

Board of Community Health  
Meeting  
December 14, 2021

**Members Present**

Norman Boyd  
Roger Folsom  
Russell Crutchfield  
David Crews  
Russ Childers  
Anthony Williamson  
Kenneth Davis  
Nelva Lee  
Cynthia Rucker

**Members Absent**

The Board of Community Health held its Special call meeting via Zoom teleconference. (An agenda and a List of Attendees are attached hereto and made an official part of these Minutes as Attachments #1 and #2). Chairman Norman Boyd presided and called the meeting to order at 11:00 a.m.

**Minutes**

None to approve.

**Opening Comments**

None to report.

**Commissioner's Report**

Commissioner Noggle thanked the Board, members of the public and staff for their participation via Zoom.

The following updates were provided to the Board:

- Centers for Medicare and Medicaid Services (CMS) issued guidance that coverage for clinical trials will become a requirement of state plans effective January 1, 2022.

Recognition to Lynnette Rhodes and the finance team for their hard work and efforts collecting the financial projections in preparation for this public notice.

Lynnette Rhodes, Executive Director, Medical Assistance Plans presented to the Board for initial adoption the Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials Public Notice.

Effective January 1, 2022, pending Centers for Medicare and Medicaid Services (CMS) approval, DCH proposes to cover any item or service provided to a Medicaid member who is participating in a qualifying clinical trial beginning January 1, 2022.

This request was based upon a December 7, 2021, directive from CMS in which they mandated coverage of items and services associated with a qualifying 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.

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:
  - The Department of Energy
  - The Department of Veterans Affairs
  - 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.

There are certain items and services that should not be covered by state Medicaid agencies. This includes 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.

States may not deny coverage based upon the location of the qualifying clinical trial, even if performed out of state. Further, states may not deny coverage on the basis that the treating provider or principal investigator is out of network.

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

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

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

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

An opportunity for public comment will be held on December 20, 2021 at 10:30 a.m. via WebEx. Written comments are due on or before December 27, 2021.

Ms. Rhodes respectfully asked for the Board's favorable consideration of initial adoption.

Russell Crutchfield MADE a MOTION to approve for initial adoption Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials Public Notice. Russ Childers SECONDED the MOTION. ON THE MOTION, the yeas were 9, nays 0, abstained 0, and the MOTION was APPROVED

(A copy of the Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials Public Notice is attached hereto and made an official part of these minutes as Attachment #3).

**New Business/Closing Comments**

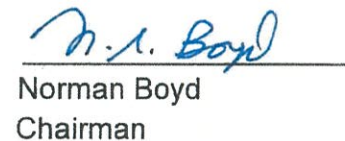
None to report.

**Adjournment**

There being no further business to be brought before the Board, Chairman Norman Boyd adjourned the meeting at 11:09 a.m.

THESE MINUTES ARE HEREBY APPROVED AND ADOPTED THIS THE 14<sup>th</sup> DAY OF December, 2021.

  
Russell Crutchfield  
Secretary

  
Norman Boyd  
Chairman

Official Attachments:

- #1 Agenda
- #2 List of Attendees
- #3 Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials Public Notice