State Board of Health – Nominating Committee
Agenda
June 4, 2015 – 8:30 a.m.
Perimeter Center – Hearing Room 4
9960 Mayland Drive
Richmond, Virginia 23233

Welcome and Introductions	Terry Brosche, Chair
Discussion	Nominating Committee Members
Adjourn	

State of Board of Health
Agenda
June 4, 2015 – 9:00 a.m.
Perimeter Center – Boardroom 2
9960 Mayland Drive
Richmond, Virginia 23233

Call to Order and Welcome	Bruce Edwards, Chair
Pledge of Allegiance	Dr. Steven Escobar
Introductions	Mr. Edwards
Review of Agenda	Joseph Hilbert Director of Governmental and Regulatory Affairs
Approval of March 19, 2015 Minutes	Mr. Edwards
Commissioner's Report	Marissa J. Levine, MD, MPH, FAAFP State Health Commissioner
Budget Update	Michael McMahon, Administration Operations Director
Abortion Facility Licensure Status Report	Erik Bodin, Director Office of Licensure and Certification
Regulatory Action Update	Mr. Hilbert
Break	
Public Comment Period	

Regulatory Action Items

Regulations Governing Virginia Newborn Screening Services 12VAC5-71 (Proposed Amendments)	Lilian Peake, MD, MPH, Director Office of Family Health Services
Virginia Radiation Protection Regulations 12VAC5-481 (Notice of Intended Regulatory Action)	Steve Harrison, Director Office of Radiological Health
Nominating Committee Report	Terry Brosche
Election of Officers and Executive Committee Members	Mr. Edwards
Working Lunch Presentation – Algae Blooms	Rebecca LePrell, Director VDH Division of Environmental Epidemiology

Regulatory Action Items

Regulations for Licensure of Hospitals In Virginia 12VAC5-410 (Fast Track Amendments)	Mr. Bodin

Member Reports

Other Business

Adjourn

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

MEMORANDUM

DATE: May 12, 2015

TO: Virginia State Board of Health

FROM: Lilian Peake, MD, MPH
Associate Commissioner and Director, Office of Family Health Services

SUBJECT: Proposed Amendments to 12VAC5-71, Regulations Governing Virginia Newborn Screening Services

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The Virginia State Board of Health (Board) is asked to review and approve the proposed amendments to 12VAC5-71, which add screening for critical congenital heart disease (CCHD) to the newborn screening regulations. The proposed amendments also include some changes to the State Plan for the Children with Special Health Care Needs Program (12VAC5-191), in order to have those regulations remain consistent with 12VAC5-71.

Emergency regulations to add CCHD screening to the newborn screening regulations were previously brought before this Board in September 2014 and they became effective December 24, 2014. Those regulatory changes were implemented in accordance with House Bill 387, which was signed by the Governor on February 20, 2014, and Senate Bill 183, which was signed by the Governor on March 5, 2014. Both bills required VDH to convene a workgroup to provide information and recommendations for the development of regulations to require all hospitals with newborn nurseries to perform a screening test for critical congenital heart disease on all babies born in the hospital. The bills also required VDH to promulgate regulations to implement these provisions within 280 days of enactment.

Following the publication of the emergency regulations, public comments were received from two parties; both of these were supportive of the regulatory amendments. VDH has 18 months (until 6/23/2016) from the publication of the emergency regulations to make them permanent; submitting these proposed amendments for review and public comment is the next step in that process.

VDH has made some changes to the regulatory text from the emergency/NOIRA stage to the proposed stage. These revisions were relatively minor and were generally intended to simplify and/or clarify text. These changes included modifying the definition of the term “newborn” to indicate that it means a person in the first 28 days of life, born in Virginia (“or on federal

property in Virginia" has been stricken from the definition). The intent was to apply these regulations to infants born in military hospitals in Virginia; however, VDH does not have regulatory authority over military hospitals, therefore it has been removed. Other changes included clarifying references and adding two elements to be recorded in the electronic birth certificate; pulse oximetry values, and whether the newborn was not screened pursuant to 12VAC5-71-220 C and 12VAC5-71-260.

Should the Board approve these proposed amendments, the amendments will be forwarded for Executive Branch Review. Following this review and approval, the proposed amendments will be published in the Virginia Register of Regulations for a 60 day public comment period.

townhall.virginia.gov

Proposed Regulation
Agency Background Document

Agency name	Virginia Department of Health (VDH)
Virginia Administrative Code (VAC) citation(s)	12VAC5-71 and 12VAC5-191
Regulation title(s)	Regulations Governing Virginia Newborn Screening Services and State Plan for the Children with Special Health Care Needs Program
Action title	Amend regulations to add critical congenital heart disease (CCHD) to the Virginia Newborn Screening System so that all babies born in hospitals with a newborn nursery in Virginia are screened for CCHD
Date this document prepared	April 27, 2015

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

Brief summary

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

These amendments to the newborn screening regulations add requirements for hospitals with a newborn nursery to screen all infants born in Virginia for critical congenital heart disease (CCHD) within 24-48 hours after birth using pulse-oximetry. These amendments require that hospitals develop protocols for the screening all newborns for CCHD, and that they have protocols for the follow-up and referral for any infants that have positive screens. Newborns that have an abnormal screen shall not be discharged from the hospital until the cause of the abnormal screen has been evaluated and an appropriate plan for care is in place. Any diagnosis resulting from an abnormal screen shall be entered in the electronic birth certificate, and the attending physician shall notify the parent and the primary care provider of the diagnosis. Infants that are diagnosed with CCHD shall be referred to the Care Connections for Children

program for care coordination services. A parent may refuse to have their child screened on the basis of religious practices or tenets. Such refusal must be documented in writing.

Most hospitals in Virginia are already voluntarily performing this screening. The proposed amendments would require a small number of additional hospitals to implement the screening. The amendments will also permit VDH to collect information via the VaCARES reporting system so that infants identified with a critical congenital heart disease could be referred to the "Care Connections for Children" program to obtain care coordination services.

This regulatory action also includes proposed amendments to the State Plan for the Children with Special Health Care Needs Program (12VAC5-191), so that those regulations remain consistent with 12VAC5-71.

Emergency regulations requiring this screening have been in effect since December 24, 2014, as required by HB387/SB183 enacted by the 2014 General Assembly and signed by the Governor. Those emergency regulations will expire on June 23, 2016. This regulatory action seeks to make those changes permanent.

Acronyms and Definitions

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

CCHD - Critical Congenital Heart Disease
VaCARES- Virginia Congenital Anomalies Reporting and Education System
VDH – Virginia Department of Health

Legal basis

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

The State Board of Health is authorized to make, adopt, promulgate and enforce regulations by Section 32.1-12 of the Code of Virginia.

Section 32.1-65.1 states that the Board of Health shall require every hospital in Virginia having a newborn nursery to screen infants for critical congenital heart disease.

