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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

To amend title XXVII of the Public Health Service Act and title XIX of the Social Security Act to require coverage of Alzheimer’s biomarker testing under group health plans, group and individual health insurance coverage, and the Medicaid program.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To amend title XXVII of the Public Health Service Act and title XIX of the Social Security Act to require coverage of Alzheimer’s biomarker testing under group health plans, group and individual health insurance coverage, and the Medicaid program.

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 “Alzheimer’s Early De-
5 tection Act of 2026”.

1 **SEC. 2. REQUIRING COVERAGE OF ALZHEIMER'S BIO-**
2 **MARKER TESTING UNDER GROUP HEALTH**
3 **PLANS, GROUP AND INDIVIDUAL HEALTH IN-**
4 **SURANCE COVERAGE, AND THE MEDICAID**
5 **PROGRAM.**

6 (a) PRIVATE INSURANCE.—

7 (1) IN GENERAL.—Part A of title XXVII of the
8 Public Health Service Act (42 U.S.C. 300gg–11 et
9 seq.) is amended by adding at the end the following
10 new section:

11 **“SEC. 2730. REQUIRED COVERAGE OF ALZHEIMER'S BIO-**
12 **MARKER TESTING.**

13 “(a) IN GENERAL.—A group health plan and a health
14 insurance issuer offering group or individual health insur-
15 ance coverage shall provide benefits under such plan or
16 coverage for Alzheimer's biomarker testing.

17 “(b) MANNER OF COVERAGE.—A group health plan
18 and a health insurance issuer offering group or individual
19 health insurance coverage shall ensure that, with respect
20 to testing for which benefits are required to be provided
21 under such plan or coverage under subsection (a)—

22 “(1) the financial requirements applicable to
23 such testing are no more restrictive than the pre-
24 dominant financial requirements applied to substan-
25 tially all medical and surgical benefits covered by the
26 plan or coverage and there are no separate cost-

1 sharing requirements that are applicable only with
2 respect to such testing;

3 “(2) the treatment limitations applicable to
4 such testing are no more restrictive than the pre-
5 dominant treatment limitations applied to substan-
6 tially all medical and surgical benefits covered by the
7 plan or coverage and there are no separate treat-
8 ment limitations that are applicable only with re-
9 spect to such testing;

10 “(3) in the case such plan or coverage imposes
11 any prior authorization requirement with respect to
12 such testing, the plan or coverage makes a deter-
13 mination with respect to a request for such author-
14 ization not later than 72 hours (or 24 hours, in the
15 case the provider submitting such request attests
16 that delay of such testing beyond 24 hours would
17 place an individual’s life or health at serious risk)
18 after receiving such request;

19 “(4) in the case such plan or coverage fails to
20 make a determination with respect to a prior author-
21 ization request for such testing in accordance with
22 paragraph (3), the plan or coverage treats such re-
23 quest as having been approved;

1 “(5) the plan or coverage does not apply any
2 step therapy requirement prior to providing benefits
3 for such testing; and

4 “(6) such benefits are provided in a manner
5 that promotes equitable access, including for rural
6 and underserved populations, and supports the use
7 of minimally invasive testing where clinically appro-
8 priate.

9 “(c) ALZHEIMER’S BIOMARKER TESTING DE-
10 FINED.—

11 “(1) IN GENERAL.—For purposes of this sec-
12 tion, the term ‘Alzheimer’s biomarker testing’ means
13 the analysis of an individual’s tissue, blood, or other
14 biospecimen for the presence of a biomarker, includ-
15 ing single-analyte tests, multiplex panel tests, pro-
16 tein expression, and whole genome, whole exome,
17 and whole transcriptome sequencing, furnished for a
18 purpose specified in paragraph (2)—

19 “(A) in accordance with any Food and
20 Drug Administration labeling indication;

21 “(B) to determine eligibility for, or to
22 manage treatment of Alzheimer’s disease with,
23 a drug approved by the Food and Drug Admin-
24 istration;

1 “(C) in accordance with any national cov-
2 erage determination under title XVIII of the
3 Social Security Act; or

4 “(D) in accordance with applicable clinical
5 practice guidelines or consensus statements re-
6 lating to the diagnosis of, treatment selection
7 for, management of, or monitoring of Alz-
8 heimer’s disease.

