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114TH CONGRESS
2D SESSION

H. R. 5506

To amend title XVIII of the Social Security Act to establish a demonstration program to provide integrated care for Medicare beneficiaries with end-stage renal disease, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 16, 2016

Mr. YOUNG of Indiana (for himself, Mr. BLUMENAUER, Mrs. MCMORRIS RODGERS, and Mr. CÁRDENAS) 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

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A BILL

To amend title XVIII of the Social Security Act to establish a demonstration program to provide integrated care for Medicare beneficiaries with end-stage renal disease, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Dialysis PATIENT Demonstration Act of 2016" or the "Patient Access To

Integrated-care, Empowerment, Nephrologists and Treatment Demonstration Act of 2016''.

SEC. 2. DEMONSTRATION PROGRAM TO PROVIDE INTEGRATED CARE FOR MEDICARE BENEFICIARIES WITH END-STAGE RENAL DISEASE.

Title XVIII of the Social Security Act is amended by inserting after section 1866E the following new section:

''DEMONSTRATION PROGRAM TO PROVIDE INTEGRATED CARE FOR MEDICARE BENEFICIARIES WITH END-STAGE RENAL DISEASE

''SEC. 1866F. (a) ESTABLISHMENT.—

''(1) IN GENERAL.—The Secretary shall conduct under this section the ESRD Integrated Care Demonstration Program (in this section referred to as the 'Program') which is voluntary for patients and providers to assess the effects of alternative care delivery models on patient care improvements under this title for Program-eligible beneficiaries (as defined in paragraph (2)). Under the Program, eligible participating providers (as defined in such paragraph) may form an ESRD Integrated Care Organization (in this section referred to as an 'Organization'). An Organization shall integrate care and serve as the medical home for Program-eligible beneficiaries.

''(2) DEFINITIONS.—In this section:

"(A) ELIGIBLE PARTICIPATING PROVIDER.—The term 'eligible participating provider' means the following:

"(i) A facility certified as a renal dialysis facility under this title.

"(ii) A dialysis organization that owns one or more of such facilities described in clause (i).

"(iii) A nephrologist or nephrology practice.

"(iv) Any other physician group practice or a group of affiliated physicians.

"(B) ELIGIBLE PARTICIPATING PARTNER.—The term 'eligible participating partner' means the following:

"(i) A Medicare Advantage plan described in section 1851(a)(2) or a Medicare Advantage organization offering such a plan.

"(ii) A prescription drug plan (as defined in section 1860D–41(a)(14)).

"(iii) A medicaid managed care organization (as defined in section 1903(m)).

"(iv) An entity able to bear risk as deemed by a State.

''(v) A third party-administrator organization.

''(C) PROGRAM-ELIGIBLE BENEFICIARY.—The term 'Program-eligible beneficiary' means, with respect to an Organization offering an ESRD Integrated Care Model, an individual entitled to benefits under part A and enrolled under part B who—

''(i) is 18 years of age or older;

''(ii) is identified by the Secretary or the Organization as receiving renal dialysis services under the original medicare fee-for-service program under parts A and B;

''(iii) resides in the service area of such Organization;

''(iv) receives renal dialysis services primarily from a facility that participates in such Organization; and

''(v) has not received a successful kidney transplant.

''(b) ESRD INTEGRATED CARE ORGANIZATION ELIGIBILITY REQUIREMENTS.—

''(1) ORGANIZATIONS.—

''(A) IN GENERAL.—One or more eligible participating providers may establish an Orga-

nization or may enter into, subject to subparagraph (B), one or more partnership, ownership, or co-ownership agreements with one or more eligible participating partners to establish an Organization.

''(B) LIMITATION ON NUMBER OF AGREEMENTS.—The Secretary may specify a limitation on the number of Organizations in which an eligible participating partner may participate under agreements described in subparagraph (A).

