

**State of Board of Health  
Agenda  
July 17, 2009 – 9:00 a.m.  
Perimeter Center  
9960 Mayland Drive  
Richmond, Virginia 23233**

Welcome and Introductions	Fred Hannett, Chairman
Review of Agenda	Joseph Hilbert, Executive Advisor
Approval of April 2009 Minutes	Fred Hannett
Commissioner's Report	Karen Remley, MD, MBA, FAAP) State Health Commissioner
Federal Economic Stimulus Update	Joseph Hilbert
Commissioner's Infant Mortality Prevention Initiative	Karen Remley, MD, MBA, FAAP.
Break	
Public Comment	
<u>Board Regulatory Action Items</u>	
(12 VAC 5-590) Waterworks Regulation (Chronically Non-Compliant Waterworks) Proposed Regulations)	Wes Kleene, P.E., Ph.D, Director Office of Drinking Water
(12 VAC 5-220) Certificate of Public Need Regulations (Non-Discretionary Amendments)	Chris Durrer, Director Office of Licensure and Certification
Lunch	
Luncheon Speaker – The Honorable Ralph Northam, M.D., Member, Virginia State Senate	
Member Reports	
Other Business	
Conflict of Interest Training	
Adjourn	



Virginia  
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## Proposed Regulation Agency Background Document

<b>Agency name</b>	Virginia Department of Health (VDH)
<b>Virginia Administrative Code (VAC) citation</b>	12VAC5-590
<b>Regulation title</b>	Waterworks Regulations
<b>Action title</b>	Chronically Noncompliant Waterworks
<b>Date this document prepared</b>	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

This proposed regulation provides a regulatory definition of a Chronically Noncompliant waterworks, and establishes an enforcement procedure that allows the Commissioner to take action against recalcitrant waterworks owners to compel compliance and protect the public health and welfare.

**Legal basis**

§ 32.1-12 of the Code of Virginia provides that State Board of Health may...promulgate...such regulations ...as may be necessary to carry out the provisions of this title and other laws of the Commonwealth administered by it, the Commissioner or the Department.

§ 32.1-167 (et seq.) empowers the State Board of Health to adopt and promulgate regulations governing waterworks, water supplies and pure water to protect the public health and promote the public welfare.

§ 32.1-167 defines a chronically noncompliant waterworks.

§ 32.1-174.4 requires the State Board of Health to promulgate regulations that create mechanisms or enforcement options for eliminating chronically noncompliant waterworks.

Chapters 648 and 774 of the 2007 General Assembly require the Department to implement a program to identify chronically noncompliant waterworks and create mechanisms or enforcement options for eliminating chronically noncompliant waterworks. (Note: An ancillary part of the General Assembly action was the amendment of Title 15.2-2146, Powers of localities to acquire certain waterworks system. This is not part of this regulatory proposal.)

**Purpose**

A limited number of waterworks owners chronically fail to comply with the Waterworks Regulations and thereby subject their consumers to unwarranted health risks. This new regulation will provide additional enforcement tools to compel these recalcitrant owners to bring their waterworks into compliance and protect public health.

This action is the result of a JLARC study and subsequent General Assembly action.

**Substance**

Section 12VAC5-590-10 includes the Code of Virginia definition of a chronically noncompliant waterworks into the body of the Waterworks Regulations.

Section 12VAC5-590-125 allows the State Health Commissioner to issue an order to the owner of a chronically noncompliant waterworks requiring the waterworks owner to submit: (1) a schedule for returning the waterworks to compliance and (2) a comprehensive business plan (§ 32.1-172 B of the Code of Virginia).

If the waterworks owner is financially incapable of performing any necessary capital improvements, the waterworks owner is required to make good faith applications to appropriate financial institutions for funding to complete the improvements. The waterworks owner is also required to notify each consumer of the Commissioner's order including a copy of the compliance schedule.

Additionally, the Commissioner is required to send a copy of the order to the chief administrative officer of the locality in which the waterworks is located.

The waterworks owner is subject to the civil fines provided in § 32.1-167 to § 32.1-176 of the Code of Virginia.

### 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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.*

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The primary issue addressed by this proposed regulation is to attempt to protect the health of consumers served by a waterworks in Virginia that has been determined to be chronically noncompliant. The proposed regulation will require recalcitrant waterworks owners to bring the chronically noncompliant waterworks into compliance with the Waterworks Regulations.

The State Health Commissioner will inform the local government in which the chronically noncompliant waterworks is located, that it may initiate action, if desired by the locality, to secure ownership of the waterworks and assume operation in compliance with the Waterworks Regulations.

This proposed regulation poses no disadvantages to the public or the Commonwealth.

### Requirements more restrictive than federal

*Please identify and describe any requirement of the proposal which are 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.*

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There are no federal regulations that parallel this requirement; therefore, the question of being more restrictive is moot.

Compliance with drinking water standards is a primary objective of the federal government (Environmental Protection Agency).

### 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.*

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This regulation does not affect any particular locality.

**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 Board of Health is seeking comments on the costs and benefits of the proposal and the potential impacts of this proposed regulation. Also, the Board of Health 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 impact 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 by mail, email or fax to Randall Swartz, Office of Drinking Water, 109 Governor Street, 6<sup>th</sup> Floor, Richmond, Virginia 23219; 804-864-7513 (tele); 804-864-7520 (fax); [Randall.Swartz@vdh.virginia.gov](mailto:Randall.Swartz@vdh.virginia.gov). Written comments must include the name and address of the commenter. To be considered, comments must be received by the last date of the public comment period.

**Economic impact**

*Please identify the anticipated economic impact of the proposed regulation.*

<b>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</b>	\$0
<b>Projected cost of the regulation on localities</b>	\$0
<b>Description of the individuals, businesses or other entities likely to be affected by the regulation</b>	Those affected by this proposed regulation are waterworks owners who continually and habitually violate the existing Waterworks Regulations and the consumers served.
<b>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 (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</b>	Approximately eight waterworks may be affected by this proposed regulation.
<b>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</b>	\$0

**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.*

This regulation is required by an act of the General Assembly.

**Regulatory flexibility analysis**

*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.*

This regulation is required by an act of the General Assembly.

**Public comment**

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

<b>Commenter</b>	<b>Comment</b>	<b>Agency response</b>
None	None	None

**Family impact**

*Please assess the impact of the proposed 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.*

By eliminating chronically noncompliant waterworks, the public can be assured of safe drinking water that will improve economic self-sufficiency and will decrease the number of illnesses that lead to lost productivity and diminished personal income.

**Detail of changes**

*Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulations, use this chart:

<b>Current section number</b>	<b>Proposed new section number, if applicable</b>	<b>Current requirement</b>	<b>Proposed change and rationale</b>
	12VAC5-591-125	None	

**Project 1136 - NOIRA**

**DEPARTMENT OF HEALTH**

**Chronically Noncompliant Waterworks**

Part I

General Framework for Waterworks Regulations

Article 1

Definitions

**12VAC5-590-10. Definitions.**

As used in this chapter, the following words and terms shall have meanings respectively set forth unless the context clearly requires a different meaning:

"Action level" means the concentration of lead or copper in water specified in 12VAC5-590-410 E, which determines, in some cases, the treatment requirements contained in 12VAC5-590-420 C, D, E and F that an owner is required to complete.

"Air gap separation" means the unobstructed vertical distance through the free atmosphere between the lowest opening from any pipe or faucet supplying pure water to a tank, plumbing fixture, or other device and the rim of the receptacle.

"Annual daily water demand" means the average rate of daily water usage over at least the most recent three-year period.

"Applied water" means water that is ready for filtration.

"Approved" means material, equipment, workmanship, process or method that has been accepted by the commissioner as suitable for the proposed use.

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"Auxiliary water system" means any water system on or available to the premises other than the waterworks. These auxiliary waters may include water from a source such as wells, lakes, or streams; or process fluids; or used water. They may be polluted or contaminated or objectionable, or constitute an unapproved water source or system over which the water purveyor does not have control.

"Backflow" means the flow of water or other liquids, mixtures, or substances into the distribution piping of a waterworks from any source or sources other than its intended source.

"Backflow prevention device" means any approved device, method, or type of construction intended to prevent backflow into a waterworks.

