AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 8816 OFFERED BY MR. SMITH OF MISSOURI

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''American Medical Innovation and Investment Act of 2024''.

SEC. 2. COGNITIVE IMPAIRMENT DETECTION BENEFIT IN THE MEDICARE ANNUAL WELLNESS VISIT AND INITIAL PREVENTIVE PHYSICAL EXAMINATION.

(a) ANNUAL WELLNESS VISIT.—

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

''(D) Detection of any cognitive impairment that shall—

''(i) be performed using one of the cognitive impairment detection tools identified by the National Institute on Aging as meeting its criteria for selecting instru-

ments to detect cognitive impairment in the primary care setting; and

''(ii) include documentation of the tool used for detecting cognitive impairment and results of the assessment in the patient's medical record.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to annual wellness visits furnished on or after January 1, 2025.

(b) INITIAL PREVENTIVE PHYSICAL EXAMINATION.—

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

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

SEC. 3. IMPROVING THE NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESSES UNDER THE MEDICARE PROGRAM.

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

''(7) LIMITATION ON DURATION OF COVERAGE WITH EVIDENCE DEVELOPMENT DETERMINATIONS.—

''(A) IN GENERAL.—Subject to subparagraph (B), in the case of a final decision under paragraph (3)(C)(i) (including any such decision made on a class-wide basis) made on or after the date of the enactment of this paragraph that results in coverage of an item or service pursuant to subsection (a)(1)(E), the Secretary shall, not later than 10 years after the date on which such coverage becomes effective pursuant to such subsection, initiate a reconsideration with respect to such item or service.

''(B) EXCEPTION.—The Secretary may delay a reconsideration described in subparagraph (A) with respect to an item or service for a period of time determined appropriate by the Secretary if the Secretary finds that such delay

is reasonable and necessary to carry out the purposes described in section 1142.

''(C) POSTING OF INFORMATION.—Not later than 1 year after the date of the enactment of this paragraph, and annually thereafter, the Secretary shall post on the public website of the Centers for Medicare & Medicaid Services the following information:

''(i) The number of items and services covered under this title pursuant to subsection (a)(1)(E).

''(ii) A description of each such item or service.

''(iii) The year in which coverage of each such item or service became effective pursuant to such subsection.''.

(b) PROVISION OF EXPLANATION IN CASE OF CERTAIN INCOMPLETE REQUESTS.—Section 1862(l) of the Social Security Act (42 U.S.C. 1395y(l)), as amended by subsection (a), is further amended by adding at the end the following new paragraph:

''(8) REQUIREMENT TO PROVIDE EXPLANATION IN CASE OF CERTAIN INCOMPLETE REQUESTS.—With respect to each document received by the Secretary on or after the date that is 1 year after the

date of the enactment of this paragraph that identifies itself as a complete, formal request for a national coverage determination (as described in the notice entitled 'Medicare Program; Revised Process for Making National Coverage Determinations' (78 Fed. Reg. 48164) or a successor regulation), the Secretary shall, not later than 90 days after receipt of such document—

''(A) determine whether such document is a complete, formal request for a national coverage determination; and

''(B) in the case that the Secretary finds that such document is not a complete, formal request for a national coverage determination but that such document contains such minimum information as specified by the Secretary, transmit to the entity submitting such document information on such finding that includes a specification of additional information needed to make such document a complete, formal request for a national coverage determination.''.

(c) IMPROVING ACCESS TO ITEMS AND SERVICES UNDER LOCAL COVERAGE DETERMINATIONS.—Section 1862(l)(5) of the Social Security Act (42 U.S.C.

1395y(l)(5)) is amended by adding at the end the following new subparagraph:

''(E) ENSURING CONSISTENCY WITH APPLICABLE RULES.—The Secretary shall require each Medicare administrative contractor that develops a local coverage determination to ensure that any such local coverage determination does not conflict with any law, ruling, regulation, national coverage determination, payment policy, or coding policy.''.

(d) FUNDING.—In addition to amounts otherwise available, there are appropriated to the Centers for Medicare & Medicaid Services Program Management Account, out of any monies in the Treasury not otherwise appropriated, $1,000,000 for each of fiscal years 2025 through 2030, to remain available until expended, to carry out the amendments made by this section.

