115TH CONGRESS
1ST SESSION

H. R. 3178

To amend title XVIII of the Social Security Act to improve the delivery of home infusion therapy and dialysis and the application of the Stark rule under the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. Brady of Texas (for himself, Mr. Neal, Mr. Walden, Mr. Pallone, Mr. Tiberi, Mr. Levin, Mr. Burgess, and Mr. Gene Green of Texas) introduced the following bill, which was referred to the Committee on

A BILL

To amend title XVIII of the Social Security Act to improve the delivery of home infusion therapy and dialysis and the application of the Stark rule under the Medicare program, 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,
3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
4 (a) SHORT TITLE.—This Act may be cited as the
5 “Medicare Part B Improvement Act of 2017”.

(Original Signature of Member)
(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—IMPROVEMENTS IN PROVISION OF HOME INFUSION THERAPY

Sec. 101. Home infusion therapy services temporary transitional payment.
Sec. 102. Extension of Medicare Patient IVIG Access Demonstration Project.
Sec. 103. Orthotist’s and prosthetist’s clinical notes as part of the patient’s medical record.

TITLE II—IMPROVEMENTS IN DIALYSIS SERVICES

Sec. 201. Independent accreditation for dialysis facilities and assurance of high quality surveys.
Sec. 202. Expanding access to home dialysis therapy.

TITLE III—IMPROVEMENTS IN APPLICATION OF STARK RULE

Sec. 301. Modernizing the application of the Stark rule under Medicare.
Sec. 302. Deposit of savings into Medicare Improvement Fund.

TITLE I—IMPROVEMENTS IN PROVISION OF HOME INFUSION THERAPY

SEC. 101. HOME INFUSION THERAPY SERVICES TEMPORARY TRANSITIONAL PAYMENT.

(a) IN GENERAL.—Section 1834(u) of the Social Security Act (42 U.S.C. 1395m(u)) is amended, by adding at the end the following new paragraph:

“(7) Home infusion therapy services temporary transitional payment.—

“(A) Temporary transitional payment.—

“(i) In general.—The Secretary shall, in accordance with the payment methodology described in subparagraph
(B) and subject to the provisions of this paragraph, provide a home infusion therapy services temporary transitional payment under this part to an eligible home infusion supplier (as defined in subparagraph (F)) for items and services described in subparagraphs (A) and (B) of section 1861(iii)(2)) furnished during the period specified in clause (ii) by such supplier in coordination with the furnishing of transitional home infusion drugs (as defined in clause (iii)).

“(ii) Period specified.—For purposes of clause (i), the period specified in this clause is the period beginning on January 1, 2019, and ending on the day before the date of the implementation of the payment system under paragraph (1)(A).

“(iii) Transitional home infusion drug defined.—For purposes of this paragraph, the term ‘transitional home infusion drug’ has the meaning given to the term ‘home infusion drug’ under section 1861(iii)(3)(C), except that clause (ii) of such section shall not apply if a drug de-
scribed in such clause is identified in clauses (i), (ii), (iii) or (iv) of subparagraph (C) as of the date of the enactment of this paragraph.

“(B) PAYMENT METHODOLOGY.—For purposes of this paragraph, the Secretary shall establish a payment methodology, with respect to items and services described in subparagraph (A)(i). Under such payment methodology the Secretary shall—

“(i) create the three payment categories described in clauses (i), (ii), and (iii) of subparagraph (C);

“(ii) assign drugs to such categories, in accordance with such clauses;

“(iii) assign appropriate Healthcare Common Procedure Coding System (HCPCS) codes to each payment category; and

“(iv) establish a single payment amount for each such payment category, in accordance with subparagraph (D), for each infusion drug administration calendar day in the individual’s home for drugs assigned to such category.
“(C) PAYMENT CATEGORIES.—

“(i) PAYMENT CATEGORY 1.—The Secretary shall create a payment category 1 and assign to such category drugs which are covered under the Local Coverage Determination on External Infusion Pumps (LCD number L33794) and billed with the following HCPCS codes (as identified as of July 1, 2017, and as subsequently modified by the Secretary): J0133, J0285, J0287, J0288, J0289, J0895, J1170, J1250, J1265, J1325, J1455, J1457, J1570, J2175, J2260, J2270, J2274, J2278, J3010, or J3285.