"Bag filters" means pressure-driven separation devices that remove particulate matter larger than one micrometer using an engineered porous filtration media. They are typically constructed of a nonrigid, fabric filtration media housed in a pressure vessel in which the direction of flow is from the inside of the bag to outside.

"Bank filtration" means a water treatment process that uses a well to recover surface water that has naturally infiltrated into groundwater through a river bed or bank(s). Infiltration is typically enhanced by the hydraulic gradient imposed by a nearby pumping water supply or other well(s).

"Best available technology (BAT)" means the best technology, treatment techniques, or other means which the commissioner finds, after examination for efficacy under field conditions and not solely under laboratory conditions and in conformance with applicable EPA regulations, are available (taking cost into consideration).

"Board" means the State Board of Health.

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"Breakpoint chlorination" means the addition of chlorine to water until the chlorine demand has been satisfied and further additions result in a residual that is directly proportional to the amount added.

"Cartridge filters" means pressure-driven separation devices that remove particulate matter larger than one micrometer using an engineered porous filtration media. They are typically constructed as rigid or semi-rigid, self-supporting filter elements housed in pressure vessels in which flow is from the outside of the cartridge to the inside.

"Chlorine" means dry chlorine.

"Chlorine gas" means dry chlorine in the gaseous state.

"Chlorine solution (chlorine water)" means a solution of chlorine in water.

"Chronically noncompliant waterworks" or "CNC" means a waterworks that is unable to provide pure water for any of the following reasons: (i) the waterworks' record of performance demonstrates that it can no longer be depended upon to furnish pure water to the persons served, (ii) the owner has inadequate technical, financial or managerial capacity to furnish pure water to the people served, (iii) the owner has failed to comply with an order issued by the Board or the commissioner, (iv) the owner has abandoned the waterworks and has discontinued supplying pure water to the persons served, or (v) the owner is subject to a forfeiture order pursuant to § 32.1-174.1 of the Code of Virginia.

"Coagulation" means a process using coagulant chemicals and mixing by which colloidal and suspended materials are destabilized and agglomerated into floc.

"Coliform bacteria group" means a group of bacteria predominantly inhabiting the intestines of man or animal but also occasionally found elsewhere. It includes all aerobic and facultative anaerobic, gram-negative, non-sporeforming bacilli that ferment lactose with production of gas. Also included are all bacteria that produce a dark, purplish-green

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colony with metallic sheen by the membrane filter technique used for coliform identification.

"Combined distribution system" means the interconnected distribution system consisting of the distribution systems of wholesale waterworks and of the consecutive waterworks that receive finished water.

"Commissioner" means the State Health Commissioner.

"Community waterworks" means a waterworks which serves at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents.

"Compliance cycle" means the nine-year calendar year cycle during which a waterworks shall monitor. Each compliance cycle consists of three three-year compliance periods. The first calendar year cycle begins January 1, 1993, and ends December 31, 2001; the second begins January 1, 2002, and ends December 31, 2010; the third begins January 1, 2011, and ends December 31, 2019.

"Compliance period" means a three-year calendar year period within a compliance cycle. Each compliance cycle has three three-year compliance periods. Within the first compliance cycle, the first compliance period runs from January 1, 1993, to December 31, 1995; the second from January 1, 1996, to December 31, 1998; the third from January 1, 1999, to December 31, 2001.

"Comprehensive performance evaluation" or "(CPE)" means a thorough review and analysis of a treatment plant's performance-based capabilities and associated administrative, operational and maintenance practices. It is conducted to identify factors that may be adversely impacting a plant's capability to achieve compliance and emphasizes approaches that can be implemented without significant capital

improvements. For purposes of compliance with 12VAC5-590-530 C 1 b (2), the comprehensive performance evaluation shall consist of at least the following components: assessment of plant performance; evaluation of major unit processes; identification and prioritization of performance limiting factors; assessment of the applicability of comprehensive technical assistance; and preparation of a CPE report.

"Confluent growth" means a continuous bacterial growth covering the entire filtration area of a membrane filter, or a portion thereof, in which bacterial colonies are not discrete.

"Consecutive waterworks" means a waterworks which has no water production or source facility of its own and which obtains all of its water from another permitted waterworks or receives some or all of its finished water from one or more wholesale waterworks. Delivery may be through a direct connection or through the distribution system of one or more consecutive waterworks.

"Consumer" means any person who drinks water from a waterworks.

"Consumer's water system" means any water system located on the consumer's premises, supplied by or in any manner connected to a waterworks.

"Contaminant" means any objectionable or hazardous physical, chemical, biological, or radiological substance or matter in water.

"Conventional filtration treatment" means a series of processes including coagulation, flocculation, sedimentation, and filtration resulting in substantial particulate removal.

"Corrosion inhibitor" means a substance capable of reducing the corrosivity of water toward metal plumbing materials, especially lead and copper, by forming a protective film on the interior surface of those materials.

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"Cross connection" means any connection or structural arrangement, direct or indirect, to the waterworks whereby backflow can occur.

"CT" or " $CT_{calc}$ " means the product of "residual disinfectant concentration" (C) in mg/L determined before or at the first customer, and the corresponding "disinfectant contact time" (T) in minutes, i.e., "C" x "T".

"Daily fluid intake" means the daily intake of water for drinking and culinary use and is defined as two liters.

"Dechlorination" means the partial or complete reduction of residual chlorine in water by any chemical or physical process at a waterworks with a treatment facility.

"Degree of hazard" means the level of health hazard, as derived from an evaluation of the potential risk to health and the adverse effect upon the waterworks.

"Diatomaceous earth filtration" means a process resulting in substantial particulate removal in which (i) a precoat cake of diatomaceous earth filter media is deposited on a support membrane (septum), and (ii) while the water is filtered by passing through the cake on the septum, additional filter media known as body feed is continuously added to the feed water to maintain the permeability of the filter cake.

"Direct filtration" means a series of processes including coagulation and filtration but excluding sedimentation resulting in substantial particulate removal.

"Disinfectant" means any oxidant (including chlorine) that is added to water in any part of the treatment or distribution process for the purpose of killing or deactivating pathogenic organisms.

"Disinfectant contact time" ("T" in CT calculations) means the time in minutes that it takes for water to move from the point of disinfectant application to the point where residual disinfectant concentration ("C") is measured.

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"Disinfection" means a process that inactivates pathogenic organisms in water by chemical oxidants or equivalent agents.

"Disinfection profile" means a summary of *Giardia lamblia* or virus inactivation through the treatment plant.

"Distribution main" means a water main whose primary purpose is to provide treated water to service connections.

"District Engineer" means the employee assigned by the Commonwealth of Virginia, Department of Health, Office of Drinking Water to manage its regulatory activities in a geographical area of the state consisting of a state planning district or subunit of a state planning district.

"Domestic or other nondistribution system plumbing problem" means a coliform contamination problem in a waterworks with more than one service connection that is limited to the specific service connection from which the coliform positive sample was taken.

"Domestic use or usage" means normal family or household use, including drinking, laundering, bathing, cooking, heating, cleaning and flushing toilets (see Article 2 (§ 32.1-167 et seq.) of Chapter 6 of Title 32.1 of the Code of Virginia).

"Double gate-double check valve assembly" means an approved assembly composed of two single independently acting check valves including tightly closing shutoff valves located at each end of the assembly and petcocks and test gauges for testing the watertightness of each check valve.

"Dual sample set" means a set of two samples collected at the same time and same location, with one sample analyzed for TTHM and the other sample analyzed for HAA5. Dual sample sets are collected for the purposes of conducting an initial distribution

system evaluation (IDSE) under 12VAC5-590-370 B 3 e (2) and determining compliance with the TTHM and HAA5 MCLs under 12VAC5-590-370 B 3 e (3).

"Effective corrosion inhibitor residual," means, for the purpose of 12VAC5-590-420 C 1 only, a concentration sufficient to form a passivating film on the interior walls of a pipe.

"Enhanced coagulation" means the addition of sufficient coagulant for improved removal of disinfection byproduct precursors by conventional filtration treatment.

"Enhanced softening" means the improved removal of disinfection byproduct precursors by precipitative softening.

"Entry point" means the place where water from the source after application of any treatment is delivered to the distribution system.

