

116TH CONGRESS
2D SESSION

S. 4574

To establish a demonstration program to provide integrated care for Medicare beneficiaries with end-stage renal disease, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 15, 2020

Mr. YOUNG (for himself and Ms. SINEMA) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To establish a demonstration program to provide integrated care for Medicare beneficiaries with end-stage renal disease, 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.**

4 This Act may be cited as the “Bringing Enhanced
5 Treatments and Therapies to ESRD Recipients (BET-
6 TER) Kidney Care Act”.

7 **SEC. 2. FINDINGS.**

8 Congress finds the following:

9 (1) Although the relative rate of end-stage renal
10 disease (referred to in this section as “ESRD”)

1 among the Nation's minority populations has de-
2 clined, significant disparities remain. Compared to
3 Whites, Black Americans are 2.6 times more likely
4 to have kidney failure, while Native Americans and
5 Alaska Natives are 1.2 times more likely. Hispanics
6 are 1.3 times more likely to have kidney failure com-
7 pared to non-Hispanics.

8 (2) Disparities also exist with respect to treat-
9 ment modalities. Specifically, although home dialysis
10 can offer advantages, Black, Hispanic, and Native
11 American and Alaska Native ESRD patients are less
12 likely to initiate home treatment than White ESRD
13 patients.

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

17 (4) In addition to their kidney disease, ESRD
18 patients across all races and ethnicities often suffer
19 from one or more comorbidities. Eighty-eight per-
20 cent of ESRD patients have a history of hyper-
21 tension, 42 percent have diabetes, and nearly 30
22 percent have congestive heart failure.

23 (5) Each month, ESRD patients see multiple
24 providers and take several medications to manage
25 their kidney disease and comorbid conditions. Of all

1 patients, those with ESRD stand to benefit greatly
2 from better coordinated care.

3 (6) The Executive Order on Advancing Amer-
4 ican Kidney Health recognizes the need to develop
5 and implement new ESRD care delivery models to
6 improve quality and value for ESRD patients and
7 the Medicare program.

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

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

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

16 (C) support such patients in receiving the
17 treatment modality, including a kidney trans-
18 plant, as prescribed by their nephrologist;

19 (D) access services to meet the nonclinical
20 needs of such patients that can affect care out-
21 comes; and

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

1 **SEC. 3. DEMONSTRATION PROGRAM TO PROVIDE INTE-**
 2 **GRATED CARE FOR MEDICARE BENE-**
 3 **FICIARIES WITH END-STAGE RENAL DISEASE.**

4 (a) IN GENERAL.—Title XVIII of the Social Security
 5 Act is amended by inserting after section 1866F the fol-
 6 lowing new section:

7 “DEMONSTRATION PROGRAM TO PROVIDE INTEGRATED
 8 CARE FOR MEDICARE BENEFICIARIES WITH END-
 9 STAGE RENAL DISEASE

10 “SEC. 1866G. (a) ESTABLISHMENT.—

11 “(1) IN GENERAL.—The Secretary shall con-
 12 duct under this section the ESRD Fee-For-Service
 13 Integrated Care Demonstration Program (in this
 14 section referred to as the ‘Program’), which is vol-
 15 untary for Program-eligible beneficiaries and eligible
 16 participating providers, to assess the effects of alter-
 17 native care delivery models and payment methodolo-
 18 gies on patient care improvements under this title
 19 for such beneficiaries. Under the Program—

20 “(A) Program-eligible beneficiaries shall be
 21 considered original Medicare fee-for-service
 22 beneficiaries (as defined in section 1899(h)(3))
 23 for the duration of the participation of such
 24 beneficiaries under the Program;

25 “(B) eligible participating providers may
 26 form an ESRD Fee-For-Service Integrated

1 Care Organization (in this section referred to as
2 an ‘Organization’); and

3 “(C) an Organization shall integrate care
4 under the original Medicare fee-for-service pro-
5 gram under parts A and B for Program-eligible
6 beneficiaries.

7 “(2) DEFINITIONS.—In this section:

8 “(A) ELIGIBLE PARTICIPATING PRO-
9 VIDER.—The term ‘eligible participating pro-
10 vider’ means any of the following:

11 “(i) A facility certified as a renal di-
12 alysis facility under this title.

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

15 “(iii) A nephrologist (including a pedi-
16 atric nephrologist) or nephrology practice.

17 “(iv) Any other physician or physician
18 group practice.

