



Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC5-540
Regulation title	RULES AND REGULATIONS FOR THE IDENTIFICATION OF MEDICALLY UNDERSERVED AREAS IN VIRGINIA
Action title	Updates for determining Medically Underserved Areas and support more timely and accurate computations
Date this document prepared	April 6, 2011

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The Virginia Medically Underserved Area designation is designed to encourage the appropriate distribution and expansion of health care services into areas where Virginia citizens often lack access to health care. State and private funding programs and agencies use these underserved criteria to support family centered primary health care services throughout the Commonwealth. The regulations were last revised in 1991 and have not been reviewed since that time. The amended regulations would update the required data resources and specify how state facilities would be designated. The amendments would also correct information regarding scholarship programs that are affected by the designation.

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.

VMUA, Virginia Medically Underserved Area

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.

The Board of Health is authorized pursuant to § 32.1-122.5 of the *Code of Virginia*, to establish criteria to identify primary care medically underserved areas within the Commonwealth and specify the data calculations to be used to estimate the level of underservice. The Board of Health is also to include criteria to estimate need for medical services in state facilities operated by the Departments of Corrections, Juvenile Justice, and Behavioral Health and Developmental Services.

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, the environmental benefits, and the problems the proposal is intended to solve.

The regulations require updating because certain state programs and private funding sources depend on the accuracy of the Virginia Medically Underserved Area designation process in awarding funds to health providers and to communities. All of the changes are in response to the availability of new data sources allowing more timely designation of underserved areas.

Substance

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

The recommended changes are designed to:

1. Allow state facilities to be automatically designated as Virginia Medically Underserved Areas.
2. Incorporate new state incentive programs into the Virginia Medically Underserved Program description.
3. Allow new data sources to be used in computing Virginia Medically Underserved Areas.
4. Establish a minimum five year update and renewal cycle for designation of Virginia Medically Underserved Areas.

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 indicate.

The changes are required to make the regulations compatible with current medical and nursing scholarship regulations and to appropriately use new data sources that were not previously available. The regulatory action poses no disadvantage to the public or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale 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 and no requirements that exceed applicable federal requirements.

Localities particularly affected

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

There are no identifiable localities that would be particularly affected by the proposed regulation.

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

Anyone wishing to submit written comments could do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail, email or fax to Kathy Wibberly, 109 Governor Street Suite 1018, Richmond, Virginia 23219, email, kathy.wibberly@vdh.virginia.gov or fax 804-864-7440. Written comments are included below. In order to be considered, comments were received before the last date of the public comment period.

Economic impact

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

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.</p>	<p>The proposed amendments will facilitate a timely and cost-effective process for identifying areas that qualify for Virginia Medically Underserved Area designation. Any incurred costs are covered within the scope of service of the Virginia HRSA Primary Care Office grant which supports recruitment and retention of healthcare professionals in medically underserved areas of the Commonwealth.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>No costs will be incurred by localities to implement these regulations.</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>The VMUA designation is a targeting device that assists individual practitioners, medical facilities (e.g., clinics, hospitals), and communities in recruiting health professionals, obtaining foundation grants, qualifying for special services, etc. The regulations will support the ability of health providers to obtain the needed health care personnel and services in designated underserved areas.</p>
<p>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>Because of the wide range of community and business entities that are supported by the designation process, the potential number of directly served entities is estimated to be on the order of 500. Indirectly, the impact of the designation process can affect most of the small businesses within an underserved community.</p>
<p>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. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. 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.</p>	<p>No projected costs, only benefits, will accrue to individuals, businesses, or other community entities.</p>

<p>Beneficial impact the regulation is designed to produce.</p>	<p>It is anticipated that the Virginia Medically Underserved Area designation will continue to be used to expand medical services to underserved populations within the Commonwealth.</p>
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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.

The Virginia Department of Health sees no viable alternative for achieving the purpose of the existing regulations.

Regulatory flexibility analysis

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

The Virginia Medically Underserved Areas regulations do not present a burden or encumber any public or private businesses or other entities. The regulations are designed to assist communities within the Commonwealth provide health care services to their residents and constituents.