''(2) ESRD INTEGRATED CARE MODEL.—

''(A) BENEFITS REQUIREMENTS.—

''(i) IN GENERAL.—Subject to clause (iii), an Organization shall offer at least one ESRD Integrated Care Model that is an open network model (as described in subparagraph (B)(i)) in each of its service areas and may offer one or more ESRD Integrated Care Models that is a preferred network model (as described in subparagraph (B)(ii)) in each of its service areas. For purposes of this section an ESRD Integrated Care Model (in this section referred to as the 'Model')—

''(I) shall cover all benefits under parts A and B (other than hospice care) and include benefits for transition (including education) into palliative care; and

''(II) may, through a partnership or other agreement with an MA–PD plan under part C or prescription drug plan under part D, cover all prescription drug benefits under such part D.

''(ii) TREATMENT OF SAVINGS.—

''(I) IN GENERAL.—Any Organization offering an ESRD Integrated Care Model shall provide for the return under subclause (IV) to a Program-eligible beneficiary enrolled in the Organization of the amount, if any, by which the payment amount described in subclause (III) with respect to the Program-eligible beneficiary for a year exceeds the revenue amount described in subclause (II) with respect to the Program-eligible beneficiary for the year.

"(II) REVENUE AMOUNT DESCRIBED.—The revenue amount described in this subclause, with respect to an Organization offering an ESRD Integrated Care Model and a Program-eligible beneficiary enrolled in such Organization, is the Organization's estimated average revenue requirements, including administrative costs and return on investment, for the Organization to provide the benefits described in clause (i) under the Model for the Program-eligible beneficiary for the year.

"(III) PAYMENT AMOUNT DESCRIBED.—The payment amount described in this subclause, with respect to an Organization offering an ESRD Integrated Care Model and a Program-eligible beneficiary enrolled in such Organization, is the payment amount to the Organization under subsection (f)(1) made with respect to the Program-eligible beneficiary for the year.

"(IV) MEANS OF RETURNING SAVINGS TO PROGRAM-ELIGIBLE BENEFICIARIES ENROLLED IN ORGANIZATIONS.—An Organization shall return the amount under subclause (I) to a Program-eligible beneficiary enrolled in the Organization in a manner specified by the Organization, which may include cost-sharing lower than otherwise applicable, benefits not covered under the original medicare fee-for-service program, or financial incentives (such as reduced cost sharing) for Program-eligible beneficiaries enrolled in the Organization to promote the delivery of high-value and efficient care and services.

"(iii) BENEFIT REQUIREMENTS FOR DUAL ELIGIBLES.—In the case of a Program-eligible beneficiary who is eligible for benefits under this title and title XIX, an Organization, in accordance with an agreement entered into under subsection (f)(4)—

''(I) may be responsible for providing, or arranging for the provision of, all benefits (other than long-term services and supports) for which the Program-eligible beneficiary is eligible for under the State Medicaid program under title XIX in which the Program-eligible beneficiary is enrolled; and

''(II) may elect to provide, or arrange for the provision of, long-term services and supports available to the Program-eligible beneficiary under the State Medicaid program.

''(B) REQUIREMENTS FOR OPEN NETWORK AND PREFERRED NETWORK MODELS.—

''(i) OPEN NETWORK MODEL.—Under an ESRD Integrated Care Model offered by an Organization that is an open network model, the Organization shall—

''(I) allow Program-eligible beneficiaries to receive such covered benefits from any provider of services or supplier regardless of whether such

provider is within the network assembled under subclause (I);

"(II) pay any Medicare-certified provider or supplier that is not within the network assembled under subclause (I) for such covered benefits an amount equal to the amount the provider or supplier would otherwise receive under this title; and

"(III) not apply any additional premium or cost sharing requirements for such covered benefits in addition to premium or cost sharing requirements, respectively, that would be applicable under part A or part B for such benefits.

"(ii) PREFERRED NETWORK MODEL.—Under an ESRD Integrated Care Model offered by an Organization that is a preferred network model, the Organization—

"(I) shall assemble a network of providers of services and suppliers identified by the Organization and confirmed by the Secretary as includ-

ing providers of services and suppliers with significant expertise in caring for individuals with end-stage renal disease through which Program-eligible beneficiaries shall receive covered benefits as described in subparagraph (A) that are required to be covered under the Model;

''(II) may apply premium and cost-sharing requirements, in addition to premium or cost-sharing requirements, respectively, that would be applicable under part B, for benefits in addition to those required to be covered under the Model; and

''(III) shall apply network standards as defined by the Secretary.

