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(Original Signature of Member)

118TH CONGRESS
2D SESSION

H. R. _____

To establish a Medicaid out-of-state provider demonstration project for administration of certain covered outpatient drugs and certain drugs administered as part of inpatient hospital services.

IN THE HOUSE OF REPRESENTATIVES

Mr. PFLUGER introduced the following bill; which was referred to the Committee on _____

A BILL

To establish a Medicaid out-of-state provider demonstration project for administration of certain covered outpatient drugs and certain drugs administered as part of inpatient hospital services.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Rare Disease Access
5 to Cross-State Specialist Services Act” or the “Rare Ac-
6 cess Act”.

1 **SEC. 2. STREAMLINED ENROLLMENT OF AN OUT-OF-STATE**
2 **PROVIDER.**

3 (a) IN GENERAL.—Section 1902 of the Social Secu-
4 rity Act (42 U.S.C. 1396a) is amended by adding at the
5 end the following:

6 “(tt) OUT-OF-STATE PROVIDER ENROLLMENT.—In
7 the case of an individual receiving medical assistance
8 under this title who, due to the nature of their symptoms
9 or diagnosis, requires an out-of-state provider to furnish
10 in-person or telehealth services, a State plan shall imme-
11 diately recognize such out-of-state provider as a partici-
12 pating provider described in subsection (kk)(7)(A) if,
13 through a web-based portal developed by the Secretary (as
14 described in section 2(b) of the Rare Access Act), such
15 out-of-state provider attests to possessing expertise in the
16 disease or condition with which such individual is diag-
17 nosed or seeking a diagnosis and that such services are
18 medically necessary.”.

19 (b) WEB-BASED PORTAL.—Not later than 1 year
20 after the date of the enactment of this Act, the Secretary
21 of Health and Human Services shall, in consultation with
22 the Office of the National Coordinator for Health Infor-
23 mation Technology, establish a national web-based portal
24 that will allow for the secure electronic transmission of
25 a health care provider—

1 (1) request for recognition as a participating
2 Medicaid provider in the State from which the indi-
3 vidual seeking medical services, including drug ad-
4 ministration and telehealth, is receiving medical as-
5 sistance under title XIX of the Social Security Act;

6 (2) submission of the diagnosis code provided in
7 the relevant fiscal year update of the “International
8 Classification of Diseases, 10th Revision, Clinical
9 Modification” (or a successor publication) for such
10 individual, or, in the case of a disease or condition
11 for which a diagnosis code is not included in such
12 publication, a description of symptoms that supports
13 its diagnosis; and

14 (3) attestation of—

15 (A) expertise in the disease or condition
16 for which such individual is diagnosed or seek-
17 ing diagnosis; and

18 (B) the medical necessity of the services
19 rendered.

20 (c) EFFECTIVE DATE.—The amendment made by
21 this section shall apply to medical services provided on or
22 after the date that is 30 days after the date of the estab-
23 lishment of the web-based portal described in subsection
24 (b).

1 **SEC. 3. MEDICAID DEMONSTRATION PROJECT PROMOTING**
2 **ACCESS FOR PATIENTS WITH RARE DIS-**
3 **ORDERS.**

4 (a) IN GENERAL.—The Secretary of Health and
5 Human Services (in this section referred to as the “Sec-
6 retary”) shall establish a 5-year project (in this section
7 referred to as the “demonstration project”) to promote
8 cross-state access to disease-specific medical experts, in-
9 cluding multi-disciplinary care teams at centers of excel-
10 lence, for patients diagnosed with a rare disorder and re-
11 ceiving medical assistance under title XIX of the Social
12 Security Act. Such demonstration project shall evaluate
13 the impact on Federal and State expenditures and on ac-
14 cess, outcomes, and burden of illness for such patients
15 stemming from—

16 (1) a comprehensive uniform Medicaid benefit
17 for telehealth services; and

18 (2) payment to States of a quarterly separate
19 furnishing fee to offset excess payments to out-of-
20 state providers for certain items and services, includ-
21 ing telehealth and drug administration, furnished in
22 the Medicaid program under title XIX of the Social
23 Security Act.

