

.....  
(Original Signature of Member)

118<sup>TH</sup> CONGRESS  
2<sup>D</sup> 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

Mr. BUCHANAN introduced the following bill; which was referred to the Committee on \_\_\_\_\_

---

## 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           PLICABLE 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.