while also ensuring the patient is avoiding potentially dangerous drug interactions and other complications.

"Nursing services" means client care services, including, but not limited to, the curative, restorative, or preventive aspects of nursing that are performed or supervised by a registered nurse according to a medical plan of care.

"Office" means a place where business is conducted. A home care organization office is a place where client records, employee personnel files, financial records and the organization's policies and procedures are stored.

"OLC" means the Office of Licensure and Certification of the Virginia Department of Health.

"Operator" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity that is responsible for the day-to-day administrative management and operation of the organization.

~~"Organization" means a home care organization.~~

"Person" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity that operates a home care organization.

"Personal care services" means the provision of nonskilled services, including assistance in the activities of daily living, and may include instrumental activities of daily living, related to the needs of the client, who has or is at risk of an illness, injury or disabling condition. A need for assistance exists when the client is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's functional level is based on

the client's need for assistance most or all of the time to perform the tasks of daily living in order to live independently.

"Primary care physician" means a physician licensed in Virginia, according to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia, or licensed in an adjacent state and identified by the client as having the primary responsibility in determining the delivery of the client's medical care. The responsibility of physicians contained in this chapter may be implemented by nurse practitioners or physician assistants as assigned by the supervising physician and within the parameters of professional licensing.

"Qualified" means meeting current legal requirements of licensure, registration or certification in Virginia or having appropriate training, including competency testing, and experience commensurate with assigned responsibilities.

"Quality improvement" means ongoing activities designed to objectively and systematically evaluate the quality of client care and services, pursue opportunities to improve client care and services, and resolve identified problems. Quality improvement is an approach to the ongoing study and improvement of the processes of providing health care services to meet the needs of clients and others.

"Registered nurse" means a person who holds a current license issued by the Virginia Board of Nursing or a current multistate licensure privilege to practice nursing in Virginia as a registered nurse.

"Service area" means a clearly delineated geographic area in which the organization arranges for the provision of home care services, personal care services, or pharmaceutical services to be available and readily accessible to persons.

"Skilled services" means ~~the provision of the home health~~ those services listed in 12VAC5-381-300.

"Skilled services director" means a physician or registered nurse who is an employee of the organization and responsible for overseeing the overall direction and management of skilled services. The administrator and the skilled services director may be the same individual if that individual is dually qualified.

"Supervision" means the ongoing process of monitoring the skills, competencies and performance of the individual supervised and providing regular, documented, face-to-face guidance and instruction.

"Sworn disclosure statement" means a document disclosing an applicant's criminal convictions and pending criminal charges occurring in Virginia or any other state.

"Third-party crime insurance" means insurance coverage that protects an organization's losses as a result of employee theft or fraud.

12VAC5-381-20. License.

A. A license to operate a home care organization is issued to a person by the department. ~~However, no~~ Such license shall be in addition to any business license required by the State Corporate Commission or by any Virginia locality. No license shall be issued to a person who has been sanctioned pursuant to 42 USC § 1320a-7b. Persons planning to seek federal certification or national accreditation pursuant to § 32.1-162.8 of the Code of Virginia must first obtain state licensure.

B. The commissioner shall issue or renew a license to establish or operate a home care organization if the commissioner finds that the home care organization is in compliance with the law and this regulation.

C. The commissioner may issue a license to a ~~home care organization~~ person authorizing the licensee to provide services at one or more branch offices serving portions of the total

geographic area served by the licensee, provided each branch office operates under the supervision and administrative control of the licensee. The address of each branch office at which services are provided by the licensee shall be included on any license issued to the licensee. The addition of a branch office shall require a survey of the new branch location and the reissuance of the organization's license.

D. Every home care organization shall be designated by an appropriate name. The name shall not be changed without first notifying the OLC.

E. Licenses shall not be transferred or assigned.

F. Any person establishing, conducting, maintaining, or operating a home care organization without a license shall be guilty of a Class 6 felony according to § 32.1-162.15 of the Code of Virginia.

G. Any person establishing, conducting, maintaining, or operating a home care organization shall obtain the required business license(s) from the State Corporation Commission and if required by any Virginia locality.

12VAC5-381-30. Exemption from licensure.

A. This chapter is not applicable to those individuals and home care organizations listed in § 32.1-162.8 of the Code of Virginia. ~~Organizations planning to seek federal certification as a home health agency or national accreditation must first obtain state licensure and provide services to clients before applying for national accreditation or federal certification.~~ In addition, this chapter is not applicable to those providers of only homemaker, chore or companion services as defined in 12VAC5-381-10.

B. Organizations planning to seek federal certification as a home health agency or national accreditation must first obtain state licensure and provide services to clients before applying for national accreditation or federal certification. Upon receiving national accreditation or federal certification an organization may be exempted from maintaining a state license. A licensed organization requesting this exemption must file a written request and pay the required fee stated in 12VAC5-381-70 (D).

C. The home care organization shall be notified in writing if the exemption from licensure listed in 12VAC5-381-30 (B) has been granted. The basis for the exemption ~~approval~~decision will be stated and the organization ~~will~~shall be advised to contact the OLC to request licensure should it no longer meet the requirement for exemption.

D. ~~Exempted organizations~~ Organizations exempted from licensure under 12VAC5-381-30 (B), are subject to complaint investigations in keeping with state law. Should a complaint investigation prove an exempted organization's noncompliance with state regulations, the OLC shall notify the authority responsible for the organization's accreditation or certification.

12VAC5-381-35. Location.

The offices of a home care organization shall be located in a building that is zoned for business or commercial use. Offices shall not be located in residentially zoned areas.

Entities licensed as of the effective date of this section with offices located within residentially zoned areas shall have one year to come into compliance with this section.

12VAC5-381-40. License application; initial and renewal.

A. ~~The OLC provides prelicensure consultation and technical assistance regarding the licensure process. The purpose of such consultation is to explain the regulation and the survey process. Prelicensure consultations are arranged after a completed initial application is on file with the OLC.~~ Licensure applications can be found on the OLC's website.

B. ~~Licensure applications are obtained from the OLC. The OLC shall consider an application complete when all requested information and the appropriate fee, stated in 12VAC5-381-70, is~~

~~submitted. If the OLC finds the application incomplete, the applicant will be notified in writing.~~ Applicants for initial licensure must at a minimum file the following documentation in order for an application to be considered complete:

1. An application obtained from the OLC;

2. The initial licensure fee of $600;

3. The required business license(s) from the State Corporation Commission or by any Virginia locality;

4. A list of the governing body members and organizing documents;

5. Evidence of the administrator's qualifications;

6. Evidence of indemnity coverage;

7. The organization's client rights policies and procedures;

8. Job descriptions of the administrator, nursing director and financial manager;

9. A copy of the organization's business plan, and working budget; and

10. Evidence of the financial controls required by 12VAC5-381-190.

The OLC reserves the right to request additional documentation before considering an initial licensure application complete.

C. The activities and services of each applicant and licensee shall be subject to an inspection by the OLC to determine if the organization is in compliance with the provisions of this chapter and state law. Applicants for initial licensure shall be notified of the time and date of the initial survey.

D. A completed application for initial licensure must be submitted at least 60 days prior to the organization's planned opening date to allow the OLC time to process the application. If the OLC finds the application incomplete, the applicant shall be notified in writing. An incomplete application shall become inactive ~~six months~~ 30 days after ~~it is received by the OLC~~the OLC's written notification. Applicants with an inactive application must ~~then~~ reapply for licensure with a completed application and application fee. An application for a license may be withdrawn at any time.

E. ~~Licenses are renewed annually. The OLC shall make~~ Annual renewal applications ~~available~~ shall be submitted by the organization at least 60 days prior to the expiration date of the current license.

F. Providers failing to submit an acceptable plan of correction as required in 12VAC5-381-80 shall not be eligible for license renewal. Failure to submit a plan of correction shall be grounds for denial, suspension, or revocation of the facility's license in accordance with in 12VAC5-381-130.

~~F~~G. It is the home care organization's responsibility to complete and return a renewal application to assure timely processing. Should a current license expire before a new license is issued, the current license shall remain in effect provided a complete and accurate application was filed on time.

~~12VAC5-381-50. Compliance appropriate for all types of HCOs.~~ (Repealed.)

~~All organizations shall be in compliance with Part I (12VAC5-381-10 et seq.) and Part II (12VAC5-381-150 et seq.) of this chapter. In addition, organizations shall be in compliance with Part III (12VAC5-381-300 et seq.), Part IV (12VAC5-381-350), or Part V (12VAC5-381-360 et seq.) of this chapter as applicable to the services provided by the organization.~~

12VAC5-381-60. Changes to or reissue of a license.

A. It is the responsibility of the organization's governing body to maintain a current and accurate license. Licenses that are misplaced or lost must be ~~replaced~~reissued.

B. An organization shall give written notification 30 working days ~~in advance of any proposed changes~~ prior to changes that ~~may~~ require the reissuance of a license. Notices shall be sent to the attention of the director of the OLC.

The following changes require the reissuance of a license and payment of a fee:

1. Operator;

2. Organization name; ~~or~~

3. Address~~.~~;

4. Addition or removal of a branch office; or

5. Addition or removal of skilled services.

C. The OLC ~~will~~ shall evaluate written information about any planned changes in operation that affect the terms of the license or the continuing eligibility for a license. A licensing representative may inspect the organization during the process of evaluating a proposed change.

D. The organization ~~will~~ shall be notified in writing whether a new application is needed.

12VAC5-381-70. Fees.

A. The OLC shall collect a fee of ~~$500~~ $600 for each initial and renewal license application. Fees shall accompany the licensure application ~~and are not refundable~~.

B. An additional late fee of ~~$50~~ $100 shall be collected for an organization's failure to file a renewal application by the date specified.

C. A processing fee of ~~$250~~$300 shall be collected for each reissuance or replacement of a license and shall accompany the written request for reissuance or replacement.

D. A one-time processing fee of ~~$75~~ $125 for exemption from licensure shall accompany the written exemption request.

E. All fees shall be nonrefundable.

12VAC5-381-80. On-site inspections.

A. Applicants for initial licensure shall be notified of the time and date of the initial survey. Failure to be fully prepared may result in the cancellation of the initial survey. In the event of the cancellation of the initial survey, the applicant shall wait 120 days before reapplying for an initial license. An applicant reapplying for licensure shall be required to submit all elements in 12VAC5-381-40 (B).

~~A.~~ B. An OLC representative shall make periodic unannounced on-site inspections of each home care organization as necessary but not less often than ~~biennially~~triennially. The organization shall be responsible for correcting any deficiencies found during any on-site inspection. Compliance with all standards ~~will~~shall be determined by the OLC according to applicable law.

~~B.~~ C. The home care organization shall make available to the OLC's representative any necessary records and shall allow access to interview the agents, employees, contractors, and any person under the organization's control, direction or supervision.

D. If the OLC's representative arrives on the premises to conduct a survey and the administrator, the nursing director, or a person authorized to give access to client records is not available on the premises, such person or the designated alternate shall be available on the premises within one hour of the surveyor's arrival. A list of current clients shall be provided to the surveyor within two hours of arrival, if requested. Failure to be available shall be grounds for penalties in accordance with § 32.1-27 of the Code of Virginia and denial, suspension, or revocation of the facility's license in accordance with 12VAC5-381-130.

~~C.~~ E. After the on-site inspection, the OLC's representative shall discuss the findings of the inspection with the administrator or his designee.

~~D.~~ F. The administrator shall submit, within 15 working days of receipt of the inspection report, an acceptable plan for correcting any deficiencies found. The plan of correction shall contain:

1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action;

2. The expected correction date;

3. A description of the measures implemented to prevent a recurrence of the violation; and

4. The signature of the person responsible for the validity of the report.

~~E.~~ G. The administrator will be notified whenever any item in the plan of correction is determined to be unacceptable.

~~F.~~ H. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

~~G.~~ I. Completion of corrective actions shall not exceed 45 working days from the ~~last day of the inspection~~date the inspection report is received by the administrator as demonstrated by certified mail.

12VAC5-381-100. Complaint investigations conducted by the OLC.

A. The OLC has the responsibility to investigate any complaints regarding alleged violations of this chapter and applicable law.

B. Complaints may be received in writing or orally and may be anonymous.

C. When the investigation is complete, the licensee and the complainant, if known, will be notified of the findings of the investigation.

D. As applicable, the administrator shall submit, within 15 working days of receipt of the complaint report, an acceptable plan of correction for any deficiencies found during a complaint investigation. The plan of correction shall contain:

1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action;

2. The expected correction date;

3. A description of the measures implemented to prevent a recurrence of the violation; and

4. The signature of the person responsible for the validity of the report.

E. The administrator ~~will~~ shall be notified ~~in writing~~ whenever any item in the plan of correction is determined to be unacceptable.

F. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

12VAC5-381-110. Criminal records checks.

A. Section 32.1-162.9:1 of the Code of Virginia requires home care providers, as defined in § 32.1-162.7 of the Code of Virginia, to obtain a criminal record report on applicants for compensated employment from the Virginia Department of State Police. ~~Section 32.1-162.9:1 of the Code of Virginia also requires that all~~ All applicants for employment in home care organizations shall provide a sworn disclosure statement regarding their past and pending criminal history. The sworn disclosure statement shall be stored with the criminal record report within the employee's personnel file.

B. The criminal record report shall be obtained within 30 days of employment. It shall be the responsibility of the organization to ensure that its employees have not been convicted of any of the barrier crimes listed in § 32.1-162.9:1 of the Code of Virginia.

C. The organization shall not accept a criminal record report dated more than 90 days prior to the date of employment.

D. Only the original criminal record report shall be accepted. An exception is permitted for organizations using temporary staffing agencies for the provision of substitute staff. The organization shall obtain a letter from the temporary staffing agency containing the following information:

1. The name of the substitute staffing person;

2. The date of employment by the temporary staffing agency; and

3. A signed statement verifying that the criminal record report has been obtained within 30 days of employment, is on file at the temporary staffing agency, and does not contain any barrier crimes listed in § 32.1-162.9:1 of the Code of Virginia.

E. No employee shall be permitted to work in a position that involves direct contact with a patient until an original criminal record report has been received by the home care organization or temporary staffing agency, unless such person works under the direct supervision of another employee for whom a background check has been completed in accordance with subsection B of this section.

F. A criminal record report remains valid as long as the employee remains in continuous service with the same organization.

G. A new criminal record report and sworn statement shall be required when an individual terminates employment at one home care organization and begins work at another home care organization. The following exceptions are permitted:

1. When an employee transfers within 30 days to an organization owned and operated by the same entity. The employee's file shall contain a statement that the original criminal record report has been transferred or forwarded to the new work location.

2. When an individual takes a leave of absence, the criminal record report and sworn statement will remain valid as long as the period of separation does not exceed six consecutive months. If six consecutive months have passed, a new criminal record report and sworn disclosure statement are required.

~~H. A sworn disclosure statement shall be completed by all applicants for employment. The sworn disclosure statement shall be attached to and filed with the criminal record report.~~

~~I~~H. Any applicant denied employment because of convictions appearing on his criminal record report shall be provided a copy of the report by the hiring organization.

~~J~~I. All criminal record reports and sworn disclosure statements shall be confidential and maintained in locked files accessible only to the administrator or designee.

~~K~~J. Further dissemination of the criminal record report and sworn disclosure statement information is prohibited other than to the commissioner's representative or a federal or state authority or court as may be required to comply with an express requirement of law for such further dissemination.

12VAC5-381-120. Variances.

~~A. The OLC can authorize variances only to its own licensing regulations, not to regulations of another agency or to any requirements in federal, state, or local laws.~~

~~B. A home care organization may request a variance to a particular regulation or requirement contained in this chapter when the standard or requirement poses a special hardship and when a variance to it would not endanger the safety or well-being of clients. The~~

~~request for a variance must describe how compliance with the current regulation is economically burdensome and constitutes a special hardship to the home care organization and to the clients it serves. When applicable, the request should include proposed alternatives to meet the purpose of the requirements that will ensure the protection and well-being of clients. At no time shall a variance approved for one individual be extended to general applicability. The home care organization may at any time withdraw a request for a variance.~~

~~C. The OLC shall have the authority to waive, either temporarily or permanently, the enforcement of one or more of these regulations provided safety, client care and services are not adversely affected.~~

~~D. The OLC may rescind or modify a variance if (i) conditions change; (ii) additional information becomes known that alters the basis for the original decision; (iii) the organization fails to meet any conditions attached to the variance; or (iv) results of the variance jeopardize the safety, comfort, or well-being of clients.~~

~~E. Consideration of a variance is initiated when a written request is submitted to the Director, OLC. The OLC shall notify the home care organization in writing of the receipt of the request for a variance. The OLC may attach conditions to a variance to protect the safety and well-being of the client.~~

~~F. The licensee shall be notified in writing if the requested variance is denied.~~

~~G. If a variance is denied, expires, or is rescinded, routine enforcement of the regulation or portion of the regulation shall be resumed.~~

~~H. The home care organization shall develop procedures for monitoring the implementation of any approved variances to assure the ongoing collection of any data relevant to the variance and the presentation of any later report concerning the variance as requested by the OLC.~~

A. The commissioner may authorize a temporary variance only to a specific provision of this chapter. In no event shall a temporary variance exceed the term of the license. A home care organization may request a temporary variance to a particular standard or requirement contained in a particular provision of this chapter when the standard or requirement poses an impractical hardship unique to the home care organization and when a temporary variance to it would not endanger the safety or well-being of patients. The request for a temporary variance shall describe how compliance with the current standard or requirement constitutes an impractical hardship unique to the home care organization. The request should include proposed alternatives, if any to meet the purpose of the standard or requirement that will ensure the protection and well-being of patients. At no time shall a temporary variance be extended to general applicability. The home care organization may withdraw a request for a temporary variance at any time.

B. The commissioner may rescind or modify a temporary variance if: (i) conditions change; (ii) additional information becomes known that alters the basis for the original decision; (iii) the home care organization fails to meet any conditions attached to the temporary variance; or (iv) results of the temporary variance jeopardize the safety or well-being of patients.

C. Consideration of a temporary variance is initiated when a written request is submitted to the commissioner or his designee. The commissioner or his designee shall notify the home care organization in writing of the receipt of the request for a temporary variance. The licensee shall be notified in writing of the commissioner's decision on the temporary variance request. If granted, the commissioner may attach conditions to a temporary variance to protect the safety and well-being of patients.

D. If a temporary variance is denied, expires or is rescinded, routine enforcement of the standard or requirement to which the temporary variance was granted shall be resumed.

12VAC5-381-130. ~~Revocation or suspension of a license.~~ Violation of This Chapter or Applicable Law; Denial, Revocation, or Suspension of License.

~~A. The commissioner is authorized to revoke or suspend any license if the licensee fails to comply with the provisions of Article 7.1 (§ 32.1-162.7 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia or the regulations of the board.~~

~~B. If a license is revoked, the commissioner may issue a new license when the conditions upon which revocation was based have been corrected and compliance with all provisions of the law and this chapter has been achieved.~~

~~C. When a license is revoked or suspended, the organization shall cease operations. If the organization continues to operate after its license has been revoked or suspended, the commissioner may request the Office of the Attorney General to petition the circuit court of the jurisdiction in which the home care organization is located for an injunction to cause such home care organization to cease operations.~~

~~D. Suspension of a license shall in all cases be for an indefinite time. The suspension may be lifted and rights under the license fully or partially restored at such time as the commissioner determines that the rights of the licensee appear to so require and the interests of the public will not be jeopardized by resumption of operation.~~

A. When the department determines that a home care organization is (i) in violation of any provision of Article 7.1 (§ 32.1-162.7 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia or of any applicable regulation, or (ii) is permitting, aiding, or abetting the commission of any illegal act in the home care organization, the department may deny, suspend, or revoke the license to operate a home care organization in accordance with § 32.1-162.13 of the Code of Virginia.

B. If a license is revoked as herein provided, a new license may be issued by the commissioner after satisfactory evidence is submitted to him that the conditions upon which revocation was based have been corrected and after proper inspection has been made and compliance with all provision of Article 7.1 of Chapter 5 of Title 32.1 of the Code of Virginia and applicable state and federal law and regulations hereunder has been obtained.

C. Suspension of a license shall in all cases be for an indefinite time. The commissioner may restore a suspended license when he determines that the conditions upon which suspension was based have been corrected and that the interests of the public will not be jeopardized by resumption of operation. No additional fee shall be required for restoring such a license.

D. The home care organization has the right to contest the denial revocation, or suspension of a license in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

E. Whenever a license is revoked or suspended and the organization continues to operate, the Commissioner shall request the Office of the Attorney General to petition the circuit court of the jurisdiction in which the home care organization is located for an injunction to cause such home care organization to cease providing services for the purpose of patient protection.

F. The Commissioner or his designee shall notify the Department of Medical Assistance Services whenever any license is revoked, suspended, or expired.

12VAC5-381-140. ~~Return of a license.~~ Discontinuation of services.

~~A. Circumstances under which a license must be returned include, but are not limited to (i) transfer of ownership and (ii) discontinuation of services.~~

~~B. The licensee shall notify its clients and the OLC, in writing, 30 days before discontinuing services.~~

~~C.~~ If the organization ~~is no longer operational~~discontinues services, or the license has been suspended or revoked, the license shall be returned to the OLC within five working days. The ~~licensee~~organization shall notify its clients and the OLC where all patient home care records will be located.

Part II
Administrative Services

12VAC5-381-150. Management and administration.

A. No person shall establish or operate a home care organization, as defined in § 32.1-162.7 of the Code of Virginia, without having obtained a license.

B. The organization ~~must~~shall comply with:

1. This chapter (12VAC5-381);

2. Other applicable federal, state or local laws and regulations; and

3. The organization's own policies and procedures.

C. The organization shall submit or make available reports and information necessary to establish compliance with this chapter and applicable law.

D. The organization shall permit representatives from the OLC to conduct inspections to:

1. Verify application information;

2. Determine compliance with this chapter;

3. Review necessary records and documents; and

4. Investigate complaints.

E. The organization shall notify the OLC 30 days in advance of changes affecting the organization, including the:

1. ~~Service area;~~ Operator;

2. ~~Mailing address of the organization;~~ Organization name;

3. ~~Ownership;~~ Physical or mailing address;

4. Branch offices;

~~4~~5. Services provided;

~~5. Operator;~~ 6. Service area

~~6. Administrator;~~ 7. Ownership

~~7. Organization name~~ 8. Administration; and

~~8.~~ 9. Closure of the organization.

Changes to E (1) – E (5) shall require reissuance of the organization's license pursuant to 12VAC5-381-60.

F. The current license from the department shall be posted for public inspection, in a conspicuous place to which members of the public have ready access. Posting of the license on the organization's website shall meet this requirement.

G. Service providers or community affiliates under contract with the organization must comply with the organization's policies and this chapter.

H. The organization shall not use any advertising that contains false, misleading or deceptive statements or claims, or false or misleading disclosures of fees and payment for services.

I. The organization shall have regular posted business hours and be fully operational during such business hours. In addition, the organization shall provide or arrange for services to their clients on an on-call basis 24 hours a day, seven days a week.

J. The organization shall accept a client only when the organization can adequately meet that client's needs in the client's place of residence.

K. The organization must have a prepared plan for emergency operations in case of inclement weather or natural disaster to include contacting and providing essential care to clients, coordinating with community agencies to assist as needed, and maintaining a current list of clients who would require specialized assistance.

L. The organization shall encourage and facilitate the availability of flu shots for its staff and clients.

12VAC5-381-170. Administrator.

A. ~~The governing body shall appoint as administrator an individual who has evidence of at least one year of training and experience in direct health care service delivery with at least one year within the last five years of supervisory or administrative management experience in home health care or a related health program.~~ The governing body shall appoint an administrator who has experience within the last five years with health care administration or management. Preference shall be given to applicants who are licensed health care professionals.

B. The administrator shall be responsible for the day-to-day management of the organization, including but not limited to:

1. Organizing and supervising the administrative function of the organization;

2. Maintaining an ongoing liaison with the governing body, the professional personnel and staff;

3. Employing qualified personnel and ensuring adequate staff orientation, training, education and evaluation;

4. Ensuring the accuracy of public information materials and activities;

5. Implementing an effective budgeting and accounting system;

6. Maintaining compliance with applicable laws and regulations and implementing corrective action in response to reports of organization committees and regulatory agencies;

7. Arranging and negotiating services provided through contractual agreement; and

8. ~~Implementing the policies and procedures approved by the governing body.~~ Ensuring the development, implementation and enforcement of all policies and procedures.

C. ~~The individual designated to perform the duties of the administrator when the administrator is absent from the organization shall be able to perform the duties of the administrator as identified in subsection B of this section.~~ The organization shall designate an individual to perform the duties of the administrator when the administrator is absent.

D. The administrator or his designee shall be available at all times during operating hours and for emergency situations.

12VAC5-381-180. Written policies and procedures.

A. The organization shall implement written policies and procedures approved by the governing body.

B. All policies and procedures shall be reviewed at least annually, with recommended changes submitted to the governing body for approval, as necessary.

C. Administrative and operational policies and procedures shall include, but are not limited to:

1. Administrative records;

2. Admission and discharge or termination from service criteria;

3. Informed consent;

4. ~~Advance~~ Providing information regarding advance directives, including Durable Do Not Resuscitate Orders;

5. Client rights;

6. Contract services;

7. Medication management, if applicable;

8. Quality improvement;

9. Mandated reporting of abuse, neglect and exploitation pursuant to § 63.2-1606 of the Code of Virginia;

10. Communicable and reportable diseases;

11. Client records, including confidentiality;

12. Record retention, including termination of services;

13. Supervision and delivery of services;

14. Emergency and on-call services;

15. Infection control;

16. Handling consumer complaints;

17. Telemonitoring; ~~and~~

18. Approved variances~~.~~ ; and

19. An emergency management plan.

D. Financial policies and procedures shall include, but are not limited to:

1. Admission agreements;

2. Data collection and verification of services delivered;

3. Methods of billing for services by the organization and by contractors;

4. Client notification of changes in fees and charges;

5. Correction of billing errors and refund policy; and

6. Collection of delinquent client accounts.

E. Personnel policies and procedures shall include, but are not limited to a:

1. Written job description that specifies authority, responsibility, and qualifications for each job classification;

2. Standards of conduct, which shall include corrective action that may be taken to address violations of the standards, and a method for enforcing the standards while an employee is in a client's residence;

~~2.~~ 3. Process for maintaining an accurate, complete and current personnel record for each employee;

~~3~~. 4. Process for verifying current professional licensing or certification and training of employees or independent contractors;

~~4~~5. Process for annually evaluating employee performance and competency;

~~5~~6. Process for verifying that contractors and their employees meet the personnel qualifications of the organization;

~~6~~7. Process for obtaining a criminal background check and maintaining a drug-free workplace pursuant to § 32.1-162.9:1 of the Code of Virginia; and

~~7~~8. Process for reporting licensed and certified medical personnel for violations of their licensing or certification to the ~~appropriate board within the Department of Health~~

~~Professions.~~ Director of the Office of Licensure and Certification at the Department of Health as required by § 54.1-2400.6.

F. Admission and discharge or termination from service policies and procedures shall include, but are not limited to:

1. Criteria for accepting clients for services offered;

2. The process for obtaining a plan of care or service;

3. Criteria for determining discharge or termination from each service and referral to other agencies or community services; and

4. Process for notifying clients of intent to discharge/terminate or refer, including:

a. Oral and written notice and explanation of the reason for discharge/termination or referral;

b. The name, address, telephone number and contact name at the referral organization; and

c. Documentation in the client record of the referral or notice.

G. Policies shall be made available for review, upon request, to clients and their ~~designated~~ representatives.

H. Policies and procedures shall be readily available for staff use at all times.

12VAC5-381-190. Financial controls.

A. Every applicant for an initial license to establish or operate a home care organization shall include as part of his application a detailed operating budget showing projected operating expenses for the three-month period after a license to operate has been issued. Further, every applicant for an initial license to establish or operate a home care organization shall include as part of his application proof of initial reserve operating funds in the amount sufficient to ensure operation of the home care organization for the three-month period after a license to operate has been issued. Such funds may include:

1. Cash;

2. Cash equivalents that are readily convertible to known amounts of cash and that present insignificant risk of change in value;

3. Borrowed funds that are immediately available to the applicant; or

4. A line of credit that is immediately available to the applicant.

Proof of funds sufficient to meet these requirements shall include a current balance sheet demonstrating the availability of funds, a letter from the officer of the bank or other financial institution where the funds are held, or a letter of credit from a lender demonstrating the current availability of and amount of a line of credit.

B. The organization shall document financial resources to operate based on a working budget showing projected revenue and expenses. The organization shall maintain records of financial resources and a working budget throughout operations and shall make these records available to any OLC representative conducting an on-site inspection in accordance with 12VAC5-381-80.

C. All financial records shall be kept according to generally accepted accounting principles (GAAP).

~~D. All financial records shall be audited at least triennially by an independent certified public accountant (CPA), or audited as otherwise provided by law.~~

~~E~~D. The organization shall have documented financial controls to minimize risk of theft or embezzlement.

12VAC5-381-200. Personnel practices.

A. Personnel management and employment practices shall comply with applicable state and federal laws and regulations.

B. The organization shall design and implement a staffing plan that reflects the types of services offered and shall provide qualified staff in sufficient numbers to meet the assessed needs of all clients.

C. Employees and contractors shall be licensed or certified as required by the Department of Health Professions.

D. The organization shall design and implement a mechanism to verify professional credentials.

E. Any person who assumes the responsibilities of any staff position or positions shall meet the minimum qualifications for that position or positions.

F. The organization shall obtain the required sworn statement and criminal record check for each compensated employee as specified in § 32.1-162.9:1 of the Code of Virginia.

G. Each employee position shall have a written job description that includes:

1. Job title;

2. Duties and responsibilities required of the position;

3. Job title of the immediate supervisor; and

4. Minimum knowledge, skills, and abilities or professional qualifications required for entry level.

H. Employees shall have access to their current position description. There shall be a mechanism for advising employees of changes to their job responsibilities.

I. New employees and contract individuals shall be oriented commensurate with their function or job-specific responsibilities. Orientation shall include but is not limited to:

1. Objectives and philosophy of the organization;

2. All of the organization's policies and procedures;

~~2~~3. Confidentiality;

~~3~~4. Client rights;

~~4~~5. Mandated reporting of abuse, neglect, and exploitation;

~~5. Applicable personnel policies;~~

~~6. Emergency preparedness procedures;~~

~~7~~6. Infection control practices and measures;

~~8~~7. Cultural awareness; and

~~9~~8. Applicable laws, regulations, and other policies and procedures that apply to specific positions, specific duties and responsibilities.

J. The organization shall develop and implement a policy for evaluating employee performance.

K. Individual staff development needs and plans shall be a part of the performance evaluation.

L. The organization shall provide opportunities for and record participation in staff development activities designed to enable staff to perform the responsibilities of their positions.

M. All individuals who enter a client's home for or on behalf of the organization shall be readily identifiable by employee nametag, uniform or other visible means.

N. The organization shall maintain an organized system to manage and protect the confidentiality of personnel files and records.

O. Employee personnel records, whether hard copy or electronic, shall include:

1. Identifying information;

2. Education and training history;

3. Employment history;

4. Results of the verification of applicable professional licenses or certificates;

5. Results of reasonable efforts to secure job-related references and reasonable verification of employment history;

6. Results of performance evaluations;

7. A record of disciplinary actions taken by the organization, if any;

8. A record of adverse action by any licensing bodies and organizations, if any;

9. A record of participation in staff development activities, including orientation; and

10. The criminal record check and sworn affidavit. For employees that work in multiple locations, the original criminal record check shall reside in their employee record located in the central office and the organization shall provide proof of this documentation to any OLC representative conducting an inspection in accordance with 12VAC5-381-80.

P. All positive results from drug testing shall be reported to the health regulatory boards responsible for licensing, certifying, or registering the person to practice, if any, pursuant to § 32.1-162.9:1 of the Code of Virginia.

Q. Each employee personnel record shall be retained in its entirety for a minimum of three years after termination of employment.

R. Personnel record information shall be safeguarded against loss and unauthorized use.

S. Employee health-related information shall be maintained separately ~~within the~~ from the remainder of the employee's personnel file.

12VAC5-381-210. Indemnity coverage.

A. The governing body shall ensure the organization and its contractors have appropriate indemnity coverage to compensate clients for injuries and losses resulting from services provided.

B. The organization shall purchase and maintain the following types and minimum amounts of indemnity coverage at all times:

1. Malpractice insurance ~~consistent~~which complies with § 8.01-581.15 of the Code of Virginia;

2. General liability insurance covering personal property damages, bodily injuries, product liability, and libel and slander of at least $1 million comprehensive general liability per occurrence; and

3. Third-party crime insurance or a blanket fidelity bond of $50,000 minimum.

12VAC5-381-220. Contract services.

A. There shall be a written agreement for the provision of services not provided by employees of the organization.

B. The written agreement shall include, but is not limited to:

1. The services to be furnished by each party to the contract;

2. The contractor's responsibility for participating in developing plans of care or service;

3. The manner in which services will be controlled, coordinated, and evaluated by the primary home care organization;

4. The procedures for submitting notes on the care or services provided, scheduling of visits, and periodic client evaluation;

5. The process for payment for services furnished under the contract; and

6. Adequate liability insurance and third-party crime insurance or a blanket fidelity bond~~.~~ as required by 12VAC5-381-210 (B).

C. The organization shall have a written plan for provision of care or services when a contractor is unable to deliver services.

D. The contractor shall conform to applicable organizational policies and procedures as specified in the contract, including the required sworn disclosure statement and criminal record check.

12VAC5-381-230. Client rights.

A. The organization shall establish and implement written policies and procedures regarding the rights of clients.

B. Client rights shall be reviewed with clients or client designees upon admission to the organization. The review shall be documented in the client's record.

C. Written procedures to implement the policies shall ensure that each client is at a minimum:

1. Treated with courtesy, consideration and respect and is assured the right of privacy;

2. Assured confidential treatment of his medical and financial records as provided by law;

3. Free from mental and physical abuse, neglect, and property exploitation;

4. Assured the right to participate in the planning of the client's home care, including the right to refuse services;

5. Served by individuals who are properly trained and competent to perform their duties;

6. Assured the right to voice grievances and complaints related to organizational services without fear of reprisal;

7. Advised, before care is initiated, of the extent to which payment for the home care organization services may be expected from federal or state programs, and the extent to which payment may be required from the client;

8. Advised orally and in writing of any changes in fees for services that are the client's responsibility. The home care organization shall advise the client of these changes as soon as possible, but no later than 30 calendar days from the date the home care organization became aware of the change;

9. Provided with advance directive information prior to start of services; ~~and~~

10. Given at least five days written notice when the organization determines to terminate services~~.~~; and

11. Afforded an opportunity to offer feedback and input regarding the services provided by the assigned home care attendant(s). The organization shall clearly inform its clients that such feedback and input is voluntary, may be anonymous, and any information provided shall not affect the client's care.

D. Before care is initiated, the home care organization shall inform the client, orally and in writing, of:

1. The nature and frequency of services to be delivered and the purpose of the service;

2. Any anticipated effects of treatment, as applicable:

3. A schedule of fees and charges for services;

4. The method of billing and payment for services, including the:

a. Services to be billed to third party payers;

b. Extent to which payment may be expected from third party payers known to the home care organization; and

c. Charges for services that will not be covered by third party payers;

5. The charges that the individual may have to pay;

6. The requirements of notice for cancellation or reduction in services by the organization and the client; and

7. The refund policies of the organization.

12VAC5-381-240. Handling complaints received from clients.

A. The organization shall establish and maintain complaint handling procedures that specify the:

1. System for logging receipt, investigation and resolution of complaints; and

2. Format of the written record of the findings of each complaint investigated.

B. The organization shall designate staff responsible for complaint resolution, including:

1. Complaint intake, including acknowledgment of complaints;

2. Investigation of the complaint;

3. Review of the investigation of findings and resolution for the complaint; and

4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint.

C. The client or his ~~designee~~representative shall be given a copy of the complaint procedures at the time of admission to service and at the time of any changes to the organization's complaint procedures. The organization shall provide each client or his ~~designee~~representative with the name, mailing address, and telephone number of the:

1. ~~Organization~~ Organization's complaint contact person;

2. State Ombudsman; and

3. Complaint Unit of the OLC.

D. The organization shall maintain documentation of all complaints received and the status of each complaint from date of receipt through its final resolution. Records shall be maintained from the date of last inspection and for no less than three years.

12VAC5-381-250. Quality improvement.

A. The organization shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The findings shall be used to correct identified problems and revise policies and practices, as necessary. Exclusive concentration on administrative or cost-of-care issues does not fulfill this requirement.

B. The following data shall be evaluated to identify unacceptable or unexpected trends or occurrences:

1. Staffing patterns and performance to assure adequacy and appropriateness of services delivered;

2. Supervision appropriate to the level of service;

3. Any medication errors;

~~3~~4. On-call responses;

~~4~~5. Client records for appropriateness of services provided;

~~5~~6. Client satisfaction;

~~6~~7. Complaint resolution;

~~7~~8. Infections;

~~8~~9. Staff concerns regarding client care; and

~~9~~10. Provision of services appropriate to the clients' needs.

C. A quality improvement committee responsible for the oversight and supervision of the program, shall consist of:

1. The director of skilled services or organization's register nurse as appropriate for the type of services provided;

2. A member of the administrative staff;

3. Representatives from each of the services provided by the organization, including contracted services; and

4. An individual with demonstrated ability to represent the rights and concerns of clients. The individual may be a member of the organization's staff, a client, or a client's ~~family member~~representative.

In selecting members of this committee, consideration shall be given to a candidate's abilities and sensitivity to issues relating to quality of care and services provided to clients.

D. Measures shall be implemented to resolve important problems or concerns that have been identified. Health care practitioners, as applicable, and administrative staff shall participate in the resolution of the problems or concerns that are identified.

E. Results of the quality improvement program shall be reported annually to the governing body and the administrator and available in the organization. The report shall be acted upon by the governing body and the organization. All corrective actions shall be documented.

12VAC5-381-270. Drop sites.

A. The organization may operate one or more drop sites for the convenience of staff providing direct client care or service. However, such sites shall not:

1. Have staff assigned;

2. Accept referrals; or

3. Be advertised as part of the organization.

B. Any client records located at the site shall be safeguarded against loss or unauthorized use. Only authorized personnel shall have access to client records as specified by state and federal law. It shall be the responsibility of the organization to assure that records maintained at the site are readily available for inspection staff.

C. ~~Operation of a drop site as a business office~~ Any location that does not meet the elements of subsection A shall constitute a separate organization and shall require licensure. Drop sites shall not be separately licensed. Should OLC discover a drop site which is separately licensed the organization shall be required to surrender the license of the drop site to the OLC.

D. Drop sites shall be subject to inspection at any time.

12VAC5-381-280. Client record system.

A. The organization shall maintain an organized client record system according to accepted standards of practice. Written policies and procedures shall specify retention, reproduction, access, storage, content, and completion of the record.

B. The client record information shall be safeguarded against loss or unauthorized use.

C. Client records shall be confidential. Only authorized personnel shall have access as specified by state and federal law.

D. Provisions shall be made for the safe storage of the original record and for accurate and legible reproductions of the original.

E. Policies shall specify arrangements for retention and protection of records if the organization discontinues operation and shall provide for notification to the OLC and the client of the location of the records.

F. An accurate and complete client record shall be maintained for each client receiving services and shall include, but shall not be limited to:

1. Client identifying information;

2. A copy of informed consent forms signed by the client, or the client's representative;

3. A copy of the consent to release of confidential information signed by the client or the client's representative;

~~2~~4. Identification of the primary care physician;

~~3~~5. Admitting information, including a client history;

~~4~~6. Information on the composition of the client's household, including individuals to be instructed in assisting the client;

~~5~~7. An initial assessment of client needs to develop a plan of care or services;

~~6~~8. A plan of care or service that includes the type and frequency of each service to be delivered either by organization personnel or contract services;

~~7~~9. Documentation of client rights review; ~~and~~

~~8~~10. A discharge or termination of service summary~~.~~; and

~~In addition, client records for skilled and pharmaceutical services shall include:~~

~~9~~11. Documentation and results of all medical tests ordered by the physician or other health care professional and performed by the organization's staff;

~~10~~12. A medical plan of care including appropriate assessment and pain management;

~~11~~13. Medication sheets that include the name, dosage, frequency of administration, possible side effects, route of administration, date started, and date changed or discontinued for each medication administered; ~~and~~

14. Any medication errors and drug reactions; and

~~12~~15. Copies of all summary reports sent to the primary care physician.

G. Signed and dated notes on the care or services provided by each individual delivering service shall be ~~written~~documented on the day the service is delivered and incorporated in the client record within ~~seven~~fourteen working days.

H. Entries in the client record shall be current, legible, dated and authenticated in writing or by electronic signature by the person making the entry. Errors shall be corrected by striking through and initialing.

I. Originals or reproductions of individual client records shall be maintained in their entirety for a minimum of five years following discharge or date of last contact unless otherwise specified by state or federal requirements. Records of minors shall be kept for at least five years after the minor reaches 18 years of age.

12VAC5-381-290. Home attendants.

Home attendants shall be able to speak, read and write English and shall meet one of the following qualifications:

1. Have satisfactorily completed a nursing education program preparing for registered nurse licensure or practical nurse licensure;

2. Have satisfactorily completed a nurse aide education program approved by the Virginia Board of Nursing;

3. Have certification as a nurse aide issued by the Virginia Board of Nursing;

4. Be successfully enrolled in a nursing education program preparing for registered nurse or practical nurse licensure and have currently completed at least one nursing course that includes clinical experience involving direct client care;

5. Have satisfactorily passed a competency evaluation program that meets the criteria of 42 CFR 484.36 (b). Home attendants of personal care services need only be evaluated on the tasks in 42 CFR 484.36 (b) as those tasks relate to the personal care services to be provided; or

6. Have satisfactorily completed ~~training using the "Personal Care Aide Training Curriculum," 2003 edition, of the Department of Medical Assistance Services. However, this training is permissible for home attendants of personal care services only.~~ a 40 hour training program in compliance with the Department of Medical Assistance Services (DMAS) Elderly or Disabled with Consumer Direction (EDCD) Waiver Regulations (12VAC30-120) and the EDCD Waiver Provider Manual.

Part III

Skilled Services

12VAC5-381-295. Discharge planning.

A. There shall be an organized discharge planning process that includes an evaluation of the client's capacity for self-care and the availability of community services to meet the needs of the client.

B. A registered nurse or qualified social worker shall develop or supervise the development of the discharge plan if the clients evaluation indicates a need for a discharge plan.

1. The organization shall arrange for the implementation of the discharge plan.

2. The organization shall transfer or refer clients to appropriate facilities agencies or services, as needed for follow-up.

C. The organization shall reassess its discharge planning process on an on-going basis. The reassessment shall include a review of discharge plans, as well as a review of patients who were discharged without plans, to ensure that the process is responsive to discharge needs.

~~Part III~~

~~Skilled Services~~

12VAC5-381-300. Skilled services.

A. The organization shall provide a program of home health services that shall include one or more of the following:

1. Nursing services;

2. Physical therapy services;

3. Occupational therapy services; or

4. Speech therapy services~~;~~ .

~~5. Respiratory therapy services; or~~

~~6. Medical social services.~~

B. All skilled services delivered shall be prescribed in a medical plan of care that contains at least the following information:

1. Diagnosis and prognosis;

2. Functional limitations;

3. Orders for all skilled services, including: (i) specific procedures, (ii) treatment modalities, and (iii) frequency and duration of the services ordered;

4. Orders for medications, when applicable; and

5. Orders for special dietary or nutritional needs, when applicable.

The medical plan of care shall be approved and signed by the client's primary care physician.

C. Verbal orders shall be documented within 24 consecutive hours in the client's record by the health care professional receiving the order and shall be countersigned by the prescribing person.

D. The primary care physician shall be notified immediately of any changes in the client's condition that indicates a need to alter the medical plan of care.

E. The medical plan of care shall be reviewed, approved, and signed by the primary care physician at least every 60 days.

F. There shall be a ~~director of~~ skilled services director, who shall be a licensed physician ~~licensed by the Virginia Board of Medicine~~ or a registered nurse, responsible for the overall direction and management of skilled services including the availability of services, the quality of services and appropriate staffing. The individual shall have the appropriate experience for the scope of services provided by the organization.