Section 32.1-67 requires the Board of Health to promulgate regulations

HB387/SB183 enacted by the General Assembly required the Board of Health to promulgate emergency regulations for CCHD screening. This regulatory action seeks to make those changes permanent.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health,

safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

Congenital heart defects are the most common birth defects in the United States, affecting about one in every 110 babies. A few babies born with congenital heart defects have more serious forms of heart disease, which are referred to as *critical* congenital heart disease (affecting approximately 2 of every 1,000 births). CCHDs are heart defects that result in abnormal blood flow and oxygen deprivation. These defects require intervention within the first year of life and delayed diagnosis can result in death. Screening newborns for CCHD using pulse oximetry has been recommended through the U.S. Department of Health and Human Services Recommended Uniform Screening Panel. The screening is simple, quick, and painless. A sensor wrapped around the baby's right hand or either foot measures the amount of oxygen in the baby's blood.

The purpose of the proposed regulatory action is to ensure that all Virginia hospitals with newborn nurseries implement CCHD screening, and to ensure that newborns diagnosed with CCHD are reported to VDH so that they may be linked to care coordination services through the "Care Connections for Children" program.

Substance

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

These proposed amendments to the newborn screening regulations require all hospitals with a newborn nursery to screen newborns for CCHD within 24-48 hours of birth. Specifically they add the following elements to the existing regulations:

- Hospitals are required to develop protocols for screening, timely evaluation, and timely referral of newborns with abnormal screening results.
- Requirements that a licensed practitioner perform the screening, and setting forth when the screening is to occur. If screening is not indicated, documentation requirements are set forth for the medical record. Hospitals are required to develop screening protocols for specialty and sub-specialty nurseries.
- Requirements that all screening results must be entered into the medical record and the electronic birth certificate system. This section also requires health care providers to report abnormal screening results immediately and to evaluate the newborn in a timely manner. Newborns shall not be discharged unless a cause for the abnormal screening result has been determined or CCHD has been ruled out. Parents or guardians and the infant's primary care provider after discharge from the hospital shall be notified of any abnormal results and any diagnoses.
- Hospitals must report individuals diagnosed with CCHD to VDH so that the newborn's parent or guardian may be referred to care coordination services through the Care Connection for Children.
- A section specifying what documents shall be provided when requested by the VaCARES system at VDH, and specifying the confidentiality rules for these documents.
- A section that permits parents to refuse CCHD screening based upon religious practices or tenets, and to specify that the hospital must report the refusal to VDH.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

These proposed amendments will permanently add CCHD screening requirements to the regulations for newborn screening. The primary advantage to VDH, the public, and the Commonwealth is that the regulations will ensure that every infant born in a hospital with a newborn nursery will be screened for CCHD and that those who screen positive will have further evaluation and follow-up as needed. The majority of hospitals that would be affected by these regulations already provide screening for CCHD voluntarily. These proposed amendments set minimum standards for this screening. There are no disadvantages to the public or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

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

There are no known localities that would be specifically impacted by these proposed regulations.

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

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to Dev Nair, 109 Governor Street, Richmond, Virginia 23219; 804-864-7662 (phone); 804-864-7380 (fax); or

Dev.Nair@vdh.virginia.gov. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

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

Economic impact

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

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	Actions to educate hospitals and develop a tracking and recording system for CCHD were supported by a CDC grant. There are no additional costs to the state to implement this regulation.
Projected cost of the new regulations or changes to existing regulations on localities.	There are no projected costs to localities for these new regulations.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	These regulations will impact infants that are born in Virginia hospitals with newborn nurseries (excluding those that are hospitalized in neonatal intensive care units [NICU]) as well as the hospitals themselves.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	Virginia hospitals with newborn nurseries: 55 Infants born in these facilities annually (excluding NICU births): 70,000 – 75,000
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	Screening infants for CCHD is considered a best practice and was adopted by most hospitals prior to the requirements enacted by the 2014 General Assembly. Additional reporting of screening results and confirmed cases that are required by these regulations occurs through existing systems (electronic birth certificate and VaCARES), therefore additional costs to implement these regulations are projected to be minimal.
Beneficial impact the regulation is designed to produce.	CCHD is a serious health condition affecting newborns that can result in death if not diagnosed and treated early. These regulations will assure that all newborns born in Virginia hospitals with newborn nurseries will be screened for CCHD prior to their discharge from the hospital.

	Approximately 200 newborns annually in Virginia have CCHD.

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.

None. The Acts of Assembly of 2014 required the Board to promulgate regulations to implement the provisions of House Bill 387 and Senate Bill 183. Section 32.1-65.1 of the Code of Virginia states that the Board of Health shall require every hospital in Virginia having a newborn nursery to screen infants for critical congenital heart disease. There are no viable alternatives to the proposed amendments.

Regulatory flexibility analysis

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

The proposed amendments do not directly impact small businesses. The Acts of Assembly of 2014 required the Board to promulgate regulations to implement the provisions of House Bill 387 and Senate Bill 183. Section 32.1-65.1 of the Code of Virginia states that the Board of Health shall require every hospital in Virginia having a newborn nursery to screen infants for critical congenital heart disease.

Periodic review and small business impact review report of findings

If you are using this form to report the result of a periodic review/small business impact review that was announced during the NOIRA stage, please indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

N/A

Public comment

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

Commenter	Comment	Agency response
Robert Shor, MD, FACC, VA Chapter American College of Cardiology	The Virginia Chapter of the American College of Cardiology (the Chapter) supports the Emergency Regulation Governing Virginia Newborn Screening Services published in the Virginia Register of Regulations, January 26, 2015. This Emergency Regulation enhances the quality of life for children born in Virginia hospitals. Pulse oximetry screening is a simple, effective, inexpensive, and noninvasive test. The Chapter is particularly pleased with the definition of screening technology which "means pulse oximetry testing in the right hand and either foot". The Chapter strongly approves that the definition allows for future contingencies.	VDH notes the support of the emergency regulations that are now in effect.
Amy Hewett, American Heart Association	The American Heart Association strongly supports the Department's new regulations that add critical congenital heart disease (CCHD) screening using pulse oximetry testing in the Commonwealth's Newborn Screening System. With this new regulation, Virginia joins dozens of other states that have taken the important steps to require this life-saving screening for newborns. The simple pulse oximetry test can detect CCHD in more than 90 percent of afflicted newborns. Moreover, pulse oximetry screening is a low-cost, non-invasive bedside diagnostic test that can be completed in as little as 45 seconds.	VDH notes the support of the emergency regulations that are now in effect.

Family impact

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

one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed amendment to the regulation will not strengthen or erode the rights of parents in the education, nurturing, and supervision of their children. Parents have the right to refuse newborn screening for religious reasons. Parents also have the right to seek additional newborn screening testing outside of the state program if desired.

The proposed amendment will not encourage or discourage economic self-sufficiency, self-pride, or the assumption of responsibility for oneself, one's spouse, one's children and/or elderly parents.

The proposed amendment will not strengthen or erode marital commitment.

The proposed amendment will not increase or decrease disposable family income.

Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre**-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s), use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-71-10	N/A	Includes definitions for words and terms that are used in the regulation.	Adds definitions for "Abnormal screening results"; "Critical congenital heart disease"; "CCHD screening"; "Echocardiogram"; "Licensed practitioner"; Newborn nursery"; "Screening technology"; "Specialty level nursery"; and "Subspecialty level nursery"
12VAC5-71-30	N/A	The Virginia Newborn Screening System includes the Virginia Newborn Screening Program and the Virginia Early Hearing Detection and Intervention Program.	CCHD is added as a third element of the Virginia Newborn Screening System.
12VAC5-71-150	N/A	Care coordination services will be provided for Virginia residents who are diagnosed with selected heritable disorders or genetic diseases.	CCHD is added as a third diagnosis group that would make an individual eligible for care coordination services.
12VAC5-191-260	N/A	The Virginia Newborn Screening System includes	CCHD is added as a third element of the Virginia Newborn Screening System. The

		the Virginia Newborn Screening Program and the Virginia Early Hearing Detection and Intervention Program.	mission, scope of services, governing regulations, criteria, and goal of the screening are documented.

If a new regulation is being promulgated, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
12VAC5-71-210	This is a new section requiring hospitals to develop protocols for screening, timely evaluation, and timely referral of newborns with abnormal screening results.	N/A	Intent is to allow hospitals to develop their own protocols in three required areas.
12VAC5-71-220	This is a new section requiring a licensed practitioner to perform the screening, and setting forth when the screening is to occur. If screening is not indicated, documentation requirements are set forth for the medical record. Hospitals shall develop screening protocols for specialty and sub-specialty nurseries.	N/A	Intent is to ensure that qualified personnel perform the screening within the relevant time frame, and to set forth exceptions when screening is not required. Intent is to permit hospitals with specialty and subspecialty nurseries to develop protocols for screening within those specialized units.
12VAC5-71-230	This is a new section requiring all screening results to be entered into the medical record and the electronic birth certificate system. The section also requires health care providers to report abnormal screening results immediately and to evaluate the newborn in a timely manner. Newborns shall not be discharged unless a cause for the abnormal screening result has been determined or CCHD has been ruled out. Parents or guardians and the infant's primary care provider after discharge from the hospital shall be notified of any abnormal results and any diagnoses.	N/A	Intent is to ensure that screening results are properly documented, responded to, and communicated to parents or guardians and the infant's primary care provider after discharge from the hospital.
12VAC5-71-240	This is a new section requiring hospitals to report individuals diagnosed with	N/A	Intent is to refer parents and guardians of infants with CCHD to care coordination services.

	CCHD to VDH so that the newborn's parent or guardian may be referred to care coordination services through the Care Connection for Children.		
12VAC5-71-250	This is a new section specifying what documents shall be provided when requested by the VaCARES system at VDH, and specifying the confidentiality rules for these documents.	N/A	Intent is to allow VDH to research final outcomes of abnormal CCHD screening results and evaluate screening activities in the state.
12VAC5-71-260	This is a new section that permits parents to refuse CCHD screening based upon religious practices or tenets, and to specify that the hospital must report the refusal to VDH.	N/A	Intent is to allow parents to refuse CCHD screening in accordance with their religious tenets, as specified in the authorizing legislation.

Summary of changes made to regulatory language from the emergency to the proposed stage:

VDH has made some changes to the regulatory text from the emergency/NOIRA stage to the proposed stage. These revisions are relatively minor and are generally intended to simplify and/or clarify text. These changes are outlined below:

- The emergency regulations listed definitions for the new CCHD requirements in their own section, 12VAC5-71-200. These have been incorporated into the general definitions section in 12VAC5-71-10.
- The definition of "Newborn" was changed to state a person in the first 28 days of life who was born in Virginia. The term "or on federal property in Virginia" has been stricken from the definition of newborn that is in the emergency regulations.
- There was a change to the reference provided for the definition of "Specialty level nursery"
- The term "premature" was removed from 12VAC5-71-220 C.3 to clarify that the regulations would not apply to any infant that is in a specialty or sub-specialty nursery, regardless of whether or not they are premature.
- Section 12VAC5-71-230 A added two additional elements to be recorded in the electronic birth certificate; pulse oximetry values, and whether the newborn was not screened pursuant to 12VAC5-71-220 C or 12VAC5-71-260.
- 12VAC5-71-240 A. was modified to change the term "under these regulations" to "under 12VAC5-71-210 through 12VAC5-71-260" to clarify that this only applies to infants diagnosed with CCHD.

Project 4176 -

DEPARTMENT OF HEALTH

Add Critical Congenital Heart Disease to the Virginia Newborn Screening System

12VAC5-71-10. Definitions.

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

"Abnormal screening results" means, in 12VAC5-71-210 through 12VAC5-71-260 only, all results that indicate the newborn has not passed the screening test.

"Attending physician" means the physician in charge of the infant's care.

"Board" means the State Board of Health.

"Business days" means Monday through Friday from 9 a.m. to 5 p.m., excluding federal and state holidays.

"Care Connection for Children" means a statewide network of centers of excellence for children with special health care needs (CSHCN) that provides leadership in the enhancement of specialty medical services, care coordination, medical insurance benefits evaluation and coordination, management of the CSHCN pool of funds, information and referral to CSHCN resources, family-to-family support, and training and consultation with community providers on CSHCN issues.

"Care coordination" means a process that links individuals and their families to services and resources in a coordinated effort to maximize their potential and provide them with optimal health care.

"Certified nurse midwife" means a person licensed to practice as a nurse practitioner in the Commonwealth pursuant to § 54.1-2957 of the Code of Virginia and in accordance with Part II (18VAC90-30-60 et seq.) of 18VAC90-30 and 18VAC90-30-121, subject to 18VAC90-30-160.

"Chief executive officer" means a job descriptive term used to identify the individual appointed by the governing body to act in its behalf in the overall management of the hospital. Job titles may include administrator, superintendent, director, executive director, president, vice-president, and executive vice-president.

"Child" means a person less than 18 years of age and includes a biological or an adopted child, as well as a child placed for adoption or foster care unless otherwise treated as a separate unit for the purposes of determining eligibility and charges under these regulations.

"Commissioner" means the State Health Commissioner, his duly designated officer, or agent.

"Confirmatory testing" means a test or a panel of tests performed following a screened-abnormal result to verify a diagnosis.

"Core panel conditions" means those heritable disorders and genetic diseases considered appropriate for newborn screening. The conditions in the core panel are similar in that they have (i) specific and sensitive screening tests, (iii) a sufficiently well understood natural history, and (iii) available and efficacious treatments.

"Critical congenital heart disease" or "CCHD" means a congenital heart disease that places a newborn at significant risk of disability or death if not diagnosed and treated soon after birth. The disease may include, but is not limited to hypoplastic left heart syndrome, pulmonary atresia (with intact septum), tetralogy of fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus.

"CCHD screening" means the application of screening technology to detect CCHD.

"Department" means the state Department of Health.

"Dried-blood-spot specimen" means a clinical blood sample collected from an infant by heel stick method and placed directly onto specially manufactured absorbent specimen collection (filter) paper.