19 “(v) A nurse practitioner, physician
20 assistant, or clinical nurse specialist (as
21 such terms are defined in section
22 1861(aa)(5)) or a clinical social worker (as
23 defined in section 1861(hh)(1)) working in
24 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

1 medical assistance under a State plan
2 under title XIX) who—

3 “(I) is identified by the Secretary
4 as having end-stage renal disease and
5 who is receiving renal dialysis services
6 under the original Medicare fee-for-
7 service program under parts A and B,
8 and is not enrolled in a Medicare Ad-
9 vantage plan under part C or group
10 health insurance coverage or indi-
11 vidual health insurance coverage (as
12 defined in section 2791(b) of the Pub-
13 lic Health Service Act (42 U.S.C.
14 300gg-91(b))) that is primary to cov-
15 erage under this title;

16 “(II) receives renal dialysis serv-
17 ices primarily from an eligible partici-
18 pating provider of such Organization,
19 including such renal dialysis services
20 received after being identified as a
21 suitable candidate for transplantation;
22 and

23 “(III) has attained the age of 18
24 years.

1 “(ii) AFFIRMATION OF PROGRAM ELI-
 2 GIBILITY UPON HOSPICE ELECTION OR
 3 KIDNEY TRANSPLANT.—A Program-eligible
 4 beneficiary who was assigned to or elected
 5 an ESRD Fee-For-Service Integrated Care
 6 Model offered by an Organization and
 7 who—

8 “(I) elects to receive hospice ben-
 9 efits under section 1852(d)(1); or

10 “(II) receives a kidney transplant
 11 as covered under this title and main-
 12 tains entitlement to benefits under
 13 part A and enrollment in part B on
 14 the basis of end-stage renal disease,
 15 shall continue to meet the definition of
 16 Program-eligible beneficiary established
 17 under this subparagraph.

18 “(b) ESRD FEE-FOR-SERVICE INTEGRATED CARE
 19 ORGANIZATION ELIGIBILITY REQUIREMENTS.—

20 “(1) ORGANIZATIONS.—

21 “(A) IN GENERAL.—One or more eligible
 22 participating providers may establish an Orga-
 23 nization and may enter into, subject to sub-
 24 paragraph (B), one or more partnership, owner-
 25 ship, or co-ownership agreements with one or

1 more eligible participating partners to establish
2 an Organization or to offer one or more ESRD
3 Fee-for-Service Integrated Care Models in ac-
4 cordance with paragraph (2).

5 “(B) LIMITATION ON NUMBER OF AGREE-
6 MENTS.—The Secretary may specify a limita-
7 tion on the number of Organizations in which
8 an eligible participating partner may participate
9 for purposes of offering one or more ESRD
10 Fee-for-Service Integrated Care Models under
11 partnership, ownership, or co-ownership agree-
12 ments described in subparagraph (A).

13 “(C) MINIMUM PROGRAM ELIGIBLE BENE-
14 FICIARY PARTICIPATION REQUIREMENT.—

15 “(i) IN GENERAL.—Subject to clause
16 (ii), the Secretary may not enter into or
17 continue an agreement with an Organiza-
18 tion unless the Organization has at least
19 350 Program-eligible beneficiaries, or at
20 least 60 percent of Program-eligible bene-
21 ficiaries receiving care from the Organiza-
22 tion’s facilities, who are assigned to or
23 elect an ESRD Fee-For-Service Integrated
24 Model offered by the Organization and who

1 continue their assignment to or election of
2 the Organization.

3 “(ii) ALLOWING TRANSITION.—The
4 Secretary may waive the requirement
5 under clause (i) for an Organization dur-
6 ing the first agreement year with respect
7 to the Organization.

8 “(D) FISCAL SOUNDNESS REQUIRE-
9 MENTS.—

10 “(i) IN GENERAL.—The Secretary
11 shall enter into appropriate agreements
12 under this section only with Organizations
13 that demonstrate sufficient capital re-
14 serves, measured as a percentage of
15 monthly prospective payments described in
16 subsection (e) and consistent with capital
17 reserve requirements established by each
18 State in which the Organization operates,
19 subject to clause (ii).

