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Proposed Regulation Agency Background Document

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

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

DMAS promulgated its original emergency regulations for the GAP Demonstration Waiver for Individuals with Serious Mental Illness (SMI), with the Governor's approval on December 10, 2014, which became effective January 1, 2015. The program was implemented through emergency regulations, and these proposed regulations will allow the program to continue past the expiration of the emergency regulations.

The program provides specified benefits to qualifying individuals who are uninsured. To qualify, these individuals must meet the GAP serious mental illness criteria as well as the financial and nonfinancial eligibility criteria. The serious mental illness criteria involved specific diagnoses

(for example, schizophrenia, bipolar disorders, PTSD), specific duration of illnesses, specific levels of impairment, and consistent need for help in accessing health care services.

Other criteria are that eligible individuals are: (i) adults between the ages of 21 and 64 years; (ii) U.S. citizens or lawfully residing aliens; (iii) residents of the Commonwealth; (iv) uninsured; (v) ineligible for any state or federal health insurance programs; (vi) not current residents of a nursing facility, mental health facility or penal institution.

In addition, these individuals must have household incomes, as determined via agency's current MAGI policies, of less than or equal to 80 percent of the Federal Poverty Level (FPL). The 2016 General Assembly, in the *2015 Acts of the Assembly*, Chapter 780, Item 306 XXX(1)(a), directed DMAS to modify this program's household income level, from 60 percent to 80% of the FPL.

A wide range of benefits, including outpatient physician and clinic services, specialists, diagnostic procedures, laboratory procedures, and pharmacy services are provided through this demonstration program. The following benefits are to be provided: (i) primary care office visits including diagnostic and treatment services performed in the physician's office, (ii) outpatient specialty care, consultation, and treatment, (iii) outpatient hospital including observation and ambulatory diagnostic procedures, (iv) outpatient laboratory, (v) outpatient pharmacy, (vi) outpatient telemedicine, (vii) medical equipment and supplies for diabetic treatment, (viii) outpatient psychiatric treatment, (ix) GAP case management, (x) psychosocial rehabilitation assessment and psychosocial rehabilitation services, (xi) mental health crisis intervention, (xii) mental health crisis stabilization, (xiii) therapeutic or diagnostic injection, (xiv) behavioral telemedicine, (xv) outpatient substance abuse treatment services, and (xvi) intensive outpatient substance abuse treatment services. Care coordination, Recovery Navigation (peer supports), crisis line and prior authorization for services shall be provided through the agency's Behavioral Health Services Administrator.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and (2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency'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 according to the Board's requirements. 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.

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 secured federal approval, with the concomitant federal funding, 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.

This action complies with the legislative mandates set out in the *2016 Acts of the Assembly*, Chapter 780, Item 306 XXX(1)(a) effective July 1, 2016, as well as the Governor's original directive to DMAS.

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.

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.

This program was originally proposed to provide uninsured individuals who have diagnoses of serious mental illness access to medical and behavioral health care in order to improve their health and lives in their families and communities.

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.

The regulations that are affected by this action are the Governor's Access Plan Demonstration Waiver for Individuals with Serious Mental Illness (12 VAC 30-135-400 et seq.).

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 charged the Secretary of Health and Human Resources to create a plan to provide Virginians with greater access to health care for uninsured citizens.

CURRENT POLICY

Prior to the adoption of DMAS' original emergency regulations, this program did not exist.

Under the authority of an original emergency regulation and two subsequent revising emergency regulations, this demonstration waiver program uses an income limit of 80 percent of the Federal Poverty Level on the incomes of persons applying for this assistance. DMAS determines financial eligibility via its current MAGI financial and household composition rules. This program also covers a wide range of medical and behavioral health services, including outpatient physician and clinic services, specialists, diagnostic procedures, laboratory procedures, and pharmacy services.

ISSUES

This program originally proposed to provide uninsured individuals who have diagnoses of serious mental illness access to medical and behavioral health care in order to improve their health and lives in their families and communities. Uninsured individuals, who have diagnoses of serious mental illness, can have profound difficulties accessing basic medical and behavioral health services, including prescription medications, and often have co-morbidities of substance abuse and chronic health conditions. Such individuals often have reduced life spans as well as limited parenting capabilities and community (jobs, schooling) participation.

RECOMMENDATIONS

DMAS recommends the approval of the permanent regulations for this new program.

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.

There are no advantages or disadvantages to private citizens in this program. The advantage to uninsured citizens, who have diagnoses of serious mental illness, will be the accessing of basic health care and behavioral health, including prescriptions, care services. Helping such affected individuals with these services will stabilize their lives, enabling them to parent and maintain employment and/or schooling.

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 more restrictive than federal requirements contained in these recommendations.

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.

This program operates statewide and, therefore, no localities are particularly affected over others.

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 Department of Medical Assistance Services 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 for the public comment file may do so by mail, email or fax to Brian Campbell, Senior Policy Analyst, Division of Integrated Care and Behavioral Services, DMAS, 600 E. Broad St., Suite 1300, Richmond, VA 23219; (804) 225-4272; fax (804) 786-1680; Brian.Campbell@dmas.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.

<p>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</p>	<p>\$38.2 M for FY 2016 (50/50 state/federal match) \$58.6 M for FY 2017 (50/50 state/federal match) \$0 from localities</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>N/A</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>This program provides basic primary health care services and behavioral health care services to adult individuals who have diagnoses of serious mental illness but who do not have other health insurance coverage.</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: 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.</p>	<p>3,873 total number of members enrolled as of 7/17/15; 8,021 applicants as of 7/17/15; Participating providers: 208 behavioral health; 3,021 medical providers; 962 pharmacy providers; 39 independent labs. DMAS does not have data on how many of its providers meet the definition of a small business.</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 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.</p>	<p>Providers are being required to maintain standard health care records for these covered adults. These requirements for the GAP program as the same as the requirements for all other DMAS programs.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>These regulations provide basic primary health and behavioral health (including drugs) to adults who do not have any other source of health care coverage.</p>

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.