"Echocardiogram" means a test that uses an ultrasound to provide an image of the heart.

"Guardian" means a parent-appointed, court-appointed, or clerk-appointed guardian of the person.

"Healthcare provider" means a person who is licensed to provide health care as part of his job responsibilities and who has the authority to order newborn dried-blood-spot screening tests.

"Heritable disorders and genetic diseases" means pathological conditions (i.e., interruption, cessation or disorder of body functions, systems, or organs) that are caused by an absent or defective gene or gene product, or by a chromosomal aberration.

"Hospital" means any facility as defined in § 32.1-123 of the Code of Virginia.

"Infant" means a child less than 12 months of age.

"Licensed practitioner" means a licensed health care provider who is permitted, within the scope of his practice pursuant to Chapter 29 (§ 54.1-2900 et seq.) or Chapter 30 (§ 54.1-3000 et seq.) of Title 54.1 of the Code of Virginia to provide care to a newborn.

"Low protein modified foods" means foods that are (i) specially formulated to have less than one gram of protein per serving, (ii) intended to be used under the direction of a physician for the dietary treatment of an inherited metabolic disease, (iii) not natural foods that are naturally low in protein, and (iv) prescribed as medically necessary for the therapeutic treatment of inherited metabolic diseases.

"Metabolic formula" means nutritional substances that are (i) prescribed by a health professional with appropriate prescriptive authority; (ii) specifically designed and formulated to be consumed or administered internally under the supervision of such health professional; (iii) specifically designed, processed, or formulated to be distinct in one or more nutrients that are present in natural food; and (iv) intended for the medical and nutritional management of patients with limited capacity to metabolize ordinary foodstuffs or limited capacity to metabolize certain nutrients contained in ordinary foodstuffs.

"Metabolic supplements" means certain dietary or nutritional substances intended to be used under the direction of a physician for the nutritional management of inherited metabolic diseases.

"Midwife" means a person licensed as a nurse practitioner in the category of certified nurse midwife by the Boards of Nursing and Medicine or licensed as a midwife by the Board of Medicine.

"Newborn" means an infant who is 28 days old or less who was born in Virginia.

"Newborn nursery" means a general level, intermediate level, or specialty level newborn service as defined in 12VAC5-410-443 B 1, B 2, and B 3.

"Nurse" means a person holding a current license as a registered nurse or licensed practical nurse by the Virginia Board of Nursing or a current multistate licensure privilege to practice in Virginia as a registered nurse or licensed practical nurse.

"Parent" means a biological parent, adoptive parent, or stepparent.

"Pediatric Comprehensive Sickle Cell Clinic Network" means a statewide network of clinics that are located in major medical centers and provide comprehensive medical and support services for newborns and children living with sickle cell disease and other genetically related hemoglobinopathies.

"Physician" means a person licensed to practice medicine or osteopathic medicine in the Commonwealth pursuant to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia and in accordance with applicable regulations.

"Pool of funds" means funds designated for payment of direct health care services. Access to the pool is not an entitlement and is subject to availability of funds and guidelines that govern its eligibility and coverage of services. Pool of funds is a mix of federal Title V funds and state matching funds.

"Population-based" means preventive interventions and personal health services developed and available for the entire infant and child health population of the Commonwealth rather than for individuals in a one-on-one situation.

"Preterm infant" means an infant whose birth occurs by the end of the last day of the 36th week following the onset of the last menstrual period.

"Repeat specimen" means an additional newborn dried-blood-spot screening specimen submitted to the testing laboratory voluntarily or by request.

"Resident" means an individual who resides within the geographical boundaries of the Commonwealth.

"Satisfactory specimen" means a newborn dried-blood-spot screening specimen that has been determined to be acceptable for laboratory analyses by the testing laboratory.

"Screened-abnormal" means a newborn dried-blood-spot screening test result that is outside the established normal range or normal value for that test method.

"Screening technology" means pulse oximetry testing in the right hand and either foot. Screening technology shall also include alternate medically accepted tests that measure the percentage of blood oxygen saturation, follow medical guideline consensus and

recommendations issued by the American Academy of Pediatrics, and are approved by the State Board of Health.

"Specialty level nursery" means the same as defined in 12VAC5-410-443(B)(3) and as further defined as Level III by the Levels of Neonatal Care, written by the American Academy of Pediatrics Committee on Fetus and Newborn and published in Pediatrics 2012.130:587.

"Subspecialty level nursery" means the same as defined in 12VAC5-410-443(B)(4).

"Testing laboratory" means the laboratory that has been selected by the department to perform newborn dried-blood-spot screening tests services.

"Total parenteral nutrition" or "TPN" means giving nutrients through a vein for babies who cannot be fed by mouth.

"Treatment" means appropriate management including genetic counseling, medical consultation, and pharmacological and dietary management for infants diagnosed with a disease listed in 12VAC5-71-30 D.

"Unsatisfactory specimen" means a newborn dried-blood-spot screening specimen that is inadequate for performing an accurate analysis.

"Virginia Genetics Advisory Committee" means a formal group that advises the department on issues pertaining to access to clinical genetics services across the Commonwealth and the provision of genetic awareness, quality services, and education for consumers and providers.

"Virginia Newborn Screening System" means a coordinated and comprehensive group of services, including education, screening, follow up, diagnosis, treatment and management, and program evaluation, managed by the department's Virginia Newborn Screening Program and Virginia Early Hearing Detection and Intervention Program for safeguarding the health of children born in Virginia.

"Virginia Sickle Cell Awareness Program" means a statewide program for the education and screening of individuals for the disease of sickle cell anemia or the sickle cell trait and for such other genetically related hemoglobinopathies.

12VAC5-71-30. Core panel of heritable disorders and genetic diseases.

A. The Virginia Newborn Screening System, which includes the Virginia Newborn Screening Program ~~and~~, the Virginia Early Hearing Detection and Intervention Program, and Virginia critical congenital heart disease screening, shall ensure that the core panel of heritable disorders and genetic diseases for which newborn screening is conducted is consistent with but not necessarily identical to the U.S. Department of Health and Human Services Secretary's Recommended Uniform Screening Panel.

B. The department shall review, at least biennially, national recommendations and guidelines and may propose changes to the core panel of heritable disorders and genetic diseases for which newborn dried-blood-spot screening tests are conducted.

C. The Virginia Genetics Advisory Committee may be consulted and provide advice to the commissioner on proposed changes to the core panel of heritable disorders and genetic diseases for which newborn dried-blood-spot screening tests are conducted.