Public comment

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

Committer	Comment	Agency response
<p>Michele L. Satterlund, VA Council of Nurse Practitioners, P. O. Box 8088 Richmond, VA 23219 & Cynthia Fagan, RN, MS, FNP-BC, President, VA</p>	<p>VCNP supports the updating of 12VAC 5-540. The regulation has not been reviewed since 1991, and given the increasing changes to health care, as well Virginia’s growing underserved population, an update to the regulations related to underserved areas is important. VCNP supports the amendment to 12 VAC5-540-20 to include a scholarship</p>	<p>The Virginia Council of Nurse Practitioners comments underscore the need for the VMUA regulations to be amended and implemented in a timely fashion to support the recruitment of medical practitioners to medically underserved areas of the Commonwealth.</p>

Council of Nurse Practitioners	from the nurse practitioner and nurse midwife program. Recruiting practitioners to medically underserved areas is crucial, and this scholarship is another tool to better help recruit practitioners.	
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Family impact

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

The Virginia Medically Underserved Area designation is designed to encourage the appropriate distribution and expansion of health care services into areas where Virginia citizens often lack access to health care. State and private funding programs and agencies use these underserved criteria to support family centered primary health care services throughout the Commonwealth. Because adverse health outcomes are a major source of educational and workforce absenteeism, improved access to health care supports not only family but social and economic well-being within the community.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact if implemented in each section. Please describe the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations 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:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, rationale, and consequences
12 VAC5-540-10	N/A	Part I General Information Authority. In accordance with the provisions of § 32.1-122.5 of the	Part I General Information Authority. In accordance with the provisions of § 32.1-122.5 of the

		<p>Code of Virginia, the State Board of Health is required to establish criteria for determining medically underserved areas within the Commonwealth. The criteria are required to be quantifiable measures, sensitive to the unique characteristics of urban and rural jurisdictions.</p>	<p>Code of Virginia, the State Board of Health is required to establish criteria for determining medically underserved areas within the Commonwealth [and include in these criteria the need for medical care services in the state facilities operated by the Departments of Corrections, Juvenile Justice, and Behavioral Health and Developmental Services] . The criteria are required to be quantifiable measures, sensitive to the unique characteristics of urban and rural jurisdictions.</p> <p>(Rationale: To conform with the Code requirements)</p>
12VAC5-540-20	N/A	<p>Purpose. The purpose of identifying medically underserved areas within the Commonwealth is to establish geographic areas in need of additional primary health care services. These areas may be selected by trained primary care physicians and other health professionals as practice sites in fulfillment of obligations that the physicians and other health professionals accepted in return for medical training and scholarship grant assistance. Each year of practice in a medically underserved area satisfies the repayment requirement of a year of scholarship support from the Virginia Medical Scholarship Program. Additionally, these medically underserved areas will be eligible locations for practicing primary care physicians and other health professionals participating in the state or federal physician loan repayment programs. Further, these medically underserved areas may become eligible for assistance, state or federal, to establish primary care medical centers.</p>	<p>Purpose. The purpose of identifying medically underserved areas within the Commonwealth is to establish geographic areas in need of additional primary health care services. These areas may be selected by trained primary care physicians and other health professionals as practice sites in fulfillment of obligations that the physicians and other health professionals accepted in return for medical training and scholarship grant assistance. Each year of practice in a medically underserved area satisfies the repayment requirement of a year of scholarship support from the Virginia Medical Scholarship Program. and the Virginia Nurse Practitioner/Nurse Midwife Scholarship Program. Additionally, these Virginia medically underserved areas (VMUA) will be eligible locations for practicing primary care physicians and other health professionals participating in the state physician loan repayment program. Further, these medically underserved areas may become eligible for assistance, state or federal, to establish primary care medical</p>