“(ii) PAYMENT CATEGORY 2.—The Secretary shall create a payment category 2 and assign to such category drugs which are covered under such local coverage determination and billed with the following HCPCS codes (as identified as of July 1, 2017, and as subsequently modified by the Secretary): J1559 JB, J1561 JB, J1562 JB, J1569 JB, or J1575 JB.

“(iii) PAYMENT CATEGORY 3.—The Secretary shall create a payment category
3 and assign to such category drugs which are covered under such local coverage determination and billed with the following HCPCS codes (as identified as of July 1, 2017, and as subsequently modified by the Secretary): J9000, J9039, J9040, J9065, J9100, J9190, J9200, J9360, or J9370.

“(iv) INFUSION DRUGS NOT OTHERWISE INCLUDED.—With respect to drugs that are not included in payment category 1, 2, or 3 under clause (i), (ii), or (iii), respectively, the Secretary shall assign to the most appropriate of such categories, as determined by the Secretary, drugs which are—

“(I) covered under such local coverage determination and billed under HCPCS codes J7799 or J7999 (as identified as of July 1, 2017, and as subsequently modified by the Secretary); or

“(II) billed under any code that is implemented after the date of the enactment of this paragraph and included in such local coverage deter-
mination or included in subregulatory
guidance as a home infusion drug de-
scribed in subparagraph (A)(i).

“(D) PAYMENT AMOUNTS.—

“(i) IN GENERAL.—Under the pay-
ment methodology, the Secretary shall pay
eligible home infusion suppliers, with re-
spect to items and services described in
subparagraph (A)(i) furnished during the
period described in subparagraph (A)(ii) by
such supplier to an individual, at amounts
equal to the amounts determined under the
physician fee schedule established under
section 1848 for services furnished during
the year for codes and units of such codes
described in clauses (ii), (iii), and (iv) with
respect to drugs included in the payment
category under subparagraph (C) specified
in the respective clause, determined with-
out application of any adjustment under
such section.

“(ii) PAYMENT AMOUNT FOR CAT-
EGORY 1.—For purposes of clause (i), the
codes and units described in this clause,
with respect to drugs included in payment
category 1 described in subparagraph (C)(i), are one unit of HCPCS code 96365 plus four units of HCPCS code 96366 (as identified as of July 1, 2017, and as subsequently modified by the Secretary).

“(iii) PAYMENT AMOUNT FOR CATEGORY 2.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 2 described in subparagraph (C)(i), are one unit of HCPCS code 96369 plus four units of HCPCS code 96370 (as identified as of July 1, 2017, and as subsequently modified by the Secretary).

“(iv) PAYMENT AMOUNT FOR CATEGORY 3.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 3 described in subparagraph (C)(i), are one unit of HCPCS code 96413 plus four units of HCPCS code 96415 (as identified as of July 1, 2017, and as subsequently modified by the Secretary).

“(E) CLARIFICATIONS.—
“(i) Infusion Drug Administration Day.—For purposes of this subsection, a reference, with respect to the furnishing of transitional home infusion drugs or home infusion drugs to an individual by an eligible home infusion supplier, to payment to such supplier for an infusion drug administration calendar day in the individual’s home shall refer to payment only for the date on which professional services (as described in section 1861(iii)(2)(A)) were furnished to administer such drugs to such individual. For purposes of the previous sentence, an infusion drug administration calendar day shall include all such drugs administered to such individual on such day.

“(ii) Treatment of Multiple Drugs Administered on Same Infusion Drug Administration Day.—In the case that an eligible home infusion supplier, with respect to an infusion drug administration calendar day in an individual’s home, furnishes to such individual transitional home infusion drugs which are not
all assigned to the same payment category under subparagraph (C), payment to such supplier for such infusion drug administration calendar day in the individual’s home shall be a single payment equal to the amount of payment under this paragraph for the drug, among all such drugs so furnished to such individual during such calendar day, for which the highest payment would be made under this paragraph.

“(F) ELIGIBLE HOME INFUSION SUPPLIERS.—In this paragraph, the term ‘eligible home infusion supplier’ means a supplier that is enrolled under this part as a pharmacy that provides external infusion pumps and external infusion pump supplies and that maintains all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered.