G. The organization shall develop and implement policies and procedures for the handling of drugs and biologicals, including procurement, storage, administration, self-administration, and disposal of drugs and shall allow clients to procure their medications from a pharmacy of their choice as required by 12VAC5-381-180.

H. All prescription drugs shall be prescribed and properly dispensed to clients according to the provisions of Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for prescription drugs authorized by § 54.1-3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushes for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol.

I. The organization shall have a policy and procedure to prevent the occurrence of pressure sores or decubitis ulcers.

12VAC5-381-320. Therapy services.

A. Physical therapy, occupational therapy, speech therapy, or respiratory therapy services shall be provided according to the medical plan of care by or under the direction of an appropriately qualified therapist currently licensed in Virginia and may include, but are not limited to:

1. Assessing client needs or admission for service as appropriate;

2. Implementing a medical plan of care and revising as necessary;

3. Initiating appropriate preventive, therapeutic, and rehabilitative techniques according to the medical plan of care;

4. Educating the client and ~~family~~ the client's representative regarding treatment modalities and use of equipment and devices;

5. Providing consultation to other health care professionals;

6. Communicating with the physician and other health care professionals regarding changes in the client's needs;

7. Supervising therapy assistants and home attendants as appropriate; and

8. Preparing clinical notes.

B. Therapy assistants may be used to provide therapy services.

1. The occupational therapy assistant shall be currently certified by the National Board for Certification in Occupational Therapy and shall practice under the supervision of a licensed occupational therapist.

2. The physical therapy assistant shall be currently licensed by the Virginia Board of Physical Therapy and shall practice under the supervision of a licensed physical therapist.

C. Duties of therapy assistants shall be within their scope of practice and may include, but are not limited to:

1. Performing services planned, delegated, and supervised by the appropriately licensed therapist; and

2. Preparing clinical notes.

D. Supervision of services shall be provided as often as necessary as determined by the client's needs, the assessment of the licensed therapist, and the organization's written policies not to exceed 90 days.

12VAC5-381-340. Medical social services.

A. Medical social services shall be provided according to the medical plan of care by or under the direction of a qualified social worker who holds, at a minimum, a bachelor's degree with major studies in social work, sociology, or psychology from a four-year college or university accredited by the Council on Social Work Education and has at least two years experience in case work or counseling in a health care or social services delivery system. The organization shall maintain documentation of the social worker's qualifications.

~~The organization shall have one year from January 1, 2006, to ensure the designated individual meets the qualifications of this standard.~~

B. The duties of a social worker may include, but are not limited to:

1. Assessing the client's psychological status;

2. Implementing a medical plan of care and revising, as necessary;

3. Providing social work services including (i) short-term individual counseling, (ii) community resource planning, and (iii) crisis intervention;

4. Providing consultation with the primary care physician and other health care professionals regarding changes in the client's needs;

5. Preparing notes on the care or services provided; and

6. Participating in discharge planning.

Part IV

~~Pharmaceutical Services~~ Medication administration

12VAC5-381-350. ~~Pharmacy services.~~ Medication administration.

A. All prescription drugs shall be prescribed and properly dispensed to the client according to the provisions of the Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for prescription drugs authorized by § 54.1-3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushes for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol.

B. Home attendants may administer normally self-administered drugs as allowed by § 54.1-3408 of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code

of Virginia). Any other drug shall be administered only by a licensed nurse or physician assistant.

C. The organization shall develop written policies and procedures for the administration of home infusion therapy medications that include, but are not limited to:

1. Developing a plan of care or service;

2. Initiation of medication administration based on a prescriber's order and monitoring of the client for response to the treatment and any adverse reactions or side effects;

3. Assessment of any factors related to the home environment that may affect the prescriber's decisions for initiating, modifying, or discontinuing medications;

4. Communication with the prescriber concerning assessment of the client's response to therapy, any other client specific needs, and any significant change in the client's condition;

5. Communication with the client's provider pharmacy concerning problems or needed changes in a client's medication;

6. Maintaining a complete and accurate record of medications prescribed, medication administration data, client assessments, any laboratory tests ordered to monitor response to drug therapy and results, and communications with the prescriber and pharmacy provider;

7. Educating or instructing the client, family members, or other caregivers involved in the administration of infusion therapy in the proper storage of medication, in the proper handling of supplies and equipment, in any applicable safety precautions, in recognizing potential problems with the client, and actions to take in an emergency; and

8. Initial and retraining of all organization staff providing infusion therapy.

D. The organization shall employ a registered nurse, who has completed training in infusion therapy, and has the knowledge, skills, and competencies to safely administer infusion therapy, to supervise medication administration by staff. This person shall be responsible for ensuring compliance with applicable laws and regulations, adherence to the policies and procedures related to administration of medications, and conducting periodic assessments of staff competency in performing infusion therapy.

Part V

Personal Care Services

12VAC5-381-355. Discharge Termination.

A. There shall be a discharge or termination summary which will provide a final written summary filed in a client record of the services delivered and final disposition at the time of the client's discharge or termination from service.

B. A registered nurse or qualified social worker shall develop or supervise the development of the discharge termination.

~~Part V~~

~~Personal Care Services~~

12VAC5-381-360. Personal care services.

A. An organization may provide personal care services in support of the client's health and safety in his home. The organization shall designate a registered nurse responsible for the ~~supervision~~coordination of personal care services.

B. The personal care services shall include:

1. Assistance with the activities of daily living. A need for assistance exists when the client is unable to complete an activity due to cognitive impairment, functional disability,

physical health problems, or safety. The client's functional level is based on the client's need for assistance most or all of the time to perform the tasks of daily living in order to live independently;

2. Administration of normally self-administered drugs as allowed in § 54.1-3408 of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia);

3. Taking and recording vital signs, if specified in the plan of service;

4. Recording and reporting to the supervisor any changes regarding the client's condition, behavior or appearance; and

5. Documenting the services delivered in the client's record.

Personal care services may also include the instrumental activities of daily living related to the needs of the client.

C. Such services shall be delivered based on a written plan of services developed by a registered nurse, ~~in collaboration~~ with the active participation of the client and client's ~~family~~representative. The plan shall include at least the following:

1. Assessment of the client's needs;

2. Functional limitations of the client;

3. Activities permitted;

4. Special dietary needs;

5. Specific personal care services to be performed; and

6. Frequency of service.

D. The plan shall be retained in the client's record. Copies of the plan shall be provided to the client receiving services and reviewed with the assigned home attendant prior to delivering services.

E. Supervision of ~~services~~ home attendants shall be provided as often as necessary ~~as determined by the client's needs, the assessment of the registered nurse, and~~ according to the organization's written policies not to exceed ~~90~~ 120 days. Such supervision may be provided by a qualified licensed practical nurse.

F. A registered nurse or licensed practical nurse shall be available during all hours that personal care services are being provided.

G. Home attendants providing personal care services shall receive at least 12 hours annually of inservice training and education. Inservice training may be in conjunction with on-site supervision.

FORMS (12VAC5-381)

Application for Licensure, Home Care organizations, eff. 01/06.

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-381)

~~Personal Care Aide Training Curriculum, 2003 Edition, Virginia Department of Medical Assistance Services.~~

MEMORANDUM

DATE: February 19, 2016

TO: Virginia State Board of Health

FROM: Dwayne Roadcap, Office of Environmental Health Services

SUBJECT: Repeal of the Authorized Onsite Soil Evaluator Regulations 12VAC5-615

The 2007 Virginia General Assembly enacted House Bill 3134, which transferred implementation, administration, and enforcement of licensing requirements for authorized onsite soil evaluators from the Virginia Department of Health (VDH) to the Board for Waterworks and Wastewater Works Operators and Onsite Sewage System Professionals at the Department of Professional and Occupational Regulation (DPOR). DPOR promulgated regulations for onsite soil evaluators on July 1, 2009 (18VAC160-20). House Bill 3134 abrogated the Board of Health's authority to license authorized onsite soil evaluators. While Title 32.1 of the Code of Virginia contains other references to the Board of Health's regulation of authorized onsite soil evaluators, VDH has successfully implemented those statutory provisions independent of 12VAC5-615. As such, 12 VAC 5-615 is no longer necessary and the Board of Health does not have authority to implement the regulation.

All requirements in 12VAC 5-615 will be repealed. Definitions and terms are adequately addressed in the Code of Virginia and through DPOR's licensing programs and policies. Deleting the terms and definitions contained in 12VAC5-615 will not impact the Board of Health's program.

The Board still has legislative authority to accept and review evaluations and designs from licensed onsite soil evaluators pursuant to Va. Code §§ 32.1-163, 32.1-163.5, 32.1-163.6, and 32.1-164.

townhall.virginia.gov

Proposed Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-615
Regulation title(s)	Authorized Onsite Soil Evaluator Regulations
Action title	Repeal the regulation
Date this document prepared	January 5, 2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The 2007 Virginia General Assembly enacted House Bill 3134, which transferred implementation, administration, and enforcement of licensing requirements for authorized onsite soil evaluators from the Virginia Department of Health (VDH) to the Board for Waterworks and Wastewater Works Operators and Onsite Sewage System Professionals at the Department of Professional and Occupational Regulation (DPOR). DPOR promulgated regulations for onsite soil evaluators on July 1, 2009 (18VAC160-20). House Bill 3134 abrogated the Board of Health's authority to license authorized onsite soil evaluators. While Title 32.1 of the *Code of Virginia* contains other references to the Board of Health's regulation of authorized onsite soil evaluators, VDH has successfully implemented those statutory provisions independent of

12VAC5-615. As such, 12 VAC 5-615 is no longer necessary and the Board of Health does not have authority to implement the regulation.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

All requirements in 12VAC 5-615 will be repealed. Definitions and terms are adequately addressed in the Code of Virginia and through DPOR's licensing programs and policies. Deleting the terms and definitions contained in 12VAC5-615 will not impact the Board of Health's program.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The Board of Health does not have a statutory mandate to establish a program for authorized onsite soil evaluators because of the amendments to the Code of Virginia (HB 3134 of the 2007 General Assembly session). The Board still has legislative authority to accept and review evaluations and designs from licensed onsite soil evaluators pursuant to Va. Code §§ 32.1-163, 32.1-163.5, 32.1-163.6, and 32.1-164.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The health, safety, and welfare of citizens will not be affected by repeal of the AOSE Regulations. The AOSE Regulations were promulgated July 1, 2002 pursuant to Va. Code §§ 32.1-163.4, 163.5, 164, and 164.1:01. During the 2007 General Assembly session, HB 3134 (2007 Acts of Assembly Ch. 892) amended and re-enacted Va. Code §§ 32.1-163, 32.1-164, 54.1-300, 54.1-2300, 54.1-2301, and 54.1-2302. The legislation rescinded certificate requirements administered by VDH. In its place, the legislation directed DPOR to promulgate regulations for persons seeking a license as an onsite soil evaluator. The legislation obviates the need for the Board of Health to administer a certificate program for AOSEs.

DPOR adopted regulations for onsite soil evaluators (18VAC160-20). The AOSE Regulations unnecessarily establish a certificate program for qualifying individuals as AOSEs, including conflict of interest requirements. Documentation requirements in the AOSE Regulations for reports and designs are now contained in VDH policies that implement other regulations (e.g., 12VAC 5-610, 12VAC5-613, 12VAC5-640, and 12VAC5-630). Processing time limits and definitions have been established in the Code and agency policies, which further render the AOSE Regulations unnecessary.

Substance

Please 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.

All requirements in 12VAC5-615 will be repealed.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.

The primary advantage to the public and the Commonwealth will be to remove unnecessary regulations that are not being implemented by VDH. Repealing the regulation will prevent confusion. There is not a disadvantage to the public and Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.

There is no requirement that would be more restrictive than federal requirements. The federal government does not regulate the profession of onsite soil evaluators.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No locality is particularly affected.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the Virginia Department of Health is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal.

Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email or fax to Dwayne Roadcap, Director, Division of Onsite Sewage, Water Supplies, Environmental Engineering, and Marina Programs, 109 Governor Street, 5th Floor, Richmond, Virginia 23219, Dwayne.roadcap@vdh.virginia.gov, or by facsimile to 804-864-7475. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last date of the public comment period.

A public hearing will not be held following the publication of this stage of this regulatory action.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	There is no cost to the state from the repeal of this regulation.
Projected cost of the new regulations or changes to existing regulations on localities.	There is no cost to any locality from the repeal of this regulation.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Rescinding the regulation will likely help individuals, businesses, and other entities because they will not need to read or understand 12VAC5-615.
Agency's best estimate of the number of such entities that will be affected. Please 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.	No stakeholder will be affected by the repeal of this regulation.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and**	No costs are projected from the repeal of this regulation.

b) Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	
Beneficial impact the regulation is designed to produce.	Repeal of the regulation will reduce confusion because another state agency regulates onsite soil evaluators.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

One alternative is to leave the regulation in place without repeal. However, this option creates unnecessary confusion. Repealing this regulation will not change any aspect of the Board of Health's program. Since enactment of HB 3134 and the adoption of regulations on July 1, 2009 by the Board for Waterworks and Wastewater Works Operators and Onsite Sewage System Professionals, the Board of Health no longer certifies authorized onsite soil evaluators. The Board of Health can fully implement its program, including application requirements and terms of practice, without the regulations.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please 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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.

The alternative is to leave the regulations in place even though they do not have any effect and are not being enforced. The Board can effectively administer its responsibilities through other applicable provisions of the Code of Virginia.

Periodic review and small business impact review report of findings

If you are using this form to report the result of a periodic review/small business impact review that was announced during the NOIRA stage, please indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity

of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

The regulation is being repealed because another state agency regulates onsite soil evaluators.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
Jeff T. Walker	The commenter objected to the fast track rescission of the AOSE Regulations. He recommended VDH work with the DPOR Waste Water Board, and consult the Professional Soil Scientist's and Engineering Boards to capture standards essential to the practice of onsite sewage system evaluation and design.	This regulatory action was initially submitted as a Fast Track action. However, since VDH received comments from 10 or more persons during the public comment period, the AOSE regulations must be rescinded through the standard three-stage promulgation process. The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. VDH does not have authority to implement ethical requirements for licensees. VDH already has authority through Va. Code § 32.1-164 to develop procedural and technical requirements to process applications for the construction or approval of onsite sewage systems and wells. The Board of Health plans to amend the Sewage Handling and Disposal Regulations, which can address additional procedural and technical issues that are desired from the stakeholder community. Site documentation procedures are

		addressed through other agency policy and regulations. There is no authority to establish standards of practice or conduct for AOSEs. The Board has already established procedures to process applications with supporting private sector work through its administration of the Sewage Handling and Disposal Regulations (12VAC 5- 610). GMP #2015-01, approved January 1, 2015, addresses expectations and submission requirements for both public and private sector OSE's.
Gary C. Renger, OSE	The commenter objected to rescinding the regulations prior to inclusion in VDH Regulations or DPOR Regulations.	In 2009, legislation transferred the AOSE program to the Department of Professional and Occupational Regulation (DPOR). The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders.
Robert Melby	The commenter objected to repeal without first having minimum standards for OSE work products.	VDH already has authority through Va. Code § 32.1-164 to develop procedural and technical requirements to process applications for the construction or approval of onsite sewage systems and wells. The Board of Health plans to amend the Sewage Handling and Disposal Regulations, which can address additional procedural and technical issues that are desired from the stakeholder community. Site documentation procedures are addressed through other agency policy and regulations. There is no authority to establish standards of practice or conduct for AOSEs. The Board has already established procedures to process applications with supporting private sector work through its administration of the

		Sewage Handling and Disposal Regulations (12VAC 5- 610). GMP #2015-01, approved January 1, 2015, addresses expectations and submission requirements for both public and private sector OSE's.
David K. Hogan, AOSE CPSS	The commenter objected to the repeal of the regulations without standards of practice and procedural considerations being captured by either VDH or DPOR.	The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. VDH does not have authority to implement ethical requirements for licensees. VDH already has authority through Va. Code § 32.1-164 to develop procedural and technical requirements to process applications for the construction or approval of onsite sewage systems and wells. The Board of Health plans to amend the Sewage Handling and Disposal Regulations, which can address additional procedural and technical issues that are desired from the stakeholder community. Site documentation procedures are addressed through other agency policy and regulations. There is no authority to establish standards of practice or conduct for AOSEs. The Board has already established procedures to process applications with supporting private sector work through its administration of the Sewage Handling and Disposal Regulations (12VAC5- 610). GMP #2015-01, approved January 1, 2015, addresses expectations and submission requirements for both public and private sector OSE's.
Kirk R, Sweeney	The commenter opposed repealing the AOSE regulations.	The Board of Health does not have authority to implement 12VAC5-615.

Nan Gray, AOSE, LPSS Soil Works, Inc.	The commenter objected to the repeal of the regulations without standards of practice and procedural considerations being captured by either VDH or DPOR.	The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. Site documentation procedures are addressed through other agency policy and regulations. There is no authority to establish standards of practice or conduct for AOSEs. The Board has already established procedures to process applications with supporting private sector work through its administration of the Sewage Handling and Disposal Regulations (12VAC5- 610).
Mark Smith Soil Consultants Drilling	The commenter opposed repealing the AOSE regulations.	In 2009, legislation transferred the AOSE program to the Department of Professional and Occupational Regulation (DPOR). The Board of Health does not have authority to implement 12VAC5-615.
Tim Parker AOSE	The commenter opposed fast track repeal of the regulations before standards of practice could be adopted.	This regulatory action was initially submitted as a Fast Track action. However, since VDH received comments from 10 or more persons during the public comment period, the AOSE regulations must be rescinded through the standard three-stage promulgation process. The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. GMP #2015-01, approved January 1, 2015, addresses expectations and submission requirements for both public and private sector OSE's.
Jeff Sledjeski,	The commenter opposed fast	This regulatory action was initially

OSE	track repeal of the regulations before standards of practice could be adopted.	submitted as a Fast Track action. However, since VDH received comments from 10 or more persons during the public comment period, the AOSE regulations must be rescinded through the standard three-stage promulgation process. In 2009, legislation transferred the AOSE program to the Department of Professional and Occupational Regulation (DPOR). The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. GMP #2015-01, approved January 1, 2015, addresses expectations and submission requirements for both public and private sector OSE's.
Steve Eitner, AOSE	The commenter objected to the repeal of the regulations without standards of practice and procedural considerations being captured by either VDH or DPOR.	In 2009, legislation transferred the AOSE program to the Department of Professional and Occupational Regulation (DPOR). The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. GMP #2015-01, approved January 1, 2015, addresses expectations and submission requirements for both public and private sector OSE's.
Dan Manweiler	The commenter opposed fast track repeal of the regulations before standards of practice could be adopted.	This regulatory action was initially submitted as a Fast Track action. However, since VDH received comments from 10 or more persons during the public comment period, the

		AOSE regulations must be rescinded through the standard three-stage promulgation process. In 2009, legislation transferred the AOSE program to the Department of Professional and Occupational Regulation (DPOR). The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. GMP #2015-01, approved January 1, 2015, addresses expectations and submission requirements for both public and private sector OSE's.
David Hall	The commenter opposed repealing the AOSE regulations.	In 2009, legislation transferred the AOSE program to the Department of Professional and Occupational Regulation (DPOR). The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. GMP #2015-01, approved January 1, 2015, addresses expectations and submission requirements for both public and private sector OSE's.
Kevin Seaford	The commenter objected to the repeal of the regulations without standards of practice and procedural considerations being captured by either VDH or DPOR.	In 2009, legislation transferred the AOSE program to the Department of Professional and Occupational Regulation (DPOR). The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR

		boards on issues affecting the industry and stakeholders. GMP #2015-01, approved January 1, 2015, addresses expectations and submission requirements for both public and private sector OSE's.
Robert Savage, AOSE	The commenter opposed fast track repeal of the regulations without a mechanism in place to capture standards of practice.	This regulatory action was initially submitted as a Fast Track action. However, since VDH received comments from 10 or more persons during the public comment period, the AOSE regulations must be rescinded through the standard three-stage promulgation process. GMP #2015-01, approved January 1, 2015, addresses expectations and submission requirements for both public and private sector OSE's.
Kym Willoughby Harper, AOSE, LRH Soil Consultants, Inc.	The commenter opposed fast track repeal of the regulations before standards of practice could be adopted.	This regulatory action was initially submitted as a Fast Track action. However, since VDH received comments from 10 or more persons during the public comment period, the AOSE regulations must be rescinded through the standard three-stage promulgation process. In 2009, legislation transferred the AOSE program to the Department of Professional and Occupational Regulation (DPOR). The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. GMP #2015-01, approved January 1, 2015, addresses expectations and submission requirements for both public and private sector OSE's.
William	The commenter objected to the	In 2009, legislation transferred the

Sledjeski, PSS, AOSE	repeal of the regulations without standards of practice and procedural considerations being captured by either VDH or DPOR.	AOSE program to the Department of Professional and Occupational Regulation (DPOR). The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. GMP #2015-01, approved January 1, 2015, addresses expectations and submission requirements for both public and private sector OSE's.
Carbaugh Environmental	The commenter objected to the repeal of the regulations without standards of practice and procedural considerations being captured by either VDH or DPOR. The commenter added repealing the regulations would violate trade laws by preventing public access to qualified parties.	The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. VDH does not have authority to implement ethical requirements for licensees. VDH already has authority through Va. Code § 32.1-164 to develop procedural and technical requirements to process applications for the construction or approval of onsite sewage systems and wells. The Board of Health plans to amend the Sewage Handling and Disposal Regulations, which can address additional procedural and technical issues that are desired from the stakeholder community. Site documentation procedures are addressed through other agency policy and regulations. There is no authority to establish standards of practice or conduct for AOSEs. The Board has already established procedures to process applications with supporting private sector work through its administration of the Sewage Handling and Disposal

		Regulations (12VAC5- 610). GMP #2015-01, effective January 1, 2015, contains Onsite Sewage Application Expectations and Requirements. Private sector providers continue to voice concerns regarding direct service delivery and perceived, and real, conflicts of interest inherent in the current paradigm. However, it should be noted that over time, and without a specific statutory mandate to require private evaluations and designs, the use of private sector designers has gained broad acceptance in many parts of the Commonwealth. In fiscal year (FY) 2015 the percentage of private sector participation was at an all-time high, with more than 42% of all applications being accompanied by work form a private sector designer. However, areas of low private sector participation persist today, particularly in more rural areas and in Southwest Virginia.
Tony Bible, Southwest Environmental Consulting, Inc.	The commenter opposed repeal of the regulations before standards of practice could be adopted.	Site documentation procedures are addressed through other agency policy and regulations. There is no authority to establish standards of practice or conduct for AOSEs. The Board has already established procedures to process applications with supporting private sector work through its administration of the Sewage Handling and Disposal Regulations (12VAC5- 610). GMP #2015-01, effective January 1, 2015, contains Onsite Sewage Application Expectations and Requirements.
Tom W. Ashton	The commenter objected to the repeal of the regulations without standards of practice and procedural considerations being captured by either VDH or DPOR.	The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. VDH does not have authority to implement ethical requirements for

		licensees. VDH already has authority through Va. Code § 32.1-164 to develop procedural and technical requirements to process applications for the construction or approval of onsite sewage systems and wells. The Board of Health plans to amend the Sewage Handling and Disposal Regulations, which can address additional procedural and technical issues that are desired from the stakeholder community. Site documentation procedures are addressed through other agency policy and regulations. There is no authority to establish standards of practice or conduct for AOSEs. The Board has already established procedures to process applications with supporting private sector work through its administration of the Sewage Handling and Disposal Regulations (12VAC 5- 610). GMP #2015-01, effective January 1, 2015, contains Onsite Sewage Application Expectations and Requirements.
Janet Swords	The commenter objected to repeal without first having minimum standards for OSE work products.	The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. VDH does not have authority to implement ethical requirements for licensees. VDH already has authority through Va. Code § 32.1-164 to develop procedural and technical requirements to process applications for the construction or approval of onsite sewage systems and wells. The Board of Health plans to amend the Sewage Handling and Disposal Regulations, which can address additional procedural and technical issues that are desired

		from the stakeholder community.
Stephen White, AOSE, LPSS	The commenter objected to the repeal of the regulations without standards of practice and procedural considerations being captured by either VDH or DPOR.	The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. VDH does not have authority to implement ethical requirements for licensees. VDH already has authority through Va. Code § 32.1-164 to develop procedural and technical requirements to process applications for the construction or approval of onsite sewage systems and wells. The Board of Health plans to amend the Sewage Handling and Disposal Regulations, which can address additional procedural and technical issues that are desired from the stakeholder community. Site documentation procedures are addressed through other agency policy and regulations. There is no authority to establish standards of practice or conduct for AOSEs. The Board has already established procedures to process applications with supporting private sector work through its administration of the Sewage Handling and Disposal Regulations (12VAC5- 610). GMP #2015-01, effective January 1, 2015, contains Onsite Sewage Application Expectations and Requirements.
Robert E. Lee, P.E.	The commenter objected to the repeal of the regulations without standards of practice and procedural considerations being captured by either VDH or DPOR.	The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. VDH does not have authority to implement ethical requirements for

		licensees. VDH already has authority through Va. Code § 32.1-164 to develop procedural and technical requirements to process applications for the construction or approval of onsite sewage systems and wells. The Board of Health plans to amend the Sewage Handling and Disposal Regulations, which can address additional procedural and technical issues that are desired from the stakeholder community.
Peter K. Kessecker, Soil Services, Inc.	The commenter objected to the repeal of the regulations without standards of practice and procedural considerations being captured by either VDH or DPOR.	The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. VDH does not have authority to implement ethical requirements for licensees. VDH already has authority through Va. Code § 32.1-164 to develop procedural and technical requirements to process applications for the construction or approval of onsite sewage systems and wells. The Board of Health plans to amend the Sewage Handling and Disposal Regulations, which can address additional procedural and technical issues that are desired from the stakeholder community.
Alan Brewer	The commenter opposed fast track repeal of the regulations before standards of practice could be adopted.	This regulatory action was initially submitted as a Fast Track action. However, since VDH received comments from 10 or more persons during the public comment period, the AOSE regulations must be rescinded through the standard three-stage promulgation process. GMP #2015-01, effective January 1, 2015, contains Onsite Sewage Application Expectations and Requirements.
S. Michael	The commenter opposed repeal	The Board of Health does not have

Lynn	of the regulations without a mechanism in place to capture standards of practice.	authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. VDH does not have authority to implement ethical requirements for licensees. VDH already has authority through Va. Code § 32.1-164 to develop procedural and technical requirements to process applications for the construction or approval of onsite sewage systems and wells. The Board of Health plans to amend the Sewage Handling and Disposal Regulations, which can address additional procedural and technical issues that are desired from the stakeholder community.
Virginia Association of Onsite Soil Evaluators	The commenter objected to the fast track repeal of the regulations without standards of practice and procedural considerations being captured by either VDH or DPOR. The commenter also included a history of the AOSE program and asked for all terms and definitions used since the program's inception in 1994 be maintained in future regulations. The commenter stated a definition of "backlog" and timeline constraints for processing applications would be lost and need to be included in future regulations.	This regulatory action was initially submitted as a Fast Track action. However, since VDH received comments from 10 or more persons during the public comment period, the AOSE regulations must be rescinded through the standard three-stage promulgation process. The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders. VDH does not have authority to implement ethical requirements for licensees. VDH already has authority through Va. Code § 32.1-164 to develop procedural and technical requirements to process applications for the construction or approval of onsite sewage systems and wells. The Board of Health plans to amend the Sewage Handling and Disposal Regulations, which can address additional procedural

		and technical issues that are desired from the stakeholder community. Site documentation procedures are addressed through other agency policy and regulations. There is no authority to establish standards of practice or conduct for AOSEs. The Board has already established procedures to process applications with supporting private sector work through its administration of the Sewage Handling and Disposal Regulations (12VAC 5- 610). GMP #2015-01, effective January 1, 2015, contains Onsite Sewage Application Expectations and Requirements. The GMP also defines the term "backlog" as well as the methods used to calculate. VDH will also incorporate the term "backlog" in future onsite regulation review processes. The General Assembly in 1994, added the procedures for determining onsite construction permit application backlogs. Prior to 1994 VDH did not accept designs from the private sector. A surge in real estate development and the fact that all onsite designs were being provided by VDH staff created lengthy waits for construction permit approvals. VDH began accepting designs from private sector designers (AOSE's) as a means to combat lengthy backlogs. Multiple attempts and proposals to remove VDH from providing any design services in the years since 1994 have failed to achieve favorable support. Applications for construction permits accompanied by private sector designs are subject to VDH review timetables. Timelines for the review process are strictly adhered to and if VDH does not take action during the specified times construction permits are

		deemed approved. In 1994 backlogs were unavoidable, today by employing a private sector designer construction permits can be reviewed and approved in 15 days.
Robert Charnley	The commenter opposed the fast track repeal of the AOSE regulations.	This regulatory action was initially submitted as a Fast Track action. However, since VDH received comments from 10 or more persons during the public comment period, the AOSE regulations must be rescinded through the standard three-stage promulgation process.
Bob Marshall/ Cloverleaf Environmental Consulting, Inc.	The commenter objected to the repeal of the regulations without standards of practice and procedural considerations being captured by either VDH or DPOR.	This regulatory action was initially submitted as a Fast Track action. However, since VDH received comments from 10 or more persons during the public comment period, the AOSE regulations must be rescinded through the standard three-stage promulgation process.
James B. Slusser	The commenter objected to the repeal of the regulations because he feels some definitions will be lost and the repeal will limit private sector input in the onsite program.	GMP #2015-01 effective January 1, 2015 contains Onsite Sewage Application Expectations and Requirements. The GMP also defines the term "backlog" as well as the methods used to calculate. VDH will also incorporate the term "backlog" in future onsite regulation review processes. The General Assembly in 1994, added the procedures for determining onsite construction permit application backlogs. Prior to 1994 VDH did not accept designs from the private sector. A surge in real estate development and the fact that all onsite designs were being provided by VDH staff created lengthy waits for construction permit approvals. VDH began accepting designs from private sector designers (AOSE's) as a means to combat lengthy backlogs. Multiple attempts and proposals to remove VDH from providing any design services in the years since 1994 have failed to achieve

		favorable support. By employing a private sector designer strict timeframes for the review process are followed which eliminate lengthy backlogs.
K.R. "Trapper" Davis	The commenter objected to the repeal of the regulations without standards of practice and procedural considerations being captured by either VDH or DPOR.	The Board of Health does not have authority to implement 12VAC5-615. VDH continues to collaborate with DPOR staff and associated DPOR boards on issues affecting the industry and stakeholders.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact of the proposed regulatory action on family.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12 VAC 5-615-10	N/A	Describes the authority for the regulations	The Board does not have authority to qualify individuals as Authorized Onsite Soil Evaluators (see HB 3134 from the 2007 General Assembly session). DPOR enacted regulations that administer a licensing program for onsite soil evaluators (18 VAC160-20).
12 VAC 5-615-20	N/A	Describes the purpose of the regulations.	The Board does not have authority to qualify individuals as AOSEs. The Board does not

			need procedures to become an AOSE or maintain a certificate. Site documentation procedures are addressed through other agency policy and regulations. There is no authority to establish standards of Practice or conduct for AOSEs.
12 VAC 5-615-30	N/A	Describes the relationship to the Sewage Handling and Disposal Regulations	The Board is repealing the regulation so its relationship to another regulation is moot.
12 VAC 5-615-40	N/A	Describes the administration of the regulation.	The Board is repealing the regulation so its administration is moot.
12 VAC 5-615-50	N/A	Describes the creation of an advisory committee.	The Board is repealing the regulation. The Sewage Handling and Disposal Regulations establish an advisory committee at 12 VAC 5-610- 50.
12 VAC 5-615-60	N/A	Describes the scope of the regulation.	The Board is repealing the regulation so its scope is moot. Content and form for site and soil evaluation reports are administered through the Sewage Handling and Disposal Regulations (12 VAC 5-610). Local ordinances are addressed in the Code of Virginia.
12 VAC 5-615-70	N/A	Describes roles and responsibilities for AOSE or professional engineers working in consultation with an AOSE.	The Board has already established procedures to process applications with supporting private sector work through its administration of the Sewage Handling and Disposal Regulations (12 VAC 5- 610). This regulation is not necessary.
12 VAC 5-615-80	N/A	Describes processing time limits and deemed approval.	Processing time limits and deemed approval are addressed in Title 32.1, Chapter 6 of the Code of Virginia. The regulation is not necessary.
12 VAC 5-615-90	N/A	Describes the practice of engineering.	The practice of engineering is defined in the Regulations for Alternative Onsite Sewage Systems. Va. Code § 54.1-400 provides additional guidance regarding the practice of engineer. This regulation is not necessary.
12 VAC 5-615-100	N/A	Requires a person to sign a certification statement for submissions to the Department of Health.	The Board does not have authority to qualify individuals as AOSEs. DPOR regulates the practice. The Board has other policies and regulations that implement this regulation. Va. Code § 32.1-163.5 of the Code of Virginia requires private sector evaluations and designs to be certified as complying with the Board's regulations. This regulation is not necessary.
12 VAC 5-615-110	N/A	Describes right of entry.	The agency already has this authority pursuant to Va. Code § 32.1-25. This regulation is not necessary.
12 VAC 5-615-120	N/A	Provides a list of definitions.	These terms are adequately addressed in the Code of Virginia and through DPOR's licensing programs and policies. Deleting these definitions will not impact the Board of Health's program. This regulation is not necessary.
12 VAC 5-615-130	N/A	Provides notice of the administrative process act.	Va. Code § 2.2-4000 applies to the agency. This regulation is not necessary.

12 VAC 5-615-140	N/A	Provides authority to develop an emergency order or rule.	12 VAC 5-615 is being repealed in its entirety so there is no need for this authority.
12 VAC 5-615-150	N/A	Provides details about the enforcement of the regulation.	The Board is repealing the regulation so details about the enforcement of the regulation are moot.
12 VAC 5-615-160	N/A	Provides notice that the regulations may be suspended during disasters.	The Board is repealing the regulation so this regulation is not necessary.
12 VAC 5-615-170	N/A	Provides ability to grant variances.	The Board is repealing the regulation so procedures to grant a variance are not necessary.
12 VAC 5-615-180	N/A	Provides requirements for agency case decisions.	The Board is repealing the regulation so notice for case decisions is not necessary.
12 VAC 5-615-190	N/A	Reserved for future use.	The Board is repealing the regulation so future use will not occur.
12 VAC 5-615-200	N/A	Provides requirements for an agency case decision.	The Board is repealing the regulation so case decisions pursuant to this regulation will not be made.
12 VAC 5-615-210	N/A	Describes renewal of AOSE certificates.	DPOR has regulatory oversight for onsite soil evaluators.
12 VAC 5-615-220	N/A	Reserved for future use.	The Board is repealing the regulation so future use will not occur.
12 VAC 5-615-230	N/A	Describes application requirements to obtain an AOSE certification.	DPOR has regulatory oversight for licensing onsite soil evaluators.
12 VAC 5-615-240	N/A	Describes processing procedures for AOSE applications.	DPOR has regulatory oversight for licensing onsite soil evaluators.
12 VAC 5-615-250	N/A	Describes fees to process applications for certification as an AOSE.	DPOR has regulatory oversight for licensing onsite soil evaluators.
12 VAC 5-615-260	N/A	Describes expiration of the AOSE certificate.	DPOR has regulatory oversight for licensing onsite soil evaluators.
12 VAC 5-615-270	N/A	Describes renewal procedures for the AOSE certificate.	DPOR has regulatory oversight for licensing onsite soil evaluators.
12 VAC 5-615-280	N/A	Describes site evaluation and design requirements for certificate holders.	The Board does not issue certificates. DPOR has regulatory oversight for licensing onsite soil evaluators. The Board of Health has regulations and policies that address applications with supporting private sector work. The Board is repealing this regulation because it is not necessary.
12 VAC 5-615-290	N/A	Describes authority to revoke or suspend an AOSE certification.	DPOR has regulatory oversight for licensing onsite soil evaluators.
12 VAC 5-615-300	N/A	Describes means to have a certificate re-instated.	DPOR has regulatory oversight for licensing onsite soil evaluators.
12 VAC 5-615-310	N/A	Describes appeal process for suspension or revocation of a certificate.	DPOR has regulatory oversight for licensing onsite soil evaluators
12 VAC 5-615-320	N/A	Provides that a certificate holder cannot certify a site that has been previously denied.	The Board of Health has other regulations and policies that address applications with supporting private sector work.
12 VAC 5-615-330	N/A	Requires an AOSE to notify when there has been a change in status.	DPOR has regulatory oversight for licensing onsite soil evaluators.
12 VAC 5-615-340	N/A	Describes minimum requirements for documentation	The Board of Health has other regulations and policies that address applications with supporting private sector work. This regulation is not necessary.

12 VAC 5-615-350	N/A	Describes minimum documentation requirements and time limits to process applications.	The Board of Health has other regulations and policies that address applications with supporting private sector work. This regulation is not necessary.
12 VAC 5-615-360	N/A	Describes minimum information needed for a site evaluation report.	The Board of Health has other regulations and policies that address applications with supporting private sector work. This regulation is not necessary.
12 VAC 5-615-370	N/A	Describes access to information	The Board of Health has other regulations and policies that address this topic. The Freedom of Information Act also adequately addresses this topic. This regulation is not necessary.
12 VAC 5-615-380	N/A	Describes minimum information needed for design and construction, including site denial.	The Board of Health has other regulations and policies that address applications with supporting private sector work. This regulation is not necessary.
12 VAC 5-615-390	N/A	Describes professional courtesy reviews.	The Board of Health has other regulations and policies that address applications with supporting private sector work. This regulation is not necessary.
12 VAC 5-615-400	N/A	Describes field checks.	The Board of Health has other regulations and policies that address applications with supporting private sector work. This regulation is not necessary.
12 VAC 5-615-410	N/A	Describes a certificate holder's responsibility to the public.	DPOR has regulatory oversight for licensing onsite soil evaluators.
12 VAC 5-615-420	N/A	Describes obligations of the certificate holder.	DPOR has regulatory oversight for licensing onsite soil evaluators.
12 VAC 5-615-430	N/A	Describes conflict of interest disclosure for a certificate holder.	DPOR has regulatory oversight for licensing onsite soil evaluators.
12 VAC 5-615-440	N/A	Describes additional obligations of a certificate holder.	DPOR has regulatory oversight for licensing onsite soil evaluators.
12 VAC 5-615-450	N/A	Describes a certificate holder's obligation to be truthful.	DPOR has regulatory oversight for licensing onsite soil evaluators.
12 VAC 5-615-460	N/A	Describes the certificate holder's other responsibilities.	The Board is repealing the regulation. DPOR has regulatory oversight for licensing onsite soil evaluators.
12 VAC 5-615-470	N/A	Describes the certificate holder's good standing in other jurisdictions.	The Board is repealing the regulation. DPOR has regulatory oversight for licensing onsite soil evaluators.

If an existing regulation or regulations (or parts thereof) are being repealed and replaced by one or more new regulations, please use the following chart:

Current chapter-section number	Proposed new chapter-section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements

If a new regulation is being promulgated, that is not replacing an existing regulation, please use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements

If the proposed regulation is intended to replace an emergency regulation, and the proposed regulation is identical to the emergency regulation, please choose and fill out the appropriate chart template from the choices above. In this case "current section number" or "current chapter-section number" would refer to the **pre**-emergency regulation.

If the proposed regulation is intended to replace an emergency regulation, and the proposed regulation includes changes since the emergency regulation, please create two charts: 1) a chart describing changes from the **pre-emergency** regulation to the proposed regulation as described in the paragraph above, and 2) a chart describing changes from the **emergency** regulation to the proposed regulation. For the second chart please use the following title: "Changes from the Emergency Regulation." In this case "current section number" or "current chapter-section number" would refer to the **emergency** regulation.

Project 3127 - Other Action

DEPARTMENT OF HEALTH

Repeal of Authorized Onsite Soil Evaluator Regulations

CHAPTER 615
AUTHORIZED ONSITE SOIL EVALUATOR REGULATIONS (REPEALED)

~~Part I~~
~~General Provisions~~

12VAC5-615-10. ~~Authority for regulations.~~ (Repealed.)

~~Section 32.1-164 of the Code of Virginia provides that the State Board of Health has the duty to qualify individuals as authorized onsite soil evaluators (AOSEs) and establish procedures for utilizing the work of AOSEs and professional engineers (PEs) in consultation with AOSEs when issuing construction permits, certification letters, and subdivision approvals. Section 32.1-163.4 of the Code of Virginia provides that the department shall contract with an AOSE for the field evaluation of backlogged application sites and that the department shall only accept private evaluations from AOSEs. Section 32.1-163.5 of the Code of Virginia provides that the department shall accept private evaluations and designs for residential development from an AOSE or a PE in consultation with an AOSE and that the department is not required to perform a field check of such evaluations and designs prior to issuing an approval; the department may, although it is not required to, accept evaluations and designs from an AOSE or a PE in consultation with an AOSE for a proprietary, pre-engineered system that has been deemed by the department to comply with the board's regulations.~~

12VAC5-615-20. ~~Purpose of regulations.~~ (Repealed.)

~~These regulations have been promulgated to:~~

~~1. Guide the state health commissioner in determining who should be listed as an authorized onsite soil evaluator.~~

~~2. Guide certified professional soil scientists and others in the procedures necessary to become and maintain the status of authorized onsite soil evaluator.~~

~~3. Guide authorized onsite soil evaluators and professional engineers in the processes and site documentation procedures necessary to secure timely responses to applications submitted to the department.~~

~~4. Establish standards of practice and conduct for AOSEs.~~

12VAC5-615-30. ~~Relationship to the Sewage Handling and Disposal Regulations.~~ (Repealed.)

~~This chapter is supplemental to the current Sewage Handling and Disposal Regulations (12VAC5-610) adopted by the State Board of Health pursuant to Title 32.1 of the Code of Virginia. This chapter addresses the department's program for qualifying authorized onsite soil evaluators, processing applications with AOSE/PE supporting documentation, quality control procedures, and enforcement.~~

12VAC5-615-40. ~~Administration of regulations.~~ (Repealed.)

~~This chapter is administered by the following:~~

~~1. The State Board of Health, hereinafter referred to as the board, has the responsibility to promulgate, amend, and repeal regulations necessary to recognize and use the work of AOSE/PEs to site and design onsite wastewater systems in a manner that protects public health and the environment.~~

2. The State Health Commissioner, hereinafter referred to as the commissioner, is the chief executive officer of the State Department of Health. The commissioner has the authority to act, within the scope of regulations promulgated by the board, for the board when it is not in session. The commissioner may delegate authority under this chapter with the exception of the authority to issue orders under § 32.1-26 of the Code of Virginia.

3. The State Department of Health, hereinafter referred to as the department, is designated as the primary agent of the commissioner for the purpose of administering this chapter.

4. The district or local health departments are responsible for implementing and enforcing the operational activities required by this chapter.

5. The Sewage Handling and Disposal Appeal Review Board may hear the appeal of an aggrieved named party in any case where the department has revoked a sewage disposal system permit, certification letter, or subdivision approval when that approval was issued in reliance upon the certified evaluation and design of an AOSE/PE.

12VAC5-615-50. ~~Authorized Onsite Soil Evaluator Advisory Committee.~~ (Repealed.)

~~The commissioner shall appoint an Authorized Onsite Soil Evaluator Advisory Committee consisting of up to 15 appointed members and one ex officio member. The commissioner shall appoint members to the Authorized Onsite Soil Evaluator Advisory Committee as follows: four AOSEs from four different regions of the Commonwealth, one or more of whom must be a member of the Virginia Association of Professional Soil Scientists; four individuals currently employed by the department as Environmental Health Specialist Senior (these may or may not also be AOSEs); two persons actively engaged in the installation of onsite sewage systems; one professional engineer; one person who is a realtor licensed in Virginia; and three discretionary voting positions intended to provide substantive expertise, when needed, from the following categories (but not limited to these categories): Homebuilder/Developer, Well Driller, Local Government, Lending Institution, Surveyor. Each member of the advisory committee may be appointed to serve a term of two years; however, the commissioner, when making initial appointments, shall designate seven of the members to serve terms of three years. The appointment, renewal and removal of each advisory committee member lies in the sole discretion of the commissioner. The commissioner should seek to ensure that one or more members of the advisory committee is a homeowner with experience with onsite sewage systems so that homeowner's interests may be represented on the committee. The director of the division, or a designee, shall serve as an ex officio member of the advisory committee. The commissioner shall designate the chairman of the committee and members shall serve at the discretion of the commissioner. The committee shall make recommendations to the commissioner regarding AOSE/PE policies, procedures, and programs. The committee shall meet at least annually. The committee shall establish its rules of order.~~

12VAC5-615-60. ~~Scope of regulations.~~ (Repealed.)

