..... (Original Signature of Member)

118TH CONGRESS 1ST SESSION



To amend title XVIII of the Social Security Act to provide coverage of external infusion pumps and non-self-administrable home infusion drugs under the Medicare program.

IN THE HOUSE OF REPRESENTATIVES

Mr. FITZPATRICK introduced the following bill; which was referred to the Committee on _____

A BILL

- To amend title XVIII of the Social Security Act to provide coverage of external infusion pumps and non-self-administrable home infusion drugs under the Medicare program.
 - 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 "Joe Fiandra Access5 to Home Infusion Act of 2023".

SEC. 1. MEDICARE COVERAGE OF EXTERNAL INFUSION
 PUMPS AND NON-SELF-ADMINISTRABLE
 HOME INFUSION DRUGS.

4 (a) CLARIFYING APPROPRIATE FOR USE IN THE 5 HOME CRITERIA FOR Dme **DEFINITION.**—Section 1861(n) of the Social Security Act (42 U.S.C. 1395x(n)) 6 7 is amended by adding at the end the following new sen-8 tence: "An external infusion pump and associated infusion 9 drug or other associated supplies shall be treated as meeting the appropriate for use in the home requirement ap-10 plied to the definition of durable medical equipment under 11 section 414.202 of title 42, Code of Federal Regulations 12 13 (or any successor to such regulation) and shall be covered 14 as durable medical equipment under this title if each of the following criteria (as described in the Notice of Pro-15 16 posed Rulemaking titled Expanded Classification of Exter-17 nal Infusion Pumps as Durable Medical Equipment published in the Federal Register on November 4, 2020 (85) 18 19 Fed. Reg. 70404)) is satisfied:

"(1) The Food and Drug Administration-required labeling requires the home infusion drug associated with the pump to be to be prepared immediately prior to administration or administered by a
health care professional or both.

25 "(2) A qualified home infusion therapy supplier
26 (as defined in subsection (iii)(3)(D)) administers the

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drug or biological in a safe and effective manner in
 the patient's home (as defined in subsection
 (iii)(3)(B)).

4 "(3) The labeling described in paragraph (1)
5 specifies infusion via an external infusion pump as
6 a possible route of administration, at least once per
7 month, for the drug.".

(b) IMPLEMENTATION.—Notwithstanding any other 8 9 provision of law, any home infusion drug associated with 10 an external infusion pump that satisfies the criteria de-11 scribed in each of paragraphs (1), (2), and (3) of section 12 1861(n) of the Social Security Act (42 U.S.C. 1395x(n)), as added by subsection (a), shall be included in the Local 13 14 Coverage Determination on External Infusion Pumps 15 made under title XVIII of such Act (42 U.S.C. 1395, et seq.) (LCD number L33794) (and any successor LCD), 16 17 and payment shall be authorized for home infusion ther-18 apy services provided in association with any such drug, 19 effective as of the date of the enactment of this section 20 or the Food and Drug Administration's approval of the 21 drug, whichever comes later.