119TH CONGRESS		
1st Session		
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To amend title XVIII of the Social Security Act to provide long-term stability for Medicare beneficiary access to clinical diagnostic laboratory tests by improving the accuracy of, and feasibility of data collection for, the private payor-based fee schedule payment rates applied under the Medicare program for such tests, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. Tillis (for himself and Mr. Warnock) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To amend title XVIII of the Social Security Act to provide long-term stability for Medicare beneficiary access to clinical diagnostic laboratory tests by improving the accuracy of, and feasibility of data collection for, the private payor-based fee schedule payment rates applied under the Medicare program for such tests, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,

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	SECTION 1	CITADA	
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2	This Act may be cited as the "Reforming and En
3	hancing Sustainable Updates to Laboratory Testing Serv
4	ices Act of 2025" or the "RESULTS Act".
5	SEC. 2. IMPROVING THE ACCURACY AND DATA COLLEC
6	TION FEASIBILITY OF THE PRIVATE PAYOR
7	BASED MEDICARE PAYMENT RATES FOR
8	CLINICAL DIAGNOSTIC LABORATORY TESTS.
9	(a) Acquiring Data for Widely Available Non
10	ADVANCED DIAGNOSTIC LABORATORY TESTS FROM A
11	QUALIFYING COMPREHENSIVE CLAIMS DATABASE OF AN
12	Independent National Nonprofit Entity.—Section
13	1834A(a) of the Social Security Act (42 U.S.C. 1395m-
14	1(a)) is amended—
15	(1) in paragraph (1)—
16	(A) in subparagraph (A)—
17	(i) by striking "REQUIREMENTS.—
18	Subject to subparagraph (B)" and insert
19	ing "REQUIREMENTS.—
20	"(i) In general.—Subject to sub
21	paragraph (B) and except as provided for
22	in clause (ii)";
23	(ii) in clause (i), as added by clause
24	(i) of this subparagraph—
25	(I) by striking "paragraph (2)"
26	and inserting "paragraph (2)(A)";

1	(II) by inserting ", in accordance
2	with the provisions of this section,"
3	before "report to the Secretary";
4	(III) by striking "applicable in-
5	formation (as defined in paragraph
6	(3)) for a data collection period (as
7	defined in paragraph (4))" and insert-
8	ing "applicable information (as de-
9	fined in paragraph (3))—
10	"(I) for a data collection period
11	(as defined in paragraph (4)) begin-
12	ning before January 1, 2027,";
13	(IV) by striking the period at the
14	end and inserting "; and; and
15	(V) by adding at the end the fol-
16	lowing new subclause:
17	"(II) for a data collection period
18	beginning on or after January 1,
19	2027, for each clinical diagnostic lab-
20	oratory test for which final payment is
21	made under this part to the labora-
22	tory during such period."; and
23	(iii) by adding at the end the fol-
24	lowing new clause;

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1	"(ii) Collection and submission
2	OF DATA.—
3	"(I) In General.—With respect
4	to data collection periods for reporting
5	periods beginning on or after January
6	1, 2028, and for purposes of this sec-
7	tion, in the case of a widely available
8	non-ADLT clinical diagnostic labora-
9	tory test (as defined in paragraph
10	(2)(E)), the Secretary shall collect
11	and use applicable information from a
12	qualifying comprehensive claims data-
13	base (as defined in paragraph (2)(C))
14	of a qualifying independent claims
15	data entity (as defined in paragraph
16	(2)(D)) with which the Secretary has
17	in effect a contract under subclause
18	(II) for each such test furnished dur-
19	ing the respective data collection pe-
20	riod and for which final payment is
21	made under this part during the year
22	in which such data collection period
23	occurs.
24	"(II) CONTRACT WITH QUALI-
25	FYING INDEPENDENT CLAIMS DATA