~~A. This chapter describes the content and form of site and soil evaluation reports submitted to the department by an AOSE/PE pursuant to an application filed for an approval under the Sewage Handling and Disposal Regulations (12VAC5-610). The department will accept applications from owners (or their agents) without any site evaluation work (bare applications), with complete supporting documentation from an AOSE/PE, and until December 31, 2005, with complete supporting documentation from non-AOSE/PE consultants. After December 31, 2005, the department will continue to accept bare applications from owners (or their agents) and will only accept site evaluation reports and designs from AOSE/PEs.~~

~~B. The provisions of local ordinances regarding onsite wastewater systems that are more restrictive than, and not inconsistent with, the Sewage Handling and Disposal Regulations are not affected by this regulation unless a locality indicates in writing to the commissioner that it wants the department to apply its more restrictive ordinances in concert with the provisions of~~

~~this chapter. When such a request is made, the department will require all AOSE/PE reports submitted in the locality to be certified as complying with both the Sewage Handling and Disposal Regulations and the more restrictive local requirements and implement the provisions of the more restrictive ordinances pursuant to this chapter. In those localities with more restrictive ordinances where the local government has not indicated to the commissioner in writing that it desires that the provisions of this chapter be applied to the more restrictive ordinances, the department will review all applications for compliance with state law and regulations only. Such applicants then must obtain a certification of compliance with local ordinances from a local official. The department shall maintain a list of all localities that have notified the commissioner in writing pursuant to this section.~~

~~C. The department may accept evaluations and designs from AOSE/PEs in accordance with this chapter that include a certification as to the suitability of sites for the construction of private wells in accordance with the Private Well Regulations (12VAC5-630).~~

12VAC5-615-70. ~~Roles and responsibilities.~~ (Repealed.)

~~A. An AOSE/PE must certify that a site meets or does not meet the requirements of either the Sewage Handling and Disposal Regulations (12VAC5-610), the Private Well Regulations (12VAC5-630), or both, and may design certain traditional systems in accordance with the same regulations. Responsibility for assuring that site evaluations and designs comply with the Sewage Handling and Disposal Regulations or the Private Well Regulations rests with the AOSE/PE submitting the work.~~

~~B. The Department of Health shall have the following responsibilities:~~

~~1. The department's role in evaluating an AOSE/PE submission will be to review the materials submitted with an application as it deems necessary to assure compliance with this chapter, the Sewage Handling and Disposal Regulations, the Private Well Regulations and the department's policies prior to approval or disapproval of an application.~~

~~2. The department is not required to conduct a field check of any evaluation and/or design submitted pursuant to this chapter prior to issuing the appropriate approval; however, it will conduct such field reviews as it deems necessary to protect public health and the environment and to assess the performance of AOSE/PEs.~~

~~3. When requested by an AOSE/PE prior to the filing of an application for a construction permit or certification letter, the department may provide a site-specific field review consultation. Such requests shall not be included in any calculation of backlogs nor shall they be subject to the time limits contained in 12VAC5-615-80 or to deemed approval. The department may limit the number of such professional courtesy reviews provided to any individual AOSE/PE as it deems reasonable and as its resources allow. The professional courtesy review shall not be considered to be a case decision.~~

~~4. The department may provide professional courtesy reviews as it deems reasonable and as its resources allow when requested by an AOSE/PE in conjunction with a proposed subdivision, provided such field reviews are general in nature (not site-specific) and provided the developer or owner has generated a base map or preliminary plat of the proposed subdivision and provided that the request for review is made prior to any submission of a subdivision package to the local government for consideration under local subdivision ordinances. Such professional courtesy reviews shall be voluntary and within the sole discretion of the department and shall not be subject to any time limits. Professional courtesy reviews shall not be considered to be case decisions.~~

~~5. Whenever the department has approved a permit, certification letter, or subdivision approval in reliance upon an AOSE/PE certification and later has reason to believe that the site or sites or system design submitted by the AOSE/PE does not substantially comply with the minimum requirements of the Sewage Handling and Disposal Regulations, the department may~~

~~initiate proceedings, in accordance with the Sewage Handling and Disposal Regulations, to revoke or modify its approval. Such approvals, when revoked, shall be deemed to be permit denials and may be appealed by the aggrieved named party to the Sewage Handling and Disposal Appeal Review Board in accordance with § 32.1-166.6 of the Code of Virginia. All requests for appeals to the Appeal Review Board must be in writing and received by the commissioner within 30 days of receipt of notice of the revocation. With the written consent of the owner, the department may revise a permit, certification letter, or subdivision approval to substantially comply with the Sewage Handling and Disposal Regulations. The owner may be required to file a new application and to provide formal or informal plans if such plans are required under the Sewage Handling and Disposal Regulations.~~

~~C. An AOSE/PE must make minor revisions that are discovered to be necessary at any time, including, but not limited to, during the installation of the system, to a permit, certification letter or subdivision approval issued in reliance on the evaluations and/or designs of an AOSE/PE. This subsection shall not be construed to require an AOSE to make revisions, minor or major, that result from actions taken by the owner including, but not limited to, improper site grading, improper location of structures, removal, compaction or other damages to soils.~~

~~1. Minor revisions do not include changes in design flow or substantive changes in square footage of absorption area.~~

~~2. All revisions must fully comply with the Sewage Handling and Disposal Regulations and must be approved by the department before the issuance of the operation permit.~~

~~3. Whenever major revisions, such as changes in system design or location, are required, a new application in accordance with Part IV (12VAC5-615- 340 et seq.) of this chapter shall be required.~~

~~D. Whenever a construction permit has been issued pursuant to a design certified by an AOSE/PE, the certifying AOSE/PE shall inspect that system at the time of installation and provide an inspection report, including an "as-built" drawing, and completion statement to the owner and the local health department. The inspection report and completion statement shall be in a form approved by the division and shall state that the AOSE/PE has inspected the installation. It shall state any deficiencies discovered and identify the methods of correction, and it shall state that the system was installed in accordance with the construction permit, approved plans where appropriate, and the requirements of 12VAC5-610. The local or district health department may, but is not required to, perform an inspection of such systems as required under 12VAC5-610-320. Whenever an AOSE/PE is unable to conduct an inspection under this section, the owner may provide an inspection report and completion statement executed by another AOSE or PE. An Operation Permit (12VAC5-610-340) shall not be issued for any system until the appropriate report and completion statement have been received by the local or district health department.~~

~~E. When the department has issued a construction permit for a private well only (no onsite sewage system), in reliance on a certification by an AOSE/PE, the construction inspection required by 12VAC5-630-320 will be performed by the local or district health department. In such cases, the owner shall provide to the local or district health department a written inspection statement signed by the AOSE/PE stating that the private well was installed in accordance with the permit and the Private Well Regulations. Whenever an AOSE/PE is unable to conduct an inspection under this section, the owner may provide an inspection report and completion statement executed by another AOSE or PE.~~

12VAC5-615-80. ~~Processing time limits and deemed approval.~~ <u>(Repealed.)</u>

~~A. The provisions of this section apply only to applications for residential development and do not apply to any application for a proprietary, pre-engineered system that has been deemed by the department to comply with the board's regulations. The department may accept~~

~~evaluations and designs for proprietary, pre-engineered systems in accordance with this chapter; however, the processing time limits and deemed approval shall not apply to any such application.~~

~~B. The department shall review applications submitted with AOSE/PE documentation in the form specified in this chapter and shall issue a written approval or denial within the time frames specified in Table 1 of this subsection. In the event the application is denied, the department shall set forth in writing the reasons for denial.~~

~~Table 1~~

~~TYPE OF APPLICATION~~	~~TIME LIMIT~~
~~Individual Permit Application~~	~~15 working days~~
~~Individual Certification Letter~~	~~20 working days~~
~~Multiple Lot Certification Letter~~	~~60 days~~
~~Subdivision Review~~	~~60 days~~

~~C. If the department does not approve or disapprove an AOSE/PE application or a request for a subdivision review properly submitted in accordance with this chapter within the time limits specified in Table 1, the application or request for subdivision review shall be deemed approved and the appropriate letter, permit, or approval shall be issued.~~

12VAC5-615-90. ~~The practice of engineering.~~ (Repealed.)

~~A. An AOSE may site and design traditional onsite systems; however, § 32.1-163.5 of the Code of Virginia provides that no one other than a licensed professional engineer may practice engineering. Section 54.1-400 of the Code of Virginia states the "practice of engineering" means any service wherein the principles and methods of engineering are applied to, but are not necessarily limited to, the following areas: consultation, investigation, evaluation, planning and design of public or private utilities, structures, machines, equipment, processes, transportation systems and work systems, including responsible administration of construction contracts. The term "practice of engineering" shall not include the service or maintenance of existing electrical or mechanical systems.~~

~~B. An AOSE may submit site and soil evaluations as described in this chapter for any traditional system regardless of whether the system design requires an engineer. An AOSE, however, may only submit system designs and specifications for systems that do not require the practice of engineering. When a system is sufficiently complex to require the practice of engineering, formal plans and specifications, sealed by a professional engineer (PE) shall be required.~~

~~C. Some traditional systems (see definition) may require the practice of engineering. An AOSE may design traditional systems that do not require the practice of engineering.~~

~~D. When engineering plans and specifications are required for an application submitted pursuant to this chapter, the site evaluation work shall be either conducted and certified by an AOSE or certified by a PE working in consultation with an AOSE. When the site and soil evaluation submitted in support of the application is submitted by a PE, the engineer shall submit a statement indicating that he consulted with a specific AOSE, giving both the name and certification number of the AOSE, on the proposal under review.~~

12VAC5-615-100. ~~AOSE certification required.~~ (Repealed.)

~~No person shall sign a certification statement for submittal to the department in support of an application for a sewage disposal system construction permit representing that he is an~~

~~AOSE/PE or otherwise represent that he is an AOSE/PE unless that person possesses a valid certification as an AOSE issued by the commissioner in accordance with 12VAC5-615-240 A or unless that person is a Virginia licensed Professional Engineer who has consulted with an AOSE in accordance with this chapter.~~

12VAC5-615-110. ~~Right of entry.~~ (Repealed.)

~~The commissioner or the commissioner's designee shall have the right to enter any property to assure compliance with this chapter in accordance with the provisions of § 32.1-25 of the Code of Virginia.~~

12VAC5-615-120. ~~Definitions.~~ (Repealed.)

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

~~"AOSE/PE" means an authorized onsite soil evaluator or a professional engineer working in consultation with an authorized onsite soil evaluator.~~

~~"Authorized onsite soil evaluator (AOSE)" means a person currently listed by the board as possessing the qualifications to evaluate soils and soil properties in relationship to the effects of these properties on the use and management of these soils as the locations for traditional onsite sewage disposal systems.~~

~~"Backlog" is deemed to exist when the processing time for more than 10% of a local or district health department's complete bare applications for construction permits exceeds a predetermined number of working days (i.e., a 15-day backlog exists when the processing time for more than 10% of permit applications exceeds 15 working days). When calculating backlogs, only applications for construction permits shall be counted.~~

~~"Bare application" means an application for a construction permit or a certification letter submitted without supporting documentation from an AOSE/PE.~~

~~"Board" means the State Board of Health.~~

~~"Certification letter" means a letter issued by the department, in lieu of a construction permit, that identifies a specific site and recognizes the appropriateness of the site for an onsite wastewater disposal system.~~

~~"Complete application" means an application for a construction permit or certification letter that includes all necessary information needed to process the application as specified in 12VAC5-610-250 including a site plan as specified in 12VAC5-610-460.~~

~~"Deemed approved" or "deemed approval" means that the department has not taken action to approve or disapprove an application for a permit, an individual lot certification letter, multiple lot certification letters, or subdivision approval for residential development within the time limits prescribed in §§ 32.1-163.5 and 32.1-164 H of the Code of Virginia. In such cases, an application submitted in proper form pursuant to this chapter is deemed approved and the appropriate letter or letters, permit, or approval shall be immediately issued by the department. Deemed approval applies only to applications for single-lot construction permits, subdivision review, and single or multiple-lot certification letters submitted with evaluations and designs certified by an AOSE/PE in accordance with the provisions of the Code of Virginia, the Sewage Handling and Disposal Regulations, and this chapter. Sites that have been previously denied by the department and proprietary, pre-engineered systems deemed by the department to comply with the board's regulations are not subject to the provisions of deemed approval. An application "deemed approved" means that it is approved only with respect to the Board of Health's regulations. In accordance with 12VAC5-615-60 B a local government may authorize the department in writing to implement the provisions of any local ordinance that are more restrictive than the Sewage Handling and Disposal Regulations through the provisions of this chapter.~~

~~"Multiple lot certification letters" means two or more applications for certification letters filed by the same owner for existing or proposed lots to serve detached, individual dwellings.~~

~~"Professional courtesy review" means a site-specific field review requested by an AOSE/PE prior to the submission of an application for a construction permit or certification letter or a general field consultation (not site-specific) regarding a proposed subdivision.~~

~~"Professional engineer in consultation with an AOSE" means that a professional engineer has communicated with an AOSE regarding the site and soil conditions present where the system is proposed, in a manner sufficient to assure compliance with the Sewage Handling and Disposal Regulations and this chapter.~~

~~"Processing time" means the number of working days from the date a complete, bare application is received by a local or district health department to the date a permit or certification letter is issued. Working days characterized by severe weather conditions shall not be included in any calculation of processing time.~~

~~"Residential development" means development, including repair or replacement systems in accordance with 12VAC5-610-280 C 2, using single family homes, which utilize individual onsite sewage systems for each structure. Mass drainfields and other cluster systems that serve more than one dwelling are not considered residential development for the purposes of this chapter.~~

~~"Single lot construction permit/certification letter" means one application filed by an owner for a sewage disposal system construction permit or certification letter to serve an individual dwelling on one lot or parcel of land.~~

~~"Subdivision review" means the review of a proposed subdivision plat by a local health department for a local government pursuant to a local ordinance or ordinances and pursuant to §§ 15.2-2242 and 15.2-2260 of the Code of Virginia and 12VAC5-610-360 of the Sewage Handling and Disposal Regulations for the purposes of determining and documenting whether an approved sewage disposal site is present on each proposed lot.~~

~~"Traditional systems" means onsite wastewater treatment and disposal systems, including proprietary, pre-engineered systems deemed by the department to comply with the board's regulations, that have received provisional or general approval under, or for which design criteria are contained in, the Sewage Handling and Disposal Regulations, except as noted below. For the purposes of this chapter, traditional systems do not include experimental permits, conditional permits issued for temporary, intermittent or seasonal use, septage stabilization systems, or systems permitted under a soil drainage management plan. Conditional construction permits issued for limited occupancy or the use of permanent water saving fixtures are not excluded (see 12VAC5-610-250 J).~~

~~Part II~~

~~Compliance With Administrative Process Act~~

12VAC5-615-130. ~~Compliance with Virginia Administrative Process Act.~~ (Repealed.)

~~The provisions of the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) shall govern the promulgation and administration of this chapter and shall be applicable to the appeal of any case decision based upon this chapter.~~

12VAC5-615-140. ~~Emergency order or rule.~~ (Repealed.)

~~If an emergency exists, the commissioner may issue an emergency order or rule as is necessary for preservation of public health, safety, and welfare. The emergency order or rule shall state the reasons and precise factual basis upon which the emergency rule or order is issued. The emergency order or rule shall state the time period for which it is effective.~~

12VAC5-615-150. ~~Enforcement of regulations.~~ (Repealed.)

~~A. All activities of an AOSE/PE pertaining to evaluations and designs of sewage treatment systems governed by the Sewage Handling and Disposal Regulations (12VAC5-610) and applications for certification as an AOSE shall comply with the requirements set forth in this chapter. The commissioner may enforce this chapter through any means lawfully available.~~

~~B. Subject to the exceptions indicated below, whenever the commissioner, the commissioner's designee, or the district or local health department has reason to believe a violation of this chapter, any law administered by the board, commissioner, or department, any regulations of the board, any order of the board or commissioner, or any conditions in a permit has occurred or is occurring, the department shall notify the alleged violator. Such notice shall be made in writing, shall be delivered personally or sent by certified mail, shall cite the regulation or regulations that are allegedly being violated, shall state the facts that form the basis for believing the violation has occurred or is occurring, shall include a request for a specific action by the recipient by a specified time and shall state the penalties associated with such violations (see § 32.1-27 of the Code of Virginia). In addition, or in the alternative, when the commissioner or the commissioner's designee deems it necessary, the department may initiate criminal prosecution or seek civil relief in circuit court through mandamus or injunctive relief without giving notice. Written notice pursuant to this section is required only when the department intends to pursue administrative enforcement pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).~~

~~C. Pursuant to the authority granted in § 32.1-26 of the Code of Virginia, the commissioner may issue orders to require any person to comply with the provisions of this chapter. The order shall be signed by the commissioner and may require, for example:~~

~~1. The immediate cessation or correction, or both, of the violation;~~

~~2. The submission of a plan to prevent future violations to the commissioner for review and approval;~~

~~3. The submission of an application for certification as an AOSE, an application for a permit, or an application for a variance; and~~

~~4. Any other corrective action deemed necessary for proper compliance with the regulations or to protect public health.~~

~~D. Before the issuance of an order described in subsection C of this section, a hearing must be held with at least 30 days notice to the affected party of the time, place and purpose thereof, for the purpose of adjudicating the alleged violation or violations of this chapter. The procedure at the hearing shall be in accordance with § 2.2-4020 of the Code of Virginia.~~

~~E. All orders shall become effective not less than 15 days after mailing a copy thereof by certified mail to the last known address of the person violating this chapter. Violation of an order is a misdemeanor. (See § 32.1-27 of the Code of Virginia.)~~

~~F. The commissioner may enforce all orders. Should any person fail to comply with any order, the commissioner may:~~

~~1. Apply to an appropriate court for an injunction or other legal process to prevent or stop any practice in violation of the order;~~

~~2. Seek mandamus against any owner or person that is a municipal corporation;~~

~~3. Request the Attorney General to bring an action for civil penalty;~~

~~4. Request the Commonwealth's Attorney to bring a criminal action.~~

~~G. Nothing contained in this section shall be interpreted to require the commissioner to issue an order prior to seeking enforcement of any regulations or statute through an injunction, mandamus or criminal prosecution.~~

12VAC5-615-160. ~~Suspension of regulations during disasters.~~ (Repealed.)

~~If in the case of a man-made or natural disaster, the commissioner finds that certain regulations cannot be complied with and that the public health is better served by not fully complying with this chapter, the commissioner may authorize the suspension of the application of the regulations for specifically affected localities and institute a provisional regulatory plan until the disaster is abated.~~

12VAC5-615-170. ~~Variances.~~ (Repealed.)

~~A. The commissioner may grant a variance to this chapter. The commissioner shall follow the appropriate procedures set forth in this section in granting a variance.~~

~~B. A variance is a conditional waiver of a specific regulation which is granted to a specific person and may be for a specified time period.~~

~~C. The commissioner may grant a variance if a thorough investigation reveals that the hardship imposed (may be economic) by this chapter outweighs the benefits that may be received by the public and that the granting of such variance does not subject the public to unreasonable health risks.~~

~~D. Any person who seeks a variance shall apply in writing for a variance. The application shall be sent to the commissioner for review. The application shall include:~~

~~1. A citation to the regulation from which a variance is requested;~~

~~2. The nature and duration of the variance requested;~~

~~3. Any relevant information in support of the request including information relating to experience or education received, or evaluations and designs conducted pursuant to the requirements of this chapter;~~

~~4. The hardship imposed by the specific requirement of this chapter;~~

~~5. A statement of reasons why the public health and welfare would be better served if the variance were granted;~~

~~6. Suggested conditions that might be imposed on the granting of a variance that would limit the detrimental impact on the public health and welfare;~~

~~7. Other information, if any, believed pertinent by the applicant; and~~

~~8. Such other information as the commissioner may require.~~

~~E. The commissioner shall act on any variance request submitted pursuant to subsection D of this section within 60 working days of receipt of the request.~~

~~F. In the commissioner's evaluation of a variance application, the commissioner shall consider the following factors:~~

~~1. The effect that such a variance would have on the performance of the AOSE/PE or system;~~

~~2. The cost and other economic considerations imposed by this requirement;~~

~~3. The effect that such a variance would have on protection of the public health;~~

~~4. Any relevant information in support of the request including information relating to experience or education received, or evaluations and designs conducted pursuant to the requirements of this chapter;~~

~~5. The hardship imposed by enforcing the specific requirement of this chapter;~~

~~6. The applicant's statement of reasons why the public health and welfare would be better served if the variance were granted;~~

~~7. The suggested conditions that might be imposed on the granting of a variance that would limit the detrimental impact on the public health and welfare;~~

~~8. Other information, if any, believed pertinent by the applicant;~~

~~9. Such other information as the commissioner may require; and~~

~~10. Such other factors as the commissioner may deem appropriate.~~

~~G. Disposition of a variance request:~~

~~1. The commissioner may reject any application for a variance by sending notice to the applicant. The rejection notice shall be in writing and shall state the reasons for rejection. The applicant may petition for a hearing to challenge the rejection pursuant to 12VAC5-615-180 within 30 calendar days of receipt of notice of rejection.~~

~~2. If the commissioner proposes to grant a variance request submitted pursuant to subsection D of this section, the applicant shall be notified in writing of this decision. Such notice shall identify the variance, person, property, or sewage handling or disposal facility covered, and shall specify the period of time for which the variance will be effective and any conditions imposed pursuant to issuing the variance. The effective date of a variance shall be 15 calendar days following its issuance.~~

~~3. No person may challenge the terms set forth in the variance after 30 calendar days have elapsed from the date of issuance.~~

~~H. All variances granted are nontransferable. A variance may be attached to a person's certification to act as an AOSE or to a permit or other approval document. A variance is revoked when the permit or other approval or AOSE certification to which it is attached is revoked.~~

~~I. Any request for a variance must be made by the applicant in writing and received by the department prior to the denial of a certification for authorization as an AOSE, or within 30 days after such denial.~~

12VAC5-615-180. ~~Case decisions.~~ (Repealed.)

~~The agency may make case decisions via informal hearings or by agreement. An informal hearing, for purposes of this chapter, is conducted by a department employee designated by the commissioner. The agency shall provide the named party with reasonable notice of violations and administrative hearings, the right to be present at administrative hearings or by counsel or other qualified representative before the agency or its subordinates for the informal presentation of factual data, argument or proof in connection with any case. A named party shall also have the right to (i) have notice of any contrary fact basis or information in the possession of the agency which can be relied upon in making an adverse decision, (ii) receive a prompt decision of any application for a permit, benefit or renewal, and (iii) to be informed, briefly and generally, in writing, of the factual basis or procedural basis for an adverse decision in any case. The commissioner's designee shall review the facts presented and based on those facts render a case decision. Such case decision shall be the final administrative decision of the agency. The agency may, but is not required to, have a verbatim record made of the hearing proceedings. When a verbatim record is made at the direction of the agency, it shall constitute the official record of the proceedings. A written copy of the decision and the basis for the decision shall be sent to the named party in a timely manner in accordance with the Administrative Process Act unless the parties mutually agree to a later date in order to allow the department to evaluate additional evidence. Only an aggrieved named party to a case decision may appeal an adverse decision to the appropriate circuit court pursuant to § 2.2-4026 of the Code of Virginia and Part Two A of the Rules of the Supreme Court of Virginia.~~

12VAC5-615-190. ~~(Reserved.)~~ (Repealed.)

12VAC5-615-200. ~~Appeal.~~ (Repealed.)

~~A. Any appeal from a denial of an application for certification as an AOSE must be made by the applicant in writing and received by the department within 30 days of the date of receipt of notice of the denial.~~

~~B. Any request for hearing on the denial of an application for a variance pursuant to 12VAC5-615-170 must be made by the applicant in writing and received within 30 days of receipt of the notice.~~

~~C. In the event a person applies for a variance within the 30-day period provided by 12VAC5-615-170 I, the date for appealing the denial of the certification pursuant to subsection B of this section shall commence from the date on which the department acts on the request for a variance.~~

~~D. Pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), an aggrieved named party may appeal an adverse case decision to an appropriate circuit court.~~

~~Part III~~

~~AOSE Certification Requirements~~

12VAC5-615-210. ~~Persons holding a valid certificate on July 1, 2002.~~ (Repealed.)

~~Any person holding a valid certificate as an AOSE on July 1, 2002, may apply for renewal in accordance with 12VAC5-615-270. Such individuals will not be required to pass the written and field tests.~~

12VAC5-615-220. ~~(Reserved.)~~ (Repealed.)

12VAC5-615-230. ~~Application requirements.~~ (Repealed.)

~~Any person may apply to the department for certification as an AOSE by filing a complete application in a form approved by the division, by paying the application fee in accordance with 12VAC5-615-250, and by submitting three professional references from an AOSE, a PE, or a Virginia Certified Professional Soil Scientist. In addition, all applicants for certification as an AOSE shall pass the AOSE written and field tests and meet at least one of the requirements below:~~

~~1. A person holding a current certificate as a Virginia Certified Professional Soil Scientist from the Board of Professional Soil Scientists shall be eligible to receive a certificate as an AOSE upon passing the AOSE written and field tests.~~

~~2. A person who demonstrates to the satisfaction of the division that he has at least four years of full-time experience evaluating site and soil conditions for onsite sewage systems in Virginia in accordance with the Board of Health's Sewage Handling and Disposal Regulations (12VAC5-610) and a related four-year college degree such as science or engineering shall be eligible to receive a certificate as an AOSE provided:~~

~~a. The applicant successfully completes a training course or courses designated and approved by the division; and~~

~~b. The applicant successfully completes the AOSE written and field tests approved by the division.~~

~~3. A person who demonstrates to the satisfaction of the division that he has at least six years of full-time experience evaluating site and soil conditions for onsite sewage systems in Virginia in accordance with the Board of Health's Sewage Handling and Disposal Regulations (12VAC5-610) and a two- or four-year college degree shall be eligible to receive a certificate as an AOSE provided:~~

~~a. The applicant successfully completes a training course or courses designated and approved by the division;~~

~~b. The applicant passes the AOSE written and field tests; and~~

~~c. The applicant provides a written statement signed by a current or former supervisor or an AOSE with a current certification stating that the person is sufficiently experienced to become an AOSE.~~

~~4. A person who demonstrates to the satisfaction of the division that he has at least eight years of experience evaluating site and soil conditions for onsite sewage systems in Virginia in accordance with the Board of Health's Sewage Handling and Disposal Regulations (12VAC5-610) shall be eligible to receive a certificate as an AOSE, provided:~~

~~a. The applicant successfully completes a training course or courses designated and approved by the division;~~

~~b. The applicant successfully completes the AOSE written and field tests approved by the division; and~~

~~c. The applicant provides a written statement signed by a current or former supervisor or an AOSE with a current certification stating that the person is sufficiently experienced to become an AOSE.~~

12VAC5-615-240. ~~Disposition of AOSE applications.~~ (Repealed.)

~~A. Upon satisfactory completion of the requirements of 12VAC5-615-230, the commissioner shall issue to the applicant a certification as an AOSE.~~

~~B. Applicants who have been found ineligible for any reason may request further consideration by submitting in writing evidence of additional qualifications, training, or experience. No additional fee will be required provided the requirements for certification are met within one year from the date the original application is received by the department. After such period, a new application shall be required.~~

~~C. If the commissioner finds that the applicant has not met the minimum requirements for certification as an AOSE, the applicant shall be notified in writing, sent by certified mail or hand delivered, and the reasons for denial of the certification shall be stated. The notice to the applicant of denial shall also state that the applicant has the right to a hearing as specified in 12VAC5-615-180 to challenge the certification denial. Any request for a hearing must be received by the commissioner within 30 days of the affected party's receipt of written notice of the decision.~~

~~D. Before approving an AOSE application, the commissioner or the commissioner's designee may make further inquiries and investigations with respect to the qualifications of the applicant and all references, etc. to confirm or amplify the information supplied. The commissioner may also require a personal interview with the applicant.~~

12VAC5-615-250. ~~Fees for applications, training, and testing.~~ (Repealed.)

~~A. The following fees will be assessed. All fees due the department shall be paid by check or money order.~~

~~B. Any person making application for certification as an AOSE or applying for renewal of an AOSE certification shall pay an application fee of $100.~~

~~C. Those persons taking a department-sponsored training course or courses as specified in 12VAC5-615-230 shall pay the fee for such course as determined by the department. Fees for such course or courses will be based on the department's actual expenses in preparing course materials and conducting the training. This section is not intended to prevent or discourage training courses recognized by the department and offered by entities other than the department. In the case of training that is not directly sponsored by the department, applicants will pay appropriate fees to the sponsoring entity.~~

~~D. Those persons taking written and field tests specified in 12VAC5-615-230 shall pay a fee for such testing as determined by the department based on the actual costs of preparing and administering the tests.~~

12VAC5-615-260. ~~Expiration of AOSE certifications.~~ (Repealed.)

~~AOSE certifications shall expire on June 30 of the second calendar year following the year in which the certificate was issued unless revoked or suspended.~~

12VAC5-615-270. ~~Renewal of expired AOSE certifications.~~ (Repealed.)

~~A. Any person whose AOSE certification has expired in accordance with 12VAC5-615-260 may apply to the department for renewal of that certification. An AOSE may apply for renewal not more than 60 days prior to the expiration of his AOSE certification. If more than six months have elapsed from the expiration of the most recent certification, the department may require an applicant to comply with the provisions of 12VAC5-615-230 and subsection C of this section. Suspended certifications are not renewable until reinstated by the department; revoked certifications cannot be renewed.~~

~~B. Any person making application for renewal of an AOSE certification shall file a complete application in a form approved by the division and pay the application fee in accordance with 12VAC5-615-250.~~

~~C. Any person making application for renewal of an AOSE certification shall provide documentation that he has earned two continuing education units (CEUs) in topics related to the evaluation of site and soil conditions for onsite sewage treatment and disposal and/or the design of onsite sewage treatment and disposal systems during the previous two years. For the purposes of this chapter, a CEU shall be equivalent to 10 contact hours of instruction in subject matter and from sources approved by the division. Each AOSE shall be responsible for maintaining appropriate records of CEUs and for providing proof of satisfactory completion of CEUs to the department.~~

12VAC5-615-280. ~~Site evaluations and design certifications to comply with regulations.~~ (Repealed.)

~~No AOSE/PE shall certify a site evaluation and/or design unless such evaluation and/or design complies with the minimum requirements of the Sewage Handling and Disposal Regulations (12VAC5-610) and such certification and/or design is produced in accordance with this chapter. An AOSE/PE shall make a good faith effort to secure complete, accurate, and timely information regarding site and soil conditions, including relevant factors on adjacent parcels, including but not limited to utilities, water supplies, and other sewage systems. The AOSE/PE shall certify that all information submitted is true and correct to the best of his knowledge and shall be required to be aware of all information in agency files pertaining to the site he is certifying.~~

12VAC5-615-290. ~~Revocation or suspension of AOSE certification.~~ (Repealed.)

~~A. The commissioner may revoke or suspend an AOSE certification for failure to comply with any law administered by the board, commissioner, or department, any regulations of the board, any order of the board or commissioner, or any conditions in a permit.~~

~~B. Actions that may result in revocation or suspension include, but are not limited to, certifying as suitable a site that does not comply with the minimum requirements of the Sewage Handling and Disposal Regulations (12VAC5-610), certifying as suitable a site that has been rejected by the department unless certified pursuant to 12VAC5-615-320, falsifying any document, and any act of misrepresentation made related to AOSE activities.~~

~~C. Whenever the commissioner or the commissioner's designee takes action to revoke or suspend an AOSE certification, there must be an informal fact-finding conference in accordance with 12VAC5-615-180 and proper notice must be given to the affected party.~~

~~1. The AOSE shall be notified in writing. The notice must be hand delivered or sent by certified mail. The notice must provide the factual and legal basis for the contemplated action and must give the date, time, place, and location of the informal fact-finding conference.~~

~~2. The informal fact-finding conference is to be conducted by an employee of the department designated by the commissioner. The conference shall be conducted in accordance with, but is not limited to, the requirements of § 2.2-4019 of the Code of Virginia and may include the creation of a verbatim or summary record of the proceedings.~~

~~3. The commissioner or the commissioner's designee shall render a decision from the informal fact-finding conference in a timely manner in accordance with § 2.2-4021 of the Code of Virginia. Such decisions shall constitute the final administrative decision and may be appealed in accordance with 12VAC5-615-180.~~

~~4. When action is taken to suspend an AOSE certification, that suspension shall be for a specified period of time. Remedial actions including, but not limited to, additional training courses, additional testing, and reevaluation of a site and/or redesign of an onsite sewage system may be specified as conditions of any suspension.~~

12VAC5-615-300. ~~Application for reinstatement of AOSE certification.~~ (Repealed.)

~~Any person whose AOSE certification has been revoked pursuant to 12VAC5-615-290 may apply to the department for reinstatement as an AOSE no sooner than 12 months after the effective date of the revocation. Any person making application for reinstatement of an AOSE certification pursuant to this section shall:~~

~~1. File a complete application in a form approved by the division and pay the application fee in accordance with 12VAC5-615-250. The AOSE application for reinstatement must also include a certification that the AOSE has not engaged in AOSE activities after his certification was revoked; and~~

~~2. Provide documentation that the applicant has satisfactorily completed any remedial actions required as a result of the revocation. Remedial actions including, but not limited to, additional training courses, additional testing, and reevaluation of a site and/or redesign of an onsite sewage system may be specified as conditions for reinstatement.~~

12VAC5-615-310. ~~Appeal of suspension or revocation.~~ (Repealed.)

~~In accordance with 12VAC5-615-180, any person whose AOSE certification has been suspended or revoked shall have the right to review by the appropriate circuit court.~~

12VAC5-615-320. ~~AOSE/PE cannot certify a site that has been previously denied by the department.~~ (Repealed.)

~~No AOSE/PE shall certify a site as meeting the minimum requirements of the Sewage Handling and Disposal Regulations (12VAC5-610) if the department has previously denied that site.~~

~~Exceptions:~~

~~1. An AOSE/PE may certify a previously denied site as meeting the requirements of the Sewage Handling and Disposal Regulations if the board's regulations or policies have changed in such a way that the site is suitable for a system that was not allowed by the board's prior regulations or policies at the time of the original denial; and~~

~~2. An AOSE/PE may certify as meeting the requirements of the Sewage Handling and Disposal Regulations a site located on the same property as a site previously denied by the department if the site being certified is not the same one that was denied by the department.~~

12VAC5-615-330. ~~Change of address or other status.~~ (Repealed.)

~~The AOSE shall be responsible for notifying the commissioner of any change in address, business partnership or affiliation, or any other status that affects his standing as an AOSE. Such notice must be in writing and must be delivered to the commissioner as soon as practicable after the effective date of the change.~~

~~Part IV~~

~~Procedures and Reports~~

12VAC5-615-340. ~~Application processing.~~ (Repealed.)

~~A. All applications that are submitted with evaluation and design documentation by an AOSE/PE shall contain the minimum required information necessary to complete the application and shall be accompanied by the required fees. Such applications when submitted for residential development will be processed within specified time limits in 12VAC5-615-80.~~

~~B. When such an application is found to be complete an approval may be issued without field review.~~

~~C. Applications that are found to be incomplete or defective in any manner shall be denied and the owner and AOSE/PE will be notified of deficiencies. If an application has been denied, the owner or his agent may submit a new application to correct the deficiency or deficiencies contained in his first application. If the application is received within 90 days, the department will waive all state fees associated with the new application. This waiver may be granted not more than once per site.~~

12VAC5-615-350. ~~Documentation requirements for AOSE/PE reports.~~ (Repealed.)

~~A. Applications may be submitted for a single lot construction permit, a single lot certification letter, multiple lot certification letters, and subdivision reviews. The minimum requirements for each type of application are listed below. Additional information may be submitted when an AOSE/PE believes it may be in the interest of public health, the environment, or the client.~~

~~B. A complete application for a construction permit shall consist of the following:~~

~~1. A complete application for a Sewage Disposal System Construction Permit (CHS 200), signed, dated, and with all pertinent information supplied;~~

~~2. The appropriate fee for the application as per the Code of Virginia;~~

~~3. A site evaluation report in accordance with 12VAC5-615-360 and the department's policies;~~

~~4. A proposed well site (when a private water supply is proposed);~~

~~5. Construction drawings and specifications for the recommended system in accordance with 12VAC5-615-380 and the department's policies; and~~

~~6. A statement in accordance with 12VAC5-615-70, 12VAC5-615-280, and 12VAC5-615-380 C certifying that the site and soil conditions and design conform with the Sewage Handling and Disposal Regulations (12VAC5-610).~~

~~C. A complete application for certification letter differs from an equivalent application for a construction permit in that a complete design is not required. It is, however, necessary to assure a system meeting the requirements specified on the application can be supported by the proposed site. Therefore, the requirements for a single certification letter are:~~

~~1. A complete application for a Sewage Disposal System Construction Permit (CHS 200), signed, dated, and with all pertinent information supplied;~~

~~2. The appropriate fee for the application;~~

~~3. A site evaluation report in accordance with 12VAC5-615-360 and the department's policies;~~

~~4. A proposed well site (when a private water supply is proposed);~~

~~5. An abbreviated system design for the type of system proposed in a form approved by the division; and~~

6. A statement in accordance with 12VAC5-615-70, 12VAC5-615-280, and 12VAC5-615-380 C certifying that the site and soil conditions and design conform with the Sewage Handling and Disposal Regulations.

D. Applications for multiple certification letters may be used as the method for reviewing proposed subdivisions in localities that do not require the local health department to review proposed subdivisions. Each application submitted must contain the following:

1. Complete applications for Sewage Disposal System Construction Permits (CHS 200), signed, dated, and with all pertinent information supplied;

2. The appropriate fee for each site to be reviewed;

3. Site evaluation reports in accordance with 12VAC5-615-360 and the department's policies;

4. Proposed well sites (when a private water supply is proposed);

5. Abbreviated system designs for the type of system proposed in a form approved by the division;

6. A statement in accordance with 12VAC5-615-70, 12VAC5-615-280, and 12VAC5-615-380 C for each proposed site certifying that the site and soil conditions and design conform with the Sewage Handling and Disposal Regulations; and

7. If the multiple certification letters are intended to establish the suitability of soils for a proposed subdivision, the information specified in subdivision E 3 c of this section is to be submitted by the applicant.

E. Section 32.1-163.5 of the Code of Virginia provides that the department shall accept private site evaluations and designs, for subdivision review for residential development, designed and certified by a licensed professional engineer in consultation with an AOSE or by an AOSE. The following shall apply to all requests for subdivision review and approval:

1. All requests for subdivision reviews must be submitted to the local health department with a request from the local government entity specifically asking for review of the proposed lots for onsite wastewater system approvals pursuant to the local ordinance governing such proposals (cite reference to local ordinance).

2. In localities where there is no subdivision ordinance, subdivisions should be handled using applications for multiple certification letters (see subsection D of this section).

3. All requests submitted by local governments for review and approval must contain the following minimum information:

a. A letter requesting subdivision review and certification by the locality that the subdivision package has been determined to be complete.

b. Individual site and soil evaluation reports in accordance with 12VAC5-615-360 for each proposed lot in the subdivision. These individual reports must be identified as to the subdivision and the proposed lot number.

c. A preliminary subdivision plat that provides the information specified in 12VAC5-610-360. This includes all information required by the local ordinance, and includes the following if not required by local ordinance: proposed streets, utilities, storm drainage, water supplies, easements, lot lines, existing and proposed water supplies for each proposed lot and within 200 feet of any proposed or existing sewage system, and original topographic contour lines by detail survey. The plat shall be prepared according to suggested scales and contour intervals contained in Appendix L of the Sewage Handling and Disposal Regulations.

4. Abbreviated system designs in a form approved by the division for the type of system proposed.

~~5. A statement in accordance with 12VAC5-615-70, 12VAC5-615-280, and 12VAC5-615-380 C for each proposed site certifying that the site and soil conditions and design conform to the Sewage Handling and Disposal Regulations.~~

~~Table 2~~
~~Types of Applications~~

	~~Single Lot Construction Permit~~	~~Single Lot Certification Letter~~	~~Multiple Lot Certification Letters~~	~~Subdivision~~
~~Application~~	~~X~~	~~X~~	~~X~~	
~~Fee~~	~~X~~	~~X~~	~~X~~	
~~Site Evaluation~~	~~X~~	~~X~~	~~X~~	~~X~~
~~Proposed Well Site~~	~~X~~	~~X~~	~~X~~	~~X~~
~~Construction Drawings~~	~~X~~			
~~Construction Specifications~~	~~X~~			
~~Design Calculations~~	~~X~~			
~~Abbreviated Design Calculations~~		~~X~~	~~X~~	~~X~~
~~Certification of Compliance~~	~~X~~	~~X~~	~~X~~	~~X~~
~~Local Government Request~~				~~X~~
~~Preliminary Subdivision Plat~~			~~X~~ ~~(as necessary)~~	~~X~~
~~Max. Time to Process~~	~~15 Working Days~~	~~20 Working Days~~	~~60 Days~~	~~60 Days~~
~~Rec. Time to Process~~	~~5 Working Days~~	~~10 Working Days~~	~~45 Days~~	~~45 Days~~

12VAC5-615-360. ~~Site evaluation reports.~~ (Repealed.)

~~All site evaluation reports submitted to the department shall be in a form approved by the division, shall contain the minimum information specified by the division, and shall be certified as fully complying with the Sewage Handling and Disposal Regulations (12VAC5-610). A statement approved by the department shall be used to certify that a site evaluation and/or design complies with the board's regulations for onsite sewage systems. No approval shall be granted pursuant to this chapter for any site that has not been certified by an AOSE/PE. Additional information required by local ordinances (i.e., Chesapeake Bay requirements) may be included with an AOSE submission in order to facilitate processing the application. However, for the purposes of an AOSE/PE certifying that an evaluation and/or design complies with the Sewage Handling and Disposal Regulations and for "deemed approval" only those requirements contained in the Board of Health's regulations are considered to apply unless a local government has requested its health department to implement a more restrictive local ordinance~~

~~in accordance with 12VAC5-615-60 B. Wastewater system sites proposed for use must be defined in a manner that allows them to be identified with an accuracy and precision of three feet or less.~~

12VAC5-615-370. ~~Access to information.~~ (Repealed.)

~~When requesting information from the department's official records, an AOSE/PE shall clearly and accurately identify property locations, using tax map numbers when possible, and specify the information requested on a form approved by the division. The department shall, as resources permit, provide the requested information in as timely a manner as possible, and shall in all cases comply with the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia).~~

12VAC5-615-380. ~~System design requirements, construction drawings, certification statement, and site denial.~~ (Repealed.)

