AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 5397

OFFERED BY M__. _____

Strike all after the enacting clause and insert the following:

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.

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: ''Beginning with the first calendar quarter beginning on or after the date that is one year after the date of the enactment of the 'Joe Fiandra Access to Home Infusion Act of 2023', an external infusion pump and associated home infusion drug (as defined in subsection (iii)(3)(C)) or other associated supplies that do not meet 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) shall be treated as meet-

ing such requirement if each of the following criteria is satisfied:

''(1) The prescribing information approved by the Food and Drug Administration for the home infusion drug associated with the pump instructs that the drug should be administered by or under the supervision of a health care professional.

''(2) A qualified home infusion therapy supplier (as defined in subsection (iii)(3)(D)) administers or supervises the administration of the drug or biological in a safe and effective manner in the patient's home (as defined in subsection (iii)(3)(B)).

''(3) The prescribing information described in paragraph (1) instructs that the drug should be infused at least 12 times per year—

''(A) intravenously or subcutaneously; or

''(B) at infusion rates that the Secretary determines would require the use of an external infusion pump.''.

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