

118TH CONGRESS
2D SESSION

H. R. 8816

To amend title XVIII of the Social Security Act to provide for a cognitive impairment detection benefit under the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 25, 2024

Mr. BUCHANAN introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to provide for a cognitive impairment detection benefit under the Medicare program, and for other purposes.

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 “American Medical In-
5 novation and Investment Act of 2024”.

1 **SEC. 2. COGNITIVE IMPAIRMENT DETECTION BENEFIT IN**
2 **THE MEDICARE ANNUAL WELLNESS VISIT**
3 **AND INITIAL PREVENTIVE PHYSICAL EXAM-**
4 **INATION.**

5 (a) ANNUAL WELLNESS VISIT.—

6 (1) IN GENERAL.—Section 1861(hhh)(2) of the
7 Social Security Act (42 U.S.C. 1395x(hhh)(2)) is
8 amended by striking subparagraph (D) and inserting
9 the following:

10 “(D) Detection of any cognitive impair-
11 ment that shall—

12 “(i) be performed using one of the
13 cognitive impairment detection tools identi-
14 fied by the National Institute on Aging as
15 meeting its criteria for selecting instru-
16 ments to detect cognitive impairment in
17 the primary care setting; and

18 “(ii) include documentation of the tool
19 used for detecting cognitive impairment
20 and results of the assessment in the pa-
21 tient’s medical record.”.

22 (2) EFFECTIVE DATE.—The amendment made
23 by paragraph (1) shall apply to annual wellness vis-
24 its furnished on or after January 1, 2025.

25 (b) INITIAL PREVENTIVE PHYSICAL EXAMINA-
26 TION.—

1 (1) IN GENERAL.—Section 1861(ww)(1) of the
2 Social Security Act (42 U.S.C. 1395x(ww)(1)) is
3 amended by striking “agreement with the individual,
4 and” and inserting “agreement with the individual,
5 detection of any cognitive impairment as described
6 in subsection (hhh)(2)(D), and”.

7 (2) EFFECTIVE DATE.—The amendment made
8 by paragraph (1) shall apply to initial preventive
9 physical examinations furnished on or after January
10 1, 2025.

11 **SEC. 3. IMPROVING THE NATIONAL AND LOCAL COVERAGE**
12 **DETERMINATION PROCESSES UNDER THE**
13 **MEDICARE PROGRAM.**

14 (a) IN GENERAL.—Section 1862(l) of the Social Se-
15 curity Act (42 U.S.C. 1395y(l)) is amended by adding at
16 the end the following new paragraph:

17 “(7) LIMITATION ON DURATION OF COVERAGE
18 WITH EVIDENCE DEVELOPMENT DETERMINA-
19 TIONS.—

20 “(A) IN GENERAL.—Subject to subpara-
21 graph (B), in the case of a final decision under
22 paragraph (3)(C)(i) (including any such deci-
23 sion made on a class-wide basis) made on or
24 after the date of the enactment of this para-
25 graph that results in coverage of an item or

1 service pursuant to subsection (a)(1)(E), the
2 Secretary shall, not later than 10 years after
3 the date on which such coverage becomes effec-
4 tive pursuant to such subsection, initiate a re-
5 determination with respect to such item or serv-
6 ice.

7 “(B) EXCEPTION.—The Secretary may
8 delay a redetermination described in subpara-
9 graph (A) with respect to an item or service for
10 a period of time determined appropriate by the
11 Secretary if—

12 “(i) the Secretary finds that such
13 item or service is reasonable and necessary
14 to carry out the purposes described in sec-
15 tion 1142; or

16 “(ii) the entity responsible for such
17 item or service requests such extension.

18 “(C) POSTING OF INFORMATION.—Not
19 later than 1 year after the date of the enact-
20 ment of this paragraph, and annually there-
21 after, the Secretary post on the public website
22 of the Centers for Medicare & Medicaid Serv-
23 ices the following information:

1 “(i) The number of items and services
2 covered under this title pursuant to sub-
3 section (a)(1)(E).