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

1 participating provider or eligible partici-
2 pating partner that—

3 “(I)(aa) is licensed under State
4 law as a risk-bearing entity eligible to
5 offer health insurance or health bene-
6 fits coverage in each State in which
7 the Organization participates in the
8 demonstration under this section; or

9 “(bb) is otherwise authorized by
10 each State in which the Organization
11 participates in the demonstration
12 under this section to bear risk for of-
13 fering health insurance or health ben-
14 efits;

15 “(II) agrees to bear risk under
16 the Organization; and

17 “(III) has the capacity to bear
18 risk commensurate with the Organiza-
19 tion’s expected expenditures under an
20 agreement under this section.

21 “(iii) DISCLOSURE.—Each Organiza-
22 tion with an agreement under this section
23 shall, in accordance with current regula-
24 tions of the Secretary that govern similar
25 disclosures, report to the Secretary finan-

1 cial information consistent with such infor-
 2 mation required to be reported by a Medi-
 3 care Advantage organization under part C
 4 to demonstrate that the Organization has
 5 a fiscally sound operation.

6 “(E) GOVERNANCE REQUIREMENTS.—

7 Each Organization with an agreement under
 8 this section shall establish a governing body
 9 with oversight responsibility for the Organiza-
 10 tion’s compliance with Program requirements
 11 that includes—

12 “(i) representation from each eligible
 13 participating provider of such Organiza-
 14 tion;

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

18 “(iii) at least one beneficiary advo-
 19 cate.

20 “(2) ESRD FEE-FOR-SERVICE INTEGRATED

21 CARE MODEL.—

22 “(A) BENEFIT REQUIREMENTS.—

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

1 Fee-For-Service Integrated Care Model
2 that shall—

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

9 “(II) include services for transi-
10 tion (particularly including education)
11 into transplantation, palliative care,
12 and hospice.

13 “(ii) DETERMINATION AND TREAT-
14 MENT OF SAVINGS.—

15 “(I) IN GENERAL.—The Sec-
16 retary shall require any Organization
17 offering an ESRD Fee-For-Service
18 Integrated Care Model to provide for
19 the return under subclause (VI) to a
20 Program-eligible beneficiary assigned
21 to or who elects an Organization sav-
22 ings equal to the amount, if any, by
23 which the payment amount described
24 in subclause (V) with respect to the
25 Program-eligible beneficiary for a year

1 exceeds the average revenue amount
2 described in subclause (IV) with re-
3 spect to the Program-eligible bene-
4 ficiary for the year.

5 “(II) SAVINGS DETERMINATION
6 PROCESS.—The Secretary shall deter-
7 mine the savings described in sub-
8 clause (I) in the same manner as the
9 rebate calculation for individuals with
10 end-stage renal disease enrolled in
11 Medicare Advantage organizations
12 under section 1859(b)(6)(B)(iii).

13 “(III) APPLICATION OF MEDICAL
14 LOSS RATIO REQUIREMENTS.—Noth-
15 ing shall preclude the Secretary from
16 applying medical loss ratio require-
17 ments described in section 1857(e)(4)
18 under this section.

19 “(IV) AVERAGE REVENUE
20 AMOUNT DESCRIBED.—The revenue
21 amount described in this subclause,
22 with respect to an Organization offer-
23 ing an ESRD Fee-For-Service Inte-
24 grated Care Model and a Program-eli-
25 gible beneficiary assigned to or who

1 elects such Organization, is the Orga-
2 nization's estimated average revenue
3 requirements, including administrative
4 costs and return on investment, for
5 the Organization to provide the bene-
6 fits described in clause (i) under the
7 Model for the Program-eligible bene-
8 ficiary for the year.

9 “(V) PAYMENT AMOUNT DE-
10 SCRIBED.—The payment amount de-
11 scribed in this subclause, with respect
12 to an Organization offering an ESRD
13 Fee-For-Service Integrated Care
14 Model and a Program-eligible bene-
15 ficiary assigned to or who elects such
16 Organization, is the payment amount
17 to the Organization under subsection
18 (e)(1) (adjusted pursuant to sub-
19 section (e)(2) and subject to the treat-
20 ment of payments for kidney acquisi-
21 tions and hospice care described in
22 paragraphs (3) and (4) of subsection
23 (e), respectively) made with respect to
24 the Program-eligible beneficiary for
25 the year.

1 “(VI) RETURNING SAVINGS TO
 2 PROGRAM-ELIGIBLE BENE-
 3 FICIARIES.—An Organization shall, in
 4 a manner specified by the Secretary
 5 and consistent with returning Medi-
 6 care Advantage rebates to individuals
 7 under part C, return the amount
 8 under subclause (I) to a Program-eli-
 9 gible beneficiary through offering ben-
 10 efits not covered under the original
 11 Medicare Fee-For-Service program
 12 consistent with the types of benefits,
 13 including non-health related benefits,
 14 that Medicare Advantage organiza-
 15 tions may offer.