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

(a) IN GENERAL.—Section 1861(n) of the Social Security Act (42 U.S.C. 1395x(n)) is amended by adding at the end the following new sentence: ''Beginning with the first calendar quarter beginning on or after the date that is 1 year after the date of the enactment of this sen-

tence, an external infusion pump and associated home infusion drug (as defined in subsection (iii)(3)(C)) or other associated supplies that do not meet the appropriate for use in the home requirement applied to the definition of durable medical equipment under section 414.202 of title 42, Code of Federal Regulations (or any successor to such regulation) shall be treated as meeting such requirement if each of the following criteria is satisfied:

''(1) The prescribing information approved by the Food and Drug Administration for the home infusion drug associated with the pump instructs that the drug should be administered by or under the supervision of a health care professional.

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

''(3) The prescribing information described in paragraph (1) instructs that the drug should be infused at least 12 times per year—

''(A) intravenously or subcutaneously; or

''(B) at infusion rates that the Secretary determines would require the use of an external infusion pump.''.

(b) COST SHARING NOTIFICATION.—The Secretary of Health and Human Services shall ensure that patients are notified of the cost sharing for electing home infusion therapy compared to other applicable settings of care for the furnishing of infusion drugs under the Medicare program.

SEC. 5. GUIDANCE ON MEDICARE PAYMENT FOR CERTAIN ITEMS INVOLVING ARTIFICIAL INTELLIGENCE.

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

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

(2) transmit information to a health care provider for purposes of management and treatment of an individual.

SEC. 6. CLARIFYING PAYMENT FOR PRESCRIPTION DIGITAL THERAPEUTICS UNDER MEDICARE.

(a) GUIDANCE TO PHYSICIANS.—Not later than January 1, 2026, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall

use existing communication mechanisms to issue guidance on requirements for payment under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.) for a prescription digital therapeutic furnished by a physician or incident to a physician's professional service.

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

(c) REPORT TO CONGRESS.—Not later than January 1, 2026, the Secretary shall submit to the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives, and the Finance Committee of the Senate, a report that includes—

(1) an analysis of any existing statutory authority for the Secretary to provide payment for prescription digital therapeutics under the Medicare program; and

(2) a description of any additional statutory authority that is needed by the Secretary to expand such coverage.

(d) DEFINITIONS.—In this section:

(1) MA TERMS.—The terms ''MA plan'', ''MA organization'', and ''supplemental benefit'' have the meanings given each such term in part C of title XVIII of the Social Security Act (42 U.S.C. 1395w–21 et seq.).

(2) MEDICARE PROGRAM.—The term ''Medicare program'' means the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

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

(4) PRESCRIPTION DIGITAL THERAPEUTIC.—The term ''prescription digital therapeutic'' means an evidence-based software product, including any such product that is a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)), intended for use in the management, prevention, or treatment of a disease or condition, that acts directly as a medical intervention or guides the delivery of a medical intervention and that—

(A) is regulated by the Food and Drug Administration as a device (as defined in section 201 of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 321)), including any such device regulated as a combination product (as described in section 503(g) of such Act (21 U.S.C. 353(g));

(B) is cleared under section 510(k), classified under section 513(f)(2), or approved under section 515 of such Act (21 U.S.C. 360(k), 360c(f)(2), 360e); and

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

SEC. 7. MEDICALLY TAILORED HOME-DELIVERED MEALS DEMONSTRATION PROGRAM.

Part E of title XVIII of the Social Security Act is amended by inserting after section 1866F (42 U.S.C. 1395cc–6) the following new section:

"SEC. 1866G. MEDICALLY TAILORED HOME-DELIVERED MEALS DEMONSTRATION PROGRAM.

''(a) ESTABLISHMENT.—For the 4-year period beginning not later than 30 months after the date of the enactment of this section, subject to subsection (f), the Secretary shall conduct, in accordance with the provisions of this section, a Medically Tailored Home-Delivered Meals Demonstration Program (in this section referred to as the 'Program') to test a payment and service delivery model under which selected hospitals provide medically tailored

home-delivered meals under part A of this title to qualified individuals, with respect to such hospitals, to improve clinical health outcomes and reduce the rate of readmissions of such individuals.

