Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	Department of Medical Assistance Services
Virginia Administrative Code (VAC) citation	12 VAC 30, Chapter 130
Regulation title	Client Medical Management Program
Action title	Client Medical Management Update
Date this document prepared	

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

Please provide a brief summary (no more than 2 short 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

A client medical management program restricts individuals who have a history of utilizing high numbers of different physicians and/or pharmacies for their primary health care services. Restriction in the program is for a defined period of time and the individual is required to establish a medical home with a single primary care physician and/or pharmacy.

These proposed changes will further improve the health, safety, and welfare of individuals who are eligible for Medicaid and who also use higher than typical amounts of services from different physicians and pharmacies.

Currently, the Medicaid State Plan provides for administration of the Client Medical Management (CMM) program with individuals being restricted for 36 months. At the end of the restriction period, if the individual is deemed to still be utilizing services inappropriately, continued restriction is for another 36 months.

This regulatory change proposes to enhance the current CMM program by assisting and educating Medicaid individuals in the appropriate use of medical and pharmacy services. The identified individuals who use covered services excessively or inappropriately, as determined by DMAS, may be assigned to a single physician or pharmacy, or both for 24 months. During the restriction period, DMAS monitors these individuals' utilization to promote appropriate utilization patterns and reviews their claims history records prior to the end of the restriction period to determine if the restriction should be terminated or continued. DMAS does permit individuals to appeal their restriction determinations.

This regulation change is less restrictive (in terms of the restriction period) than the policies it is replacing; however, it provides more of an opportunity to focus on educating individuals on appropriate and inappropriate utilization patterns, thereby decreasing recidivism.

The proposed regulatory change does not have an impact on current provider Client Medical Management regulations or procedures.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

I hereby approve the foregoing Agency Background Summary with the attached amended regulations entitled Client Medical Management Update (12 VAC 30-130-800, 12 VAC30-130-810, and 12 VAC 30-130-820) and adopt the action stated therein. I certify that this final regulatory action has completed all the requirements of the *Code of Virginia* § 2.2-4012.1 of the Administrative Process Act.

Date

Cynthia B. Jones, Director

Dept. of Medical Assistance Services

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 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.

Title 42 of the Code of Federal Regulations § 431.54(e), permits state Medicaid agencies to have programs that restrict Medicaid individuals who have been found to be over-utilizing either physician or pharmacy services, or both. DMAS' Client Medical Management program operates under the authority of a § 1915(b) (of the *Social Security Act*) waiver granted by CMS. The waiver permits DMAS to deny the standard freedom of choice (42 CFR § 431.51) to these identified recipients and restrict them to specified physicians or pharmacies, or both.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail 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.

The purpose of this action is to promulgate permanent regulatory changes for the CMM program. Chapter 2 of the *2014 Acts of the Assembly*, Item 301 RR directed DMAS to make programmatic changes to this program to ensure appropriate utilization, prevent abuse, promote improved and cost efficient medical management of essential health care, and assist and educate beneficiaries in appropriately using medical and pharmacy services.

These changes will not impact the health and safety of the Commonwealth citizens who do not receive Medicaid services. These changes will not affect Medicaid enrolled providers.

Rationale for using fast track process

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

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

DMAS believes that the fast track process is appropriate because these proposed changes are more liberal than the current policies. DMAS does not anticipate any objections to these changes. CMM program is still DMAS' utilization control program for fee-for-service individuals. DMAS

did not receive any objections to the emergency regulations or comments during the NOIRA comment period.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

The *Virginia Administrative Code* affected by this action is the Client Medical Management program (12 VAC 30-130-800, 12 VAC 30-130-810 and 12 VAC 30-130-820).

Currently, the regulations that provide for the administration of the CMM program affect the fee-for-service Medicaid eligible population which is only potentially 31% of the entire Medicaid population. These regulations do not affect those individuals who participate in the managed care model of service delivery.

Medicaid's managed care program is now statewide and as of April 2014 cared for 69% of all Medicaid eligible individuals. The *Virginia Administrative Code* at 12 VAC 30-120-370 sets out the reasons that individuals can be exempted from participating in the managed care program. Some of the reasons are: (i) individuals who are inpatients in state mental hospitals, nursing facilities, Intermediate Care Facilities for Individuals with Intellectual Disabilities, hospice; (ii) individuals who are affected by Medicaid spend-down policies; (iii) individuals who are in either home and community based waiver programs; (iv) individuals who are eligible for Part C services through the Department of Behavioral Health and Developmental Services; (v) individuals whose eligibility period is less than three months in duration or who have retroactive eligibility; (vi) children enrolled in the Virginia Birth-Related Neurological Injury Compensation Program established pursuant to Chapter 50 (§ 38.2-5000 et seq.) of Title 38.2 of the *Code of Virginia*. Only the individuals who fit any of these exemption reasons receive their medical care via the fee-for-service model and therefore can be affected by CMM.