~~A. Any application for a construction permit accompanied by an AOSE/PE certification shall contain construction drawings, plans, and specifications in a form approved by the division sufficient to allow the system to be installed by the contractor in accordance with the Sewage Handling and Disposal Regulations (12VAC5-610) and the proposed permit. When a system is sufficiently complex to require the practice of engineering, a professional engineer shall seal the plans and specifications. The design information necessary to issue a sewage disposal system construction permit includes:~~

~~1. All the information required on form CHS 202 A and B (see Forms, Sewage Handling and Disposal Regulations);~~

~~2. System construction drawings containing the minimum information as determined by the division;~~

~~3. Plans and specifications sufficient to allow the successful installation of a system when the application is for a construction permit;~~

~~4. Design calculations used to establish the design parameters of the recommended system, including the minimum information deemed appropriate by the division; and~~

~~5. Three copies of the construction drawings and specifications.~~

~~Subdivisions 1 through 5 of this subsection establish the minimum information necessary to issue a construction permit. Additional information may be necessary depending on the specific site. Applications that do not contain this minimum data set shall be denied.~~

~~B. Certification letters and subdivision submittals do not normally require a complete design with specifications. Prior to applying for a certification letter or preparing a package for subdivision review an AOSE/PE shall conduct evaluations and provide documentation sufficient to verify that specific and sufficient area is available for the proposed system, including setback distances, and that the soils are capable of supporting the proposed design flow.~~

~~C. All site evaluation work submitted in support of a construction permit, certification letter, or subdivision review shall be in the form specified above and shall be certified as fully complying with the Sewage Handling and Disposal Regulations. A certification statement approved by the department shall be used to make such certification.~~

~~D. In some cases an owner may desire to submit an application with a certification by an AOSE/PE stating that a site does not comply with the minimum requirements of the Sewage Handling and Disposal Regulations. In such cases an AOSE/PE may submit the appropriate reports and information as required by this chapter and the department shall process the application in accordance with the procedures for processing applications for permits and letters. Instead of issuing a permit or letter, the department will issue a denial letter.~~

12VAC5-615-390. ~~Professional courtesy review.~~ (Repealed.)

~~A. Any AOSE/PE may request a site-specific professional courtesy review, prior to the submission of an application for a construction permit or certification letter, where he has determined that the site and soil conditions in a specific area proposed for an onsite sewage system are marginal or where he has not been able to determine with certainty that the conditions comply with the requirements of the Sewage Handling and Disposal Regulations (12VAC5-610). A request for review shall be in a form approved by the division and shall include written authorization from the owner giving the department permission to enter the property and a complete evaluation report as described in 12VAC5-615-360, with the exception of the certification statement. In place of the certification statement required under 12VAC5-615-360 the AOSE/PE shall provide a brief description of the particular site and soil features or characteristics that the AOSE/PE has identified as marginal or questionable and which form the basis for the request for review and a preliminary opinion as to whether the site meets the requirements of the Sewage Handling and Disposal Regulations. Professional courtesy reviews are not intended to replace the AOSE/PE's responsibility to exercise professional judgement in determining whether a site meets the minimum requirements of the Sewage Handling and Disposal Regulations. The department is not required to perform such reviews but may do so in its sole discretion.~~

~~B. In accordance with 12VAC5-615-70 B 3, the department may limit professional courtesy reviews for construction permits and certification letters. Whenever the department determines that it will not provide a requested review, it shall notify the AOSE/PE and the applicant in writing within a reasonable time. When the department elects to provide professional courtesy reviews, it shall do so in a reasonable time.~~

~~C. Any AOSE/PE may request a general (not site-specific) professional courtesy review, prior to the submission of a proposal for subdivision approval to a local government entity, where he has determined that the site and soil conditions in an area proposed for a subdivision with onsite sewage systems are marginal or where he has not been able to determine with certainty that the conditions comply with the requirements of the Sewage Handling and Disposal Regulations. A request for review shall be in a form approved by the division and shall include written authorization from the owner giving the department permission to enter the property and a summary evaluation report that generally comports with the requirements of 12VAC5-615-360, with the exception of the certification statement. In place of the certification statement required under 12VAC5-615-360, the AOSE/PE shall provide a brief description of the particular site and soil features or characteristics that the AOSE/PE has identified as marginal or questionable and which form the basis for the request for review and a preliminary opinion as to whether the area generally meets the requirements of the Sewage Handling and Disposal Regulations. Such requests are intended to allow the department to consult with AOSE/PEs in a nonsite-specific manner where the local health department's knowledge of general site and soil conditions and the requirements of the Sewage Handling and Disposal Regulations can assist the AOSE/PE and local governments in the planning stages of subdivision approval. Professional courtesy reviews are not intended to replace the AOSE/PE's responsibility to exercise professional judgment in determining whether a specific site meets the minimum requirements of the Sewage Handling and Disposal Regulations.~~

~~D. In accordance with 12VAC5-615-70 B 4, the department may limit professional courtesy reviews for proposed subdivisions. Whenever the department determines that it will not provide a requested review, it shall notify the AOSE/PE and the applicant in writing within a reasonable time. When the department elects to provide professional courtesy reviews, it shall do so in a reasonable time.~~

~~E. Professional courtesy reviews shall not be construed as case decisions.~~

12VAC5-615-400. ~~Field checks.~~ (Repealed.)

~~The department is not required to perform a field check of AOSE/PE evaluations and designs prior to issuing a permit, certification letter, or subdivision approval; however, it may conduct a field analysis as it deems necessary to protect public health and the environment. Whenever the department performs such field checks, it shall make a record of the results of the analysis in a form approved by the division. The department shall mail a copy of such report to the owner and to the AOSE/PE at the address provided by the AOSE/PE with the evaluation and design reports or at the address supplied to the department with the AOSE's application for AOSE certification or renewal of certification.~~

~~Part V~~

~~Conflict of Interest and Disclosure~~

12VAC5-615-410. ~~Responsibility to the public.~~ (Repealed.)

~~The primary obligation of the AOSE is to the public. If the judgment of the AOSE is overruled under circumstances when the safety, health, property and welfare of the public are endangered, the AOSE shall inform the employer or client of the possible consequences and notify appropriate authorities.~~

12VAC5-615-420. ~~Public statements.~~ (Repealed.)

~~A. The AOSE shall be truthful in all AOSE matters.~~

~~B. When serving as an expert or technical witness, the AOSE shall express an opinion only when it is based on an adequate knowledge of the facts and in areas on which he is competent to testify. Except when appearing as an expert witness in court or an administrative proceeding where the parties are represented by counsel, the AOSE shall issue no statements, reports, criticisms, or arguments on matters relating to AOSE practice that are inspired or paid for by an interested party or parties, unless the AOSE has prefaced the comment by disclosing the identities of the party or parties on whose behalf the AOSE is speaking and by revealing any self-interest.~~

~~C. An AOSE shall not knowingly make a materially false statement or fail deliberately to disclose a material fact requested in connection with his application for licensure, certification, registration, renewal or reinstatement.~~

~~D. An AOSE shall not knowingly make a materially false statement or fail to deliberately disclose a material fact requested in connection with an application submitted to the department by any other individual or business entity for licensure, certification, registration, renewal or reinstatement.~~

12VAC5-615-430. ~~Conflicts of interest.~~ (Repealed.)

~~A. The AOSE shall promptly and fully inform an employer or client of any business association, interest, or circumstance or circumstances that may influence the AOSE's judgment or the quality of service.~~

~~B. The AOSE shall not accept compensation, financial or otherwise, from more than one party for services on or pertaining to the same project, unless the circumstances are fully disclosed in writing to all parties of current interest and he obtains the parties' written approval.~~

~~C. The AOSE shall neither solicit nor accept financial or other valuable consideration from suppliers for specifying their products or services.~~

~~D. The AOSE shall not solicit or accept gratuities, directly or indirectly, from contractors, their agents, or other parties dealing with a client or employer in connection with work for which the AOSE is responsible.~~

12VAC5-615-440. ~~Solicitation of work.~~ (Repealed.)

~~In the course of soliciting work:~~

~~1. The AOSE shall not bribe.~~

~~2. The AOSE shall not falsify or permit misrepresentation of the AOSE's work or an associate's academic or AOSE qualifications, nor shall the AOSE misrepresent the degree of responsibility for prior assignments. Materials used in the solicitation of employment shall not misrepresent facts concerning employers, employees, associates, joint ventures or past accomplishments of any kind.~~

12VAC5-615-450. ~~Competency for assignments.~~ (Repealed.)

~~An AOSE shall not misrepresent to a prospective or existing client or employer his qualifications and the scope of his responsibility in connection with work for which he is claiming credit.~~

12VAC5-615-460. ~~AOSE responsibility.~~ (Repealed.)

~~A. The AOSE shall not knowingly associate in a business venture with, or permit the use of the AOSE's name or firm name by, any person or firm where there is reason to believe that person or firm is engaging in activity of a fraudulent or dishonest nature or is violating any law or regulations of the department.~~

~~B. An AOSE who has direct knowledge that another individual or firm may be violating any of these provisions, or the provisions of Article 1 (§ 32.1-163 et seq.) of Chapter 6 of Title 32.1 of the Code of Virginia, shall immediately inform the commissioner in writing and shall cooperate in furnishing any further information or assistance that may be required.~~

~~C. The AOSE shall, upon request or demand, produce to the commissioner, or any of his agents, any plan, document, book, record or copy thereof in his possession concerning a transaction covered by this chapter, and shall cooperate in the investigation of a complaint filed with the commissioner against a certificate holder.~~

~~D. Except as provided in subsection E of this section, an AOSE shall not utilize the evaluations, design, drawings or work of another AOSE without the knowledge and written consent of the AOSE or organization of ownership that originated the design, drawings or work. In the event that the AOSE who generated the original document is no longer employed by the firm retaining ownership of the original documents or is deceased, another AOSE who is a partner or officer in the firm retaining ownership of the original documents may authorize utilization of the original documents by another AOSE or firm. This fact must be disclosed to the department when submitting applications supported by AOSE materials and certifications.~~

~~E. The information contained in Department of Health records, on which a decision to approve or deny a site has been made, shall be considered to be in the public domain and may be utilized by an AOSE without permission.~~

~~F. An AOSE who relies on information in Department of Health files or has received permission to modify or otherwise utilize the evaluation, design, drawings or work of another AOSE pursuant to subsection D or E of this section may certify that work only after a thorough review of the evaluation, design, drawings or work and after he determines that he is willing to assume full responsibility for all design, drawings or work on which he relies for his opinion.~~

~~G. The information contained in recorded plats or surveys may be utilized by an AOSE without permission. If modifications are to be made to the plats or surveys, such modifications shall only be made by a person or persons authorized pursuant to Chapter 4 (§ 54.1-400 et seq.) of Title 54.1 and Title 13.1 of the Code of Virginia to make such changes or modifications to the plats or surveys.~~

12VAC5-615-470. ~~Good standing in other jurisdictions.~~ (Repealed.)

~~An AOSE licensed or certified to practice site and soil evaluations or to design onsite wastewater systems in other jurisdictions shall be in good standing in every jurisdiction where licensed or certified, and shall not have had a license or certificate suspended, revoked or~~

~~surrendered in connection with a disciplinary action or have been the subject of discipline in another jurisdiction.~~

~~FORMS (12VAC5-615)~~

~~Application to Become an Authorized Onsite Soil Evaluator (eff 9/01).~~

~~Renewal Application-Authorized Onsite Soil Evaluator (eff. 9/01).~~

~~Continuing Education Classes attended in the previous two years (eff. 7/02).~~

COMMONWEALTH of VIRGINIA
Department of Health
Marissa J. Levine, MD, MPH
STATE HEALTH COMMISSIONER
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RICHMOND, VA 23218
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1-800-828-1120

MEMORANDUM

DATE: February 5, 2016

TO: Virginia State Board of Health

FROM: Dwayne Roadcap, Office of Environmental Health Services

SUBJECT: Final Amendments for Sewage Handling and Disposal Regulations (12VAC5-610) for Gravelless Material and Drip Dispersal

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Va. Code Section 32.1-164.9 mandates the Board of Health promulgate regulations for chamber and bundled expanded polystyrene systems, and other technologies as deemed necessary. The Board of Health approved emergency regulations for gravelless material and drip dispersal during the September 12, 2013 meeting and submitted the emergency regulations for executive branch review. The emergency regulations were approved by Governor McDonnell and became effective on March 14, 2014.

The emergency regulations were set to expire on September 13, 2015. On April 24, 2015, staff requested a six month extension. Governor McAuliffe approved the extension on August 3, 2015, moving the expiration date of the emergency regulations to March 14, 2016. Staff have issued a policy that will allow for the continued uses of gravelless material and drip dispersal in accordance with the emergency regulations until such time that the final regulations are promulgated.

As part of the process to promulgate emergency regulations, the agency submitted a Notice of Intended Regulatory Action to create permanent regulations for gravelless material and drip dispersal. The draft final regulations amend 12VAC5-610 (the Sewage Handling and Disposal Regulations) by permanently incorporating the requirements of the emergency regulations, with several minor revisions. Agency staff convened two technical advisory committees to review public comments and propose revisions to the emergency regulation.

Upon approval by the Board of Health, the draft final regulations will undergo executive branch review and approval. Following publication of the draft final regulations, there will be a 30-day final adoption period. After the final adoption period closes, the final regulations become effective.

townhall.virginia.gov

Final Regulation
Agency Background Document

Agency name	Board of Health – Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-610
Regulation title(s)	Sewage Handling and Disposal Regulations (the Regulations)
Action title	Establish requirements for the physical construction, design, and installation of gravelless material, and requirements for the physical construction, design and installation of drip dispersal.
Date this document prepared	December 29, 2015

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The proposed amendments to the Regulations (12VAC5-610) will permanently incorporate the requirements for gravelless material and drip dispersal established by emergency regulations. These requirements can be summarized as follows:

1. Specifications for the physical construction of gravelless material including minimum exterior width, height, effluent storage capacity, and structural capacity.
2. Requirements for a permeable interface between gravelless material and trench sidewall soil surfaces for the absorption of effluent.

3. Criteria for the allowable slope, maximum length, minimum sidewall depth, and minimum lateral separation of gravelless material absorption trenches.
4. Criteria for determining the minimum absorption area required when utilizing gravelless material.
5. Criteria for substitution of gravelless material in place of gravel for gravity percolation lines and low pressure distribution systems.
6. Specifications for the physical construction of drip dispersal system components.
7. Minimum requirements for the design of drip dispersal systems.
8. Minimum installation requirements for drip dispersal systems.

The final regulation has several minor revisions compared to the emergency regulations for gravelless material and drip dispersal. The revisions address public comments and comments from two technical advisory committees (the Chamber and Bundled Expanded Polystyrene Technical Advisory Committee, and the Drip Dispersal Technical Advisory Committee) and are intended to clarify requirements outlined in the emergency regulations.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

Acronyms

AOSS – Alternative Onsite Sewage System
CBEP TAC – the Chamber and Bundled Expanded Polystyrene Technical Advisory Committee
DD TAC – the Drip Dispersal Technical Advisory Committee
DEQ – Virginia Department of Environmental Quality
GMP – Virginia Department of Health Guidance, Memorandum, and Policies
OEHS – Virginia Department of Health's Office of Environmental Health Services
OSE – Licensed Onsite Soil Evaluator
PE – Licensed Professional Engineer
VDH – Virginia Department of Health

Definitions

Drip dispersal means an onsite sewage system that applies wastewater in an even and controlled manner over an absorption area. Drip dispersal components may include treatment components, a flow equalization pump tank, a filtration system, a flow measurement method, supply and return piping, small diameter pipe with emitters, air/vacuum release valves, redistribution controls, and electromechanical components or controls.

Gravelless material means a proprietary product specifically manufactured to disperse effluent within the absorption trench of an onsite sewage system without the use of gravel. Gravelless material may include chamber, bundled expanded polystyrene, and multi-pipe systems.

Statement of final agency action

Please 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.

On March 17, 2016, the Board of Health approved final amendments to the Sewage Handling and Disposal Regulations (12VAC5-610) regarding gravelless material and drip dispersal.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Section 32.1-164.9 of the Code of Virginia mandates the Board to promulgate regulations for physical construction, design, and installation of chamber and bundled expanded polystyrene systems. Additionally, the Board is authorized pursuant to § 32.1-12 of the Code of Virginia to promulgate and enforce regulations. Section 32.1-164 of the Code of Virginia authorizes the Board to promulgate regulations governing the collection, conveyance, transportation, treatment, and disposal of sewage by onsite sewage systems to protect public health, surface water, and ground water.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The need for the final amendments is to implement § 32.1-164.9 of the Code of Virginia and incorporate requirements for gravelless material and drip dispersal into the Regulations. The emergency regulations currently include construction, design, and installation requirements for gravelless material and drip dispersal systems. However, the emergency regulations will expire on March 14, 2016. Since 1995, VDH has recognized through Guidance Memoranda and Policy (GMP) that gravelless material and drip dispersal are acceptable means of dispersing effluent. The final amendments establish the physical construction, design, and installation standards for gravelless material and drip dispersal necessary to protect public health, safety and welfare of citizens. The goal of the final amendments is to permanently add the construction, design, and installation standards for gravelless material and drip dispersal found in the emergency regulations into the Regulations.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

The proposed regulation establishes minimum physical construction, design, and installation requirements for gravelless material and drip dispersal. The proposed regulation permanently incorporates sections 30, 920, 930(F), 940(D), 950, Table 5.4, and 955 of the emergency regulations, with a few minor revisions.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.

The primary advantage to the public of the final amendments is that it provides a clear standard for the use of gravelless material and drip dispersal; products that have been allowed through a series of GMPs for more than 20 years. The final amendments also provide manufacturers of new gravelless materials with a clear understanding of the physical construction requirements for gravelless materials in Virginia, along with a clear process for seeking approval of new technologies. The primary advantages to VDH are similar to those for the public; clear regulations and a clear process for approving new technologies. Additionally, the final amendments implement the requirements of § 32.1-164.9 of the Code of Virginia. The final amendments benefit the regulated community by providing a clear set of regulations for gravelless material and drip dispersal designs submitted pursuant to § 32.1-163.5 of the Code of Virginia.

The final amendments pose no disadvantages to the public or the Commonwealth. However, two issues have generated a considerable amount of interest and concern: 1) a perception that gravelless material systems sized in accordance with the proposed regulation will fail prematurely; and 2) VDH employees do not possess the same latitude as private sector designers to specify which materials are used in their designs.

A number of commenters during the Notice of Intended Regulatory Action stage voiced concern that gravelless material sized in accordance with the final amendments will result in premature system failure. The CBEP TAC discussed at length the issue of gravelless material sizing. Under previous GMPs, gravelless material could be used at up to a 50% reduction in sizing when compared to gravel trench systems. The CBEP TAC came to a general agreement that the reduction should be limited to 25% in Class I, II, and III soils, and 15% in class IV soils.

OEHS has performed two reviews to evaluate claims that the use of gravelless material will increase premature failure rates. The first review looked at indemnification fund cases where gravelless materials were used. In those cases, improper evaluation of soil permeability rates and depth to water table where found to be the primary causes of failure. The second review looked at malfunction assessments entered into the Virginia Environmental Information System database between January 1, 2015, and October 12, 2015, where the malfunctioning system was less than 15 years old. The causes of failure were similar among both gravel trench systems and gravelless material systems. More information on this review is included in the November 23, 2015, CBEP TAC meeting summary. The summary can be found at www.townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\\meeting\58\23698\Minutes_VDH_23698_v1.pdf .

Gravelless materials have been approved for use through GMPs for more than 20 years, with smaller minimum sizing requirements than those in the final amendments. Additionally, reviews conducted by OEHS did not find clear evidence that gravelless material sizing allowed under previous GMPs resulted in increased rates of premature failure. However, VDH agrees that the performance of all materials approved for use in onsite sewage systems should be tracked to inform future VDH policies and regulations. VDH has identified several improvements for malfunction assessment reporting that will enhance the ability to evaluate the performance of onsite sewage system components.

Commenters during the Notice of Intended Regulatory Action stage also voiced concern that VDH employees are not given the same latitude as private sector designers to specify which materials are used in their designs. Specifically, commenters raised concerns that VDH employees must accept the substitution of gravelless material for gravel trenches when done in accordance with the minimum requirements of the final amendments for gravelless materials. However, this requirement for VDH employees is not new and is not limited to gravelless materials.

VDH employees must approve onsite sewage system installations that adhere to the Regulations and GMPs. For the last 20 years VDH employees have approved the use of gravelless materials installed in accordance with GMPs. The final amendments simply move those GMPs into the Regulations. Other onsite sewage system components, such as distribution boxes and header lines, have multiple material options. VDH employees must approve these components as well, provided each meets the Regulations and GMPs.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no known localities that would be particularly affected by the final amendments. The Regulations apply to all localities.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The final amendments will have no family impact.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

Section number	Requirement at proposed stage	What has changed	Rationale for change
930.F.4	Requires installation of gravelless material to comply with the requirements of the Regulations.	"Installation of gravelless material shall comply with this chapter and the approved installation manual unless the department grants a deviation pursuant to 12VAC5-610-660 or the division has granted a deviation identified in the installation manual." Requires installation of gravelless material to also comply with the requirements of the manufacturer's installation manual, as approved by VDH.	This change is proposed to address a comment from the CBEP TAC that the proposed regulation did not make it clear that an installer must follow the manufacturer's approved installation manual, in addition to the minimum requirements of the proposed regulation.
930.F.8	Requires the system designer to identify on the inspection report any	"Gravelless material may be substituted for gravel in accordance with this chapter, provided that the	This change addresses a public comment asking VDH to identify the

	substitution of gravelless material for gravel trenches.	certifying licensed professional engineer or onsite soil evaluator approves the substitution. The certifying licensed professional engineer or onsite soil evaluator shall ~~identify~~ document the substitution and related design changes on the inspection report submitted in accordance with 12VAC5-610-330. A new construction permit pursuant to 12VAC5-610-310 is not required for the substitution." Requires the system designer to also document any additional modifications to the system made as a result of substituting gravelless material for gravel trenches (e.g. modification of pump drawdown specifications).	responsible party for alteration of pump designs as a result of a substitution of gravelless material for gravel trenches. The proposed change requires the certifying designers to document any changes to the pump or other system components resulting from a substitution as part of their inspection report approving or denying the installation.
955.B.3	This section currently sets installation depth requirements for drip systems dispersing septic tank effluent, and minimum cover requirements for drip systems dispersing secondary effluent.	"Except as provided by 12VAC5-613, drip systems dispersing septic tank effluent shall comply with the requirements of 12VAC5-610-594. 4. Drip systems dispersing secondary effluent or better require a minimum of six inches of cover over the tubing. Cover may be achieved by a combination of installation depth and Group II or Group III soil cover or other approved material over the drip field" Removes the minimum cover requirement for drip systems dispersing secondary effluent or better from 955.B.3 and moves it to a new section, 955.B.4.	This change was recommended by the DD TAC in response to a public comment regarding 955.B.3. The change is intended to provide a clear distinction between requirements for drip systems dispersing septic tank effluent and those dispersing secondary or better effluent.
955.B.4	"4. The discharge rate of any two emitters shall not vary by more than 10% in order to ensure that the effluent is uniformly distributed over the entire drip field or zone."	"~~4~~5. The discharge rate of any two emitters shall not vary by more than 10% in order to ensure that the effluent is uniformly distributed over the entire drip field or zone." Changes the section number to address the separation of language in section B.3 that creates a new section B.4.	This change simply incorporates a numbering changes based on revisions to 955.B.3.

955.B.5	"5. The emitters shall be evenly spaced along the length of the drip tubing at not less than six inches or more than 24 inches apart."	"~~5~~6. The emitters shall be evenly spaced along the length of the drip tubing at not less than six inches or more than 24 inches apart." Changes the section number to address the separation of language in section B.3. that creates a new section B.4.	This change simply incorporates a numbering changes based on revisions to 955.B.3.
955.B.6	"6. The system design shall protect the drip emitters and system from the effects of siphoning or backflow through the emitters."	"~~6~~7. The system design shall protect the drip emitters and system from the effects of siphoning or backflow through the emitters." Changes the section number to address the separation of language in section B.3 that creates a new section B.4.	This change simply incorporates a numbering changes based on revisions to 955.B.3.
955.C.3	Establishes minimum landscape linear loading rate requirements for drip dispersal systems.	"~~3. Landscape linear loading rates shall be considered for sloping absorption areas. For sites where effluent flow is primarily horizontal, linear loading rates shall be less than four gallons per day per linear foot. For sites where the flow is primarily vertical, the linear loading rate shall be less than 10 gallons per day per linear foot.~~" Removes landscape linear loading rate requirements from the proposed regulation.	This change addresses two public comments requesting that this section be removed. Several solutions were evaluated by the DD TAC. Removing this section from the proposed regulation received the highest level of support. Drip dispersal systems are AOSS subject to the performance requirements contained in the Regulations for Alternative Onsite Sewage Systems (12VAC5-613, the AOSS Regulations). The AOSS Regulations already establish necessary requirements to assure that water mounding will not adversely affect the functioning of the soil treatment area or create ponding on the surface for all AOSS.
955.C.4	"4. Air/vacuum release valves shall be located at	"~~4~~3. Air/vacuum release valves shall be located at the high point of	This change simply incorporates a numbering

	the high point of the supply and return manifolds to each zone."	the supply and return manifolds to each zone." Changes the section number to address the removal of the section regarding landscape linear loading rates.	changes based on removal of 955.C.3.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Commenter	Comment	Agency response
Nan Gray	Why not say 20,000 pound crush strength for gravelless material instead of H-10 or H-20 loading?	The H-10 and H-20 standards provided in the proposed regulation are derived from International Association of Plumbing and Mechanical Officials (IAPMO) and American Association of State Highway and Transportation Officials (AASHTO) vehicle loading specifications. The CBEP TAC discussed these standards and determined that H-10 and H-20 standards are more appropriate than establishing a specific weight for crush strength.
Nan Gray	Why is the minimum absorption area sizing for gravelless material less than the minimum absorption area sizing for gravel trenches?	This issue was discussed in great detail during the CBEP TAC meetings, and the proposed minimum area sizing is the result of those discussions. Gravelless material has been approved for use in Virginia for more than 20 years; in some cases at an even greater reduction in area sizing than is provided in the proposed regulation. Section 448 of the Regulations directs VDH to include in the Regulations systems and components approved through policy.
Nan Gray	What is the justification for the proposed installation and cover depth requirements for drip dispersal?	The proposed requirements for installation and cover depth of drip systems dispersing septic tank effluent is based on existing requirements for all in-ground system dispersing septic tank effluent contained in section 594 of the Regulations. The cover requirement for drip systems dispersing secondary effluent is based on the minimum cover necessary to protect the drip tubing from damage and to prevent surfacing of effluent. The DD TAC recommended separating the requirements for septic tank effluent versus secondary effluent contained in section 955.B.3 to

		avoid confusion on the issue of cover and installation depth. This recommendation is reflected in the proposed regulation.
Tom Ashton	Section 955.B.6 is redundant and not necessary for drip dispersal as these elements are captured in other proposed sections dealing with air relief valves and prevention of gravity redistribution. Recommend section 955.B.6 be removed.	Section 955.B.6 was added to the proposed regulation to address concerns raised by a DD TAC member that the language in the emergency regulations was not sufficient to ensure that all drip system are designed to prevent drain back.
Tom Ashton	Language in 955.C.3 may be in conflict with section 12VAC5-613-80 of the Regulations for Alternative Onsite Sewage Systems. The proposed minimum landscape linear loading rates are based on above ground mound systems, not drip dispersal. Additional factors are involved in appropriately sizing a drip dispersal system. Section 955.C.3 should be removed.	The section regarding landscape linear loading rates has been removed from the proposed regulation. Drip dispersal systems are AOSS. In addition to the proposed regulation, all drip dispersal systems are subject to the performance requirements contained in the AOSS Regulations. The AOSS Regulations already establish necessary requirements to assure that water mounding will not adversely affect the functioning of the soil treatment area or create ponding on the surface for all AOSS.
Jeff Walker	Could VDH offer guidance on who is responsible for alteration of the pump design to reflect the change in area and/or number of trenches when gravelless material is substituted for gravel trenches?	To address this comment the CBEP TAC suggested modifying the proposed language in section 930.F.8 to state: "…the certifying licensed professional engineer or onsite soil evaluator shall ~~identify~~ document the substitution and related design changes on the inspection report…" The inclusion of "related design changes" assures that the designer must also approve and document any alterations to other system components (e.g. pump design) as a result of the substitution of gravelless material for gravel trenches.
Jeff Walker	VDH OSE designs do not clarify whether the selection of materials is made by a contractor, homeowner, or the designer. How does VDH intend to amend policy requiring design of onsite systems to conform with the engineering responsibilities of the licensed designer? Once a permit is issued, does the substitution of one generally approved product for another generally approved product require endorsement by the designer, and	Proposed section 930.F.8 states: "Gravelless material may be substituted for gravel in accordance with this chapter, provided that the certifying licensed professional engineer or onsite soil evaluator approves the substitution." This section places the decision to grant final approval of the gravelless material with the designer, regardless of whether the selection of material is made by the contractor, homeowner, or designer.

	how does the public know who is responsible for the change?	
Jeff Walker	How will VDH assure that a property owner has been advised of increased area loading rates, and risk of reduced system performance when gravelless material is installed at the minimum sizing in the proposed regulation?	Gravelless materials have been approved for use in Virginia for more than 20 years. The proposed regulation is based on those existing GMPs and comments from the CBEP TAC. Systems installed in accordance with the proposed regulation are not expected to reduce system performance.
Jeff Walker	When will VDH share information regarding gravelless system performance statistics and malfunction assessments?	Malfunction assessment data was shared at the November 23, 2015, CBEP TAC meeting. An overview of that data can be found at www.townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\\meeting\58\23698\Minutes_VDH_23698_v1.pdf .
Bob Marshall	Recommend a revision to section 880.B.6 to allow utilization of submersible turbine pumps. Section 880.B.6 is narrowly worded.	The recommended revision is outside the scope of this regulatory action. However, the CBEP TAC and the DD TAC felt this was a good comment that VDH should consider during periodic review of the Regulations.
Harold Mathews	Septic effluent tends to clog drip dispersal emitters and filters. Owners are reluctant to pay for the necessary service to keep system functioning properly. Recommend removing septic tank effluent drip dispersal as an option in the proposed regulation.	The inclusion of septic tank effluent drip dispersal was discussed in great detail during the DD TAC meetings. The primary concern raised deals with the proper maintenance of the drip dispersal system. Drip dispersal systems are subject to the AOSS Regulations, which require that all AOSS receive at least an annual inspection. Operation, maintenance, and inspection schedules for some AOSS may exceed this minimum requirement to ensure proper performance.
Harold Mathews	Recommend adding a requirement that all header lines must be a minimum of 8 inches above the drainfield trench bottom.	The recommended revision is outside the scope of this regulatory action. However, the CBEP TAC and the DD TAC felt this was a good comment that VDH should consider during periodic review of the Regulations.
Harold Mathews	Recommend adding a requirement that all control panel boxes must be mounted a minimum of 30 inches above the ground surface.	The recommended revision is outside the scope of this regulatory action. However, the CBEP TAC and the DD TAC felt this was a good comment that VDH should consider during periodic review of the Regulations.
Bob Mayer	Section 955.C.3, regarding landscape linear loading rates, should be removed. The section does not adequately cover the issue of linear loading, and may be misleading.	The section regarding landscape linear loading rates has been removed from the proposed regulation. Drip dispersal systems are AOSS. In addition to the proposed regulation, all drip dispersal systems are subject to the performance requirements contained in the AOSS Regulations. The AOSS Regulations already establish necessary requirements to assure that water mounding will not adversely affect the functioning of the soil

		treatment area or create ponding on the surface for all AOSS.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
30	N/A	States the Regulations are supplemental to rules for sewerage systems administered by the DEQ.	"~~This chapter is supplemental to the current Virginia Sewerage Regulations, or their successor, which were adopted jointly by the State Board of Health and the Department of Environmental Quality pursuant to § 62.1-44.19 of the Code of Virginia. This chapter addresses the handling and disposal of sewage not regulated by a Virginia Pollutant Discharge Elimination System (VPDES) Permit.~~ A. This chapter addresses the handling and disposal of those portions of sewage flows not regulated by a Virginia Pollutant Discharge Elimination System (VPDES) Permit or a Virginia Pollutant Abatement (VPA) Permit issued in accordance with 9VAC25-31 or 9VAC25-32, respectively. B. Reclamation and reuse of sewage may be subject to permitting by the Department of Environmental Quality under 9VAC25-740." Identifies other potentially applicable regulations and clarifies areas of responsibility between VDH and DEQ.
920	N/A	Establishes that distribution methods begin at the point of flow splitting (e.g. distribution box) and end at the point where effluent is dispersed to a gravel trench or sand.	"The term distribution methods refers to the piping, flow splitting devices, gravel, and other appurtenances beginning at the point of flow splitting and ending at the ~~soil-gravel or sand interface~~ application of effluent to the soil absorption area. Two basic method are considered: A. Gravity; and B. Pressure." The revision ensures the Regulations also address gravelless material and drip dispersal systems instead of only addressing gravel trench and sand

			systems.
N/A	930.F	N/A	"Gravelless material is a proprietary product specifically manufactured to disperse effluent within the absorption trench of an onsite sewage system without the use of gravel. Gravelless material may include chamber, bundled expanded polystyrene, and multi-pipe systems. The division shall maintain a list of all generally approved gravelless material. Gravelless material on the generally approved list may be used in accordance with Table 5.4 of 12VAC5-610-950." This proposed new section provides a definition of gravelless material and identifies that VDH will maintain a list of approved gravelless material.
N/A	930.F.1	N/A	"Gravelless material that received general approval as of December 12, 2013, shall retain such status when used in accordance with the requirements of this chapter. After December 12, 2013, the division shall review and evaluate new applications for general approval pursuant to the requirements of this chapter. a. Any manufacturer of gravelless material may submit an application for general approval to the division using a form provided by the division. A complete application shall include the manufacturer's contact information, product specifications, product approvals in other states or territories, installation manual, and other information deemed necessary by the division to determine compliance with this chapter. b. The manufacturer of gravelless material shall identify in the application for general approval any recommendation that deviates from the requirements of this chapter. If the recommendation is approved by the division, then the manufacturer shall include the deviation in the gravelless material's installation manual." This section allows gravelless material that received approval under previous GMPs to retain approval status. Additionally, this section provides a process for evaluating approval requests for new gravelless materials.
N/A	930.F.2.a	N/A	"Gravelless material shall have the following minimum characteristics for general approval:

			a. The minimum exterior width shall be at least 90 percent of the total width of the absorption trench. The exterior width of a chamber system shall be measured at the edge or outer limit of the product's contact with the trench bottom unless the division determines a different measurement is required based on the gravelless material's design. The exterior width of bundled expanded polystyrene and multi-pipe systems shall be measured using the outside diameter of the bundled gravelless material unless the division determines a different measurement is required based on the gravelless material's design. The division shall establish the exterior width of any gravelless material that is not considered a chamber, bundled expanded polystyrene, or multi-pipe system." This section creates a minimum exterior width for gravelless material as required by §32.1-164.9 of the Code of Virginia. The requirement is based on previous GMPs and discussion among the CBEP TAC.
N/A	930.F.2.b	N/A	"Gravelless material shall have a minimum height of eight inches to provide a continuous exchange of air through a permeable interface." This section creates a minimum height requirement for gravelless material as required by §32.1-164.9 of the Code of Virginia. The requirement is based on previous GMPs and discussion among the CBEP TAC.
N/A	930.F.2.c	N/A	"Gravelless material shall have a permeable interface that shall be located along the trench bottom and trench sidewalls within the absorption trench." This section creates a requirement for a permeable interface between gravelless material and the trench sidewall as required by §32.1-164.9 of the Code of Virginia.
N/A	930.F.2.d	N/A	"Gravelless material shall provide a minimum storage capacity of 1.3 gallons per square foot of trench bottom area." This section creates a minimum storage capacity requirement for gravelless material as required by § 32.1-164.9 of the Code of Virginia. The required

			storage capacity is equivalent to the storage capacity below the pipe in a gravel trench system. The requirement is based on previous GMPs and discussion among the CBEP TAC.
N/A	930.F.2.e	N/A	"Gravelless material shall pose no greater risk to surface water and groundwater quality than gravel in absorption trenches. Gravelless material shall be constructed to maintain structural integrity such that it does not decay or corrode when exposed to effluent." This section creates a minimum structural capacity requirement for gravelless material as required by § 32.1-164.9 of the Code of Virginia. The requirement assures that gravelless material will pose no greater risk to public health and the environment that materials using in gravel trenches.
N/A	930.F.2.f	N/A	"Gravelless material shall have a minimum load rating of H-10 or H-20 from the American Association of State Highway and Transportation Officials or equivalent when installed in accordance with the manufacturer's specifications and minimum specified depth of cover in non-traffic or traffic areas, respectively." This section creates a minimum structural capacity requirement for gravelless material as required by § 32.1-164.9 of the Code of Virginia. The H-10 and H-20 standards provided in the proposed regulation are derived from IAPMO and AASHTO vehicle loading specifications.
N/A	930.F.3	N/A	"For designs using gravelless material, the absorption trenches shall receive an equal volume of effluent per square foot of trench. Trench bottom area shall be equal to or greater than the minimum area requirements contained in Table 5.4 of 12VAC5-610-950. Trench sidewall shall not be included when determining minimum area requirements. When open-bottom gravelless material is utilized, it shall provide a splash plate at the inlet of the trench or other suitable method approved by the manufacturer to reduce effluent velocity." This section requires that effluent be dispersed evenly throughout a gravelless system and that the trench bottom be protected from erosion. These requirements are based on current requirements in the Regulations and comments from the CBEP TAC.

N/A	930.F.4	N/A	"Installation of gravelless material shall comply with this chapter and the approved installation manual unless the department grants a deviation pursuant to 12VAC5-610-660 or the division has granted a deviation identified in the installation manual." Requires gravelless material to be designed and installed in compliance the Regulations and the manufacturer's installation manual that has received approval from VDH. This section allows gravelless material installations to deviate from the Regulations if approved by the division as part of the product's general approval or if granted an exception pursuant to 12VAC5-610-660. This section implements § 32.1-164.9 of the Code of Virginia.
N/A	930.F.5	N/A	"Gravelless material shall contain a pressure percolation line along the entire length of the trench when low pressure distribution is utilized pursuant to 12VAC5-610-940 D." This section, along with 940.D, sets minimum requirements for low pressure distribution systems that use gravelless material to bed the pressure percolation lines. These minimums are based on requirements in previous GMPs and recommendations from the CBEP TAC. This section is also intended to meet requirements of § 32.1-164.9 of the Code of Virginia.
N/A	930.F.6	N/A	"6. When pumping effluent to overcome gravity, any open-bottom gravelless material shall provide a high-flow splash plate at the inlet of the trench or other suitable method approved by the manufacturer to reduce effluent velocity." Section 930(F)(6) and 930(F)(7) set minimum requirements for pump-to-gravity, open-bottom gravelless material. These requirements ensure that effluent velocity is reduced prior to entering the absorption. Dosing volume requirements are based on 12VAC5-610-890.C.
N/A	930.F.7	N/A	"7. When enhanced flow distribution is used, open-bottom gravelless material shall contain a percolation pipe that extends a minimum of 10 feet from the trench's intersection with the header line. The percolation pipe shall be installed in accordance with the manufacturer's approved installation manual. The dosing volume shall be a minimum 39 gallons per 100 linear feet of absorption trench."

			Section 930(F)(6) and 930(F)(7) set minimum requirements for pump-to-gravity, open-bottom gravelless material. These requirements ensure that effluent velocity is reduced prior to entering the absorption. Dosing volume requirements are based on 12VAC5-610-890.C.
N/A	930.F.8	N/A	"Gravelless material may be substituted for gravel in accordance with this chapter, provided that the certifying licensed professional engineer or onsite soil evaluator approves the substitution. The certifying licensed professional engineer or onsite soil evaluator shall document the substitution and related design changes on the inspection report submitted in accordance with 12VAC5-610-330. A new construction permit pursuant to 12VAC5-610-310 is not required for the substitution." This section sets criteria for the substitution of gravelless material in lieu of gravel when gravelless material is not specified as part of the system design. Substitution of gravelless material does not require a new permit and requires approval by the certifying PE or OSE. This section implements § 32.1-164.9 of the Code of Virginia.
940.C.7.c	N/A	This section sets the minimum separation between low pressure distribution lines and seasonal water table, but includes in inaccurate reference to the definition of "seasonal water table".	"However, under no circumstance shall the invert of the pressure percolation lines be placed closer than 16-1/2 inches to the seasonal water table as defined in ~~12VAC5-610-950-A-3~~ 12VAC5-610-470 D." This revision removes the inaccurate reference to the definition of "seasonal water table" contained in the Regulations.
N/A	940.D	N/A	"Gravelless material with general approval may be used for low pressure distribution in accordance with the manufacturer's approved installation manual, Table 5.4 of 12VAC5-610-950, and the applicable requirements of this chapter." This section, along with 930.F.5, sets minimum requirements for low pressure distribution systems that use gravelless material to bed the pressure percolation lines. This section implements § 32.1-164.9 of the Code of Virginia.
950.A	N/A	This section establishes that an absorption area starts at the beginning of a	"The absorption area is the undisturbed soil medium ~~beginning at the soil gravel or sand interface which is~~ utilized for absorption of the effluent. The absorption area includes the infiltrative

		gravel trench or sand fill.	surface in the absorption trench and the soil between and around the trenches <u>when trenches are used</u>." This revision ensures inclusion of gravelless material and drip dispersal as potential starting points for absorption areas.
950.D.2	N/A	This section references the area reductions allowed for low pressure distribution systems contained in the Table 5.4 sizing chart.	"Area reduction. See Table 5.4 for ~~percent~~ area reduction when <u>gravelless material or</u> low pressure distribution is utilized. A reduction in area shall not be permitted when flow diversion is utilized with low pressure distribution. <u>When gravelless material is utilized, the design width of the trench shall be used to calculate minimum area requirements for absorption trenches."</u> This section, along with Table 5.4, sets criteria for determining the minimum area requirements for gravelless material. The minimum area for gravelless material is reduced by 25% in class I, II, and III soils, and by 15% in class IV soils when compared to gravel trenches. The requirement is based on previous GMPs and discussion among the CBEP TAC.
Table 5.4	N/A	This section established the minimum sizing requirements for systems using gravel trenches or low pressure distribution.	Revisions to Table 5.4 include minimum sizing for gravelless material equivalent to a 25 percent reduction when compared to gravel and pipe sizing in texture group I, II, and III soils, and equivalent to a 15 percent reduction when compared to gravel and pipe sizing in texture group IV soils. This section, along with section 950.D.2, sets criteria for determining the minimum area requirements for gravelless material. The minimum area for gravelless material is reduced by 25% in class I, II, and III soils, and by 15% in class IV soils when compared to gravel trenches. The requirement is based on previous GMPs and discussion among the CBEP TAC.
N/A	955.A	N/A	"<u>Drip dispersal applies wastewater in an even and controlled manner over an absorption area. Drip dispersal system components may include treatment components, a flow equalization pump tank, a filtration system, a flow measurement method, supply and return piping, small diameter pipe with emitters, air/vacuum release valves, redistribution control, and electromechanical components or controls."</u> This section provides a definition of drip dispersal.

