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116TH CONGRESS
2D SESSION

H. R. 8254

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

SEPTEMBER 15, 2020

Mr. BLUMENAUER (for himself, Mr. SMITH of Missouri, Mr. CÁRDENAS, Mrs. RODGERS of Washington, Mr. BUTTERFIELD, Mr. WENSTRUP, and Ms. SHALALA) 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 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 ''Bringing Enhanced Treatments and Therapies to ESRD Recipients Kidney Care Act'' or the ''BETTER Kidney Care Act''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Although the relative rate of end-stage renal disease (referred to in this section as ''ESRD'') among the Nation's minority populations has declined, significant disparities remain. Compared to Whites, Black Americans are 2.6 times more likely to have kidney failure, while Native Americans and Alaska Natives are 1.2 times more likely. Hispanics are 1.3 times more likely to have kidney failure compared to non-Hispanics.

(2) Disparities also exist with respect to treatment modalities. Specifically, although home dialysis can offer advantages, Black, Hispanic, and Native American and Alaska Native ESRD patients are less likely to initiate home treatment than White ESRD patients.

(3) Numerous studies show that individuals with low incomes and in low-income communities are at greater risk for ESRD.

(4) In addition to their kidney disease, ESRD patients across all races and ethnicities often suffer from one or more comorbidities. Eighty-eight percent of ESRD patients have a history of hypertension, 42 percent have diabetes, and nearly 30 percent have congestive heart failure.

(5) Each month, ESRD patients see multiple providers and take several medications to manage their kidney disease and comorbid conditions. Of all patients, those with ESRD stand to benefit greatly from better coordinated care.

(6) The Executive Order on Advancing American Kidney Health recognizes the need to develop and implement new ESRD care delivery models to improve quality and value for ESRD patients and the Medicare program.

(7) In alignment with that goal, it is imperative that Medicare test new models that have at their core an interdisciplinary care team, among other structural requirements, to—

(A) help ESRD patients better navigate the health care system;

(B) empower such patients to manage their plan of care and medication regimen;

(C) support such patients in receiving the treatment modality, including a kidney transplant, as prescribed by their nephrologist;

(D) access services to meet the nonclinical needs of such patients that can affect care outcomes; and

(E) receive additional services, such as transplant evaluation, palliative care, evaluation for hospice eligibility, and vascular access care.

SEC. 3. DEMONSTRATION PROGRAM TO PROVIDE INTEGRATED CARE FOR MEDICARE BENEFICIARIES WITH END-STAGE RENAL DISEASE.

(a) IN GENERAL.—Title XVIII of the Social Security Act is amended by inserting after section 1866F the following new section:

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

''SEC. 1866G. (a) ESTABLISHMENT.—

''(1) IN GENERAL.—The Secretary shall conduct under this section the ESRD Fee-For-Service Integrated Care Demonstration Program (in this section referred to as the 'Program'), which is voluntary for Program-eligible beneficiaries and eligible participating providers, to assess the effects of alternative care delivery models and payment methodologies on patient care improvements under this title for such beneficiaries. Under the Program—

''(A) Program-eligible beneficiaries shall be considered original Medicare Fee-For-Service beneficiaries (as defined in section 1899(h)(3))

for the duration of the participation of such beneficiaries under the Program;

''(B) eligible participating providers may form an ESRD Fee-For-Service Integrated Care Organization (in this section referred to as an 'Organization'); and

''(C) an Organization shall integrate care under the original Medicare Fee-For-Service program under parts A and B for Program-eligible beneficiaries.

''(2) DEFINITIONS.—In this section:

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

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

''(ii) An entity that owns one or more of such facilities described in clause (i).

''(iii) A nephrologist (including a pediatric nephrologist) or nephrology practice.

''(iv) Any other physician or physician group practice.

''(v) A nurse practitioner, physician assistant, or clinical nurse specialist (as such terms are defined in section

1861(aa)(5)) or a clinical social worker (as defined in section 1861(hh)(1)) working in conjunction with such a nurse practitioner, physician assistant, or clinical nurse specialist.

''(B) ELIGIBLE PARTICIPATING PARTNER.—The term 'eligible participating partner' means, with respect to an Organization, any of the following:

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

''(ii) A medicaid managed care organization (as defined in section 1903(m)).

''(iii) A hospital or an academic medical center experienced in the care of patients receiving dialysis.

''(iv) Any other entity determined appropriate by the Secretary.

''(C) PROGRAM-ELIGIBLE BENEFICIARY.—

''(i) IN GENERAL.—The term 'Program-eligible beneficiary' means, with respect to an Organization offering an ESRD Fee-For-Service Integrated Care

Model, an individual entitled to benefits under part A and enrolled under part B (including such an individual entitled to medical assistance under a State plan under title XIX) who—

''(I) is identified by the Secretary as having end-stage renal disease and who is receiving renal dialysis services under the original Medicare Fee-For-Service program under parts A and B, and is not enrolled in a Medicare Advantage plan under part C or group health insurance coverage or individual health insurance coverage (as defined in section 2791(b) of the Public Health Service Act (42 U.S.C. 300gg–91(b))) that is primary to coverage under this title;

''(II) receives renal dialysis services primarily from an eligible participating provider of such Organization, including such renal dialysis services received after being identified as a suitable candidate for transplantation; and

"(III) has attained the age of 18 years.

