



Final Regulation Agency Background Document

Agency name	Department of Medical Assistance Services
Virginia Administrative Code (VAC) citation	12 VAC 30, Chapter 120
Regulation title	Medallion II
Action title	Changes from BBA
Document preparation date	

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style, and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Brief summary

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

This proposed regulation reflects several changes to the Medallion II managed care system. This regulation revises and updates the Medallion II regulations to address several operational and waiver changes in the Medallion II program. Some of these changes are due to changes in federal law pursuant to the Balanced Budget Act (BBA), which DMAS has elected to incorporate. Other changes are being made to clarify existing regulations. Finally, certain of the amendments in this package are being made in order to conform these regulations to reflect changes in the Medicaid program that have an impact on managed care. Revisions are being made in the following sections of the Medallion II regulations: Definitions (12 VAC 30-120-360), Medallion II enrollees (12 VAC 30-120-370), Managed Care Organization (MCO) responsibilities (12 VAC 30-120-380), Quality Control and Utilization Review (12 VAC 30-120-400), Sanctions (12 VAC 30-120-410) and Grievances and Appeals (12 VAC 30-120-420).

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 Regulatory Review Summary with the attached amended State Regulations: Medallion II 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, of the Administrative Process Act.

Date

Patrick W. Finnerty, Director
Dept. of Medical Assistance Services

Legal basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly bill and chapter numbers, 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 Code of Virginia (1950) as amended, section 32.1-325, grants to the Board of Medical Assistance Services the authority to administer the Plan for Medical Assistance. The Code of Virginia (1950) as amended, section 32.1-324, authorizes the Director of the Department of Medical Assistance Services (DMAS) to administer and amend the Plan for Medical Assistance according to the Board’s requirements. The Medicaid authority was established by § 1902 (a) of the *Social Security Act* [42 U.S.C. 1396a], which provides the governing authority for DMAS to administer the State’s Medicaid program.

Purpose

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

This regulatory action is expected to have a positive impact on the health, safety and welfare of Virginia citizens. The changes set forth in this regulation enhance the ability of Medallion II enrollees to make health care choices, specifically with regard to enrollment and disenrollment. These changes also provide improved access to appeal and grievance procedures in cases where a recipient is aggrieved by an MCO or agency decision.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the “All changes made in this regulatory action” section.

The sections of the Virginia Administrative Code that are affected by this change are 12 VAC 30-120-360 through 30-120-420. Because Chapter 120 consists of Non-State Plan regulations, no sections of the State Plan for Medical Assistance are affected. The particular sections of Chapter 120 that are affected are as follows:

Definitions (12 VAC 30-120-360)

The definitions of “Health care plan” and “School based services” are both updated with newer language that reflects both the language of the BBA and more current usage in the health care industry. The definition of “Managed care organization” is amended to bring it in line with the BBA. DMAS has added a new definition, “Newborn enrollment period,” to clarify that children born to mothers enrolled in Medallion II are covered “from the child’s date of birth plus the next two calendar months.”

Medallion II enrollees (12 VAC 30-120-370)

Changes are being made to this section with regard to when an enrollee may be excluded from participation in the Medallion II program. These changes include clarifications of certain exclusions and the addition of new exclusions. In addition, the section covering disenrollment is amended to require DMAS to provide written responses to good cause requests for disenrollment by Medallion II clients.

Managed Care Organization (MCO) responsibilities (12 VAC 30-120-380)

Formerly, MCOs were not permitted to charge Medallion II clients co-payments. This regulatory change adds language permitting MCOs to impose cost-sharing obligations on Medallion II clients consistent with the co-payment schedules set forth in 12 VAC 30-20-150 and 12 VAC 30-20-160.

Grievances and Appeals (12 VAC 30-120-420)

Several procedural changes are being made in this section. Language is added requiring enrollees, their provider or their representative to follow up on an oral request for appeal with a written request for appeal within ten business days, unless it is for an expedited appeal. The requirement that MCOs provide DMAS copies of all requests for appeals and appeal decisions is being deleted. Finally, the timeframe of 14 days for MCOs to issue appeal decisions is being changed to 30 days to conform to other standard appeal timeframes in DMAS appeals regulations.

