

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 5397
OFFERED BY M . _____**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the “Joe Fiandra Access
3 to Home Infusion Act of 2023”.

**4 SEC. 2. MEDICARE COVERAGE OF EXTERNAL INFUSION
5 PUMPS AND NON-SELF-ADMINISTRABLE
6 HOME INFUSION DRUGS.**

7 (a) CLARIFYING APPROPRIATE FOR USE IN THE
8 HOME CRITERIA FOR DME DEFINITION.—Section
9 1861(n) of the Social Security Act (42 U.S.C. 1395x(n))
10 is amended by adding at the end the following new sen-
11 tence: “An external infusion pump and associated home
12 infusion drug (as defined in subsection (iii)(3)(C)) or
13 other associated supplies shall be treated as meeting the
14 appropriate for use in the home requirement applied to
15 the definition of durable medical equipment under section
16 414.202 of title 42, Code of Federal Regulations (or any
17 successor to such regulation) and shall be covered as dura-
18 ble medical equipment under this title if each of the fol-

1 lowing criteria (as described in the Notice of Proposed
2 Rulemaking titled Expanded Classification of External In-
3 fusion Pumps as Durable Medical Equipment published
4 in the Federal Register on November 4, 2020 (85 Fed.
5 Reg. 70404)) is satisfied:

6 “(1) The prescribing information approved by
7 the Food and Drug Administration for the home in-
8 fusion drug associated with the pump instructs that
9 the drug should only be administered by a health
10 care professional.

11 “(2) A qualified home infusion therapy supplier
12 (as defined in subsection (iii)(3)(D)) administers the
13 drug or biological in a safe and effective manner in
14 the patient’s home (as defined in subsection
15 (iii)(3)(B)).

16 “(3) The prescribing information described in
17 paragraph (1) instructs a health care professional to
18 administer the drug intravenously via an external in-
19 fusion pump at least once per month.”.

20 (b) IMPLEMENTATION.—Notwithstanding any other
21 provision of law, any home infusion drug associated with
22 an external infusion pump that satisfies the criteria de-
23 scribed in each of paragraphs (1), (2), and (3) of section
24 1861(n) of the Social Security Act (42 U.S.C. 1395x(n)),
25 as added by subsection (a), shall be included in the Local

1 Coverage Determination on External Infusion Pumps
2 made under title XVIII of such Act (42 U.S.C. 1395, et
3 seq.) (LCD number L33794) (and any successor LCD),
4 and payment shall be authorized for home infusion ther-
5 apy services provided in association with any such drug,
6 effective as of the date that is 1 year after the date of
7 the enactment of this section.

