



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	DEPT. OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation	12 VAC 30-135– 400, <i>et seq.</i>
Regulation title	Demonstration Waiver: Individuals with Serious Mental Illness (SMI)
Action title	GAP Demo Waiver for Individuals with SMI
Date this document prepared	

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

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*.

Preamble

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006.

- 1) *Please explain why this is an emergency situation as described above.*
- 2) *Summarize the key provisions of the new regulation or substantive changes to an existing regulation.*

Section 2.2-4011(A) of the *Code of Virginia* states that agencies may adopt regulations in emergency situations after the agency submits a written request stating the nature of the emergency and the Governor approves the action. This action qualifies as an emergency

regulation pursuant to Code of Virginia § 2.2-4011(A) because the Agency has determined that these changes “are necessitated by an emergency situation.” On September 5, 2014, DMAS submitted a request to the Governor stating in writing the nature of this emergency and specifically requesting his authority pursuant to Virginia Code § 2.2-4011(A) to promulgate emergency regulations to address the emergency. In the letter, DMAS Director Cynthia B. Jones stated the following:

It has come to our attention that the lack of health insurance coverage for approximately one half of the population of the Commonwealth has created an urgent situation that necessitates the implementation of emergency regulations to speedily address the significant medical needs of Virginia’s uninsured population.

....

The primary concern is the need for accessible mental health care for Virginians who suffer with serious mental illness. It is estimated that about 308,000 Virginia adults have experienced a serious mental illness (SMI) during the past year. Of that number, approximately 54,000 are uninsured. While these individuals face profound difficulties in accessing treatment, almost half of them also have a co-occurring substance use disorders and have increased risk for medical conditions such as diabetes, heart disease and obesity. The average lifespan of an individual with SMI is 25 years shorter than those without.

More importantly, Virginia’s recent history with the shootings at Virginia Tech, and the tragedy experienced by State Senator Creigh Deeds, point to the dire consequences that may arise from the lack of effective treatment of SMI. Providing persons with SMI access to behavioral health and needed medical services would help prevent the reoccurrence of such tragedies, and it would provide a means for such individuals to recover and participate fully in the community.

In light of this situation the Governor has charged the Secretary of Health and Human Resources to create a plan to provide Virginians with greater access to health care for uninsured citizens. This emergency regulation is part of DMAS’ response to that directive.

The Governor is hereby requested to approve this agency’s adoption of the emergency regulations entitled GAP Demo Waiver for Individuals with SMI (12 VAC 30-135-400 et seq.) and also authorize the initiation of the regulation promulgation process provided for in § 2.2-4007 of the *Code*.

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 *Code of Virginia* (1950) as amended, § 32.1-325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance. The *Code of Virginia* (1950) as amended, § 32.1-324, authorizes the Director of DMAS to administer and amend the Plan for Medical Assistance when the Board is not in session, subject to such rules and regulations as may be prescribed by the Board. Item 301.E.1. of Chapter 2 of the *2014 Acts of the Assembly* provides as follows: "The Director, Department of Medical Assistance Services[,] shall seek the necessary waivers from the United States Department of Health and Human Services to authorize the Commonwealth to cover health care services and delivery systems, as may be permitted by Title XIX of the *Social Security Act*, which may provide less expensive alternatives to the State Plan for Medical Assistance."

The Medicaid authority as established by § 1902 (a) of the *Social Security Act* [42 U.S.C. 1396a] provides governing authority for payments for services. Section 1115 [42 U.S.C. 1315] of the Social Security Act provides authority for DMAS to create a demonstration program of limited services that waives certain designated federal Medicaid requirements, as set out below.