Issues

Please identify the issues associated with the proposed regulatory action, including:
 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
 2) the primary advantages and disadvantages to the agency or the Commonwealth; and
 3) other pertinent matters of interest to the regulated community, government officials, and the public.

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

No disadvantages to the public have been identified in connection with this regulation. The agency projects no negative issues involved in implementing this regulatory change.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

Section number	Requirement in proposed regulation	Proposed change in final regulation and rationale
12 VAC 30-120-360	Definitions section: “Enrollment broker” responsibilities include recipient enrollment. “MCO” definition refers to an executed agreement. Network definition refers to a mutually-agreed upon sum. Definition of “School health services” includes “school health assistant” services. No definition of “newborn enrollment period” in Definitions section	“Enrollment broker” responsibilities include recipient MCO enrollment “MCO” definition refers to an executed contractual agreement. Network definition refers to a mutually-agreed upon sum as determined by the MCO and provider . The reference to “school health assistant” was dropped from the final definition of “school health services,” since this service is not yet approved for Medallion II enrollees. Final regulation includes a definition for “newborn enrollment period” is the period that includes the month of the child’s birth plus the next two calendar months.
12VAC30-120-370(A)	“DMAS reserves the right to restrict from participation in Medallion II ...”	DMAS reserves the right to exclude from participation in Medallion II ...”
12VAC30-120-370(B)	List of persons excluded from Medallion II include “Individuals who receive services through the Commonwealth’s Title XXI SCHIP program.”	This language is changed to “Individuals who are enrolled in the Commonwealth’s Title XXI SCHIP program.”

12 VAC 30-120-370(D)(4)	Newborns whose mothers are enrolled with an MCO are considered an enrollee of the same MCO for at least three months from date of birth.	DMAS is replacing all references in 12 VAC 30-120-370 from “ <u>the birth month plus 2 months</u> ” to the “ newborn enrollment period ” to avoid any confusion over the length of time a newborn is considered enrolled in Medallion II. Reference to mothers enrolled with an MCO is changed to mothers enrolled with an MCO at the time of birth .
12 VAC 30-120-370(D)(4)	“Infants who do not receive a Medicaid identification number prior to By the end of that the third month, the child will be disenrolled unless the Enrollment Broker specifies continued enrollment. will be enrolled in managed care through the preassignment process upon receiving a Medicaid identification number.”	Clarifying language is being added to this provision as follows: “ <u>Infants who do not receive a Medicaid identification number prior to By the end of that the [third month newborn enrollment period] , the child will be disenrolled unless the Enrollment Broker specifies continued enrollment. [will be disenrolled. Newborns who remain eligible to participate in Medallion II] will be [re-]enrolled in [managed care an MCO] through the preassignment process upon receiving a Medicaid identification number.</u> ”
12 VAC 30-120-370(H)(2)	DMAS shall determine whether good cause exists for disenrollment.	DMAS removed the word good from this phrase to coincide with other regulatory changes in this package.
12 VAC 30-120-380(A)	“Services that shall be provided outside the MCO network, and reimbursed by DMAS shall include, but are not limited to, those services defined by the contract between DMAS and the MCO.” Reference in proposed regulation to school health services lists the services.	“Services that shall be provided outside the MCO network, and reimbursed by DMAS shall include, but are not limited to, those services <u>[identified and]</u> defined by the contract between DMAS and the MCO.” Final regulation replaces the listing of school health services from reference with a reference to 12 VAC 30-120-360.
12 VAC 30-120-410(A)	Sanctions: Civil monetary penalties listed as No. 1 in list of sanctions in section (A).	Civil monetary penalties is moved to No. 7 in section (A).
12 VAC 30-120-410(D)	Reference to protections State may provide.	The reference to protections the State may provide was changed to protections the Commonwealth may provide.
12 VAC 30-120-420(A)(1)	Two statements in this section of the proposed were changed from “must” to “shall.”	In the final regulation the two “shall” statements are changed back to “must.”