D. Infants under six months of age who are born in Virginia shall be screened in accordance with the provisions set forth in this chapter for the following heritable disorders and genetic diseases, which are identified through newborn dried-blood-spot screening tests:

1. Argininosuccinic aciduria (ASA);

2. Beta-Ketothiolase deficiency (BKT);

3. Biotinidase deficiency (BIOT);

4. Carnitine uptake defect (CUD);

5. Classical galactosemia (galactose-1-phosphate uridyltransferase deficiency) (GALT);

6. Citrullinemia type I (CIT-I);

7. Congenital adrenal hyperplasia (CAH);

8. Cystic fibrosis (CF);

9. Glutaric acidemia type I (GA I);

10. Hb S beta-thalassemia (Hb F,S,A);

11. Hb SC-disease (Hb F,S,C);

12. Hb SS-disease (sickle cell anemia) (Hb F, S);

13. Homocystinuria (HCY);

14. Isovaleric acidemia (IVA);

15. Long chain L-3-Hydroxy acyl-CoA dehydrogenase deficiency (LCHAD);

16. Maple syrup urine disease (MSUD);

17. Medium-chain acyl-CoA dehydrogenase deficiency (MCAD);

18. Methylmalonic acidemia (Methylmalonyl-CoA mutase deficiency) (MUT);

19. Methylmalonic acidemia (Adenosylcobalamin synthesis deficiency) (CBL A, CBL B);

20. Multiple carboxylase deficiency (MCD);

21. Phenylketonuria (PKU);

22. Primary congenital hypothyroidism (CH);

23. Propionic acidemia (PROP);

24. Severe combined immunodeficiency (SCID);

25. Tyrosinemia type I (TYR I);

26. Trifunctional protein deficiency (TFP);

27. Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD);

28. 3-hydroxy 3-methyl glutaric aciduria (HMG); and

29. 3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC).

E. Infants born in Virginia shall be screened for hearing loss in accordance with provisions set forth in §§ 32.1-64.1 and 32.1-64.2 of the Code of Virginia and as governed by 12VAC5-80.

F. Newborns born in Virginia shall be screened for critical congenital heart disease in accordance with provisions set forth in §§ 32.1-65.1 and 32.1-67 of the Code of Virginia and as governed by 12VAC5-71-210 through 12VAC5-71-260.

12VAC5-71-150. Responsibilities of the Care Connection for Children network.

A. The Care Connection for Children network shall provide the following services:

1. Care coordination services for residents of the Commonwealth who are diagnosed with selected heritable disorders ~~or,~~ genetic diseases, or critical congenital heart disease and are referred to the network by the Virginia Newborn Screening Program.

2. Other network services for eligible individuals in accordance with ~~the~~ § 32.1-77 of the Code of Virginia and applicable regulations.

B. The Care Connection for Children network shall provide data as needed by the department's newborn screening program.

12VAC5-71-210. Critical congenital heart disease screening protocols.

A. Hospitals shall develop protocols for critical congenital heart disease screening in accordance with 12VAC5-71-210 through 12VAC5-71-260 and consistent with current national recommendations from the American Academy of Pediatrics, as specified in Implementing Recommended Screening for Critical Congenital Heart Disease; Pediatrics; 2013;132;1.

B. Hospitals shall develop protocols for the physical evaluation by licensed practitioners of newborns with abnormal screening results.

C. Hospitals shall develop protocols for the referral of newborns with abnormal screening results, if needed, after evaluation.

12VAC5-71-220. Critical congenital heart disease screening.

A. A licensed practitioner shall perform the screening.

B. Except as specified in subsection C of this section and 12VAC5-71-260, CCHD screening shall be performed on every newborn in the birth hospital between 24 and 48 hours of life, or if the newborn is discharged from the hospital before reaching 24 hours of life, the CCHD screening shall be performed as late as practical before discharge.

C. If CCHD screening is not indicated, the reason shall be documented in the newborn's medical record. The reasons include but are not limited to:

1. The newborn's current clinical evaluation has included an echocardiogram that ruled out CCHD;

2. The newborn has confirmed CCHD; or

3. The newborn is under the care of a specialty level or subspecialty level nursery.

D. Hospitals shall develop protocols for screening newborns in specialty level and subspecialty level nurseries.

12VAC5-71-230. Critical congenital heart disease screening results.

A. Recording results.

1. All CCHD screening results shall be recorded in the newborn's medical record.

2. All CCHD screening results shall be entered into the electronic birth certificate system with the following information:

a. CCHD screening completed; and

b. CCHD pass or fail; and

c. pulse oximetry values; or

d. Not screened pursuant to 12VAC5-71-220(C) or 12VAC5-71-260.

B. Abnormal screening results.

1. Abnormal screening results shall be reported by the authorized health care provider who conducted the screening to the attending physician or his designee as soon as the result is obtained.

2. A newborn shall be evaluated by an attending physician or his designee according to the timeframes within the hospital protocol developed in accordance with 12VAC5-71-210.

3. A newborn shall not be discharged from care until:

a. A cause for the abnormal screening result has been determined and a plan is in place for immediate evaluation at another medical facility; or

b. An echocardiogram has been performed and read and an appropriate clinical plan has been developed.

4. Any diagnosis arising from abnormal screening results shall be entered into the electronic birth certificate system.

5. The attending physician or his designee shall provide notification of abnormal results and any diagnoses to the newborn's parent or guardian and to the primary care provider in charge of the newborn's care after the newborn leaves the hospital.

12VAC5-71-240. Referral for care coordination.

A. For any person diagnosed under 12VAC5-71-210 through 12VAC5-71-260, the chief administrative officer of every hospital, as defined in § 32.1-123 of the Code of Virginia, shall make or cause to be made a report to the commissioner in accordance with § 32.1-69.1 of the Code of Virginia.

B. Upon receiving the notification described in subsection A of this section, the Newborn Screening Program at the Virginia Department of Health shall refer the newborn's parent or guardian to the Care Connection for Children network for care coordination services.

12VAC5-71-250. Congenital heart disease screening records.

A. The screening of newborns pursuant to this chapter is a population-based public health surveillance program as defined by the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191; 110 Stat. 2033).

B. Upon request, a hospital shall make available to the Virginia Congenital Anomalies Reporting and Education System (VaCARES):

1. Medical records;

2. Records of laboratory tests; and

3. Any other information that VaCARES considers necessary to:

a. Determine final outcomes of abnormal CCHD screening results; or

b. Evaluate CCHD screening activities in the Commonwealth, including performance of follow-up evaluations and diagnostic tests, initiation of treatment when necessary, and surveillance of the accuracy and efficacy of the screening.

C. Information that the Virginia Department of Health receives under this section is confidential and may only be used or disclosed:

1. For research and collective statistical purposes, pursuant to § 32.1-67.1 of the Code of Virginia;

2. For state or federally mandated statistical reports;

3. To ensure that the information received by the Virginia Department of Health is accurate and reliable; or

4. For reporting to the Virginia Congenital Anomalies Reporting and Education System pursuant to § 32.1-69.1 of the Code of Virginia and 12VAC5-191-280. The Newborn Screening Program shall refer the newborn's parent or guardian to the Care Connection for Children network for care coordination services.

D. The hospital administrator shall ensure that CCHD screening is included in the perinatal quality assurance program and provide the results of the quality improvement program to the Virginia Department of Health upon request.

12VAC5-71-260. Parent or guardian refusal for screening.

A. In the instance of parent or guardian refusal of the CCHD screening based on religious practices or tenets, the parent or guardian refusal shall be documented on a refusal form provided by the Virginia Department of Health and made a part of the newborn's medical record.