"Equivalent residential connection" means a volume of water used equal to a residential connection which is 400 gallons per day unless supportive data indicates otherwise.

"Exception" means an approved deviation from a "shall" criteria contained in Part III (12VAC5-590-640 et seq.) of this chapter.

"Exemption" means a conditional waiver of a specific PMCL or treatment technique requirement which is granted to a specific waterworks for a limited period of time.

"Filter profile" means a graphical representation of individual filter performance, based on continuous turbidity measurements or total particle counts versus time for an entire filter run, from startup to backwash inclusively, that includes an assessment of filter performance while another filter is being backwashed.

"Filtration" means a process for removing particulate matter from water by passage through porous media.

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“Finished water” means water that is introduced into the distribution system of a waterworks and is intended for distribution and consumption without further treatment, except as treatment necessary to maintain water quality in the distribution system (e.g., booster disinfection, addition of corrosion control chemicals).

"First draw sample" means a one-liter sample of tap water, collected in accordance with 12VAC5-590-370 B 6 a (2), that has been standing in plumbing pipes at least six hours and is collected without flushing the tap.

"Flocculation" means a process to enhance agglomeration or collection of smaller floc particles into larger, more easily settleable particles through gentle stirring by hydraulic or mechanical means.

“Flowing stream” means a course of running water flowing in a definite channel.

"Free available chlorine" means that portion of the total residual chlorine remaining in water at the end of a specified contact period which will react chemically and biologically as hypochlorous acid or hypochlorite ion.

"GAC10" means granular activated carbon filter beds with an empty-bed contact time of 10 minutes based on average daily flow and a carbon reactivation frequency of every 180 days, except that the reactivation frequency for GAC10 used as a best available technology for compliance with 12VAC5-590-410 C 2 b (1) (b) shall be 120 days.

“GAC20” means granular activated carbon filter beds with an empty-bed contact time of 20 minutes based on average daily flow and a carbon reactivation frequency of every 240 days.

"Governmental entity" means the Commonwealth, a town, city, county, service authority, sanitary district or any other governmental body established under the Code of Virginia, including departments, divisions, boards or commissions.

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"Gross alpha particle activity" means the total radioactivity due to alpha particle emission as inferred from measurements on a dry sample.

"Gross beta particle activity" means the total radioactivity due to beta particle emission as inferred from measurements on a dry sample.

"Groundwater" means all water obtained from sources not classified as surface water (or surface water sources).

"Groundwater under the direct influence of surface water" means any water beneath the surface of the ground with significant occurrence of insects or other macroorganisms, algae, or large-diameter pathogens such as *Giardia lamblia*, or *Cryptosporidium*. It also means significant and relatively rapid shifts in water characteristics such as turbidity, temperature, conductivity, or pH that closely correlate to climatological or surface water conditions. The commissioner in accordance with 12VAC5-590-430 will determine direct influence of surface water.

"Haloacetic acids (five)" or "(HAA5)" means the sum of the concentrations in milligrams per liter of the haloacetic acid compounds (monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid, and dibromoacetic acid), rounded to two significant figures after addition.

"Halogen" means one of the chemical elements chlorine, bromine, fluorine, astatine or iodine.

"Health hazard" means any condition, device, or practice in a waterworks or its operation that creates, or may create, a danger to the health and well-being of the water consumer.

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"Health regulations" means regulations which include all primary maximum contaminant levels, treatment technique requirements, and all operational regulations, the violation of which would jeopardize the public health.

"Hypochlorite" means a solution of water and some form of chlorine, usually sodium hypochlorite.

"Initial compliance period" means for all regulated contaminants, the initial compliance period is the first full three-year compliance period beginning at least 18 months after promulgation with the exception of waterworks with 150 or more service connections for contaminants listed at Table 2.3, VOC 19-21; Table 2.3, SOC 19-33; and antimony, beryllium, cyanide (as free cyanide), nickel, and thallium which shall begin January 1993.

"Interchangeable connection" means an arrangement or device that will allow alternate but not simultaneous use of two sources of water.

"Karstian geology" means an area predominantly underlain by limestone, dolomite, or gypsum and characterized by rapid underground drainage. Such areas often feature sinkholes, caverns, and sinking or disappearing creeks. In Virginia, this generally includes all that area west of the Blue Ridge and, in Southwest Virginia, east of the Cumberland Plateau.

"Lake/reservoir" means a natural or man-made basin or hollow on the Earth's surface in which water collects or is stored that may or may not have a current or single direction of flow.

"Large waterworks" means, for the purposes of 12VAC5-590-370 B 6, 12VAC5-590-420 C through F, 12VAC5-590-530 D, and 12VAC5-590-550 D only, a waterworks that serves more than 50,000 persons.

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"Lead free" means the following:

1. When used with respect to solders and flux refers to solders and flux containing not more than 0.2% lead;
2. When used with respect to pipes and pipe fittings refers to pipes and pipe fittings containing not more than 8.0% lead;
3. When used with respect to plumbing fittings and fixtures intended by the plumbing manufacturer to dispense water for human ingestion refers to fittings and fixtures that are in compliance with standards established in accordance with 42 USC § 300g-6(e).

"Lead service line" means a service line made of lead which connects the water main to the building inlet and any lead pigtail, gooseneck or other fitting that is connected to such lead line.

"Legionella" means a genus of bacteria, some species of which have caused a type of pneumonia called Legionnaires Disease.

"Liquid chlorine" means a liquefied, compressed chlorine gas as shipped in commerce.

"Locational running annual average" or "LRAA" means the average of sample analytical results for samples taken at a particular monitoring location during the previous four calendar quarters.

"Log inactivation (log removal)" means that a 99% reduction is a 2-log inactivation; a 99.9% reduction is a 3-log inactivation; a 99.99% reduction is a 4-log inactivation.

"Man-made beta particle and photon emitters" means all radionuclides emitting beta particles and/or photons listed in the most current edition of "Maximum Permissible Body

Burdens and Maximum Permissible Concentration of Radionuclides in Air or Water for Occupational Exposure," National Bureau of Standards Handbook 69, except the daughter products of thorium-232, uranium-235 and uranium-238.

"Maximum daily water demand" means the rate of water usage during the day of maximum water use.

"Maximum contaminant level (MCL)" means the maximum permissible level of a contaminant in water which is delivered to any user of a waterworks, except in the cases of turbidity and VOCs, where the maximum permissible level is measured at each entry point to the distribution system. Contaminants added to the water under circumstances controlled by the user, except those resulting from corrosion of piping and plumbing caused by water quality, are excluded from this definition. MCLs are set as close to the MCLGs as feasible using the best available treatment technology. Maximum contaminant levels may be either "primary" (PMCL), meaning based on health considerations or "secondary" (SMCL) meaning based on aesthetic considerations.

"Maximum residual disinfectant level (MRDL)" means a level of a disinfectant added for water treatment that may not be exceeded at the consumer's tap without an unacceptable possibility of adverse health effects. For chlorine and chloramines, a waterworks is in compliance with the MRDL when the running annual average of monthly averages of samples taken in the distribution system, computed quarterly, is less than or equal to the MRDL. For chlorine dioxide, a waterworks is in compliance with the MRDL when daily samples are taken at the entrance to the distribution system and no two consecutive daily samples exceed the MRDL. MRDLs are enforceable in the same manner as maximum contaminant levels. There is convincing evidence that addition of a disinfectant is necessary for control of waterborne microbial contaminants. Notwithstanding the MRDLs listed in Table 2.12, operators may increase residual

disinfectant levels of chlorine or chloramines (but not chlorine dioxide) in the distribution system to a level and for a time necessary to protect public health to address specific microbiological contamination problems caused by circumstances such as distribution line breaks, storm runoff events, source water contamination, or cross-connections.

"Maximum residual disinfectant level goal (MRDLG)" means the maximum level of a disinfectant added for water treatment at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. MRDLGs are nonenforceable health goals and do not reflect the benefit of the addition of the chemical for control of waterborne microbial contaminants.

"Maximum total trihalomethane potential (MTP)" means the maximum concentration of total trihalomethanes produced in a given water containing a disinfectant residual after seven days at a temperature of 25°C or above.

