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118TH CONGRESS
1ST SESSION

H. R. 5397

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

SEPTEMBER 12, 2023

Mr. FITZPATRICK (for himself and Mr. DUNN of Florida) 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 coverage of external infusion pumps and non-self-administrable home infusion drugs under the Medicare program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Joe Fiandra Access to Home Infusion Act of 2023''.

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

(a) CLARIFYING APPROPRIATE FOR USE IN THE HOME CRITERIA FOR DME DEFINITION.—Section 1861(n) of the Social Security Act (42 U.S.C. 1395x(n)) is amended by adding at the end the following new sentence: ''An external infusion pump and associated infusion drug or other associated supplies shall be treated as meeting the appropriate for use in the home requirement applied to the definition of durable medical equipment under section 414.202 of title 42, Code of Federal Regulations (or any successor to such regulation) and shall be covered as durable medical equipment under this title if each of the following criteria (as described in the Notice of Proposed Rulemaking titled Expanded Classification of External Infusion Pumps as Durable Medical Equipment published in the Federal Register on November 4, 2020 (85 Fed. Reg. 70404)) is satisfied:

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

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

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

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

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

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