4 “(ii) A description of each such item
5 or service.

6 “(iii) The year in which coverage of
7 each such item or service became effective
8 pursuant to such subsection.”.

9 (b) PROVISION OF EXPLANATION IN CASE OF CER-
10 TAIN REJECTED REQUESTS.—Section 1862(l) of the So-
11 cial Security Act (42 U.S.C. 1395y(l)), as amended by
12 subsection (a), is further amended by adding at the end
13 the following new paragraph:

14 “(8) REQUIREMENT TO PROVIDE EXPLANATION
15 IN CASE OF CERTAIN REJECTED REQUESTS.—With
16 respect to each document received by the Secretary
17 on or after the date that is 1 year after the date of
18 the enactment of this paragraph that identifies itself
19 as a complete, formal request for a national coverage
20 determination (as described in the notice entitled
21 ‘Medicare Program; Revised Process for Making Na-
22 tional Coverage Determinations’ (78 Fed. Reg.
23 48164) or a successor regulation), the Secretary
24 shall, not later than 90 days after receipt of such
25 document—

1 “(A) determine whether such document is
2 a complete, formal request for a national cov-
3 erage determination; and

4 “(B) in the case that the Secretary finds
5 that such document is not a complete, formal
6 request for a national coverage determination,
7 transmit to the entity submitting such docu-
8 ment information on such finding that includes
9 a specification of additional information needed
10 to make such document a complete, formal re-
11 quest for a national coverage determination.”.

12 (c) IMPROVING ACCESS TO ITEMS AND SERVICES
13 UNDER LOCAL COVERAGE DETERMINATIONS.—Section
14 1862(l)(5) of the Social Security Act (42 U.S.C.
15 1395y(l)(5)) is amended by adding at the end the fol-
16 lowing new subparagraph:

17 “(E) ENSURING CONSISTENCY WITH AP-
18 PPLICABLE RULES.—The Secretary shall require
19 each Medicare administrative contractor that
20 develops a local coverage determination to en-
21 sure that any such local coverage determination
22 does not conflict with any law, ruling, regula-
23 tion, national coverage determination, payment
24 policy, or coding policy.”.

1 (d) FUNDING.—There are authorized to be appro-
2 priated \$1,000,000 for fiscal year 2024 for purposes of
3 carrying out the amendments made by this section.

4 **SEC. 4. MEDICARE COVERAGE OF EXTERNAL INFUSION**
5 **PUMPS AND NON-SELF-ADMINISTRABLE**
6 **HOME INFUSION DRUGS.**

7 Section 1861(n) of the Social Security Act (42 U.S.C.
8 1395x(n)) is amended by adding at the end the following
9 new sentence: “Beginning with the first calendar quarter
10 beginning on or after the date that is 1 year after the
11 date of the enactment of this sentence, an external infu-
12 sion pump and associated home infusion drug (as defined
13 in subsection (iii)(3)(C)) or other associated supplies that
14 do not meet the appropriate for use in the home require-
15 ment applied to the definition of durable medical equip-
16 ment under section 414.202 of title 42, Code of Federal
17 Regulations (or any successor to such regulation) shall be
18 treated as meeting such requirement if each of the fol-
19 lowing criteria is satisfied:

20 “(1) The prescribing information approved by
21 the Food and Drug Administration for the home in-
22 fusion drug associated with the pump instructs that
23 the drug should be administered by or under the su-
24 pervision of a health care professional.

1 “(2) A qualified home infusion therapy supplier
2 (as defined in subsection (iii)(3)(D)) administers or
3 supervises the administration of the drug or biological
4 in a safe and effective manner in the patient’s
5 home (as defined in subsection (iii)(3)(B)).

6 “(3) The prescribing information described in
7 paragraph (1) instructs that the drug should be in-
8 fused at least 12 times per year—

9 “(A) intravenously or subcutaneously; or

10 “(B) at infusion rates that the Secretary
11 determines would require the use of an external
12 infusion pump.”.