1	ENTITY FOR ACCESS TO APPLICABLE
2	INFORMATION.—As soon as prac-
3	ticable after the date of enactment of
4	this clause, the Secretary shall iden-
5	tify and enter into a contract with a
6	qualifying independent claims data en-
7	tity for the purpose of, with respect to
8	widely available non-ADLT clinical di-
9	agnostic laboratory tests furnished
10	during a data collection period, such
11	entity reporting to the Secretary ap-
12	plicable information from a qualifying
13	comprehensive claims database of the
14	entity for such tests for which final
15	payment is made under this part dur-
16	ing the year in which such data collec-
17	tion period occurs and for which there
18	is applicable information within such
19	database for such period.".
20	(B) in subparagraph (B)—
21	(i) in clause (i), by striking "2025"
22	and inserting "2027";
23	(ii) in clause (ii), by striking "begin-
24	ning January 1, 2026, and ending March
25	31, 2026" and inserting "beginning Janu-

1	ary 1, 2028, and ending March 31, 2028";
2	and
3	(iii) in clause (iii), by striking "three
4	years" and inserting "4 years"; and
5	(2) in paragraph (2)—
6	(A) by striking "Definition of Applica-
7	BLE LABORATORY.—In this section, the term
8	'applicable laboratory' means" and inserting
9	"Definitions.—In this section:"
10	"(A) APPLICABLE LABORATORY.—
11	"(i) Reporting periods before
12	2028.—With respect to reporting periods
13	beginning before January 1, 2028, the
14	term 'applicable laboratory' means';
15	(B) in subparagraph (A), as inserted by
16	subparagraph (A) of this paragraph—
17	(i) in clause (i), in the second sen-
18	tence, by striking "paragraph" and insert-
19	ing "clause"; and
20	(ii) by adding at the end the following
21	new clause:
22	"(ii) Reporting periods beginning
23	DURING 2028 AND SUBSEQUENT YEARS.—
24	With respect to reporting periods begin-
25	ning on or after January 1, 2028, the term

1	'applicable laboratory' shall have the mean-
2	ing given such term in section 414.502 of
3	title 42, Code of Federal Regulations, as in
4	effect on May 1, 2025, except without ap-
5	plication of paragraph (3) of such sec-
6	tion."; and
7	(C) by adding at the end the following new
8	subparagraphs:
9	"(B) Non-widely available non-adlt
10	CLINICAL DIAGNOSTIC LABORATORY TEST.—
11	The term 'non-widely available non-ADLT clin-
12	ical diagnostic laboratory test' means, with re-
13	spect to a reporting period, a clinical diagnostic
14	laboratory test that is not an advanced diag-
15	nostic laboratory test and that is not described
16	in subparagraph (E).
17	"(C) Qualifying independent claims
18	DATA ENTITY.—The term 'qualifying inde-
19	pendent claims data entity' means an entity
20	that satisfies each of the following criteria:
21	"(i) The entity is a national nonprofit
22	organization that is not affiliated with any
23	Government agency, insurance issuer,
24	group health plan, provider of services or

1	supplier, or other organization in the
2	health care sector.
3	"(ii) The entity collects data and
4	maintains a qualifying comprehensive
5	claims database (as defined in subpara-
6	graph (D)).
7	"(iii) The entity is certified by the
8	Secretary to be a qualified entity (as de-
9	fined in paragraph (2) of section 1874(e))
10	with respect to having access to data de-
11	scribed in paragraph (3) of such section.
12	"(iv) The entity, with respect to all
13	data included in the qualifying comprehen-
14	sive claims database of the entity, complies
15	with all applicable Federal and State pri-
16	vacy and security requirements, including
17	HIPAA privacy and security law (as de-
18	fined in section 3009 of the Public Health
19	Service Act).
20	"(v) The entity applies quality assur-
21	ance processes to validate all data that is
22	included in the qualifying comprehensive
23	claims database of the entity, including
24	comprehensive statistical testing.

1	"(D) QUALIFYING COMPREHENSIVE
2	CLAIMS DATABASE.—The term 'qualifying com-
3	prehensive claims database' means an inde-
4	pendent database of private payor claims data,
5	which—
6	"(i) includes at least 50,000,000,000
7	claims from more than 50 private payors
8	and claims administrators;
9	"(ii) is a statistically significant repos-
10	itory of claims data that is representative
11	for all 50 States and the District of Co-
12	lumbia;
13	"(iii) includes only data that is vali-
14	dated by quality assurance processes, in-
15	cluding comprehensive statistical testing;
16	"(iv) complies with all applicable Fed-
17	eral and State privacy and security re-
18	quirements, as described in subparagraph
19	(C)(iv);
20	"(v) provides for version control of
21	claims to enable the collation and submis-
22	sion, for purposes of this section, of only
23	claims representative of final payment
24	amounts; and