Via its demonstration waiver application, DMAS has sought federal approval, which is still pending, to waive the following standard Title XIX requirements to implement this program:

- 1) Amount, Duration, and Scope of Services – Section 1902(a)(10)(B) allowing Virginia to offer program individuals a benefit package that differs from the State Plan for Medical Assistance.
- 2) Freedom of Choice – Section 1902(a)(23)(A) (42 CFR §431.51) allowing Virginia the flexibility to assign program individuals to the most appropriate program provider partner for peer supports GAP case management. This will include Different Delivery Systems allowing Virginia to provide different delivery systems for the population under this demonstration for peer supports.
- 3) Reasonable Promptness – Section 1902(a)(8) Allowing Virginia to limit enrollment via modification to eligibility thresholds. 1902(a)(8) provide that all individuals wishing to make application for medical assistance under the plan shall have opportunity to do so, and that such assistance shall be furnished with reasonable promptness to all eligible individuals;
- 4) Methods of Administration – Transportation – Section 1902(a)(4) insofar as it incorporates 42 CFR §431.53 allowing Virginia, to the extent necessary, to not provide non-emergency transportation to and from providers for individuals.

- 5) Retroactive Eligibility – DMAS is waiving the requirements of Section 1902(a)(34) (42 CFR §435.914) regarding retroactive eligibility for demonstration participation.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

Absent an expansion of the Medicaid program to uninsured Virginians, this program proposes to provide individuals who have diagnoses of serious mental illness access to some basic medical and behavioral health services. The three main goals of this initiative are:

1. Improve access to health care for a segment of the uninsured population in Virginia who have significant behavioral and medical needs;
2. Improve health and behavioral health outcomes of demonstration participants; and,
3. Serve as a bridge to closing the insurance coverage gap for uninsured Virginians.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

According to national statistics, in the past year, it is estimated that 20% of adults (age 18 years or older) experienced some form of behavioral illness and approximately 4.1% of Americans experience a serious mental illness (SMI). These figures are significantly higher among low income, uninsured populations. In addition, nearly 50% of individuals with a serious mental illness (SMI) also have a co-occurring substance use disorder. Also, individuals with SMI have an increased risk for co-morbid medical conditions such as diabetes, heart disease, and obesity. Consequently, individuals with SMI have significantly decreased longevity, and in fact, die an average of 25 years earlier than individuals without a SMI.

The tragedy is that SMI and substance use disorders are the most common co-morbid medical conditions and are all highly treatable. Effective treatment is available and people can recover. Without access to such treatment, however, individuals with SMI are often unnecessarily hospitalized, may be unable to find and sustain employment, struggle with affordable and available housing, become involved with the criminal justice system, and suffer with social and interpersonal isolation.

Enabling persons with SMI to access both behavioral health and primary health services will enhance the treatment they can receive, allow their care to be coordinated among providers, and significantly decrease the severity of their condition. With treatment, individuals with SMI and co-occurring or co-morbid conditions can recover and live, work, parent, learn and participate fully in their community.

Substance

Please detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.

This action creates a new series of Virginia Administrative Code sections for the GAP Demonstration Waiver for Individuals with Serious Mental Illness (12 VAC 30-135-400 et seq.)

CURRENT POLICY

At the present time, there is no program that provides these benefits to this defined population of the Commonwealth's uninsured citizens.

ISSUES

A significant portion of the citizens across the Commonwealth who are uninsured not only lack basic health care, but also suffer from conditions that lead to complex behavioral health needs. These health and behavioral health needs cannot continue to go unmet. A targeted benefit package of services is needed that builds on a successful model of using existing partnerships to provide and integrate basic medical and behavioral health care services.

RECOMMENDATIONS

DMAS recommends a demonstration waiver under the authority of section 1115 of the *Social Security Act*. A demonstration waiver would allow DMAS to develop: (i) a targeted population of citizens to be served; (ii) targeted, limited benefit package; (iii) targeted, limited provider population for peer supports and GAP case management services, and; (iv) a care management system that improves health outcomes and reduces costs to the overall health system.

This demonstration will target participants who meet eligibility parameters, as set out in the regulations, resulting from a diagnosis of serious mental illness (SMI). DMAS has worked with stakeholders and behavioral health experts to determine the eligibility criteria to assist in this waiver's design.

Proposed Health Care Delivery System

The ultimate goal of this demonstration is to enable program eligible individuals who have diagnoses of SMI to gain access to a limited array of behavioral and primary health services. To implement this program quickly, DMAS proposes to utilize existing partnerships and provider networks. Virginians who meet the program eligibility criteria will receive a coordinated, limited, benefit package that includes both medical and behavioral health services.