"(ii) AFFIRMATION OF PROGRAM ELIGIBILITY UPON HOSPICE ELECTION OR KIDNEY TRANSPLANT.—A Program-eligible beneficiary who was assigned to or elected an ESRD Fee-For-Service Integrated Care Model offered by an Organization and who—

"(I) elects to receive hospice benefits under section 1852(d)(1); or

"(II) receives a kidney transplant as covered under this title and maintains entitlement to benefits under part A and enrollment in part B on the basis of end stage renal disease,

shall continue to meet the definition of Program-eligible beneficiary established under this subparagraph.

"(b) ESRD FEE-FOR-SERVICE INTEGRATED CARE ORGANIZATION ELIGIBILITY REQUIREMENTS.—

"(1) ORGANIZATIONS.—

"(A) IN GENERAL.—One or more eligible participating providers may establish an Organization and may enter into, subject to sub-

paragraph (B), one or more partnership, ownership, or co-ownership agreements with one or more eligible participating partners to establish an Organization or to offer one or more ESRD Fee-For-Service Integrated Care Models in accordance with paragraph (2).

''(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 for purposes of offering one or more ESRD Fee-For-Service Integrated Care Models under partnership, ownership, or co-ownership agreements described in subparagraph (A).

''(C) MINIMUM PROGRAM ELIGIBLE BENEFICIARY PARTICIPATION REQUIREMENT.—

''(i) IN GENERAL.—Subject to clause (ii), the Secretary may not enter into or continue an agreement with an Organization unless the Organization has at least 350 Program-eligible beneficiaries, or at least 60 percent of Program-eligible beneficiaries receiving care from the Organization's facilities, who are assigned to or elect an ESRD Fee-For-Service Integrated

Model offered by the Organization and who continue their assignment to or election of the Organization.

''(ii) ALLOWING TRANSITION.—The Secretary may waive the requirement under clause (i) for an Organization during the first agreement year with respect to the Organization.

''(D) FISCAL SOUNDNESS REQUIREMENTS.—

''(i) IN GENERAL.—The Secretary shall enter into appropriate agreements under this section only with Organizations that demonstrate sufficient capital reserves, measured as a percentage of monthly prospective payments described in subsection (e) and consistent with capital reserve requirements established by each State in which the Organization operates, subject to clause (ii).

''(ii) ALTERNATIVE MECHANISM TO DEMONSTRATE RISK-BEARING CAPACITY.—An Organization shall be considered to meet the requirement in clause (i) if the Organization includes at least one eligible

participating provider or eligible participating partner that—

"(I)(aa) is licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Organization participates in the demonstration under this section; or

"(bb) is otherwise authorized by each state in which the Organization participates in the demonstration under this section to bear risk for offering health insurance or health benefits;

"(II) agrees to bear risk under the Organization; and

"(III) has the capacity to bear risk commensurate with the Organization's expected expenditures under an agreement under this section.

"(iii) DISCLOSURE.—Each Organization with an agreement under this section shall, in accordance with current regulations of the Secretary that govern similar disclosures, report to the Secretary finan-

cial information consistent with such information required to be reported by a Medicare Advantage organization under part C to demonstrate that the Organization has a fiscally sound operation.

''(E) GOVERNANCE REQUIREMENTS.—Each Organization with an agreement under this section shall establish a governing body with oversight responsibility for the Organization's compliance with Program requirements that includes—

''(i) representation from each eligible participating provider of such Organization;

''(ii) at least two nephrologists, one of which may be affiliated with an eligible participating provider; and

''(iii) at least one beneficiary advocate.

''(2) ESRD FEE-FOR-SERVICE INTEGRATED CARE MODEL.—

''(A) BENEFIT REQUIREMENTS.—

''(i) IN GENERAL.—Subject to clause (iii), an Organization shall offer an ESRD

Fee-For-Service Integrated Care Model that shall—

"(I) cover all benefits under parts A and B (subject to payment rules regarding the treatment of and payment for kidney organ acquisitions and hospice described in subsections (e)(3) and (4)); and

"(II) include services for transition (particularly including education) into transplantation, palliative care, and hospice.

"(ii) DETERMINATION AND TREATMENT OF SAVINGS.—

"(I) IN GENERAL.—The Secretary shall require any Organization offering an ESRD Fee-For-Service Integrated Care Model to provide for the return under subclause (VI) to a Program-eligible beneficiary assigned to or who elects an Organization savings equal to the amount, if any, by which the payment amount described in subclause (V) with respect to the Program-eligible beneficiary for a year

exceeds the average revenue amount described in subclause (IV) with respect to the Program-eligible beneficiary for the year.

''(II) SAVINGS DETERMINATION PROCESS.—The Secretary shall determine the savings described in subclause (I) in the same manner as the rebate calculation for individuals with end-stage renal disease enrolled in Medicare Advantage organizations under section 1859(b)(6)(B)(iii).

''(III) APPLICATION OF MEDICAL LOSS RATIO REQUIREMENTS.—Nothing shall preclude the Secretary from applying medical loss ratio requirements described in section 1857(e)(4) under this section.

