US Policy & Government Affairs

Improving Access to Clinical Trials: The Role of State Medicaid Departments

November 19, 2022

Megan Lydon

Bristol Myers Squibb™

Clinical trial diversity is a pressing issue for health equity and regulatory decision-making

Lack of Participant Diversity in Clinical Trials

Clinical trials are rarely representative of true patient populations or U.S. demographics.

- Racially and ethnically diverse communities remain severely underrepresented in clinical trials as both participants and investigators.[1]
- Exclusion criteria and other common clinical trial practices often exclude people with intellectual, developmental, or physical disabilities.[2]
- In the next 20 years, the United States and patient population are expected to become more diverse, highlighting the growing need to make trial populations more diverse now. [3]

Guidance from Regulatory Agencies

Diversity in clinical trials has been an imperative of the FDA and global regulatory agencies for the last two decades.

- Increased diversity in clinical trials can enhance the safety and efficacy findings related to a particular therapy. [4]
- The Food and Drug Administration (FDA) and international regulatory bodies have issued guidance documents related to diversity in trials, highlighting it as an important factor in testing new medical products.

Champions for Action

Stakeholders have advocated for the removal of barriers for patients and increased access to life-saving therapies

- Patients, providers, survivors of disease, researchers and other have advocated to increased access to clinical trials by removing barriers, like financial obstacles.
- Groups like the American Society of Clinical Oncologists, the American Cancer Society Cancer Action Network, and the National Minority Quality Forum supported this issue for years before the passage of the Clinical Treatment Act.

In an important step forward, Congress passed the Bipartisan Clinical Treatment Act (CTA) in 2020

The CTA requires state Medicaid programs to cover routine patient costs for items and services that are provided in connection with a qualifying clinical trial regarding cancer or other life-threatening conditions.

Prior to its effective date of January 1, 2022, Medicaid was the only major payer not required to provide coverage of routine costs associated with enrollment in clinical trials

- Medicare has provided access to this benefit since 2000.
- The Affordable Care Act (2010) guaranteed coverage for many patients with commercial insurance.

Medicaid insures approximately 27% of the US population

- Prior to CTA passage, only 16 states and D.C. had laws in place to cover routine costs.
- Millions of Medicaid patients across the country still lacked access to this benefit.

The CTA aims to address a portion of the very real affordability barriers for lower-income patients who want to participate in clinical trials.

State Medicaid departments are responsible for implementation of the Clinical Treatment Act (CTA)

The benefits afforded by the CTA are implemented in Medicaid programs through State Plan Amendments (SPAs)

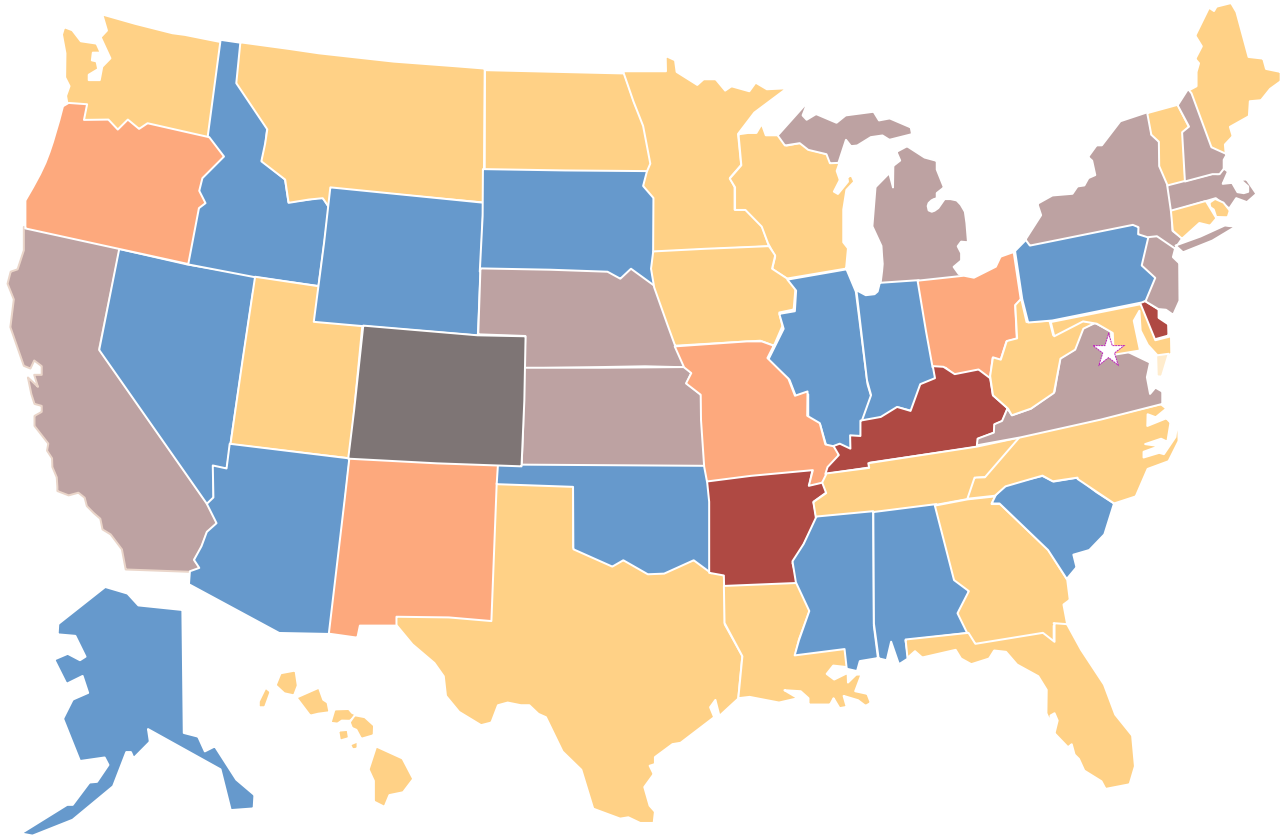
SPAs allow a state to make changes to its Medicaid program and remain in compliance with federal statute to claim matching funds

