

118TH CONGRESS  
1ST SESSION

# H. R. 4438

To amend title XVIII of the Social Security Act to provide for coverage and payment of Alpha-1 Antitrypsin Deficiency Disorder treatment under part B of such title, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 30, 2023

Ms. SALAZAR (for herself, Ms. PINGREE, Mr. POSEY, Mr. TONKO, Ms. WASSERMAN SCHULTZ, Mr. KEATING, Mr. PANETTA, Mr. CONNOLLY, and Mr. HIGGINS of New York) 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

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## A BILL

To amend title XVIII of the Social Security Act to provide for coverage and payment of Alpha-1 Antitrypsin Deficiency Disorder treatment under part B of such title, 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 “John W. Walsh Alpha-  
5 1 Home Infusion Act of 2023”.

## 1 SEC. 2. MEDICARE COVERAGE OF ALPHA-1 ANTITRYPSIN

2 **DISORDER TREATMENT.**3 (a) IN GENERAL.—Section 1861 of the Social Secu-  
4 rity Act (42 U.S.C. 1395x) is amended—

5 (1) in subsection (s)(2)—

6 (A) by striking “and” at the end of sub-  
7 paragraph (II);8 (B) by inserting “and” at the end of sub-  
9 paragraph (JJ); and10 (C) by inserting at the end the following  
11 new subparagraph:12 “(KK) Alpha-1 Antitrypsin Deficiency Dis-  
13 order treatment (as defined in subsection  
14 (nnn)); and15 (2) by adding at the end the following new sub-  
16 section:

17 “(nnn) ALPHA-1 ANTITRYPSIN DEFICIENCY DIS-

18 ORDER TREATMENT.—(1) The term ‘Alpha-1 Antitrypsin  
19 Deficiency Disorder treatment’ means augmentation ther-  
20 apy (as defined in paragraph (2)(C)) furnished by qual-  
21 fied home infusion therapy suppliers (as defined in para-  
22 graph (2)(D)) which are furnished in the individual’s  
23 home (as defined in paragraph (2)(B)) to an individual—24 (A) who is under the care of an applicable pro-  
25 vider;

1           “(B) who is enrolled under both parts A and B  
2       of this title, and is not enrolled in an MA plan under  
3       part C of such title; and

4           “(C) who requires augmentation therapy (as de-  
5       fined in paragraph (2)(C)).

6       “(2) For purposes of this subsection:

7           “(A) The term ‘applicable provider’ means—

8              “(i) a physician;

9              “(ii) a nurse practitioner; and

10             “(iii) a physician assistant.

11           “(B) The term ‘home’ means a place of resi-  
12       dence used as the home of an individual (as defined  
13       for purposes of subsection (n)).

14           “(C) The term ‘augmentation therapy’ means  
15       an Alpha-1 Proteinase Inhibitor indicated for chron-  
16       ic augmentation and maintenance therapy in adults  
17       with clinical evidence of emphysema due to severe  
18       hereditary deficiency of Alpha-1 Antitrypsin.

19           “(D) The term ‘qualified home infusion therapy  
20       supplier’ has the meaning given such term in sub-  
21       section (iii)(3)(D)(i).”.

22       (b) PAYMENT FOR INTRAVENOUS ADMINISTRATION  
23       KITS AND NURSING SERVICES FOR ALPHA-1  
24       ANTITRYPSIN DEFICIENCY DISORDER TREATMENT.—  
25       Section 1834 of the Social Security Act (42 U.S.C.

1 1395m) is amended by adding at the end the following  
2 new subsection:

3       “(aa) PAYMENT FOR INTRAVENOUS ADMINISTRA-  
4 TION KITS AND NURSING SERVICES FOR ALPHA-1  
5 ANTITRYPSIN DEFICIENCY DISORDER TREATMENT.—The  
6 Secretary shall implement a payment system under which  
7 payment is made under this title to a qualified home infu-  
8 sion therapy supplier (as defined in section  
9 1861(nnn)(3)(D)) for intravenous administration kits and  
10 nursing services for up to 2 hours of care by a qualified  
11 home infusion therapy supplier in coordination with the  
12 furnishing of augmentation therapy (as defined in section  
13 1861(nnn)(2)(C)).”.

14       (c) CONFORMING AMENDMENTS.—

15           (1) PAYMENT REFERENCE.—Section  
16 1833(a)(1) of the Social Security Act (42 U.S.C.  
17 1395l(a)(1)) is amended—

18                  (A) by striking “and” before “(HH)”; and  
19                  (B) by inserting before the semicolon at  
20 the end the following: “, and (II) with respect  
21 to intravenous administration kits and nursing  
22 services described in section 1834(aa) for  
23 Alpha-1 Antitrypsin Disorder treatment (as de-  
24 fined in subsection (nnn)(1)), the amount paid  
25 for such kits and services shall be an amount

1           equal to 80 percent of the lesser of the actual  
2           charge for the services or the amount deter-  
3           mined under section 1834(aa)’.

4           (2) DIRECT PAYMENT.—The first sentence of  
5           section 1842(b)(6) of the Social Security Act (42  
6           U.S.C. 1395u(b)(6)) is amended—

7                 (A) by striking “and” before “(J)”; and  
8                 (B) by inserting before the period at the  
9                 end the following: “, and (K) in the case of in-  
10                 travenous administration kits and nursing serv-  
11                 ices described in section 1834(aa), payment  
12                 shall be made to the qualified home infusion  
13                 therapy supplier (as defined in section  
14                 1861(nnn)(2)(D))”.

15           (3) EXCLUSION FROM HOME HEALTH SERV-  
16           ICES.—Section 1861(m) of the Social Security Act  
17           (42 U.S.C. 1395x(m)) is amended, in the first sen-  
18           tence, by inserting the following before the period at  
19           the end: “and intravenous administration kits and  
20           nursing services described in section 1834(aa) for  
21           Alpha-1 Antitrypsin Deficiency Disorder treatment  
22           (as defined in subsection (nnn)(1))”.

1       (d) EFFECTIVE DATE.—The amendments made by  
2 this section shall apply to items and services furnished on  
3 or after January 1, 2025.