''(iii) PROMOTING ACCESS TO HIGH-QUALITY PROVIDERS.—An Organization offering an ESRD Integrated Care Model may develop and implement performance-based incentives for providers of services and suppliers to promote delivery of high quality and efficient care. Such incentives shall be based on clinical measures and

non-clinical measures, such as with respect to notification of patient discharge from a hospital, patient education (such as with respect to treatment options and nutrition), and the interoperability of electronic health records developed by an Organization according to requirements and standards specified by the Secretary pursuant to subparagraph (C).

''(C) QUALITY AND REPORTING REQUIREMENTS.—

''(i) CLINICAL MEASURES.—Under the Program, the Secretary shall—

''(I) require each participating Organization to submit to the Secretary data on clinical measures consistent with those measures submitted by organizations participating in the Comprehensive ESRD Care Initiative operated by the Center for Medicare and Medicaid Innovation as of October 1, 2016, to assess the quality of care provided;

''(II) establish requirements for participating Organizations to report

to the Secretary, in a form and manner specified by the Secretary, information on such measures; and

"(III) establish quality performance standards on such measures to assess the quality of care.

"(ii) REQUIREMENT FOR STAKEHOLDER INPUT.—In developing requirements and standards under subclauses (II) and (III) of clause (i), the Secretary shall request and consider input from a stakeholder board, at least one nephrologist, other suppliers and providers of services, renal dialysis facilities, and beneficiary advocates, and respond in writing to such input.

"(iii) ADDITIONAL ASSESSMENTS AND REPORTING REQUIREMENTS.—The Secretary shall assess the extent to which an Organization delivers integrated and patient-centered care through analysis of information obtained from Program-eligible beneficiaries enrolled in the Organization through surveys, such as the In-Center

Hemodialysis Consumer Assessment of Healthcare Providers and Systems.

''(D) REQUIREMENTS FOR ESRD INTEGRATED CARE STRATEGY.—

''(i) IN GENERAL.—An Organization seeking a contract under this section to offer one or more ESRD Integrated Care Models must develop and submit for the Secretary's approval, subject to clause (ii), an ESRD Integrated Care Strategy.

''(ii) ESRD INTEGRATED CARE STRATEGY.—In assessing an ESRD Integrated Care Strategy under clause (i), the Secretary shall consider the extent to which the Strategy includes elements, such as the following:

''(I) Interdisciplinary care teams led by at least one nephrologist, and comprised of registered nurses, social workers, renal dialysis facility managers, and other representatives from alternative settings described in subclause (VI).

''(II) Health risk and other assessments to determine the physical,

psychosocial, nutrition, language, cultural, and other needs of Program-eligible beneficiaries enrolled in the Organization involved.

''(III) Development and at least annual updating of individualized care plans that incorporate at least the medical, social, and functional needs, preferences, and care goals of Program-eligible beneficiaries enrolled in the Organization.

''(IV) Coordination and delivery of non-clinical services, such as transportation, aimed at improving the adherence of Program-eligible beneficiaries enrolled in the Organization with care recommendations.

''(V) Services, such as transplant evaluation and vascular access care.

''(VI) In the case of an individual who, while enrolled in the Organization, receives confirmation that a kidney transplant is imminent, the provision by an interdisciplinary care team described in subclause (I) of coun-

seling services to such individual on preparation for and potential challenges surrounding such transplant.

''(VII) Delivery of benefits and services in alternative settings, such as the home of the Program-eligible beneficiary enrolled in the Organization, in coordination with the provider or other appropriate stakeholder involved in such delivery serving on an interdisciplinary care team described in subclause (I).

''(VIII) Use of patient reminder systems.

''(IX) Education programs for patients, families, and caregivers.

''(X) Use of health care advice resources, such as nurse advice lines.

''(XI) Use of team-based health care delivery models that provide comprehensive and continuous medical care, such as medical homes.

''(XII) Co-location of providers and services.

"(XIII) Use of a demonstrated capacity to share electronic health record information across sites of care.

