

Office of Regulatory Management
Economic Review Form

Agency name	Department of Medical Assistance Services
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 30-50-20 and 12 VAC 30-50-60
VAC Chapter title(s)	Amount, Duration, and Scope of Medical and Remedial Care Services
Action title	Clinical Trials
Date this document prepared	September 30, 2022

Cost Benefit Analysis

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> Describe first proposed impactful change here. <p>DMAS must cover routine patient cost for items and services as defined in 1905(gg) of the Social Security Act that are furnished in connection with participation in a qualified clinical trial.</p> <p>Direct Costs: DMAS consulted with its rate-setting contractor, Mercer, a national organization with a strong reputation, which determined that there would be no quantifiable direct costs as a result of these changes. The services covered and the payment methodologies will remain the same as the underlying services. DMAS will pay for those items in the context of a clinical trial if any Medicaid members are enrolled in a clinical trial.</p> <p>Direct Benefits: DMAS is not aware of any quantifiable direct benefits at this time.</p>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) \$0	(c) \$0	
Direct Benefits	(b) \$0	(d) \$0	
(3) Benefits-Costs Ratio	Undefined (zero divided by zero)	(4) Net Benefit	\$0

(5) Indirect Costs & Benefits	DMAS is not aware of either any quantifiable indirect costs or indirect benefits.
(6) Information Sources	Section 210 of the Consolidated Appropriations Act of 2021, the Centers for Medicare & Medicaid Services (CMS) State Medicaid Director (SMD) letter #21-005 , DMAS' Budget Division and Office of the Chief Medical Officer.
(7) Optional	There are no direct or indirect costs or benefits resulting from these changes.

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct Costs & Benefits	The changes being made by this regulatory action are non-discretionary.		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) See response to (1) above	(c) See response to (1) above	
Direct Benefits	(b) See response to (1) above	(d) See response to (1) above	
(3) Benefits-Costs Ratio	See response to (1) above	(4) Net Benefit	See response to (1) above
(5) Indirect Costs & Benefits	See response to (1) above		
(6) Information Sources	See response to (1) above		
(7) Optional	See response to (1) above		

Table 1c: Costs and Benefits under an Alternative Approach

(1) Direct Costs & Benefits	The changes being made by this regulatory action are non-discretionary.		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	

Direct Costs	(a) See response to (1) above	(c) See response to (1) above	
Direct Benefits	(b) See response to (1) above	(d) See response to (1) above	
(3) Benefits-Costs Ratio	See response to (1) above	(4) Net Benefit	See response to (1) above
(5) Indirect Costs & Benefits	See response to (1) above		
(6) Information Sources	See response to (1) above		
(7) Optional	See response to (1) above		

Impact on Local Partners

- (1) Describe the direct costs and benefits (as defined on page 1) for local partners in terms of real monetary costs and FTEs. Local partners include local or tribal governments, school divisions, or other local or regional authorities, boards, or commissions. If local partners are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of total (overall) direct costs described above.
 - (b) Enter estimated dollar value of total (overall) direct benefits described above.
- (3) Indirect Costs & Benefits: Describe any indirect benefits and costs (as defined on page 1) for local partners that are associated with all significant changes. If there are no indirect costs or benefits, include a specific statement to that effect.
- (4) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why they are not.
- (5) Assistance: Identify the amount and source of assistance provided for compliance in both funding and training or other technical implementation assistance.
- (6) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits	Local partners will not incur any direct costs or benefits of the regulatory change as they do not operate services subject to the mandates contained in the regulatory action.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	DMAS is not aware of any quantifiable indirect costs. DMAS is not aware of any quantifiable indirect benefits.
(4) Information Sources	Section 210 of the Consolidated Appropriations Act of 2021, the Centers for Medicare & Medicaid Services (CMS) State Medicaid Director (SMD) letter #21-005 , DMAS' Budget Division and Office of the Chief Medical Officer.
(5) Assistance	N/A
(6) Optional	There are no direct or indirect costs or benefits resulting from these changes.

Economic Impacts on Families

- (1) Describe the direct costs and benefits (as defined on page 1) to a typical family of three (average family size in Virginia according to the U. S. Census) arising from any proposed regulatory changes that would affect the costs of food, energy, housing, transportation, healthcare, and education. If families are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of direct costs.
 - (b) Enter estimated dollar value of direct benefits.
- (3) Indirect Costs & Benefits: Describe any indirect costs and benefits (as defined on page 1) to a typical family of three that are most likely to result from the proposed changes.
- (4) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why not.
- (5) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 3: Impact on Families

(1) Direct Costs & Benefits	Families will not incur any direct costs or benefits of the regulatory change as they are not subject to the mandates contained in this regulatory action.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	DMAS is not aware of any quantifiable indirect costs. DMAS is not aware of any quantifiable indirect benefits.
(4) Information Sources	Section 210 of the Consolidated Appropriations Act of 2021, the Centers for Medicare & Medicaid Services (CMS) State Medicaid Director (SMD) letter #21-005 , DMAS’ Budget Division and Office of the Chief Medical Officer.
(5) Optional	There are no direct or indirect costs or benefits resulting from these changes.

Impacts on Small Businesses

- (1) Describe the direct costs and benefits (as defined on page 1) for small businesses. For purposes of this analysis, “small business” means the same as that term is defined in § 2.2-4007.1. If small businesses are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of direct costs.
 - (b) Enter estimated dollar value of direct benefits.
- (3) Indirect Costs & Benefits: Describe the indirect benefits and costs (as defined on page 1) for small businesses that are most likely to result from the proposed changes.
- (4) Alternatives: Add a qualitative discussion of any equally effective alternatives that would make the regulatory burden on small business more equitable compared to other affected business sectors, and how those alternatives were identified.
- (5) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why not.
- (6) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 4: Impact on Small Businesses

(1) Direct Costs & Benefits	<p>Direct Costs: DMAS is not aware of any quantifiable direct costs at this time.</p> <p>Direct Benefits: DMAS is not aware of any quantifiable direct benefits at this time.</p>
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	<p>DMAS is not aware of any quantifiable direct costs at this time.</p> <p>DMAS is not aware of any quantifiable direct benefits at this time.</p>
(4) Alternatives	Because the change being made by this regulatory action are non-discretionary, there are not alternatives for DMAS to consider. DMAS is required to comply with Section 210 of the Consolidated Appropriations Act of 2021 and the Centers for Medicare and Medicaid Services (CMS) State Medicaid Director (SMD) letter #21-005 .
(5) Information Sources	Section 210 of the Consolidated Appropriations Act of 2021, the Centers for Medicare & Medicaid Services (CMS) State Medicaid Director (SMD) letter #21-005 , DMAS' Budget Division and Office of the Chief Medical Officer.
(6) Optional	

Changes to Number of Regulatory Requirements

For each individual VAC Chapter amended, repealed, or promulgated by this regulatory action, list (a) the initial requirement count, (b) the count of requirements that this regulatory package is adding, (c) the count of requirements that this regulatory package is reducing, (d) the net change in the number of requirements. This count should be based upon the text as written when this stage was presented for executive branch review. Five rows have been provided, add or delete rows as needed.

Table 5: Total Number of Requirements

	Number of Requirements
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Chapter number	Initial Count	Additions	Subtractions	Net Change
50	1,532	0	0	1,532