



## Proposed Regulation Agency Background Document

<b>Agency name</b>	Virginia Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 5-190 (Current) 12 VAC 5-191 (Proposed)
<b>Regulation title</b>	State Plan for the Children with Special Health Care Needs Program
<b>Action title</b>	Repeal of 12 VAC 5-190-10 et seq. and replace with 12 VAC 5-191-10 et seq. using new title <i>State Plan for the Children with Special Health Care Needs Program</i>
<b>Document preparation date</b>	March 10, 2005

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.*

12 VAC 5-191, State Plan for the Children with Special Health Care Needs Program, is a comprehensive revision of the regulation governing several programs serving individuals with special health care needs administered by the Department of Health.

Due to the need for extensive revisions, this regulatory action proposes repeal of the current regulation (12 VAC 5-190) State Plan for the Provision of Children's Specialty Services. The current regulation governs a diagnosis-based, direct clinic service model that is no longer operating throughout the Commonwealth due to significant changes in health care coverage among children, federal goals for children with special health care needs, and identified needs of this population and their families.

The proposed regulation, 12 VAC 5-191, State Plan for the Children with Special Health Care Needs Program, identifies current program components, the scope of services provided and eligibility requirements. The regulation establishes the authority to operate a program-specific

Pool of Funds contingent upon available funding, outlines appeals processes and defines relationships and automatic referrals from other state-mandated screening and surveillance programs. The regulation recognizes that the Children with Special Health Care Needs Program is not an entitlement or federal/state/local public benefit program.

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

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Section 32.1-12 of the Code of Virginia authorizes the Board of Health to make, adopt, promulgate and enforce regulations.

Section 32.1-77 authorizes the Board of Health to prepare, amend, and submit state plans for maternal and child health services and children's specialty services pursuant to Title V of the United States Social Security Act to the U.S. Secretary of Health and Human Services. Section 32.1-77 authorizes the State Health Commissioner to administer the plan and to receive and expend federal funds for the administration of the plan in accordance with applicable federal and state laws and regulations.

Section 32.1-64.1 of the Code of Virginia mandates the Commissioner of Health to “establish and maintain the Virginia Hearing Impairment Identification and Monitoring System...for the purpose of identifying and monitoring infants with hearing impairment to ensure that such infants receive appropriate early intervention through treatment, therapy, and education.” Subsection D mandates the Board to establish regulations for the screening. Subsection F authorizes the Board of Health to promulgate “rules and regulations as may be necessary to implement this identification and monitoring system”.

Section 32.1-65 of the Code of Virginia mandates certain newborn screening testing of all infants, except for those exempted from testing by law, for specified disorders.

Section 32.1-66 of the Code of Virginia mandates the Commissioner of Health to “notify forthwith the attending physician of any newborn screening test results that indicate a suspicion of a disorder and to perform or provide for any additional testing required to confirm or disprove the diagnosis” of the specified disorders.

Section 32.1-67 of the Code of Virginia mandates the Board of Health to recommend procedures for the treatment of disorders identified by a newborn screening test.

Section 32.1-68 of the Code of Virginia mandates the Commissioner, in cooperation with local health directors, to “establish a voluntary program for the screening of individuals for the disease of sickle cell anemia or the sickle cell trait and for such other genetically related diseases and genetic traits and inborn errors of metabolism as the Board may deem necessary. The Board shall review the program from time to time to determine the appropriate age and the method of

screening for such conditions or traits in the light of technological changes. The screening program shall include provisions for education concerning the nature and treatment of sickle cell anemia, other genetically related diseases and inborn errors of metabolism and a post-screening counseling program for the treatment of any person determined to have such a condition. The program may include the provision of laboratory testing.”