24 (b) DURATION AND SCOPE.—The demonstration
25 project conducted under this section shall operate during
26 a period of fiscal years 2025 through 2029 and be limited

1 to medical assistance (as defined in section 1905(a) of the
2 Social Security Act (42 U.S.C. 1396d(a))) by partici-
3 pating States in accordance with subsection (c)(4).

4 (c) STATE PARTICIPATION.—

5 (1) IN GENERAL.—The Secretary shall in-
6 clude—

7 (A) subject to paragraph (2), a minimum
8 of fifteen States to participate in this dem-
9 onstration project; and

10 (B) any other States electing to participate
11 pursuant to paragraph (3).

12 (2) PRIORITY STATES.—Of the participating
13 States described in paragraph (1), the Secretary
14 shall select—

15 (A) at least two States in which at least 65
16 percent of the counties in the State are counties
17 that have 6 or less residents per square mile, as
18 determined by the Secretary; and

19 (B) at least eight States that have the
20 highest concentration, as determined by the
21 Secretary, of medical facilities for the treatment
22 of rare disorders, including metabolic clinics,
23 hemophilia treatment centers, and centers of
24 excellence expressly recognized by disease spe-

1 cific patient advocacy and research organiza-
2 tions.

3 (3) STATE OPT-IN.—States that are not se-
4 lected by the Secretary may elect to participate in
5 the project by providing written notice to the Sec-
6 retary on or before September 30, 2025.

7 (4) CONDITIONS.—As a condition of participa-
8 tion in the demonstration project, a State described
9 in paragraph (1) shall—

10 (A) through its Board of Medicine, De-
11 partment of Health, or other body that regu-
12 lates licensure of medical professionals, provide
13 licensure reciprocity for fully licensed eligible
14 telehealth providers in accordance with sub-
15 subsection (e)(3)(B) furnishing eligible telehealth
16 services to eligible individuals receiving medical
17 assistance under title XIX of the Social Secu-
18 rity Act from the State in which they reside;
19 and

20 (B) provide payment in accordance with
21 subsection (d)(1) for—

22 (i) eligible telehealth services (as de-
23 fined in subsection (e)(4) (and an origi-
24 nating site facility fee except when such
25 site is the home of the eligible individual)

1 furnished by an eligible telehealth provider
2 (as defined in subsection (e)(3)) to, or in
3 the case of a peer-to peer consult for the
4 benefit of, an eligible individual (as defined
5 in subsection (e)(2)) receiving medical as-
6 sistance under this title and who accesses
7 such telehealth services from any location;

8 (ii) acquisition and administration
9 costs for an eligible drug (as defined in
10 subsection (e)(1)) administered to an eligi-
11 ble individual (as defined in subsection
12 (e)(2)) by an out-of-state provider enrolled
13 as a participating provider (as defined in
14 section 1902(kk)(7)(A) of the Social Secu-
15 rity Act (42 U.S.C. 1396a(kk)(7)(A))) in
16 the State of the beneficiary; and

17 (iii) an eligible recommended service
18 (defined in subsection (e)(5)) furnished to
19 an eligible individual (as defined in sub-
20 section (e)(2)) by an out-of-State provider
21 enrolled as a participating provider (as de-
22 scribed in section 1902(kk)(7)(A) of the
23 Social Security Act (42 U.S.C.
24 1396a(kk)(7)(A))) in the State where the
25 individual is located..

1 (d) PAYMENT.—

2 (1) IN GENERAL.—Payment for eligible tele-
3 health services, including payment to both providers
4 in a peer-to-peer consult, the acquisition and admin-
5 istration of an eligible drug, and an eligible rec-
6 ommended service shall be no less than the payment
7 rate for such services or such acquisition and admin-
8 istration under the State plan for the State where
9 the participating provider is located during the quar-
10 ter in which such provider furnishes such services or
11 administers such drug.

12 (2) QUARTERLY FURNISHING FEES.—Subject
13 to paragraphs (3) and (4), the Secretary shall pro-
14 vide for a separate furnishing fee payment on a
15 quarterly basis to a State whose quarterly expendi-
16 tures for eligible telehealth services, eligible drug ac-
17 quisition and administration, and eligible rec-
18 ommended services under this demonstration project
19 exceeds the amount that otherwise would be payable
20 for the service or acquisition and administration to
21 a participating provider under the State plan if such
22 State were not participating in the demonstration
23 project.