''(IV) AVERAGE REVENUE AMOUNT DESCRIBED.—The revenue amount described in this subclause, with respect to an Organization offering an ESRD Fee-For-Service Integrated Care Model and a Program-eligible beneficiary assigned to or who

elects 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.

''(V) PAYMENT AMOUNT DESCRIBED.—The payment amount described in this subclause, with respect to an Organization offering an ESRD Fee-For-Service Integrated Care Model and a Program-eligible beneficiary assigned to or who elects such Organization, is the payment amount to the Organization under subsection (e)(1) (adjusted pursuant to subsection (e)(2) and subject to the treatment of payments for kidney acquisitions and hospice care described in paragraphs (3) and (4) of subsection (e), respectively) made with respect to the Program-eligible beneficiary for the year.

''(VI) RETURNING SAVINGS TO PROGRAM-ELIGIBLE BENEFICIARIES.—An Organization shall, in a manner specified by the Secretary and consistent with returning Medicare Advantage rebates to individuals under part C, return the amount under subclause (I) to a Program-eligible beneficiary through offering benefits not covered under the original Medicare Fee-For-Service program consistent with the types of benefits, including non-health related benefits, that Medicare Advantage organizations may offer.

''(iii) BENEFIT REQUIREMENTS FOR DUAL ELIGIBLES.—In the case of a Program-eligible beneficiary who is entitled to medical assistance under a State plan under title XIX, an Organization, in accordance with a mutual agreement entered into between the State and Organization under subsection (e)(7)—

''(I) shall provide, or arrange for the provision of, all benefits (other

than long-term services and supports) for which the Program-eligible beneficiary is entitled to under a State plan under title XIX; and

''(II) may elect to provide, or arrange for the provision of, long-term services and supports for which the Program-eligible beneficiary is entitled under a State plan under title XIX, including services related to the transition into palliative care or hospice.

''(iv) APPLICATION OF MEDICARE FFS PROVIDER CHOICE AND COST-SHARING REQUIREMENTS.—Under an ESRD Fee-For-Service Integrated Care Model offered by an Organization, the Organization shall—

''(I) allow Program-eligible beneficiaries to receive benefits as described in subsection (b)(2)(A)(i)(I) from any provider of services or supplier enrolled under this title and who otherwise meets all applicable requirements under this title;

''(II) not apply any cost-sharing requirements for benefits described in

subsection (b)(2)(A)(i)(I) in addition to premium and cost-sharing requirements, respectively, that would be applicable under part A or part B for such benefits.

''(v) PROMOTING ACCESS TO HIGH-QUALITY PROVIDERS.—An Organization offering an ESRD Fee-For-Service Integrated Care Model shall develop and implement performance-based incentives, including financial incentives funded through payments made to an Organization under subsection (e), for providers of services and suppliers to promote delivery of high quality and efficient care. Such incentives shall comply with section 1852(j)(4) and section 422.208 of title 42, Code of Federal regulations (as in effect on the date of enactment of this section) and be based on clinical measures or non-clinical measures, such as with respect to notification of patient discharge from a hospital, patient education (such as with respect to treatment options, including disease maintenance, and nutrition), rates of completion

of patient education categorized by race, rates of completion of transplant evaluation for patients who are clinically eligible for transplant, rates of completion of transplant evaluation categorized by race, and the interoperability of electronic health records developed by an Organization according to requirements and standards specified by the Secretary pursuant to subparagraph (B).

''(B) 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 developed using, as a reference, measures submitted by organizations participating in the Comprehensive ESRD Care Initiative operated by the Center for Medicare and Medicaid Innovation to assess the quality of care provided;

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

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

''(III) establish standards for making information on quality under the Program established under this section as assessed using clinical measures described in subclause (I) available to the public.

As part of the standards described in subclause (III) the Secretary shall, in consultation with relevant stakeholders, develop standards that would establish a minimum threshold for the volume of individual patients to be listed for transplant in an Organ Procurement and Transplant Network under contract with the Secretary and that would measure the number of individuals that an Organization moved on to, kept on, or removed from the transplant list and the number of individuals that receive a transplant after participating in the Organization. The number of Program-eligible beneficiaries assigned to an Organization on the transplant list that

have not opted out at the time of the agreement between the Secretary and an Organization shall be noted as part of such agreement. Organizations shall submit such measures as a condition of payment and Program-eligible beneficiary assignment under this subsection.

''(ii) REQUIREMENT FOR STAKEHOLDER INPUT.—In developing measures and requirements under subclauses (I) and (II) of clause (i), the Secretary shall request and consider input from a stakeholder board that includes at least one nephrologist, a pediatric nephrologist, other suppliers and providers of services as determined appropriate by the Secretary, renal dialysis facilities, beneficiary advocates, a health equity expert, a mental health provider, a transplant surgeon, and Medicare-approved transplant programs. Section 14 of the Federal Advisory Committee Act shall not apply to the stakeholder board.

''(iii) ADDITIONAL ASSESSMENTS AND REPORTING REQUIREMENTS.—The Sec-

retary shall assess the extent to which an Organization offers integrated and patient-centered care through analysis of information obtained from Program-eligible beneficiaries assigned to or who elect the Organization through surveys, such as the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems.