Referrals for this program will arise from a variety of sources, including, but not limited to: (i) self-referral; (ii) community mental health providers; (iii) health care providers; (iv) community organizations; (v) law enforcement; (vi) jail/prisons (upon discharge), and; (vii)

hospitals. Once determined eligible, individuals will be enrolled into the program. Participants will receive benefits defined for the program, and will do so through existing provider networks which will be paid the existing rates and using the same service authorization processes currently in use for the Medicaid and FAMIS programs. DMAS anticipates that the benefits that are included in the program, and that are currently covered by the Behavioral Health Services Administrator agreement (BHSA), will continue to be provided through the BHSA. DMAS' eligibility contractor will implement the eligibility rules; the benefits and terms of payment will be specified in a contract document that will be executed with existing partners.

Through this program, Virginia will seek to demonstrate that integrating care coordination and a limited benefit of primary care, specialty care, pharmacy, and behavioral health care for this uninsured population will result in better health and sustained living for these individuals. It is anticipated that such individuals will also have fewer improper emergency department (ED) visits, less inpatient hospital utilization, and decreased negative interaction with the criminal justice system; thereby reducing other often-uncompensated health care costs. It is anticipated that the use of program benefits will support a reduction of other high cost services (such as emergency room visits).

Benefits and Cost-Sharing Requirements

The benefit package for this demonstration will be limited in scope while still providing access to the most critical services for the SMI population. Specific benefits in the benefit package include, generally: (i) basic medical coverage (such as outpatient physician services, physician specialists, diagnostic procedures, laboratory procedures, and pharmacy services); (ii) care coordination (such as, crisis line and peer support); and (iii) community behavioral health services (such as, crisis intervention and stabilization, psychosocial rehabilitation assessments and services, substance abuse treatments). SMI diagnostic screenings will also be covered.

The demonstration program will not pay for any services beyond the limited benefit package such as: (i) inpatient and outpatient hospital visits; (ii) emergency department visits; (iii) home health services; (iv) durable medical equipment, other than diabetes care products (which are covered); (iv) nursing home and long-term care services; (v) routine dental services; (vi) non-emergency transportation, or; (vii) routine optometry services. Demonstration program enrolled individuals who require these services will need to access other payment sources or secure charity care.

This program also does not include any cost-sharing (such as co-payments, co-insurance or deductibles) requirements for the participating individuals.

Increase or Decreases in Enrollment and Expenditures

Although no increase in state appropriations is required for this two-year demonstration project, enrollment into the program must be limited due to funding constraints. Enrollment will not be capped but financial eligibility criteria may be amended in the future, in order for the program to remain budget neutral.

The estimate for the cost of services will be based on benefits covered, service utilization, and the rate of enrollment. DMAS estimates that up to 20,000 individuals may receive services over the period of this program (January 2015 through at least December 2017) at an average cost of \$7,000 to \$8,600 per individual. Fifty percent of the costs of this program will be paid with federal funds.

The estimated total cost for State Fiscal Year (SFY) 2015 is \$27 million in total funds. In SFY 2016, the estimated total cost is \$156 million. DMAS will closely monitor the utilization and cost data to ensure that the funds available for this project are not exceeded. This two year demonstration will be implemented from January 2015 through at least January 2017 or until Virginia implements a plan to provide health coverage for individuals up to 100% of the Federal Poverty Level, whichever is sooner.

To ensure budget neutrality as required by all §1115 waiver demonstrations, cost savings will be realized by the effective medical and behavioral management of uninsured individuals who experience SMI. This will enable eligible Virginians to remain in their communities, remain employed, and support them in their efficient use of the health care system. Further, if these individuals have access to the limited services available under the GAP program, this will significantly reduce the likelihood that their medical and behavioral condition will decline to the point that they will may be determined as disabled and eligible for enrollment into the full-benefit Medicaid program. The ratio of the cost for full-benefit Medicaid coverage for an individual versus GAP coverage for that same individual is approximately \$1,500 versus \$780.