"Medium-size waterworks," means, for the purpose of 12VAC5-590-370 B 6, 12VAC5-590-420 C through F, 12VAC5-590-530, and 12VAC5-590-550 D only, a waterworks that serves greater than 3,300 and less than or equal to 50,000 persons.

"Membrane filtration" means a pressure or vacuum-driven separation process in which particulate matter larger than one micrometer is rejected by an engineered barrier, primarily through a size exclusion mechanism, and that has a measurable removal efficiency of a target organism that can be verified through the application of a direct integrity test. This definition includes the common membrane technologies of microfiltration, ultrafiltration, nanofiltration, and reverse osmosis.

"Method detection limit" means the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater

than zero and is determined from analysis of a sample in a given matrix containing the analyte.

"Most probable number (MPN)" means that number of organisms per unit volume that, in accordance with statistical theory, would be more likely than any other number to yield the observed test result or that would yield the observed test result with the greatest frequency, expressed as density of organisms per 100 milliliters. Results are computed from the number of positive findings of coliform-group organisms resulting from multiple-portion decimal-dilution plantings.

"Noncommunity waterworks" means a waterworks that is not a community waterworks, but operates at least 60 days out of the year.

"Nonpotable water" means water not classified as pure water.

"Nontransient noncommunity waterworks (NTNC)" means a waterworks that is not a community waterworks and that regularly serves at least 25 of the same persons over six months out of the year.

"Office" means the Commonwealth of Virginia, Department of Health, Office of Drinking Water.

"One hundred year flood level" means the flood elevation which will, over a long period of time, be equaled or exceeded on the average once every 100 years.

"Operator" means any individual employed or appointed by any owner, and who is designated by such owner to be the person in responsible charge, such as a supervisor, a shift operator, or a substitute in charge, and whose duties include testing or evaluation to control waterworks operations. Not included in this definition are superintendents or directors of public works, city engineers, or other municipal or industrial officials whose duties do not include the actual operation or direct supervision of waterworks.

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"Optimal corrosion control treatment" means the corrosion control treatment that minimizes the lead and copper concentrations at users' taps while ensuring that the treatment does not cause the waterworks to violate any other section of this chapter.

"Owner" or "water purveyor" means an individual, group of individuals, partnership, firm, association, institution, corporation, governmental entity, or the federal government which supplies or proposes to supply water to any person within this state from or by means of any waterworks (see Article 2 (§ 32.1-167 et seq.) of Chapter 6 of Title 32.1 of the Code of Virginia).

"Picrocurie (pCi)" means that quantity of radioactive material producing 2.22 nuclear transformations per minute.

"Plant intake" means the works or structures at the head of a conduit through which water is diverted from a source (e.g., river or lake) into the treatment plant.

"Point of disinfectant application" means the point where the disinfectant is applied and water downstream of that point is not subject to recontamination by surface water runoff.

"Point-of-entry treatment device (POE)" means a treatment device applied to the water entering a house or building for the purpose of reducing contaminants in the water distributed throughout the house or building.

"Point-of-use treatment device (POU)" means a treatment device applied to a single tap for the purpose of reducing contaminants in the water at that one tap.

"Pollution" means the presence of any foreign substance (chemical, physical, radiological, or biological) in water that tends to degrade its quality so as to constitute an unnecessary risk or impair the usefulness of the water.

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"Pollution hazard" means a condition through which an aesthetically objectionable or degrading material may enter the waterworks or a consumer's water system.

"Post-chlorination" means the application of chlorine to water subsequent to treatment.

"Practical quantitation level (PQL)" means the lowest level achievable by good laboratories within specified limits during routine laboratory operating conditions.

"Prechlorination" means the application of chlorine to water prior to filtration.

"Presedimentation" means a preliminary treatment process used to remove gravel, sand and other particulate material from the source water through settling before the water enters the primary clarification and filtration processes in a treatment plant.

"Process fluids" means any fluid or solution which may be chemically, biologically, or otherwise contaminated or polluted which would constitute a health, pollutional, or system hazard if introduced into the waterworks. This includes, but is not limited to:

1. Polluted or contaminated water;
2. Process waters;
3. Used waters, originating from the waterworks which may have deteriorated in sanitary quality;
4. Cooling waters;
5. Contaminated natural waters taken from wells, lakes, streams, or irrigation systems;
6. Chemicals in solution or suspension; and
7. Oils, gases, acids, alkalis, and other liquid and gaseous fluid used in industrial or other processes, or for fire fighting purposes.

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"Pure water" or "potable water" means water fit for human consumption and domestic use which is sanitary and normally free of minerals, organic substances, and toxic agents in excess of reasonable amounts for domestic usage in the area served and normally adequate in quantity and quality for the minimum health requirements of the persons served (see Article 2 (§ 32.1-167 et seq.) of Chapter 6 of Title 32.1 of the Code of Virginia).

"Raw water main" means a water main which conveys untreated water from a source to a treatment facility.

"Reduced pressure principle backflow prevention device (RPZ device)" means a device containing a minimum of two independently acting check valves together with an automatically operated pressure differential relief valve located between the two check valves. During normal flow and at the cessation of normal flow, the pressure between these two checks shall be less than the supply pressure. In case of leakage of either check valve, the differential relief valve, by discharging to the atmosphere, shall operate to maintain the pressure between the check valves at less than the supply pressure. The unit shall include tightly closing shut-off valves located at each end of the device, and each device shall be fitted with properly located test cocks. These devices shall be of the approved type.

"REM" means the unit of dose equivalent from ionizing radiation to the total body or any internal organ or organ system. A "millirem" (MREM) is 1/1000 of a REM.

"Repeat compliance period" means any subsequent compliance period after the initial compliance period.

"Residual disinfectant concentration ("C" in CT Calculations)" means the concentration of disinfectant measured in mg/L in a representative sample of water.

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"Responsible charge" means designation by the owner of any individual to have duty and authority to operate or modify the operation of waterworks processes.

"Sanitary facilities" means piping and fixtures, such as sinks, lavatories, showers, and toilets, supplied with potable water and drained by wastewater piping.

"Sanitary survey" means an investigation of any condition that may affect public health.

"Secondary water source" means any approved water source, other than a waterworks' primary source, connected to or available to that waterworks for emergency or other nonregular use.

"Sedimentation" means a process for removal of solids before filtration by gravity or separation.

"Service connection" means the point of delivery of water to a customer's building service line as follows:

1. If a meter is installed, the service connection is the downstream side of the meter;
2. If a meter is not installed, the service connection is the point of connection to the waterworks;
3. When the water purveyor is also the building owner, the service connection is the entry point to the building.

"Service line sample" means a one-liter sample of water, collected in accordance with 12VAC5-590-370 B 6 a (2) (c), that has been standing for at least six hours in a service line.

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"Sewer" means any pipe or conduit used to convey sewage or industrial waste streams.

"Single family structure," means, for the purpose of 12VAC5-590-370 B 6 (a) only, a building constructed as a single-family residence that is currently used as either a residence or a place of business.

"Slow sand filtration" means a process involving passage of raw water through a bed of sand at low velocity (generally less than 0.4 m/h) resulting in substantial particulate removal by physical and biological mechanisms.

"Small waterworks," means, for the purpose of 12VAC5-590-370 B 6, 12VAC5-590-420 C through F, 12VAC5-590-530 D and 12VAC5-590-550 D only, a waterworks that serves 3,300 persons or fewer.

"Standard sample" means that portion of finished drinking water that is examined for the presence of coliform bacteria.

"Surface water" means all water open to the atmosphere and subject to surface runoff.

"SUVA" means specific ultraviolet absorption at 254 nanometers (nm), an indicator of the humic content of water. It is a calculated parameter obtained by dividing a sample's ultraviolet absorption at a wavelength of 254 nm ( $UV_{254}$ ) (in  $m^{-1}$ ) by its concentration of dissolved organic carbon (DOC) (in mg/L).

"Synthetic organic chemicals (SOC)" means one of the family of organic man-made compounds generally utilized for agriculture or industrial purposes.

"System hazard" means a condition posing an actual, or threat of, damage to the physical properties of the waterworks or a consumer's water system.

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"Terminal reservoir" means an impoundment providing end storage of water prior to treatment.