''(iv) NO EFFECT ON OTHER RENAL DIALYSIS FACILITY QUALITY REQUIREMENTS.—Nothing in this section shall be construed as affecting the requirements established under section 1881(h).

''(C) REQUIREMENTS FOR ESRD FEE-FOR-SERVICE INTEGRATED CARE STRATEGY.—

''(i) IN GENERAL.—An Organization seeking a contract under this section to offer one or more ESRD Fee-For-Service Integrated Care Models shall develop and submit for the Secretary's approval as part of the application of the Organization to participate in the Program under this section, subject to clauses (ii) and (iii), an

ESRD Fee-For-Service Integrated Care Strategy.

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

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

''(II) Use of a decision process for care plans and care management that includes the nephrologist, a member of the transplant evaluation team, and other practitioners responsible for direct delivery of care to Program-eligible beneficiaries assigned to or who elect the Organization involved.

''(III) Use of health risk and other assessments to determine the physical, psychosocial, nutrition, language, cultural, and other needs of Program-eligible beneficiaries assigned to or who elect the Organization involved.

''(IV) 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 assigned to or who elect the Organization, including a discussion on reconsideration of the method and location of dialysis.

''(V) Coordination and furnishing of non-clinical coordination benefits, such as transportation, aimed at improving the adherence of Program-eligible beneficiaries assigned to or who elect the Organization with care recommendations.

''(VI) As appropriate, coordination services, such as transplant eval-

uation, palliative care, evaluation for hospice eligibility, and vascular access care.

''(VII) In the case of an individual who, during an assignment to, or an election of an ESRD Fee-For-Service Integrated Care model offered by an Organization, receives confirmation that a kidney transplant is imminent, the provision of counseling services by an interdisciplinary care team described in subclause (I) to such individual on preparation for and potential benefits and risks associated with such transplant.

''(VIII) Delivery of benefits and services in settings alternative to traditional clinical settings, such as the home of the Program-eligible beneficiary.

''(IX) Use of patient reminder systems.

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

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

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

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

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

''(XV) Use of programs to promote better adherence to recommended treatment regimens, including prescription drug, by individuals, including by addressing barriers to access to care by such individuals, including strategies to coordinate any prescription drug benefits under any prescription drug plan under part D in which a Program-eligible beneficiary is enrolled.

''(XVI) Use of defined protocols, developed in conjunction with the pe-

diatric nephrology community, to facilitate the transition of pediatric individuals into adult end-stage renal disease care.

"(XVII) Use of health equity experts to implement programs and protocols which seek to decrease gender, racial, ethnic, and language inequities.

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

"(3) BENEFICIARY PROTECTIONS.—

"(A) SEAMLESS ACCESS TO CARE.—The Secretary shall ensure that the Organization establishes processes and takes steps necessary, including educating relevant providers of services and suppliers about the Program, to ensure that Program-eligible beneficiaries assigned to or who elected an ESRD Fee-For-Service Integrated Care Model offered by an Organization do not experience any disruption in access to providers of services and suppliers furnishing benefits under this title due to such assignment or election. Assignment to or an election of an

ESRD Fee-For-Service Integrated Care Model offered by an Organization shall not be construed as affecting a Program-eligible beneficiary's ability to receive benefits described in subsection (b)(2)(A)(i)(I) from any provider of services or suppliers enrolled and who otherwise meets requirements under this title, as described in subsection (b)(2)(A)(iv).

''(B) ANTI-DISCRIMINATION.—Each agreement between the Secretary and an Organization under this section shall—

''(i) provide that each eligible participating provider of such Organization may not deny, limit, or condition the furnishing of services, or affect the quality of services furnished, under this title to Program-eligible beneficiaries on whether or not such a beneficiary is assigned to or elects the Organization; and

''(ii) prohibit the Organization from engaging in any activity that could reasonably be expected to have the effect of denying or discouraging assignment to or an election of an ESRD Fee-For-Service Integrated Care Model offered by an Organiza-

tion by a Program-eligible beneficiary whose medical condition or history indicates a need for substantial future medical services.

''(C) QUALITY ASSURANCE; PATIENT SAFEGUARDS.—Each agreement between the Secretary and an Organization under this section shall require that such Organization have in effect at a minimum—

''(i) a written plan of quality assurance and improvement, and procedures implementing such plan, in accordance with regulations; and

''(ii) written safeguards of the rights of Program-eligible beneficiaries assigned to or who elect the Organization (including a patient bill of rights and procedures for grievances and appeals) in accordance with regulations and with other requirements of this title and applicable Federal and State laws designed to protect Program-eligible beneficiaries (including those who are entitled to medical assistance under a State plan under title XIX).

"(D) OVERSIGHT.—The Secretary shall develop and implement an oversight program to monitor an Organization's compliance with Program requirements under an agreement under this section.

"(4) TREATMENT AS ALTERNATIVE PAYMENT MODEL AND ELIGIBLE ALTERNATIVE PAYMENT ENTITY.—

"(A) TREATMENT OF PROGRAM.—The ESRD Fee-For-Service Integrated Care Demonstration Program established under this section shall meet the definition of an alternative payment model described in section 1833(z)(3)(C)(iv).

