

AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 4993
OFFERED BY MR. SMITH OF MISSOURI

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”.

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

7 (a) IN GENERAL.—Section 1861(n) of the Social Se-
8 curity Act (42 U.S.C. 1395x(n)) is amended by adding
9 at the end the following new sentence: “Beginning with
10 the first calendar quarter beginning on or after the date
11 that is 1 year after the date of the enactment of this sen-
12 tence, an external infusion pump and associated home in-
13 fusion drug (as defined in subsection (iii)(3)(C)) or other
14 associated supplies that do not meet the appropriate for
15 use in the home requirement applied to the definition of
16 durable medical equipment under section 414.202 of title
17 42, Code of Federal Regulations (or any successor to such

1 regulation) shall be treated as meeting such requirement
2 if each of the following criteria is satisfied:

3 “(1) The prescribing information approved by
4 the Food and Drug Administration for the home in-
5 fusion drug associated with the pump instructs that
6 the drug should be administered by or under the su-
7 pervision of a health care professional.

8 “(2) A qualified home infusion therapy supplier
9 (as defined in subsection (iii)(3)(D)) administers or
10 supervises the administration of the drug or biologi-
11 cal in a safe and effective manner in the patient’s
12 home (as defined in subsection (iii)(3)(B)).

13 “(3) The prescribing information described in
14 paragraph (1) instructs that the drug should be in-
15 fused at least 12 times per year—

16 “(A) intravenously or subcutaneously; or

17 “(B) at infusion rates that the Secretary
18 determines would require the use of an external
19 infusion pump.”.

20 (b) COST SHARING NOTIFICATION.—The Secretary
21 of Health and Human Services shall ensure that patients
22 are notified of the cost sharing for electing home infusion
23 therapy compared to other applicable settings of care for

1 the furnishing of infusion drugs under the Medicare pro-
2 gram.