24 (3) PROHIBITION ON COVERAGE RESTRIC-
25 TIONS.—To be eligible for the furnishing fee de-

1 scribed in paragraph (2), the State shall not require
2 as a condition of payment for the acquisition and
3 administration of an eligible drug, a prerequisite
4 drug, test (other than a test to confirm the diag-
5 nosis), or service (such as emergency room interven-
6 tion), or place any other restrictions relating to the
7 use or prescribing of such eligible drug, unless such
8 requirements or limitations are specified in the “In-
9 dication and Usage” section of its label.

10 (4) STABILIZATION OF PAYMENT RATE.—

11 (A) IN GENERAL.—For the calculation of
12 the quarterly furnishing fee described in para-
13 graph (2), following selection or election as a
14 participating State, such State (as described in
15 subsection (c)) receiving such fee shall not
16 lower its payment rates for the acquisition and
17 administration of covered outpatient drugs or
18 for the furnishing of telehealth services or eligi-
19 ble recommended services.

20 (B) STABILIZATION.—If such State has
21 lowered such rates during the 12-month period
22 prior to selection or election, the rates on which
23 such fee is based shall not be lower than the
24 Medicaid national three-year payment average
25 for such items and services.

1 (e) DEFINITIONS.—

2 (1) ELIGIBLE DRUG.—The term “eligible drug”
3 means a physician administered drug—

4 (A) that is a covered outpatient drug (as
5 defined in section 1927(k)(2) of the Social Se-
6 curity Act (42 U.S.C. 1396r-8(k)(2)) or admin-
7 istered as part of inpatient hospital services (if
8 separately paid); and

9 (B) that is prescribed for a medically ac-
10 cepted indication (as defined in section
11 1927(k)(6) of such Act (42 U.S.C. 1396r-
12 8(k)(2)) in a rare disease or condition (as de-
13 fined in section 526(a)(2)(A) of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C.
15 360bb(a)(2)(A)); and

16 (C) that is more readily available for ad-
17 ministration in a State other than the State of
18 the individual receiving medical assistance
19 under title XIX due to—

20 (i) its complexity;

21 (ii) the fact that there are limited
22 sites of service for such drug because of
23 the rarity or complexity of the disease or
24 condition for which it is prescribed;

1 (iii) the fact that the distance from
2 the primary residence of the eligible indi-
3 vidual to the site of service administering
4 such drug within such State exceeds the
5 distance to travel from the primary resi-
6 dence of such individual for the adminis-
7 tration of such drug in a neighboring
8 State; or

9 (iv) the fact that the site of service
10 administering such drug within such State
11 is not recognized as having expertise in the
12 condition by the patient advocacy and re-
13 search organization representing the dis-
14 ease or condition for which the drug has a
15 medically accepted indication, but the out-
16 of-state site of service has such recogni-
17 tion.

18 (2) ELIGIBLE INDIVIDUAL.—The term “eligible
19 individual” means an individual who is—

20 (A) a “child with medically complex condi-
21 tions” (as defined in section 1945A(i)(1) of the
22 Social Security Act (42 U.S.C. 1396w-4a(i)(1));

23 (B) a “qualified severely impaired indi-
24 vidual” (as defined in section 1905(q) of such
25 Act (42 U.S.C. 1396d(q))); or

1 (C) diagnosed with a rare metabolic dis-
2 order, bleeding disorder, blood disorder, or
3 nervous system disorder.

4 (3) ELIGIBLE TELEHEALTH PROVIDER.—

5 (A) IN GENERAL.—Subject to subpara-
6 graph (B), the term “eligible telehealth pro-
7 vider” means an individual who is a partici-
8 pating provider (as defined in section
9 1902(kk)(7)(A) of the Social Security Act (42
10 U.S.C. 1396a(kk)(7)(A))) who furnishes tele-
11 health services and is a—

- 12 (i) physician;
13 (ii) psychologist;
14 (iii) neuropsychologist;
15 (iv) genetic counselor;
16 (v) social worker;
17 (vi) nurse practitioner;
18 (vii) case manager;
19 (viii) dietitian;
20 (ix) behavioral therapist;
21 (x) speech therapist;
22 (xi) audiologist;
23 (xii) physical therapist;
24 (xiii) occupational therapist; or

1 (xiv) any other providers determined
2 by the Secretary.