Public comment

Please summarize all comment received during the public comment period following the publication of the proposed stage, and provide the agency response. If no public comment was received, please so indicate.

DMAS' proposed regulations were published in the 6/28/2004, *Virginia Register* (VR 20:21) for their public comment period from 6/28/2004 through 8/27/2004. One comment was received.

Commenter	Comment	Agency response
<p>National Assoc. of Chain Drug Stores (NACDS)</p>	<p>NACDS expressed concern that lifting the prohibition on cost sharing as proposed in the Medallion II regulations would create added administrative and financial burdens on pharmacists, while failing to reduce pharmacy expenditures:</p> <p>Cost sharing can help to discourage overuse of drugs and encourage use of lower cost generic alternatives. However, because Medicaid co-payments are not required to be paid by a Medicaid beneficiary who states that he / she is unable to pay, co-payments are likely to have only minimal impact on drug utilization while increasing the administrative and financial burden on community pharmacies whose reimbursements are reduced by unpaid co-payments.</p> <hr/> <p>NACDS believes that pharmacists would lose money because they will be unable to collect most Medicaid co-pays, and that this could lead to reduced access to pharmacy services for Medallion II enrollees:</p> <p>If Medallion II managed care plans choose to require co-payments for prescribed drugs, pharmacy reimbursement will be reduced by the amount of the co-payment whether it is collected or not.</p>	<p>DMAS agrees with NACDS that co-payment collection is an added administrative and financial burden on pharmacists. However, DMAS proposes to lift the restriction on co-payments because the Balanced Budget Act of 1997 (BBA) (42CFR.438.108) lifted the restriction on co-payments for managed care organizations (MCOs) for categorically needy.</p> <p>The BBA further requires that, if MCOs implement co-payments, the MCOs must charge the same co-payments that are in place under the Medicaid fee-for-service system.</p> <p>DMAS is required by Federal regulations (42CFR.447.58) to calculate MCO capitation rates based upon the assumption that co-payments are being collected. DMAS therefore is allowing MCOs to impose cost sharing if they so choose.</p> <hr/> <p>The Department does not agree with NACDS that the potential additional burden of co-payments will result in a lack of access to services for Medallion II enrollees.</p> <p>DMAS does not believe that MCOs will begin imposing cost sharing measures for the following reasons:</p> <ol style="list-style-type: none"> 1. Co-payments would only be applicable to approximately 20% of their population (80% are children). 2. The administrative costs associated with implementing copayments outweigh the financial advantages. Change to member handbooks, identification cards, provider