Pursuant to current CMM regulations and after patterns of inappropriate or excessive service use are identified, individuals are restricted to one pharmacy/physician for a minimum of 36 months. At the end of the restriction period, if the recipient continues to demonstrate inappropriate use of services, he is being re-enrolled in the program for another 36 months. DMAS tracks this inappropriate use with computer claim denial codes which result from providers' bills for services that may have been rendered.

Even though the recidivism rate averages about 7.8%, DMAS believes changing the restriction period to 24-months initially and 12 months for re-enrollment to be appropriate. With the managed care statewide expansion, the CMM potential population has substantially decreased. This reduction in CMM restricted members along with the changes to the restrictions periods will allow staff to facilitate resolution of any early enrollment issues and also be more proactive in assisting and educating Medicaid individuals in appropriately using medical and pharmacy services. DMAS staff will continue to work with members who are over-utilizing services, but

also more closely assess under-utilization that results in abusive practices. These changes may also contribute to cost avoidance.

This action continues to provide for the medical care needs of individuals with multiple diagnoses and complex health care needs, which require care from physicians and specialists in addition to their primary care physicians. Provision is also retained for individuals who have legitimate complex medical conditions that require high numbers of prescription medications. Provisions are being retained for such complex care recipients to appeal a restriction status and be exempted from restriction.

Providers are required to require that Medicaid individuals present their Medicaid identification cards when they present for services. When providers input the unique identification number, they are advised that the individual's access to physician and/or pharmacy services is restricted. This action continues to provide that if the individual's restriction pharmacy does not have the required drug or in emergency situations, the individual may receive the required medication from an alternative pharmacy. Such alternative pharmacies are paid for providing medications in such situations.

Individuals demonstrating the following utilization patterns will be evaluated to determine if they warrant being restricted to designated physician and/or pharmacy providers:

- An individual receiving narcotic prescriptions from two or more prescribers without supporting diagnoses indicative of use.
- An individual having two occurrences of filling prescriptions for the same drug two or more times on the same or the subsequent day.
- An individual receiving more than 24 prescriptions in a three month period.
- An individual receiving more than 12 psychotropic prescriptions, more than 12 analgesic prescriptions, or more than 12 prescriptions for controlled drugs that have the potential for abuse, in a three month period.
- An individual who uses emergency hospital services for three or more emergency room visits for non-emergency care during a three month period to include cases of self referral, non-acute episodes of care, or solely for non-acute management of chronic diagnoses or symptoms.
- Utilizing services from three or more prescribers and three or more dispensing pharmacies in a three-month period.
- Exceeding the maximum therapeutic dosage of the same drug or multiple drugs in the same therapeutic class, which have been prescribed by two or more practitioners, for a period exceeding four weeks.
- Receiving two or more drugs, duplicative in nature or potentially addictive (even within acceptable therapeutic levels), dispensed by more than one pharmacy or prescribed by more than one practitioner for a period exceeding four weeks.
- Utilizing three or more different physicians of the same type or specialty in a three-month period for treatment of the same or similar condition or conditions.
- Two or more occurrences of seeing two or more physicians of the same type or specialty on the same or subsequent day for the same or similar diagnosis.

- Duplicative, excessive, or contraindicated utilization of medications, medical supplies, or appliances dispensed by or prescribed by more than one provider for the time period specified by DMAS.
- One or more providers recommend restriction for medical management because the recipient has demonstrated inappropriate utilization practices.
- A pattern of noncompliance which is inconsistent with sound fiscal or medical practices. For example, noncompliance may be characterized by: (a) Failure to disclose to a provider any treatment or services provided by another provider; (b) Failure to follow a drug regimen or other recommended treatment; (c) Requests for medical services or medications which are not medically necessary; (d) Use of hospital emergency services via self-referral for non-acute episodes of care, or solely for non-acute management of the medical condition; or (e) Under-use or under-utilization of medically necessary services that result in higher costs for the management of the medical condition.
- Any documented occurrences of use of the eligibility card to obtain drugs under false pretenses, which includes, but is not limited to the purchase or attempt to purchase drugs via a forged or altered prescription.
- Any documented occurrences of card-sharing.
- Any documented occurrences of alteration of the recipient eligibility card.

Controls placed on individuals who may be abusing services will improve cost-efficiency of care and enable better monitoring and improved coordination of the health care needs toward the overall goal of improved health care outcomes. The following are examples of individuals whose use of Medicaid covered services warranted being included in the CMM program.