1	(vi) includes claims data with respect
2	to widely available non-ADLT clinical diag-
3	nostic laboratory tests.
4	"(E) WIDELY AVAILABLE NON-ADLT CLIN-
5	ICAL DIAGNOSTIC LABORATORY TEST.—The
6	term 'widely available non-ADLT clinical diag-
7	nostic laboratory test' means, with respect to a
8	reporting period, a clinical diagnostic laboratory
9	test that is not an advanced diagnostic labora-
10	tory test and for which, during the first 6
11	months of the year immediately preceding the
12	data collection period for such reporting period
13	the number of providers of services and sup-
14	pliers receiving payments under this section (as
15	determined by the Secretary using the national
16	provider identifier of the provider of services or
17	supplier on the claim submitted for payment
18	under this part for such test) exceeds 100.";
19	(3) in paragraph (5)—
20	(A) by inserting "final" after "The"; and
21	(B) by inserting "or from a qualifying
22	comprehensive claims database pursuant to
23	paragraph (1)(A)(ii)" after "reported by a lab-
24	oratory under this subsection";
25	(4) in paragraph (6)—

1	(A) by inserting "(or, with respect to a
2	widely available non-ADLT clinical diagnostic
3	laboratory test, the qualifying comprehensive
4	claims database of the qualifying independent
5	claims data entity with a contract under para-
6	graph (1)(A)(ii))" after "In the case where an
7	applicable laboratory";
8	(B) by striking "payment rate" each place
9	it appears and inserting "final payment rate";
10	(C) by inserting "(and such different pay-
11	ment rates do not relate to the same claim)"
12	after "for the same payor for the same test";
13	and
14	(D) by inserting "or qualifying inde-
15	pendent claims data entity, as applicable," after
16	"the applicable laboratory";
17	(5) in paragraph (9)(A), by inserting "required
18	to be reported by such laboratory" after "in report-
19	ing information";
20	(6) in paragraph (10)—
21	(A) by striking "by a laboratory" after
22	"information disclosed"; and
23	(B) by inserting "by a laboratory or the
24	qualifying independent claims data entity with a

1	contract under paragraph (1)(A)(11) after
2	"under this subsection"; and
3	(7) in paragraph (12)—
4	(A) by striking "Regulations.—Not later
5	than June 30, 2015," and inserting "Regula-
6	TIONS.—
7	"(A) For data collection periods be-
8	FORE 2027.—Not later than June 30, 2015, for
9	data collection periods beginning before Janu-
10	ary 1, 2027,"; and
11	(B) by adding at the end the following new
12	subparagraph:
13	"(B) For data collection periods be-
14	GINNING WITH 2027.—Not later than December
15	31, 2026, the Secretary shall establish through
16	notice and comment rulemaking parameters for
17	data collection periods beginning on or after
18	January 1, 2027.".
19	(b) Incorporating Data Collection Improve-
20	MENTS INTO PRIVATE PAYOR-BASED MEDICARE PAY-
21	MENT RATES FOR CLINICAL DIAGNOSTIC LABORATORY
22	TESTS THAT ARE NOT ADVANCED DIAGNOSTIC LABORA-
23	TORY TESTS.—
24	(1) CALCULATION OF WEIGHTED MEDIAN OF
25	PRIVATE PAYOR-BASED RATES.—Section

1 1834A(b)(2) of the Social Security Act (42 U.S.C. 2 1395m-1(b)(2) is amended— 3 (A) by inserting "and, in the case of widely 4 available non-ADLT clinical diagnostic labora-5 tory tests, with respect to data collection peri-6 ods for reporting periods beginning on or after 7 January 1, 2028, for each such test furnished 8 by an applicable laboratory with respect to 9 which there is applicable information made 10 available to the Secretary pursuant to para-11 graph (1)(A)(ii)) of such subsection" after 12 "under subsection (a) for a data collection pe-13 riod"; and 14 (B) by inserting "final" before "payment rates reported". 15 16 (2) Default adjustment in cases of wide-17 AVAILABLE NON-ADLT CLINICAL DIAGNOSTIC 18 LABORATORY TESTS FOR PERIODS FOR WHICH 19 THERE IS NO CONTRACT WITH A QUALIFYING INDE-20 PENDENT CLAIMS ENTITY OR NO APPLICABLE IN-21 FORMATION IN THE QUALIFYING COMPREHENSIVE 22 CLAIMS DATABASE.—Section 1834A(b) of the Social 23 Security Act (42 U.S.C. 1395m-1(b)) is amended—

