

Suspend the Rules and Pass the Bill, H.R. 5526, With Amendments

(The amendments strike all after the enacting clause and insert a new text and a new title)

118TH CONGRESS
1ST SESSION

H. R. 5526

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

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Seniors’ Access to Crit-
3 ical Medications Act of 2024”.

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

9 (a) IN GENERAL.—Section 1877(b)(2) of the Social
10 Security Act (42 U.S.C. 1395nn(b)(2)) is amended by
11 adding at the end the following new sentence: “With re-
12 spect to services described in subsection (h)(6)(J) con-
13 sisting of covered part D drugs (as defined in section
14 1860D–2(e)) furnished to an individual during the period
15 beginning on January 1, 2025, and ending on December
16 31, 2029, such drugs shall be treated as having been fur-
17 nished in accordance with subparagraph (A)(ii) if such
18 drugs are picked up in a building described in subclause
19 (I) or (II) of such subparagraph by such individual, or
20 a family member or caregiver on behalf of such individual,
21 or delivered to such individual by a mail, delivery, or cou-
22 rier service, but only if, during the 1-year period ending
23 on the date such drugs were so furnished, such individual
24 had a face-to-face encounter with the prescriber of such
25 drugs (not including any such encounter conducted via
26 telehealth), and only if such prescriber (or another physi-

1 cian or practitioner (as described in section
2 1842(b)(18)(C)) in the same practice as such prescriber
3 (as determined by tax identification number)) furnished
4 to such individual, during such 1-year period, another item
5 or service for which payment was made under this title,
6 and only if such individual has an ongoing relationship
7 with such prescriber.”.

8 (b) REPORT.—Not later than 3 years after the date
9 of the enactment of this Act, the Secretary of Health and
10 Human Services shall submit to Congress a report that
11 contains—

12 (1) the number of individuals who were fur-
13 nished drugs in a manner that would constitute a
14 violation of section 1877 of the Social Security Act
15 (42 U.S.C. 1395nn) but for the amendment made by
16 subsection (a);

17 (2) an analysis of the change in expenditures
18 under title XVIII of such Act (42 U.S.C. 1395 et
19 seq.) attributable to such amendment;

20 (3) a description of which drugs were furnished
21 in a manner described in paragraph (1); and

22 (4) such amendment’s impact on prices for such
23 drugs.

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

4 Section 1861(n) of the Social Security Act (42 U.S.C.
5 1395x(n)) is amended by adding at the end the following
6 new sentence: “Beginning with the first calendar quarter
7 beginning on or after the date that is one year after the
8 date of the enactment of the ‘Seniors’ Access to Critical
9 Medications Act of 2024’, an external infusion pump and
10 associated home infusion drug (as defined in subsection
11 (iii)(3)(C)) or other associated supplies that do not meet
12 the appropriate for use in the home requirement applied
13 to the definition of durable medical equipment under sec-
14 tion 414.202 of title 42, Code of Federal Regulations (or
15 any successor to such regulation) shall be treated as meet-
16 ing such requirement if each of the following criteria is
17 satisfied:

18 “(1) The prescribing information approved by
19 the Food and Drug Administration for the home in-
20 fusion drug associated with the pump instructs that
21 the drug should be administered by or under the su-
22 pervision of a health care professional.

23 “(2) A qualified home infusion therapy supplier
24 (as defined in subsection (iii)(3)(D)) administers or
25 supervises the administration of the drug or biologi-

1 cal in a safe and effective manner in the patient's
2 home (as defined in subsection (iii)(3)(B)).

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

6 “(A) intravenously or subcutaneously; or

7 “(B) at infusion rates that the Secretary
8 determines would require the use of an external
9 infusion pump.”.

10 **SEC. 4. MEDICARE IMPROVEMENT FUND.**

11 Section 1898(b)(1) of the Social Security Act (42
12 U.S.C. 1395iii(b)(1)) is amended by striking “\$0” and in-
13 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.”.