"(B) TREATMENT OF ORGANIZATION.—An Organization offering one or more ESRD Fee-For-Service Integrated Care Models shall be treated under this section as an eligible alternative payment entity as described in clauses (i) and (ii)(I) of section 1833(z)(3)(D).

"(c) PROGRAM OPERATION AND SCOPE.—

"(1) IN GENERAL.—The Secretary shall develop a process such that an Organization can apply to offer one or more ESRD Fee-For-Service 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 cover benefits described in subsection (b)(2)(A)(i)(I).

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

"(C) A description of the Organization's ESRD Fee-For-Service Integrated Care strategy specified in subsection (b)(2)(D), including a detailed explanation of the Organization's approach to fulfill the requirement to coordinate the delivery of multidisciplinary health and social services that, pursuant to a mutual agreement between a State and Organization, integrates acute and long-term care services and supports.

"(2) PROGRAM INITIATION.—The Secretary shall initiate the Program such that Organizations begin serving Program-eligible beneficiaries not later than January 1, 2024.

"(3) INITIAL AGREEMENT PERIOD.—The Secretary shall enter into agreements for an initial period of not less than 5 years with all Organizations

that meet all Program requirements established under this section, as determined by the Secretary through the application process described in paragraph (1).

''(4) ALLOWANCE FOR SERVICE AREA EXPANSIONS.—During each year of the Program's operation, the Secretary shall allow an Organization with an agreement under this section to expand its service area during the initial agreement period upon the Secretary's determination, through the application process described in paragraph (1), that the Organization meets all Program requirements established under this section.

''(5) CONTRACT SUSPENSION AND TERMINATION PROCESS.—

''(A) IN GENERAL.—Subject to subparagraph (B)(ii), the Secretary may suspend assignment to or an election of an ESRD Fee-For-Service Integrated Care Model offered by an Organization if the Organization fails to comply with any Program requirements specified in an agreement under this section. An Organization also shall be considered not in compliance if, for any calendar month during an agreement year, more than 50 percent of the

total number of Program-eligible beneficiaries assigned to or who elect an ESRD Fee-For-Service Integrated Care Model offered by the Organization opt out of the Program.

''(B) OPPORTUNITY FOR CORRECTIVE ACTION PLAN AND APPEAL.—

''(i) IN GENERAL.—Prior to suspending assignment to or an election of an ESRD Fee-For-Service Integrated Care Model offered by an Organization or terminating an agreement under this section, the Secretary shall afford an Organization sufficient opportunity to remedy any deficiencies in complying with any Program requirements under this section by implementing a corrective action plan. Any corrective action plan implemented under this subparagraph shall specify a date by which the Organization shall resolve such deficiencies and shall remain in effect until such time that the Secretary confirms that the Organization has achieved compliance.

''(ii) IMPOSITION OF AGREEMENT SUSPENSION OR TERMINATION.—In the case of an Organization that fails to achieve

compliance by the date specified in corrective action plan, subject to clause (iii) and depending on the severity of a compliance deficiency, the Secretary in a manner consistent with processes established under part C of this title may—

"(I) suspend Program-eligible beneficiaries' assignments to or an election of an ESRD Fee-For-Service Integrated Care Model offered by an Organization; or

"(II) terminate an agreement with an Organization under this section.

"(iii) IMMEDIATE AGREEMENT TERMINATION FOR VIOLATING THE PROHIBITION ON DISCRIMINATION.—Notwithstanding the corrective action plan process established under clause (i), the Secretary may, in addition to the circumstances under which a contract under part C may be immediately terminated, immediately terminate an agreement under this section with an Organization if the Secretary—

"(I) notifies the Organization of the intent to investigate allegations of systematic activities with the intent of violating the prohibition on discrimination established under subsection (b)(3)(B)(ii);

"(II) determines, after conducting a rigorous analysis of all available data based on a sufficient sample size, that the Organization engaged in systematic activities with the intent of violating the prohibition on discrimination established in subsection (b)(3)(B)(ii); and

"(III) discloses credible evidence to the Organization regarding a determination made under subclause (II).

"(iv) RECOVERY OF MONTHLY PROSPECTIVE PAYMENTS.—The Secretary may recover the prorated share of any monthly prospective payments described in subsection (e) covering the period of the month following an agreement termination if such agreement termination is effective in the middle of a calendar month.

"(v) NOTIFICATION OF PROGRAM-ELIGIBLE BENEFICIARY UPON AGREEMENT TERMINATION.—Each agreement under this section between the Secretary and an Organization shall require the Organization to provide and pay for written notice in advance of an agreement's termination, as well as a description of alternatives for obtaining benefits under this title, in a manner consistent with beneficiary notification requirements in the event of a contract termination under part C.

"(6) PROGRAM EVALUATION.—The Secretary shall conduct an evaluation of the Program under this section to inform a determination regarding a Program expansion under paragraph (7). Such evaluation shall include an analysis of—

"(A) the quality of care furnished under the Program, including the measurement of patient-level outcomes and patient experience and patient-reported outcome measures determined appropriate by the Secretary; and

"(B) the changes in spending under parts A and B by reason of the Program.