16 “(iii) BENEFIT REQUIREMENTS FOR
 17 DUAL ELIGIBLES.—In the case of a Pro-
 18 gram-eligible beneficiary who is entitled to
 19 medical assistance under a State plan
 20 under title XIX, an Organization, in ac-
 21 cordance with a mutual agreement entered
 22 into between the State and Organization
 23 under subsection (e)(7)—

24 “(I) shall provide, or arrange for
 25 the provision of, all benefits (other

1 than long-term services and supports)
 2 for which the Program-eligible bene-
 3 ficiary is entitled to under a State
 4 plan under title XIX; and

5 “(II) may elect to provide, or ar-
 6 range for the provision of, long-term
 7 services and supports for which the
 8 Program-eligible beneficiary is entitled
 9 under a State plan under title XIX,
 10 including services related to the tran-
 11 sition into palliative care or hospice.

12 “(iv) APPLICATION OF MEDICARE FFS
 13 PROVIDER CHOICE AND COST-SHARING RE-
 14 QUIREMENTS.—Under an ESRD Fee-For-
 15 Service Integrated Care Model offered by
 16 an Organization, the Organization shall—

17 “(I) allow Program-eligible bene-
 18 ficiaries to receive benefits as de-
 19 scribed in subsection (b)(2)(A)(i)(I)
 20 from any provider of services or sup-
 21 plier enrolled under this title and who
 22 otherwise meets all applicable require-
 23 ments under this title; and

24 “(II) not apply any cost-sharing
 25 requirements for benefits described in

1 subsection (b)(2)(A)(i)(I) in addition
2 to premium and cost-sharing require-
3 ments, respectively, that would be ap-
4 plicable under part A or part B for
5 such benefits.

6 “(v) PROMOTING ACCESS TO HIGH-
7 QUALITY PROVIDERS.—An Organization
8 offering an ESRD Fee-For-Service Inte-
9 grated Care Model shall develop and imple-
10 ment performance-based incentives, includ-
11 ing financial incentives funded through
12 payments made to an Organization under
13 subsection (e), for providers of services and
14 suppliers to promote delivery of high qual-
15 ity and efficient care. Such incentives shall
16 comply with section 1852(j)(4) and section
17 422.208 of title 42, Code of Federal regu-
18 lations (as in effect on the date of enact-
19 ment of this section) and be based on clin-
20 ical measures or non-clinical measures,
21 such as with respect to notification of pa-
22 tient discharge from a hospital, patient
23 education (such as with respect to treat-
24 ment options, including disease mainte-
25 nance, and nutrition), rates of completion

1 of patient education categorized by race,
2 rates of completion of transplant evalua-
3 tion for patients who are clinically eligible
4 for transplant, rates of completion of
5 transplant evaluation categorized by race,
6 and the interoperability of electronic health
7 records developed by an Organization ac-
8 cording to requirements and standards
9 specified by the Secretary pursuant to sub-
10 paragraph (B).

11 “(B) QUALITY AND REPORTING REQUIRE-
12 MENTS.—

13 “(i) CLINICAL MEASURES.—Under the
14 Program, the Secretary shall—

15 “(I) require each participating
16 Organization to submit to the Sec-
17 retary data on clinical measures devel-
18 oped using, as a reference, measures
19 submitted by organizations partici-
20 pating in the Comprehensive ESRD
21 Care Initiative operated by the Center
22 for Medicare and Medicaid Innovation
23 to assess the quality of care provided;

24 “(II) establish requirements for
25 participating Organizations to submit

1 to the Secretary, in a form and man-
2 ner specified by the Secretary, infor-
3 mation on such measures; and

4 “(III) establish standards for
5 making information on quality under
6 the Program established under this
7 section as assessed using clinical
8 measures described in subclause (I)
9 available to the public.