"Too numerous to count" means that the total number of bacterial colonies exceeds 200 on a 47-mm diameter membrane filter used for coliform detection.

"Total effective storage volume" means the volume available to store water in distribution reservoirs measured as the difference between the reservoir's overflow elevation and the minimum storage elevation. The minimum storage elevation is that elevation of water in the reservoir that can provide a minimum pressure of 20 psi at a flow as determined in 12VAC5-590-690 C to the highest elevation served within that reservoir's service area under systemwide maximum daily water demand.

"Total organic carbon" (TOC) means total organic carbon in mg/L measured using heat, oxygen, ultraviolet irradiation, chemical oxidants, or combinations of these oxidants that convert organic carbon to carbon dioxide, rounded to two significant figures.

"Total trihalomethanes (TTHM)" means the sum of the concentrations of the trihalomethanes expressed in milligrams per liter (mg/L) and rounded to two significant figures. For the purpose of these regulations, the TTHM's shall mean trichloromethane (chloroform), dibromochloromethane, bromodichloromethane, and tribromomethane (bromoform).

"Transmission main" means a water main whose primary purpose is to move significant quantities of treated water among service areas.

"Treatment technique requirement" means a requirement which specifies for a contaminant a specific treatment technique(s) demonstrated to the satisfaction of the division to lead to a reduction in the level of such contaminant sufficient to comply with these regulations.

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"Trihalomethane (THM)" means one of the family of organic compounds, named as derivatives of methane, wherein three of the four hydrogen atoms in methane are each substituted by a halogen atom in the molecular structure.

"Two-stage lime softening" means a process in which chemical addition and hardness precipitation occur in each of two distinct unit clarification processes in series prior to filtration.

"Uncovered finished water storage facility" means a tank, reservoir, or other facility used to store water that will undergo no further treatment to reduce microbial pathogens (except residual disinfection) and is directly open to the atmosphere.

"Unregulated contaminant (UC)" means a contaminant for which a monitoring requirement has been established, but for which no MCL or treatment technique requirement has been established.

"Used water" means any water supplied by a water purveyor from the waterworks to a consumer's water system after it has passed through the service connection.

"Variance" means a conditional waiver of a specific regulation which is granted to a specific waterworks. A PMCL Variance is a variance to a Primary Maximum Contaminant Level, or a treatment technique requirement. An Operational Variance is a variance to an operational regulation or a Secondary Maximum Contaminant Level. Variances for monitoring, reporting and public notification requirements will not be granted.

"Virus" means a microbe that is infectious to humans by waterborne transmission.

"Volatile synthetic organic chemical (VOC)" means one of the family of manmade organic compounds generally characterized by low molecular weight and rapid vaporization at relatively low temperatures or pressures.

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"Waterborne disease outbreak" means the significant occurrence of acute infectious illness, epidemiologically associated with the ingestion of water from a waterworks which is deficient in treatment, as determined by the commissioner or the State Epidemiologist.

"Water purveyor" (same as owner).

"Water supply" means water that shall have been taken into a waterworks from all wells, streams, springs, lakes, and other bodies of surface waters (natural or impounded), and the tributaries thereto, and all impounded groundwater, but the term "water supply" shall not include any waters above the point of intake of such waterworks (see Article 2 (§ 32.1-167 et seq.) of Chapter 6 of Title 32.1 of the Code of Virginia).

"Water supply main" or "main" means any water supply pipeline that is part of a waterworks distribution system.

"Water Well Completion Report" means a report form published by the State Water Control Board entitled "Water Well Completion Report" which requests specific information pertaining to the ownership, driller, location, geological formations penetrated, water quantity and quality encountered as well as construction of water wells. The form is to be completed by the well driller.

"Waterworks" means a system that serves piped water for drinking or domestic use to (i) the public, (ii) at least 15 connections, or (iii) an average of 25 individuals for at least 60 days out of the year. The term "waterworks" shall include all structures, equipment and appurtenances used in the storage, collection, purification, treatment and distribution of pure water except the piping and fixtures inside the building where such water is delivered (see Article 2 (§ 32.1-167 et seq.) of Chapter 6 of Title 32.1 of the Code of Virginia).

"Waterworks with a single service connection" means a waterworks which supplies drinking water to consumers via a single service line.

"Wholesale waterworks" means a waterworks that treats source water as necessary to produce finished water and then delivers some or all of that finished water to another waterworks. Delivery may be through a direct connection or through the distribution system of one or more consecutive waterworks.

**12VAC5-590-125. Chronically noncompliant waterworks.**

A. The commissioner may identify a waterworks as chronically noncompliant (CNC) whenever he determines that:

1. The waterworks has a documented performance record that demonstrates the waterworks is not a dependable supplier of potable water, or
2. The owner has shown inadequate technical, financial or managerial capabilities to provide potable water, or
3. The owner has failed to comply with an order issued by the commissioner; or
4. The owner has abandoned the waterworks and has discontinued providing potable water to the consumers; or
5. The owner is subject to a forfeiture order pursuant to § 32.1-174.1 of the Code of Virginia.

B. Once the commissioner determines that a waterworks is CNC, he shall issue an order to the owner containing a schedule to bring the waterworks into compliance with this chapter and require the submission of a comprehensive business plan pursuant to § 32.1-172 B of the Code of Virginia. If capital improvements are necessary to bring the waterworks into compliance, and the owner does not possess sufficient assets to make

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the necessary improvements, the order shall require the owner to make annual, good faith applications for loans/grants to appropriate financial institutions to secure funding for such improvements, until such improvements are complete and operational. The owner shall provide a copy of the order to each consumer with a copy of the compliance schedule within ten (10) calendar days of issuance of the order.

C. The owner shall provide the commissioner a copy of the notice distributed and a signed certification of the distribution completion date within five (5) calendar days of completing the notification required in subsection B of this section.

D. The commissioner shall send a copy of the order to the chief administrative officer of the locality in which the waterworks is located for appropriate action under § 15.2-2146 of the Code of Virginia.

E. In addition to the provisions of § 32.1-27 of the Code of Virginia, any owner who violates this chapter, an order of the board or statute governing public water supplies shall be subject to those civil penalties provided in § 32.1-167 to § 32.1-176 of the Code of Virginia.

Certification Statement:

I certify that this regulation is full, true, and correctly dated.

\_\_\_\_\_ (Signature of certifying official)

Name and title of certifying official: \_\_\_\_\_

Name of agency: \_\_\_\_\_

Date: \_\_\_\_\_



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## Exempt Action Final Regulation Agency Background Document

<b>Agency name</b>	Virginia Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 5-220
<b>Regulation title</b>	Medical Care Facilities Certificate of Public Need Rules and Regulations
<b>Action title</b>	To amend specific sections pursuant to HB1598 (2009)
<b>Final agency action date</b>	
<b>Document preparation date</b>	

When a regulatory action is exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the Virginia Administrative Process Act (APA), the agency is encouraged to provide information to the public on the Regulatory Town Hall using this form.

Note: While posting this form on the Town Hall is optional, the agency must comply with requirements of the Virginia Register Act, the *Virginia Register Form, Style, and Procedure Manual*, and Executive Orders 36 (06) and 58 (99).

### Summary

*Please provide a brief summary of all regulatory changes, including the rationale behind such changes. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.*

HB1598 (2009) is a comprehensive amendment of Article 1.1 of Chapter 4 of Title 32.1 of the Code of Virginia related to the Certificate of Public program. The amendments to the Code included, but were not limited to: (i) replacing the 21 considerations used in making a determination of need with eight modified and abbreviated considerations; (ii) adding beds for psychiatric or substance abuse treatment services and the establishment of new psychiatric or substance abuse treatment services to the Request for Applications (RFA) process currently used for distributing nursing facility beds; (iii) extending the expedited review process to certain capital expenditure projects; and (iv) modifying the requirements of the annual report. Therefore, applicable sections of 12VAC5-220 must be amended to conform to the law. In addition, a technical correction to 12VAC5-220-105 corrects a misquoted statutory citation.

**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.*

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At its July 17, 2009 meeting, the Board of Health approved this nondiscretionary action to amend sections 12VAC5-220- 90, 105, 160, 180, 210, 280, 335, 345, 355, and 375.