"(7) PROGRAM EXPANSION.—

"(A) IN GENERAL.—The Secretary may, through rulemaking, expand the duration and scope of the Program under this section, to the extent determined appropriate by the Secretary, if—

"(i) the Secretary determines that such expansion is expected to—

"(I) reduce spending under this title without reducing the quality of patient care; or

"(II) improve the quality of patient care without increasing spending under this title;

"(ii) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce (or would not result in any increase in) net program spending under this title; and

"(iii) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under this title for applicable individuals.

"(B) ENSURING PROGRAM CONTINUITY.—The Secretary shall implement any Program expansion made in accordance with this para-

graph in a manner that ensures that Program-eligible beneficiaries and Organizations with an agreement under this section do not experience any disruptions in the Program.

''(8) PART D DATA SHARING ARRANGEMENT.—The Secretary on a monthly basis shall, in accordance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, provide access to Organizations to part D data claims that include part D data on Program-eligible beneficiaries assigned to or an election of an ESRD Fee-For-Service Integrated Care Model offered by an Organization unless a Program-eligible beneficiary opts out of such data sharing.

''(9) FUNDING.—The Secretary shall allocate funds made available under section 1115A(f)(1) to implement and evaluate the demonstration program established under this section.

''(d) IDENTIFICATION AND ASSIGNMENT OF PROGRAM-ELIGIBLE BENEFICIARIES.—

''(1) IN GENERAL.—The Secretary shall establish a process for the initial and ongoing identification of Program-eligible beneficiaries.

''(2) ASSIGNMENT OF PROGRAM-ELIGIBLE BENEFICIARIES TO AN ORGANIZATION'S ESRD FEE-FOR-SERVICE INTEGRATED CARE MODEL.—

''(A) IN GENERAL.—Under the Program, the Secretary shall assign all Program-eligible beneficiaries to an ESRD Fee-For-Service Integrated Care Model offered by an Organization that includes the dialysis facility at which the Program-eligible beneficiary primarily receives renal dialysis services.

''(B) OPT-OUT PERIOD AND CHANGES UPON INITIAL ASSIGNMENT OR ELECTION.—The Secretary shall provide for a 90-day period beginning on the date on which the assignment of or election made by a Program-eligible beneficiary into an ESRD Fee-For-Service Integrated Care Model offered by an Organization becomes effective during which a Program-eligible beneficiary may—

''(i) opt out of the Program; or

''(ii) make a one-time change of assignment or election into an ESRD Fee-For-Service Integrated Care Model offered by a different Organization.

"(C) DEEMED RE-ASSIGNMENT AND RE-ELECTION.—The Secretary shall establish a process through which a Program-eligible beneficiary assigned to or who elects an ESRD Fee-For-Service Integrated Care Model offered by an Organization with respect to a year is deemed, unless the Program-eligible beneficiary otherwise changes such assignment or election under this paragraph, to have elected to continue such assignment or election with respect to the subsequent year.

"(D) ANNUAL OPPORTUNITY TO OPT OUT OR ELECT AN ESRD FEE-FOR-SERVICE INTEGRATED CARE MODEL OFFERED BY A DIFFERENT ORGANIZATION.—

"(i) IN GENERAL.—Annually, a Program-eligible beneficiary shall be given a 90-day period to—

"(I) opt out of the Program; or

"(II) make a one-time change of assignment or election into an ESRD Fee-For-Service Integrated Care Model offered by a different Organization.

"(ii) ALIGNMENT WITH MEDICARE ADVANTAGE OPEN ENROLLMENT PERIOD.—To the extent practicable, the Secretary shall align the annual 90-day period described in clause (i) with the Medicare Advantage open enrollment period.

"(E) OPT OUT FOR CHANGE IN PRINCIPAL DIAGNOSIS OR ENTERING HOME DIALYSIS TREATMENT.—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 or enters into home dialysis treatment, such individual shall be given the opportunity to opt out of the Program during such period as specified by the Secretary.

"(3) PROGRAM-ELIGIBLE BENEFICIARY NOTIFICATION.—

"(A) IN GENERAL.—The Secretary shall ensure that an Organization notifies Program-eligible beneficiaries about the Program under

this section and provides them with materials explaining the Program, including—

"(i) information about receiving benefits under this title through such Organization; and

"(ii) an explanation that they retain the right to receive care from any Medicare provider.

"(B) TIMING OF NOTIFICATION.—Upon assignment to or election of an ESRD Fee-For-Service Integrated Care Model offered by an Organization, the Secretary shall provide the Organization written notification confirming the beneficiary's assignment or election and not later than 15 business days after the date of receipt of such notification, the Organization shall provide written notice to the Program-eligible beneficiary of such assignment or election.

"(C) CONTENT OF WRITTEN NOTICE.—Subject to subparagraph (D), such notification shall—

"(i) inform Program-eligible beneficiaries about the Program using an information guide developed by the Organization and approved by the Secretary;

''(ii) include the distribution of other Program materials developed by the Organization and approved by the Secretary;

''(iii) inform Program-eligible beneficiaries about the importance of transplantation as the best outcome, as well as minimum requirements for transplant eligibility before and during dialysis treatment; and

''(iv) provide contact information for representatives of the Organization to respond to Program-eligible beneficiaries' questions.