9 “(2) PURPOSES SPECIFIED.—For purposes of
10 paragraph (1), the purposes specified in this para-
11 graph are the early detection, risk stratification, di-
12 agnosis, treatment, appropriate management, or on-
13 going monitoring of Alzheimer’s disease.

14 “(3) ADDITIONAL DEFINITIONS.—For purposes
15 of paragraph (1):

16 “(A) BIOMARKER.—The term ‘biomarker’
17 means a characteristic that is objectively meas-
18 ured and evaluated as an indicator of normal
19 biological processes, pathogenic processes, or
20 pharmacologic responses to a specific thera-
21 peutic intervention, including gene-drug inter-
22 actions.

23 “(B) CONSENSUS STATEMENT.—The term
24 ‘consensus statement’ means statements devel-
25 oped by an independent, multidisciplinary panel

1 of experts that uses a transparent methodology
2 and reporting structure and include a conflict-
3 of-interest policy.

4 “(C) CLINICAL PRACTICE GUIDELINE.—
5 The term ‘clinical practice guideline’ means an
6 evidence-based guideline developed by an inde-
7 pendent organization or medical professional so-
8 ciety that uses a transparent methodology and
9 reporting structure and includes a conflict-of-in-
10 terest policy.”.

11 (2) EFFECTIVE DATE.—The amendment made
12 by this subsection shall apply with respect to plan
13 years beginning on or after the date that is 1 year
14 after the date of the enactment of this Act.

15 (b) MEDICAID.—

16 (1) INCLUSION AS MEDICAL ASSISTANCE.—Sec-
17 tion 1905(a) of the Social Security Act (42 U.S.C.
18 1396d(a)) is amended—

19 (A) in paragraph (31), by striking “and”
20 at the end;

21 (B) by redesignating paragraph (32) as
22 paragraph (33); and

23 (C) by inserting after paragraph (31) the
24 following new paragraph:

1 “(32) biomarker testing (as defined in section
2 2730(c) of the Public Health Service Act); and”.

3 (2) MANDATORY COVERAGE.—Section
4 1902(a)(10)(A) of the Social Security Act (42
5 U.S.C. 1395a(a)(10)(A)) is amended, in the matter
6 preceding clause (i), by striking “and (30)” and in-
7 serting “(30), and (32)”.

8 (3) MANNER OF COVERAGE.—Section 1902(a)
9 of the Social Security Act (42 U.S.C. 1396a(a)) is
10 amended—

11 (A) in paragraph (89), by striking “and”
12 at the end;

13 (B) in paragraph (90), by striking the pe-
14 riod at the end and inserting “; and”; and

15 (C) by inserting after paragraph (90) the
16 following new paragraph:

17 “(91) provide, in the case of biomarker testing
18 (as defined in subsection (c) of section 2730 of the
19 Public Health Service Act), for coverage of such
20 testing in the same manner as such testing is re-
21 quired to be covered by a group health plan or
22 health insurance issuer offering group or individual
23 health insurance coverage under subsection (b) of
24 such section.”.

1 (4) EFFECTIVE DATE.—The amendments made
2 by this subsection shall apply with respect to cal-
3 endar quarters beginning on or after the date that
4 is 1 year after the date of the enactment of this Act.

5 (c) REPORT.—Not later than 1 year after the date
6 of the enactment of this Act, and on an annual basis for
7 the 2 succeeding years, the Director of the National Insti-
8 tutes of Health shall, through contract with the National
9 Academies of Sciences, Engineering, and Medicine, con-
10 duct a study and submit to Congress a report on the value
11 of biomarker testing in detecting and treating Alzheimer’s
12 disease.