B. The administrator of the hospital shall ensure that the Newborn Screening Program at the Virginia Department of Health is notified in writing of the parent or guardian refusal within five days of the newborn's birth.

FORMS (12VAC5-71)

Notification of Parental Refusal of Dried-Blood-Spot and Critical Congenital Heart Disease Screening (undated)

12VAC5-191-260. Scope and content of the Virginia Newborn Screening System.

A. The Virginia Newborn Screening System consists of ~~two~~ three components: (i) Virginia Newborn Screening Services ~~and~~, (ii) Virginia Early Hearing Detection and Intervention Program, and (iii) Virginia critical congenital heart disease screening.

B. Virginia Newborn Screening Services.

1. Mission. The Virginia Newborn Screening Services prevents ~~mental retardation~~ intellectual disability, permanent disability, or death through early identification and treatment of infants who are affected by selected inherited disorders.

2. Scope of services. The Virginia Newborn Screening Services provides a coordinated and comprehensive system of services to assure that all infants receive a screening test after birth for selected inherited metabolic, endocrine, and hematological disorders as defined in Regulations Governing the Newborn Screening and Treatment Program, ~~12VAC5-70~~ 12VAC5-71.

These population-based, direct, and enabling services are provided through:

a. Biochemical dried bloodspot screening tests.

b. Follow up of abnormal results.

c. Diagnosis.

d. Education to health professionals and families.

e. Expert consultation on abnormal results, diagnostic testing, and medical and dietary management for health professionals.

Medical and dietary management is provided for the diagnosed cases and includes assistance in accessing specialty medical services and referral to Care Connection for Children.

The screening and management for specified diseases are governed by Regulations Governing ~~the~~ Virginia Newborn Screening ~~and Treatment Program~~ Services, ~~12VAC5-70~~ 12VAC5-71.

3. Criteria to receive Virginia Newborn Screening Services. All infants born in the Commonwealth are eligible for the screening test for selected inherited disorders.

4. Goal. The Title V national performance measures, as required by the federal Government Performance and Results Act (GPRA-Pub. L. 103-62), are used to establish the program goals. The following goal shall change as needed to be consistent with the Title V national performance measures:

All infants will receive appropriate newborn bloodspot screening, follow up testing, and referral to services.

C. Virginia Early Hearing Detection and Intervention Program.

1. Mission. The Virginia Early Hearing Detection and Intervention Program promotes early detection of and intervention for infants with congenital hearing loss to maximize linguistic and communicative competence and literacy development.

2. Scope of services. The Virginia Early Hearing Detection and Intervention Program provides services to assure that all infants receive a hearing screening after birth, that infants needing further testing are referred to appropriate facilities, that families have the information that they need to make decisions for their children, and that infants and young children diagnosed with a hearing loss receive appropriate and timely intervention services. These population-based and enabling services are provided through:

a. Technical assistance and education to new parents.

b. Collaboration with physicians and primary care providers.

c. Technical assistance and education to birthing facilities and those persons performing home births.

d. Collaboration with audiologists.

e. Education to health professionals and general public.

Once diagnosed, the infants are referred to early intervention services. The screening and management for hearing loss are governed by the regulation, Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring System, 12VAC5-80.

3. Criteria to receive services from the Virginia Early Hearing Detection and Intervention Program.

a. All infants born in the Commonwealth are eligible for the hearing screening.

b. All infants who are residents of the Commonwealth and their families are eligible for the Virginia Early Hearing Detection and Intervention Program.

4. Goals. The Title V national performance measures, as required by the federal Government Performance and Results Act (GPRA-Pub. L. 103-62), are used to establish the program goals. The following goals shall change as needed to be consistent with the Title V national performance measures:

All infants will receive screening for hearing loss no later than one month of age, achieve identification of congenital hearing loss by three months of age, and enroll in appropriate intervention by six months of age.

D. Virginia critical congenital heart disease screening.

1. Mission. Virginia critical congenital heart disease screening promotes early detection of and intervention for newborns with critical congenital heart disease to maximize positive health outcomes and help prevent disability and death early in life.

2. Scope of services. Newborns receive a critical congenital heart disease screening 24 to 48 hours after birth in a hospital with a newborn nursery, as provided in §§ 32.1-67 and 32.1-69.1 of the Code of Virginia and the regulations governing critical congenital heart disease screening (12VAC5-71-210 through 12VAC5-71-260). These population-based, direct, and enabling services are provided through:

a. Critical congenital heart disease screening tests using pulse oximetry or other screening technology as defined in 12VAC5-71-10;

b. Hospital reporting of test results pursuant to § 32.1-69.1 of the Code of Virginia and 12VAC5-191-280; and

c. Follow-up, referral processes, and services, as appropriate, through Care Connection for Children.

3. The screening and management for newborn critical congenital heart disease are governed by the regulations governing critical congenital heart disease screening (12VAC5-71-210 through 12VAC5-71-260).

4. Criteria to receive critical congenital heart disease screening. Except as specified in 12VAC5-71-220 C and 12VAC5-71-260, all newborns born in the Commonwealth in a hospital with a newborn nursery shall receive the screening test for critical congenital heart disease 24 to 48 hours after birth using pulse oximetry or other screening technology.

5. Goal. Except as specified in 12VAC5-71-220 C and 12VAC5-71-260, all newborns born in the Commonwealth in a hospital with a newborn nursery shall receive appropriate critical congenital heart disease screening 24 to 48 hours after birth.

COMMONWEALTH of VIRGINIA
Department of Health
Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER
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TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: April 10, 2015

TO: Virginia State Board of Health

FROM: Steven A. Harrison, Director
Office of Radiological Health

SUBJECT: Notice of Intended Regulatory Action (NOIRA) to Amend Virginia Radiation Protection Regulations: Fee Schedule (12VAC5-490)

The Virginia Department of Health's Office of Radiological Health (ORH) proposes to amend the existing Virginia Radiation Protection Regulations: Fee Schedule (12VAC5-490) in order to update fees for non-medical X-ray equipment that is inspected on a three-year frequency; establish fees for the registration of baggage, cabinet/analytical and industrial X-ray equipment; establish fees that would allow an ORH inspector to perform an inspection of this equipment; and establish an associated inspection frequency.

Purpose of Regulations

The purpose of the X-ray program is to protect the public from unnecessary radiation due to faulty X-ray equipment or substandard practices. The purpose of registering and inspecting facilities that use X-ray machines, including those for non-medical purposes, is to have an accurate database of the machines, to track their inspections and to ensure the machines are properly functioning so as to protect the health and safety of equipment operators and the public.

Upcoming Steps

The NOIRA, upon approval by the Board of Health, will be submitted for executive branch review, posted on the Regulatory Town Hall, and published in the Virginia Register of Regulations. A 30-day public comment period will commence, at the end of which the agency will consider the comments, make necessary adjustments, and then submit the proposed amendments for approval by the Board of Health at a future meeting.