"(XIV) Use of programs to promote better adherence to recommended treatment regimens by individuals, including by addressing barriers to access to care by such individuals.

"(XV) Other services, strategies, and approaches identified by the Organization to improve care coordination and delivery.

"(3) DIALYSIS FACILITY OWNERSHIP REQUIREMENT.—The Secretary shall enter into contracts under this section only with Organizations that have at least one eligible participating provider with an ownership interest in a renal dialysis facility in the Organization's service area.

"(4) REQUIREMENT FOR CAPITAL RESERVES.—

"(A) IN GENERAL.—The Secretary shall enter into contracts under this section only with Organizations that demonstrate sufficient capital reserves, measured as a percentage of capitated payments and consistent with require-

ments established by the State in which the Organization operates.

''(B) ALTERNATIVE MECHANISM TO DEMONSTRATE CAPACITY TO BEAR RISK.—An Organization shall be considered to meet the requirement in subparagraph (A) if the Organization includes at least one eligible participating provider or eligible participating partner that is licensed as a risk-bearing entity or deemed by a State as able to bear risk.

''(5) NON-APPLICATION OF CERTAIN PROVISIONS OF LAW.—For purposes of sections 162(m)(6) and 414(m) of the Internal Revenue Code of 1986 and section 9010 of the Patient Protection and Affordable Care Act (26 U.S.C. 4001 note prec.), in the case of an eligible participating provider that establishes an Organization or that enters into a partnership, ownership, or co-ownership agreement to establish an Organization, or an Organization with a contract under this section, risk-based payments in exchange for providing medical care shall not be considered premiums for health insurance coverage.

''(6) TREATMENT AS MEDICARE ADVANCED ALTERNATIVE PAYMENT MODEL.—Alternative care delivery models under the Program shall be treated

under this title as an advanced alternative payment model.

''(c) PROGRAM OPERATION AND SCOPE.—

''(1) IN GENERAL.—Not later than 6 months after the date of enactment of this section, the Secretary shall establish a process through which an Organization can apply to offer one or more ESRD Integrated Care Models. Such application shall include information on at least the following:

''(A) The estimated average revenue amount described in subsection (b)(2)(A)(ii)(II) for the Organization to deliver benefits described in subsection (b)(2)(A).

''(B) Any benefits offered by the Organization beyond those described in such subsection.

''(C) A listing of network providers of services and supplier.

''(D) Information on the expertise of network providers of services and suppliers in serving ESRD patients.

''(E) A description of the ESRD Integrated Care Strategy of the Organization described in subsection (b)(2)(D).

''(2) PROGRAM INITIATION.—The Secretary shall initiate the Program such that Organizations

begin serving Program-eligible beneficiaries not later than January 1, 2018.

''(3) CONTRACT AWARD AND PERIOD.—The Secretary shall enter into contracts for an initial period of not less than 5 years with all Organizations that meet Program requirements.

''(4) PROGRAM EXPANSION.—The Secretary may expand the duration and scope of the Program under this section, to the extent determined appropriate by the Secretary, if the Secretary determines that such expansion will result in improved quality of care under the Medicare program under this title.

''(5) ALLOWANCE FOR LARGER SERVICE AREAS AND EXPANSION OF SERVICE AREAS.—Organizations shall demonstrate in their application that the proposed service area has the capacity to serve Program-eligible beneficiaries through an adequate provider network and is reflective of the communities in which beneficiaries live, work, and obtain health care services.

''(6) CONTRACT TERMINATION.—

''(A) IN GENERAL.—The Secretary may terminate a contract with an Organization under this section if the Secretary determines that an Organization has failed to meet quality

requirements described in subsection (b) or violates other terms of the contract.

"(B) REMEDY AND APPEALS PROCESS.—Prior to the Secretary terminating a contract with an Organization under this section, the Secretary shall afford such Organization sufficient opportunity to remedy any contract violations and appeal a contract termination.