Section 32.1-69.1 of the Code of Virginia mandates the Commissioner to “establish and maintain a Virginia Congenital Anomalies Reporting and Education System using data from birth certificates filed with the State Registrar of Vital Records and data obtained from hospital medical records. The chief administrative officer of every hospital, as defined in §32.1-123, shall make or cause to be made a report to the Commissioner of any person under two years of age diagnosed as having a congenital anomaly.” Subsection B mandates the Board to promulgate regulations “as may be necessary to implement this reporting and education system”. These regulations may include “scope of information to be collected” and “relationships between the reporting and education system and other agencies”.

Section 32.1-89 of the Code of Virginia mandates the Board of Health to establish “a program for the care and treatment of persons suffering from hemophilia and other related bleeding diseases” who cannot pay for the entire cost of their needed medical care. Subsection B authorizes the Board of Health to provide services “through cooperative agreements with medical facilities or other appropriate means.” This subsection also states that charges for persons receiving care shall be determined by the Board of Health.

All of these authorized and mandated programs serve children with special health care needs. Separate regulations 12 VAC5-70 “Regulations Governing the Newborn Screening and Treatment Program” and 12 VAC5-80 “Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring System” exist for these programs. Relationships among the programs are addressed in the proposed 12 VAC5-191.

## Purpose

*Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.*

Repeal of the current regulation, 12 VAC 5-190 State Plan for the Provision of Children’s Specialty Services, is necessary because this regulation does not adequately address the existing model for providing services.

The proposed regulation, 12 VAC 5-191 State Plan for the Children with Special Health Care Needs Program, is an extensive revision necessary for adequate and current program governance. Although the program is not an entitlement or federal/state/local public benefit, it offers certain services and assistance, contingent upon adequate funding, which may affect the rights of individuals.

The purpose of the proposed regulation is to provide a State Plan for the administration, eligibility, and scope of services provided through the Department of Health for residents of the Commonwealth with special health care needs. The Children with Special Health Care Needs Program encompasses various initiatives to serve individuals with special health care needs including the Care Connection for Children network, Child Development Services program, and the Virginia Bleeding Disorders Program. Following a federally mandated comprehensive needs assessment in 1999, the previous Children's Specialty Services program was phased out and replaced with the Care Connection for Children network. The current program operates very differently, and therefore needs new regulations.

Other state-mandated initiatives, such as the Virginia Newborn Screening System, Virginia Congenital Anomalies Reporting and Education System, Virginia Sickle Cell Awareness Program, and Pediatric Comprehensive Sickle Cell Clinic Network also identify and serve children with special health care needs. These programs, several of which have separate regulations, are now referenced in this regulation as well.

The proposed regulation is designed to ensure that program services are made available to eligible residents within available appropriations, are able to respond to changing needs of the population, and can qualify for federal Title V and other available funds for plan administration. It is intended to support consistent program administration statewide, and assure that resources are expended and distributed fairly across the Commonwealth.

## Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)*

- Due to the extensive nature of the changes needed, the current regulation is proposed for repeal and a replacement regulation is proposed.
- The proposed regulation reflects changes which have occurred in the program's service delivery model for children with special health care needs since the 1990s. The service delivery model has changed from a diagnosis-based direct clinic service to a model emphasizing care coordination, network services, and financial assistance for eligible uninsured and underinsured clients. Despite these changes, the program remains a non-entitlement program subject to limitations of the federal Maternal and Child Health block grant and matching state appropriations. Eligibility requirements remain unchanged and the range of conditions served has not declined but has in fact expanded with the new federal definition of children with special health care needs.
- The proposed regulation differs from the existing regulation on the following substantive items:

- The Care Connection for Children component of the program focuses on enabling services such as parent to parent support, care coordination, and information and referral. Direct clinical services have been phased out in most areas of the state where adequate private and public sector pediatric specialty resources exist.
- The program places an emphasis on helping families obtain, understand, and access health insurance coverage.
- The annual fee charged to clients has been eliminated. Care coordination services are provided to all participants free of charge.
- The program operates a Pool of Funds for Care Connection and Bleeding Disorders to help for services for uninsured and underinsured clients who meet financial eligibility requirements. Preauthorization is required for all expenditures. Details of what may be covered under the Pool of Funds is not detailed in the regulation but is available through a guidance document that is reviewed and revised at least annually. In the previous regulation, available clinical services were detailed and only large purchases, such as hospitalizations required preauthorization.
- The proposed regulation now describes linkages and referrals with other screening, surveillance, and service initiatives: Virginia Newborn Screening System, Virginia Congenital Anomalies Reporting and Education System, Virginia Sickle Cell Awareness Program, and Pediatric Comprehensive Sickle Cell Clinic Network. These are all administered by the Department of Health and identify infants and children who may benefit from follow up or other services available through the Children with Special Health Care Needs Program.
- Sections describing services provided for specific diseases or conditions are not part of the proposed regulation. The new federal definition of children with special health care needs is used. This definition focuses on a higher degree of service need and impact of the physical condition to identify the target population.
- The proposed replacement regulation keeps some provisions from the current regulation such as the authority to suspend services in an emergency, operate demonstration projects, and the right to use paraprofessionals in service delivery.
- The proposed regulation describes the scope of services, goals, and eligibility requirements for major program components-including Care Connection for Children network (new service in this regulation), Child Development Services (continued service), and the Virginia Bleeding Disorders Program (formerly known as the Hemophilia Program).
- The proposed regulation also addresses the following:
  - Provides authority to contract for needed services.

- Updates applicable federal and state requirements relating to privacy; confidentiality of medical records; contractual assurances and certifications; access to minor's health records; minor's authority to consent to surgical and medical treatment; surveillance, investigation, sharing, and security of data; and allowable uses of federal funds for the program and its contractors.
- Establishes the authority to operate program-specific Pool of Funds contingent upon available funds. Designed to pay for health care services for eligible uninsured and underinsured persons, the Pool of Funds is considered the payor of last resort and not an entitlement. Providers accepting Pool of Funds must meet certain requirements, including acceptance of payment at the Medicaid rate.
- Acknowledges that the Commissioner of Health may interpret and implement this regulation or components in a Guidance Document. This is necessary to respond to changes in population needs, funding levels, and federal goals and requirements on a time-sensitive basis.
- Outlines program appeal rights and processes, with the Commissioner of Health, or designee, rendering a final decision.

## 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 advantages of the proposed regulation to the public and the agency are:

- Clarification of the current program, eligibility requirements, and services available to children with special health care needs and their families through the Department of Health and its contractors such as:
  - Availability of family support and care coordination services to families with resident children who have special health care needs of physical origin regardless of income. These services help families understand and fully utilize health insurance benefits, as well as assist families with applications to public and other appropriate assistance programs (e.g. Medicaid);
  - Availability of financial assistance, contingent upon available funding, to obtain medical services for eligible uninsured and underinsured persons in the Care Connection for Children network and the Virginia Bleeding Disorders Program;

- Availability of evaluation services regarding potential developmental and psychosocial delays through Child Development Services provided on a sliding fee scale in accordance with Department of Health eligibility regulations (12 VAC 5-200 and 210);
- Availability of care coordination and insurance case management for all residents with Bleeding Disorders; and
- Definition of a two-tiered appeals process.

The primary disadvantages of the proposed regulation to the public and agency are:

- Services are not an entitlement. Services are subject to availability of funds and program capacity. The program is financed primarily through federal Maternal and Child Health Block Grant funds (Title V) and matching state general funds.
- Some services require financial screening and have income eligibility requirements. The Pool of Funds is available only for income eligible uninsured and underinsured persons and is subject to fund availability. Some persons who apply may not receive financial assistance.
- Not all services are eligible for financial assistance through a designated Pool of Funds. A program-specific Pool of Funds may be limited to certain services to assure and maintain financial viability. Some medically necessary services may be needed by individuals but not able to be paid for through a Pool of Funds.