**Family impact**

*Assess the impact of this regulatory action on the institution of the family and family stability.*

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There is no direct impact on the family or family stability.

## Medical Care Facilities Certificate of Public Need Rules and Regulations

**Project 2003 - none****DEPARTMENT OF HEALTH  
CH220 amend the COPN rules resulting from HB1598****12VAC5-220-90. Annual report.**

~~The Pursuant to § 32.1-102.12 of the Code of Virginia, the commissioner shall annually report to the Governor and the General Assembly on the status of Virginia's certificate of public need program. The report shall be issued by October 1 of each year and shall include, but need not be limited to:-~~

- ~~1. A summary of the commissioner's actions during the previous fiscal year pursuant to Virginia's certificate of public need law;-~~
- ~~2. A five-year schedule for analysis of all project categories, which provides for the analysis of at least three project categories per year;-~~
- ~~3. An analysis of the appropriateness of continuing the certificate of public need program for at least three project categories in accordance with the five-year schedule for analysis of all project categories;-~~
- ~~4. An analysis of the effectiveness of the application review procedures used by the regional health planning agencies and the department required by § 32.1-102.6 of the Code of Virginia that details the review time required during the past year for various project categories, the number of contested or opposed applications and the project categories of these contested or opposed projects, the number of applications upon which the regional health planning agencies have failed to act in accordance with the timelines of § 32.1-102.6 B, and the number of deemed approvals from the department because of their failure to comply with the timelines required by § 32.1-102.6 E, and any other data determined by the commissioner to be relevant to the efficient operation of the program;-~~
- ~~5. An analysis of health care market reform in the Commonwealth and the extent, if any, to which such reform obviates the need for the certificate of public need program;-~~
- ~~6. An analysis of the accessibility by the indigent to care provided by medical care facilities regulated pursuant to Virginia's certificate of public need law;-~~
- ~~7. An analysis of the relevance of Virginia's certificate of public need law to the quality of care provided by medical care facilities regulated pursuant to this law; and-~~
- ~~8. An analysis of equipment registrations required pursuant to § 32.1-102.1:1, including type of equipment, whether an addition or replacement, and the equipment costs.-~~

**12VAC5-220-105. Requirements for registration of the replacement of existing medical equipment.**

Within 30 days of any person contracting to make, or otherwise legally obligating to make, a capital expenditure for the replacement of medical equipment or otherwise

## Medical Care Facilities Certificate of Public Need Rules and Regulations

acquiring replacement medical equipment for the provision of services listed in subdivision 7 of the definition of "project" in 12VAC5-220-10, the person shall register in writing such equipment replacement with the commissioner and the appropriate regional health planning agency. Such registration shall be made on forms provided by the department. The registration shall identify the specific unit of equipment to be replaced and the estimated capital cost of the replacement and shall include documentation that the equipment to be replaced has previously been authorized through issuance of a certificate of public need, registered pursuant to former § 32.1-102.3:4 of the Code of Virginia or exempted pursuant to § 32.1-102.11 of the Code of Virginia as allowed by law.

Part IV  
Determination of Public Need (Required Considerations)

**12VAC5-220-160. Required considerations.**

In determining whether a public need exists for a proposed project, ~~the following factors shall be taken into account when applicable:~~ the applicable requirements of § 32.1-102.2:1 of the Code of Virginia will be considered.

- ~~1. The recommendation and the reasons therefor of the appropriate regional health planning agency.~~
- ~~2. The relationship of the project to the applicable health plans of the regional health planning agency and the Board of Health.~~
- ~~3. The relationship of the project to the long-range development plan, if any, of the person applying for a certificate.~~
- ~~4. The need that the population served or to be served by the project has for the project, including, but not limited to, the needs of rural populations in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.~~
- ~~5. The extent to which the project will be accessible to all residents of the area proposed to be served and the effects on accessibility of any proposed relocation of an existing service or facility.~~
- ~~6. The area, population, topography, highway facilities and availability of the services to be provided by the project in the particular part of the health planning region in which the project is proposed, in particular, the distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.~~
- ~~7. Less costly or more effective alternate methods of reasonably meeting identified health service needs.~~
- ~~8. The immediate and long-term financial feasibility of the project.~~
- ~~9. The relationship of the project to the existing health care system of the area in which the project is proposed; however, for projects proposed in rural areas, the relationship of the project to the existing health care services in the specific rural locality shall be considered.~~
- ~~10. The availability of resources for the project.~~

## Medical Care Facilities Certificate of Public Need Rules and Regulations

- ~~11. The organizational relationship of the project to necessary ancillary and support services.~~
- ~~12. The relationship of the project to the clinical needs of health professional training programs in the area in which the project is proposed.~~
- ~~13. The special needs and circumstances of an applicant for a certificate, such as a medical school, hospital, multidisciplinary clinic, specialty center or regional health service provider, if a substantial portion of the applicant's services or resources or both is provided to individuals not residing in the health planning region in which the project is to be located.~~
- ~~14. The need and the availability in the health planning region for osteopathic and allopathic services and facilities and the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.~~
- ~~15. The special needs and circumstances of health maintenance organizations. When considering the special needs and circumstances of health maintenance organizations, the commissioner may grant a certificate for a project if the commissioner finds that the project is needed by the enrolled or reasonably anticipated new members of the health maintenance organizations or the beds or services to be provided are not available from providers which are not health maintenance organizations or from other health maintenance organizations in a reasonable and cost effective manner.~~
- ~~16. The special needs and circumstances for biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.~~
- ~~17. The costs and benefits of the construction associated with the proposed project.~~
- ~~18. The probable impact of the project on the costs of and charges for providing health services by the applicant for a certificate and on the costs and charges to the public for providing health services by other persons in the area.~~
- ~~19. Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness.~~
- ~~20. In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities in the area similar to those proposed, including, in the case of rural localities, any distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.~~
- ~~21. In the case of proposed health services or facilities, the extent to which a proposed service or facility will increase citizen accessibility, demonstrate documented community support, and introduce institutional competition into a health planning region.~~

**12VAC5-220-180. Application forms.**

A. Letter of intent. An applicant shall file a letter of intent with the commissioner to request appropriate application forms, and submit a copy of that letter to the appropriate

## Medical Care Facilities Certificate of Public Need Rules and Regulations

regional health planning agency, by the later of (i) 30 days prior to the submission of an application for a project included within a particular batch group or (ii) 10 days after the first letter of intent is filed for a project within a particular batch group for the same or similar services and facilities which are proposed for the same planning district or medical service area. The letter shall identify the owner, the type of project for which an application is requested, and the proposed scope (size) and location of the proposed project. The department shall transmit application forms to the applicant within seven days of the receipt of the letter of intent. A letter of intent filed with the department shall be considered void one year after the date of receipt of such letter. (See 12VAC5-220-310 C.)

B. Application fees. The department shall collect application fees for applications that request a certificate of public need. The fee required for an application shall be 1.0% of the proposed expenditure for the project, but not less than \$1,000 and no more than \$20,000.

No application will be deemed to be complete for review until the required application fee is paid. (See 12VAC5-220-310 C.)

C. Filing application forms. Applications must be submitted at least 40 days prior to the first day of a scheduled review cycle to be considered for review in the same cycle. ~~All applications including the required data and information shall be prepared in triplicate; two copies to be submitted to the department; one copy to be submitted to the appropriate regional health planning agency.~~ In order to verify the date of the department's and the appropriate regional health planning agency's receipt of the application, the applicant shall transmit the document electronically or prepare in triplicate; two copies to be submitted to the department; one copy to be submitted to the appropriate regional health planning agency and sent by certified mail or a delivery service, return receipt requested, or shall deliver the document by hand, with a signed receipt to be provided. No application shall be deemed to have been submitted until required copies have been received by the department and the appropriate regional health planning agency. (See 12VAC5-220-200.)

**12VAC5-220-210. Requests for application (RFA).**

The commissioner may request the submission of applications for his consideration which address a specific need for services and facilities as identified in the State Medical Facilities Plan. The department shall give notice of such RFA in a newspaper of general circulation in the locality or the planning district where the specific services or facility is requested. Such notice shall be published at least 120 days prior to the first day of the appropriate review cycle for the type of project being requested. A written copy of an RFA shall also be available upon request from the department and the regional health planning agency in the appropriate geographic area. The process for adoption of an RFA by the commissioner for projects ~~other than nursing home bed projects (see 12VAC5-220-325) shall be set forth in the State Medical Facilities Plan listed in § 32.1-102.3:2~~ subsections A, B, and C of the Code of Virginia are set forth in 12VAC5-220-335 of this chapter.