10 As part of the standards described in sub-
11 clause (III) the Secretary shall, in con-
12 sultation with relevant stakeholders, de-
13 velop standards that would establish a
14 minimum threshold for the volume of indi-
15 vidual patients to be listed for transplant
16 in an Organ Procurement and Transplant
17 Network under contract with the Secretary
18 and that would measure the number of in-
19 dividuals that an Organization moved on
20 to, kept on, or removed from the trans-
21 plant list and the number of individuals
22 that receive a transplant after partici-
23 pating in the Organization. The number of
24 Program-eligible beneficiaries assigned to
25 an Organization on the transplant list that

1 have not opted out at the time of the
2 agreement between the Secretary and an
3 Organization shall be noted as part of such
4 agreement. Organizations shall submit
5 such measures as a condition of payment
6 and Program-eligible beneficiary assign-
7 ment under this subsection.

8 “(ii) REQUIREMENT FOR STAKE-
9 HOLDER INPUT.—In developing measures
10 and requirements under subclauses (I) and
11 (II) of clause (i), the Secretary shall re-
12 quest and consider input from a stake-
13 holder board that includes at least one
14 nephrologist, a pediatric nephrologist,
15 other suppliers and providers of services as
16 determined appropriate by the Secretary,
17 renal dialysis facilities, beneficiary advo-
18 cates, a health equity expert, a mental
19 health provider, a transplant surgeon, and
20 Medicare-approved transplant programs.
21 Section 14 of the Federal Advisory Com-
22 mittee Act shall not apply to the stake-
23 holder board.

24 “(iii) ADDITIONAL ASSESSMENTS AND
25 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

1 ESRD Fee-For-Service Integrated Care
2 Strategy.

3 “(ii) ESRD FEE-FOR-SERVICE INTE-
4 GRATED CARE STRATEGY.—In assessing an
5 ESRD Fee-For-Service Integrated Care
6 Strategy under clause (i), the Secretary
7 shall consider the extent to which the
8 Strategy includes elements such as the fol-
9 lowing:

10 “(I) Use of interdisciplinary care
11 teams led by at least one nephrologist,
12 and comprised of registered nurses,
13 social workers, renal dialysis facility
14 managers, and as appropriate other
15 representatives from alternative set-
16 tings described in subclause (VIII).

17 “(II) Use of a decision process
18 for care plans and care management
19 that includes the nephrologist, a mem-
20 ber of the transplant evaluation team,
21 and other practitioners responsible for
22 direct delivery of care to Program-eli-
23 gible beneficiaries assigned to or who
24 elect the Organization involved.

1 “(III) Use of health risk and
2 other assessments to determine the
3 physical, psychosocial, nutrition, lan-
4 guage, cultural, and other needs of
5 Program-eligible beneficiaries assigned
6 to or who elect the Organization in-
7 volved.

8 “(IV) Development and at least
9 annual updating of individualized care
10 plans that incorporate at least the
11 medical, social, and functional needs,
12 preferences, and care goals of Pro-
13 gram-eligible beneficiaries assigned to
14 or who elect the Organization, includ-
15 ing a discussion on reconsideration of
16 the method and location of dialysis.

17 “(V) Coordination and furnishing
18 of non-clinical coordination benefits,
19 such as transportation, aimed at im-
20 proving the adherence of Program-eli-
21 gible beneficiaries assigned to or who
22 elect the Organization with care rec-
23 ommendations.

24 “(VI) As appropriate, coordina-
25 tion services, such as transplant eval-

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

4 “(VII) In the case of an indi-
5 vidual who, during an assignment to,
6 or an election of an ESRD Fee-For-
7 Service Integrated Care model offered
8 by an Organization, receives confirma-
9 tion that a kidney transplant is immi-
10 nent, the provision of counseling serv-
11 ices by an interdisciplinary care team
12 described in subclause (I) to such in-
13 dividual on preparation for and poten-
14 tial benefits and risks associated with
15 such transplant.

16 “(VIII) Delivery of benefits and
17 services in settings alternative to tra-
18 ditional clinical settings, such as the
19 home of the Program-eligible bene-
20 ficiary.

21 “(IX) Use of patient reminder
22 systems.

23 “(X) Education programs for pa-
24 tients, families, and caregivers.

1 “(XI) Use of health care advice
2 resources, such as nurse advice lines.

3 “(XII) Use of team-based health
4 care delivery models that provide com-
5 prehensive and continuous medical
6 care, such as medical homes.

7 “(XIII) Co-location of providers
8 and services.

9 “(XIV) Use of a demonstrated
10 capacity to share electronic health
11 record information across sites of
12 care.