SPAs used to implement the Clinical Treatment Act identify specific groups in the Medicaid population:

Population Group	Definition
Categorically Needy	Individuals who qualify for cash assistance.
Medically Needy	Those whose income or assets are too high to qualify as categorically needy, but medical needs or costs qualify them for assistance.
Alternative Benefit Plan	State option to provide alternative benefits tailored for certain groups, areas of the state, or delivery systems instead of following the traditional Medicaid benefit plan

As of November 18th, 2022, there is a patchwork of State Plan Amendment (SPA) implementation

Legend	
3	No approved SPA; no state mandates prior to Dec 2020
1	No approved SPA; state mandates prior to dec 2020
14	Approved SPA for categorically needy only
19	Approved SPA for categorically needy and medically needy
4	Approved SPA for categorically needy and alternative benefit plan
9	Approved SPA for categorically needy, medically needy, and alternative benefit plan



SPA implementation is a positive step forward, yet other barriers remain

When surveyed after the passage of the Clinical Treatment Act, Medicaid stakeholders did not perceive Medicaid enrollment as an obstacle to participating in a clinical trial. However, barriers remain:

Practical Obstacles

- Research is often conducted at large, academic, medical centers that can be difficult to navigate.
- Cost of Transportation and Lodging
- Cost of missing work, childcare coverage, and other caregiving responsibilities.
- Variable understanding on what the patient will need to participate and how it will impact the patient's daily life.

Medical and Research Institutions

- Low trust in pharma and medical research.
- Gaps in Health Literacy that impact patient understanding of clinical trials and their results.
- Lack of diverse investigators and research personnel.
- Clinical Trial sites are just getting back up and running after COVID-19 and may not have staff that are familiar with processing Medicaid claims.

Public and Provider Awareness

- Low physician awareness of Clinical Treatment Act passage.
  - Physicians play a vital role in referring patients to trials and assuring there is a clinical benefit to participation.
- Low public awareness of the clinical treatment act and the additional benefits that it provides to Medicaid enrollees.
  - Patients with cancer and life-threatening conditions may benefit from participating in a trial as early as possible.

Despite progress, changes to Medicaid eligibility could restrict access to healthcare and impact trial diversity

Unwinding of the COVID-19 Public Health Emergency (PHE)

- During the pandemic, Medicaid enrollment increased from **71.3M to 90M total enrollees**
- Once the PHE expires, those that fail to meet redetermination requirements and have not aged into Medicare or qualified for some other form of insurance will lose health coverage, including coverage of routine clinical trial costs
  - **5.3M-14.2M will lose coverage**, with an unknown amount able to find new insurance
- Underrepresented populations may continue to face disproportionate barriers to access clinical trials, mitigating potential advances in diverse clinical trial participation

Streamlining Eligibility and Enrollment Proposed Rule [CMS 2421-P]

Brief Summary:

This rule would make it easier for millions of eligible people to enroll in and retain Medicaid coverage by reducing red tape and simplifying applications, verifications, enrollment, and renewals for health care coverage through Medicaid and the Children's Health Insurance Program (CHIP)

Impact on Clinical Trials:

- The average clinical trial lasts for a few months to a couple years. This rule could make it easier to retain coverage and reduce financial uncertainty for trial participants covered by Medicaid

Pull-through of the clinical treatment act is still needed to ensure full access for patients

State Health Plan "confused" by a federal law that was supposed to cover life-or-death cancer treatment

The Clinical Treatment Act went into effect on January 1st, 2022, but patients were still denied coverage for approximately eight months

References

1. Kwiatkowski K, Coe K, Bailar JC, Swanson GM. Inclusion of minorities and women in cancer clinical trials, a decade later: Have we improved? *Cancer.* 2013;119(16):2956-2963.
2. Improving Public Health Requires Inclusion of Underrepresented Populations in Research | Pediatrics | JAMA | JAMA Network
3. Chow CJ, Habermann EB, Abraham A, Zhu Y, Vickers SM, Rothenberger DA, Al-Refaie WB. Does enrollment in cancer trials improve survival? J Am Coll Surg. 2013 Apr;216(4):774-80; discussion 780-1. doi: 10.1016/j.jamcollsurg.2012.12.036. Epub 2013 Feb 13. PMID: 23415510; PMCID: PMC4096556.
4. Clark LT, Watkins L, Piña IL, Elmer M, Akinboboye O, Gorham M, Jamerson B, McCullough C, Pierre C, Polis AB, Puckrein G, Regnante JM. Increasing Diversity in Clinical Trials: Overcoming Critical Barriers. Curr Probl Cardiol. 2019 May;44(5):148-172. doi: 10.1016/j.cpcardiol.2018.11.002. Epub 2018 Nov 9. Erratum in: Curr Probl Cardiol. 2021 Mar;46(3):100647. PMID: 30545650.