

House Bill 521

By: Representatives Hilton of the 48<sup>th</sup>, Cooper of the 45<sup>th</sup>, Hawkins of the 27<sup>th</sup>, Douglas of the 78<sup>th</sup>, and Newton of the 127<sup>th</sup>

A BILL TO BE ENTITLED  
AN ACT

1 To amend Article 7 of Chapter 4 of Title 49 of the Official Code of Georgia Annotated,  
2 relating to medical assistance generally, so as to provide for Medicaid coverage of rapid  
3 whole genome sequencing; to define a term; to provide for eligibility criteria; to provide for  
4 coverage criteria; to provide for necessary approvals and administrative actions; to provide  
5 for related matters; to repeal conflicting laws; and for other purposes.

6 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

7 **SECTION 1.**

8 Article 7 of Chapter 4 of Title 49 of the Official Code of Georgia Annotated, relating to  
9 medical assistance generally, is amended by adding a new Code section to read as follows:

10 "49-4-159.2.

11 (a) As used in this Code section, the term 'rapid whole genome sequencing' means an  
12 investigation of the entire human genome, including coding and non-coding regions and  
13 mitochondrial deoxyribonucleic acid, to identify disease-causing genetic changes that  
14 returns the preliminary positive results within five days and final results within 14 days.  
15 Such term includes patient-only whole genome sequencing and duo and trio whole genome  
16 sequencing of the patient and the biological parent or parents.

17 (b) Subject to any required approval by the federal Centers for Medicare and Medicaid  
18 Services, the department shall include coverage of rapid whole genome sequencing as a  
19 separately payable service for Medicaid recipients when the recipient:

20 (1) Is 21 years of age or younger;

21 (2) Has a complex or acute illness of unknown etiology that is not confirmed to be  
22 caused by environmental exposure, toxic ingestion, infection with normal response to  
23 therapy, or trauma; and

24 (3) Is receiving inpatient hospital services in an intensive care unit or high acuity  
25 pediatric care unit.

26 (c) The coverage provided pursuant to this Code section may be subject to applicable  
27 evidence based medical necessity criteria based on the following:

28 (1) The patient has symptoms that suggest a broad differential diagnosis that would  
29 require an evaluation by multiple genetic tests if rapid whole genome sequencing is not  
30 performed;

31 (2) The patient's treating healthcare provider has determined that timely identification  
32 of a molecular diagnosis is necessary to guide clinical decision-making and testing results  
33 may provide additional guidance as to the treatment or management of the patient's  
34 condition; and

35 (3) The patient is experiencing complex or acute illness of unknown etiology that  
36 includes at least one of the following conditions:

37 (A) Congenital anomalies involving at least two organ systems or complex or multiple  
38 congenital anomalies in one organ system;

39 (B) Specific organ malformations highly suggestive of a genetic etiology;

40 (C) Abnormal laboratory tests or abnormal chemistry profiles suggesting the presence  
41 of a genetic disease, complex metabolic disorder, or inborn error of metabolism like,  
42 but not limited to, an abnormal newborn screen, hyperammonemia, or severe lactic  
43 acidosis not due to poor perfusion;

- 44 (D) Refractory or severe hypoglycemia or hyperglycemia;  
45 (E) Abnormal response to therapy related to an underlying medical condition affecting  
46 vital organs or bodily systems;  
47 (F) Severe muscle weakness (hypotonia), rigidity, or spasticity (hypertonia);  
48 (G) Refractory seizures;  
49 (H) A high-risk stratification on evaluation for a brief resolved unexplained event with  
50 any of the following, or lack of coordination (ataxia):  
51 (i) A recurrent event without respiratory infection;  
52 (ii) A recurrent event witnessed seizure-like event; or  
53 (iii) A recurrent cardiopulmonary resuscitation;  
54 (I) Abnormal cardiac diagnostic testing results suggestive of possible channelopathies,  
55 arrhythmias, cardiomyopathies, myocarditis, or structural heart disease;  
56 (J) Abnormal diagnostic imaging studies, such as magnetic resonance imaging,  
57 computed tomography (CT) scanning, or ultrasound services, suggestive of underlying  
58 genetic condition, such as storage disorders or brain white matter disease;  
59 (K) Abnormal physiologic function studies suggestive of an underlying genetic  
60 etiology, such as bleeding disorders or immune deficiency disorders; or  
61 (L) Family genetic history related to the patient's condition.  
62 (d) The department shall take any actions necessary to implement the provisions of this  
63 Code section, which may include, but shall not be limited to:  
64 (1) Promulgation of rules and regulations to provide for Medicaid coverage pursuant to  
65 this Code section;  
66 (2) Submission to the federal Centers for Medicare and Medicaid Services of any new  
67 waiver application, amendment to an existing waiver, or Medicaid state plan amendment  
68 necessary to ensure federal financial participation for Medicaid coverage pursuant to this  
69 Code section; and