The new regulations created by this action are: 12 VAC 30-135-400 et seq.

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
135-400	Establishes the name of this new waiver program.	Title XI of the Social Security Act, § 1115.	Intent is to establish this new program and the associated regulation section numbers.
135-401	Establishes this new waiver program.	Title XI of the Social Security Act, § 1115.	Intent is to establish this new program and the associated regulation section numbers.
135-410	Definitions.	Title XI of the Social Security Act, § 1115.	Defines terms in the new program.
135-420	Administration; authority.	Title XI of the Social Security Act, § 1115.	Establishes the administration of the new program and the statutory authority for it.
135-430	Individual eligibility requirements; limitations	Title XI of the Social Security Act, § 1115.	Establishes requirements that individuals must meet in order to be approved to receive the covered services.
135-440	Individual screening requirements.	Title XI of the Social Security Act, § 1115.	Establishes the individual screening requirements.
135-450	Covered services; limitations; restrictions.	Title XI of the Social Security Act, § 1115.	Establishes the new program's covered services and the limits on those services.
135-469	Non-covered medical and behavioral health services.	Title XI of the Social Security Act, § 1115.	Lists services not covered in the new program.

135-470	Provider qualifications; requirements.	Title XI of the Social Security Act, § 1115.	Establishes provider qualification requirements.
135-480	Quality assurance.	Title XI of the Social Security Act, § 1115.	Establishes quality assurance requirements in the new program.
135-490	Reimbursement.	Title XI of the Social Security Act, § 1115.	Establishes the reimbursement methodologies to be used.
135-487 through - 495	Client and provider appeal rights and processes.	Title XI of the Social Security Act, § 1115.	Establishes the participating individuals' rights and the appeal process to be used.
135-498	Individual rights	Title XI of the Social Security Act, § 1115..	Establishes individuals' rights to being treated with dignity and provides for no cost sharing.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

This program is recommended because it will address some of the unmet health care needs of some of Virginia's uninsured citizens within the constraints of state and federal law and requirements associated with Title XIX, the medical assistance services program.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments on this notice.

Please also indicate, pursuant to your Public Participation Guidelines, whether a Regulatory Advisory Panel or a Negotiated Rulemaking Panel has been used in the development of the emergency regulation and whether it will also be used in the development of the permanent regulation.

The agency is seeking comments on the regulation that will permanently replace this emergency regulation, including but not limited to 1) ideas to be considered in the development of the permanent replacement regulation, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) the potential impacts of the regulation.

DMAS has already received public comments on this issue. The Department posted public notice of its intent to submit a § 1115 demonstration waiver application and hold public meetings, DMAS posted its notice in the Virginia Regulatory Town Hall on September 11, 2014. The comment period lasted from September 11, 2014, through October 7, 2014. Comments were received from 64 individuals, NAMI, the Mental Health Association of Fauquier, and Concerned Fairfax who expressed support for the concept of the program and some individuals chose to

relate personal experiences. In addition, DMAS held two public meetings to provide information and receive public comment. These meetings were held in Fairfax, Virginia on September 16, 2014 and in Richmond, Virginia on September 17, 2014. Finally, the Centers for Medicare and Medicaid Services (CMS), the federal agency that administers the Medicaid program in partnership with the states, opened an online public forum for the receipt of comments regarding Virginia's GAP Demonstration Waiver program.

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 1) projected reporting, recordkeeping and other administrative costs, 2) the probable effect of the regulation on affected small businesses, and 3) 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 Molly Huffstetler, Senior Advisor for Special Projects, DMAS, 600 East Broad Street, Suite 1300, Richmond, VA 23219; (804) 298-3846; (804) 786-1680 fax; Molly.Huffstetler@dmas.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 meeting will not be held following the publication of the proposed stage of this regulatory action.

Family impact

Assess the potential 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.

These changes do not strengthen or erode the authority or rights of parents in the education, nurturing, and supervision of their children; nor 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. It does not strengthen or erode the marital commitment.