	<p>Virginia’s pharmacists could be required to collect co-payments from many more Medicaid recipients under the proposed regulations than they are required to collect under existing regulations.</p> <p>While federal law does not permanently forgive Medicaid recipients from co-payment responsibility, it is virtually impossible to collect these moneys if they cannot be collected at the point of service. Pharmacies would have to take on the administrative cost and burden of billing the recipient for the unpaid co-payment, which could rapidly exceed the cost of the uncollected co-payment.</p> <p>To the extent that pharmacy is financially harmed by the uncollectability of these co-payments, continued beneficiary access to pharmacy services is threatened.</p> <hr/> <p>NACDS suggests that beneficiaries and health plans should be liable for uncollected co-payments, and requests that DMAS modify the final regulations to permit pharmacists to treat enrollees with unpaid co-payments like any other customer with unpaid bills (i.e. refuse service until debt is paid):</p> <p>Pharmacy providers have no way of knowing whether a Medicaid recipient is truly unable to pay a co-payment, so it should not be the role of the pharmacy provider to have to determine whether a beneficiary is unable to pay. Instead, the Department should require that contracting health plans make this determination and that they notify the pharmacy</p>	<p>notifications, Bureau of Insurance filings, etc., would need to be addressed.</p> <p>3. Where potential enrollees have a choice between more than one MCO or between an MCO and a Primary Care Case Management program, the absence of co-payments is a strong marketing tool for Medallion II MCOs.</p> <hr/> <p>NACDS proposes that pharmacists be permitted to, in effect, deny pharmacy services to Medallion II recipients that fail to fulfill their co-pay obligations. Federal law strictly prohibits this practice. 42 USC. 1396o(e) (Prohibition of denial of services on basis of individual's inability to pay certain charges), states:</p> <p>“The State plan shall require that no provider participating under the State plan may deny care or services to an individual eligible for such care or services under the plan on account of such individual's inability to pay a deduction, cost sharing, or similar charge.”</p> <p>This law prohibits providers from denying enrollees services due an inability to pay copayments.</p>
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	<p>provider through the point-of-sale system at the time that a prescription is submitted for payment whether that beneficiary is unable to pay the co-payment. In these cases, the recipient should not have to pay the copayment, and the copayment amount should not be deducted from the pharmacy's reimbursement.</p> <p>In the alternative, NACDS suggests that health plans reimburse pharmacists for unpaid co-payments:</p> <p>Further, many states stress to beneficiaries that they remain liable for unpaid co-payments. In fact, a number of state Medicaid provider manuals make clear that providers may bill enrollees for unpaid co-payments and may treat Medicaid recipients who have past-due co-payments as they would treat any other patient who has past-due debts. We ask that the proposed regulations and any notice to enrollees allow pharmacy providers to treat a Medicaid recipient who has past-due co-payments as they would treat any other patient who has past-due debts.</p> <p>We suggest that the following language, similar to that contained in the Nebraska Medicaid Provider Manual be included in communications to Medicaid recipients. That manual states at Rule 3-008.04:</p> <p>If it is the routine business practice of the provider to refuse service to any individual with uncollected debt, the provider may include uncollected co-payments under this practice.</p>	
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	Providers shall give sufficient notice to the client...	
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All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

Current section number	Current requirement	Proposed change and rationale
12VAC30-120-360	<p>Contains definitions for “Health care plan” that references “health maintenance organization (HMO).</p> <p>Contains a definition for “Managed care organization” incorporating the Managed Care Health Insurance Plan (MCHIP) model.</p>	<p>► Health care plan now references “managed care organization” because this term is used throughout the BBA in lieu of “HMO.” The substance of the definition is changed to conform to the requirements of the BBA (42 CFR part 438). The definition of “Managed care organization” now references the participation/solvency criteria of 42 CFR Part 438 and the MCHIP reference is dropped because the Virginia Dept. of Health does not require Medallion II MCO’s to meet the MCHIP definition.</p>
12VAC30-120-360	<p>Contains a definition for; “School based services.”</p>	<p>► “School based services” has been replaced in other state regulations with the term “School health services,” so this change is being made to harmonize the managed care regulations with state school health regulations; “school health assistant” removed.</p>
12VAC30-120-360	<p>Contains no definition of “Newborn enrollment period.”</p>	<p>Definition of “Newborn enrollment period” added to be used in place of former language, “birth month plus two months,” regarding extension of coverage to newborns whose mothers are in Medallion II.</p>
12VAC30-120-370(A)	<p>Medallion Enrollees [12VAC30-120-370(A)]</p>	<p>Adds a clause that DMAS may exclude non-compliant recipients from Medallion II</p>
12VAC30-120-370(B)	<p>List of persons excluded from participation in Medallion II [12 VAC 30-120-370.B (1-13)]:</p> <ul style="list-style-type: none"> ► Individuals enrolled in residential treatment or treatment foster care (TFC). ► Pregnant women (third trimester) newly enrolled in managed care if their obstetrical 	<p>Clarifications to list of persons excluded from participation in Medallion II are as follows:</p> <ul style="list-style-type: none"> ► Individuals <u>under age 21</u> enrolled in residential treatment or TFC. Language was added to clarify that the exclusion is for those under age 21. ► Pregnant women (third trimester) newly enrolled in managed care if their obstetrical