N/A	955.B	N/A	"Drip dispersal system tubing shall be color coded and certified by the manufacturer as designed and manufactured for the dispersal of wastewater. All drip dispersal system tubing shall be equipped with emitters approved for use with wastewater. For the application of septic tank effluent, the tubing must have self cleaning emitters." This section sets minimum physical construction criteria for drip dispersal tubing. The requirement is based on previous GMPs and discussion among the DD TAC.
N/A	955.B.1	N/A	"The minimum linear feet of tubing in the system shall be one-half of the minimum soil absorption area in square feet." This section sets minimum design criteria for the minimum linear feet of tubing in a drip dispersal system. The requirement is based on previous GMPs and discussion among the DD TAC.
N/A	955.B.2	N/A	"All tubing shall be placed on contour." This section requires that drip dispersal system be installed on contour, as is required for other systems contained in the Regulations. The requirement is based on discussion among the DD TAC.
N/A	955.B.3	N/A	"Except as provided by 12 VAC 5-613, drip systems dispersing septic tank effluent shall comply with the requirements of 12 VAC 5-610-594." This section clarifies that drip systems dispersing septic tank effluent must comply with the installation depth requirements contained in section 594 of the Regulations. The requirement is based on discussion among the DD TAC.
N/A	955.B.4	N/A	"Drip systems dispersing secondary effluent or better require a minimum of six inches of cover over the tubing. Cover may be achieved by a combination of installation depth and Group II or Group III soil cover or other approved material over the drip field." This section sets minimum cover requirements for drip systems dispersing secondary effluent. The requirement is based discussion among the DD TAC.
N/A	955.B.5	N/A	"The discharge rate of any two emitters shall not vary by more than 10 percent in order to ensure that the effluent is uniformly distributed over the entire

			drip field or zone." This section sets the minimum allowable variation for drip emitter discharge rates. The requirement is based on discussion among the DD TAC.
N/A	955.B.6	N/A	"The emitters shall be evenly spaced along the length of the drip tubing at not less than six inches or more than 24 inches apart." This section sets minimum drip emitter spacing requirements. The requirement is based on discussion among the DD TAC.
N/A	955.B.7	N/A	"The system design shall protect the drip emitters and system from the effects of siphoning, or backflow through the emitters." This section sets criteria to protect drip dispersal systems from drain back. The requirement is based on discussion among the DD TAC.
N/A	955.C.1	N/A	"For the dispersal of septic tank effluent, the minimum soil absorption area for a drip system shall be calculated by multiplying the trench bottom area required for a low pressure distribution system in Table 5.4 of this chapter, by three." This section sets minimum sizing criteria for drip systems dispersing septic tank effluent. The requirement is based on previous GMPs and discussion among the DD TAC.
N/A	955.C.2	N/A	"For the dispersal of secondary or better effluent, the minimum soil absorption area shall be calculated by multiplying the trench bottom area for pressure distribution systems in accordance with 12VAC5-613-80.10 by three." This section sets minimum sizing criteria for drip systems dispersing secondary effluent. The requirement is based on previous GMPs and discussion among the DD TAC.
N/A	955.C.3	N/A	"Air/vacuum release valves shall be located at the high points of the supply and return manifolds to each zone." This section sets minimum criteria for the location of air/vacuum release valves. The requirement is based on previous GMPs and discussion among the DD TAC.
N/A	955.D	N/A	"All drip dispersal systems shall be equipped with devices or methods to restrict effluent from draining

			by gravity to portions of a zone or laterals lower in elevation. Variable distribution due to gravity drainage shall be 10 percent or less within a zone." This section set criteria to prevent gravity drainage of effluent with a drip dispersal system. The requirement is based on previous GMPs and discussion among the DD TAC.
N/A	955.E	N/A	"A minimum of six hours of emergency storage above the high water alarm in the pump chamber shall be provided. The equalization volume shall be equal to 18 hours of storage. The equalization volume shall be measured from the pump off level to the high water alarm level. An audio/visual alarm meeting the requirements of 12VAC5-610-880.B.8 shall be provided for the pump chamber." This section sets minimum criteria pump design criteria for drip dispersal, including flow equalization, emergency storage, and audio/visual alarm requirements. The requirement is based on previous GMPs and discussion among the DD TAC.
N/A	955.F	N/A	"Each drip dispersal zone shall be time-dosed over a 24 hour period. The dose volume and interval shall be set to provide unsaturated flow conditions. Demand dosing is prohibited. Minimum dose volume per zone shall be 3.5 times the liquid capacity of the drip laterals in the zone plus the liquid capacity of the supply and return manifold lines (which drain between doses) accounting for instantaneous loading and drain back." This section requires that all drip systems be dosed in a manner to provide unsaturated flow conditions. The requirement is based on previous GMPs and discussion among the DD TAC.
N/A	955.F.1	N/A	"At each dosing cycle, the system design shall only allow a full dose volume to be delivered." This section assures that time dosing will be overridden when there is not a sufficient volume of effluent to provide for a full dose volume to the dispersal area. The requirement is based on previous GMPs and discussion among the DD TAC.
N/A	955.F.2	N/A	"For design flows greater than 1,000 gallons per day, a means to take each zone off line separately shall be provided. The system shall have the capability to bypass each zone that is taken out of

			service such that each subsequent dose is dispersed to the next available zone in sequence." This section establishes bypass requirements that will allow for continued operation of large AOSS while maintenance is being performed. The requirement is based on discussion among the DD TAC
N/A	955.G	N/A	"Filtration shall be provided to remove suspended solids and prevent clogging of emitters. The filtration design shall meet the drip tubing manufacturer's particle size requirements for protection of the emitters at a flow rate equal to or greater than the rate of forward flushing. Filter flush water shall be returned to the treatment system at a point where the residuals and volume of the flush water do not negatively impact the effluent quality or exceed the hydraulic design capacity of the treatment system." This section establishes the necessary filtration and flush requirements to prevent clogging of drip emitters. The requirement is based on discussion among the DD TAC
N/A	955.H	N/A	"A means for measuring or estimating total flow dispersed to the soil absorption area and to verify field dosing and field flushing rates shall be provided." This section ensures that total flow, field dosing, and field flushing rates can be measured. The requirement is based on discussion among the DD TAC
N/A	955.I	N/A	"The system shall provide forward field flushing to achieve scouring velocity as specified by the drip tubing manufacturer. Field flushing shall occur on a routine schedule to prevent excessive solids accumulation and clogging. Flush water shall be returned to the treatment system at a point where the residuals and volume of the flush water do not negatively impact the effluent quality or exceed the hydraulic design capacity of the treatment system." This section sets the minimum field flushing criteria for drip dispersal necessary to prevent the accumulation of solids within the system. The requirement is based on discussion among the DD TAC.

N/A	955.J	N/A	"Electrical components shall be Underwriters Laboratory (UL) listed for the intended purpose. The designer shall provide a description with a schematic diagram of the electrical and control functions in the operation and maintenance manual. The electrical control equipment shall be mounted within a National Electrical Manufacturers Association (NEMA) 4X rated enclosure with a rigid latching door. All switches shall be clearly identified and all internal wiring shall be factory installed. All wiring shall be installed according to applicable electrical safety codes and the manufacturer's installation schematic." This section sets minimum design criteria for drip dispersal system control equipment. The requirement is based on discussion among the DD TAC.
N/A	955.K	N/A	"All components in a drip dispersal system shall be rated to withstand contact with wastewater and recommended for this application by the manufacturer. All components shall be protected from freezing." This section requires all drip dispersal components to be designed in a manner to withstand contact with wastewater and be protected from freezing. The requirement is based on discussion among the DD TAC.
N/A	955.L	N/A	"The startup inspection conducted by the designer of the drip dispersal system shall verify the dosing rates, the flushing rates, and other parameters critical to the proper operation of the system. A summary of the startup inspection shall be included in the operation and maintenance manual and shall include, at a minimum, the dosing volume; the forward flow flushing rate; the pressure head of the system; and verification of proper cycling between zones." This section establishes the minimum parameters that must be checked by the system designer during the startup inspection to assure that the system functions properly. The requirement is based on discussion among the DD TAC.

Project 3665 - Proposed

DEPARTMENT OF HEALTH

Amend Regulations to establish requirements for gravelless material and drip dispersal

12VAC5-610-30. Relationship to ~~Virginia Joint Sewerage Regulations~~ other regulations.

~~This chapter is supplemental to the current Virginia Sewerage Regulations, or their successor, which were adopted jointly by the State Board of Health and the Department of Environmental Quality pursuant to § 62.1-44.19 of the Code of Virginia. This chapter addresses the handling and disposal of sewage not regulated by a Virginia Pollutant Discharge Elimination System (VPDES) Permit.~~

A. This chapter addresses the handling and disposal of those portions of sewage flows not regulated by a Virginia Pollutant Discharge Elimination System (VPDES) Permit or a Virginia Pollutant Abatement (VPA) Permit issued in accordance with 9VAC25-31 or 9VAC25-32, respectively.

B. Reclamation and reuse of sewage may be subject to permitting by the Department of Environmental Quality under 9VAC25-740.

12VAC5-610-920. Distribution methods.

The term distribution methods refers to the piping, flow splitting devices, gravel, and other appurtenances beginning at the point of flow splitting and ending at the ~~soil-gravel or sand interface~~ application of effluent to the soil absorption area. Two basic methods are considered:

A. Gravity; and

B. Pressure.

12VAC5-610-930. Gravity distribution.

Gravity distribution is the conveyance of effluent from a distribution box through the percolation lines at less than full flow conditions. Flow to the initial distribution box may be initiated by pump, siphon or gravity.

A. Enhanced flow distribution. Enhanced flow distribution is the initiation of the effluent flow to the distribution box by pump or siphon for the purpose of assuring more uniform flow splitting to the percolation lines. Enhanced flow distribution shall be provided on systems where the flow is split more than 12 times or the system contains more than 1200 linear feet of percolation lines. For the purpose of this chapter, enhanced flow distribution is considered to produce unsaturated soil conditions.

B. System size. Distribution systems containing 1800 or more linear feet of percolation piping shall be split into multiple systems containing a maximum of 1200 linear feet of percolation piping per system.

C. Distribution boxes. The distribution box is a device for splitting flow equally by gravity to points in the system. Improperly installed distribution boxes are a cause for absorption field malfunction.

1. Materials. The preferred material for use in constructing distribution boxes is concrete (3000 psi). Other materials may be considered on a case-by-case basis. All materials must be resistant to both chemical and electrolytic corrosion and must have sufficient structural strength to contain sewage and resist lateral compressive and bearing loads.

2. Design. Each distribution box shall be designed to split the influent flow equally among the multiple effluent ports. All effluent ports shall be at the same elevation and be of the same diameter. The elevation of the effluent ports shall be at a lower elevation than the influent port. The placement of the influent ports shall be such as to prevent

short circuiting unless baffling is provided to prevent short circuiting. The minimum inside width of a gravity flow distribution box shall be equal to or greater than 12 inches. The inside bottom shall be at least four inches below the invert of the effluent ports and at least five inches below the invert of the influent port. A minimum of eight inches freeboard above the invert of the effluent piping shall be provided. The distribution box shall be fitted with a watertight, removable lid for access.

3. Installation. The hole for placement of the distribution box shall be excavated to undisturbed soil. The distribution box shall be placed in the excavation and stabilized. The preferred method of stabilizing the distribution box is to bond the distribution box to a four inch poured in place Portland cement concrete pad with dimensions six inches greater than the length and width dimensions of the distribution box. The box shall be permanently leveled and checked by water testing. Conduits passing through the walls of a distribution box shall be provided with a water stop.

D. Lead or header lines. Header or lead lines are watertight, semirigid or rigid lines that convey effluent from a distribution box to another box or to the percolation piping.

1. Size. The lead or header lines shall have an internal diameter of four inches.

2. Slope. Minimum slope shall be two inches per 100 feet.

3. Materials. The lead or header lines shall have a minimum crush strength of 1500 pounds per foot and may be constructed of cast iron, plastic, vitrified clay or other material resistant to the corrosive action of sewage.

4. Appurtenances.

a. Joints. Lead or header lines shall have joints of the compressions type with the exception of plastic lead or header lines which may be welded sleeve, chemically fused or clamped (noncorrosive) flexible sleeve.

b. Adapters. Joining of lead or header lines of different size and/or material shall be accomplished by use of a manufactured adapter specifically designed for the purpose.

c. Valves. Valves shall be constructed of materials resistant to the corrosive action of sewage. Valves placed below ground level shall be provided with a valve box and a suitable valve stem so that it may be operated from the ground surface.

5. Construction.

a. Bedding. All lead or header lines shall be bedded to supply uniform support and maintain grade and alignment along the length of the lead or header lines. Special care shall be taken when using semirigid pipe.

b. Backfilling and tamping. Lead and header lines shall be backfilled and tamped as soon as possible after the installation of the lead or header lines has been approved. Material for backfilling shall be free of large stones and debris.

6. Termination. Header or lead lines shall extend for a minimum distance of two feet into the absorption trenches.

E. Gravity percolation lines. Gravity percolation lines are perforated or open joint pipes that are utilized to distribute the effluent along the length of the absorption trenches.

1. Size. All gravity percolation lines shall have an internal diameter of four inches.

2. Slope. The slope of the lines shall be uniform and shall not be less than two inches or more than four inches per 100 feet.

3. Design. Effluent shall be split by the distribution system so that all gravity percolation lines installed shall receive an equal volume of the total design effluent load per square foot of trench, i.e., the fraction of the flow received by each percolation line divided by

the length of the gravity percolation lines shall be equal for all gravity percolation lines in a system.

4. Length. No individual gravity percolation line shall exceed 100 feet in length.

5. Materials.

a. Clay. Clay tile shall be extra-strength and meet current ASTM standards for clay tile.

b. Perforated plastic drainage tubing. Perforated plastic drainage tubing shall meet ASTM standards. At not greater than 10 feet intervals the pipe shall be plainly marked, embossed or engraved thereby showing the manufacturer's name or hallmark and showing that the product meets a bearing load of 1,000 lb. per foot. In addition, a painted or other clearly marked line or spot shall be marked at not greater than 10 feet intervals to denote the top of the pipe.

The tubing shall have three holes, 1/2 to 3/4 inch in diameter evenly spaced and placed within an arc of 130 degrees, the center hole being directly opposite the top marking.

Spacing of each set of three holes shall be at four inch intervals along the tube. If there is any break in the continuity of the tubing, an appropriate connection shall be used to join the tubing.

6. Installation

a. Crushed stone or gravel. Clean gravel or crushed stone having a size range from 1/2 inch to 1-1/2 inches shall be utilized to bed the gravity percolation lines.

Minimum depth of gravel or crushed stone beneath the percolation lines shall be six inches. Clean course silica sand (does not effervesce in presence of dilute hydrochloric acid) may be substituted for the first two inches (soil interface) of the ~~require~~ required six inches of gravel beneath the percolation lines. The absorption trench shall be backfilled to a depth of two inches over the gravity percolation lines with the same gravel or crushed stone. Clean sand, gravel or crushed stone shall be free of fines, clay and organic materials.

b. Grade boards and/or stakes. Grade boards and/or stakes placed in the bottom or sidewalls of the absorption trench shall be utilized to maintain the grade on the gravel for placement of the gravity percolation lines. Grade stakes shall not be placed on centers greater than 10 feet.

c. Placement and alignment. Perforated gravity percolation piping shall be placed so that the center hole is in the horizontal plane and interfaces with the minimum six inches of graded gravel. When open joint piping is utilized the upper half of the top of the 1/4-inch open space shall be covered with tar paper or building paper to block the entrance of fines into the pipe during the backfilling operation. All gravity percolating piping shall be placed in the horizontal center of the absorption trench and shall maintain a straight alignment and uniform grade.

d. Backfilling. After the placement of the gravity percolation piping the absorption trench shall be backfilled evenly with crushed stone or gravel to a depth of two inches over the piping. Untreated building paper~~,~~ or other suitable material shall be placed at the interface of the gravel and soil to prevent migration of fines to the trench bottom. The remainder of the trench shall be backfilled with soil to the ground surface.

F. Gravelless material is a proprietary product specifically manufactured to disperse effluent within the absorption trench of an onsite sewage system without the use of gravel. Gravelless material may include chamber, bundled expanded polystyrene, and multi-pipe systems. The

division shall maintain a list of all generally approved gravelless material. Gravelless material on the generally approved list may be used in accordance with Table 5.4 of 12VAC5-610-950.

1. Gravelless material that received general approval as of December 12, 2013, shall retain such status when used in accordance with the requirements of this chapter. After December 12, 2013, the division shall review and evaluate new applications for general approval pursuant to the requirements of this chapter.

a. Any manufacturer of gravelless material may submit an application for general approval to the division using a form provided by the division. A complete application shall include the manufacturer's contact information, product specifications, product approvals in other states or territories, installation manual, and other information deemed necessary by the division to determine compliance with this chapter.

b. The manufacturer of gravelless material shall identify in the application for general approval any recommendation that deviates from the requirements of this chapter. If the recommendation is approved by the division, then the manufacturer shall include the deviation in the gravelless material's installation manual.

2. Gravelless material shall have the following minimum characteristics for general approval:

a. The minimum exterior width shall be at least 90% of the total width of the absorption trench. The exterior width of a chamber system shall be measured at the edge or outer limit of the product's contact with the trench bottom unless the division determines a different measurement is required based on the gravelless material's design. The exterior width of bundled expanded polystyrene and multi-pipe systems shall be measured using the outside diameter of the bundled gravelless material unless the division determines a different measurement is required based on the gravelless material's design. The division shall establish the exterior width of any gravelless material that is not considered a chamber, bundled expanded polystyrene, or multi-pipe system.

b. Gravelless material shall have a minimum height of eight inches to provide a continuous exchange of air through a permeable interface.

c. Gravelless material shall have a permeable interface that shall be located along the trench bottom and trench sidewalls within the absorption trench.

d. Gravelless material shall provide a minimum storage capacity of 1.3 gallons per square foot of trench bottom area.

e. Gravelless material shall pose no greater risk to surface water and groundwater quality than gravel in absorption trenches. Gravelless material shall be constructed to maintain structural integrity such that it does not decay or corrode when exposed to effluent.

f. Gravelless material shall have a minimum load rating of H-10 or H-20 from the American Association of State Highway and Transportation Officials or equivalent when installed in accordance with the manufacturer's specifications and minimum specified depth of cover in non-traffic or traffic areas, respectively.

3. For designs using gravelless material, the absorption trenches shall receive an equal volume of effluent per square foot of trench. Trench bottom area shall be equal to or greater than the minimum area requirements contained in Table 5.4 of 12VAC5-610-950. Trench sidewall shall not be included when determining minimum area requirements. When open-bottom gravelless material is utilized, it shall provide a splash plate at the inlet of the trench or other suitable method approved by the manufacturer to reduce effluent velocity.

4. Installation of gravelless material shall comply with this chapter [and the approved installation manual] unless the department grants a deviation pursuant to 12VAC5-610-660 or the division has granted a deviation identified in the installation manual.

5. Gravelless material shall contain a pressure percolation line along the entire length of the trench when low pressure distribution is utilized pursuant to 12VAC5-610-940 D.

6. When pumping effluent to overcome gravity, any open-bottom gravelless material shall provide a high-flow splash plate at the inlet of the trench or other suitable method approved by the manufacturer to reduce effluent velocity.

7. When enhanced flow distribution is used, open-bottom gravelless material shall contain a percolation pipe that extends a minimum of 10 feet from the trench's intersection with the header line. The percolation pipe shall be installed in accordance with the manufacturer's approved installation manual. The dosing volume shall be a minimum 39 gallons per 100 linear feet of absorption trench.

8. Gravelless material may be substituted for gravel in accordance with this chapter, provided that the certifying licensed professional engineer or onsite soil evaluator approves the substitution. The certifying licensed professional engineer or onsite soil evaluator shall [~~identify~~ document] the substitution [and related design changes] on the inspection report submitted in accordance with 12VAC5-610-330. A new construction permit pursuant to 12VAC5-610-310 is not required for the substitution.

12VAC5-610-940. Low pressure distribution.

Low pressure distribution is the conveyance of effluent through the pressure percolation lines at full flow conditions into the absorption area with the prime motive force being a pump or siphon. Low pressure systems are limited to a working pressure of from one to four feet of head at the distal end of the pressure percolation lines. For the purpose of this chapter low pressure distribution is considered to provide unsaturated soil conditions.

A. Dosing cycle. Systems shall be designed so that the effluent volume applied to the absorption area per dosing cycle is from seven to 10 times the volume of the distribution piping, however, the volume per dosing cycle should not result in a liquid depth in the absorption trench greater than two inches.

B. Manifold lines. Manifold lines are watertight lines that convey effluent from the initial point of flow splitting to the pressure percolation lines.

1. Size. The manifold line shall be sized to provide a minimum velocity of two feet per second and a maximum velocity of eight feet per second.

2. Materials. All pipe used for manifolds shall be of the pressure type with pressure type joints.

3. Bedding. All manifolds shall be bedded to supply uniform support along its length.

4. Backfilling and tamping. Manifold trenches shall be backfilled and tamped as soon as possible after the installation of the manifold has been approved. Material for backfilling shall be free of large stones and debris.

5. Valves. Valves for throttling and check valves to prevent backflow are required wherever necessary. Each valve shall be supplied with a valve box terminating at the surface.

C. Pressure percolation lines. Pressure percolation lines are perforated pipes utilized to distribute the flow evenly along the length of the absorption trench.

1. Size. Pressure percolation lines should normally have a 1-1/4 inch inside diameter.

2. Hole size. Normal hole size shall be 3/16 inch to 1/4 inch.

3. Hole placement. Center to center hole separation shall be between three and five feet.

4. Line length. Maximum line length from manifold should not exceed 50 feet.

5. Percent flow variation. Actual line size, hole size and hole separation shall be determined on a case-by-case basis based on a maximum flow variation of 10% along the length of the pressure percolation lines.

6. Materials and construction. The preferred material is plastic, either PVC or ABS, designed for pressure service. The lines shall have burr free and counter sunk holes (where possible) placed in a straight line along the longitudinal axis of the pipe. Joining of pipes shall be accomplished with manufactured pressure type joints.

7. Installation.

a. Crushed stone or gravel. Clean gravel or crushed stone having a size range from 1/2 inch to 3/4 inch shall be utilized to bed the pressure percolation lines. Minimum depth of gravel or crushed stone beneath the percolation lines shall be 8-1/2 inches. Clean course silica sand (does not effervesce in the presence of dilute hydrochloric acid) may be substituted for the first two inches (soil interface) of the required 8-1/2 inches of gravel beneath the pressure percolation lines. The absorption trench shall be backfilled to a depth of two inches over the pressure percolation lines with the same gravel or crushed stone. Clean sand, gravel or crushed stone shall be free of fines, clay and organic materials.

b. Grade boards and/or stakes. Grade boards and/or stakes placed in the bottom or sidewalls of the absorption trench shall be utilized to maintain the gravel level for placement of the pressure percolation lines. Grade stakes shall not be placed on centers greater than 10 feet.

c. Placement and alignment. Pressure percolation lines shall be placed so that the holes face vertically downward. All pressure percolation piping shall be placed at the same elevation, unless throttling valves are utilized, and shall be level. The piping shall be placed in the horizontal center of the trench and shall maintain a straight alignment. Normally the invert of the pressure percolation lines shall be placed 8-1/2 inches above the trench bottom. However, under no circumstance shall the invert of the pressure percolation lines be placed closer than 16-1/2 inches to the seasonal water table as defined in ~~12VAC5-610-950 A 3~~ 12VAC5-610-470 D. When the invert of the pressure percolation lines must be placed at an elevation greater than 8-1/2 inches above the trench bottom, landscaping over the absorption area may be required to provide the two inches of gravel and six inches of fill over the pressure percolation lines required in subdivision 7 a of this subsection.

d. Backfilling. After the placement of the pressure percolation piping the absorption trench shall be backfilled evenly with crushed stone or gravel to a depth of two inches over the opening. Untreated building paper or other suitable material shall be placed at the interface of the gravel and soil to prevent migration of fines to the trench bottom. The remainder of the trench shall be backfilled with soil to the ground surface.

8. Appurtenances. The distal (terminal) end of each pressure percolation lines shall be fitted with a vertical riser and threaded cap extending to the ground surface. Systems requiring throttling valves will be supplied with couplings and threaded riser extensions at least four feet long so that the flow may be adjusted in each line.

D. Gravelless material with general approval may be used for low pressure distribution in accordance with the manufacturer's approved installation manual, Table 5.4 of 12VAC5-610-950, and the applicable requirements of this chapter.

12VAC5-610-950. Absorption area design.

A. The absorption area is the undisturbed soil medium ~~beginning at the soil-gravel or sand interface which is~~ utilized for absorption of the effluent. The absorption area includes the infiltrative surface in the absorption trench and the soil between and around the trenches when trenches are used.

B. Suitability of soil horizon. The absorption trench bottom shall be placed in the soil horizon or horizons with an average estimated or measured percolation rate less than 120 minutes per inch. Soil horizons are to be identified in accordance with 12VAC5-610-480. The soil horizon must meet the following minimum conditions:

1. It shall have an estimated or measured percolation rate equal to or less than 120 minutes per inch.

2. The soil horizon or horizons shall be of sufficient thickness so that at least 12 inches of absorption trench sidewall is exposed to act as an infiltrative surface; and

3. If no single horizon meets the conditions in subdivision 2 of this subsection, a combination of adjacent horizons may be utilized to provide the required 12-inch sidewall infiltrative surface. However, no horizon utilized shall have an estimated or measured percolation rate greater than 120 minutes/inch.

C. Placement of absorption trenches below soil restrictions. Placement of the soil absorption trench bottom below soil restrictions as defined in 12VAC5-610-490 D, whether or not there is evidence of a perched water table as indicated by free standing water or gray mottlings or coloration, requires a special design based on the following criteria:

1. The soil horizon into which the absorption trench bottom is placed shall be a Texture Group I, II or III soil or have an estimated or measured percolation rate of less than 91 minutes per inch.

2. The soil horizon shall be a minimum of three feet thick and shall exhibit no characteristics that indicate wetness on restriction of water movement. The absorption trench bottom shall be placed so that at least two feet of the soil horizon separates the trench bottom from the water table and/or rock. At least one foot of the absorption trench side wall shall penetrate the soil horizon.

3. A lateral ground water movement interceptor (LGMI) shall be placed upslope of the absorption area. The LGMI shall be placed perpendicular to the general slope of the land. The invert of the LGMI shall extend into, but not through, the restriction and shall extend for a distance of 10 feet on either side of the absorption area (See 12VAC5-610-700 D 3).

4. Pits shall be constructed to facilitate soil evaluations as necessary.

D. Sizing of absorption trench area.

1. Required area. The total absorption trench bottom area required shall be based on the average estimated or measured percolation rate for the soil horizon or horizons into which the absorption trench is to be placed. If more than one soil horizon is utilized to meet the sidewall infiltrative surface required in subsection B of this section, the absorption trench bottom area shall be based on the average estimated or measured percolation rate of the "slowest" horizon. The trench bottom area required in square feet per 100 gallons (Ft^2/100 Gals) of sewage applied for various soil percolation rates is tabulated in Table 5.4. The area requirements are based on the equation:

$$\log y = 2.00 + 0.008 (x)$$

where $y = Ft^2$/100 Gals

x = Percolation rate in minutes/inch

Notwithstanding the above, the minimum absorption area for single family residential dwellings shall be 400 square feet.

2. Area reduction. See Table 5.4 for ~~percent~~ area reduction when gravelless material or low pressure distribution is utilized. A reduction in area shall not be permitted when flow diversion is utilized with low pressure distribution. When gravelless material is utilized, the design width of the trench shall be used to calculate minimum area requirements for absorption trenches.

E. Minimum cross section dimensions for absorption trenches.

1. Depth. The minimum trench sidewall depth as measured from the surface of the mineral soil shall be 12 inches when placed in a landscape with a slope less than 10%. The installation depth shall be measured on the downhill side of the absorption trench. When the installation depth is less than 18 inches, the depth shall be measured from the lowest elevation in the microtopography. All systems shall be provided with at least 12 inches of cover to prevent frost penetration and provide physical protection to the absorption trench; however, this requirement for additional cover shall not apply to systems installed on slopes of 30% or greater. Where additional soil cover must be provided to meet this minimum, it must be added prior to construction of the absorption field, and it must be crowned to provide positive drainage away from the absorption field. The minimum trench depth shall be increased by at least five inches for every 10% increase in slope. Sidewall depth is measured from the ground surface on the downhill side of the trench.

2. Width. All absorption trenches utilized with gravity distribution shall have a width of from 18 inches to 36 inches. All absorption trenches utilized with low pressure distribution shall have a width of eight inches to 24 inches.

F. Lateral separation of absorption trenches. The absorption trenches shall be separated by a center to center distance no less than three times the width of the trench for slopes up to 10%. However, where trench bottoms are two feet or more above rock, pans and impervious strata, the absorption trenches shall be separated by a center to center distance no less than three times the width of the trench for slopes up to 20%. The minimum horizontal separation distance shall be increased by one foot for every 10% increase in slope. In no case shall the center to center distance be less than 30 inches.

G. Slope of absorption trench bottoms.

1. Gravity distribution. The bottom of each absorption trench shall have a uniform slope not less than two inches or more than four inches per 100 feet.

2. Low pressure distribution. The bottom of each absorption trench shall be uniformly level to prevent ponding of effluent.

H. Placement of absorption trenches in the landscape.

1. The absorption trenches shall be placed on contour.

2. When the ground surface in the area over the absorption trenches is at a higher elevation than any plumbing fixture or fixtures, sewage from the plumbing fixture or fixtures shall be pumped.

I. Lateral ground water movement interceptors. Where subsurface, laterally moving water is expected to adversely affect an absorption system, a lateral ground water movement interceptor (LGMI) shall be placed upslope of the absorption area. The LGMI shall be placed perpendicular to the general slope of the land. The invert of the LGMI shall extend into, but not through, the restriction and shall extend for a distance of 10 feet on either side of the absorption area.

Table 5.4.
Area Requirements for Absorption Trenches.

Percolation Rate (Minutes/Inch)	Area Required (Ft^2/100 Gals)			Area Required (Ft^2/Bedroom)		
	Gravity	Gravity Gravelless	Low Pressure Distribution	Gravity	Gravity Gravelless	Low Pressure Distribution
5	110	83	110	165	124	165
10	120	90	120	180	135	180
15	132	99	132	198	149	198
20	146	110	146	218	164	218
25	158	119	158	237	178	237
30	174	131	164	260	195	255
35	191	143	170	286	215	260
40	209	157	176	314	236	264
45	229	172	185	344	258	279
50	251	188	193	376	282	293
55	275	206	206	412	309	309
60	302	227	217	452	339	325
65	331	248	228	496	372	342
70	363	272	240	544	408	359
75	398	299	251	596	447	375
80	437	328	262	656	492	394
85	479	359	273	718	539	409
90	525	394	284	786	590	424
95	575	489	288	862	733	431
100	631	536	316	946	804	473
105	692	588	346	1038	882	519
110	759	645	379	1138	967	569
115	832	707	416	1248	1061	624
120	912	775	456	1368	1163	684

J. Controlled blasting. When rock or rock outcroppings are encountered during construction of absorption trenches the rock may be removed by blasting in a sequential manner from the top to remove the rock. Percolation piping and sewer lines shall be placed so that at least one foot

of compacted clay soil lies beneath and on each side of the pipe where the pipe passes through the area blasted. The area blasted shall not be considered as part of the required absorption area.

12VAC5-610-955. Drip dispersal.

A. Drip dispersal applies wastewater in an even and controlled manner over an absorption area. Drip dispersal system components may include treatment components, a flow equalization pump tank, a filtration system, a flow measurement method, supply and return piping, small diameter pipe with emitters, air/vacuum release valves, redistribution control, and electromechanical components or controls.

B. Drip dispersal system tubing shall be color coded and certified by the manufacturer as designed and manufactured for the dispersal of wastewater. All drip dispersal system tubing shall be equipped with emitters approved for use with wastewater. For the application of septic tank effluent, the tubing must have self-cleaning emitters.

1. The minimum linear feet of tubing in the system shall be one-half of the minimum soil absorption area in square feet.

2. All tubing shall be placed on contour.

3. Except as provided by 12VAC5-613, drip systems dispersing septic tank effluent shall comply with the requirements of 12VAC5-610-594.

[4.] Drip systems dispersing secondary effluent or better require a minimum of six inches of cover over the tubing. Cover may be achieved by a combination of installation depth and Group II or Group III soil cover or other approved material over the drip field.

[~~4~~ 5] . The discharge rate of any two emitters shall not vary by more than 10% in order to ensure that the effluent is uniformly distributed over the entire drip field or zone.

[~~5~~ 6] . The emitters shall be evenly spaced along the length of the drip tubing at not less than six inches or more than 24 inches apart.

[~~6~~ 7] . The system design shall protect the drip emitters and system from the effects of siphoning or backflow through the emitters.

C. Drip dispersal systems shall comply with the following minimum soil absorption area requirements:

1. For the dispersal of septic tank effluent, the minimum soil absorption area for a drip system shall be calculated by multiplying the trench bottom area required for a low pressure distribution system in Table 5.4 of 12VAC5-610-950 by three.

2. For the dispersal of secondary or better effluent, the minimum soil absorption area shall be calculated by multiplying the trench bottom area for pressure distribution systems in accordance with subdivision 10 of 12VAC5-613-80 by three.

[~~3. Landscape linear loading rates shall be considered for sloping absorption areas. For sites where effluent flow is primarily horizontal, linear loading rates shall be less than four gallons per day per linear foot. For sites where the flow is primarily vertical, the linear loading rates shall be less than 10 gallons per day per linear foot.~~]

[~~4~~ 3] . Air/vacuum release valves shall be located at the high points of the supply and return manifolds to each zone.

D. All drip dispersal systems shall be equipped with devices or methods to restrict effluent from draining by gravity to portions of a zone or laterals lower in elevation. Variable distribution due to gravity drainage shall be 10% or less within a zone.

E. A minimum of six hours of emergency storage above the high water alarm in the pump chamber shall be provided. The equalization volume shall be equal to 18 hours of storage. The equalization volume shall be measured from the pump off level to the high water alarm level. An

audio/visual alarm meeting the requirements of 12VAC5-610-880 B 8 shall be provided for the pump chamber.

F. Each drip dispersal zone shall be time-dosed over a 24-hour period. The dose volume and interval shall be set to provide unsaturated flow conditions. Demand dosing is prohibited. Minimum dose volume per zone shall be 3.5 times the liquid capacity of the drip laterals in the zone plus the liquid capacity of the supply and return manifold lines (which drain between doses) accounting for instantaneous loading and drain back.

1. At each dosing cycle, the system design shall only allow a full dose volume to be delivered.

2. For design flows greater than 1,000 gallons per day, a means to take each zone off line separately shall be provided. The system shall have the capability to bypass each zone that is taken out of service such that each subsequent dose is dispersed to the next available zone in sequence.

G. Filtration shall be provided to remove suspended solids and prevent clogging of emitters. The filtration design shall meet the drip tubing manufacturer's particle size requirements for protection of the emitters at a flow rate equal to or greater than the rate of forward flushing. Filter flush water shall be returned to the treatment system at a point where the residuals and volume of the flush water do not negatively impact the effluent quality or exceed the hydraulic design capacity of the treatment system.

H. A means for measuring or estimating total flow dispersed to the soil absorption area and to verify field dosing and field flushing rates shall be provided.

I. The system shall provide forward field flushing to achieve scouring velocity as specified by the drip tubing manufacturer. Field flushing shall occur on a routine schedule to prevent excessive solids accumulation and clogging. Flush water shall be returned to the treatment system at a point where the residuals and volume of the flush water do not negatively impact the effluent quality or exceed the hydraulic design capacity of the treatment system.

J. Electrical components shall be Underwriters Laboratory (UL) listed for the intended purpose. The designer shall provide a description with a schematic diagram of the electrical and control functions in the operation and maintenance manual. The electrical control equipment shall be mounted within a National Electrical Manufacturers Association (NEMA) 4X rated enclosure with a rigid latching door. All switches shall be clearly identified, and all internal wiring shall be factory installed. All wiring shall be installed according to applicable electrical safety codes and the manufacturer's installation schematic.

K. All components in a drip dispersal system shall be rated to withstand contact with wastewater and recommended for this application by the manufacturer. All components shall be protected from freezing.

L. The designer of the drip dispersal system shall verify the dosing rates, the flushing rates, and other parameters critical to the proper operation of the system at the startup inspection. A summary of the startup inspection shall be included in the operation and maintenance manual and shall include, at a minimum, the dosing volume, the forward flow flushing rate, the pressure head of the system, and verification of proper cycling between zones.

FORMS (12VAC5-610)

Application for a Sewage Disposal System Construction Permit, C.H.S. 200 (rev. 4/83)

Sewage Disposal System Construction Permit, C.H.S. 202A (rev. 6/84)

Schematic Drawing of Sewage Disposal System and Topographic, C.H.S. 202B (rev. 6/84)

Application for Sewage Handling Permit, B.W.E. 23–1

Application for Pump and Haul, B.W.E. 25-1

474 Pump and Haul Storage Facility Construction Permit, B.W.E. 26-1
475 Soil Evaluation Form, C.H.S. 201 (rev. 4/83)
476 Soils Evaluation Percolation Test Data
477 Record of Inspection - Non-Public Drinking Water Supply System
478 Completion Statement, C.H.S. 204 (rev. 4/83)
479 Gravelless Material: Application for General Approval (undated)

COMMONWEALTH of VIRGINIA
Department of Health
Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER
P O BOX 2448
RICHMOND, VA 23218
TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: March 17, 2016

TO: Virginia State Board of Health

FROM: Steven A. Harrison, Director
Office of Radiological Health

SUBJECT: **PROPOSED (TH02) Request to Amend 12VAC5-490, Radiation Protection Fee Schedule**

The Virginia Department of Health's Office of Radiological Health (ORH) proposes to amend the existing Virginia Radiation Protection Regulations: Fee Schedule (12VAC5-490) in order to update fees for non-medical X-ray equipment that is inspected on a three-year frequency; establish fees for the registration of baggage, cabinet/analytical and industrial X-ray equipment; establish fees that would allow an ORH inspector to perform an inspection of this equipment; and establish an associated inspection frequency. A Notice of Intended Regulatory Action was published in the Virginia Register on November 16, 2015 (Vol. 32, Issue 6) notifying the public of our intent to propose changes to this regulation, and no public comments were received.

Purpose of Regulations

The purpose of the X-ray program is to protect the public from unnecessary radiation due to faulty X-ray equipment or substandard practices. The purpose of registering and inspecting facilities that use X-ray machines, including those for non-medical purposes, is to have an accurate database of the machines, to track their inspections and to ensure the machines are properly functioning so as to protect the health and safety of equipment operators and the public.

Upcoming Steps

The proposed regulation (TH02), upon approval by the Board of Health, will be submitted for executive branch review. Pending gubernatorial approval, the proposal will be posted on the Regulatory Town Hall, a notice will be sent to all registered Town Hall users, and it will be published in the Virginia Register of Regulations. A 60-day public comment period will commence, at the end of which the agency will consider the comments, make necessary adjustments, and then submit the proposed amendments for final approval by the Board of Health at a future meeting.

townhall.virginia.gov

Proposed Regulation
Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-490
Regulation title(s)	Virginia Radiation Protection Regulations: Fee Schedule
Action title	Modify radiation protection X-ray device registration and inspection fees.
Date this document prepared	January 28, 2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The Virginia Department of Health's Office of Radiological Health proposes to amend 12VAC5-490, Radiation Protection Fee Schedule. Specifically, this amendment:

- Amends registration fees for equipment inspected every three years;
- Adds three (3) categories and associated fees for the registration of non-medical X-ray equipment (X-ray equipment not used in the healing arts):
  - Baggage, Cabinet and Analytical, and Industrial X-ray equipment.
- Adds three (3) categories and associated fees for the inspection of non-medical X-ray equipment (X-ray equipment not used in the healing arts):
  - Baggage, Cabinet and Analytical, and Industrial X-ray Equipment.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

KVp – Peak tube potential; the maximum value of the potential difference across the x-ray tube during an exposure
NOIRA - Notice of Intended Regulatory Action
ORH - Office of Radiological Health

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

These regulations are authorized by §§ 32.1-229 et seq. of the Code of Virginia. Section 32.1-229.1 authorizes the Board of Health to set fees for X-ray equipment and requires the Board of Health to promulgate regulations for the registration, inspection, and certification of X-ray machines by Department of Health personnel (except for audit inspections initiated by the Department). Section 32.1-229.2 requires the Board of Health to set inspection fees to minimize competition with the private sector and include all reasonable costs.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The proposed regulatory action addresses two sets of fees levied by the X-ray machine program: X-ray machine registration fees and X-ray machine inspection fees.

Radiological Control Program regulations currently require the registration of non-medical X-ray equipment (Baggage, Cabinet, Analytical, and Industrial equipment) but do not establish a fee for registration of this equipment, do not establish a fee for the Office of Radiological Health (ORH) to inspect this equipment, and do not specify associated inspection frequencies. Registration and inspection fees for X-ray equipment not used in the healing arts are charged in other states.

The harmful effects of radiation are well known, as well as the many beneficial applications of radiation in industry and healthcare. Adequate regulatory controls for the useful application of radiation are necessary to protect the health, safety and welfare of citizens. The potential exists for accidents associated with this equipment, which have in fact occurred. Accordingly, regulatory attention needs to be applied to promote the safety of non-medical X-ray equipment. These fees will help offset the cost of administrative activities involved in the registration, inspection, and certification of non-medical X-ray equipment. These costs were once absorbed from general funds allocated to ORH, but those general funds have since been abolished.

Substance

Please 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.

In Section 10 of the Regulations, the fee for each machine and additional tube(s) that has an inspection frequency of every three years is proposed to increase from $50 to $60, collected every three years.

The following annual registration fees are proposed for all operators or owners of baggage, cabinet or analytical, or industrial X-ray machines capable of producing radiation:

- $20 for each machine used for baggage inspection;
- $25 for each machine identified as cabinet or analytical; and
- $50 for each machine used for industrial radiography.

Section 20 of the Regulations is proposed to be amended to add the following inspection fees and required inspection frequencies for operators or owners of baggage, cabinet, analytical, or industrial X-ray machines capable of producing radiation:

- Baggage X-Ray Unit: $100 per inspection, inspected every 5 years;
- Cabinet/Analytical X-ray Unit: $150 per inspection, inspected every 3 years;
- Industrial Radiography X-Ray Unit: $200 per inspection, inspected annually.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.

The primary advantage of this change to the public and the regulated community is that registering all X-ray machines allows ORH to maintain an accurate database of the devices, track inspections and ensure that the machines are functioning properly so as to minimize the risk of equipment malfunction and accidental overexposures.

1. Primary advantages and disadvantages to the public:
   The primary advantage to the public is that the X-ray machine registration and inspection fees rely on owners/operators of the X-ray equipment.

   There are no disadvantages to the public in promulgating the proposed fee schedule.

2. Primary advantages and disadvantages to the agency and Commonwealth:
   Approving the proposed fee structure will allow the Commonwealth to recover more of the costs associated with carrying out the legislative mandate.

   There are no disadvantages to the agency and Commonwealth in promulgating the proposed fee schedule.

3. Other pertinent matters of interest to the regulated community:

   X-ray machine registrants have an interest in keeping inspection fees as low as possible.

Private inspectors of X-ray machines have an interest in ensuring that inspection fees by agency inspectors do not hurt their business by undercutting the private sector pricing, and Virginia Code § 32.1-229.2 requires the agency to establish inspection fees in such a manner so as to minimize competition with the private inspector while recovering costs.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.

There are no applicable federal requirements or no requirements that exceed applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities that would be disproportionately affected by this action.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal; the costs and benefits of the alternatives stated in this background document or other alternatives; and, the potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**) or by mail, email, or fax to **Stan Orchel, Jr., Virginia Department of Health, Office of Radiological Health, 109 Governor Street, Room 733, Richmond, VA 23219; Office Phone: (804) 864-8170; Fax: (804) 864-8175; email: stan.orchel@vdh.virginia.gov**. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	a) Fund Source: X-ray Machines, 0200. The X-ray program is not supported by state general funds, but rather by fees collected from x-ray device registrations and inspections. Program expenditures are primarily on-going and sometimes increase with salary adjustments such as cost of living raises. b) One-time: The purchase of one X-ray inspection device, including an annual calibration and repair service agreement at about $20,000, with which to conduct inspections. Ongoing: An X-ray program staff member will be needed to track device registrations, conduct inspections (when not conducted by Private Inspectors), issue certificates, etc. at a cost of about $75,000/year (average for Radiation Safety Specialists including salary, benefits and office/administrative overhead).
Projected cost of the new regulations or changes to existing regulations on localities.	$0. There are no direct charges to the localities, which are exempt from registration fees for X-ray machines. Nevertheless these facilities are required to register their X-ray machines. The indirect cost would include postage and staff time (approximately 15 minutes) to complete the registration form.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	This amendment affects anyone who uses an X-ray device in the Commonwealth.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are currently 630 non-medical facilities with 1,597 X-ray machines. Approximately 190 facilities are state or local government entities. Approximately 110 facilities might be classified as small business.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	a) X-ray machines are already required to be registered. • The fee for each machine and additional tube(s) that has an inspection frequency of every three years is proposed to increase from $50 to $60, collected every three years. • Proposed annual fees for non-medical device registrations are: o $20 for each machine used for baggage inspection; o $25 for each machine identified as cabinet or analytical; and o $50 for each machine used for industrial radiography • Proposed fees for non-medical device inspections, if conducted by VDH staff, are: o Baggage X-Ray Unit: $100 per inspection, inspected every 5 years; o Cabinet/Analytical X-ray Unit: $150 per

	inspection, inspected every 3 years; o Industrial Radiography X-Ray Unit: $200 per inspection, inspected annually. b) None.
Beneficial impact the regulation is designed to produce.	Ensure Virginia's X-ray regulations meet current standards and practices.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

Failure to update the existing regulation would be inconsistent with the agency's mission and the need to provide an adequate regulatory program that protects public health and safety with regard to the maintenance and operation of non-medical X-ray devices. VDH will consider recommendations from the Radiation Advisory Board and the regulated community for alternative means of meeting the intent of the regulations or additional requirements to address concerns that may be unique within the Commonwealth.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please 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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.