- CASE A: For an individual who receives medical services for multiple diagnoses, a utilization review process documents the use of 7 physicians, 3 pharmacies and non-emergency services. In some of these instances, DMAS has found such individuals refusing regular therapies and opting instead for treatment in emergency rooms and hospitals. During such an individual's CMM enrollment, DMAS staff (RMU case manager) would make multiple contacts with the individual, providers, other DMAS units and resources in the individual’s community to identify and facilitate coordination of care with one treatment center. After enrollment in CMM, such an individual would receive scheduled services at one treatment center and pharmaceutical services are received at one pharmacy, while non-emergency services are denied or paid at reduced rates. In this manner such an individual's health would be stabilized through appropriate use of available services.

- CASE B: For an individual, who is receiving medical services for multiple diagnoses (such as diabetes, depression and chronic pain), a utilization review process documents the use of 4 physicians and 1 pharmacy with simultaneous prescriptions for narcotic analgesics and medicine for maintenance treatment of opioid dependence. Since enrollment in CMM, the individual’s health care is coordinated by a primary care physician who has referred this individual to other health care providers that treat such diagnoses. Pharmaceutical services are received at one pharmacy.

- CASE C: For an individual, who is receiving medical services for multiple diagnoses (such as back pain, bipolar disorder, diabetes, and asthma), a utilization review process documented the use of 5 physicians and 10 pharmacies with duplicate prescriptions from the several physicians. The individual also had the same day/subsequent day filling of syringe supplies. RMU staff discussed inappropriate utilization identified during the review process with the individual prior to enrollment in CMM. Since enrollment in CMM, the individual's pharmaceutical services are coordinated through one pharmacy and one primary care physician who is the primary prescriber of medications. During routine monitoring of services, there have been documented attempts by the individual to use non-designated pharmacies for services.

Issues

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

The primary advantage to the general public and private citizens with this proposed regulation is that it decreases the duplicative efforts of doctors and pharmacies by allowing them to provide the same level of care for all patients. It also reduces an individual's access to excessive amounts of medications that have therapeutic properties that could cause harm to himself and other individuals in the community if they are re-sold to other persons.

The primary advantage to the Commonwealth is the close monitoring of the fee-for-service Medicaid population's utilization patterns and identifying instances of over-utilization and non-compliance which could result in misappropriations of state and federal funding. Restriction of individuals to one pharmacy and/or physician has resulted in reductions in Medicaid expenditures for individuals during Client Medical Management restriction periods.

There are no disadvantages to the public or the Commonwealth.

Requirements more restrictive than federal

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

These regulatory changes are not more restrictive than federal regulations.

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 will be no localities that are more affected than others as these requirements will apply statewide.

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.

This regulatory action is not expected to affect small businesses as it does not impose compliance or reporting requirements, nor deadlines for reporting, nor does it establish performance standards to replace design or operational standards.

Economic impact

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

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	There are no funds required for the implementation of this change as the medical expenses for the members are currently covered by the fee-for-service benefit package. There is no economic impact or projected cost to the state anticipated as a result of these proposed changes.
Projected cost of the *new regulations or changes to existing regulations* on localities.	There are no projected costs for localities anticipated as a result of these proposed regulation changes.
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	All fee-for-service Medicaid enrollees, current Client Medical Management enrollees and physicians and pharmacists who accept fee-for-service individuals
Agency's best estimate of the number of such entities that will be affected. Please include an	DMAS contracts with numerous physicians and pharmacist and based upon the utilization patterns

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.	of fee-for-service enrollees (307,670) the possibility of being affected by this regulation change is minimal. The best estimate for the number who will be impacted by this regulation is 23,407 physicians and 1,957 pharmacies that provide primary care to Medicaid recipients.
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.	There are no projected new costs anticipated as a result of these projected regulation changes.
Beneficial impact the regulation is designed to produce.	Potentially reduced costs of services as a consequence of reduced use.

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.

Based upon research conducted on other states' CMM programs and the cost savings demonstrated in the first two years for current enrollees, it is expected that a restriction period of 24 months is sufficient time for continuous monitoring of the utilization patterns, coordination of services and education of enrollees. DMAS believes that these recommended changes create the best alternative to either not having a CMM program at all or retaining or increasing the restriction periods.

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; or 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.

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. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre**-emergency regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12 VAC 30-130-800		Definitions "Card-sharing" means the intentional sharing of a recipient eligibility card for use by someone other than the recipient for whom it was issued; or a **pattern of repeated** unauthorized use of a recipient eligibility card by one or more persons other than the recipient for whom it was issued due to the failure of the recipient to safeguard the card.	Emergency regulations changed definitions for improved clarity and interpretation. 'A pattern of abuse' was removed because a single incident of card sharing is indicative of fraud and abuse. Fast-track adds new definitions and modifies existing regulations for improved clarity and readability.

