

## Medicaid Coverage for Clinical Trials in Minnesota HF3026/SF3125

**Patients enrolled in Medicaid with blood cancers and disorders often lack guaranteed coverage for participation in clinical trials.** Clinical trials may provide a patient with a life-saving therapy or cure for their disease. For most patients enrolled in clinical trials, their insurance covers the standard or routine cost of care for treatment of the illness, with the clinical trial sponsor paying for the costs associated with the experimental drug or treatment. Eighteen-percent or 983,800 Minnesotans are covered by state-funded Medicaid.<sup>1</sup> Patients who use Medicaid as their primary insurer also make up a significant portion of those who receive a transplant at National Marrow Donor Program. Without guaranteed coverage, Medicaid patients could lose the opportunity to try treatments provided through clinical trials, which may be an opportunity for life.

### History

In 2000, Medicare issued a national coverage decision on clinical trials, authorizing payment for routine patient care costs for enrollees in clinical trials. A brief from the Centers for Medicare and Medicaid (CMS) states that routine costs for clinical trials are covered by Medicaid to the extent that they are covered in the state plan –leaving the responsibility for coverage with each individual state.<sup>2</sup> To enforce this national decision, Minnesota enacted a law in 2001 stating that a health plan must inform patients who inquire that their participation in a clinical trial will be covered by the plan, or as federally mandated for Medicare ([MN §62D.109](#)).

In 2010, the Patient Protection and Affordable Care Act (ACA) mandated that health plans cannot keep patients from joining a clinical trial, cannot limit or deny coverage of routine costs to patients who join an approved clinical trial and cannot increase costs because a patient joins a clinical trial.<sup>3</sup> Minnesota followed suit and enacted state-level legislation in 2013 which also stated that health plans could not keep a patient from joining a clinical trial, limit or deny coverage for routine costs, or discriminate against a patient with cancer or a life-threatening condition because they are participating in a clinical trial ([MN §62Q.526](#)). Unfortunately, both the ACA and MN §62Q.526 excluded Medicaid plans from their laws.

### Current Status

Without guaranteed coverage for routine costs of care, Medicaid patients may be unable to enroll in clinical trials. This leaves nearly 1 million Minnesotans with Medical Assistance plans without the guaranteed option for a potentially curative treatment through a clinical trial. The American Society of Clinical Oncology (ASCO) cites that 13 states and the District of Columbia require coverage for routine costs of clinical trial participation through their Medicaid programs.<sup>4</sup> These states include Alaska, California, Florida, Hawaii, Indiana, Iowa, Maryland, Montana, New Mexico, North Carolina, Texas, Vermont and West Virginia. Coverage policies differ greatly by state. Routine costs include those such as costs of

physician visits and lab tests. In order to be an FDA-approved clinical trial, the effectiveness of a drug, device, or treatment must meet legal and scientific standards for effectiveness set by the FDA. Additionally, the FDA must deem the quantity of evidence as appropriate. Actual costs of drugs or devices associated with the clinical trial are almost always covered by the trial sponsor.

## Recommendations and Impact

Minnesota Medical Assistance plans should be required to cover routine care costs of the illness for a patient who enrolls in a clinical trial. This will ensure that Medicaid patients have access to one of the nearly 2,000<sup>5</sup> clinical trials open in Minnesota. HF3026/SF3125 which would accomplish this aim and allow access to clinical trials for those with life-threatening or severely debilitating diseases. This bill would require coverage for the same routine costs, or standard of care costs, that a patient would be receiving if they were not enrolled in a clinical trial. The anticipated fiscal note for this bill is \$0, since the same routine costs would be covered by Medical Assistance if a patient were not enrolled in a clinical trial and instead, receiving standard of care treatment. Ten other states plus the District of Columbia that have enacted laws requiring state Medicaid plans to cover clinical trial enrollment have also reported a fiscal note of \$0 or those with a negligible anticipated impact.<sup>6</sup>

<sup>1</sup> [Kaiser Family Foundation \(2018\). Health Insurance Coverage of the Total Population, Minnesota.](#)

<sup>2</sup> [Centers for Medicare & Medicaid Services \(2007\). Decision Memo for Clinical Trial Policy.](#)

<sup>3</sup> [Centers for Medicare & Medicaid Services \(2010\). Fact Sheets & Frequently Asked Questions: Affordable Care Act Implementation FAQs.](#)

<sup>4</sup> [American Society of Clinical Oncology \(2018\). Guarantee Coverage of Clinical Trials Participation for Medicaid Patients.](#)

<sup>5</sup> [U.S. National Library of Medicine \(2020\). Clinical Trials.gov, recruiting studies, Minnesota, United States.](#)

<sup>6</sup> Detailed fiscal impact information available upon request.