In the absence of a full expansion of Medicaid eligibility to all uninsured low-income Virginians, this program is designed to address a critical health care need of persons with serious mental illness.

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.

There may be some small businesses (physicians' offices, pharmacies) that are affected by this program. There are no reporting requirements or performance standards contained herein that affect small businesses. No small business is required to enroll as providers in this program.

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.

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, but may decrease disposable family income depending upon which provider the recipient chooses for the item or service prescribed.

Public comment

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

DMAS submitted its Notice of Intended Regulatory Action to the Registrar on December 10, 2014, for publication in the *Virginia Register* (VR 31:10) for comment period from January 12, 2015, through February 11, 2015. No comments were received.

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.*

DMAS' original emergency regulations (TH 4252/7084) provided for:

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.

The first revising emergency regulations (TH 4252/7190) provided for:

Current section	Proposed new section	Current requirement	Proposed change and rationale
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number	number, if applicable		
	12 VAC 30-135-400(A)	Provides for incomes up to 100% of the Federal Poverty Level (FPL) with a 5% household income disregard.	Provides for incomes up to 60% of the FPL (plus a 5% household income disregard)
	12 VAC 30-135-420 (A) and (E)	Provides for incomes up to 95% of the FPL with 5% household income disregard	Provides for incomes up to 60% of the FPL (plus a 5% household income disregard)
	12 VAC 30-135-430 (G)	Provides for incomes up to 95% of the FPL with 5% household income disregard	Provides for incomes up to 60% of the FPL (plus a 5% household income disregard)
	12 VAC 30-135-450 (C)	Provides for specified services.	Provides for services as specified in the legislative mandate.

The second revising emergency regulations (TH 4252/7600) provided for:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
	12 VAC 30-135-400(A)	Provides for incomes up to 100% of the Federal Poverty Level (FPL) with a 5% household income disregard.	Provides for incomes up to 80% of the FPL using the MAGI eligibility methodology (which includes a 5% household income disregard)
	12 VAC 30-135-420 (A) and (E)	Provides for incomes up to 95% of the FPL with 5% household income disregard	Provides for incomes up to 60% of the FPL using the MAGI eligibility methodology (which includes a 5% household income disregard)
	12 VAC 30-135-430 (G)	Provides for incomes up to 95% of the FPL with 5% household income disregard	Provides for incomes up to 60% of the FPL using the MAGI eligibility methodology (which includes a 5% household income disregard)

The changes between the second revising emergency regulations and the current proposed stage are:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Through-Out		The term substance abuse is used.	The term is updated to "substance use disorder."
135-400		Text uses future tense.	Changed from future tense to current tense.
135-410		Definitions include text from other regulatory sections.	Definitions changed to cross-reference (rather than repeat) regulatory text in other sections for terms: BHSA, intensive outpatient services, ISP, LMHP, progress notes, service authorization, service specific

			provider intake.
135-410			The definitions for the following terms have been revised: action, agency, CSB, client appeal, Cover Virginia, department, direct services, duration of illness, expedited appeal, final decision, GAP screening entity, good cause, grievance, hearing, individual, remand, reverse, serious mental illness, state fair hearing, sustain, virtual engagement, warm line. Note: the definition for "GAP screening entity" now includes local or regional jails and the Department of Corrections to allow those agencies to screen individuals to determine eligibility for GAP-SMI services upon discharge.
135-410		No definitions for the terms used in the regulations.	New definitions inserted for the terms "client," "ex parte renewal," "high intensity case management," "MAGI," and "regular case management."
135-410		Definitions for terms no longer used in the regulations.	Definitions were removed for terms that no longer appear in the regulations: QPPMH, QSAP, psychoeducational activities and services
135-430		The term "individual" is used.	The term individual is changed to "applicant" or "enrollee."
135-430		The term eligibility is used.	References to eligibility are clarified to indicate financial or nonfinancial eligibility.
135-430			A new paragraph H is added.
135-440		The term "individual" is used.	The term individual is changed to "applicant" or "enrollee."
135-440			New paragraphs G1 an G2 were added.
135-440			The text in paragraph I was clarified to indicate the steps taken by Cover Virginia.
135-450			Cross-references to other regulations were updated and additional cross-references were inserted.
135-450			Re-lettered and re-organized text sections. Community mental health is now paragraph D; outpatient psychotherapy is now paragraph E; community substance use disorder is now paragraph F, and care coordination is now paragraph G.
135-450			A new paragraph D2 includes information about GAP case management that was previously found elsewhere.
135-470		Provider requirements from other regulations are included in the text of this regulation.	Provider requirements are removed and cross-references are inserted instead.
135-475		ISP requirements from other regulations are included in the text of this regulation.	ISP requirements are removed and cross-references are inserted instead.

135-480		Utilization review requirements from other regulations are included in the text of this regulation.	Utilization review requirements are removed and cross-references are inserted instead.
135-485			Paragraph B was removed – this was a provider requirement, and was not related to reimbursement.
135-487			References to "division" are changed to "DMAS Appeals Division." Other clarifying edits were also made to this section.
135-489			Clarifying edits were made to this section.
135-491			Clarifying edits were made to this section.
135-494			Clarifying edits were made to this section.
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