''(b) SELECTION OF HOSPITALS TO PARTICIPATE IN PROGRAM.—

''(1) SELECTED HOSPITALS.—Under the Program, the Secretary shall, not later than January 1, 2025, select to participate in the Program at least, subject to subsection (f), 40 eligible hospitals that the Secretary determines have the capacity to satisfy the requirements described in subsection (c). In this section, each such eligible hospital so selected shall be referred to as a 'selected hospital'.

''(2) ELIGIBLE HOSPITALS.—For purposes of this section, the term 'eligible hospital' means a subsection (d) hospital (as defined in section 1886(d)(1)(B)) or a critical access hospital that—

''(A) submits to the Secretary an application, at such time and in such form and manner as specified by the Secretary, that contains—

''(i) an attestation (in such form and manner as specified by the Secretary) that such hospital has the ability, or is under an arrangement with a provider of services

or supplier or other entity that has the ability, to comply with the requirements described in subsection (c); and

"(ii) such other information as the Secretary may require;

"(B) in the case of a subsection (d) hospital, has, for the 2 most recent fiscal years ending prior to the date of selection by the Secretary under paragraph (1), averaged at least 3 stars for the overall hospital quality star rating on the Internet website of the Centers for Medicare & Medicaid Services (including Care Compare or a successor website); and

"(C) is not, as of the date of selection by the Secretary under paragraph (1), subject to—

"(i) the requirement to return any overpayment pursuant to section 1128J(d); or

"(ii) any activity described in section 1893(b) (relating to Medicare integrity program actions).

"(c) MINIMUM PROGRAM REQUIREMENTS.—Under the Program, a selected hospital shall comply with each of the following requirements:

''(1) STAFFING.—The selected hospital shall provide (including through an arrangement described in subsection (b)(2)(A)(i)), for the duration of the participation of the hospital under the Program, a physician, registered dietitian or nutrition professional, or clinical social worker to carry out the screening and re-screening pursuant to paragraph (2), medical nutrition therapy pursuant to paragraph (3)(B).

''(2) SCREENING AND RE-SCREENING.—The selected hospital (including through an arrangement described in subsection (b)(2)(A)(i)) shall—

''(A) as part of the discharge planning process described in section 1861(ee), screen individuals that are inpatients of such selected hospital with validated screening tools (as developed by the Secretary) to determine whether such individuals are qualified individuals; and

''(B) in the case of an individual determined pursuant to subparagraph (A) or this subparagraph to be a qualified individual, re-screen such individual with validated screening tools (as determined by the Secretary) every 12 weeks after such determination occurring during the participation of the hospital under the

Program to determine whether such individual continues to be a qualified individual.

''(3) PROVIDING MEDICALLY TAILORED HOME-DELIVERED MEALS AND MEDICAL NUTRITION THERAPY.—In the case of an individual that is determined by the selected hospital pursuant to paragraph (2) to be a qualified individual, the selected hospital (including through an arrangement described in subsection (b)(2)(A)(i)) shall with respect to the period during which such hospital is participating in the Program—

''(A) provide, for each day during a period of at least 12 weeks, for the preparation and delivery to such individual of at least 2 medically tailored home-delivered meals (or a portioned equivalent) that meet at least two-thirds of the daily nutritional needs of the qualified individual; and

''(B) provide to such qualified individual, in connection with delivering such meals and for a period of at least 12 weeks and not more than 1 year, medical nutrition therapy.

''(4) DATA SUBMISSION.—The selected hospital shall submit to the Secretary data, in such form, manner, and frequency as designated by the Sec-

retary, so that the Secretary may determine the affect of the Program with respect to the factors described in subsection (e)(2)[(B)].

''(5) ADDITIONAL REQUIREMENTS.—The selected hospital shall satisfy such additional requirements as may be specified by the Secretary.

''(d) PAYMENT; COST-SHARING.—

''(1) PAYMENT.—The Secretary shall determine the form, manner, and amount of payment to be provided to a selected hospital under the Program.

''(2) COST-SHARING.—Items and services for which payment may be made under the Program shall be provided without application of deductibles, copayments, coinsurance, or other cost-sharing under this title.