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-490
Regulation title(s)	Virginia Radiation Protection Regulations
Action title	Modify Radiation Protection X-ray Device Fee Schedule
Date this document prepared	March 19, 2015

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

Subject matter and intent

Radiological Control Program regulations currently require the registration of non-medical X-ray equipment (Baggage, Cabinet, Analytical, and Industrial equipment). The regulations, though, do not establish a fee for registration of this equipment, do not establish a fee that would allow an Office of Radiological Health (ORH) inspector to perform an inspection of this equipment, and do not establish associated inspection frequencies. Registration and inspection fees for X-ray equipment not used in the healing arts are charged in other states. The potential exists for accidents associated with this equipment, which have in fact occurred. Accordingly, regulatory attention needs to be applied to promote the safety of non-medical X-ray equipment. These fees will help offset the cost of administrative activities involved in the registration, inspection, and certification of non-medical X-ray equipment. These costs were once absorbed from general funds allocated to ORH, but those general funds have since been abolished.

Legal basis

These regulations are authorized by the Code of Virginia Sections 32.1-229 et seq.
Section 32.1-229.1 authorizes the Board of Health to set fees for X-ray equipment and requires the Board of Health to promulgate regulations for the registration, inspection, and certification of X-ray machines.

Refer to the following web site for viewing the statutory authority cited in Section 32.1-229.1 of the Code of Virginia:

http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229.1

Purpose

The Virginia Department of Health (VDH), ORH proposes to amend 12VAC5-490, Radiation Protection Fee Schedule. Specifically, this amendment:

- Amends registration fees for equipment inspected every three years;
- Adds three (3) categories and associated fees for the registration of non-medical X-ray equipment (X-ray equipment not used in the healing arts):
  - Baggage, Cabinet and Analytical, and Industrial X-ray equipment.
- Adds three (3) categories and associated fees for the inspection of non-medical X-ray equipment (X-ray equipment not used in the healing arts):
  - Baggage, Cabinet and Analytical, and Industrial X-ray Equipment.

Substance

Radiological Control Program regulations currently require the registration of non-medical X-ray equipment, i.e., equipment that is not used in the healing arts. This equipment includes Baggage, Cabinet and Analytical, and Industrial X-ray machines. However, associated registration and inspection fees and inspection frequencies have not been established. Registration and inspection fees for X-ray equipment not used in the healing arts are charged in other states. The potential for accidents associated with equipment not used in the healing arts exists and has in fact occurred. Accordingly, regulatory attention needs to be applied to promote the safety of non-medical X-ray equipment use. This action proposes to modify registration fees for non-medical devices that are inspected on a three-year frequency, proposes to institute registration and inspection fees for non-medical X-ray equipment, and proposes to establish associated inspection frequencies. The fees will help offset administrative activities involved in the registration, inspection, and certification of non-medical X-ray equipment that were once absorbed from general funds allocated to ORH and which have since been abolished. Specifically:

- The current fee for each machine and additional tube(s) that have an inspection frequency of every three years is proposed to increase from $50 to $60, collected every three years.
- The following annual registration fees are proposed for all operators or owners of baggage, cabinet or analytical, or industrial X-ray machines capable of producing radiation:
  - $20 for each machine used for baggage inspection;
  - $25 for each machine identified as cabinet or analytical; and
  - $50 for each machine used for industrial radiography.
- The following inspection fees and required inspection frequencies are proposed for all operators or owners of baggage, cabinet or analytical, or industrial X-ray machines capable of producing radiation:
  - Baggage X-Ray Unit: $100 per inspection, inspected every 5 years;
  - Cabinet/Analytical X-ray Unit: $150 per inspection, inspected every 3 years;
  - Industrial Radiography X-Ray Unit: $200 per inspection, inspected annually.

Alternatives

Failure to update the existing regulation would be inconsistent with the agency's mission and the need to provide an adequate regulatory program that protects public health and safety with regard to the maintenance and operation of non-medical X-ray devices. VDH will consider recommendations from the Radiation Advisory Board and the regulated community for alternative means of meeting the intent of the model regulations or additional requirements to address concerns that may be unique within the Commonwealth.

Public participation

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal; the costs and benefits of the alternatives stated in this background document or other alternatives; and, the potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to **Stan Orchel, Jr., Virginia Department of Health, Office of Radiological Health, 109 Governor Street, Room 733, Richmond, VA 23219, (804)864-8170 (Office Phone), (804)864-8175 (fax), stan.orchel@vdh.virginia.gov**. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

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

Periodic review / small business impact review announcement

In addition, pursuant to Executive Order 17 (2014) and § 2.2-4007.1 of the Code of Virginia, the agency is conducting a periodic review and small business impact review of this regulation to determine whether this regulation should be terminated, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

Periodic review and small business impact review report of findings

If this NOIRA is the result of a periodic review/small business impact review, use this NOIRA to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been

evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Commenter	Comment	Agency response

COMMONWEALTH of VIRGINIA

Department of Health

MARISSA J. LEVINE, MD, MPH
INTERIM STATE HEALTH COMMISSIONER

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MEMORANDUM

DATE: May 12, 2015

TO: Virginia State Board of Health

FROM: Erik Bodin
Director, Office of Licensure and Certification

SUBJECT: Fast Track Amendments – Regulations for the Licensure of Hospitals in Virginia

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The agency is proposing to amend the Regulations for the Licensure of Hospitals in Virginia (12VAC5-410) to reflect changes to federal regulations. The Centers for Medicare and Medicaid Services (CMS) issued a final rule on May 12, 2014, which enables a qualified dietitian or a qualified nutrition professional to become privileged to independently order both standard and therapeutic diets within the hospital and critical care hospital settings. This rule became effective on July 11, 2014. 12VAC5-410 is currently written in a manner that is more restrictive than the federal regulations. This regulatory action will amend the regulations to remove restrictions that are more stringent than federal law.

The Board of Health is asked to approve this fast track action at its June 2015 meeting. Following approval, the proposed amendment would be submitted to the Virginia Regulatory Town Hall to initiate Executive Branch review.

townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-410
Regulation title(s)	Regulations for the Licensure of Hospitals in Virginia
Action title	Update the Regulations to reflect a CMS issued final rule enabling registered dietitian nutritionists in the hospital setting to order therapeutic diets
Date this document prepared	May 12, 2015

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

Brief summary

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

The State Board of Health (Board) proposes to amend 12VAC5-410 et. seq. Regulations for the Licensure of Hospitals in Virginia to reflect changes to federal regulations. The Centers for Medicare and Medicaid Services (CMS) issued a final rule on May 12, 2014, which enables a qualified dietitian or qualified nutrition professional to become privileged to independently order both standard and therapeutic diets within the hospital and critical access hospital settings (https://www.federalregister.gov/articles/2014/05/12/2014-10687/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and#h-22). This rule change became effective on July 11, 2014. The Regulations for the Licensure of Hospitals in Virginia, 12VAC5-410-260 is

currently written in a manner that is more restrictive than the federal regulations. This regulatory action will amend the regulations to remove restrictions that are more stringent than federal law.

Acronyms and Definitions

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

CMS means the Centers for Medicare and Medicaid Services

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.