“(G) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.”.

(b) CONFORMING AMENDMENT.—Section 1842(b)(6)(I) of the Social Security Act (42 U.S.C.
1395u(b)(6)(I)) is amended by inserting “or, in the case of items and services described in clause (i) of section 1834(u)(7)(A) furnished to an individual during the period described in clause (ii) of such section, payment shall be made to the eligible home infusion therapy supplier” after “payment shall be made to the qualified home infusion therapy supplier”.

SEC. 102. EXTENSION OF MEDICARE PATIENT IVIG ACCESS DEMONSTRATION PROJECT.

Section 101(b) of the Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 (42 U.S.C. 1395l note) is amended—

(1) in paragraph (1), by inserting after “for a period of 3 years” the following: “and, subject to the availability of funds under subsection (g)—

“(A) if the date of enactment of the Medicare Part B Improvement Act of 2017 is on or before September 30, 2017, for the period beginning on October 1, 2017, and ending on December 31, 2020; and

“(B) if the date of enactment of such Act is after September 30, 2017, for the period beginning on the date of enactment of such Act and ending on December 31, 2020’’”; and
(2) in paragraph (2), by adding at the end the following new sentence: “Subject to the preceding sentence, a Medicare beneficiary enrolled in the demonstration project on September 30, 2017, shall be automatically enrolled during the period beginning on the date of the enactment of the Medicare Part B Improvement Act of 2017 and ending on December 31, 2020, without submission of another application.”.

SEC. 103. ORTHOTIST’S AND PROSTHETIST’S CLINICAL NOTES AS PART OF THE PATIENT’S MEDICAL RECORD.

Section 1834(h) of the Social Security Act (42 U.S.C. 1395m(h)) is amended by adding at the end the following new paragraph:

“(5) Documentation created by orthotists and prosthetists.—For purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the patient’s medical record to support documentation created by eligible professionals described in section 1848(k)(3)(B).”.

TITLE II—IMPROVEMENTS IN DIALYSIS SERVICES

SEC. 201. INDEPENDENT ACCREDITATION FOR DIALYSIS FACILITIES AND ASSURANCE OF HIGH QUALITY SURVEYS.

(a) ACCREDITATION AND SURVEYS.—

(1) IN GENERAL.—Section 1865 of the Social Security Act (42 U.S.C. 1395bb) is amended—

(A) in subsection (a)—

(i) in paragraph (1), in the matter preceding subparagraph (A), by striking “or the conditions and requirements under section 1881(b)”; and

(ii) in paragraph (4), by inserting “(including a renal dialysis facility)” after “facility”; and

(B) by adding at the end the following new subsection:

“(e) With respect to an accreditation body that has received approval from the Secretary under subsection (a)(3)(A) for accreditation of provider entities that are required to meet the conditions and requirements under section 1881(b), in addition to review and oversight authorities otherwise applicable under this title, the Secretary shall (as the Secretary determines appropriate) conduct,
with respect to such accreditation body and provider entities, any or all of the following more frequently than is otherwise required to be conducted under this title with respect to other accreditation bodies or other provider entities:

“(1) Validation surveys referred to in subsection (d).

“(2) Accreditation program reviews (as defined in section 488.8(e) of title 42 of the Code of Federal Regulations, or a successor regulation).

“(3) Performance reviews (as defined in section 488.8(a) of title 42 of the Code of Federal Regulations, or a successor regulation).”.

(2) **Timing for acceptance of requests from accreditation organizations.**—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall begin accepting requests from national accreditation bodies for a finding described in section 1865(a)(3)(A) of the Social Security Act (42 U.S.C. 1395bb(a)(3)(A)) for purposes of accrediting provider entities that are required to meet the conditions and requirements under section 1881(b) of such Act (42 U.S.C. 1395rr(b)).
(b) Requirement for Timing of Surveys of New Dialysis Facilities.—Section 1881(b)(1) of the Social Security Act (42 U.S.C. 1395rr(b)(1)) is amended by adding at the end the following new sentence: “Beginning 180 days after the date of the enactment of this sentence, an initial survey of a provider of services or a renal dialysis facility to determine if the conditions and requirements under this paragraph are met shall be initiated not later than 90 days after such date on which both the provider enrollment form (without regard to whether such form is submitted prior to or after such date of enactment) has been determined by the Secretary to be complete and the provider’s enrollment status indicates approval is pending the results of such survey.”.

