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Exempt Action: Final Regulation
Agency Background Document

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
Final agency action date	April 28, 2022
Date this document prepared	April 28, 2022

Although a regulatory action may be exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the *Code of Virginia*, the agency is still encouraged to provide information to the public on the Regulatory Town Hall using this form. However, the agency may still be required to comply with the Virginia Register Act, Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

This regulatory action provides coverage for routine patient costs furnished in connection with a member's participation in a qualifying clinical trial in accordance 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. Per the SMD letter, DMAS will cover any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the state plan or waiver, including a demonstration project under section 1115

of the Social Security Act. Such routine services and costs also include any item or service required to administer the investigational item or service.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, internal staff review, petition for rulemaking, periodic review, or board decision). "Mandate" is defined as "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The Code of Virginia § 32.1 325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance and to promulgate regulations. The Code of Virginia § 32.1-324, grants the Director of the Department of Medical Assistance Services the authority of the Board when it is not in session.

Section 210 of the Consolidated Appropriations Act of 2021 amended section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit at section 1905(a)(30). Section 210 mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials effective January 1, 2022.

As a result, this regulatory package includes the following new text in 12 VAC 30-50-20 and 12 VAC 30-50-60: "Coverage of 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 qualifying clinical trial."

Statement of Final Agency Action

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.

DMAS has submitted Final Exempt changes to 12 VAC 30-50-20, "Services Provided to the Categorically Needy Without Limitations" and 12 VAC 30-50-60, "Services Provided to all Medically Needy Groups without Limitations" in order to meet the Consolidated Appropriations Act of 2021 mandate.