

118TH CONGRESS
2^D SESSION

H. R. 5526

[Report No. 118-]

To amend title XVIII of the Social Security Act to clarify the application of the in-office ancillary services exception to the physician self-referral prohibition for drugs furnished under the Medicare program.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 18, 2023

Mrs. HARSHBARGER (for herself, Ms. WASSERMAN SCHULTZ, Mr. FLEISCHMANN, Mr. DAVIS of North Carolina, Mrs. MILLER-MEEKS, and Mr. BALDERSON) 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

JUNE --, 2024

Reported from the Committee on Energy and Commerce with amendments

[Strike out all after the enacting clause and insert the part printed in *italic*]

[For text of introduced bill, see copy of bill as introduced on September 18, 2023]

A BILL

To amend title XVIII of the Social Security Act to clarify the application of the in-office ancillary services exception to the physician self-referral prohibition for drugs furnished 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 “Seniors’ Access to Crit-*
5 *ical Medications Act of 2024”.*

6 **SEC. 2. CLARIFYING THE APPLICATION OF THE IN-OFFICE**
7 **ANCILLARY SERVICES EXCEPTION TO THE**
8 **PHYSICIAN SELF-REFERRAL PROHIBITION**
9 **FOR COVERED OUTPATIENT DRUGS FUR-**
10 **NISHED UNDER THE MEDICARE PROGRAM.**

11 *(a) IN GENERAL.—Section 1877(b)(2) of the Social Se-*
12 *curity Act (42 U.S.C. 1395nn(b)(2)) is amended by adding*
13 *at the end the following new sentence: “With respect to serv-*
14 *ices described in subsection (h)(6)(J) consisting of covered*
15 *part D drugs (as defined in section 1860D–2(e)) furnished*
16 *to an individual during the period beginning on January*
17 *1, 2025, and ending on December 31, 2029, such drugs shall*
18 *be treated as having been furnished in accordance with sub-*
19 *paragraph (A)(ii) if such drugs are picked up in a building*
20 *described in subclause (I) or (II) of such subparagraph by*
21 *such individual, or a family member or caregiver on behalf*
22 *of such individual, or delivered to such individual by a*
23 *mail, delivery, or courier service, but only if, during the*
24 *1-year period ending on the date such drugs were so fur-*
25 *nished, such individual had a face-to-face encounter with*

1 *the prescriber of such drugs (not including any such en-*
2 *counter conducted via telehealth), and only if such indi-*
3 *vidual has an ongoing on preexisting relationship with such*
4 *prescriber.”.*

5 (b) *REPORT.—Not later than 3 years after the date*
6 *of the enactment of this Act, the Secretary of Health and*
7 *Human Services shall submit to Congress a report that con-*
8 *tains—*

9 (1) *the number of individuals who were fur-*
10 *nished drugs in a manner that would constitute a*
11 *violation of section 1877 of the Social Security Act*
12 *(42 U.S.C. 1395nn) but for the amendment made by*
13 *subsection (a);*

14 (2) *an analysis of the change in expenditures*
15 *under title XVIII of such Act (42 U.S.C. 1395 et seq.)*
16 *attributable to such amendment;*

17 (3) *a description of which drugs were furnished*
18 *in a manner described in paragraph (1); and*

19 (4) *such amendment’s impact on prices for such*
20 *drugs.*

21 **SEC. 3. MEDICARE COVERAGE OF EXTERNAL INFUSION**
22 **PUMPS AND NON-SELF-ADMINISTRABLE**
23 **HOME INFUSION DRUGS.**

24 *Section 1861(n) of the Social Security Act (42 U.S.C.*
25 *1395x(n)) is amended by adding at the end the following*

1 *new sentence: “Beginning with the first calendar quarter*
2 *beginning on or after the date that is one year after the*
3 *date of the enactment of the ‘Seniors’ Access to Critical*
4 *Medications Act of 2024’, an external infusion pump and*
5 *associated home infusion drug (as defined in subsection*
6 *(iii)(3)(C)) or other associated supplies that do not meet*
7 *the appropriate for use in the home requirement applied*
8 *to the definition of durable medical equipment under sec-*
9 *tion 414.202 of title 42, Code of Federal Regulations (or*
10 *any successor to such regulation) shall be treated as meeting*
11 *such requirement if each of the following criteria is satis-*
12 *fied:*

13 *“(1) The prescribing information approved by*
14 *the Food and Drug Administration for the home infu-*
15 *sion drug associated with the pump instructs that the*
16 *drug should be administered by or under the super-*
17 *vision of a health care professional.*

18 *“(2) A qualified home infusion therapy supplier*
19 *(as defined in subsection (iii)(3)(D)) administers or*
20 *supervises the administration of the drug or biological*
21 *in a safe and effective manner in the patient’s home*
22 *(as defined in subsection (iii)(3)(B)).*

23 *“(3) The prescribing information described in*
24 *paragraph (1) instructs that the drug should be in-*
25 *fused at least 12 times per year—*

1 “(A) intravenously or subcutaneously; or
2 “(B) at infusion rates that the Secretary de-
3 termines would require the use of an external in-
4 fusion pump.”.

5 **SEC. 4. MEDICARE IMPROVEMENT FUND.**

6 Section 1898(b)(1) of the Social Security Act (42
7 U.S.C. 1395iii(b)(1)) is amended by striking “\$0” and in-
8 serting “\$114,000,000”.

Amend the title so as to read: “A bill to amend title XVIII of the Social Security Act to clarify the application of the in-office ancillary services exception to the physician self-referral prohibition for covered outpatient drugs furnished under the Medicare program, and to provide coverage of external infusion pumps and non-self-administrable home infusion drugs under such program.”.