## Economic impact

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

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No changes in funding will be required to implement these regulations. Funding for the Children with Special Health Care Needs Program is through federal Title V Maternal and Child Health Block Grant Funds and state matching funds. There are no costs associated with regulation implementation for program contractors. There are no costs associated for vendors receiving reimbursement through the Pool of Funds; however, vendors must be willing to accept the Virginia Medicaid fee for service rate.

The program no longer levies an annual charge for participants and this is excluded from the proposed regulation. There are no costs to patients for program services with the following exceptions, which are unchanged from the current regulation. Health department financial eligibility regulations (12 VAC 5-200) govern patient charges for Child Development Services and Virginia Sickle Cell Awareness Program clients being screened for hemoglobin variants through local health departments. Amendments to this regulation were finalized in July 2004. Children receiving direct health care services through the Pediatric Comprehensive Sickle Cell

Clinic Network are subject to financial eligibility requirements and subsequent sliding scale fees of the contracted major medical center.

### 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.*

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During the comprehensive review conducted under Executive Order 15 (94), alternatives to this regulation were considered. At that time, use of guidance documents, applicable federal directives, the annual plan submitted for receipt of federal Title V funds, and program policy and procedure guides were considered to be a viable alternative to the promulgation of regulations. The Office of the Attorney General determined in 2004, however, that a regulation is necessary to protect the rights of affected persons.

### Public comment

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

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No comments were received following the publication of the Notice of Intended Regulatory Action.

### Family impact

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability.*

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The proposed regulation should not have a negative effect on the institution of the family and family stability.

In accordance with federal goals and guidelines, the Children with Special Health Care Needs Program promotes family-centered care and services. Family-to family support is provided through several components of the program. The Children with Special Health Care Needs Program may also provide limited Pool of Funds resources to assist Virginia's uninsured and underinsured individuals with special health care needs to receive care they otherwise could not afford. The proposed regulation outlines eligibility for and delivery of services, which serve to strengthen the institution of the family and family stability.

Families choose whether to have their child participate in services offered by the Children with Special Health Care Needs Program. The only exception to voluntary participation would be if a child under state supervision were ordered by a judge to undergo evaluation at a Child Development Clinic.

**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>
10	10	Definitions	Definitions were modified, deleted, or added to reflect the proposed regulation.
20, 40, 70	20	Authority	Reorganizes several sections into one section. Authority to enact regulations further defined to reflect applicable sections of the Code. Specifies that Commissioner may interpret regulations through guidance document. Authorizes Commissioner to delegate authority for daily program supervision.
30	30	Purpose	General purpose of plan remains the same.
50	50	Reserved	Section now establishes that program operations are contingent upon available funds and federal plan approval. Section also established that program is not an entitlement.
60	60	Emergency suspension of services	Section remains the same authorizing Commissioner to suspend any portion of plan in an emergency as needed to maintain financial integrity and report to Board of Health
80	90	Confidentiality	Section expanded to address applicable federal and state privacy, confidentiality, data sharing, surveillance, minor's access to records, and minor's consent to care laws.
90	100	Medicaid-based contracts	Section retains standard that payment for any goods or services purchased for patients is equal to Medicaid fee for service reimbursement rates. Establishes program as payor of last resort. Establishes elective to have Pool of Funds. Requires contractors to have necessary credentials, licensure or certification to provide approved services.
100,110		Services, Records	Sections deleted. Content not needed in regulation but will be put into contracts as necessary.
120	110	Demonstration projects	Section maintains ability for Commissioner or designee to establish special projects and adds ability to seek additional funding for such projects.
130	100	Volunteers	Ability to maintain use of paraprofessionals as needed put into contracts section.
140	40, 170,	Relationships of the	Section no longer needed as it relates to old program