These amendments to the Regulations for the Licensure of Hospitals in Virginia (12VAC5-410) were approved by the State Board of Health on _____ 2015.

Legal basis

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

The regulation is promulgated under the authority of §§ 32.1-12 and 32.1-127 of Chapter 5 of Title 32.1 of the Code of Virginia (Code). Section 32.1-12 grants the board the legal authority "to make, adopt, promulgate, and enforce such regulations necessary to carry out the provisions of Title 32.1 of the Code." Section 32.1-127 of the Code of Virginia directs the Board to promulgate regulations with minimum standards for the construction and maintenance of hospitals, the operation, staffing and quipping of hospitals, qualifications and training of staff of hospitals, conditions under which a hospital may provide medical and nursing services to patients in their places of residence and policies related to infection prevention, disaster preparedness and facility security.

Purpose

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

CMS issued a final rule on May 12, 2014, which enables a qualified dietitian or qualified nutrition professional to become privileged to independently order both standard and therapeutic diets within the hospital and critical access hospital settings. According to the CMS rule, hospitals will have the flexibility to either appoint registered dieticians to the medical staff and grant them specific nutritional ordering privileges or authorize ordering privileges without appointment to the medical staff through the hospital's

appropriate medical staff rules, regulations and bylaws. This rule change became effective on July 11, 2014. The Regulations for the Licensure of Hospitals in Virginia, 12VAC5-410-260 is currently written in a manner that is more restrictive than the federal regulations. The Regulations only allow registered dieticians to write independent nutrition orders in hospitals if they are appointed to the medical staff. This regulatory action will amend the regulations to remove restrictions that are more stringent than federal law. This regulatory action will protect the health and welfare of Virginians by ensuring that patients within a hospital setting are able to obtain the proper standard and therapeutic diets within the Commonwealth.

Rationale for using fast-track process

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

These amendments simply ensure that the Commonwealth's regulations are not more restrictive than federal regulations. These amendments have also been prepared with input from the Virginia Academy of Nutrition and Dietetics. Therefore, the Department does not expect that this regulatory action will be controversial.

Substance

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

12VAC5-410-260. Remove the requirement that all patient diets be ordered in writing by a member of the medical staff. Add language which allows practitioners responsible for the care of the patient, or qualified dieticians authorized by the medical staff, to order patient diets. Add a subsection which allows a hospital or medical staff to privilege qualified dietitians to prescribe diets and order tests to determine appropriate diets for the patient. Add a subsection to specify that therapeutic diets include the provision of enteral and parenteral nutrition

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

The primary advantage to the agency, the Commonwealth and the public of the proposed regulatory action will be less burdensome regulations. The proposed regulatory action will also lead to greater access to well rounded patient care. There are no known disadvantages to the agency, the Commonwealth or the public.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

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

Localities particularly affected

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

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

Regulatory flexibility analysis

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

The alternative regulatory methods are not applicable. The regulations are required by the Code and the proposed amendments are attempting to reduce the burden of the existing requirements.

Economic impact

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

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	None
Projected cost of the new regulations or changes to existing regulations on localities.	None

Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Qualified dietitians throughout the Commonwealth, Hospitals licensed within the Commonwealth, Patients served by hospitals throughout the Commonwealth
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are 106 licensed hospitals and critical access hospitals within the Commonwealth.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	No projected cost
Beneficial impact the regulation is designed to produce.	Less burdensome nature of the regulations.

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.

There are no other viable alternatives other than the proposed amendments to obtain the objectives of the board.

Public participation notice

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

Family impact

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

The board has assessed the impact the proposed amendments will have on the institution of the family and family stability. The board anticipates no impact to the family or family stability.

Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre**-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-410-260. Dietary Service.		A. Each hospital shall maintain a dietary service directed by a full-time person, qualified as allowed in 12VAC5-421. B. Each hospital shall have at least one dietitian, meeting the criteria of § 54.1-2731 of the Code of Virginia, employed on either a full-time, part-time or on a consultative basis, to direct nutritional aspects of patient care and to advise on food preparation and service. C. Space, equipment and supplies shall be provided for the efficient, safe and sanitary receiving, storage, refrigeration, preparation and serving of food. D. The hospital food service operation shall comply with applicable standards in 12VAC5-421.	A. Each hospital shall maintain a dietary service directed by a full-time person, qualified as allowed in 12VAC5-421. B. Each hospital shall have at least one dietitian, meeting the criteria of § 54.1-2731 of the Code of Virginia, employed on either a full-time, part-time or on a consultative basis, to direct nutritional aspects of patient care and to advise on food preparation and service. C. Space, equipment and supplies shall be provided for the efficient, safe and sanitary receiving, storage, refrigeration, preparation and serving of food. D. The hospital food service operation shall comply with applicable standards in 12VAC5-421. E. A diet manual, approved by the medical staff shall be maintained by the dietary service. Diets served to patients shall comply with the principles set forth in the diet manual. F. All patient diets, including therapeutic diets, shall be ordered in

		E. A diet manual, approved by the medical staff shall be maintained by the dietary service. Diets served to patients shall comply with the principles set forth in the diet manual. F. All patient diets shall be ordered in writing by a member of the medical staff. G. Pertinent observations and information relative to the special diets and to dietetic treatment shall be recorded in the patient's medical record. A hospital contracting for food service shall require, as part of the contract, that the contractor comply with the provisions of this section.	writing by a practitioner responsible for the care of the patient or by a qualified dietitian as authorized by the medical staff. ~~shall be ordered in writing by a member of the medical staff.~~ 1. Hospitals and their medical staffs may grant privileges to qualified dietitians meeting the criteria of § 54.1-2731 of the Code of Virginia to order patient diets, including therapeutic diets, and to order laboratory tests to help determine appropriate diets for the patient. 2. Therapeutic diets include the provision of enteral and parenteral nutrition. G. Pertinent observations and information relative to the special diets and to dietetic treatment shall be recorded in the patient's medical record. A hospital contracting for food service shall require, as part of the contract, that the contractor comply with the provisions of this section.

Project 4180 - none

DEPARTMENT OF HEALTH

Chapter 410- Fast Track- CMS Rule update

12VAC5-410-260. Dietary service.

A. Each hospital shall maintain a dietary service directed by a full-time person, qualified as allowed in 12VAC5-421.

B. Each hospital shall have at least one dietitian, meeting the criteria of § 54.1-2731 of the Code of Virginia, employed on either a full-time, part-time or on a consultative basis, to direct nutritional aspects of patient care and to advise on food preparation and service.

C. Space, equipment and supplies shall be provided for the efficient, safe and sanitary receiving, storage, refrigeration, preparation and serving of food.

D. The hospital food service operation shall comply with applicable standards in 12VAC5-421.

E. A diet manual, approved by the medical staff shall be maintained by the dietary service. Diets served to patients shall comply with the principles set forth in the diet manual.

F. All patient diets, including therapeutic diets, shall be ordered in writing by a practitioner responsible for the care of the patient or by a qualified dietitian as authorized by the medical staff. ~~shall be ordered in writing by a member of the medical staff.~~

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