''(e) EVALUATIONS.—

''(1) MONITORING AND ASSESSING CLINICAL HEALTH OUTCOMES.—The Secretary shall monitor and assess the clinical health outcomes of each individual who is determined by a selected hospital pursuant to subsection (c)(2) to be a qualified individual for a period of at least 12 weeks and not more than 1 year after the date on which such individual is so determined under subparagraph (A) of such subsection.

''(2) INTERMEDIATE AND FINAL EVALUATIONS.—The Secretary shall conduct an intermediate and final evaluation of the Program. Each such evaluation shall—

''(A) based on the monitoring and assessments conducted under paragraph (1), with respect to individuals determined to be qualified individuals and the periods for which such assessments are so conducted, determine—

''(i) the number of inpatient admissions of such individuals;

''(ii) the number of admissions to skilled nursing facilities of such individuals; and

''(iii) the total expenditures under part A with respect to such individuals;

''(B) determine the extent to which the Program has—

''(i) improved clinical health outcomes, as defined by the Secretary;

''(ii) reduced the cost of care under part A (including costs associated with readmission as defined in section 1866(q)(5)(E)); and

''(iii) increased patient satisfaction, as defined by the Secretary;

''(C) specify the form, manner, and amounts of payments made under the Program pursuant to subsection (d)(1) and the effectiveness of such payment form, manner, and amounts;

''(D) examine the feasibility and impact of implementing cost sharing requirements for items and services furnished under the Program;

''(E) an analysis of health outcomes of individuals receiving items and services under the Program compared to health outcomes of individuals receiving items and services under a similar program offered by a Medicare Advantage plan; and

''(F) the number of individuals who have received benefits under the Program while receiving benefits under any other similar program operated by the Federal Government or a State.

''(3) REPORTS.—The Secretary shall submit to Congress—

''(A) not later than 3 years after the date of implementation of the Program, a report with respect to the intermediate evaluation under paragraph (2); and

''(B) not later than 6 years after such date of implementation, a report with respect to the final evaluation under such paragraph.

''(f) COORDINATION.—The Secretary shall coordinate with other Federal and State agencies to ensure that the benefits provided to an individual under the Program do not duplicate any benefits being provided to such individual under any other program operated by such an agency.

''(g) FUNDING.—

''(1) IN GENERAL.—Payments for items and services furnished under the Program shall be made from the Hospital Insurance Trust Fund under section 1817.

''(2) BUDGET NEUTRALITY.—The Secretary shall reduce payments made to subsection (d) hospitals under section 1886(d) in a manner such that the total amount of such reductions for a year are estimated to be equal to the total amount of payments made under the Program during such year.

''(h) DEFINITIONS.—In this section:

''(1) MEDICAL NUTRITION THERAPY.—The term 'medical nutrition therapy' has the meaning given such term in section 1861(vv)(1).

''(2) MEDICALLY TAILORED HOME-DELIVERED MEAL.—The term 'medically tailored home-delivered meal' means, with respect to a qualified individual, a meal that is designed by a registered dietitian or nutritional professional for the treatment plan of the qualified individual.

''(3) QUALIFIED INDIVIDUAL.—The term 'qualified individual' means an individual, with respect to a selected hospital, who—

''(A) is entitled to benefits under part A;

''(B) has a diet-impacted disease (such as kidney disease, congestive heart failure, diabetes, chronic obstructive pulmonary disease, or any other disease the Secretary determines appropriate);

''(C) at the time of discharge from such hospital—

''(i) lives at home;

''(ii) is not eligible for—

''(I) extended care services (as defined in section 1861(h)); or

''(II) post-hospital extended care services (as defined in section 1861(i));

''(iii) has not made an election under section 1812(d)(1) to receive hospice care;

''(iv) is certified by a physician at the time of discharge to be limited with respect to at least 2 of the activities of daily living (as described in section 7702B(c)(2)(B) of the Internal Revenue Code of 1986); and

''(v) meets any other criteria for high-risk of readmission (as determined by the Secretary).

''(4) REGISTERED DIETITIAN OR NUTRITION PROFESSIONAL.—The term 'dietitian or nutrition professional' has the meaning given such term in section 1861(vv)(2).''.

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