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
	180, 210, 220, 230, 250, 260, 270, 280, 290	Division of Children's Specialty Services	model. As applicable relationships between program components and other entities are specified with sections dealing with specific program components.
	120, 130	Federally required assurances; Federal stipulations for use of funds	New section added to reference federal requirements for assurances and certifications and for allowable uses of program funds in accordance with Title V federal law.
150, 160, 170	40	Mission, scope of services, goals and objectives	Sections condensed into one section, which describes current mission, scope of services, program components, target population, and goals. Current programs have greater focus on care coordination versus primary provision of clinic-based direct health care.
180, 190, 200, 210, 220, 230, 260, 270, 280, 290, 300, 310, 340, 350, 360, 370		Amputee, Cardiology, Cerebral Palsy, Cystic Fibrosis, Endocrinology, Eye Surgery, Maxillofacial, Neurology, Neurosurgery, Orthopedics, Plastic Surgery, Rheumatology, Scoliosis, Spina Bifida, Surgery, Tumors, Urology	Sections no longer applicable. These sections prescribed services provided through program according to specified conditions. Current program does not operate these clinic services. Current program contracts with pediatric specialty centers to provide care coordination and family support services. The majority of children with special health care needs in Virginia (96%) have health insurance coverage and pediatric specialty networks exist for access to care. The current program focuses on coordinating care and maximizing health insurance benefits. Limited program funds exist to help pay for care for the uninsured and underinsured.
240	260	Hearing Impairment	Section addresses current state mandated hearing impairment and newborn screening services and relationship to State Plan.
250	220, 230, 240	Hemophilia	Previous section language deleted. New sections address state mandated Virginia Bleeding Disorders Program including mission, scope of services, eligibility, goals, and availability of a Pool of Funds. This component may operate a Pool of Funds, as such funds are available, to pay for direct health services of uninsured and underinsured clients.
330	290, 300, 310, 320	Sickle Cell anemia	Previous section language deleted. New sections address mission, scope of services, eligibility, goals, and availability of sickle cell comprehensive care centers.
380, 390, 400	70	Application, eligibility, and approval procedures	Previous sections deleted. Application and annual patient charge no longer required for program participation. New section references program components requiring financial screening (e.g. Child Development Services) will be done in accordance with Department eligibility regulations 12 VAC 5-200. Requires application to appropriate state and federal

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			assistance programs for clients seeking financial assistance.
410, 420, 430		Preauthorization, Clinic, and Hospital Services	Sections no longer applicable.
440, 450, 460, 490,	180, 190	Genetic, Nutrition, and Physical Therapy Services; Drugs; and Follow up	Sections no longer applicable. Services are not routinely provided for all clients through the program. Care coordination is provided to link clients to needed services and available resources. Clients with no payment source may apply to Pool of Funds for financial assistance in purchasing certain services upon fund availability.
470, 480	210	Psychological Services, Pediatric evaluations;	New section describes Child Development Services Program which may include pediatric medical exam and psychological assessment
500	140, 150	Follow up/after care	Section language no longer applicable, however language relating to parent, legal guardian and client rights and responsibilities and closure to program placed into new sections. These items will be described in program policies. Rights and responsibilities will be provided to clients upon program entry.
510	160	Transfers	No substantive changes
520, 530, 540, 550		General, Variance panel, Form of variance requests, Retroactive requests	Sections no longer applicable to current program.
560, 570, 580	80	General, appeals in writing, judicial review	Previous sections revised and condensed into one section outlining appeal rights and process. Two levels of appeals exist with final determination made by Commissioner or designee.
590	50, 100	Source of payment funds	General part of section rewritten into new section to reference program funds received through federal Title V block grant and matching state funds as well as federal requirements to obtain funding. Section language on annual patient fee not applicable, no longer required. Pertinent section language on insurance and medical assistance programs incorporated into contracts with providers.
600, 610, 620, 630	100	Rates of payment, limitations, prerequisite, and billing requirements	Sections no longer applicable. Language related to acceptance of Medicaid fee for service rate and acceptance of payment in full incorporated into new section.
640, 650, 660, 670, 680, 690	200, 210	Child Development Services program description, scope and content, goals, patient services, organizational relationships,	Sections reorganized and condensed to describe Child Development Services program, mission, scope of services, criteria, and goals.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		application, financial regulations	