12 VAC 30-130-810 (A), (B), (C)		SURS	ER added language clarifications and specified important details to improve clarity and readability JSURS- System name updated Fast Track added that individuals in managed care organizations are excluded from CMM
12 VAC 30-130-810 (D)		Restricted individuals shall have 'reasonable access' to all essential medical services. These restrictions shall not apply to hospital emergency services	Location of item moved from -130-810 G to -130-810-D. 'Reasonable access' standard changed to 'medically necessary' standard. Fast track re-organizes existing criteria, adds a few new ones, and removes old criteria where the utilization is addressed by MCOs and adds new criteria for non-compliance.
		A pattern of non-compliance which is inconsistent with sound fiscal or medical practices. Non-compliance conditions are set out in -130-810 D 3 n	Non-compliance pattern now character-ized by 5 example behaviors.
		Use of transportation services with no corresponding medical services	Deleted. DMAS has a transportation contractor which controls service use. Added new criteria for noncompliance: A pattern of non-compliance which is inconsistent with sound fiscal or medical practices. Criteria: Under-use or underutilization of medically necessary services that result in higher costs for the management of the medical condition.

			Under-use or underutilization of medically necessary services is not medically responsible or fiscally sound and can result in the further deterioration of an otherwise manageable health condition. Criteria: Use of hospital emergency services via self-referral for non-acute episodes of care, or solely for non-acute management of chronic diagnoses/symptoms is not cost-effective and typically the ER cannot provide the continuity of care a primary care physician provides.
		One or more documented occurrences of the use of the eligibility card to obtain drugs under false pretenses, which includes, but is not limited to, purchase or attempt to purchase drugs via a forged or altered prescription	
		One or more documented occurrences of card-sharing.	Fast track adds new criteria, and clarifies criteria to indicate any single documented incidence is indicative of fraud and abuse.
		One or more documented occurrences of alteration of the individual eligibility card.	Fast track adds new criteria, and clarifies criteria to indicate any single documented incidence is indicative of fraud and abuse.
		One or more documented occurrences of paying cash for controlled substances, analgesic drugs, or psychotropic drugs in addition to the use of the eligibility card to obtain similar or duplicative controlled substances	Fast track adds new criteria, and clarifies criteria to indicate any single documented incidence is indicative of fraud and abuse.
12 VAC 30-130-		DMAS shall restrict	DMAS shall restrict individuals to their designated pharmacy, or both, for 24

810 (E)		recipients to their designated provider for 36 months	months in both ER and Fast Track
12 VAC 30-130-810 (F)		A designated transportation provider must be enrolled as a taxi; registered driver, or wheelchair van and be unrestricted b y DMAS. Recipients shall be assigned to the type of provider who meets the appropriate level of transportation that is medically necessary	Deleted outdated references to transportation because this service is now regulated by a contractor. Deleted at ER/NOIRA stage and deletion retained in FT.
12 VAC 30-130-810 (J)		DMAS shall extend utilization control restrictions for 36 months if any of the following conditions is identified: The recipient has not complied with Client Medical Management Program procedures resulting in services or medications received from one or more nondesignated providers without a written referral or in the absence of a medical emergency. The recipient has not complied with Client Medical Management Program procedures as demonstrated by a pattern of documented attempts to receive services or medications from one or more nondesignated providers without a written	12VAC 30-130-810 I. Emergency and Fast track actions changed <u>continued restriction</u> from 36 months to 12 months. Clarifications and modifications to regulations for continuing individuals in CMM. The individual has not complied with CMM procedures resulting in services or medications received from any nondesignated provider, as demonstrated by their submitted claims, without a written referral or in the absence of a medical emergency. The individual has not complied with CMM procedures as demonstrated by a pattern of documented attempts to receive medications from any nondesignated provider in the absence of a medical emergency when the designated pharmacy is closed, or when the designated pharmacy does not stock, or is unable to obtain the

		referral or in the absence of a medical emergency. One or more of the designated providers recommends continued restriction status because the recipient has demonstrated noncompliant behavior which is being controlled by Client Medical Management Program restrictions. Any changes of designated provider have been made due to the breakdown of the recipient/provider relationship as a result of the recipient's noncompliance.	medication in a timely manner. One or more of the designated providers recommends continued restriction status because the individual has demonstrated noncompliant behavior which is being controlled by CMM Program restrictions.
12 VAC 30-120-810 (D)			Fast Track provides for individuals to be further monitored or provided with education if utilization patterns do not fully meet restriction criteria.
12 VAC 30-120-810 (K)			Fast Track removes the qualifier 'adverse' upon the advice of the Office of the Attorney General because the underlying federal regulations (42 CFR 431.200 et. seq.) do not use this term.
12 VAC 30-120-820 (G)			Fast Track removes the qualifier 'adverse' upon the advice of the Office of the Attorney General because the underlying federal regulations (42 CFR 431.200 et. seq.) do not use this term.