1	(A) in paragraph (1)(A), by striking
2	"paragraph (3)" and inserting "paragraphs (3)
3	and (6)"; and
4	(B) by adding at the end the following new
5	paragraph:
6	"(6) Default payment for widely avail-
7	ABLE NON-ADLT CLINICAL DIAGNOSTIC LABORATORY
8	TESTS FOR PERIODS FOR WHICH THERE IS NO CON-
9	TRACT WITH AN INDEPENDENT ENTITY OR WITH
10	RESPECT TO WHICH THERE IS NO DATA.—
11	"(A) IN GENERAL.—With respect to data
12	collection periods for reporting periods begin-
13	ning on or after January 1, 2028, in the case
14	of a widely available non-ADLT clinical diag-
15	nostic laboratory test with respect to which sub-
16	section (c) does not apply, if a circumstance de-
17	scribed in subparagraph (B) applies with re-
18	spect to such a reporting period and such a
19	clinical diagnostic laboratory test, payment for
20	such test under this section for a year begin-
21	ning during the qualified rate period described
22	in subparagraph (C), shall be equal to the
23	amount of payment for such clinical diagnostic
24	laboratory test under this section for the pre-
25	vious year, increased by the percentage increase

1	in the Consumer Price Index for all urban con-
2	sumers (all items; United States city average)
3	over the previous year.
4	"(B) CIRCUMSTANCES DESCRIBED.—For
5	purposes of subparagraph (A), with respect to
6	a data collection period and a widely available
7	non-ADLT clinical diagnostic laboratory test
8	the circumstances described in this subpara-
9	graph are if the Secretary—
10	"(i) is not able to enter into a con-
11	tract under subsection $(a)(1)(A)(ii)$ with a
12	qualifying independent claims data entity
13	with respect to such data collection period
14	or
15	"(ii) determines that there is no appli-
16	cable information with respect to such clin-
17	ical diagnostic laboratory test and data col-
18	lection period in the qualifying comprehen-
19	sive claims database of such qualifying
20	independent claims data entity.
21	"(C) QUALIFIED RATE PERIOD DE
22	SCRIBED.—For purposes of subparagraph (A)
23	the qualified rate period, with respect to a data
24	collection period and a widely available non-
25	ADLT clinical diagnostic test to which a cir-

1	cumstance described in subparagraph (B) ap-
2	plies, is the period—
3	"(i) beginning on the first day of the
4	second year following the first data collec-
5	tion period with respect to which such cir-
6	cumstance applies with respect to such
7	test; and
8	"(ii) ending with the last day of the
9	year following the first data collection pe-
10	riod with respect to which such cir-
11	cumstance no longer applies with respect
12	to such test.".
13	(3) Payment in cases in which there is no
14	REPORTED APPLICABLE INFORMATION FOR NON-
15	WIDELY AVAILABLE NON-ADLTS.—Section 1834A of
16	the Social Security Act (42 U.S.C. 1395m-1), is
17	amended—
18	(A) in subsection (b), as amended by para-
19	graph (2)—
20	(i) in paragraph (1)(A), by striking
21	"paragraphs (3) and (6)" and inserting
22	"paragraphs (3), (6), and (7)"; and
23	(ii) by adding at the end the following
24	new paragraph:

1	"(7) PAYMENT FOR NON-WIDELY AVAILABLE
2	NON-ADLT CLINICAL DIAGNOSTIC LABORATORY
3	TESTS FOR WHICH THERE IS NO APPLICABLE IN-
4	FORMATION.—
5	"(A) In general.—For determining pay-
6	ment under this subsection for a year in the
7	case of a non-widely available non-ADLT clin-
8	ical diagnostic laboratory test with respect to
9	which subsection (c) does not apply, if the Sec-
10	retary determines that no applicable informa-
11	tion has been reported under subsection
12	(a)(1)(A)(i) by any applicable laboratory for
13	such test with respect to the most recent data
14	collection period (beginning with data collection
15	periods for reporting periods beginning on or
16	after January 1, 2028), payment for such test
17	under this section for such year shall be deter-
18	mined as follows:
19	"(i) In the case that a process de-
20	scribed in subparagraph (B) was not ap-
21	plied pursuant to this subparagraph for de-
22	termining payment for such test for a pre-
23	vious year with respect to such data collec-
24	tion period, payment for such test and year
25	shall be determined using such a process

1	"(ii) In the case that a process de-
2	scribed in subparagraph (B) was applied
3	pursuant to this subparagraph for deter-
4	mining payment for such test for a pre-
5	vious year with respect to such data collec-
6	tion period, payment for such test and year
7	shall be equal to the amount of payment
8	for such test under this section for the pre-
9	vious year.
10	"(B) Process described.—For purposes
11	of subparagraph (A), a process described in this
12	subparagraph, with respect to a non-widely
13	available non-ADLT clinical diagnostic labora-
14	tory test for which there is no reported data (as
15	described in such subparagraph) with respect to
16	a data collection period, is—
17	"(i) cross-walking (as described in
18	section 414.508(a) of title 42, Code of
19	Federal Regulations, or any successor reg-
20	ulation) to the most appropriate clinical di-
21	agnostic laboratory test under the fee
22	schedule under this section during that pe-
23	riod; or
24	"(ii) if no other clinical diagnostic lab-
25	oratory test is comparable to the test for

1	which there is no reported applicable infor-
2	mation, according to the gapfilling process
3	described in subsection (c)(2)."; and
4	(B) in subsection (c)(3), by inserting "or
5	subsection (b)(7)" after "under this sub-
6	section".
7	(4) Publicly available explanation of
8	PAYMENT RATES.—Section 1834A(b) of the Social
9	Security Act (42 U.S.C. 1395m-1(b)), as amended
10	by paragraphs (2) and (3)(A), is amended by adding
11	at the end the following new paragraph:
12	"(8) Explanation of payment rates.—In
13	the case of a clinical diagnostic laboratory test for
14	which payment is made under this subsection, the
15	Secretary shall make available to the public an ex-
16	planation of the payment rate for such test, includ-
17	ing any supporting data as may be necessary for a
18	laboratory to assess the accuracy of the calcula-
19	tions.".
20	(5) Technical correction clarifying pe-
21	RIOD OF APPLICATION OF MARKET RATES.—Section
22	1834A(b)(4)(A) of the Social Security Act (42
23	U.S.C. 1395m-1(b)(4)(A)) is amended by striking
24	"until the year following" and inserting "through
25	the year following".

1	(c) ADDITIONAL IMPROVEMENTS TO ENSURE UP-
2	DATED, ACCURATE MARKET-BASED DATA FOR CLINICAL
3	DIAGNOSTIC LABORATORY TESTS.—
4	(1) Updates to applicable information to
5	BETTER REFLECT FINAL PAYMENT RATES.—Section
6	1834A(a)(3) of the Social Security Act (42 U.S.C.
7	1395m-1(a)(3)) is amended—
8	(A) in the heading, by inserting "AND
9	FINAL PAYMENT RATE" after "INFORMATION";
10	(B) in subparagraph (A)—
11	(i) in the heading, by striking "IN
12	GENERAL" and inserting "Data collec-
13	TION PERIODS BEFORE JANUARY 1, 2027";
14	and
15	(ii) in the matter preceding clause
16	(i)—
17	(I) by striking "subparagraph
18	(B)" and inserting "subparagraph
19	(C)"; and
20	(II) by inserting "beginning be-
21	fore January 1, 2027" after "for a
22	data collection period";
23	(C) by redesignating subparagraph (B) as
24	subparagraph (C);