1. Approximately two thirds of the facilities are on a three-year registration and inspection cycle rather than an annual registration and inspection cycle. Small businesses represent many of those facilities on a three-year cycle.
2. The establishment of schedules or deadlines for compliance with registration or inspection requirements is consistent with other states. Less stringent inspection requirements may result in undetected non-compliances that may adversely affect patient care and safety. Less stringent registration requirements may adversely impact the reliability and value of the X-ray machine database.
3. The fee schedules were kept as simple as possible.
4. Establishment of performance standards in place of operational standards does not appear to be applicable to implementing a fee schedule.
5. Many of the entities this regulation applies to are small businesses. The Code of Virginia does not provide exemptions for the requirements of this regulation.

Periodic review and small business impact review report of findings

If you are using this form to report the result of a periodic review/small business impact review that was announced during the NOIRA stage, please indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Not applicable.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

No comments received.

Commenter	Comment	Agency response

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed changes would not have a direct impact on the institution of the family and family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-490-10		All operators or owners of diagnostic X-ray machines used in the healing arts and capable of producing radiation shall pay the following registration fee: $50 for each machine and additional tube(s) that have a required annual inspection, collected annually; $50 for each machine and additional tube(s) that have a required inspection every three years, collected every three years. All operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines used in the healing arts capable of producing radiation shall pay the following annual registration fee: $50 for each machine with a maximum beam energy of less than 500 KVp; $50 for each machine with a maximum beam energy of 500 KVp or greater. Where the operator or owner of the aforementioned machines is a state agency or local government, that agency is exempt from the payment of the registration fee.	All operators or owners of diagnostic X-ray machines used in the healing arts and capable of producing radiation shall pay the following registration fee: $50 for each machine and additional tube(s) that have a required annual inspection, collected annually; ~~$50~~ *$60* for each machine and additional tube(s) that have a required inspection every three years, collected every three years. All operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines used in the healing arts capable of producing radiation shall pay the following annual registration fee: $50 for each machine with a maximum beam energy of less than 500 KVp; $50 for each machine with a maximum beam energy of 500 KVp or greater. *All operators or owners of baggage, cabinet or analytical, or industrial X-ray machines capable of producing radiation shall pay the following annual registration fee:* *$20 for each machine used for baggage inspection;* *$25 for each machine identified as cabinet or analytical; and* *$50 for each machine used for industrial radiography.* Where the operator or owner of the aforementioned machines is a state agency or local government, that agency is exempt from the payment of the registration fee. **Intent/Rationale/Impact**: This change would increase fees for x-ray producing devices that are required to be registered

<table>
<tr><td></td><td></td><td></td><td>every three years; and levy fees to register non-medical x-ray producing devices. Owners of x-ray producing devices are already required to register the equipment with ORH, but ORH has not, in the past, been authorized to collect a fee to cover administrative costs. Administrative, personnel, travel and other expenses have increased since the fee schedule was last revised in 2009, and the use of general funds to support the X-ray program was eliminated in SFY16. Instituting these fees will help to sustain the X-ray program.</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>12VAC5-490-20</td><td></td><td>The following fees shall be charged for surveys requested by the registrant and performed by a Department of Health inspector:

<table><tr><th>Type</th><th>Cost Per Tube</th></tr><tr><td>General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)</td><td>$230</td></tr><tr><td>Fluoroscopic, C-arm Fluoroscopic</td><td>$230</td></tr><tr><td>Combination (General Purpose-Fluoroscopic)</td><td>$460</td></tr><tr><td>Dental Intraoral and Panographic</td><td>$90</td></tr><tr><td>Veterinary</td><td>$160</td></tr><tr><td>Podiatric</td><td>$90</td></tr><tr><td>Cephalometric</td><td>$120</td></tr><tr><td>Bone Densitometry</td><td>$90</td></tr><tr><td>Combination (Dental Panographic and Cephalometric)</td><td>$210</td></tr><tr><td>Shielding Review for Dental Facilities</td><td>$250</td></tr><tr><td>Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities</td><td>$450</td></tr></table></td><td>The following table lists the fees that shall be charged for surveys requested by the registrant and performed by a Department of Health inspector, as well as the required inspection frequencies for each type of X-ray machine:

<table><tr><th>Type</th><th>Cost Per Tube</th><th>Inspection Frequency</th></tr><tr><td>General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)</td><td>$230</td><td>Annually</td></tr><tr><td>Fluoroscopic, C-arm Fluoroscopic</td><td>$230</td><td>Annually</td></tr><tr><td>Combination (General Purpose-Fluoroscopic)</td><td>$460</td><td>Annually</td></tr><tr><td>Dental Intraoral and Panographic</td><td>$90</td><td>Every 3 years</td></tr><tr><td>Veterinary</td><td>$160</td><td>Every 3 years</td></tr><tr><td>Podiatric</td><td>$90</td><td>Every 3 years</td></tr><tr><td>Cephalometric</td><td>$120</td><td>Every 3 years</td></tr><tr><td>Bone Densitometry</td><td>$90</td><td>Every 3 years</td></tr><tr><td>Combination (Dental Panographic and Cephalometric)</td><td>$210</td><td>Every 3 years</td></tr><tr><td>Shielding Review for Dental Facilities</td><td>$250</td><td>Initial/Prior to use</td></tr><tr><td>Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities</td><td>$450</td><td>Initial/prior to use</td></tr><tr><td>Baggage X-Ray Unit</td><td>$100</td><td>Every 5 years</td></tr><tr><td>Cabinet/Analytical X-ray Unit</td><td>$150</td><td>Every 3 years</td></tr><tr><td>Industrial Radiography X-Ray Unit</td><td>$200</td><td>Annually</td></tr></table>
Intent/Rationale/Impact: This change would add the inspection frequency for x-</td></tr>
</table>

			ray producing devices that appear elsewhere in regulations so that they are consolidated into one table; and, adds inspection fees and frequencies for non-medical x-ray producing devices. Administrative, personnel, travel and other expenses have increased since the fee schedule was last revised in 2009, and the use of general funds to support the X-ray program was eliminated in SFY16.Administrative, personnel, travel and other expenses have increased since the fee schedule was last revised in 2009, and the use of general funds to support the X-ray program was eliminated in SFY16. Instituting these fees will help to sustain the X-ray program.

Project 4550 - PROPOSED

DEPARTMENT OF HEALTH

Non-Medical X-Ray Device Registration and Inspection Fee Schedule

12VAC5-490-10. Registration fees.

All operators or owners of diagnostic X-ray machines used in the healing arts and capable of producing radiation shall pay the following registration fee:

$50 for each machine and additional tube(s) that have a required annual inspection, collected annually;

~~$50~~ $60 for each machine and additional tube(s) that have a required inspection every three years, collected every three years.

All operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines used in the healing arts capable of producing radiation shall pay the following annual registration fee:

$50 for each machine with a maximum beam energy of less than 500 KVp;

$50 for each machine with a maximum beam energy of 500 KVp or greater.

All operators or owners of baggage, cabinet or analytical, or industrial X-ray machines capable of producing radiation shall pay the following annual registration fee:

$20 for each machine used for baggage inspection;

$25 for each machine identified as cabinet or analytical; and

$50 for each machine used for industrial radiography.

Where the operator or owner of the aforementioned machines is a state agency or local government, that agency is exempt from the payment of the registration fee.

12VAC5-490-20. Inspection fees and inspection frequencies for X-ray machines.

The following table lists the fees that shall be charged for surveys requested by the registrant and performed by a Department of Health inspector, as well as the required inspection frequencies for each type of X-ray machine:

Type	Cost Per Tube	Inspection Frequency
General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)	$230	Annually
Fluoroscopic, C-arm Fluoroscopic	$230	Annually
Combination (General Purpose-Fluoroscopic)	$460	Annually
Dental Intraoral and Panographic	$90	Every 3 years
Veterinary	$160	Every 3 years
Podiatric	$90	Every 3 years
Cephalometric	$120	Every 3 years
Bone Densitometry	$90	Every 3 years

Combination (Dental Panographic and Cephalometric)	$210	Every 3 years
Shielding Review for Dental Facilities	$250	Initial/Prior to use
Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities	$450	Initial/Prior to use
Baggage X-ray Unit	$100	Every 5 years
Cabinet/Analytical X-ray Unit	$150	Every 3 years
Industrial Radiography X-ray Unit	$200	Annually

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March 17, 2016

MEMORANDUM

TO: Virginia State Board of Health

FROM: Gary R. Brown
Director, Office of Emergency Medical Services

SUBJECT: Regulations Governing Durable Do Not Resuscitate Orders (12VAC5-66)

Enclosed for your review is a Fast Track action to amend the Regulations Governing Durable Do Not Resuscitate Orders (12VAC5-66).

The State Board of Health has promulgated regulations in order to carry out the intent of Virginia law that a person shall have the opportunity to execute a durable do not resuscitate (DNR) order that comports with his or her wishes. In compliance with Executive Order 17 that requires a periodic review of all regulations, and based on those comments submitted, it is recommended that the regulations be amended to clarify that other DNR orders may be recognized. Specifically, this Fast Track action amends the definition of a durable DNR order to include a physician orders for scope of treatment (POST) form completed by a licensed practitioner and signed by the patient or the patient's authorized representative.

The Board of Health is requested to approve this Fast Track action at its March 2016 meeting. Should the Board of Health approve the Fast Track action, the proposed 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 amendments 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 regulations will become effective.

townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-66
Regulation title(s)	Regulations Governing Durable Do Not Resuscitate Orders
Action title	Amend the Regulations Governing Durable Do Not Resuscitate Orders
Date this document prepared	February 17, 2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

This Fast Track action proposes to amend the definition of durable do not resuscitate (DNR) order or durable DNR order such that it includes a physician orders for scope of treatment (POST) form completed by a licensed practitioner and signed by the patient or the patient's authorized representative.

POST means a set of portable medical orders (Section A of which is a valid durable DNR order) resulting from a patient's or a patient's authorized representative's informed decision-making with health care professionals that respects the patient's goals for care regarding the use of medical interventions, is applicable across health care settings, and can be reviewed and revised as needed or desired by the patient or the patient's authorized representative. The Virginia POST form is being used by various localities and emergency medical services (EMS) providers in Virginia and POST forms are also recognized in more than 26 other states. Adding the term POST within the definition of durable DNR will

clarify to EMS providers and health care professionals working at medical facilities that the POST form is a recognized durable DNR form.

POST has been recognized by the Virginia Department of Health's Office of EMS as a durable DNR order. In addition, the Office of the Attorney General has interpreted that the current regulations are broad enough to permit the POST form to be considered as a durable DNR. However, with the addition of the terminology of POST, it affords the public a clearer understanding of other acceptable durable DNR forms as identified within the regulations. This permits greater flexibility for practitioners and other allied health care workers to include the patient and EMS providers in the utilization of documentation that clearly recognizes and acknowledges the patient's wishes concerning their end-of-life decisions.

The Virginia POST Task Force has reviewed existing state laws and regulations, and created a form and process that is compatible with these laws and regulations. The Virginia POST Collaborative Executive Committee submitted comments requesting that the regulations be amended to designate Section A of the Virginia POST form as a durable DNR Order.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

"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 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 DNR" are used in this article, a durable DNR order or other DNR order is not and shall not be construed as an advance directive. When used in these regulations, the term "durable DNR order" shall include any authorized alternate durable DNR jewelry issued in conjunction with an original durable DNR Order.

"Emergency 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.

"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 and/or rendering immediate medical care to such persons who are sick, injured, wounded or otherwise incapacitated or helpless.

"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 form under policies and procedures of the health care facility to which the individual who is the subject of the order has been admitted.

Statement of final agency action

Please 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.

The Board of Health approved the fast track amendments to the Regulations Governing Durable Do Not Resuscitate Orders 12VAC5-66 on March 17, 2016.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Section 54.1-2987.1 of the Code of Virginia vests authority for the Regulations Governing Durable Do Not Resuscitate 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 DNR orders.
Section 32.1-111.4 Regulations, Emergency Medical Services Personnel and vehicles; Response times; Enforcement provisions; Civil penalties states in part that the Board of Health has authority to promulgate regulations for EMS personnel to follow DNR orders pursuant to § 54.1-2987.1.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

Adding the term POST within the definition of durable DNR will clarify to EMS providers and health care professionals working at medical facilities that the POST form is a recognized other DNR form. This amendment is essential to protect the health and safety of citizens because it will clarify to EMS providers and health care professionals working at medical facilities that the POST form is an approved durable DNR form. This, in turn, will provide greater adherence to a patient's end-of-life decisions.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

During the periodic review, there were four submitted comments, all supporting the addition of POST to the definition of durable DNR form. No other stakeholders have voiced any opposition to this recommended addition. For that reason, the regulatory action is expected to be non-controversial.

Substance

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

The definition of "Durable Do Not Resuscitate Order" or "Durable DNR Order" is amended to specify that a durable DNR order shall include a POST form completed by a licensed practitioner and signed by the patient or patient's authorized representative.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.

The primary advantage of this action is that, with the addition of the terminology of POST, it affords the public a clearer understanding of other acceptable durable DNR forms as identified within the regulations. This permits greater flexibility for practitioners and other allied health care workers to include the patient and EMS providers in the utilization of documentation that clearly recognizes and acknowledges a patient's wishes concerning their end of life decisions. This action does not pose any disadvantages to the public or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no disproportionate impacts to the citizens or localities of the Commonwealth.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please 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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.

There are no alternative regulatory methods that will accomplish the objectives of applicable law. The proposed amendments do not impact small business.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	No cost
Projected cost of the new regulations or changes to existing regulations on localities.	No cost
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Health care professionals, facilities, and patients
Agency's best estimate of the number of such entities that will be affected. Please 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.	More than 51,000 physicians, nurse practitioners, and physician assistants Approximately 100 hospitals and 279 nursing facilities
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	No cost
Beneficial impact the regulation is designed to produce.	Recognition of other documentation to express a patient's end-of-life decisions.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

No additional alternatives have been identified.

Public participation notice

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.

Periodic review and small business impact review report of findings

If this fast-track is the result of a periodic review/small business impact review, use this form to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Commenter	Comment	Agency response
Paula Avery Drummer	Section A of Virginia POST form to be designated as a durable DNR The Virginia POST Collaborative Executive Committee is hereby submitting a comment regarding the Regulations Governing Durable Do Not Resuscitate Orders (12 VAC 5-66). We are in agreement with previous comments submitted by Nathan Kottkamp, Ken Faulkner and Lois Shepherd, that the definition of durable DNR should be amended to designate Section A of the Virginia POST form as a durable DNR order. The Virginia POST form is being used by more and more providers around the state, and this designation as a durable DNR will strengthen the clarity and portability of the form. We are, therefore, requesting that Section A of the Virginia POST form be included in 12 VAC5-66 as a Durable DNR order. We also submit a definition of POST such as: "Physician Orders for Scope of Treatment" ("POST") means a set of portable medical orders (section A of which is a valid durable DNR order) resulting from a patient's or a patient's authorized representative's informed decision-making with health care professionals that respects the patient's goals for care regarding the use of medical interventions, is applicable across health care settings, and can be reviewed and revised as needed or desired by the patient or the patient's authorized representative.	Section A of the Virginia POST form to be recognized as a durable DNR form.

	Thank you for your consideration in this comment and please contact the Virginia POST Collaborative for any additional information.	
Lois Shepherd	I echo the comments of Nathan Kottkamp that the definition of durable DNR should be amended to incorporate the POST form.	POST Form to be recognized as a durable DNR form.
Ken Faulkner	Physician Orders for the Scope of Treament (POST) should be included as a full durable DNR The definition of durable DNR should be amended to incorporate the POST form that is being used by more and more providers around the state. POST is a physicians order that enables a patient's wishes and care plan to be established on a common form that is effective regardless of a patient's location. The only edit that appears to be necessary is a revision to the definitions, 12VAC5-66-10, such as: “The term durable DNR shall include a Physician Orders for Scope of Treatment (POST) form completed by a licensed practitioner and signed by the patient or patient’s authorized representative.” Currently, the comprehensive use of the POST form is hindered by the fact that the immunity provided in the Health care Decisions Act (Va. Code 54.1-2988) is not expessly available to providers. Thank you for considering this comment	Definition of durable DNR should be amended to specifically include POST.
Nathan Kottkamp	POST should be included in the definition of durable DNR The definition of durable DNR should be amended to incorporate the POST form that is being used by more and more providers around the state. POST is a physicians order that enables a patient's wishes and care plan to be established on a common form that is effective regardless of a patient's location. The only edit that appears to be necessary is a revision to the definitions, 12VAC5-66-10, such as: “The term durable DNR shall include a Physician Orders for Scope of Treatment (POST) form completed by a licensed practitioner and signed by the patient or patient’s authorized representative.” Currently, the comprehensive use of the POST form is hindered by the fact that the immunity provided in the Health care Decisions Act (Va. Code 54.1-2988) is not expessly available to providers. Thank you for considering this comment.	Amend the definition of durable DNR form to include POST.
Barbara Matusiak	Please consider this as public comment on the Virginia Department of Health periodic review of VAC citation: 12VAC5-66 Regulations Governing Durable Do Not Resuscitate Orders specifically on Section 60 Other Do Not Resuscitate Orders. I am requesting that 12VAC5-66-60 Other Do Not Resuscitate Orders be amended to require signed and witnessed informed consent for Do Not Resuscitate (DNR) orders. In a letter to you dated April 24, 2015 I explained the reason for my request and made recommendations for change. Please include that letter as part of my public comment.	The issues presented in this public comment involve an internal challenge not regulated by these set of regulations. The writer has pursued the proper channels to address her concerns. The

	The addition of a requirement for informed consent is not unprecedented as such a requirement exists in other sections of Virginia Administrative Code i.e. 12VAC5-20-100; 12VAC35-180-100; 12VAC35-115-70; 6VAC 15-26-10; 6VAC15-45-1560; 6VAC35-170-80; 8VAC20-565-30; 18VAC85-20-350; 22VAC30-40-100; 22VAC30-40-10; 22VAC40-890-50 etc. The amendment is necessary for the protection of public health, safety and welfare. The current language can be misinterpreted to mean that signed informed consent is not required because of the specific language that a signature is not required on the order itself. At least one hospital in Richmond does not require signed and witnessed informed consent for DNR orders. There may be other hospitals in Virginia that are doing the same. This must be rectified. As a result of not requiring signed consent a physician at the Richmond hospital wrote a DNR order without the consent of the patient's decision maker. Patients and decision makers must be informed of and agree to a change in code status. The informed consent must be signed and witnessed to ensure that it is properly obtained. Not requiring signed and witnessed informed consent for a critical life ending DNR order allows practitioners to abuse the use of DNR orders to end the lives of patients and influence the care provided. Although according to the hospital at which this incident occurred a do not resuscitate order indicates only that resuscitative measures will not be initiated if the patient's heart stops or breathing ceases and until that time, the same standard of care applies to all patients, in reality medical care decisions are affected prior to cardiopulmonary arrest by DNR orders. The same patient referenced in my April letter to you was hospitalized at the same hospital in 2008. During that hospitalization the neurologist clearly stated that since she was a full code he had to move her to ICU. If she had been a DNR he would not have transferred her to the ICU and she may not have survived to enjoy the additional five years of life. Thank you for your consideration of this serious matter.	existing regulations address the requirement of a signature from the attending physician and the patient or patient representative for the purposes of completing the durable DNR order form required by Code. Secttion 54.1-2987.1 of the Code of Virginia does not require that all DNR orders include a physician signature, a patient signature, or any evidence that consent has been witnessed.

As a result of a periodic review conducted July of 2015, four comments were submitted via Townhall supporting the addition of the definition of the terminology POST. One submission was a letter outside of the Townhall noting an occurrence from an in-hospital event that was reported to the appropriate agencies to address. The proposed amendment meets the requirements as set forth in Executive Order 17 (2014) as it directly impacts the health, safety, and welfare of the public (individual) and is easily written and understood. There is a continued need for this set of regulations as it aids individuals in the legal recognition of their end-of-life decisions. There are no known overlaps or duplications of any federal or state law addressed by this amendment.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage

economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The amending of these regulations will strengthen the self sufficiency, self-pride, assumption of responsibility for oneself, and decision making for the individual as it pertains to their end-of-life decisions.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
10		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.	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 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, a Durable Do Not Resuscitate Order or other DNR Order is not and shall not be construed as an advance directive. When used in these regulations, 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 Orders for Scope of Treatment (POST) form

		"Commissioner" means the State Health Commissioner. "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 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, a Durable Do Not Resuscitate Order or other DNR Order is not and shall not be construed as an advance directive. When used in these regulations, the term "Durable DNR Order" shall include any authorized Alternate Durable DNR jewelry issued in conjunction with an original Durable DNR Order. "Emergency 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. "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 and/or rendering immediate medical care to such persons who are sick,	<u>completed by a licensed practitioner and signed by the patient or patient's authorized representative.</u> Rationale: Recognition of POST as a specific type of durable DNR form. POST means a set of portable medical orders resulting from a patient's or a patient's authorized representative's informed decision-making with health care professionals that respects the patient's goals for care regarding the use of medical interventions, is applicable across health care settings, and can be reviewed and revised as needed or desired by the patient or the patient's authorized representative.

		injured, wounded or otherwise incapacitated or helpless. "Incapable of making an informed decision" means the inability of an adult patient, because of mental illness, mental retardation, 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. "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 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 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 or by the Department of Behavioral Health and Developmental Services (DBHDS) or operated, licensed, or owned by another state agency. "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.	

Project 4580 - none

DEPARTMENT OF HEALTH

Amend DDNR Regulations following Periodic Review

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.

"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 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, a Durable Do Not Resuscitate Order or other DNR Order is not and shall not be construed as an advance directive. When used in these regulations, 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 Orders for Scope of Treatment (POST) form completed by a licensed practitioner and signed by the patient or patient's authorized representative.

"Emergency 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.

"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 and/or rendering immediate medical care to such persons who are sick, injured, wounded or otherwise incapacitated or helpless.

"Incapable of making an informed decision" means the inability of an adult patient, because of mental illness, mental retardation, 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.

"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 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 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 or by the Department of Behavioral Health and Developmental Services (DBHDS) or operated, licensed, or owned by another state agency.

"Qualified health care personnel" means any qualified emergency medical services personnel and any licensed healthcare 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.

COMMONWEALTH of VIRGINIA
Department of Health
Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER
P O BOX 2448
RICHMOND, VA 23218
TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: February 12, 2016

TO: Virginia State Board of Health

FROM: Vanessa Walker-Harris, MD, MPH
Director, Office of Family Health Services

SUBJECT: Amendments to 12VAC5-71, Regulations Governing Virginia Newborn Screening Services – Final Amendments

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The Virginia State Board of Health (Board) is asked to review and approve the final amendments to 12VAC5-71, which add screening for critical congenital heart disease (CCHD) to the newborn screening regulations. This is the final stage of the regulatory process. The Board must approve the final amendments for them to become permanent prior to the emergency regulations expiring on June 23, 2016.

The proposed amendments to add CCHD screening to the newborn screening regulations were brought before the Board in June 2015. That proposal was to make permanent the emergency regulations that added screening of CCHD to the newborn screening requirements, which became effective on December 24, 2014. These regulatory changes were implemented in accordance with House Bill 387, which was signed by the Governor on February 20, 2014, and Senate Bill 183, which was signed by the Governor on March 5, 2014. Both bills required VDH to convene a workgroup to provide information and recommendations for the development of regulations to require all hospitals with newborn nurseries to perform a screening test for critical congenital heart disease on all babies born in the hospital. The bills also required VDH to promulgate regulations to implement the statutory provisions within 280 days of enactment.

Following the publication of the proposed amendments, public comments were received from two parties; one was supportive and one opposed the adoption of the amendments. The American Heart Association noted they were supportive and that the regulations would make Virginia one of 40 states that require this screening for newborns. They noted that pulse oximetry is low-cost and non-invasive and can detect CCHD in more than 90% of afflicted newborns. The commenter that opposed the regulations stated that they opposed practicing

medicine from the General Assembly and that mandating tests adds to the costs of our health care system. Two comments received after publication of the emergency regulations were both supportive of the regulatory amendments.

VDH has made some changes to the regulatory text from the proposed stage to the final stage. Based on guidance from the Registrar of Regulations, section 210 A was revised to specify the source document from the Academy of Pediatrics that provides screening recommendations. Although these recommendations may change over time, regulations that incorporate guidelines or standards from other sources must refer to the specific source of those guidelines or recommendations. In addition, section 220 C was revised to add parent or guardian refusal on religious grounds as one of the reasons that CCHD screening may not be completed. Finally section 230 B.1 was revised to specify the timeframe in which the attending physician would need to be notified of abnormal screening results.

Should the Board approve the final amendments, they will be submitted for Executive Branch Review. Following this review and approval, the regulations will be published in the Virginia Register of Regulations for a 30 day final adoption period, after which they will become final.

townhall.virginia.gov

Final Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-71 and 12VAC5-191
Regulation title(s)	Regulations Governing Virginia Newborn Screening Services and State Plan for the Children with Special Health Care Needs Program
Action title	Amend regulations to add critical congenital heart disease (CCHD) to the Virginia Newborn Screening System so that all infants born in hospitals with a newborn nursery in Virginia are screened for CCHD
Date this document prepared	February 17, 2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The amendments to the newborn screening regulations add requirements for hospitals with a newborn nursery to screen all infants born in Virginia for critical congenital heart disease (CCHD) within 24-48 hours after birth using pulse-oximetry. These amendments require that hospitals develop protocols for the screening of all newborns for CCHD, and that they have protocols for the follow-up and referral for any infants that have positive screens. Newborns that have an abnormal screen shall not be discharged from the hospital until the cause of the abnormal screen has been evaluated and an appropriate plan for care is in place. Any diagnosis resulting from an abnormal screen shall be entered in the electronic birth certificate, and the attending physician shall notify the parent and the primary care provider of the diagnosis. Infants that are diagnosed with CCHD shall be referred to the Care Connection for Children

program for care coordination services. A parent may refuse to have their child screened on the basis of religious practices or tenets. Such refusal must be documented in writing.

Most hospitals in Virginia are already voluntarily performing this screening. The amendments would require a small number of additional hospitals to implement screening. The amendments will also permit VDH to collect information via the VaCARES reporting system so that infants identified with a critical congenital heart disease can be referred to the Care Connections for Children program to obtain care coordination services.

This regulatory action also includes final amendments to the State Plan for Children with Special Health Care Needs Program (12VAC5-191), so that those regulations remain consistent with 12VAC5-71.

Emergency regulations requiring this screening have been in effect since December 24, 2014, as required by HB387/SB183 enacted by the 2014 General Assembly and signed by the Governor. Those emergency regulations will expire on June 23, 2016. This regulatory action seeks to make those changes permanent.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

CCHD – Critical Congenital Heart Disease
VaCARES – Virginia Congenital Anomalies Reporting and Education System
VDH – Virginia Department of Health

Statement of final agency action

Please 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.

The Virginia State Board of Health approved the text of the final amendments for the Regulations Governing Virginia Newborn Screening Services and the State Plan for the Children with Special Health Care Needs Program, 12VAC5-71 and 12VAC5-191 on March 17, 2016.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The State Board of Health is authorized to make, adopt, promulgate and enforce regulations by Section 32.1-12 of the Code of Virginia.

Section 32.1-65.1 states that the Board of Health shall require every hospital in Virginia having a newborn nursery to screen infants for critical congenital heart disease.

Section 32.1-67 requires the Board of Health to promulgate regulations.

HB387/SB183 enacted by the General Assembly required the Board of Health to promulgate emergency regulations for CCHD screening. This regulatory action seeks to make those changes permanent.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

Congenital heart defects are the most common birth defects in the United States, affecting about one in every 110 infants. A few infants born with congenital heart defects have more serious forms of heart disease, which are referred to as critical congenital heart disease (affecting approximately 2 of every 1,000 births). CCHDs are heart defects that result in abnormal blood flow and oxygen deprivation. These defects require intervention within the first year of life and delayed diagnosis can result in death. Screening newborns for CCHD using pulse oximetry has been recommended through the U.S. Department of Health and Human Services Recommended Uniform Screening Panel. The screening is simple, quick, and painless. A sensor wrapped around the baby's right hand or either foot measures the amount of oxygen in the baby's blood.

In order to help protect the health, safety, and welfare of Virginians, this regulatory action seeks to ensure that all Virginia hospitals with newborn nurseries implement CCHD screening, and that newborns diagnosed with CCHD are reported to VDH so that they may be linked to care coordination services through the Care Connections for Children program.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

The final amendments to the newborn screening regulations require all hospitals with a newborn nursery to screen newborns for CCHD within 24-48 hours of birth. Specifically they add the following elements to the existing regulations:

- Hospitals are required to develop protocols for screening, timely evaluation, and timely referral of newborns with abnormal screening results.

- Requirements that a licensed practitioner perform the screening, and setting forth when the screening is to occur. If screening is not indicated, documentation requirements are set forth for the medical record. Hospitals are required to develop screening protocols for specialty and sub-specialty nurseries.

- Requirements that all screening results must be entered into the medical record and the electronic birth certificate system. This section also requires health care providers to report abnormal screening results immediately and to evaluate the newborn in a timely manner. Newborns shall not be discharged unless a cause for the abnormal screening result has been determined or CCHD has been ruled out. Parents or guardians and the infant's primary care provider after discharge from the hospital shall be notified of any abnormal results and any diagnoses.

- Hospitals must report individuals diagnosed with CCHD to VDH so that the newborn's parent or guardian may be referred to care coordination services through the Care Connection for Children program.

- A section specifying what documents shall be provided when requested by the VaCARES system at VDH, and specifying the confidentiality rules for these documents.

- A section that permits parents to refuse CCHD screening based upon religious practices or tenets, and to specify that the hospital must report the refusal to VDH.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.

These amendments will permanently add CCHD screening requirements to the regulations for newborn screening. The primary advantage to VDH, the public, and the Commonwealth is that the regulations will ensure that every infant born in a hospital with a newborn nursery will be screened for CCHD and that those who screen positive will have further evaluation and follow-up as needed. The majority of hospitals that would be affected by these regulations already provide screening for CCHD voluntarily. These amendments to the regulations set minimum standards for this screening. There are no disadvantages to the public or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no known localities that would be specifically impacted by these regulations.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

These amended regulations will not strengthen or erode the rights of parents in the education, nurturing, and supervision of their children. Parents have the right to refuse newborn screening for religious reasons. Parents also have the right to seek additional newborn screening testing outside of the state program if desired.

The amendments will not encourage or discourage economic self-sufficiency, self-pride, or the assumption of responsibility for oneself, one's spouse, one's children and/or elderly parents.

The amended regulations will not strengthen or erode marital commitment.

The amended regulations will not increase or decrease disposable family income.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC5-71-210 A.	Requires hospitals to develop protocols for screening, timely evaluation, and timely referral of newborns with abnormal screening results that are in accordance with recommendations from the American Academy of Pediatrics (AAP).	Adds a specific reference to the AAP document that specifies screening protocols is included in the regulation.	1VAC7-10-160 states that an agency adopting textual matter by reference to another document, must include the name of the document, the publication date, version number, and publisher.
12VAC5-71-220 C.	States that the reasons that screening is not indicated shall be documented in the newborn's medical record and identifies the primary reasons.	Adds parental or guardian refusal on the basis of religious practices or tenets as a basis for not conducting the screening.	Clarifies the text and makes it consistent with 12VAC5-71-260.
12VAC5-71-230 B.	Specifies how abnormal screening results are to be handled.	Specifies the timeframe as "immediately" in which abnormal results must be reported to the attending physician.	Provides greater specificity to the timeframe, and clarifies the urgency, for reporting abnormal results.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Commenter	Comment	Agency response
TAilshire	Opposes practicing medicine from the Statehouse or General Assembly. Mandating tests adds to the costs of the health care system.	Although this screening is mandated by the Code of Virginia, the majority of hospitals are already including this as part of their newborn screening and it has been identified as a standard practice by the American Academy of Pediatrics.
Robin Gahan, American Heart Association	Support the addition of CCHD screening. This test is a low-cost, non-invasive test that detects over 90% of afflicted newborns.	VDH notes the support of the emergency regulations that are now in effect.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-71-10	N/A	Includes definitions for words and terms that are used in the regulation.	Adds definitions for “Abnormal screening results”; “Critical congenital heart disease”; “CCHD screening”; “Echocardiogram”; “Licensed practitioner”; Newborn nursery”; “Screening technology”; “Specialty level nursery”; and “Subspecialty level nursery”
12VAC5-71-30	N/A	The Virginia Newborn Screening System includes the Virginia Newborn Screening Program and the Virginia Early Hearing Detection and Intervention Program.	CCHD is added as a third element of the Virginia Newborn Screening System.
12VAC5-71-150	N/A	Care coordination services will be provided for Virginia residents who are diagnosed with selected heritable disorders or genetic diseases.	CCHD is added as a third diagnosis group that would make an individual eligible for care coordination services.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
	12VAC5-71-210		This is a new section requiring hospitals to develop protocols for screening, timely evaluation, and timely referral of newborns with abnormal screening results. The intent is to allow hospitals to develop their own protocols in three required areas.
	12VAC5-71-220		This is a new section requiring a licensed practitioner to perform the screening, and setting forth when the screening is to occur. If screening is not indicated, documentation requirements are set forth for the medical record. Hospitals shall develop screening protocols for specialty and sub-specialty nurseries. Intent is to ensure that qualified personnel perform the screening within the relevant time frame, and to set forth exceptions when screening is not required. Intent is to permit hospitals with specialty and subspecialty nurseries to develop protocols for screening within those specialized units.
	12VAC5-71-230		This is a new section requiring all screening results to be entered into the medical record and the electronic birth certificate system. The section also requires health care providers to report abnormal screening results immediately and to evaluate the newborn in a timely manner. Newborns shall not be discharged unless a cause for the abnormal screening result has been determined or CCHD has been ruled out. Parents or guardians and the infant's primary care provider after discharge from the hospital shall be notified of any abnormal results and any diagnoses. Intent is to ensure that screening results are properly documented, responded to, and communicated to parents or guardians and the infant's primary care provider after discharge from the hospital.
	12VAC5-71-240		This is a new section requiring hospitals to report individuals diagnosed with CCHD to VDH so that the newborn's parent or guardian may be referred to

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			care coordination services through the Care Connection for Children. Intent is to refer parents and guardians of infants with CCHD to care coordination services.
	12VAC5-71-250		This is a new section specifying what documents shall be provided when requested by the VaCARES system at VDH, and specifying the confidentiality rules for these documents. Intent is to allow VDH to research final outcomes of abnormal CCHD screening results and evaluate screening activities in the state.
	12VAC5-71-260		This is a new section that permits parents to refuse CCHD screening based upon religious practices or tenets, and to specify that the hospital must report the refusal to VDH. Intent is to allow parents to refuse CCHD screening in accordance with their religious tenets, as specified in the authorizing legislation.
12VAC5-191-260	N/A	The Virginia Newborn Screening System includes the Virginia Newborn Screening Program and the Virginia Early Hearing Detection and Intervention Program.	CCHD is added as a third element of the Virginia Newborn Screening System. The mission, scope of services, governing regulations, criteria, and goal of the screening are documented.

Project 4176 - Final

DEPARTMENT OF HEALTH

Add Critical Congenital Heart Disease to the Virginia Newborn Screening System

12VAC5-71-10. Definitions.

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

"Abnormal screening results" means, in 12VAC5-71-210 through 12VAC5-71-250 only, all results that indicate the newborn has not passed the screening test.

"Attending physician" means the physician in charge of the infant's care.

"Board" means the State Board of Health.

"Business days" means Monday through Friday from 9 a.m. to 5 p.m., excluding federal and state holidays.

"Care Connection for Children" means a statewide network of centers of excellence for children with special health care needs (CSHCN) that provides leadership in the enhancement of specialty medical services, care coordination, medical insurance benefits evaluation and coordination, management of the CSHCN pool of funds, information and referral to CSHCN resources, family-to-family support, and training and consultation with community providers on CSHCN issues.

"Care coordination" means a process that links individuals and their families to services and resources in a coordinated effort to maximize their potential and provide them with optimal health care.

"Certified nurse midwife" means a person licensed to practice as a nurse practitioner in the Commonwealth pursuant to § 54.1-2957 of the Code of Virginia and in accordance with Part II (18VAC90-30-60 et seq.) of 18VAC90-30 and 18VAC90-30-121, subject to 18VAC90-30-160.

"Chief executive officer" means a job descriptive term used to identify the individual appointed by the governing body to act in its behalf in the overall management of the hospital. Job titles may include administrator, superintendent, director, executive director, president, vice-president, and executive vice-president.

"Child" means a person less than 18 years of age and includes a biological or an adopted child, as well as a child placed for adoption or foster care unless otherwise treated as a separate unit for the purposes of determining eligibility and charges under these regulations.

"Commissioner" means the State Health Commissioner, his duly designated officer, or agent.

"Confirmatory testing" means a test or a panel of tests performed following a screened-abnormal result to verify a diagnosis.

"Core panel conditions" means those heritable disorders and genetic diseases considered appropriate for newborn screening. The conditions in the core panel are similar in that they have (i) specific and sensitive screening tests, (iii) a sufficiently well understood natural history, and (iii) available and efficacious treatments.

"Critical congenital heart disease" or "CCHD" means a congenital heart disease that places a newborn at significant risk of disability or death if not diagnosed and treated soon after birth. The disease may include, but is not limited to, hypoplastic left heart syndrome, pulmonary atresia (with intact septum), tetralogy of fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus.

"CCHD screening" means the application of screening technology to detect CCHD.

"Department" means the state Department of Health.

"Dried-blood-spot specimen" means a clinical blood sample collected from an infant by heel stick method and placed directly onto specially manufactured absorbent specimen collection (filter) paper.

"Echocardiogram" means a test that uses an ultrasound to provide an image of the heart.

"Guardian" means a parent-appointed, court-appointed, or clerk-appointed guardian of the person.

"Healthcare provider" means a person who is licensed to provide health care as part of his job responsibilities and who has the authority to order newborn dried-blood-spot screening tests.

"Heritable disorders and genetic diseases" means pathological conditions (i.e., interruption, cessation or disorder of body functions, systems, or organs) that are caused by an absent or defective gene or gene product, or by a chromosomal aberration.

"Hospital" means any facility as defined in § 32.1-123 of the Code of Virginia.

"Infant" means a child less than 12 months of age.

"Licensed practitioner" means a licensed health care provider who is permitted, within the scope of his practice pursuant to Chapter 29 (§ 54.1-2900 et seq.) or Chapter 30 (§ 54.1-3000 et seq.) of Title 54.1 of the Code of Virginia, to provide care to a newborn.

"Low protein modified foods" means foods that are (i) specially formulated to have less than one gram of protein per serving, (ii) intended to be used under the direction of a physician for the dietary treatment of an inherited metabolic disease, (iii) not natural foods that are naturally low in protein, and (iv) prescribed as medically necessary for the therapeutic treatment of inherited metabolic diseases.

"Metabolic formula" means nutritional substances that are (i) prescribed by a health professional with appropriate prescriptive authority; (ii) specifically designed and formulated to be consumed or administered internally under the supervision of such health professional; (iii) specifically designed, processed, or formulated to be distinct in one or more nutrients that are present in natural food; and (iv) intended for the medical and nutritional management of patients with limited capacity to metabolize ordinary foodstuffs or limited capacity to metabolize certain nutrients contained in ordinary foodstuffs.

"Metabolic supplements" means certain dietary or nutritional substances intended to be used under the direction of a physician for the nutritional management of inherited metabolic diseases.

"Midwife" means a person licensed as a nurse practitioner in the category of certified nurse midwife by the Boards of Nursing and Medicine or licensed as a midwife by the Board of Medicine.

"Newborn" means an infant who is 28 days old or less who was born in Virginia.

"Newborn nursery" means a general level, intermediate level, or specialty level newborn service as defined in 12VAC5-410-443 B 1, B 2, and B 3.

"Nurse" means a person holding a current license as a registered nurse or licensed practical nurse by the Virginia Board of Nursing or a current multistate licensure privilege to practice in Virginia as a registered nurse or licensed practical nurse.

"Parent" means a biological parent, adoptive parent, or stepparent.

"Pediatric Comprehensive Sickle Cell Clinic Network" means a statewide network of clinics that are located in major medical centers and provide comprehensive medical and support services for newborns and children living with sickle cell disease and other genetically related hemoglobinopathies.

"Physician" means a person licensed to practice medicine or osteopathic medicine in the Commonwealth pursuant to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia and in accordance with applicable regulations.

"Pool of funds" means funds designated for payment of direct health care services. Access to the pool is not an entitlement and is subject to availability of funds and guidelines that govern its eligibility and coverage of services. Pool of funds is a mix of federal Title V funds and state matching funds.

"Population-based" means preventive interventions and personal health services developed and available for the entire infant and child health population of the Commonwealth rather than for individuals in a one-on-one situation.

"Preterm infant" means an infant whose birth occurs by the end of the last day of the 36th week following the onset of the last menstrual period.

"Repeat specimen" means an additional newborn dried-blood-spot screening specimen submitted to the testing laboratory voluntarily or by request.

"Resident" means an individual who resides within the geographical boundaries of the Commonwealth.

"Satisfactory specimen" means a newborn dried-blood-spot screening specimen that has been determined to be acceptable for laboratory analyses by the testing laboratory.

"Screened-abnormal" means a newborn dried-blood-spot screening test result that is outside the established normal range or normal value for that test method.

"Screening technology" means pulse oximetry testing in the right hand and either foot. Screening technology shall also include alternate medically accepted tests that measure the percentage of blood oxygen saturation, follow medical guideline consensus and

recommendations issued by the American Academy of Pediatrics, and are approved by the State Board of Health.

"Specialty level nursery" means the same as defined in 12VAC5-410-443 B 3 and as further defined as Level III by the Levels of Neonatal Care, written by the American Academy of Pediatrics Committee on Fetus and Newborn.

"Subspecialty level nursery" means the same as defined in 12VAC5-410-443 B 4.

"Testing laboratory" means the laboratory that has been selected by the department to perform newborn dried-blood-spot screening tests services.

"Total parenteral nutrition" or "TPN" means giving nutrients through a vein for babies who cannot be fed by mouth.

"Treatment" means appropriate management including genetic counseling, medical consultation, and pharmacological and dietary management for infants diagnosed with a disease listed in 12VAC5-71-30 D.

"Unsatisfactory specimen" means a newborn dried-blood-spot screening specimen that is inadequate for performing an accurate analysis.

"Virginia Genetics Advisory Committee" means a formal group that advises the department on issues pertaining to access to clinical genetics services across the Commonwealth and the provision of genetic awareness, quality services, and education for consumers and providers.

"Virginia Newborn Screening System" means a coordinated and comprehensive group of services, including education, screening, follow up, diagnosis, treatment and management, and program evaluation, managed by the department's Virginia Newborn Screening Program and Virginia Early Hearing Detection and Intervention Program for safeguarding the health of children born in Virginia.

"Virginia Sickle Cell Awareness Program" means a statewide program for the education and screening of individuals for the disease of sickle cell anemia or the sickle cell trait and for such other genetically related hemoglobinopathies.

12VAC5-71-30. Core panel of heritable disorders and genetic diseases.

A. The Virginia Newborn Screening System, which includes the Virginia Newborn Screening Program ~~and~~, the Virginia Early Hearing Detection and Intervention Program, and Virginia critical congenital heart disease screening, shall ensure that the core panel of heritable disorders and genetic diseases for which newborn screening is conducted is consistent with but not necessarily identical to the U.S. Department of Health and Human Services Secretary's Recommended Uniform Screening Panel.

B. The department shall review, at least biennially, national recommendations and guidelines and may propose changes to the core panel of heritable disorders and genetic diseases for which newborn dried-blood-spot screening tests are conducted.

C. The Virginia Genetics Advisory Committee may be consulted and provide advice to the commissioner on proposed changes to the core panel of heritable disorders and genetic diseases for which newborn dried-blood-spot screening tests are conducted.

