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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

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 “Joseph Fiandra Access
5 to Home Infusion Act of 2023”.

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

4 (a) CLARIFYING APPROPRIATE FOR USE IN THE
5 HOME CRITERIA FOR DME DEFINITION.—Section
6 1861(n) of the Social Security Act (42 U.S.C. 1395x(n))
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 meet-
10 ing the appropriate for use in the home requirement ap-
11 plied to the definition of durable medical equipment under
12 section 414.202 of title 42, Code of Federal Regulations
13 (or any successor to such regulation) and shall be covered
14 as durable medical equipment under this title if each of
15 the following criteria (as described in the Notice of Pro-
16 posed Rulemaking titled Expanded Classification of Exter-
17 nal Infusion Pumps as Durable Medical Equipment pub-
18 lished in the Federal Register on November 4, 2020 (85
19 Fed. Reg. 70404)) is satisfied:

20 “(1) The Food and Drug Administration-re-
21 quired labeling requires the home infusion drug as-
22 sociated with the pump to be to be prepared imme-
23 diately prior to administration or administered by a
24 health care professional or both.

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

1 drug or biological in a safe and effective manner in
2 the patient's home (as defined in subsection
3 (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.”.

8 (b) IMPLEMENTATION.—Notwithstanding any other
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)),
13 as added by subsection (a), shall be included in the Local
14 Coverage Determination on External Infusion Pumps
15 made under title XVIII of such Act (42 U.S.C. 1395, et
16 seq.) (LCD number L33794) (and any successor LCD),
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.