''(D) LIMITATION ON UNSOLICITED NOTIFICATION.—

''(i) IN GENERAL.—Under the Program, no person or entity (other than the Secretary, an employee of the Secretary, or an employee or volunteer of a federally authorized State Health Insurance Assistance Program (SHIP)), subject to clause (ii), may provide any information about the Program, including information, materials, and assistance described in subparagraph (B), to a Program-eligible beneficiary un-

less such Program-eligible beneficiary requests such information, materials, or assistance.

''(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 a facility that participates in such Organization.

''(iii) PARITY IN NOTIFICATION.—In the case that an eligible participating provider that is part of an Organization participates in notifying Program-eligible beneficiaries about the Program under this subparagraph, such notification shall be provided in the same manner to all Program-eligible beneficiaries to which, pursuant to clause (ii), such eligible participating provider may provide information, materials, and assistance described in such clause.

''(E) PROGRAM-ELIGIBLE BENEFICIARY GRIEVANCE AND APPEAL RIGHTS.—Program-eligible beneficiaries participating in the Program under this section shall have grievance and appeal rights and procedures consistent with those rights and procedures established under subsections (f) and (g) of section 1852.

''(e) ESRD FEE-FOR-SERVICE INTEGRATED CARE PROGRAM MONTHLY PAYMENT AND CLAIMS PROCESSING MECHANISM.—

''(1) IN GENERAL.—For each Program-eligible beneficiary receiving care through an Organization, the Secretary shall make a monthly prospective payment in accordance with payment rates that would be determined under section 1853(a)(1)(H).

''(2) APPLICATION OF HEALTH STATUS RISK ADJUSTMENT METHODOLOGY.—The Secretary shall adjust the monthly prospective payment 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) TREATMENT OF AND PAYMENT FOR KIDNEY ACQUISITION COSTS.—

''(A) EXCLUDING COSTS FOR KIDNEY ACQUISITIONS FROM MA BENCHMARK.—The Sec-

retary shall adjust the payment amount to an Organization to exclude from such payment amount the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants in the area involved for the year.

''(B) FFS TREATMENT OF AND PAYMENT FOR KIDNEY ACQUISITIONS.—An Organization shall provide all benefits described in subsection (b)(2)(A)(i), except for kidney acquisition costs. Payment for kidney acquisition costs covered under this title furnished to a Program-eligible beneficiary shall be made in accordance with this title and in such amounts as would otherwise be made and determined for such items and services provided to such a beneficiary not participating in the Program under this section.

''(4) TREATMENT OF AND PAYMENT FOR HOSPICE CARE.—

''(A) IN GENERAL.—An agreement under this section shall require an Organization to inform each Program-eligible beneficiary who is assigned to or elects an ESRD Fee-For-Service Integrated Care Model offered by the Organization about the availability of hospice care if—

"(i) a hospice program participating under this title is located within the Organization's service area; or

"(ii) it is common practice to refer patients to hospice programs outside such service area.

"(B) PAYMENT.—If a Program-eligible beneficiary who is assigned to or elects an ESRD Fee-For-Service Integrated Care Model offered by an Organization with an agreement under this section makes an election under section 1812(d)(1) to receive hospice care from a particular hospice program—

"(i) payment for the care furnished to the Program-eligible beneficiary shall be made by the Secretary to the hospice program elected by the Program-eligible beneficiary;

"(ii) payment for other services for which the Program-eligible beneficiary individual is eligible notwithstanding the Program-eligible beneficiary's election of hospice care under section 1812(d)(1), including services not related to the Program-eligible beneficiary's terminal illness,

shall be made by the Secretary to the Organization or the provider or supplier of the service instead of the monthly prospective payment determined under subsection (f); and

''(iii) the Secretary shall continue to make monthly payments to the Organization in an amount equal to the value of benefits and services determined under subsection (b)(2)(A)(ii)(IV).

''(5) APPLICATION OF CMI CLAIMS PROCESSING FRAMEWORK.—

''(A) IN GENERAL.—Under the Program, the Secretary shall apply a claims processing framework based on those that the Center for Medicare and Medicaid Innovation applies under various direct contracting models under section 1115A such that—

''(i) providers of services and suppliers serving Program-eligible beneficiaries continue to submit claims to a medicare administrative contractor;

''(ii) the Secretary forwards claims to the Organization for payment; and

"(iii) the Organization pays providers of services and suppliers an amount equal to the amount that they would otherwise receive under the original Medicare Fee-For-Service program plus any additional amount to which the provider may be eligible under subsection (b)(2)(A)(v) of this section.

"(B) APPLICATION OF BALANCE BILLING LIMITATIONS.—Section 1852(a)(2)(A) (relating to payments made by an MA organization to a non-contract provider of services), section 1852(k)(1) (relating to limitations on balance billing), and section 1866(a)(1)(o) (relating to payments made by an MA organization to a non-contract supplier) shall apply to the Program.

"(C) PAYMENTS FOR GRADUATE MEDICAL EDUCATION.—Section 1886(d)(11) and section 1886(h)(3)(D) (relating to payments for graduate medical education) shall apply to Organizations and providers of services under the Program.