"(C) PROGRAM-ELIGIBLE BENEFICIARY NOTICE AT TIME OF CONTRACT TERMINATION.—Each contract under this section with an Organization shall require the Organization to provide (and pay for) written notice in advance of the contract's termination, as well as a description of alternatives for obtaining benefits under this title, to each Program-eligible beneficiary assigned to or who elected to receive benefits through the Organization under this section.

"(d) IDENTIFICATION OF PROGRAM-ELIGIBLE BENEFICIARIES.—The Secretary shall establish a process for the initial and ongoing identification of Program-eligible beneficiaries that provides for the identification of Program-eligible beneficiaries by Organizations.

"(e) PROGRAM-ELIGIBLE BENEFICIARIES ASSIGNED INTO AN ESRD INTEGRATED CARE ORGANIZATION OPEN NETWORK MODEL.—

"(1) ASSIGNMENT.—

"(A) IN GENERAL.—Under the Program, subject to the succeeding provisions of this paragraph, the Secretary shall, upon the Secretary or an Organization identifying a beneficiary as a Program-eligible beneficiary, assign such Program-eligible beneficiary to an open network model offered by an Organization that includes the dialysis facility at which the Program-eligible beneficiary primarily receives renal dialysis services.

"(B) PROGRAM-ELIGIBLE BENEFICIARY NOTIFICATION OF ASSIGNMENT.—

"(i) IN GENERAL.—Upon assignment of a Program-eligible beneficiary to an Organization, the Secretary shall provide to the Organization written notification of such assignment of such Program-eligible beneficiary and not later than 15 business days after the date of receipt of such notification, the Organization shall provide

written notice of such assignment to the Program-eligible beneficiary.

''(ii) OPT–OUT PERIOD AND CHANGES UPON INITIAL ASSIGNMENT.—The Secretary shall provide for a 75-day period beginning on the date on which the assignment of a Program-eligible beneficiary into an open network model offered by an Organization becomes effective during which a Program-eligible beneficiary may—

''(I) opt out of the Program;

''(II) make a one-time change of assignment into an open network model offered by a different Organization; or

''(III) elect a preferred network model offered by the same or different Organization.

''(C) DEEMED RE-ENROLLMENT.—A Program-eligible beneficiary assigned under this paragraph to an ESRD Integrated Care Model offered by an Organization with respect to a year is deemed, unless the individual elects otherwise under this paragraph, to have elected to

continue such assignment with respect to the subsequent year.

''(D) ADDITIONAL OPPORTUNITY TO OPT OUT OR ELECT DIFFERENT MODEL OR ORGANIZATION.—On the date that is one year after the effective date of the initial assignment of a Program-eligible beneficiary to an open network model offered by an Organization (and annually thereafter), a Program-eligible beneficiary shall be given the opportunity to—

''(i) opt out of the Program;

''(ii) make a one-time change of assignment into an open network model offered by a different Organization; or

''(iii) elect a preferred network model offered by the same or different Organization.

''(E) CHANGE IN PRINCIPAL DIAGNOSIS OPT OUT.—In addition to any other period during which a Program-eligible beneficiary may, pursuant to this paragraph, opt out of the Program, in the case of a Program-eligible beneficiary who, after assignment under this paragraph, is diagnosed with a principal diagnosis (as defined by the Secretary) other than end-

stage renal disease, such individual shall be given the opportunity to opt out of the Program during such period as specified by the Secretary.

''(F) SPECIAL ELECTION PERIODS.—The Secretary shall offer Program-eligible beneficiaries special election periods consistent with those described in section 1851(e)(4).

''(2) PROGRAM-ELIGIBLE BENEFICIARY NOTIFICATION.—

''(A) IN GENERAL.—The Secretary shall notify Program-eligible beneficiaries about the Program under this section and provide them with information about receiving benefits under this title through an Organization.

''(B) REQUIREMENTS.—Notwithstanding any other provision of law, subject to subparagraph (C), such notification shall allow for eligible participating providers that are part of an Organization to—

''(i) inform Program-eligible beneficiaries about the Program;

''(ii) distribute Program materials to Program-eligible beneficiaries; and

"(iii) assist Program-eligible beneficiaries in assessing the options of such beneficiaries under the Program.