			centers. (Rationale: Eliminates specific programs from the regulations.)
12VAC5-540-30	N/A	<p>Part II Designating Medically Underserved Areas 12VAC5-540-30. Criteria for determining medically underserved areas. The following five criteria, as available, and as indicated, shall be used to evaluate and identify medically underserved areas throughout the Commonwealth of Virginia:</p> <ol style="list-style-type: none"> 1. Percentage of population with income at or below 100% of the federal poverty level. The source for these data shall be the most recent available publication of the Bureau of the Census of the U.S. Department of Commerce. 2. Percentage of population that is 65 years of age or older. The source for these data shall be the Economic Services Division of the Virginia Employment Commission. 3. The primary care physician to population ratio. The source for these data shall be the Department of Family Practice of the Medical College of Virginia of Virginia Commonwealth University. 4. The four-year aggregate infant mortality rate. The source for these data shall be the Center of Health Statistics of the Virginia Department of Health. 5. The most recent annual civilian unemployment rate. The source for these data shall be Information Services Division of the Virginia Employment Commission. 	<p>Part II Designating [Virginia] Medically Underserved Areas The following five criteria, as available, and as indicated, shall be used to evaluate and identify medically underserved areas throughout the Commonwealth of Virginia [and the criteria shall be applied at a minimum five year interval using the most recent data available to update the designations] :</p> <ol style="list-style-type: none"> 1. Percentage of population with income at or below 100% of the federal poverty level. The source for these data shall be the most recent available publication of the Bureau of the Census of the U.S. Department of Commerce- [or appropriate intercensorial estimates of poverty accepted by the Health Resources and Services Administration Shortage Designation Branch for federal health professional shortage area and medical underserved area designations]. 2. Percentage of population that is 65 years of age or older. The source for these data shall be the [Bureau of the Census of the U.S. Department of Commerce, or the latest estimates from the Weldon Cooper Center for Public Service at the University of Virginia, or the] Economic Services Division of the Virginia Employment Commission. 3. The primary care physician to population ratio. The source for these data shall be the Department of Family Practice of the Medical College of Virginia of Virginia Commonwealth University. [Virginia Department of Health Professions, Board of Medicine physician profile database. Primary care physicians are defined as board certified or self-

			<p>designated generalist practitioners who practice family medicine, pediatrics, internal medicine, or obstetrics/gynecology.]</p> <p>4. The four-year aggregate infant mortality rate. The source for these data shall be the [most recent four-year infant mortality data for each jurisdiction from the] Division of Health Statistics of the Virginia Department of Health.</p> <p>5. The most recent annual [seasonally adjusted quarterly] civilian unemployment [rate for each jurisdiction] . The source for these data shall be [the] Information Services Division of the Virginia Employment Commission.</p> <p>(Rationale: Provides flexibility in using databases which did not exist when the regulations for VMUA were initially promulgated and it establishes a review cycle for the designation process.)</p>
12VAC5-540-40	N/A	<p>Application of the Criteria</p> <p>A. Determining medically underserved cities and counties. The criteria enumerated in 12VAC5-540-30 shall be used to construct a numerical index by which the relative degree of medical underservice shall be calculated for each city and county within the Commonwealth. Observations for each of the five criteria will be listed for each Virginia city and county. An interval scale will be used to assign a particular value to each observation. This will be done for each of the five criteria. Each interval scale will consist of four ranges or outcomes of observations. The ranges will be numerically equal. The four ranges will be labeled as Level 1, Level 2, Level 3, and Level 4. The numerical difference between the ranges will be established beginning with the</p>	<p>Application of the Criteria</p> <p>A. Determining medically underserved cities and counties. The criteria enumerated in 12VAC5-540-30 shall be used to construct a numerical index by which the relative degree of medical underservice shall be calculated for each city and county within the Commonwealth. Observations for each of the five criteria will be listed for each Virginia city and county. An interval scale will be used to assign a particular value to each observation. This will be done for each of the five criteria. Each interval scale will consist of four ranges or outcomes of observations. The ranges will be numerically equal. The four ranges will be labeled as Level 1, Level 2, Level 3, and Level 4. The numerical difference between the ranges will be established beginning with the</p>