1	(D) by inserting after subparagraph (A)
2	the following new subparagraph:
3	"(B) Subsequent data collection pe-
4	RIODS.—In this section, subject to subpara-
5	graph (C), for a data collection period begin-
6	ning on or after January 1, 2027, the term 'ap-
7	plicable information' means—
8	"(i) with respect to a widely available
9	non-ADLT clinical diagnostic laboratory
10	test furnished during such period—
11	"(I) the final payment rate (as
12	determined in accordance with para-
13	graph (5) and defined in subpara-
14	graph (D)) that was paid by each pri-
15	vate payor for the test during the year
16	in which such period occurs; and
17	"(II) the volume, for each such
18	payor, of such test for which final
19	payment was made during such year;
20	and
21	"(ii) with respect to a non-widely
22	available non-ADLT clinical diagnostic lab-
23	oratory test or an advanced diagnostic lab-
24	oratory test—

1	"(1) the final payment rate (as
2	determined in accordance with para-
3	graph (5) and defined in subpara-
4	graph (D)) that was paid by each pri-
5	vate payor for the test during the
6	data collection period; and
7	"(II) the volume, for each such
8	payor, of such test for which final
9	payment was made during such pe-
10	riod."; and
11	(E) by inserting after subparagraph (C),
12	the following new subparagraph:
13	"(D) Final payment rate.—In this sec-
14	tion, for a data collection period beginning on
15	or after January 1, 2027, the term 'final pay-
16	ment rate'—
17	"(i) means—
18	"(I) with respect to a widely
19	available non-ADLT clinical diag-
20	nostic laboratory test furnished during
21	a data collection period, the last pay-
22	ment made for a test during the year
23	in which the data collection period oc-
24	curs; and

1	"(II) with respect to a non-widely
2	available non-ADLT clinical diag-
3	nostic laboratory test or an advanced
4	diagnostic laboratory test paid during
5	a data collection period, the last pay-
6	ment made during the data collection
7	period; and
8	"(ii) does not include—
9	"(I) denied payments;
10	"(II) payments under appeal or
11	under review by the private payor;
12	"(III) payments made in error
13	or
14	"(IV) payments that are re-
15	couped by the private payor.".
16	(2) Updating data collection periods.—
17	Section 1834A(a)(4)(B) of the Social Security Act
18	(42 U.S.C. 1395m-1(a)(4)(B)) is amended—
19	(A) by striking "January 1, 2019" and in-
20	serting "January 1, 2027";
21	(B) by striking "June 30, 2019" and in-
22	serting "June 30, 2027"; and
23	(C) by adding at the end the following new
24	sentence: "In the case of the reporting period
25	after the reporting period described in para-

1	graph (1)(B)(11) and each subsequent reporting
2	period with respect to clinical diagnostic labora-
3	tory tests that are not advanced diagnostic lab-
4	oratory tests, the term 'data collection period'
5	means the 6-month period beginning January
6	1st of the year preceding the year during which
7	such reporting period begins.".
8	(3) Ensuring data is market-based by ex-
9	CLUDING RATES OF MEDICAID MANAGED CARE OR-
10	GANIZATIONS.—Section 1834A(a)(8)(C) of the So-
11	cial Security Act (42 U.S.C. 1395m-1(a)(8)(C)) is
12	amended by striking "A medicaid managed care or-
13	ganization" and inserting "With respect to data col-
14	lection periods for reporting periods beginning before
15	January 1, 2028, a medicaid managed care organi-
16	zation.".
17	(4) Modifications to limits on payment
18	REDUCTIONS.—Section 1834A(b)(3) of the Social
19	Security Act (42 U.S.C. 1395m-1(b)(3)) is amend-
20	ed —
21	(A) in subparagraph (A), by striking "each
22	of 2017 through 2028" and inserting "2017
23	and each subsequent year";
24	(B) in subparagraph (B)—

1	(i) in clause (ii), by striking "2025"
2	and inserting "2028"; and
3	(ii) in clause (iii), by striking "for
4	each of 2026 through 2028, 15 percent"
5	and inserting "for 2029 and each subse-
6	quent year, 5 percent"; and
7	(C) in subparagraph (C)(ii), by inserting
8	"laboratory" after "advanced diagnostic".
9	(5) Sunsetting review limitations.—Sec-
10	tion $1834A(h)(1)$ of the Social Security Act (42)
11	U.S.C. 1395m-1(h)(1)) is amended by inserting
12	"before January 1, 2029" before the period at the
13	end.