118TH CONGRESS 2D SESSION

H. R. 5526

AN ACT

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.

- 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
- 12 Security Act (42 U.S.C. 1395nn(b)(2)) is amended by
- 13 adding at the end the following new sentence: "With re-
- 14 spect to services described in subsection (h)(6)(J) con-
- 15 sisting of covered part D drugs (as defined in section
- 16 1860D-2(e)) furnished to an individual during the period
- 17 beginning on January 1, 2025, and ending on December
- 18 31, 2029, such drugs shall be treated as having been fur-
- 19 nished in accordance with subparagraph (A)(ii) if such
- 20 drugs are picked up in a building described in subclause
- 21 (I) or (II) of such subparagraph by such individual, or
- 22 a family member or caregiver on behalf of such individual,
- 23 or delivered to such individual by a mail, delivery, or cou-
- 24 rier service, but only if, during the 1-year period ending
- 25 on the date such drugs were so furnished, such individual

- 1 had a face-to-face encounter with the prescriber of such
- 2 drugs (not including any such encounter conducted via
- 3 telehealth), and only if such prescriber (or another physi-
- 4 cian or practitioner (as described in section
- 5 1842(b)(18)(C)) in the same practice as such prescriber
- 6 (as determined by tax identification number)) furnished
- 7 to such individual, during such 1-year period, another item
- 8 or service for which payment was made under this title,
- 9 and only if such individual has an ongoing relationship
- 10 with such prescriber.".
- 11 (b) Report.—Not later than 3 years after the date
- 12 of the enactment of this Act, the Secretary of Health and
- 13 Human Services shall submit to Congress a report that
- 14 contains—
- 15 (1) the number of individuals who were fur-
- nished drugs in a manner that would constitute a
- violation of section 1877 of the Social Security Act
- 18 (42 U.S.C. 1395nn) but for the amendment made by
- 19 subsection (a);
- 20 (2) an analysis of the change in expenditures
- 21 under title XVIII of such Act (42 U.S.C. 1395 et
- seq.) attributable to such amendment;
- 23 (3) a description of which drugs were furnished
- in a manner described in paragraph (1); and

1	(4) such amendment's impact on prices for such
2	drugs.
3	SEC. 3. MEDICARE COVERAGE OF EXTERNAL INFUSION
4	PUMPS AND NON-SELF-ADMINISTRABLE
5	HOME INFUSION DRUGS.
6	Section 1861(n) of the Social Security Act (42 U.S.C.
7	1395x(n)) is amended by adding at the end the following
8	new sentence: "Beginning with the first calendar quarter
9	beginning on or after the date that is one year after the
10	date of the enactment of the 'Seniors' Access to Critical
11	Medications Act of 2024', an external infusion pump and
12	associated home infusion drug (as defined in subsection
13	(iii)(3)(C)) or other associated supplies that do not meet
14	the appropriate for use in the home requirement applied
15	to the definition of durable medical equipment under sec-
16	tion 414.202 of title 42, Code of Federal Regulations (or
17	any successor to such regulation) shall be treated as meet-
18	ing such requirement if each of the following criteria is
19	satisfied:
20	"(1) The prescribing information approved by
21	the Food and Drug Administration for the home in-
22	fusion drug associated with the pump instructs that
23	the drug should be administered by or under the su-
24	pervision of a health care professional.

1	"(2) A qualified home infusion therapy supplier
2	(as defined in subsection (iii)(3)(D)) administers or
3	supervises the administration of the drug or biologi-
4	cal in a safe and effective manner in the patient's
5	home (as defined in subsection (iii)(3)(B)).
6	"(3) The prescribing information described in
7	paragraph (1) instructs that the drug should be in-
8	fused at least 12 times per year—
9	"(A) intravenously or subcutaneously; or
10	"(B) at infusion rates that the Secretary
11	determines would require the use of an external
12	infusion pump.".
13	SEC. 4. MEDICARE IMPROVEMENT FUND.
14	Section 1898(b)(1) of the Social Security Act (42
15	U.S.C. 1395iii(b)(1)) is amended by striking "\$0" and in-
16	serting "\$114,000,000".
	Passed the House of Representatives September 23,
	2024.

Clerk.

Attest:

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