		<p>Level 2 range.</p> <p>The Level 2 range shall have the statewide average for each respective criterion, except the population to primary care physician ratio, as its upper limit. The Level 2 upper limit for the primary care physician to population ratio is established by dividing the difference between the Level 4 upper limit for this criterion and the Level 1 upper limit by two. Each observation which is equal to or less than the Level 2 upper limit, but greater than the Level 1 upper limit, will be assigned a numerical value of two.</p> <p>The Level 1 range shall have an upper limit which is the quotient of the statewide average divided by two. For the ratio of population to primary care physician criterion, the upper limit of Level 1 shall be the ratio 2500:1 as recommended by the American Academy of Family Physicians. Each observation that is equal to or less than the Level 1 upper limit will be assigned a numerical value of one.</p> <p>The Level 3 range shall have an upper limit that is equal to the sum of the upper limit of the Level 1 range and the upper limit of the Level 2 range. For the ratio of population to primary care physician criterion, the upper limit of level 3 shall be established at 3500:1, the federal standard for designating health manpower shortage areas. Each observation that is equal to or less than the Level 3 upper limit will be assigned a numerical value of three.</p> <p>The Level 4 range will include any observation greater than the upper limit of Level 3 range. Each observation in the Level 4 range will be assigned a numerical value of four.</p> <p>The values for each of the ranges of the five criteria will be summed for each Virginia city</p>	<p>Level 2 range.</p> <p>The Level 2 range shall have the statewide average for each respective criterion, except the population to primary care physician ratio, as its upper limit. The Level 2 upper limit for the primary care physician to population ratio is established by dividing the difference between the Level 4 upper limit for this criterion and the Level 1 upper limit by two. Each observation which is equal to or less than the Level 2 upper limit, but greater than the Level 1 upper limit, will be assigned a numerical value of two.</p> <p>The Level 1 range shall have an upper limit which is the quotient of the statewide average divided by two. For the ratio of population to primary care physician criterion, the upper limit of Level 1 shall be the ratio 2500:1 as recommended by the American Academy of Family Physicians. Each observation that is equal to or less than the Level 1 upper limit will be assigned a numerical value of one.</p> <p>The Level 3 range shall have an upper limit that is equal to the sum of the upper limit of the Level 1 range and the upper limit of the Level 2 range. For the ratio of population to primary care physician criterion, the upper limit of level 3 shall be established at 3500:1, the federal standard for designating health manpower shortage areas. Each observation that is equal to or less than the Level 3 upper limit will be assigned a numerical value of three.</p> <p>The Level 4 range will include any observation greater than the upper limit of Level 3 range. Each observation in the Level 4 range will be assigned a numerical value of four.</p> <p>The values for each of the ranges of the five criteria will be summed for each Virginia city</p>
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		<p>and county. Each Virginia city and county will have an assigned value of five or greater, to a maximum of 20. A statewide average value will be determined by summing the total city and county values and dividing by the number of cities and counties. Any city or county assigned a value that is greater than the statewide average value shall be considered medically underserved. The application of criteria for determining medically underserved cities and counties shall be performed annually and published by the board.</p> <p>B. Determining medically underserved areas within cities and counties. Geographic subsections of cities or counties may be designated as medically underserved areas when the entire city or county is not eligible if the subsection has: (i) a population to primary care physician ratio equal to or greater than 3500:1; and (ii) a population whose rate of poverty is greater than the statewide average poverty rate; and (iii) a minimum population of 3,500 persons residing in a contiguous, identifiable, geographic area. The board shall from time to time, on petition of any person, or as a result of its own decision, apply criteria for determining medically underserved subareas of cities and counties. Once determined to be medically underserved, any subarea of a city or county shall appear on the next list of medically underserved areas published by the board. Areas which qualify as medically underserved areas under 12VAC5-540-40 A and that are within Standard Metropolitan Areas as defined by the U.S. Department of Commerce, must also qualify under this section for purposes of placement of health professionals.</p>	<p>and county. Each Virginia city and county will have an assigned value of five or greater, to a maximum of 20. A statewide average value will be determined by summing the total city and county values and dividing by the number of cities and counties. Any city or county assigned a value that is greater than the statewide average value shall be considered medically underserved. The application of criteria for determining medically underserved cities and counties shall be performed annually and published by the board.</p> <p>B. Determining medically underserved areas within cities and counties. Geographic subsections of cities or counties may be designated as medically underserved areas when the entire city or county is not eligible if the subsection has: (i) a population to primary care physician ratio equal to or greater than 3500:1; and (ii) a population whose rate of poverty is greater than the statewide average poverty rate; and (iii) a minimum population of 3,500 persons residing in a contiguous, identifiable, geographic area. The Board shall from time to time, on petition of any person, or as a result of its own decision, apply criteria for determining medically underserved sub-areas of cities and counties. Once determined to be medically underserved, any subarea of a city or county shall appear on the next list of medically underserved areas published by the Board. Areas which qualify as medically underserved areas under 12VAC5-540-40 A and that are within Standard Metropolitan Areas as defined by the U.S. Department of Commerce, must also qualify under this section for purposes of placement of health professionals.</p> <p>[C. Medical care services in</p>
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			<p>state facilities operated by the Departments of Corrections, Juvenile Justice, and Behavioral Health and Developmental Services will be deemed Virginia medically underserved areas.]</p> <p>(Rationale: To conform to the requirement that designations be performed on a minimum five year interval and to conform with the Code requirements that provisions be made for certain state facilities.)</p>
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