## Medical Care Facilities Certificate of Public Need Rules and Regulations

Part VI  
Expedited Review Process**12VAC5-220-280. Applicability.**

~~Projects of medical care facilities~~ Capital expenditures as contained in subsection 8 of 'project' as defined in § 32.1-102 of the Code of Virginia or projects that involve relocation at the same site of 10 beds or 10% of the beds, whichever is less, from one existing physical facility to another, when the cost of such relocation is less than \$5 million, shall be subject to an expedited review process.

**12VAC5-220-335. Request for Applications (RFA).**

~~A. Frequency. The Pursuant to § 32.1-102.3:2, subsections A, B, and C of the Code of Virginia, the commissioner shall periodically issue, in consultation and cooperation with the Department of Medical Assistance Services, a Request for Applications (RFA) from project applicants proposing projects which would result in an increase in the number of beds in which nursing facility or extended care services are provided. An RFA shall be issued at least annually. (See 12VAC5-220-325).~~

~~B. Issuance. At least 60 days prior to the issuance of a RFA, the board shall publish the proposed RFA in the Virginia Register for public comment together with an explanation of (i) the regulatory basis for the planning district bed needs set forth in the proposed RFA and (ii) the rationale for the RFA's planning district designations. Any person objecting to the contents of the proposed RFA may notify, within 14 days of the publication, the board and the commissioner of his objection and the objection's regulatory basis. The commissioner shall prepare, and deliver by registered mail, a written response to each such objection within two weeks of the date of receiving the objection. The objector may file a rebuttal to the commissioner's response in writing within five days of receiving the commissioner's response. If objections are received, the board shall, after considering the provisions of the RFA, any objections, the commissioner's responses, and if filed, any written rebuttals of the commissioner's responses, hold a public hearing to receive comments on the specific RFA. Prior to making a decision on the RFA, the commissioner shall consider any recommendations made by the board.~~

~~C. Content. A RFA from project applicants proposing projects which would result in an increase in the number of beds in which nursing facility or extended care services are provided shall be based on analyses of the need for increases in the nursing home bed supply in each of Virginia's planning districts in accordance with the applicable standards included in the State Medical Facilities Plan. Such RFAs shall also include a schedule for the review of applications submitted in response to the RFA which allows for at least 120 days between the day on which the RFA is issued and the first day of the review cycle for such applications.~~

**12VAC5-220-345. Limitation on acceptance of nursing home bed RFA applications.**

~~Applications for projects which would result in an increase in the number of beds in which nursing facility or extended care services are provided (see 12VAC5-22-325) listed in § 32.1-102.3:2, subsections A, B, and C of the Code of Virginia shall only be accepted for review when properly filed in response to a RFA. Furthermore, the~~

## Medical Care Facilities Certificate of Public Need Rules and Regulations

commissioner shall only accept for review applications which propose projects located in the planning districts from which applications are requested in the RFA and propose authorization of a number of new beds in ~~which nursing facility or extended care services~~ are provided which is less than or equal to the total number of beds identified as needed for the planning district in which the project will be located.

**12VAC5-220-355. ~~Application RFA project application forms.~~**

A. Letter of intent. A ~~nursing home bed~~ RFA project applicant shall file a letter of intent with the commissioner to request appropriate application forms, and submit a copy of that letter to the appropriate regional health planning agency by the letter of intent deadline specified in the RFA. The letter shall identify the owner, the type of project for which an application is requested, and the proposed scope (size) and location of the proposed project. The department shall transmit application forms to the applicant within seven days of the receipt of the letter of intent. A letter of intent filed with the department shall be considered void if an application is not filed for the project by the application deadline specified in the RFA.

B. Application fees. The department shall collect application fees for RFA applications that request a ~~nursing home bed~~ certificate of public need. The fee required for an application is 1.0% of the proposed capital expenditure for the project but no less than \$1,000 and no more than \$20,000. No application will be deemed to be complete for review until the required application fee is paid.

C. Filing application forms. Applications must be submitted to the department and the appropriate regional health planning agency by the application filing deadline specified in the RFA. ~~All applications including the required data and information shall be prepared in triplicate; two copies to be submitted to the department; and one copy to be submitted to the appropriate regional health planning agency.~~ In order to verify the department and the appropriate regional health planning agency's receipt of the application, the applicant shall transmit the document electronically or prepare in triplicate; two copies to be submitted to the department; and one copy to be submitted to the appropriate regional health planning agency and sent by certified mail or a delivery service, return receipt requested, or ~~shall deliver the document by hand, with the a~~ signed receipt to be provided. No application shall be deemed to have been submitted until required copies have been received by the department and the appropriate regional health planning agency.

**12VAC5-220-375. Consideration of RFA applications.**

~~Nursing home bed~~ RFA applications proposed for the same planning district shall be considered as competing applications by the commissioner. The commissioner shall determine whether an application is competing and provide written notification to the competing applicants and the regional health planning agency.



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## Exempt Action Final Regulation Agency Background Document

<b>Agency name</b>	Virginia Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 5-220-110 and 200
<b>Regulation title</b>	Medical Care Facilities Certificate of Public Need Rules and Regulations
<b>Action title</b>	To amend specific sections pursuant to HB2546 (2007)
<b>Final agency action date</b>	July 17, 2009
<b>Document preparation date</b>	June 1, 2009

When a regulatory action is exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the Virginia Administrative Process Act (APA), the agency is encouraged to provide information to the public on the Regulatory Town Hall using this form.

Note: While posting this form on the Town Hall is optional, the agency must comply with requirements of the Virginia Register Act, the *Virginia Register Form, Style, and Procedure Manual*, and Executive Orders 36 (06) and 58 (99).

### Summary

*Please provide a brief summary of all regulatory changes, including the rationale behind such changes. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.*

HB2546 (2007) amends §32.1-102.1 of the Code of Virginia related to the Certificate of Public Need program by requiring an annual increase in the threshold for capital expenditure projects to “reflect inflation using appropriate measures incorporating construction costs and medical inflation.” Therefore, 12 VAC 5-220-110 and 200 must be amended to conform to the law. Using the Consumer Price Index recently published by the U.S. Department of Labor, the capital expenditure threshold for projects requiring a COPN increased from \$15,615,000 to \$ 16,083,450.

### 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.*

At its July 17, 2009 meeting, the Board of Health approved this nondiscretionary action to amend 12VAC5-220-110 and 200.

### Family impact

*Assess the impact of this regulatory action on the institution of the family and family stability.*

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There is no direct impact on the family.

## Medical Care Facilities Certificate of Public Need Rules and Regulations

**Project 1948 - none**

**DEPARTMENT OF HEALTH**  
**0220 COPN capital expenditure update**

**12VAC5-220-110. Requirements for registration of certain capital expenditures.**

At least 30 days before any person contracts to make or is otherwise legally obligated to make a capital expenditure by or on behalf of a medical care facility that is \$5 million or more but is less than ~~\$15,645,000~~ \$16,083,450 and has not been previously authorized by the commissioner, the owner of any medical care facility as defined in this chapter shall register in writing such expenditure with the commissioner. The format for registration shall include information concerning the purpose of such expenditure and projected impact that the expenditure will have upon the charges for services. For purposes of registration, the owner shall include any person making the affected capital expenditure. See definition of "project."

**12VAC5-220-200. One hundred ninety-day review cycle.**

The department shall review the following groups of completed applications in accordance with the following 190-day scheduled review cycles and the following descriptions of projects within each group, except as provided for in 12VAC5-220-220.