"(6) NO EFFECT ON MA ESRD RATE SETTING OR RISK ADJUSTMENT MODEL.—To ensure the in-

tegrity of the Medicare Advantage end stage renal disease rate setting process and risk adjustment factors applied to Medicare Advantage end stage renal disease rates, claims paid on behalf of Program-eligible beneficiaries shall not be included in neither the determination of such rates nor the development of such risk adjustment factors.

''(7) AGREEMENT BETWEEN A STATE AND ORGANIZATION FOR MEDICAID BENEFITS.—In the case that a State and Organization enter into a mutual agreement under which the Organization coordinates benefits under title XIX for Program-eligible beneficiaries eligible for benefits under this title and title XIX such mutual agreement shall specify the payment from the State for providing or arranging for the provision of such benefits.

''(8) AFFIRMATION OF STATE OBLIGATIONS TO PAY PREMIUM AND COST-SHARING AMOUNTS.—A State shall continue to make medical assistance under the State plan under title XIX available for the duration of the Program for Medicare 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 assigned to or who

elect an Organization and entitled to medical assistance for premiums and such cost-sharing under the State plan under title XIX in an amount equal to the amount of medical assistance that would be made available by such State if such Program-eligible beneficiaries were not participating in the Program under this section.

''(f) WAIVER AUTHORITY.—

''(1) IN GENERAL.—The Secretary shall waive those requirements waived under section 1899 determined by the Secretary to be relevant and necessary for the operation of the Program under this section and may waive, as necessary, such additional requirements that have been or may be waived based on authority established under section 1115A for purposes of models tested by the Centers for Medicare and Medicaid Innovation in order to carry out the Program under this section.

''(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.

''(g) REPORT.—Not later than December 31, 2025, the Medicare Payment Advisory Commission shall submit to Congress an interim report on the Program.''.

(b) RULES OF CONSTRUCTION.—

(1) USE OF MEDICARE SUPPLEMENTAL POLICY UNDER AN ESRD FEE-FOR-SERVICE INTEGRATED CARE MODEL.—Nothing in the provisions of, or amendments made by, this Act shall be construed to prevent a Program-eligible beneficiary assigned to, or who elects, an ESRD Fee-For-Service Integrated Care Model offered by an Organization with an agreement under this section from enrolling in or continuing enrollment in a medicare supplemental policy available to such Program-eligible beneficiary or receiving benefits under such medicare supplemental policy throughout the duration of the Program-eligible beneficiary's participation in an ESRD Fee-For-Service Integrated Care model offered by an Organizations with an agreement under this section.

(2) APPLICATION OF STATE RULES REGARDING ISSUANCE OF MEDICARE SUPPLEMENTAL POLICIES TO INDIVIDUAL UNDER AGE 65.—Nothing in the provisions of, or amendments made by, this Act shall be construed to establish a Federal requirement on an issuer of a medicare supplemental policy to offer

such medicare supplemental policy to individuals under age 65.

(3) CONTINUED AVAILABILITY OF MEDICARE SUPPLEMENTAL POLICIES TO INDIVIDUALS UNDER AGE 65.—Nothing in the provisions of, or amendments made by, this Act shall be construed to affect a State's authority to require an issuer of a medicare supplemental policy to offer such medicare supplemental policy to individual.

(c) GAO STUDY AND REPORT ON PAYMENT ADEQUACY FOR PEDIATRIC ESRD SERVICES.—

(1) STUDY ON PAYMENT FOR PEDIATRIC ESRD SERVICES.—The Comptroller General of the United States shall conduct a study to examine the accuracy of pediatric data reported to the Centers for Medicare & Medicaid Services as part of the ESRD prospective payment system. The study shall evaluate whether the organizations described in section 1866G of the Social Security Act, as added by subsection (a), and the existing prospective payment system accurately capture and reimburse costs of pediatric dialysis care and include an analysis of the following factors that influence such costs:

(A) Increased acuity of nursing care compared to adult dialysis patients, especially for

smaller and younger pediatric hemodialysis patients.

(B) Need for developmental and behavioral specialists, including child life specialists.

(C) Need for more frequent assessment by pediatric dieticians to adjust formulas and diet for the specialized growth and nutrition requirements of children treated with dialysis.

(D) Need for social workers, school liaisons, and other trained individuals designated to help families navigate challenging psychosocial situations and to coordinate with schools to ensure school attendance and optimize school performance among pediatric dialysis patients.

(E) Need for a broader array of dialysis supplies, including different-sized dialyzers, tubing, and peritoneal fluid bags to accommodate care provided infants through young adults.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

(d) GAO STUDY AND REPORT ON THE IMPACT OF RACE-BASED CORRECTION OF EGFR ON REFERRAL OF ESRD PATIENTS FOR TRANSPLANT EVALUATION.—

(1) STUDY ON IMPACT OF RACE-BASED CORRECTION OF EGFR ON REFERRAL OF ESRD PATIENTS FOR TRANSPLANT EVALUATION.—The Comptroller General of the United States shall conduct a study to examine the impact of race-based correction of the estimated glomerular filtration rate (referred to in this subsection as ''eGFR'') on the referral of ESRD patients for transplant evaluation.

(2) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

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