By Senator Yarborough

	4-00579B-23 2023616
1	A bill to be entitled
2	An act relating to Medicaid coverage of rapid whole
3	genome sequencing; creating s. 409.9063, F.S.;
4	defining the term "rapid whole genome sequencing";
5	requiring the Agency for Health Care Administration,
6	subject to federal approval, to include coverage of
7	rapid whole genome sequencing as a separately payable
8	service for certain Medicaid recipients; requiring
9	that genetic data generated as a result of the rapid
10	whole genome sequencing be used only for specified
11	purposes; providing for the use of such data in
12	scientific research if the patient or his or her legal
13	guardian provides express consent for that use;
14	providing for the rescission of such consent;
15	requiring the entities conducting the scientific
16	research, upon receipt of a written revocation of
17	consent, to cease use of the patient's data and
18	expunge it from any data repositories where it is
19	held; requiring the agency to seek federal approval to
20	amend current waivers, request a new waiver, and amend
21	contracts as necessary for a specified purpose;
22	requiring the agency to adopt rules; providing an
23	effective date.
24	
25	WHEREAS, rapid whole genome sequencing is a powerful
26	diagnostic tool for individuals with rare genetic conditions in
27	which the specific genetic etiology is unclear, and
28	WHEREAS, rapid whole genome sequencing for critically ill
29	children with an undiagnosed condition who are receiving
1	

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30	treatment in an intensive care unit demonstrates significant
31	clinical utility, is cost-effective, and yields life-changing
32	outcomes when ordered as a first-line test, and
33	WHEREAS, studies have shown that with rapid whole genome
34	sequencing, providers have been able to identify the exact cause
35	of rare genetic diseases in a matter of days, instead of the
36	standard 4 to 6 weeks that other genetic testing currently
37	offers, and this allows providers to deliver timely treatment
38	tailored to the child's specific condition, and
39	WHEREAS, access to the results of rapid whole genome
40	sequencing empowers parents to join providers in making the most
41	informed care decisions, thereby avoiding other costly tests and
42	invasive procedures, which is shown to result in fewer days
43	spent in the hospital, and
44	WHEREAS, if ordered by the provider, rapid whole genome
45	sequencing should be covered by all plans in this state when
46	clinical criteria are met, NOW, THEREFORE,
47	
48	Be It Enacted by the Legislature of the State of Florida:
49	
50	Section 1. Section 409.9063, Florida Statutes, is created
51	to read:
52	409.9063 Rapid whole genome sequencing services for
53	Medicaid recipients
54	(1) As used in this section, the term "rapid whole genome
55	sequencing" means an investigation of the entire human genome,
56	including coding and noncoding regions and mitochondrial
57	deoxyribonucleic acid, to identify disease-causing genetic
58	changes which yields preliminary results within 5 days and the

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 final results within 14 days. The term includes patient-only whole genome sequencing and duo and trio whole genome sequencing of the patient and biological parent or parents. (2) Subject to any required approval of the Centers for Medicare and Medicaid Services, the agency shall include coverage of rapid whole genome sequencing as a separately payable service for a Medicaid recipient who: (a) Is 21 years of age or younger; (b) Has a complex or acute illness of unknown etiology which is confirmed not to have been caused by an environmental exposure, a toxic ingestion, an infection with normal response to therapy, or trauma; and (c) Is receiving inpatient hospital services in an intensive care unit or a high-acuity pediatric care unit. (3) (a) Except as specified in paragraph (b), genetic data generated as a result of performing rapid whole genome sequencing covered by this section must be used only to assist the ordering health care professional and treating care team in diagnosing and treating the patient. As protected health information, this patient genetic data is subject to the privacy provisions of the federal Health Insurance Portability and Accountability Act of 1996 and its implementing regulations. (b) Genetic data generated from rapid whole genome sequencing covered under this section may be used in scientific research if the patient, or the patient's legal guardian if the patient is a minor, has given express consent for that use of the data. A patient or patient's legal guardian, as applicable, has the right to rescind the original consent to the use of the data in scientific research at any time, and upon receipt of a 		4-00579B-23 2023616
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88	written revocation of the consent, the health care provider or
89	other entity using the data must cease its use of the data and
90	expunge the data from any data repository where it is held.
91	(4) The agency shall seek approval to amend current
92	waivers, request a new waiver, and amend contracts as necessary
93	to provide for coverage of services under this section.
94	(5) The agency shall adopt rules to implement this section.
95	Section 2. This act shall take effect July 1, 2023.

SB 616