

**Explanation of Changes Reflected in the Chairman’s  
Amendment in the Nature of a Substitute to  
H.R. 8816, *American Medical Innovation and Investment Act***

June 27, 2024

The Chairman’s amendment in the nature of a substitute includes the following changes to H.R. 8816 as introduced:

1. Pg. 4, line 4-5: replace “redetermination” with “reconsideration”.
2. Pg. 4, line 8: replace “redetermination” with “reconsideration”.
3. Pg. 4, line 12-15: replace “(i) the finds that such item or service is reasonable and necessary to carry out the purposes described in section 1142; or (ii) the entity responsible for such item or service requests such extension.” with “--the Secretary finds that such delay is reasonable and necessary to carry out the purposes described in section 1142.”
4. Pg. 4, line 21: Insert “shall” after “Secretary”
5. Pg. 5, line 10: Replace “Rejected” with “Incomplete”
6. Pg. 5, line 15: Replace “Rejected” with “Incomplete”
7. Pg. 6, lines 4-11: Replace “(B) in the case that the Secretary finds that such document is not a complete, formal request for a national coverage determination, 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.” with “(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.”
8. Pg. 7, lines 1-3: Replace “(d) FUNDING.—There are authorized to be appropriated \$1,000,000 for fiscal year 2024 for purposes of carrying out the amendments made by this section.” with “(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.”
9. Pg. 8, line 1-6: Insert “(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.”
10. Pg. 11, Line 18: Insert “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 Secretary, 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).”.”