D. Infants under six months of age who are born in Virginia shall be screened in accordance with the provisions set forth in this chapter for the following heritable disorders and genetic diseases, which are identified through newborn dried-blood-spot screening tests:

1. Argininosuccinic aciduria (ASA);

2. Beta-Ketothiolase deficiency (BKT);

3. Biotinidase deficiency (BIOT);

4. Carnitine uptake defect (CUD);

5. Classical galactosemia (galactose-1-phosphate uridyltransferase deficiency) (GALT);

6. Citrullinemia type I (CIT-I);

7. Congenital adrenal hyperplasia (CAH);

8. Cystic fibrosis (CF);

9. Glutaric acidemia type I (GA I);

10. Hb S beta-thalassemia (Hb F,S,A);

11. Hb SC-disease (Hb F,S,C);

12. Hb SS-disease (sickle cell anemia) (Hb F, S);

13. Homocystinuria (HCY);

14. Isovaleric acidemia (IVA);

15. Long chain L-3-Hydroxy acyl-CoA dehydrogenase deficiency (LCHAD);

16. Maple syrup urine disease (MSUD);

17. Medium-chain acyl-CoA dehydrogenase deficiency (MCAD);

18. Methylmalonic acidemia (Methylmalonyl-CoA mutase deficiency) (MUT);

19. Methylmalonic acidemia (Adenosylcobalamin synthesis deficiency) (CBL A, CBL B);

20. Multiple carboxylase deficiency (MCD);

21. Phenylketonuria (PKU);

22. Primary congenital hypothyroidism (CH);

23. Propionic acidemia (PROP);

24. Severe combined immunodeficiency (SCID);

25. Tyrosinemia type I (TYR I);

26. Trifunctional protein deficiency (TFP);

27. Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD);

28. 3-hydroxy 3-methyl glutaric aciduria (HMG); and

29. 3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC).

E. Infants born in Virginia shall be screened for hearing loss in accordance with provisions set forth in §§ 32.1-64.1 and 32.1-64.2 of the Code of Virginia and as governed by 12VAC5-80.

F. Newborns born in Virginia shall be screened for critical congenital heart disease in accordance with provisions set forth in §§ 32.1-65.1 and 32.1-67 of the Code of Virginia and as governed by 12VAC5-71-210 through 12VAC5-71-260.

12VAC5-71-150. Responsibilities of the Care Connection for Children network.

A. The Care Connection for Children network shall provide the following services:

1. Care coordination services for residents of the Commonwealth who are diagnosed with selected heritable disorders ~~or,~~ genetic diseases, or critical congenital heart disease and are referred to the network by the Virginia Newborn Screening Program.

2. Other network services for eligible individuals in accordance with ~~the~~ § 32.1-77 of the Code of Virginia and applicable regulations.

B. The Care Connection for Children network shall provide data as needed by the department's newborn screening program.

12VAC5-71-210. Critical congenital heart disease screening protocols.

A. Hospitals shall develop protocols for critical congenital heart disease screening [(i)] in accordance with [~~this section,]~~ 12VAC5-71-220 through 12VAC5-71-260 [~~,~~ ;] and [(ii) modeled after] national recommendations from the American Academy of Pediatrics [regarding CCHD, such as those specified in Strategies for Implementing Screening

for Critical Congenital Heart Disease (Kemper et. al. Pediatrics; 2011; 128;e1259) and Implementing Recommended Screening for Critical Congenital Heart Disease (Martin et al. Pediatrics; 2013;132;1) and subsequent revisions/editions] .

B. Hospitals shall develop protocols for the physical evaluation by licensed practitioners of newborns with abnormal screening results.

C. Hospitals shall develop protocols for the referral of newborns with abnormal screening results, if needed, after evaluation.

12VAC5-71-220. Critical congenital heart disease screening.

A. A licensed practitioner shall perform the CCHD screening.

B. Except as specified in subsection C of this section and 12VAC5-71-260, CCHD screening shall be performed on every newborn in the birth hospital between 24 and 48 hours of life, or if the newborn is discharged from the hospital before reaching 24 hours of life, the CCHD screening shall be performed as late as practical before discharge.

C. If CCHD screening is not indicated, the reason shall be documented in the newborn's medical record. The reasons include but are not limited to:

1. The newborn's current clinical evaluation has included an echocardiogram that ruled out CCHD;

2. The newborn has confirmed CCHD; [~~or~~]

3. The newborn is under the care of a specialty level or subspecialty level nursery [~~,~~ or;]

[4. The parent or guardian refuses CCHD screening on the basis of religious practices or tenets pursuant to 12VAC5-71-260.]

D. Hospitals shall develop protocols for screening newborns in specialty level nurseries and subspecialty level nurseries.

12VAC5-71-230. Critical congenital heart disease screening results.

A. Recording results.

1. All CCHD screening results shall be recorded in the newborn's medical record.

2. All CCHD screening results shall be entered into the electronic birth certificate system with the following information:

a. CCHD screening completed, CCHD pass or fail, and pulse oximetry values; or

b. Not screened pursuant to 12VAC5-71-220 C.

B. Abnormal screening results.

1. Abnormal screening results shall be reported by the authorized health care provider who conducted the screening to the attending physician or his designee [immediately].

2. A newborn shall be evaluated by an attending physician or his designee according to the timeframes within the hospital protocol developed in accordance with 12VAC5-71-210.

3. A newborn shall not be discharged from care until:

a. A cause for the abnormal screening result has been determined and a plan is in place for immediate evaluation at another medical facility; or

b. An echocardiogram has been performed and read, and an appropriate clinical plan has been developed.

4. Any diagnosis arising from abnormal screening results shall be entered into the electronic birth certificate system.

5. The attending physician or his designee shall provide notification of abnormal results and any diagnoses to the newborn's parent or guardian and to the primary care provider in charge of the newborn's care after the newborn leaves the hospital.

12VAC5-71-240. Referral for care coordination.

A. For any person diagnosed under 12VAC5-71-210 through 12VAC5-71-250, the chief administrative officer of every hospital, as defined in § 32.1-123 of the Code of Virginia, shall make or cause to be made a report to the commissioner in accordance with § 32.1-69.1 of the Code of Virginia.

B. Upon receiving the notification described in subsection A of this section, the Newborn Screening Program at the Virginia Department of Health shall refer the newborn's parent or guardian to the Care Connection for Children network for care coordination services.

12VAC5-71-250. Congenital heart disease screening records.

A. The screening of newborns pursuant to this chapter is a population-based public health surveillance program as defined by the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191; 110 Stat. 2033).

B. Upon request, a hospital shall make available to the Virginia Congenital Anomalies Reporting and Education System (VaCARES):

1. Medical records;

2. Records of laboratory tests; and

3. Any other information that VaCARES considers necessary to:

a. Determine final outcomes of abnormal CCHD screening results; or

b. Evaluate CCHD screening activities in the Commonwealth, including performance of follow-up evaluations and diagnostic tests, initiation of treatment when necessary, and surveillance of the accuracy and efficacy of the screening.

C. Information that the Virginia Department of Health receives under this section is confidential and may only be used or disclosed:

1. For research and collective statistical purposes pursuant to § 32.1-67.1 of the Code of Virginia;

2. For state or federally mandated statistical reports;

3. To ensure that the information received by the Virginia Department of Health is accurate and reliable; or

4. For reporting to the Virginia Congenital Anomalies Reporting and Education System pursuant to § 32.1-69.1 of the Code of Virginia and 12VAC5-191-280. The Newborn Screening Program shall refer the newborn's parent or guardian to the Care Connection for Children network for care coordination services.

D. The hospital administrator shall ensure that CCHD screening is included in the perinatal quality assurance program and provide the results of the quality improvement program to the Virginia Department of Health upon request.

12VAC5-71-260. Parent or guardian refusal for screening.

A. In the instance of parent or guardian refusal of the CCHD screening based on religious practices or tenets, the parent or guardian refusal shall be documented on a refusal form provided by the Virginia Department of Health and made a part of the newborn's medical record.

B. The administrator of the hospital shall ensure that the Newborn Screening Program at the Virginia Department of Health is notified in writing of the parent or guardian refusal within five days of the newborn's birth.

FORMS (12VAC5-71)

Notification of Parental Refusal of Dried-Blood-Spot and Critical Congenital Heart Disease Screening ([~~undated~~April 2015])

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-71)

Levels of Neonatal Care, Policy Statement from Committee on Fetus and Newborn, American Academy of Pediatrics, August 27, 2012

12VAC5-191-260. Scope and content of the Virginia Newborn Screening System.

A. The Virginia Newborn Screening System consists of ~~two~~ three components: (i) Virginia Newborn Screening Services ~~and~~, (ii) Virginia Early Hearing Detection and Intervention Program, and (iii) Virginia critical congenital heart disease screening.

B. Virginia Newborn Screening Services.

1. Mission. The Virginia Newborn Screening Services prevents ~~mental retardation~~ intellectual disability, permanent disability, or death through early identification and treatment of infants who are affected by selected inherited disorders.

2. Scope of services. The Virginia Newborn Screening Services provides a coordinated and comprehensive system of services to assure that all infants receive a screening test after birth for selected inherited metabolic, endocrine, and hematological disorders as defined in Regulations Governing ~~the~~ Virginia Newborn Screening ~~and Treatment Program~~ Services, ~~12VAC5-70~~ 12VAC5-71.

These population-based, direct, and enabling services are provided through:

a. Biochemical dried bloodspot screening tests.

b. Follow up of abnormal results.

c. Diagnosis.

d. Education to health professionals and families.

e. Expert consultation on abnormal results, diagnostic testing, and medical and dietary management for health professionals.

Medical and dietary management is provided for the diagnosed cases and includes assistance in accessing specialty medical services and referral to Care Connection for Children.

The screening and management for specified diseases are governed by Regulations Governing ~~the~~ Virginia Newborn Screening ~~and Treatment Program~~ Services, ~~12VAC5-70~~ 12VAC5-71.

3. Criteria to receive Virginia Newborn Screening Services. All infants born in the Commonwealth are eligible for the screening test for selected inherited disorders.

4. Goal. The Title V national performance measures, as required by the federal Government Performance and Results Act ~~(GPRA Pub. L.~~ (Public Law 103-62), are used to establish the program goals. The following goal shall change as needed to be consistent with the Title V national performance measures:

All infants will receive appropriate newborn bloodspot screening, follow up testing, and referral to services.

C. Virginia Early Hearing Detection and Intervention Program.

1. Mission. The Virginia Early Hearing Detection and Intervention Program promotes early detection of and intervention for infants with congenital hearing loss to maximize linguistic and communicative competence and literacy development.

2. Scope of services. The Virginia Early Hearing Detection and Intervention Program provides services to assure that all infants receive a hearing screening after birth, that infants needing further testing are referred to appropriate facilities, that families have the information that they need to make decisions for their children, and that infants and young children diagnosed with a hearing loss receive appropriate and timely intervention services. These population-based and enabling services are provided through:

a. Technical assistance and education to new parents.

b. Collaboration with physicians and primary care providers.

c. Technical assistance and education to birthing facilities and those persons performing home births.

d. Collaboration with audiologists.

e. Education to health professionals and general public.

Once diagnosed, the infants are referred to early intervention services. The screening and management for hearing loss are governed by the regulation, Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring System, 12VAC5-80.

3. Criteria to receive services from the Virginia Early Hearing Detection and Intervention Program.

a. All infants born in the Commonwealth are eligible for the hearing screening.

b. All infants who are residents of the Commonwealth and their families are eligible for the Virginia Early Hearing Detection and Intervention Program.

4. Goals. The Title V national performance measures, as required by the federal Government Performance and Results Act ~~(GPRA Pub. L.~~ (Public Law 103-62), are used to establish the program goals. The following goals shall change as needed to be consistent with the Title V national performance measures:

All infants will receive screening for hearing loss no later than one month of age, achieve identification of congenital hearing loss by three months of age, and enroll in appropriate intervention by six months of age.

D. Virginia critical congenital heart disease screening.

1. Mission. Virginia critical congenital heart disease screening promotes early detection of and intervention for newborns with critical congenital heart disease to maximize positive health outcomes and help prevent disability and death early in life.

2. Scope of services. Newborns receive a critical congenital heart disease screening 24 to 48 hours after birth in a hospital with a newborn nursery, as provided in §§ 32.1-67 and 32.1-69.1 of the Code of Virginia and the regulations governing critical congenital heart disease screening (12VAC5-71-210 through 12VAC5-71-260). These population-based, direct, and enabling services are provided through:

a. Critical congenital heart disease screening tests using pulse oximetry or other screening technology as defined in 12VAC5-71-10;

b. Hospital reporting of test results pursuant to § 32.1-69.1 of the Code of Virginia and 12VAC5-191-280; and

c. Follow-up, referral processes, and services, as appropriate, through Care Connection for Children.

3. The screening and management for newborn critical congenital heart disease are governed by the regulations governing critical congenital heart disease screening (12VAC5-71-210 through 12VAC5-71-260).

4. Criteria to receive critical congenital heart disease screening. Except as specified in 12VAC5-71-220 C and 12VAC5-71-260, all newborns born in the Commonwealth in a hospital with a newborn nursery shall receive the screening test for critical congenital heart disease 24 to 48 hours after birth using pulse oximetry or other screening technology.

5. Goal. Except as specified in 12VAC5-71-220 C and 12VAC5-71-260, all newborns born in the Commonwealth in a hospital with a newborn nursery shall receive appropriate critical congenital heart disease screening 24 to 48 hours after birth.

COMMONWEALTH of VIRGINIA
Department of Health
Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER
P O BOX 2448
RICHMOND, VA 23218
TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: March 1, 2016

TO: Virginia State Board of Health

FROM: Marissa J. Levine, MD, MPH, FAAFP
State Health Commissioner

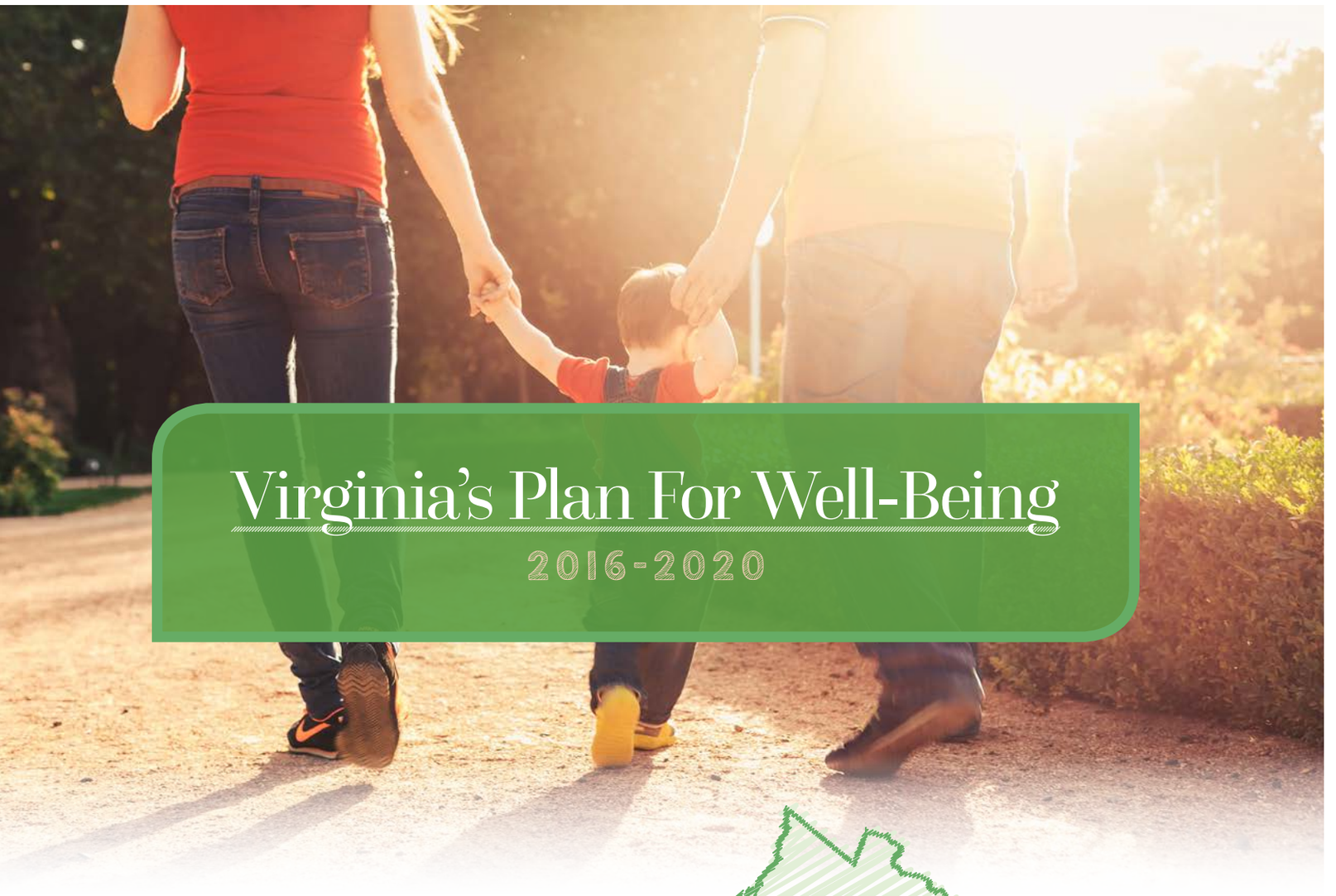
SUBJECT: Virginia Department of Health Annual Report

Enclosed for your review is the Annual Report of the Virginia Department of Health (Report), as set forth by Virginia Code § 32.1-14, titled *Virginia's Plan for Well-Being* (Plan).

Annually, the Board of Health is required to submit a report to the Governor and General Assembly that describes the status of three primary indicators: vital records and health statistics; analysis and summary of health care issues affecting the citizens of Virginia; and the health status and conditions of minority populations in the state. The Plan is a call-to-action for Virginians to create and sustain conditions that support health and well-being. It is a companion plan to Virginia's 2016 State Innovation Model Health Improvement Plan that calls for accountable care communities across the state to achieve the triple aim in health care: improving health care quality, improving the health of populations, and reducing the per capita cost of health care.

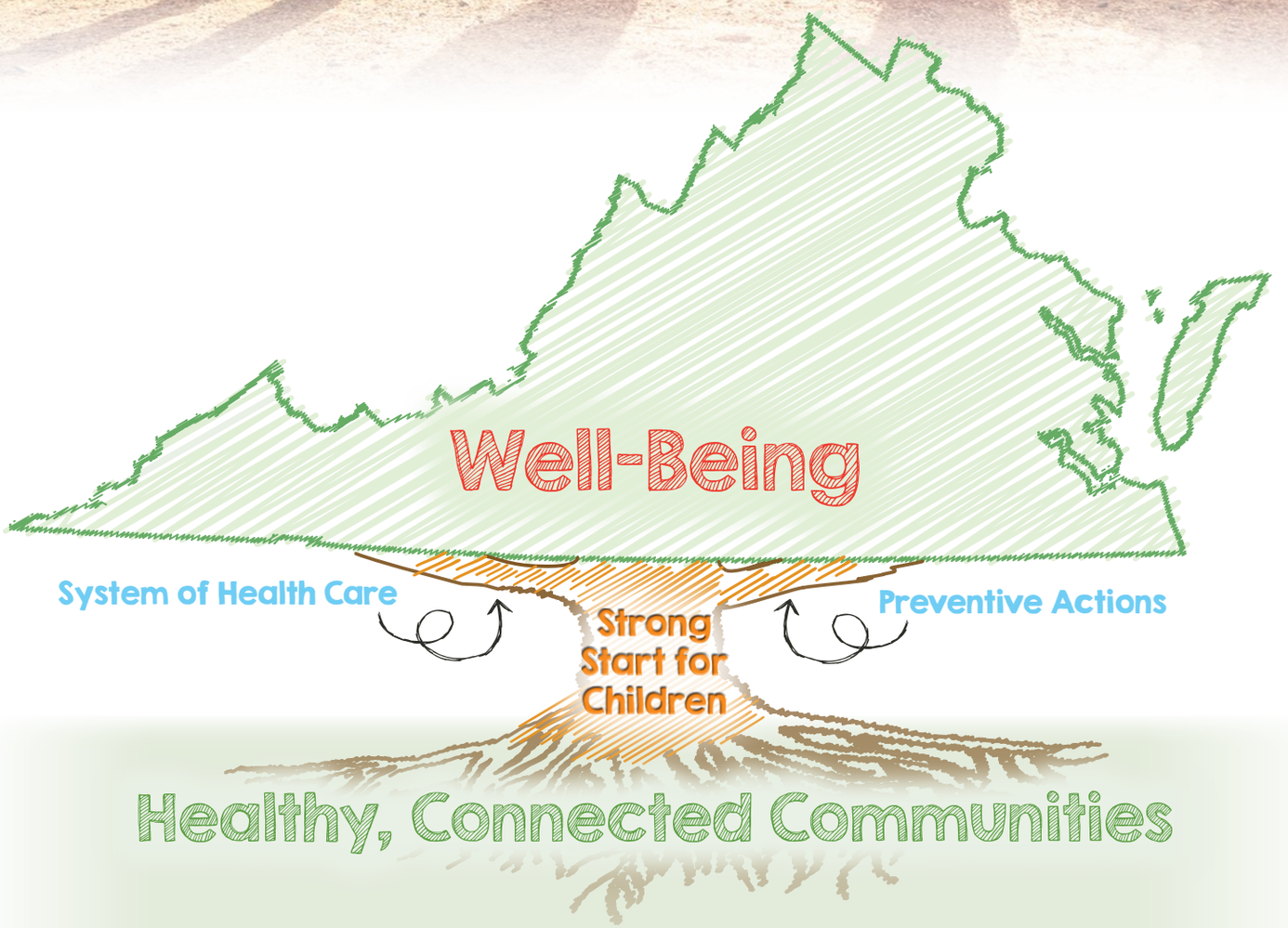
The Plan casts a broad vision of "well-being for all Virginians" by articulating four primary aims: creating healthy, connected communities; providing a strong start for our children; taking preventive actions to promote a healthy, long life; and ensuring we have a strong system of health care across the Commonwealth.

The Board of Health is requested to approve the Report at its March 17, 2016 meeting. Should the Board of Health approve the Report, it will be submitted to the Governor of Virginia and members of the General Assembly.



Virginia's Plan For Well-Being

2016-2020



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VISION: WELL-BEING FOR ALL VIRGINIANS

Virginia's Plan for Well-Being (The Plan) is a call to action for Virginians to create and sustain conditions that support health and well-being. Right now, in Virginia, many local communities are coming together to improve health. Communities, stakeholders, and partners can use this plan to build on work being done to assure clarity of effort and align scarce resources. The Plan lays out 13 priority goals that address issues significantly impacting the health and well-being of the people of Virginia. It provides a framework to guide the development of projects, programs, and policies to advance Virginians' health. From these goals, communities can choose one or two that represent a priority to them and around which they can focus efforts in the short term. The strategies in The Plan have been shown to be promising or best practices. The Plan also identifies some of the key community partners needed to achieve results.

Virginia's Plan for Well-Being is a companion plan to *Virginia's 2016 State Innovation Model Health Improvement Plan*, which calls for Accountable Care Communities in Virginia to achieve the triple aim in health care: improving health care quality; improving the health of populations; and reducing the per capita cost of health care. *The Virginia Center for Health Innovation* and the *Virginia Department of Health* are committed to tracking the progress of Virginia's health improvement and to annually report on specific measures identified in the two plans. Using population health data to evaluate our progress can help Virginians assess whether our systems and strategies are effective and can guide us to change course where needed.

Achieving population health improvement requires alignment, clarity and intentionality. Alignment includes coordination and collaboration of all sectors of the community: government, health care, education, businesses, community organizations including the faith community, and the public. Clarity refers to focused effort on issues that matter to people with corresponding measurable outcomes. Intentionality refers to designing our communities, policies and processes to specifically lead to improved outcomes in well-being, while avoiding unintended unhealthy outcomes. Virginians working together in alignment, with clarity and with a shared intention to improve the health of all Virginians provides the basis for success. Please join us in this effort - there is a role for everyone as we move Virginia toward becoming the healthiest state in the nation.

Marissa Levine, MD, MPH
Virginia State Health Commissioner

William Murray, PhD
Chair, VCHI Board of Directors
Managing Director of Public Policy and Senior Advisor for Regulatory and State and Local Affairs, Dominion Resources Services, Inc.

Nancy Howell Agee
Past Chair, VCHI Board of Directors
President and CEO of Carilion Clinic

VISION: WELL-BEING FOR ALL VIRGINIANS

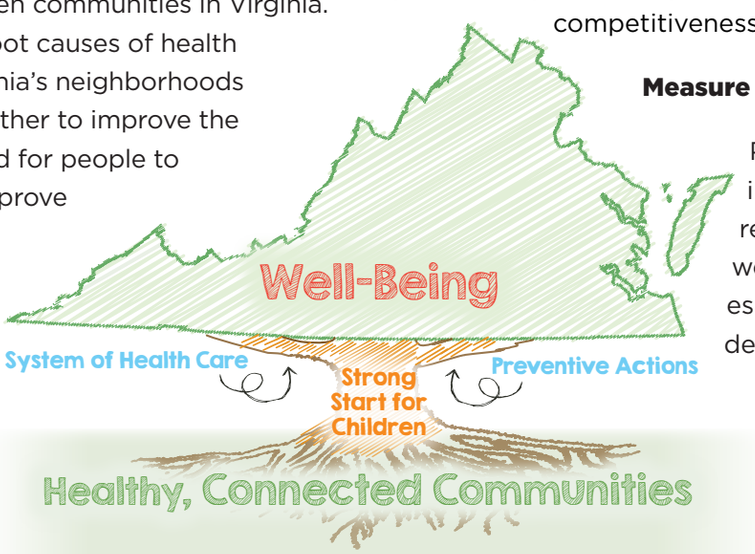
VIRGINIANS LIVE LONGER, HEALTHIER lives today than ever before. Medical care is only part of the reason. Health begins where Virginians live, work, and play. Virginia's economy paves the way for its communities to create conditions for people to be healthy. Disinfecting drinking water, vaccinating people, controlling mosquitos and rodents, and tracking contagious illnesses keep once common diseases like measles and polio at bay. Passing laws to make transportation safer and to protect workers reduces injuries.

The definition of well-being is "a state characterized by health, happiness, and prosperity". It is valuable as a population outcome measure because it reflects how Virginians perceive their life is going. Well-being is dependent on having good physical and emotional health. Social circumstances, financial resources, and community factors also play important roles.

The opportunity for health begins with our families, neighborhoods, schools and jobs. There are striking differences in health within and between communities in Virginia. Uncovering the root causes of health inequities in Virginia's neighborhoods and working together to improve the conditions needed for people to be healthy will improve well-being for all Virginians.

This begins with the community coming together to review local and state level data that reflect the health of the community. Examining trends and variation among subsets of the population can assist the state and communities in analyzing health outcomes and identifying priority issues to address.

Virginia's Plan for Well-Being lays out the foundation for giving everyone a chance to live a healthy life: (1) Factoring health into policy decisions related to education, employment, housing, transportation, land use, economic development, and public safety; (2) Investing in the health, education, and development of Virginia's children; (3) Promoting a culture of health through preventive actions; and (4) Creating a connected system of health care. The plan highlights specific goals and strategies on which communities can focus so the state can make measureable health improvement by 2020. *Virginia's Plan for Well-Being* is a call to action for all Virginians to work together to make Virginia the healthiest state in the nation. Improving well-being can lower health care costs and increase productivity, ultimately enhancing Virginia's competitiveness and resiliency.



Measure of Success

Percent of adults in Virginia who report positive well-being increases (metric under development)

VIRGINIAN'S PLAN FOR WELL-BEING MEASURES

VISION

By 2020, the percent of adults who report positive well-being increases (metric under development)

AIM 1 » Healthy, Connected Communities

Goal 1.1: VIRGINIA'S FAMILIES MAINTAIN ECONOMIC STABILITY

By 2020, the percent of Virginia high school graduates enrolled in an institute of higher education within 16 months after graduation increases from 70.9% to 75.0%

By 2020, the percent of cost-burdened households in Virginia (more than 30% of monthly income spent on housing costs) decreases from 31.4% to 29.0%

By 2020, the Consumer Opportunity Index score in Virginia increases from 81.8% to 83.7%

By 2020, the Economic Opportunity Index Score in Virginia increases from 70.7% to 73.7%

Goal 1.2: VIRGINIA'S COMMUNITIES COLLABORATE TO IMPROVE THE POPULATION'S HEALTH

By 2020, the percent of Virginia health planning districts that have established an on-going collaborative community health planning process increases from 43% to 100%

AIM 2 » Strong Start for Children

Goal 2.1: VIRGINIANS PLAN THEIR PREGNANCIES

By 2020, Virginia's teen pregnancy rate decreases from 27.9 to 25.1 pregnancies per 1,000 females ages 15 to 19 years

Goal 2.2: VIRGINIA'S CHILDREN ARE PREPARED TO SUCCEED IN KINDERGARTEN

By 2020, the percent of children in Virginia who do not meet the PALS K benchmarks in the fall of kindergarten and require literacy interventions decreases from 12.7% to 12.2%

By 2020, the percent of third graders in Virginia who pass the Standards of Learning third grade reading assessment increases from 69% to 80%

Goal 2.3: THE RACIAL DISPARITY IN VIRGINIA'S INFANT MORTALITY RATE IS ELIMINATED

By 2020, Virginia's Black Infant Mortality Rate equals the White Infant Mortality Rate

AIM 3 » Preventive Actions

Goal 3.1: VIRGINIANS FOLLOW A HEALTHY DIET AND LIVE ACTIVELY

By 2020, the percent of Virginia adults who did not participate in any physical activity during the past 30 days decreases from 23.5% to 20.0%

By 2020, the percent of Virginia adults who are overweight or obese decreases from 64.7% to 63.0%

By 2020, the percent of Virginia households that are food insecure for some part of the year decreases from 11.9% to 10.0%

Goal 3.2: VIRGINIA PREVENTS NICOTINE DEPENDENCY

By 2020, the percent of adults aged 18 years and older in Virginia who report using tobacco decreases from 21.9% to 12.0%

VIRGINIAN'S PLAN FOR WELL-BEING MEASURES

Goal 3.3: VIRGINIANS ARE PROTECTED AGAINST VACCINE-PREVENTABLE DISEASES

By 2020, the percent of adults in Virginia who receive an annual influenza vaccine increases from 48.2% to 70%

By 2020, the percent of girls aged 13-17 in Virginia who receive three doses of HPV vaccine increases from 35.9% to 80%

By 2020, the percent of boys aged 13-17 in Virginia who receive three doses of HPV vaccine increases from 22.5% to 80%

Goal 3.4: CANCERS ARE PREVENTED OR DIAGNOSED AT THE EARLIEST STAGE POSSIBLE

By 2020, the percent of adults aged 50 to 75 years in Virginia who receive colorectal cancer screening increases from 69.1% to 85.0%

Goal 3.5: VIRGINIANS HAVE LIFE-LONG WELLNESS

By 2020, the average years of disability-free life expectancy for Virginians increases from 66.1 years to 67.3 years

By 2020, the percent of adults in Virginia who report adverse childhood experiences decreases (metric under development)

AIM 4 » System of Health Care

Goal 4.1: VIRGINIA HAS A STRONG PRIMARY CARE SYSTEM LINKED TO BEHAVIORAL HEALTH CARE, ORAL HEALTH CARE, AND COMMUNITY SUPPORT SYSTEMS

By 2020, the percent of adults in Virginia who have a regular health care provider increases from 69.3% to 85.0%

By 2020, the rate of avoidable hospital stays for ambulatory care sensitive conditions in Virginia decreases from 1,294 to 1,100 per 100,000 persons

By 2020, the rate of avoidable deaths from heart disease, stroke, or hypertensive disease in Virginia decreases from 46.76 to 40.00 per 100,000 persons

By 2020, the rate of adult mental health and substance use disorder hospitalizations in Virginia decreases from 668.5 to 635.1 per 100,000 adults

By 2020, the percent of adults in Virginia who report having one or more days of poor health that kept them from doing their usual activities decreases from 19.5% to 18.0%

Goal 4.2: VIRGINIA'S HEALTH IT SYSTEM CONNECTS PEOPLE, SERVICES, AND INFORMATION TO SUPPORT OPTIMAL HEALTH OUTCOMES

By 2020, the percent of health-care providers in Virginia who have implemented a certified electronic health record increases from 70.6% to 90.0%

By 2020, the number of entities in Virginia connected through Connect Virginia HIE Inc., the electronic health information exchange, and the national e-Health Exchange increases from 3,800 to 7,600

By 2020, the number of Virginia's local health districts that have electronic health records and connect to community providers through Connect Virginia increases from 0 to 35

Goal 4.3: HEALTH CARE-ASSOCIATED INFECTIONS ARE PREVENTED AND CONTROLLED IN VIRGINIA

By 2020, the percentage of hospitals in Virginia meeting the state goal for prevention of hospital-onset *Clostridium difficile* infections increases from 36% to 100%

AIM I: HEALTHY, CONNECTED COMMUNITIES

WHERE VIRGINIANS LIVE AFFECTS their health. Feeling safe, supported, and connected to family, neighborhood, and the community is critical for well-being. Place matters: the conditions in which people live, work, and play shape their health. For example, having safe, clean parks provides Virginians with recreational opportunities. This supports active living, which results in improved physical and emotional health. Conditions that foster well-being include:

- Safe, walkable neighborhoods
- Accessible public transportation
- Access to health care
- Employment opportunities with safe working conditions
- Quality educational systems
- Spaces for social gatherings and physical activity
- Clean air and water

Improving environmental and social conditions at the neighborhood level provides greater opportunity for all Virginians to be healthy. Communities can improve health by considering implications to health when developing policies and systems related to education, employment, housing, transportation, land use, economic development, and public safety.

The Virginia Department of Health has developed a Health Opportunity Index (HOI) to help communities understand the factors that lead to health so they can work to improve health outcomes for everyone. The HOI is a composite measure of the "social determinants of health", factors that relate to a community's well-being and the health status of its population. It is comprised of 13 indices in four categories:

Environment: (1) Air quality; (2) Population density; (3) Population churning; (4) Walkability

Consumer Opportunity: (1) Affordability; (2) Education; (3) Food accessibility; (4) Material deprivation

Economic Opportunity: (1) Employment; (2) Income inequality; (3) Job participation

Wellness: (1) Segregation; (2) Access to care

The HOI is calibrated with life expectancy, disability-adjusted life expectancy, and low birth weight measures, and is strongly predictive of key health outcomes. The HOI provides communities with a tool to identify areas and populations that are most vulnerable, giving Virginia an opportunity to develop strategic, targeted approaches to improve health and well-being.

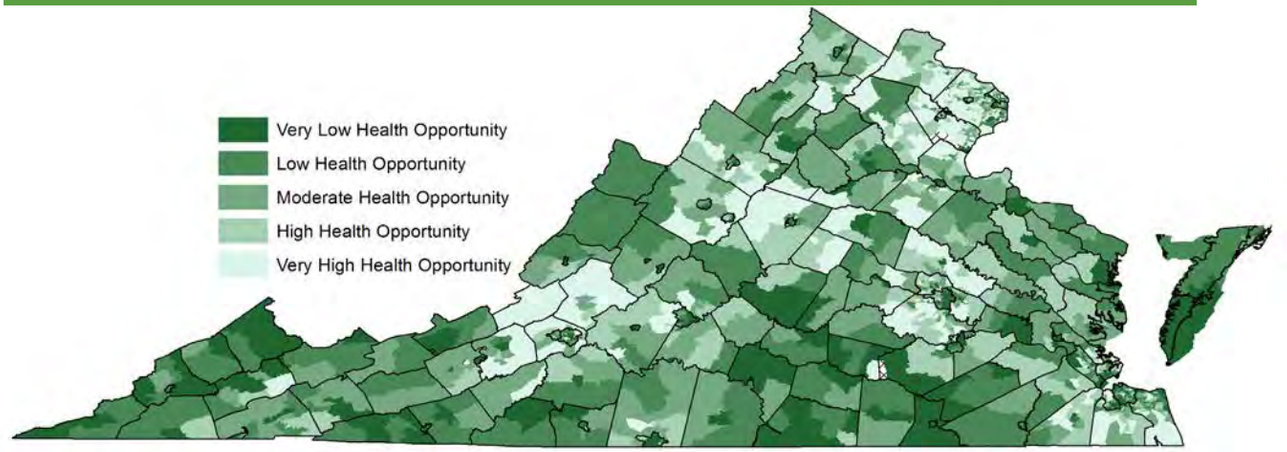
Foundational Goals for Creating Healthy, Connected Communities

- Virginians receive a quality education
- Virginians complete job training or college after high school
- Virginians live in housing they can afford
- **Virginia's families maintain economic stability**
- Virginians are socially engaged
- Virginians have access to clean air and water
- Virginians have access to safe food
- Virginians are prepared to respond to manmade and natural disasters
- Virginians have access to quality emergency medical services
- Virginians are protected from fires
- Virginians are protected from crime
- Virginia's public transportation systems provide access to and from geographically isolated areas
- Virginia businesses partner with the community to address environmental and social drivers of workforce health
- **Virginia's communities collaborate to improve the population's health**

During 2016-2020, Virginia is focusing attention on these foundational goals:

1.1 Virginia's families maintain economic stability

1.2 Virginia's communities collaborate to improve the population's health



Health Opportunity Index (HOI) – The HOI is a composite measure comprised of 13 indices that reflect a broad array of social determinants of health

AIM I: HEALTHY, CONNECTED COMMUNITIES
2020 FOCUS GOALS

GOAL 1.1: VIRGINIA'S FAMILIES MAINTAIN ECONOMIC STABILITY

Health and poverty are inextricably linked; ill health not only affects the poor disproportionately, it is also associated with lower income.1 Virginia is perennially one of the wealthiest states in the nation. Unfortunately, a wealth gap prevents some Virginians from experiencing equitable opportunities for optimal health and longevity. Reducing poverty and maintaining economic stability are vital to keeping all Virginians well. An education that prepares Virginians for today's job market provides increased opportunity for employment, which in turn improves access to stable housing, healthy food, transportation, and health care. Strategic investments in the physical and social infrastructure as well as investments in educational resources are important for sustained economic stability.

Strategies

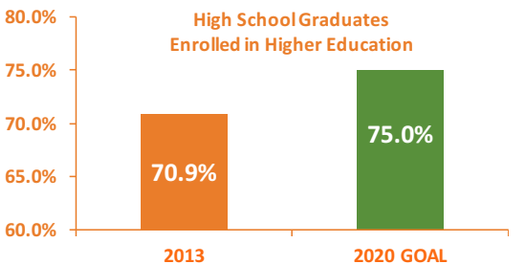
- Provide alternative pathways to graduation and post-secondary training for disconnected youth and those with special needs
- Develop and use early warning systems to prevent failure and help at-risk students

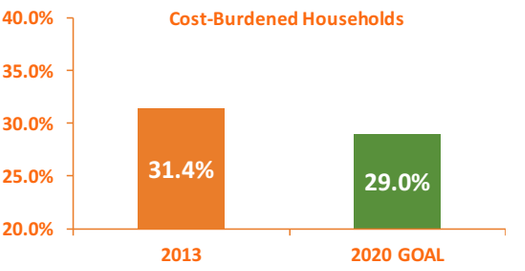
- Develop school policies to assess and address physical, social, and environmental health barriers that impede learning
- Expand training and work-linked learning opportunities for youth
- Support opportunities for mid-career retraining
- Build affordable housing, and rehabilitate existing affordable housing to accommodate low-income families

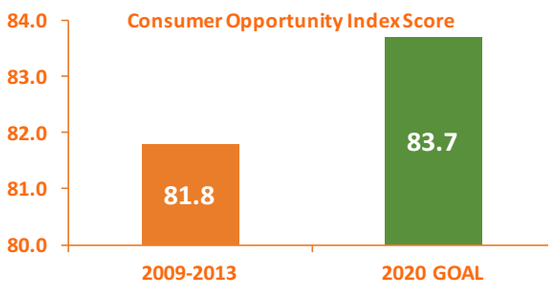
Key Community Partners

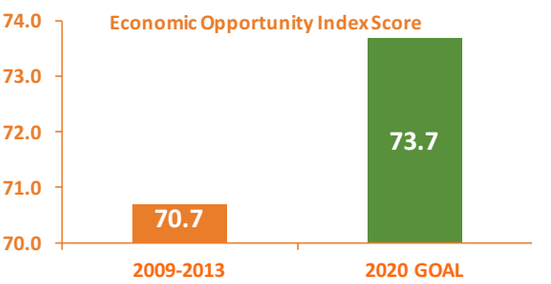
Community Organizations
Community Planners
Economic Development Agencies
Educators
Elected Officials
Employers
Families
Justice System

Measures of Success









AIM I: HEALTHY, CONNECTED COMMUNITIES
2020 FOCUS GOALS

Goal 1.2: VIRGINIA'S COMMUNITIES COLLABORATE TO IMPROVE THE POPULATION'S HEALTH

Adopting a collaborative community approach to health assessment and planning supports population-level health improvement. Both state and community-level assessments are valuable to identify opportunities to achieve and maintain well-being in the Commonwealth. This process involves bringing together people from many sectors of the community to review data; identify priorities; develop goals and measurable objectives; and recommend evidence-based policies, programs, and actions for the community to pursue. The assessments include social, economic, and environmental data, such as the number of mothers who did not graduate from high school, in addition to health outcome data, like the number of people who have lung cancer.

State and community health improvement plans can be a catalyst for empowering community action. They can be shared with elected officials, the health care community, governmental and community-based agencies, and the public. The information can foster the allocation of resources to areas that will maximize benefits to the collective health of the community.

