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PUBLIC NOTICE

Public Notice of Final Action to Enter into Value Based Agreements and Direct Manufacturer Supplemental Rebate Agreements

The South Carolina Department of Health and Human Services (SCDHHS) gives notice of the following actions regarding the ability to enter into value-based agreements (VBAs) and direct manufacturer supplemental rebate agreements under the State Plan under Title XIX of the Social Security Act Medical Assistance Program (Medicaid).

On July 1, 2022, Centers for Medicare and Medicaid Services (CMS) ruled that Medicaid agencies can engage in VBAs with approval from CMS. VBAs may link outcome-based measurements of a drug's actual performance in a patient to the cost of the drug.

With high-cost therapies and accelerated pathways for medications on the rise, VBAs and direct manufacturer supplemental rebate agreements will increase access to high-cost therapies, save state funds and improve patient outcomes. The newly approved U.S. Food and Drug Administration gene therapies are expensive and require complicated pre and post treatment regimens that traditional rebate programs were not designed to accommodate. It is anticipated that more than 15 new gene therapies will be released in 2024, which makes the ability to enter into VBAs and direct manufacturer supplemental rebate agreements even more important.

Effective on or after Jan. 1, 2024, SCDHHS will update the State Plan to allow the state to enter into VBAs and direct manufacturer supplemental rebate agreements to decrease the overall cost of therapies to the state.

Based on the action above, SCDHHS anticipates a positive impact on the fee-for-service medical benefit budget. The degree of the impact will depend on the VBAs and direct manufacturer supplemental rebate agreements that the state will decide to enter into.

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

Any written comments submitted may be reviewed by the public at SCDHHS, Office of Medical Directors and Pharmacy Services, 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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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 <u>https://ocrportal.hhs.gov/ocr/portal/lobby.jsf</u> 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 <u>http://www.hhs.gov/ocr/office/file/index.html</u>.