SEC. 202. EXPANDING ACCESS TO HOME DIALYSIS THERAPY.

(a) Allowing Use of Telehealth for Monthly End Stage Renal Disease-related Visits.—

(1) In General.—Paragraph (3) of section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)) is amended—

(A) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively;
(B) in clause (i), as redesignated by sub-paragraph (A), by striking “under this subpara- graph” and inserting “under this clause”;

(C) in clause (ii), as redesignated by sub- paragraph (A), by inserting “subject to sub- paragraph (B),” before “on a comprehensive”;

(D) by striking “With respect to” and in- restoring “(A) With respect to”; and

(E) by adding at the end the following new subparagraph:

“(B)(i) Subject to clause (ii), an individual who is determined to have end stage renal disease and who is re- ceiving home dialysis may choose to receive monthly end stage renal disease-related visits, furnished on or after January 1, 2019, via telehealth.

“(ii) Clause (i) shall apply to an individual only if the individual receives a face-to-face visit, without the use of telehealth—

“(I) in the case of the initial three months of home dialysis of such individual, at least monthly; and

“(II) after such initial three months, at least once every three consecutive months.”.
(2) CONFORMING AMENDMENT.—Paragraph (1) of such section is amended by striking “paragraph (3)(A)” and inserting “paragraph (3)(A)(i)”.

(b) EXPANDING ORIGINATING SITES FOR TELEHEALTH TO INCLUDE RENAL DIALYSIS FACILITIES AND THE HOME FOR PURPOSES OF MONTHLY END STAGE RENAL DISEASE-RELATED VISITS.—

(1) IN GENERAL.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) is amended—

(A) in paragraph (4)(C)(ii), by adding at the end the following new subclauses:

“(IX) A renal dialysis facility, but only for purposes of section 1881(b)(3)(B).

“(X) The home of an individual, but only for purposes of section 1881(b)(3)(B).”; and

(B) by adding at the end the following new paragraph:

“(5) TREATMENT OF HOME DIALYSIS MONTHLY ESRD-RELATED VISIT.—The geographic requirements described in paragraph (4)(C)(i) shall not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of section
1881(b)(3)(B), at an originating site described in subclause (VI), (IX), or (X) of paragraph (4)(C)(ii), subject to applicable State law require-
ments, including State licensure requirements.”.

(2) NO FACILITY FEE IF ORIGINATING SITE FOR HOME DIALYSIS THERAPY IS THE HOME.—Sec-

tion 1834(m)(2)(B) of the Social Security (42 U.S.C. 1395m(m)(2)(B)) is amended—

(A) by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively, and by inden-
ting each of such subclauses 2 ems to the right;

(B) in subclause (II), as redesignated by subparagraph (A), by striking “clause (i) or this clause” and inserting “subclause (I) or this subclause”;

(C) by striking “SITE.—With respect to” and inserting “SITE.—

“(i) IN GENERAL.—Subject to clause (ii), with respect to”; and

(D) by adding at the end the following new clause:

“(ii) NO FACILITY FEE IF ORIGIN- NATING SITE FOR HOME DIALYSIS THER-
APY IS THE HOME.—No facility fee shall
be paid under this subparagraph to an
originating site described in subclause (X)
of paragraph (4)(C)(ii).”.

(c) Clarification Regarding Telehealth Provided to Beneficiaries.—Section 1128A(i)(6) of the
Social Security Act (42 U.S.C. 1320a–7a(i)(6)) is amend-
ed—

(1) in subparagraph (H), by striking “; or” and
inserting a semicolon;

(2) in subparagraph (I), by striking the period
at the end and inserting “; or”; and

(3) by adding at the end the following new sub-
paragraph:

“(J) the provision of telehealth on or after
January 1, 2019, to individuals with end stage
renal disease under title XVIII by a health care
provider for the purpose of furnishing of tele-
health.”.

(d) Study and Report on Further Expansion.—

(1) Study.—The Comptroller General of the
United States shall conduct a study to examine the
benefits and drawbacks of expanding the coverage
under the Medicare program under title XVIII of
the Social Security Act of renal dialysis services as
telehealth services, pursuant to the amendments made by this section, to include coverage of renal dialysis services furnished via telehealth and store-and-forward technologies.