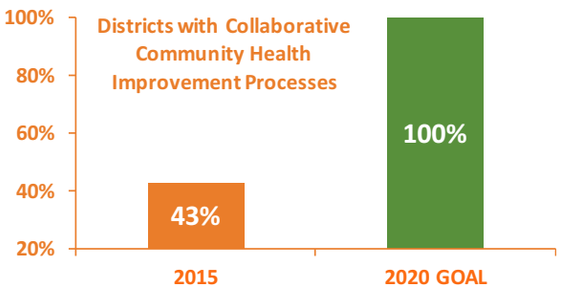
Strategies

- Establish collaborative health assessment and strategic health improvement planning processes throughout the Commonwealth that include public health, health care systems, and community partners
- Align health system community benefit programs with community health improvement plans
- Enhance data systems and public health information technology to collect, manage, track, analyze, and report state and county-level data for use in health assessments

Key Community Partners

Community Organizations
Educators
Elected Officials
Employers
Families
Health-Care Providers
Hospital Systems
Local Governments
Public
Public Health

Measure of Success



AIM 2: STRONG START FOR CHILDREN

A CHILD'S HEALTH IS AFFECTED BY biological influences, including nutrition, illness, and each parent's health, as well as environmental influences, including education and quality health and social services.[2] Compared to children without chronic health problems, children with chronic health problems have a greater risk of having poorer health outcomes and lower job status as adults.[3,4] Health-related factors affect school performance, and in turn academic success is associated with health outcomes during childhood and later in adulthood.[5] Investing in programs that lead to improved health for Virginia's children benefits everyone and reduces long-term costs to the Commonwealth.[6]

Foundational Goals for Giving Children a Strong Start

- **Virginians plan their pregnancies**
- Virginians are as healthy as possible before becoming pregnant
- Pregnant women in Virginia receive recommended prenatal care services
- Virginia mothers breastfeed
- Virginia parents practice positive parenting
- Virginia fathers are engaged in family planning, health, parenting, and child development-focused activities
- Virginia infants and children are not exposed to secondhand smoke
- **Virginia's children are prepared to succeed in kindergarten**
- Virginia's adolescents choose not to engage in behaviors that put their well-being at risk
- **The racial disparity in Virginia's infant mortality rate is eliminated**

During 2016-2020, Virginia is focusing attention on these foundational goals:

2.1 Virginians plan their pregnancies

2.2 Virginia's children are prepared to succeed in kindergarten

2.3 The racial disparity in Virginia's infant mortality rate is eliminated

AIM 2: STRONG START FOR CHILDREN

2020 FOCUS GOALS

Goal 2.1: VIRGINIANS PLAN THEIR PREGNANCIES

Comprehensive family planning and preconception health lead to improved birth outcomes, which are associated with better health and cognition as children mature. Family planning services include providing education and contraception. These services help families have children when they are financially, emotionally, and physically ready. Publicly-supported family planning services prevent an estimated 1.3 million unintended pregnancies a year in the United States. The trend toward having smaller families and waiting at least 24 months between pregnancies has contributed to better health of infants and children.[7] Preconception health services for females and males include health screenings, counseling, and clinical services that enable them to become as healthy as possible before pregnancy.[8]

Strategies

- Increase access to quality family planning services for all women of child-bearing age
- Expand evidence-based programs that promote healthy relationships

- Educate women and men about the effectiveness of contraceptive methods and increase access to the most effective methods
- Expand access to and use of preconception health services

Key Community Partners

Community Organizations

Faith-based Communities

Families

Federally Qualified Health Centers

Health-Care Providers

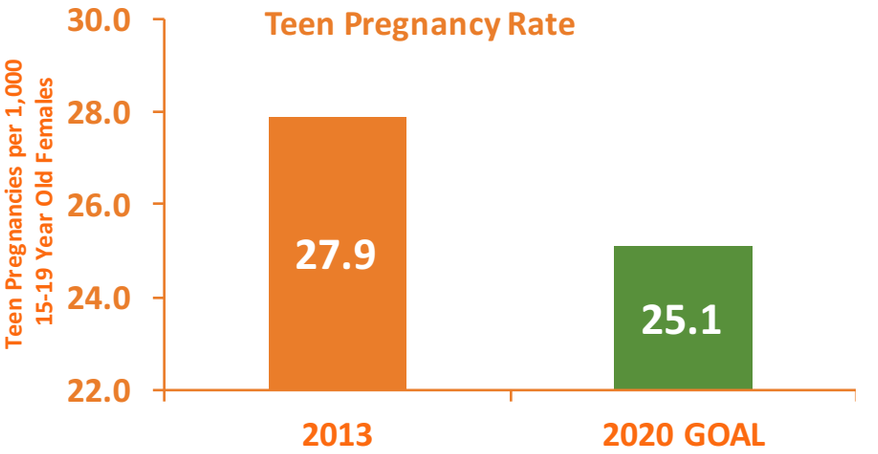
Health Insurers

Public Health

Schools

Social Services

Measure of Success



AIM 2: STRONG START FOR CHILDREN

2020 FOCUS GOALS

Goal 2.2: VIRGINIA'S CHILDREN ARE PREPARED TO SUCCEED IN KINDERGARTEN

Succeeding or failing in school affects a child's well-being, self-esteem, and motivation. Being developmentally ready to learn and participate in classroom activities not only sets the stage for the kindergarten year but can have lifelong influence on well-being. According to a report by the University of Virginia's Curry School of Education, one out of three children in Virginia is not prepared to succeed in literacy, math, self-regulation, and/or social skills at the beginning of kindergarten. The report finds that "children who enter kindergarten behind their peers rarely catch up; instead, the achievement gap widens over time."[9] Investing in programs to prepare children to succeed in school prevents them from falling behind and dropping out of high school.

Strategies

- Increase developmental screening for childhood milestones and delays
- Increase enrollment of three to five year-old children in early childhood education programs that include quality educational components that address literacy, numeracy, cognitive development, socio-emotional development, and motor skills
- Increase the number of providers and educators who screen for adverse childhood events (ACEs) and are trained in using a trauma-informed approach to care
- Expand programs that help families affected by ACEs, toxic stress, domestic violence, mental illness, and substance abuse create safe, stable, and nurturing environments
- Expand programs that teach positive parenting and help parents fully engage with their children in productive ways
- Increase opportunities for fathers to be engaged in programs and services for their children

Key Community Partners

Businesses

Childcare Providers

Community Organizations

Educators

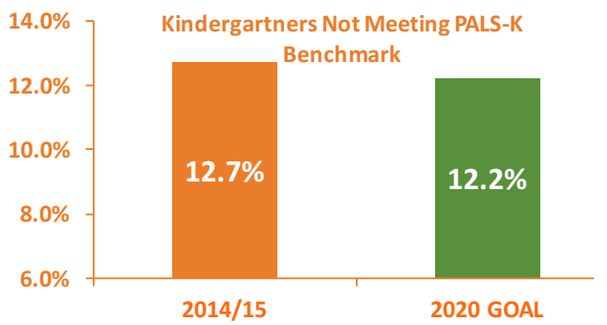
Families

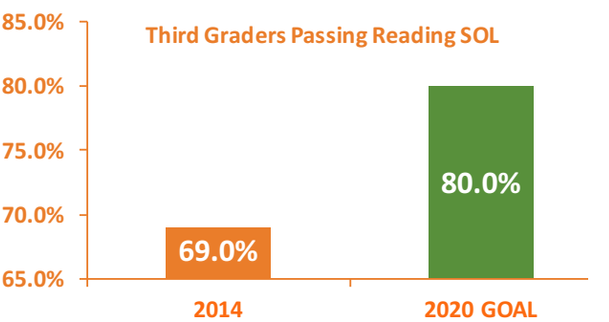
Health-Care Providers

Public Health

Social Services

Measures of Success





AIM 2: STRONG START FOR CHILDREN

2020 FOCUS GOALS

Goal 2.3: THE RACIAL DISPARITY IN VIRGINIA'S INFANT MORTALITY RATE IS ELIMINATED

The Commonwealth has made significant progress in helping its infants thrive; however, some communities have worse outcomes than others. If the rate at which black infants and white infants died were equal, Virginia would have the lowest infant mortality rate in the country. Giving everyone a chance to live a healthy life benefits not only those currently disadvantaged but the whole community. Closing this gap requires addressing the root causes of disparities throughout life. To achieve equity, all sectors of the community—from policy makers to grassroots community organizations to community members—must work together.

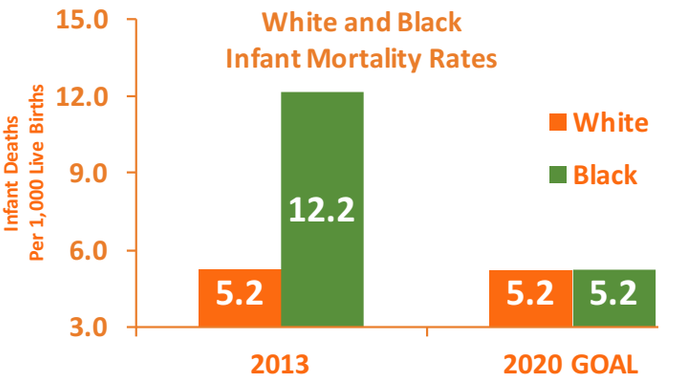
Strategies

- Form neighborhood collaboratives co-led by community members in under-resourced communities to identify obstacles and develop plans to address the root causes of health inequities
- Increase the number of providers who screen postpartum women for depression and provide or refer for treatment
- Eliminate early elective deliveries
- Expand outreach to pregnant women and increase the number of group prenatal care classes
- Implement policies that support women and their families in breastfeeding for at least six months
- Expand home visiting and family support programs

Key Community Partners

Community Organizations
Educators
Elected Officials
Families
Federally Qualified Health Centers
Health-Care Providers
Health Insurers
Hospital Association
Medical Societies
Mental Health Providers
Public Health
Social Services

Measure of Success



AIM 3: PREVENTIVE ACTIONS

A CULTURE OF HEALTH AND WELLNESS is built on preventive actions. Virginia can substantially decrease the burden of disease and reduce health care spending by creating conditions that lead to health. Communities, health care systems, and individuals all have a role to play. For example, reversing Virginia's high prevalence of obesity will require (1) community design and policies that promote healthy eating and active living; (2) clinical interventions and education; and (3) individual behavior modification.

Policy makers can create the conditions that support the healthy choice becoming the easy choice. Fluoridating drinking water, developing walkable communities, and prohibiting smoking in public buildings are actions that prevent disease.

Clinical interventions that promote health include vaccination, cancer screenings, treatment for high blood pressure, dental cleanings, and early identification and treatment of persons addicted to substances. According to the Centers for Disease Control and Prevention (CDC), Americans receive preventive health services "at about half the recommended rate".[10] This results in complex, advanced disease that is more costly to treat.

Personal behaviors that prevent disease include not using tobacco; eating appropriately-sized portions; daily dental flossing; practicing safe sex; exercising regularly; and taking medicines as prescribed.

Foundational Goals for Preventive Actions

- **Virginians follow a healthy diet and live actively**
- **Virginia prevents nicotine dependency**
- Virginia conducts comprehensive surveillance and investigation of diseases
- **Virginians are protected against vaccine-preventable diseases**
- Virginians are free from sexually transmitted infections
- Virginia prevents and controls animal diseases from spreading to people (for example, rabies and bird flu)

- In Virginia, injuries are prevented
- Virginians have good oral health
- Virginians have access to, can afford, and receive preventive clinical services
- **In Virginia, cancers are prevented or diagnosed at the earliest stage possible**
- **Virginians have lifelong wellness**

During 2016-2020, Virginia is focusing attention on these foundational goals:

3.1 Virginians follow a healthy diet and live actively

3.2 Virginia prevents nicotine dependency

3.3 Virginians are protected against vaccine-preventable diseases

3.4 In Virginia, cancers are prevented or diagnosed at the earliest stage possible

3.5 Virginians have lifelong wellness

AIM 3: PREVENTIVE ACTIONS

2020 FOCUS GOALS

Goal 3.1: VIRGINIANS FOLLOW A HEALTHY DIET AND LIVE ACTIVELY

Following a healthy diet and living actively have long-term health benefits. Maintaining a healthy weight is associated with improved quality of life and reduced risk of cardiovascular disease, diabetes, dementia, cancer, liver disease, and arthritis. Obesity results from a combination of factors: genetics; behavior; education; access to nutritious food; an environment that supports active living; and food marketing and promotion.[11]

A nutritious diet includes balancing the number of calories consumed with the number of calories the body uses. It is necessary for optimal growth and development of children.[12] Healthy eating is associated with improved thinking, memory, and mood among school children.[13] The inability to afford enough food for an active, healthy life is associated with poor health outcomes among children, adults, and the elderly.[14]

Living an active lifestyle supports wellness, improves mood, and reduces chronic disease. Among children, it alleviates depression, decreases body fat, creates stronger bones, and is even associated with better grades in school.[15] Among older adults, physical activity lowers the risk of falls, a leading cause of injury. Factors that positively contribute to physical activity levels include higher income, enjoyment of exercise, and social support from peers and family. Factors that discourage adequate physical activity include a low income, lack of time, rural residency, and obesity.

Policies can be created and neighborhoods can be designed to support healthy eating and active living. People make decisions based on their environment; for example, a person may choose not to take a walk because there are no sidewalks. Creating opportunities in the community, child care, school, and workplace settings can make it easier to engage in physical activity and eat a healthy diet.

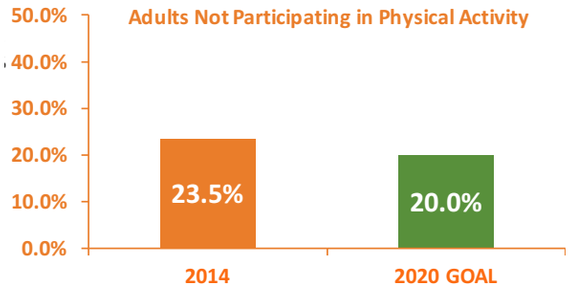
Key Community Partners

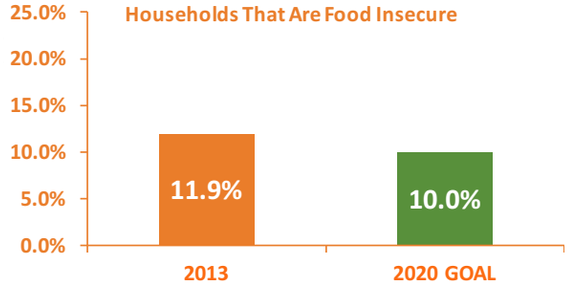
Businesses
Childcare Providers
Community Organizations
Community Planners
Economic Development Agencies
Educators
Farmers
Families
Health-Care Providers
Public Health

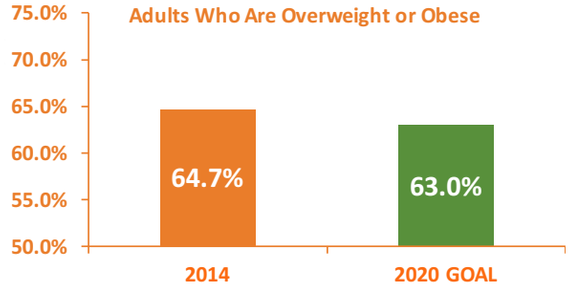
Strategies

- Integrate health planning into local and regional comprehensive planning
- Adopt community designs that support active living, including concentrated mixed use development and bicycle- and pedestrian-friendly communities
- Expand opportunities during and after school for children to get healthy meals and the recommended amount of daily physical activity
- Create parks, recreation facilities or open space in all neighborhoods
- Increase access to healthy and affordable foods in all neighborhoods
- Implement organizational and programmatic nutrition standards and policies
- Expand programs and services to eliminate childhood hunger
- Help people recognize and make healthy food and beverage choices
- Increase the number of evidence-based employee wellness programs

Measures of Success







AIM 3: PREVENTIVE ACTIONS

2020 FOCUS GOALS

Goal 3.2: VIRGINIA PREVENTS NICOTINE DEPENDENCY

According to the CDC, "tobacco use is the single most preventable cause of death and disease in the United States."[16] The Campaign for Tobacco Free Kids reports that health care costs in Virginia directly caused by smoking are $3.11 billion a year.[17] Smoking is associated with heart disease, stroke, chronic lung disease, diabetes, bone disease, and many types of cancer. Tobacco accounts for 30% of all cancer deaths. Secondhand smoke causes heart disease, stroke, and lung cancer. It affects the health of infants and children by increasing the risk for asthma attacks, respiratory and ear infections, and Sudden Infant Death Syndrome.[18, 19]

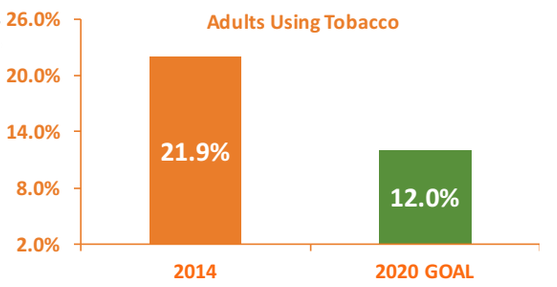
Key Community Partners

- Academic Partners
- Businesses
- Elected Officials
- Faith-based Communities
- Health-Care Providers
- Health Insurers
- Public Health
- School Districts

Strategies

- Establish smoke-free policies and social norms
- Promote tobacco cessation and support tobacco users in quitting
- Prevent initiation of tobacco use

Measure of Success



AIM 3: PREVENTIVE ACTIONS

2020 FOCUS GOALS

Goal 3.3: VIRGINIANS ARE PROTECTED AGAINST VACCINE-PREVENTABLE DISEASES

Virginians who receive their recommended vaccines protect themselves from illness and protect others by decreasing the spread of disease. Virginia benefits from high childhood immunization rates. However, in two other areas, it lags behind. While the percent of adults receiving an annual flu vaccine has increased, it is still below the national goal. The area of most concern, however, is a low rate of adolescent vaccinations that prevent meningococcal meningitis and cancers caused by the Human Papillomavirus (HPV).

Key Community Partners

Families

Federally Qualified Health Centers

Health-Care Providers

Hospital Systems

Health Insurers

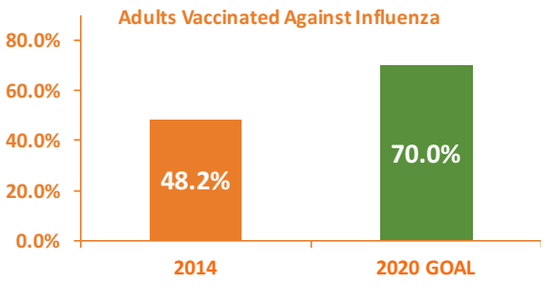
Medical Societies

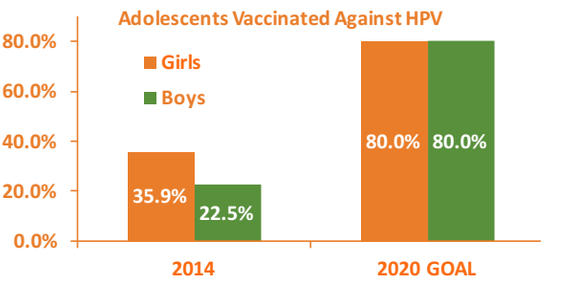
Public Health

Strategies

- Use patient registries to identify patients due for vaccination and send them reminders
- Evaluate data from the Vaccines for Children program and target outreach to providers who have the opportunity to improve vaccination rates
- Evaluate data from the Virginia Immunization Information System to assess immunization coverage and develop targeted interventions to address gaps
- Educate Virginians about the effectiveness of HPV vaccination in preventing HPV-associated cancers
- Increase the number of adolescents who receive well visits in patient-centered medical homes
- Establish policies to ensure health-care providers receive annual influenza vaccine

Measures of Success





AIM 3: PREVENTIVE ACTIONS

2020 FOCUS GOALS

Goal 3.4: CANCERS ARE PREVENTED OR DIAGNOSED AT THE EARLIEST STAGE POSSIBLE

Cancer is the leading cause of death for Virginians. It is caused by changes to the genes that lead to the uncontrolled growth of specific cells in the body. There are many types of cancer, and the risks associated with each type vary. Preventive actions can keep some cancers from developing. These include not using tobacco, minimizing alcohol consumption, and vaccination against HPV and Hepatitis B. In some cases, when cancer does form, it can be identified early through evidence-based screenings, resulting in better treatment options and outcomes.

Key Community Partners

Community Organizations

Employers

Families

Federally Qualified Health Centers

Health Care Providers

Health Insurers

Hospital Systems

Lay Health Workers

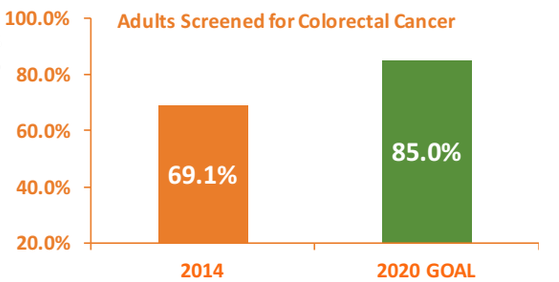
Medical Societies

Public Health

Strategies

- Increase tobacco prevention and cessation programs
- Increase percent of medical practices that implement evidence-based client reminder systems to increase recommended cancer screenings for patients
- Increase the number of providers, lay health advisors, and volunteers trained in health literacy to provide one-on-one education in medical, community, worksite, and household settings to support people in seeking recommended cancer screenings
- Implement evidence-based strategies to reduce structural barriers to cancer screenings
- Implement provider assessment and feedback interventions to increase cancer screenings

Measure of Success



AIM 3: PREVENTIVE ACTIONS

2020 FOCUS GOALS

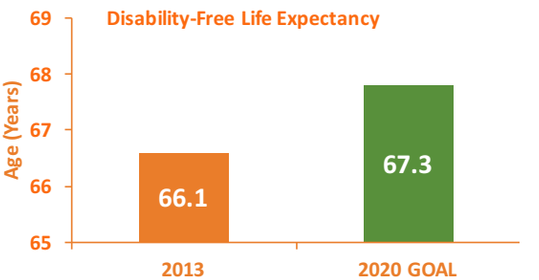
Goal 3.5: VIRGINIANS HAVE LIFE-LONG WELLNESS

Nearly one out of every eight Virginians today is 65 or older. In two decades, almost one in every five will be. Preventive actions and support systems can result in people living in their own home and community safely, independently, and comfortably, regardless of age, income, or ability level.

Strategies

- Encourage construction of safe, congregate and retirement housing for the aging population
- Increase access to internet usage for aging Virginians
- Increase the number of fitness and physical therapy facilities that promote senior fitness
- Develop a statewide senior falls prevention program
- Implement community-wide value-neutral programs to support Virginians in planning in advance for future healthcare choices

Measure of Success



AIM 4: SYSTEM OF HEALTH CARE

VIRGINIA IS HOME TO EXCELLENT providers and hospitals that deliver state-of-the-art health care services. However, like the rest of the United States, many health measures, including patient outcomes and quality, lag behind other developed countries. Health care spending in the United States is the highest in the world and continues to increase. Increased longevity and chronic health problems place new demands on the utilization of medical services and medical technology and contribute to higher spending.

The leading category of health care spending in Virginia is hospitalization. Many hospital stays can be avoided through prevention and primary care. In Virginia in 2013, there were 1,294 avoidable hospital stays for every 100,000 people. The rate ranges significantly across Virginia, from 233 to 6,934 per 100,000. A Kaiser Family Foundation poll found that 40% of Americans were "very worried" about "having to pay more for their health care or health insurance".[20] The challenge for Virginia is to improve health care quality by providing care that is safe, effective, patient-centered, timely, efficient, and equitable while controlling health care spending.

Meeting this challenge is difficult because health care is delivered across many disparate and independent settings and by many providers. The average Medicare beneficiary with chronic illness in the U.S. sees an average of 13 physicians a year.[21] The Commonwealth Fund Commission challenged health care systems to improve performance by 2020. Strategies include making patient's clinical information available at the point of care through shared electronic health records and actively coordinating care across providers and settings.[22]

Foundational Goals for a System of Health Care

- Health care in Virginia is affordable to families and businesses
- Virginia assures adequate regulation of health care facilities
- **Virginia has a strong primary care system linked to behavioral health care, oral health care, and community support systems**
- Virginians obtain, process, and understand basic health information and services needed to make appropriate health decisions
- **Virginia's health IT system connects people, services, and information to support optimal health outcomes**
- All health care professionals in Virginia are licensed and/or certified
- **Health care-associated infections are prevented and controlled in Virginia**

2020 FOCUS GOALS

4.1 Virginia has a strong primary care system linked to behavioral health care, oral health care, and community support systems

4.2 Virginia's health IT system connects people, services, and information to support optimal health outcomes

4.3 Health care-associated infections are prevented and controlled in Virginia

AIM 4: SYSTEM OF HEALTH CARE

2020 FOCUS GOALS

Goal 4.1: VIRGINIA HAS A STRONG PRIMARY CARE SYSTEM LINKED TO BEHAVIORAL HEALTH CARE, ORAL HEALTH CARE, AND COMMUNITY SUPPORT SYSTEMS

A primary care provider is an important point of entry into the complex health care delivery system. This is especially important for people living with chronic conditions like diabetes. As the number of Virginians with chronic disease increases, the need for patient-centered care coordination and programs to help them manage their medications and monitor their illness increases.

Untreated mental health disorders and substance misuse and abuse have serious impact on physical health and are associated with the prevalence, progression, and outcome of some of today's most pressing chronic diseases, including diabetes, heart disease, and cancer. Integrating behavioral health care, substance abuse prevention and treatment services, and primary care services produces the best outcomes and proves the most effective approach to caring for people with complex health care needs.[23]

Bringing together hospital systems, health care providers, insurers and community partners to develop shared strategies to improve population health can lead to improved delivery systems and better coordination of care across settings.

Strategies

- Create Accountable Care Communities throughout Virginia, groups of health-care providers and community partners that voluntarily coordinate high quality care to ensure patients get the right care at the right time; avoid duplication of services; and prevent medical errors
- Incentivize payment for healthcare that leads to prevention and management of health and wellness rather than episodic treatment of disease
- Improve access to comprehensive primary care in patient-centered medical homes
- For patients with complex conditions, integrate primary care with behavioral health care, substance abuse services, and oral health care
- Increase the number of Virginia-certified community behavioral health clinics
- Expand telemedicine services in rural areas of Virginia

Key Community Partners

Businesses

Community Organizations

Faith-based Communities

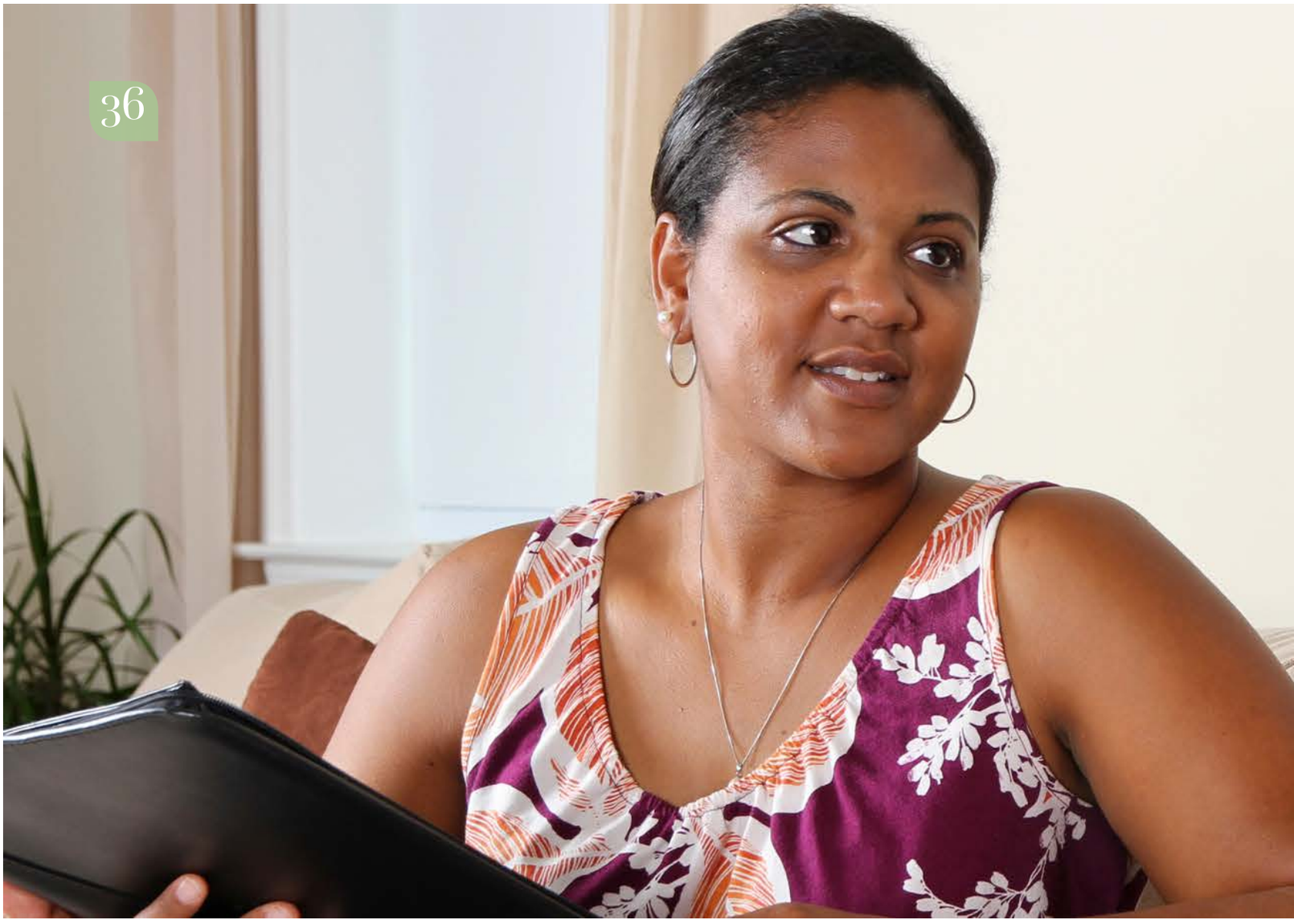
Federally Qualified Health Centers

Health-Care Providers

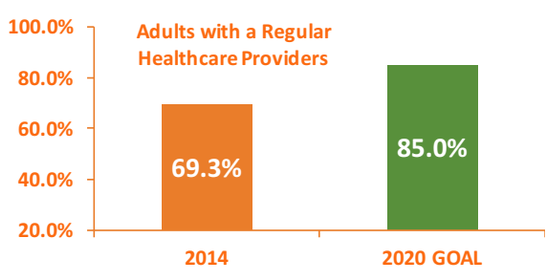
Hospital Systems

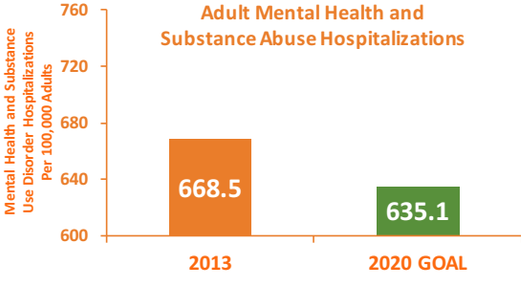
Public Health

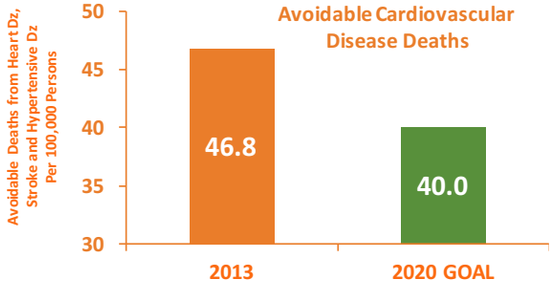
- Increase care coordination across providers and settings
- Expand adoption of the community health worker model by health care organizations
- Develop patient-centered health communications that have a positive impact on health, health care, and health equity
- Increase the number of providers who screen for nicotine use, including smokeless tobacco and e-cigarettes, and provide or refer for cessation services
- Expand access to and use of community-based programs for treatment of mental health disorders
- Promote drug-prescribing protocols in health care settings
- In primary care and other settings, increase use of the Screening, Brief Intervention, Referral and Treatment tool (an evidence-based practice used to identify, reduce, and prevent problematic use, abuse, and dependence on alcohol and illicit drugs)
- Increase the number of providers who screen for domestic violence and refer victims to organizations that can assist them
- Educate Virginians about how to avoid wasteful or unnecessary medical tests, treatments and procedures

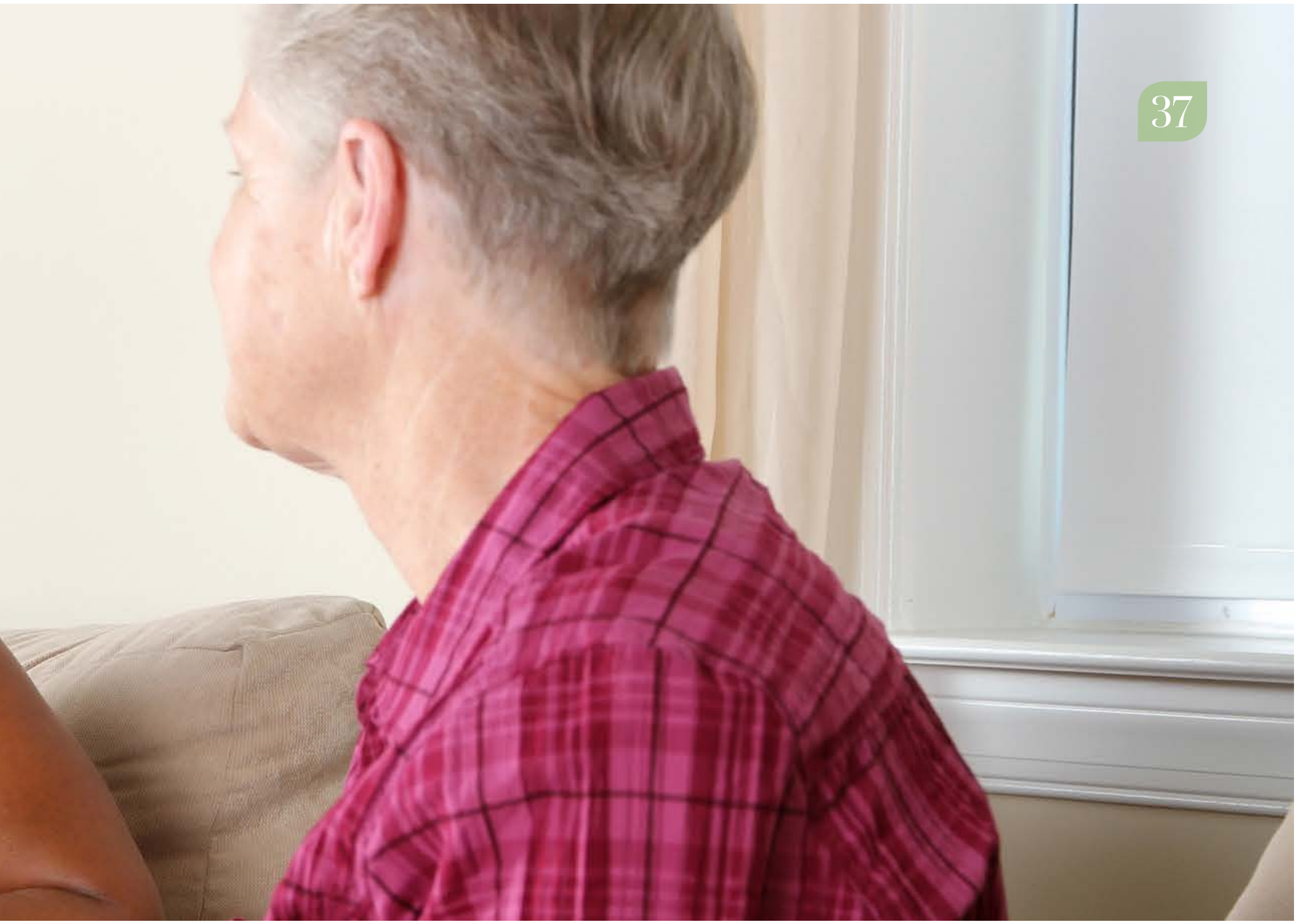


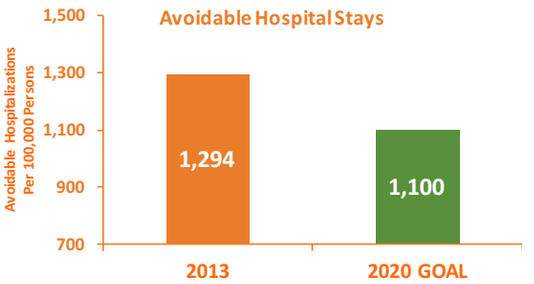
Measures of Success

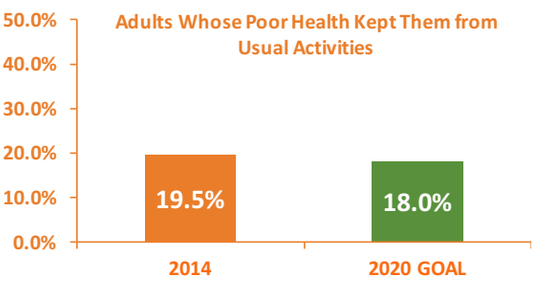









Avoidable Hospital Stays
Avoidable Hospitalizations Per 100,000 Persons
1,500
1,300
1,100
900
700
1,294
1,100
2013
2020 GOAL


Adults Whose Poor Health Kept Them from Usual Activities
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
19.5%
18.0%
2014
2020 GOAL

AIM 4: SYSTEM OF HEALTH CARE

2020 FOCUS GOALS

Goal 4.2: VIRGINIA'S HEALTH IT SYSTEM CONNECTS PEOPLE, SERVICES, AND INFORMATION TO SUPPORT OPTIMAL HEALTH OUTCOMES

Virginians and their health-care providers benefit from access to comprehensive, secure, easily accessible health information that can inform better decision making. Connect Virginia HIE, Inc. is the Commonwealth's health-information exchange designed to promote collaboration and information sharing between consumers, health-care providers, and purchasers of health care services. Developing the capacity to collect, analyze, and share population health information provides the opportunity for Virginia to create policies and systems to bring about meaningful health improvement for all Virginians.

Key Community Partners

Businesses

Elected Officials

Federally Qualified Health Centers

Free Clinics

Health-Care Providers

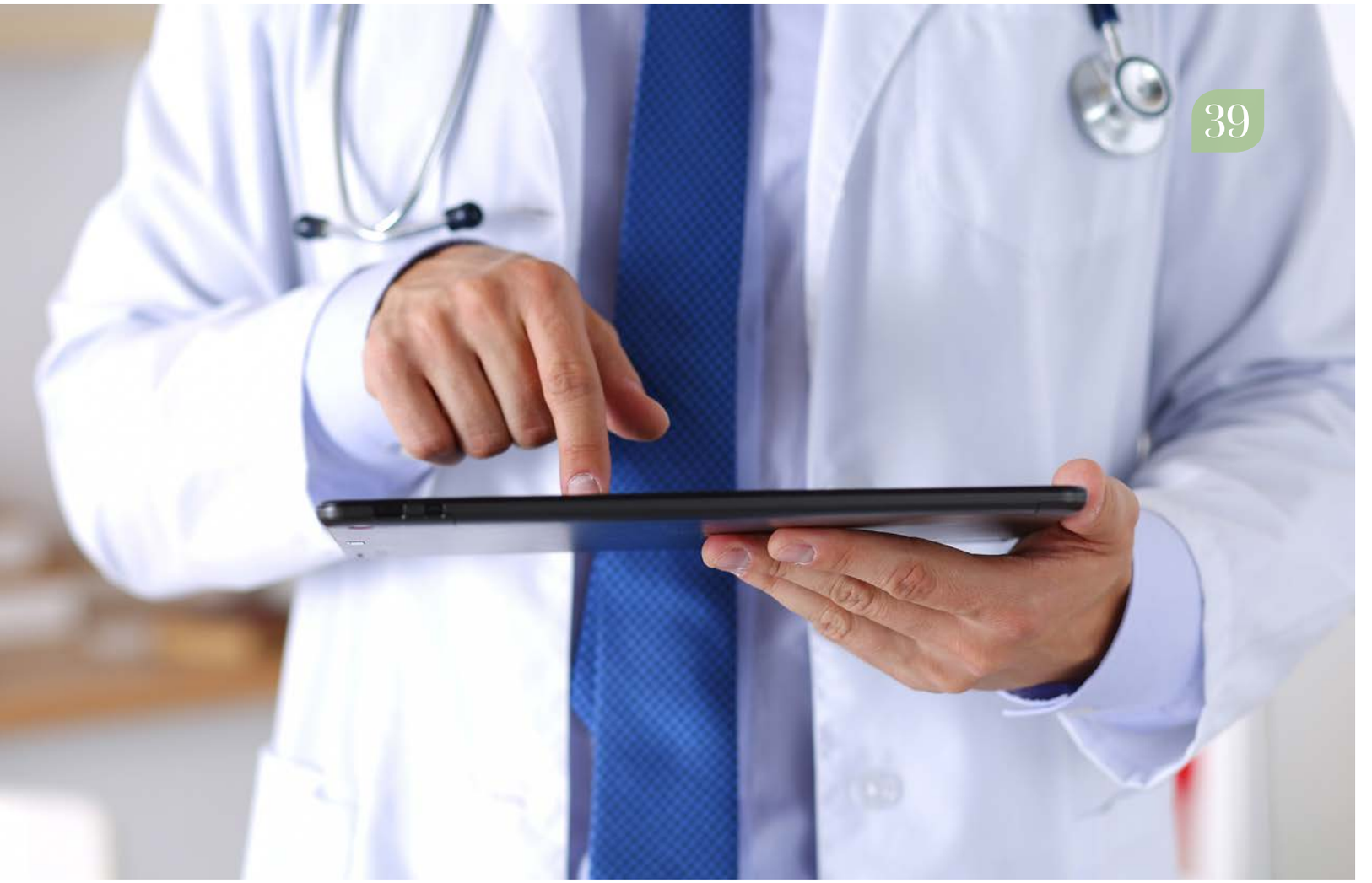
Health Insurers

Hospital Systems

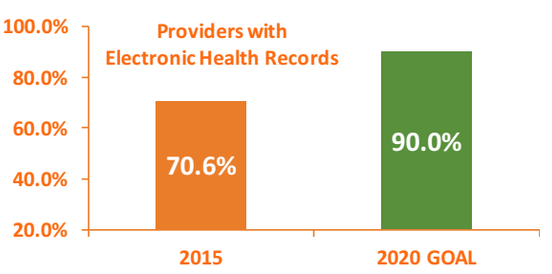
Public Health

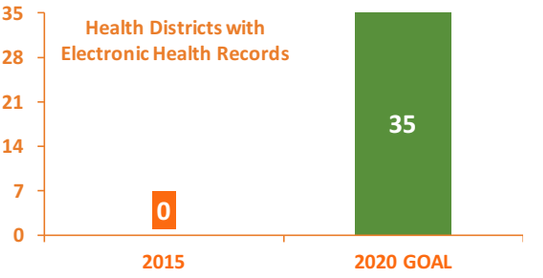
Strategies

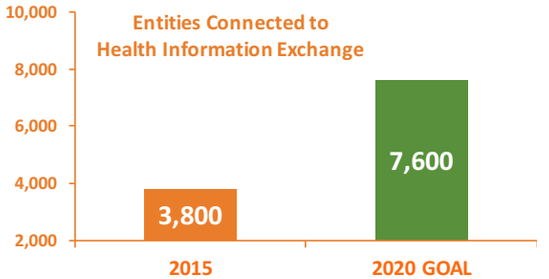
- Adopt electronic health records in all clinical and care coordination settings
- Expand the use of specific disease registries and reports (for example, patients with hypertension) by medical practices and hospital systems to evaluate and track patient outcomes and develop targeted interventions to improve patient outcomes
- Connect providers, hospitals, and community partners through Connect Virginia HIE, Inc. to allow for statewide health information exchange
- Develop the capacity to create aggregated data reports through Connect Virginia HIE, Inc. that can be used to analyze and track population health measures
- Enhance public and private data systems and public health information technology to collect, manage, track, analyze, and report population health data
- Support Health Information Technology training opportunities and jobs



Measures of Success







AIM 4: SYSTEM OF HEALTH CARE

2020 FOCUS GOALS

Goal 4.3: HEALTH CARE-ASSOCIATED INFECTIONS ARE PREVENTED AND CONTROLLED IN VIRGINIA

Developing systems to assure patient safety has improved but remains an important goal in providing quality care. Health care-associated infections (HAIs), those resulting from the receipt of medical care in health care settings, are estimated to account for $28 to $45 billion in direct health care costs in the United States annually.[24] When health care facilities employ evidence-based prevention strategies, HAIs can be prevented and controlled. For example, Clostridium difficile, a type of bacteria that causes gastrointestinal illness, accounts for 12% of HAIs in hospitals.[25] Strategies to prevent spread include complying with hand hygiene guidelines, ensuring adequate cleaning and disinfection of the environment, and prescribing antibiotics appropriately.

Key Community Partners

Academic Partners

Businesses

Health-Care Providers

Hospital Systems

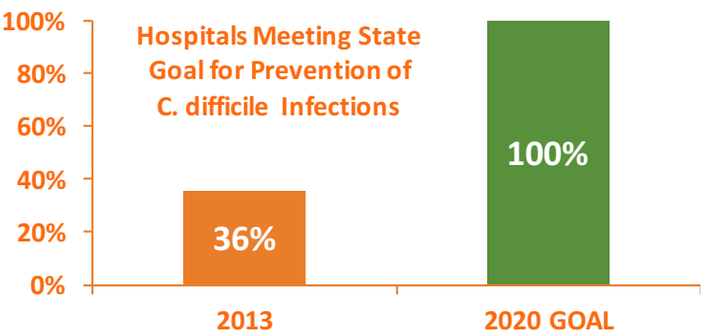
Insurers

Public Health

Strategies

- Create a culture of safety in health care facilities that encourages effective communication between health-care providers, patients, and family members
- Perform hand hygiene frequently
- Use antibiotics wisely to prevent bacteria from developing resistance to the drugs that are used to treat them
- Implement standard precautions in the care of all patients in all health care settings all of the time
- Use evidence-based methods to clean medical equipment and the health care environment
- Collect, analyze, and use data to engage healthcare providers in quality improvement activities
- Increase knowledge and practice of key prevention strategies for the various HAIs across and within healthcare settings
- Use health information systems to reinforce clinical practices that improve patient safety

Measure of Success



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