BATCH GROUP	GENERAL DESCRIPTION	REVIEW CYCLE	
		Begins	Ends
A	General Hospitals/Obstetrical Services/Neonatal Special Care Services	Feb. 10 Aug. 10	Aug. 18 Feb. 16
B	Open Heart Surgery/Cardiac Catheterization/Ambulatory Surgery Centers/Operating Room Additions/Transplant Services	Mar. 10 Sep. 10	Sep. 16 Mar. 19
C	Psychiatric Facilities/Substance Abuse Treatment/Mental Retardation Facilities	Apr. 10 Oct. 10	Oct. 17 Apr. 18
D/F	Diagnostic Imaging Facilities/Services Selected Therapeutic Facilities/Services	May 10 Nov. 10	Nov. 16 May 19
E	Medical Rehabilitation Beds/Services	June 10 Dec. 10	Dec. 17 Jun. 18
D/F	Selected Therapeutic Facilities/Services Diagnostic Imaging Facilities/Services	July 10 Jan. 10	Jan. 16 Jul. 18

## Medical Care Facilities Certificate of Public Need Rules and Regulations

G	Nursing Home Beds at Retirement Communities/Bed Relocations/Miscellaneous Expenditures by Nursing Homes	Jan. 10	Jul. 18
		Mar. 10	Sep. 16
		May 10	Nov. 16
		July 10	Jan. 16
		Sep. 10	Mar. 19
		Nov. 10	May 19

## Batch Group A includes:

1. The establishment of a general hospital.
2. An increase in the total number of general acute care beds in an existing or authorized general hospital.
3. The relocation at the same site of 10 general hospital beds or 10% of the general hospital beds of a medical care facility, whichever is less, from one existing physical facility to another in any two-year period if such relocation involves a capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more (see 12VAC5-220-280).
4. The introduction into an existing medical care facility of any new neonatal special care or obstetrical services that the facility has not provided in the previous 12 months.
5. Any capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more, not defined as a project category included in Batch Groups B through G, by or in behalf of a general hospital.

## Batch Group B includes:

1. The establishment of a specialized center, clinic, or portion of a physician's office developed for the provision of outpatient or ambulatory surgery or cardiac catheterization services.
2. An increase in the total number of operating rooms in an existing medical care facility or establishment of operating rooms in a new facility.
3. The introduction into an existing medical care facility of any new cardiac catheterization, open heart surgery, or organ or tissue transplant services that the facility has not provided in the previous 12 months.
4. The addition by an existing medical care facility of any medical equipment for the provision of cardiac catheterization.
5. Any capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more, not defined as a project category in Batch Group A or Batch Groups C through G, by or in behalf of a specialized center, clinic, or portion of a physician's office developed for the provision of outpatient or ambulatory surgery or cardiac catheterization services.
6. Any capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more, not defined as a project category in Batch Group A or Batch Groups C through G, by or in behalf of a medical care facility, that is primarily related to the provision of surgery, cardiac catheterization, open heart surgery, or organ or tissue transplant services.

## Batch Group C includes:

## Medical Care Facilities Certificate of Public Need Rules and Regulations

1. The establishment of a mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facility.
2. An increase in the total number of beds in an existing or authorized mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facility.
3. An increase in the total number of mental hospital, psychiatric hospital, substance abuse treatment and rehabilitation, or mental retardation beds in an existing or authorized medical care facility which is not a dedicated mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facility.
4. The relocation at the same site of 10 mental hospital, psychiatric hospital, substance abuse treatment and rehabilitation, or mental retardation beds or 10% of the mental hospital, psychiatric hospital, substance abuse treatment and rehabilitation, or mental retardation beds of a medical care facility, whichever is less, from one existing physical facility to another in any two-year period if such relocation involves a capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more (see 12VAC5-220-280).
5. The introduction into an existing medical care facility of any new psychiatric or substance abuse treatment service that the facility has not provided in the previous 12 months.
6. Any capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more, not defined as a project category in Batch Groups A and B or Batch Groups D/F through G, by or in behalf of a mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facilities.
7. Any capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more, not defined as a project category in Batch Groups A through B or Batch Groups D/F through G, by or in behalf of a medical care facility, which is primarily related to the provision of mental health, psychiatric, substance abuse treatment or rehabilitation, or mental retardation services.

## Batch Group D/F includes:

1. The establishment of a specialized center, clinic, or that portion of a physician's office developed for the provision of computed tomographic (CT) scanning, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging, except for the purpose of nuclear cardiac imaging.
2. The introduction into an existing medical care facility of any new computed tomography (CT), magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging services, except for the purpose of nuclear cardiac imaging that the facility has not provided in the previous 12 months.

## Medical Care Facilities Certificate of Public Need Rules and Regulations

3. The addition by an existing medical care facility of any equipment for the provision of computed tomography (CT), magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning.
4. Any capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more, not defined as a project category in Batch Groups A B, C, E, and G, by or in behalf of a specialized center, clinic, or that portion of a physician's office developed for the provision of computed tomographic (CT) scanning, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging, except that portion of a physician's office dedicated to providing nuclear cardiac imaging.
5. Any capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more, not defined as a project category in Batch Groups A B, C, E, and G, by or in behalf of a medical care facility, which is primarily related to the provision of computed tomographic (CT) scanning, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging, except for the purpose of nuclear cardiac imaging.

## Batch Group E includes:

1. The establishment of a medical rehabilitation hospital.
2. An increase in the total number of beds in an existing or authorized medical rehabilitation hospital.
3. An increase in the total number of medical rehabilitation beds in an existing or authorized medical care facility that is not a dedicated medical rehabilitation hospital.
4. The relocation at the same site of 10 medical rehabilitation beds or 10% of the medical rehabilitation beds of a medical care facility, whichever is less, from one existing physical facility to another in any two-year period, if such relocation involves a capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more (see 12VAC220-280).
5. The introduction into an existing medical care facility of any new medical rehabilitation service that the facility has not provided in the previous 12 months.
6. Any capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more, not defined as a project category in Batch Groups A B, C, D/F, and G, by or in behalf of a medical rehabilitation hospital.
7. Any capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more, not defined as a project category in Batch Groups A B, C, D/F, and G, by or in behalf of a medical care facility, that is primarily related to the provision of medical rehabilitation services.

## Batch Group D/F includes:

1. The establishment of a specialized center, clinic, or that portion of a physician's office developed for the provision of gamma knife surgery, lithotripsy, or radiation therapy.
2. Introduction into an existing medical care facility of any new gamma knife surgery, lithotripsy, or radiation therapy services that the facility has not provided in the previous 12 months.

## Medical Care Facilities Certificate of Public Need Rules and Regulations

3. The addition by an existing medical care facility of any medical equipment for the provision of gamma knife surgery, lithotripsy, or radiation therapy.
4. Any capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more, not defined as a project in Batch Groups A B, C, E, and G, by or in behalf of a specialized center, clinic, or that portion of a physician's office developed for the provision of gamma knife surgery, lithotripsy, or radiation therapy.
5. Any capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more, not defined as a project in Batch Groups A B, C, E, and G, by or in behalf of a medical care facility, which is primarily related to the provision of gamma knife surgery, lithotripsy, or radiation therapy.

## Batch Group G includes:

1. The establishment of a nursing home, intermediate care facility, or extended care facility of a continuing care retirement community by a continuing care provider registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia.
2. The establishment of a nursing home, intermediate care facility, or extended care facility that does not involve an increase in the number of nursing home facility beds within a planning district.
3. An increase in the total number of beds in an existing or authorized nursing home, intermediate care facility, or extended care facility of a continuing care retirement community by a continuing care provider registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia.
4. An increase in the total number of beds in an existing or authorized nursing home, intermediate care facility, or extended care facility that does not involve an increase in the number of nursing home facility beds within a planning district.
5. The relocation at the same site of 10 nursing home, intermediate care facility, or extended care facility beds or 10% of the nursing home, intermediate care facility, or extended care facility beds of a medical care facility, whichever is less, from one physical facility to another in any two-year period, if such relocation involves a capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more (see 12VAC5-220-280).
6. Any capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more, not defined as a project category in Batch Groups A through D/F, by or in behalf of a nursing home, intermediate care facility, or extended care facility, which does not increase the total number of beds of the facility.
7. Any capital expenditure of ~~\$15,615,000~~ \$16,083,450 or more, not defined as a project category in Batch Groups A through D/F, by or in behalf of a medical care facility, that is primarily related to the provision of nursing home, intermediate care, or extended care services, and does not increase the number of beds of the facility.