3 (B) LICENSURE AND PROFESSIONAL CON-
4 DUCT.—An “eligible telehealth provider” de-
5 scribed in subparagraph (A) shall have a full,
6 unrestricted license in the jurisdiction in which
7 such provider primarily practices medicine and
8 no history of—

9 (i) alcohol and substance abuse;

10 (ii) prescribing controlled substances
11 in excess or without legitimate reason;

12 (iii) felony convictions; or

13 (iv) failing to meet continuing medical
14 education requirements.

15 (4) ELIGIBLE TELEHEALTH SERVICES.—The
16 term “eligible telehealth services” means health care
17 services that an eligible telehealth provider furnishes
18 from a distant site via interactive audio and video
19 technologies that provide real time communication to
20 facilitate—

21 (A) diagnosis, treatment, or care manage-
22 ment for an eligible individual;

23 (B) peer-to-peer consults, including those
24 that an originating site provider initiates with

1 an asynchronous store and forward trans-
2 mission to a distant site provider;

3 (C) patient education, including, in the
4 case of a covered outpatient drug subject to an
5 approved risk evaluation and mitigation strat-
6 egy pursuant to section 505(p) of the Federal
7 Food, Drug and Cosmetic Act (21 U.S.C.
8 355(p)), education by an eligible telehealth pro-
9 vider who is certified in such strategy for such
10 drug regarding the benefit and risk of its use;
11 or

12 (D) patient monitoring, including any
13 monitoring that follows the administration of a
14 rare disease gene therapy.

15 (5) ELIGIBLE RECOMMENDED SERVICE.—

16 (A) IN GENERAL.—Subject to subpara-
17 graph (B), the term “eligible recommended
18 service” means a health care service that a pro-
19 vider furnishes in accordance with the most re-
20 cently published peer-reviewed treatment guide-
21 lines for the management and care coordination
22 of the rare disease or condition with which the
23 eligible individual is diagnosed.

24 (B) LIMITATION.—The “eligible rec-
25 ommended service” described in subparagraph

1 (A) shall occur on the same day and at the
2 same site of service as the drug administration
3 described in paragraph (4)(B)(ii).

4 (f) REPORT.—Within 180 days of the conclusion of
5 the demonstration project, the Secretary shall submit to
6 Congress a report—

7 (1) analyzing the financial impact of the quar-
8 terly furnishing fee on the Federal budget;

9 (2) evaluating the impact of the demonstration
10 project on patient outcomes derived from—

11 (A) timely Medicaid beneficiary access to
12 physician-administered drugs, including gene
13 therapy;

14 (B) post-administration monitoring of gene
15 therapy recipients via telehealth;

16 (C) timely Medicaid beneficiary access to
17 multi-disciplinary care teams in person or via
18 telehealth for proper case management and care
19 coordination; and

20 (D) leveraging telehealth for multi-discipli-
21 nary care team long-term follow-up, including
22 support for the transition from pediatric to
23 adult care, of eligible individuals who are diag-
24 nosed with metabolic disorders;

25 (3) providing statistics on—

1 (A) the types of medical specialists partici-
2 pating in the demonstration project;

3 (B) the qualification of eligible individuals
4 participating in the demonstration project;

5 (C) eligible drugs administered in the dem-
6 onstration project, including diagnosis codes as-
7 sociated with such therapies;

8 (D) eligible telehealth services provided in
9 the demonstration project, including the diag-
10 nosis codes associated with such services;

11 (E) eligible recommended services provided
12 in the demonstration project, including diag-
13 nosis codes associated with such services; and

14 (F) the amount of State and Federal reim-
15 bursement for eligible telehealth services, the
16 acquisition and administration of eligible drugs,
17 and eligible recommended services; and

18 (4) recommending whether Congress should—

19 (A) require State plans that provide med-
20 ical assistance for telehealth services under title
21 XIX of the Social Security Act comply with
22 comprehensive uniform benefit design require-
23 ments; and

1 (B) continue payment of the quarterly fur-
2 nishing fee provided under the demonstration
3 project indefinitely.