

May 18, 2022

PUBLIC NOTICE

Public Notice of Final Action for Mandatory Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials

The South Carolina Department of Health and Human Services (SCDHHS) gives notice of the following actions regarding coverage of routine patient costs associated with participation in qualifying clinical trials under the State Plan under Title XIX of the Social Security Act Medical Assistance Program (Medicaid).

Effective on or after Jan. 1, 2022, SCDHHS will amend the South Carolina Title XIX State Plan to extend coverage of routine patient costs associated with participation in qualifying clinical trials, as outlined in Center for Medicaid and CHIP Services SMD #21-005 [RE:UPDATED: Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials](#), dated April 13, 2022. SMD #21-005 was provided subsequent to the passage of Division CC, Title II, Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) (section 210) amended section 1905(a) of the Social Security Act (the Act), by adding to the definition of medical assistance a new benefit at section 1905(a)(30) for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials, subject to further provisions in a new section 1905(gg). Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the State Plan and any benchmark or benchmark equivalent coverage also referred to as alternative benefit plans, or ABPs with respect to items and services furnished on or after Jan. 1, 2022.

Pursuant to section 1905(a)(30) and 1905(gg)(1) of the Act, the routine patient costs that must be covered for a beneficiary participating in a qualifying clinical trial are 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 Act. Such routine services and costs also include any item or service required solely for the provision of the investigational item or service that is the subject of the qualifying clinical trial, including the administration of the investigational item or service.

Based on the actions above, SCDHHS anticipates a budget impact of approximately \$500,000 - \$2,000,000 per year in total dollars.

Copies of this notice are available at each South Carolina Healthy Connections Medicaid county office and at www.scdhhs.gov for public review. Additional information regarding these actions is available upon request at the address cited below.

Any written comments submitted may be reviewed by the public at the SCDHHS, Bureau of Policy, 1801 Main Street, Columbia, South Carolina, Monday through Friday between the hours of 9 a.m. and 5 p.m.

Robert M. Kerr
Director

Notice of Non-Discrimination

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SCDHHS provides free aids and services to people with disabilities, such as qualified sign language interpreters and written information in other formats (large print, braille, audio, accessible electronic formats, other formats). We provide free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, please contact the Americans with Disabilities Act (ADA)/Civil Rights Official by mail at: PO Box 8206, Columbia, SC 29202-8206, by phone at: 1-888-549-0820 (TTY: 1-888-842-3620), or by email at: civilrights@scdhhs.gov.

If you believe SCDHHS has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with the Civil Rights Official using the contact information provided above. You can file a grievance in person, by mail, or via email. If you need help filing a grievance, we are available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf> or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue, SW, Room 509F, HHH Building, Washington, D.C. 20201 or by phone at: 800-368- 1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html> .