"(C) LIMITATION ON UNSOLICITED MARKETING.—

"(i) IN GENERAL.—Under the Program, an eligible participating provider may not provide marketing information or materials, including information, materials, and assistance described in subparagraph (B), to a Program-eligible beneficiary unless the Program-eligible beneficiary requests such marketing information or materials.

"(ii) EXCEPTION FOR PROVIDERS TREATING BENEFICIARIES.—An eligible participating provider that is part of an Organization may provide information, materials, and assistance described in subparagraph (B) to a Program-eligible beneficiary, without prior request of such beneficiary, if such beneficiary is receiving renal dialysis services from such provider.

"(3) PROGRAM-ELIGIBLE BENEFICIARY PROTECTIONS.—Program-eligible beneficiaries enrolled

in an Organization shall have the same right to appeal any denial of benefits under this title as such a Program-eligible beneficiary would have under this title if such Program-eligible beneficiary were not so enrolled.

''(f) PAYMENT.—

''(1) IN GENERAL.—For each Program-eligible beneficiary receiving care through an Organization, the Secretary shall make a monthly capitated payment equal to the amount that would be determined under section 1853(a)(1)(H).

''(2) APPLICATION OF HEALTH STATUS RISK ADJUSTMENT METHODOLOGY.—The Secretary shall adjust the payment amount to an Organization under this subsection in the same manner in which the payment amount to a Medicare Advantage plan is adjusted under section 1853(a)(1)(C).

''(3) PAYMENT FOR PART D BENEFITS.—In the case where an Organization elects to offer part D prescription drug coverage under the Program under this section, payments to the Organization for such benefits provided to Program-eligible beneficiaries by the Organization shall be made in the same manner and amount as those payments would be made in

the case of an Organization with a contract under such part.

''(4) AGREEMENT WITH STATE MEDICAID AGENCY.—In the event of an Organization that elects to cover benefits under title XIX for Program-eligible beneficiaries eligible for benefits under this title and title XIX such Organization shall enter into an agreement with the State Medicaid agency to provide benefits, or arrange for benefits to be provided, for which such beneficiaries are entitled to receive medical assistance under title XIX and to receive payment from the State for providing or arranging for the provision of such benefits.

''(5) AFFIRMATION OF STATE OBLIGATIONS TO PAY PREMIUM AND COST-SHARING AMOUNTS.—

''(A) IN GENERAL.—A State shall continue to make medical assistance under the State plan under title XIX available in the amount described in subparagraph (B) for the duration of the Program for cost-sharing (as defined in section 1905(p)(3)) under this title for qualified medicare beneficiaries described in section 1905(p)(1) and other individuals who are Program-eligible beneficiaries enrolled in an Organization and entitled to medical assistance for

premiums and such cost-sharing under the State plan under title XIX.

"(B) AMOUNTS MADE AVAILABLE FOR COST-SHARING.—For purposes of subparagraph (A):

"(i) IN GENERAL.—Subject to clause (ii), the amount of medical assistance described in this clause to be made available for cost-sharing pursuant to subparagraph (A) for an individual described in such subparagraph entitled to medical assistance for such cost-sharing under a State plan under title XIX shall be equal to the amount of medical assistance that would be made available under such State plan as in effect as of January 1, 2016.

"(ii) AMOUNTS IN THE CASE OF A STATE THAT INCREASES PAYMENTS FOR COST-SHARING.—If a State increases the amount of medical assistance made available under the State plan under title XIX for cost-sharing described in subparagraph (A) after such date, such increased amounts shall be made available under

subparagraph (A) for the remaining duration of the Program.

''(g) WAIVER AUTHORITY.—

''(1) IN GENERAL.—In order to carry out the Program under this section, the Secretary shall waive those requirements waived under section 1899 and may waive such additional requirements consistent with those waived under programs administered through the Center for Medicare and Medicaid Innovation as may be necessary.

''(2) NOTICE OF WAIVERS.—Not later than 3 months after the date of enactment of this section, the Secretary shall publish a notice of waivers that will apply in connection with the Program. The notice shall include the specific conditions that an Organization must meet to qualify for each waiver, and commentary explaining the waiver requirements.''.

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