(2) REPORT.—Not later than two years after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the results of the study conducted under paragraph (1).

TITLE III—IMPROVEMENTS IN APPLICATION OF STARK RULE

SEC. 301. MODERNIZING THE APPLICATION OF THE STARK RULE UNDER MEDICARE.

(a) Clarification of the Writing Requirement and Signature Requirement for Arrangements Pursuant to the Stark Rule.—

(1) Writing requirement.—Section 1877(h)(1) of the Social Security Act (42 U.S.C. 1395nn(h)(1)) is amended by adding at the end the following new subparagraph:

“(D) Written requirement clarified.—In the case of any requirement pursuant to this section for a compensation arrangement to be in writing, such requirement shall be satisfied by such means as determined by the Secretary, including by a collec-
tion of documents, including contemporaneous docu-
ments evidencing the course of conduct between the
parties involved.”.

(2) Signature requirement.—Section
1877(e) of the Social Security Act (42 U.S.C.
1395nn(e)) is amended—

(A) in paragraph (1)(A)(i), by inserting
“before or not later than 90 days after the ef-
fective date of the lease” after “signed by the
parties”;

(B) in paragraph (1)(B)(i), by inserting
“before or not later than 90 days after the ef-
fective date of the lease” after “signed by the
parties”; and

(C) in paragraph (3)(A)(i), by inserting
“before or not later than 90 days after the ef-
fective date of the arrangement” after “signed
by the parties”.

(b) Indefinite Holdover for Lease Arran-
gements and Personal Services Arrangements Pur-
suant to the Stark Rule.—Section 1877 of the Social
Security Act (42 U.S.C. 1395nn) is amended—

(1) in subsection (e)—

(A) in paragraph (1), by adding at the end
the following new subparagraph:
“(C) HOLDOVER LEASE ARRANGEMENTS.—In the case of a holdover lease arrangement for the lease of office space or equipment, which immediately follows a lease arrangement described in subparagraph (A) for the use of such office space or subparagraph (B) for the use of such equipment and that expired after a term of at least one year, payments made by the lessee to the lessor pursuant to such holdover lease arrangement, if—

“(i) the lease arrangement met the conditions of subparagraph (A) for the lease of office space or subparagraph (B) for the use of equipment when the arrangement expired;

“(ii) the holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement; and

“(iii) the holdover arrangement continues to satisfy the conditions of subparagraph (A) for the lease of office space or subparagraph (B) for the use of equipment.”; and

(B) in paragraph (3), by adding at the end the following new subparagraph:
“(C) HOLDOVER PERSONAL SERVICE ARRANGEMENT.—In the case of a holdover personal service arrangement, which immediately follows an arrangement described in subparagraph (A) that expired after a term of at least one year, remuneration from an entity pursuant to such holdover personal service arrangement, if—

“(i) the personal service arrangement met the conditions of subparagraph (A) when the arrangement expired;

“(ii) the holdover personal service arrangement is on the same terms and conditions as the immediately preceding arrangement; and

“(iii) the holdover arrangement continues to satisfy the conditions of subparagraph (A).”; and

(2) in subsection (h)(1), as amended by subsection (a)(1)—

(A) in the heading, by inserting “; HOLDOVER ARRANGEMENT” after “REMUNERATION”; and

(B) by adding at the end the following new subparagraph:
“(E) HOLDOVER ARRANGEMENT.—The term ‘holdover arrangement’ means an arrangement, with respect to an agreement (including a lease or other arrangement) that has expired but as of the date of such expiration had been in compliance with the applicable requirements of this section, under which the parties to such expired agreement have, since such date of expiration, continued to perform under the terms and conditions of such expired agreement.”.

SEC. 302. DEPOSIT OF SAVINGS INTO MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)) is amended by inserting after “during and after fiscal year 2021, $270,000,000” the following: “minus such dollar amount equal to the amount by which the projected expenditures under this title after application of the provisions of (including amendments made by) the Medicare Part B Improvement Act of 2017 (other than section 302 of such Act) are estimated to exceed the projected expenditures under this title without application of such provisions (other than such section 302)”.