13 **SEC. 5. GUIDANCE ON MEDICARE PAYMENT FOR CERTAIN**
14 **ITEMS INVOLVING ARTIFICIAL INTEL-**
15 **LIGENCE.**

16 Not later than January 1, 2026, the Secretary of
17 Health and Human Services shall use existing communica-
18 tions mechanisms to issue guidance on requirements for
19 payment under part B of title XVIII of the Social Security
20 Act (42 U.S.C. 1395j et seq.) for remote monitoring de-
21 vices, such as continuous glucose monitors, that—

22 (1) use an artificial intelligence component
23 (such as a continuous adjustment component); and

1 (2) transmit information to a health care pro-
2 vider for purposes of management and treatment of
3 an individual.

4 **SEC. 6. CLARIFYING PAYMENT FOR PRESCRIPTION DIG-**
5 **ITAL THERAPEUTICS UNDER MEDICARE.**

6 (a) **GUIDANCE TO PHYSICIANS.**—Not later than Jan-
7 uary 1, 2026, the Secretary of Health and Human Serv-
8 ices (in this section referred to as the “Secretary”) shall
9 use existing communication mechanisms to issue guidance
10 on requirements for payment under part B of title XVIII
11 of the Social Security Act (42 U.S.C. 1395j et seq.) for
12 a prescription digital therapeutic furnished by a physician
13 or incident to a physician’s professional service.

14 (b) **GUIDANCE TO MA ORGANIZATIONS.**—Not later
15 than 1 year after the date of the enactment of this Act,
16 the Secretary shall issue to MA organizations guidance to
17 clarify the requirements relating to when such organiza-
18 tions may provide a prescription digital therapeutic as a
19 supplemental benefit to an individual enrolled under a MA
20 plan.

21 (c) **REPORT TO CONGRESS.**—Not later than January
22 1, 2026, the Secretary shall submit to the Committee on
23 Ways and Means and the Committee on Energy and Com-
24 merce of the House of Representatives, and the Finance
25 Committee of the Senate, a report that includes—

1 (1) an analysis of any existing statutory author-
2 ity for the Secretary to provide payment for pre-
3 scription digital therapeutics under the Medicare
4 program; and

5 (2) a description of any additional statutory au-
6 thority that is needed by the Secretary to expand
7 such coverage.

8 (d) DEFINITIONS.—In this section:

9 (1) MA TERMS.—The terms “MA plan”, “MA
10 organization”, and “supplemental benefit” have the
11 meanings given each such term in part C of title
12 XVIII of the Social Security Act (42 U.S.C. 1395w-
13 21 et seq.).

14 (2) MEDICARE PROGRAM.—The term “Medicare
15 program” means the Medicare program under title
16 XVIII of the Social Security Act (42 U.S.C. 1395 et
17 seq.).

18 (3) PHYSICIAN.—The term “physician” has the
19 meaning given such term in section 1861(r) of the
20 Social Security Act (42 U.S.C. 1395x(r)).

21 (4) PRESCRIPTION DIGITAL THERAPEUTIC.—
22 The term “prescription digital therapeutic” means
23 an evidence-based software product, including any
24 such product that is a combination product de-
25 scribed in section 503(g) of the Federal Food, Drug,

1 and Cosmetic Act (21 U.S.C. 353(g)), intended for
2 use in the management, prevention, or treatment of
3 a disease or condition, that acts directly as a medical
4 intervention or guides the delivery of a medical
5 intervention and that—

6 (A) is regulated by the Food and Drug Ad-
7 ministration as a device (as defined in section
8 201 of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 321)), including any such device
10 regulated as a combination product (as de-
11 scribed in section 503(g) of such Act (21
12 U.S.C. 353(g));

13 (B) is cleared under section 510(k), classi-
14 fied under section 513(f)(2), or approved under
15 section 515 of such Act (21 U.S.C. 360(k),
16 360c(f)(2), 360e); and

17 (C) may not be furnished to an individual
18 without a prescription from a physician.

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