PUBLIC NOTICE

Pursuant to 42 C.F.R. § 447.205, the Georgia Department of Community Health is required to give public notice of any significant proposed change in its methods and standards for setting payment rates for services.

Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials

Pending Centers for Medicare and Medicaid Services' (CMS) approval and effective for services provided on or after January 1, 2022 the Department proposes to modify its State Plan to allow for coverage of routine patient costs associated with participation in qualifying clinical trials.

This change is estimated to increase Medicaid expenditures for SFY 2022 as follows:

Program	State Funds	Federal Funds	Total Funds
Aged, Blind, and Disabled	$1,040,534	$2,422,140	$3,462,674
Low Income Medicaid	$3,580	$8,335	$11,915
Total	**$1,044,114**	**$2,430,475**	**$3,474,589**

This change is estimated to increase Medicaid expenditures for SFY 2023 as follows:

Program	State Funds	Federal Funds	Total Funds
Aged, Blind, and Disabled	$2,412,359	$4,731,138	$7,143,497
Low Income Medicaid	$8,301	$16,280	$24,581
Total	**$2,420,660**	**$4,747,418**	**$7,168,078**

Federal regulations define a "qualifying clinical trial" as a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition. Additionally, a qualifying clinical trial must also be one or more of the following:

- A study or investigation that is approved, conducted, or supported (including by funding through in-kind contributions) by one or more of the following:
    - The National Institutes of Health (NIH)
    - The Centers for Disease Control and Prevention (CDC)
    - The Agency for Health Care Research and Quality (AHRQ)
    - The Centers for Medicare & Medicaid Services (CMS)
    - A cooperative group or center of any of the entities described above or the Department of Defense or the Department of Veterans Affairs
    - A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants
- A clinical trial, approved or funded by any of the following entities, that has been reviewed and approved through a system of peer review that the Secretary determines comparable to

the system of peer review of studies and investigations used by the NIH, and that assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review:

o The Department of Energy
o The Department of Veterans Affairs
o The Department of Defense

- A clinical trial that is one conducted pursuant to an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or an exemption for a biological product undergoing investigation under section 351(a)(3) of the Public Health Service Act; or

- A clinical trial that is a drug trial exempt from being required to have one of the exemptions in the prior bullet.

Coverage Requirements

Routine patient costs associated with a qualifying clinical trial that must be covered include 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 clinical trial, *to the extent that the provision of such items or services 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 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. For example, physician services or laboratory or medical imaging services that assist with the prevention, diagnosis, monitoring or treatment of complications arising from clinical trial participation.

Coverage must be based on an attestation regarding the appropriateness of the qualifying clinical trial by the health care provider and principal investigator.

Items and Services Not Covered

Routine patient costs do not include any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project. Additionally, routine patient costs do not include any item or service that is provided to the member solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the member and is not otherwise covered under the state plan, waiver, or demonstration project.

For example, if a member has a condition that typically requires monitoring through an annual medical imaging scan and the member is participating in a clinical trial with a protocol that requires monthly medical imaging scans only to collect data on the effects of the investigational item or service, the additional monthly scans for purposes of clinical trial data collection would not be included in the member's routine patient costs to the extent they are not used for the direct clinical management of the member or are not otherwise covered under the state plan, waiver, or demonstration project.

This public notice is available for review at each county Division of Family and Children Services office. An opportunity for public comment will be held on **December 20, 2021 at 10:30 a.m., via Zoom audio**. There will be **no in-person** attendance at the Department of Community Health (DCH).

Individuals who are disabled and need assistance to participate during this meeting should call (404) 656-4479 at least three (3) business days prior to the scheduled public hearing to ensure any necessary accommodations can be provided.

To join the online event:

Meeting ID: 864 9037 0252
Passcode: Open

Copy the following link to a browser:

https://us02web.zoom.us/j/86490370252?pwd=NFNZWjhGTFpjcmYwaUhtMHA4cUVoZz09

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833 548 0276 US Toll-free
833 548 0282 US Toll-free
877 853 5247 US Toll-free
888 788 0099 US Toll-free
Meeting ID: 864 9037 0252

Individuals wishing to comment in writing on any of the proposed changes should do so on or before **December 27, 2021** to the Board of Community Health, Post Office Box 1966, Atlanta, Georgia 30301-1966. You may also email comments to Danisha Williams, danwilliams@dch.ga.gov or fax to 404-651-6880.

Comments submitted will be available for review by submitting a request via email to Danisha Williams, danwilliams@dch.ga.gov. Comments from written and public testimony will be provided to the Board of Community Health prior to the **January 13, 2022 Board** meeting. The Board will vote on the proposed changes at the Board meeting to be held at 10:30 a.m. at the Department of Community Health.

NOTICE IS HEREBY GIVEN THIS 14th DAY OF DECEMBER 2021
Caylee Noggle, Commissioner