<p>12VAC30-120-370(B)</p>	<p>provider does not participate with any state MCOs. ► Individuals with Medicare.</p> <p>► Terminally ill individuals who have been preassigned but not yet enrolled, whose life expectancy is six months or less.</p> <p>List of persons excluded from participation in Medallion II (12 VAC 30-120-370.B):</p>	<p>provider does not participate with <u>the enrollee's assigned MCO.</u> ► Individuals with other comprehensive health insurance (including Medicare).</p> <p>► Terminally ill (< 6 mo.) individuals who request exclusion during preassignment or within a later timeframe designated by DMAS.</p> <p>List expanded to include the following, found in [(12 VAC 30-120-370.B (14-17))]:</p> <p>► Individuals with an eligibility period less than 3 months;</p> <p>► Individuals enrolled in the Commonwealth's Title XXI (SCHIP) program;</p> <p>► Individuals whose eligibility period is retroactive only;</p> <p>► Individuals who have been consistently non-compliant with policies and procedures of DMAS or their MCO(s).</p>
<p>12VAC30-120-370(D)</p>	<p>Newborn enrollment procedures (12 VAC 30-120-370.D.4)</p> <p>Newborn remains enrolled with mother's MCO for birth month plus two months or until discharged from inpatient care.</p> <p>Infants with no Medicaid I.D. number by end of third month will be enrolled in managed care through preassignment process.</p>	<p>Newborn enrollment procedures (12 VAC 30-120-370.D.4)</p> <p>► Clarifies that automatic enrollment doesn't disqualify newborn from disenrollment by choice. Final revision uses "newborn enrollment period" in place of "birth month plus two months."</p> <p>► Clarifies that newborn's enrollment is not contingent upon mother's continued enrollment.</p> <p>► Clarifies that such infants will be disenrolled and, if eligible for managed care, be re-enrolled through the established preassignment process.</p>
<p>12VAC30-120-370(H)(2)</p>	<p>Client disenrollment procedures (12 VAC 30-120-370.H.2)</p> <p>Procedures for requesting disenrollment for cause from the Medallion II program.</p>	<p>Client disenrollment procedures (12 VAC 30-120-370.H.2)</p> <p>Amended to clarify that a written response be provided to a good cause request in the timeframe set by DMAS and in compliance with 42 CFR § 438.56.</p>

12VAC30-120-380.I	MCO responsibilities (12VAC30-120-380.I): does not allow for cost-sharing measures.	Revised to conform to 42 CFR § 438.108, which allows MCOs to impose cost-sharing obligations on Medallion II enrollees.
12VAC30-120-420.C.1	Client grievances/appeals: allows for oral notice of grievance/request for appeal.	Change specifies that oral requests for appeal must be followed up in writing within 10 business days. This change is being made to conform the Medallion II regulations to 42 CFR § 438.402.b.3.ii, which allows DMAS discretion in setting the timeframe.
12VAC30-120-420.G/J	Specifies that MCOs submit to DMAS documentation of any written requests for appeal.	Deletes this requirement because MCOs already submit monthly appeal/grievance reports to DMAS.
12VAC30-120-420.H	Specifies a 14-day timeframe in which DMAS must issue standard appeal decisions.	Timeframe changed to 30 days to be consistent with other timeframes in appeals process.

Family impact

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

This regulation is projected to have a positive impact on recipients and their families. Items were amended to clarify interpretation and facilitate a better understanding for recipients, MCOs and providers with regard to several definitions, and to expand client choice by providing enhanced availability of exclusion exceptions found in 12 VAC 30-120-370. Changes were made to provide greater access to recipient grievance and appeal procedures, and to afford greater protection for recipient appeal rights. The changes to this regulation will not strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; encourage or discourage self-pride; the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; they will not strengthen or erode the marital commitment. Changes to allow the MCOs the option of imposing cost sharing obligations to Medallion II recipients may decrease disposable family income. The impact of this particular change is anticipated to be small and any amounts charged would be consistent with the state’s maximum copayment schedules found in 12 VAC 30-20-150 and –160.