13 “(XV) Use of programs to pro-
14 mote better adherence to rec-
15 ommended treatment regimens, in-
16 cluding prescription drug, by individ-
17 uals, including by addressing barriers
18 to access to care by such individuals,
19 including strategies to coordinate any
20 prescription drug benefits under any
21 prescription drug plan under part D
22 in which a Program-eligible bene-
23 ficiary is enrolled.

24 “(XVI) Use of defined protocols,
25 developed in conjunction with the pe-

1 diatric nephrology community, to fa-
 2 cilitate the transition of pediatric indi-
 3 viduals into adult end-stage renal dis-
 4 ease care.

5 “(XVII) Use of health equity ex-
 6 perts to implement programs and pro-
 7 tocols which seek to decrease gender,
 8 racial, ethnic, and language inequities.

9 “(XVIII) Other services, strate-
 10 gies, and approaches identified by the
 11 Organization to improve care coordi-
 12 nation and delivery.

13 “(3) BENEFICIARY PROTECTIONS.—

14 “(A) SEAMLESS ACCESS TO CARE.—The
 15 Secretary shall ensure that the Organization es-
 16 tablishes processes and takes steps necessary,
 17 including educating relevant providers of serv-
 18 ices and suppliers about the Program, to ensure
 19 that Program-eligible beneficiaries assigned to
 20 or who elected an ESRD Fee-For-Service Inte-
 21 grated Care Model offered by an Organization
 22 do not experience any disruption in access to
 23 providers of services and suppliers furnishing
 24 benefits under this title due to such assignment
 25 or election. Assignment to or an election of an

1 ESRD Fee-For-Service Integrated Care Model
 2 offered by an Organization shall not be con-
 3 strued as affecting a Program-eligible bene-
 4 ficiary's ability to receive benefits described in
 5 subsection (b)(2)(A)(i)(I) from any provider of
 6 services or suppliers enrolled and who otherwise
 7 meets requirements under this title, as de-
 8 scribed in subsection (b)(2)(A)(iv).

9 “(B) ANTI-DISCRIMINATION.—Each agree-
 10 ment between the Secretary and an Organiza-
 11 tion under this section shall—

12 “(i) provide that each eligible partici-
 13 pating provider of such Organization may
 14 not deny, limit, or condition the furnishing
 15 of services, or affect the quality of services
 16 furnished, under this title to Program-eli-
 17 gible beneficiaries on whether or not such
 18 a beneficiary is assigned to or elects the
 19 Organization; and

20 “(ii) prohibit the Organization from
 21 engaging in any activity that could reason-
 22 ably be expected to have the effect of deny-
 23 ing or discouraging assignment to or an
 24 election of an ESRD Fee-For-Service Inte-
 25 grated Care Model offered by an Organiza-

1 tion by a Program-eligible beneficiary
2 whose medical condition or history indi-
3 cates a need for substantial future medical
4 services.

5 “(C) QUALITY ASSURANCE; PATIENT SAFE-
6 GUARDS.—Each agreement between the Sec-
7 retary and an Organization under this section
8 shall require that such Organization have in ef-
9 fect at a minimum—

10 “(i) a written plan of quality assur-
11 ance and improvement, and procedures im-
12 plementing such plan, in accordance with
13 regulations; and

14 “(ii) written safeguards of the rights
15 of Program-eligible beneficiaries assigned
16 to or who elect the Organization (including
17 a patient bill of rights and procedures for
18 grievances and appeals) in accordance with
19 regulations and with other requirements of
20 this title and applicable Federal and State
21 laws designed to protect Program-eligible
22 beneficiaries (including those who are enti-
23 tled to medical assistance under a State
24 plan under title XIX).

1 “(D) OVERSIGHT.—The Secretary shall
 2 develop and implement an oversight program to
 3 monitor an Organization’s compliance with Pro-
 4 gram requirements under an agreement under
 5 this section.

6 “(4) TREATMENT AS ALTERNATIVE PAYMENT
 7 MODEL AND ELIGIBLE ALTERNATIVE PAYMENT EN-
 8 TITY.—

9 “(A) TREATMENT OF PROGRAM.—The
 10 ESRD Fee-for-Service Integrated Care Dem-
 11 onstration Program established under this sec-
 12 tion shall meet the definition of an alternative
 13 payment model described in section
 14 1833(z)(3)(C)(iv).

15 “(B) TREATMENT OF ORGANIZATION.—An
 16 Organization offering one or more ESRD Fee-
 17 for-Service Integrated Care Models shall be
 18 treated under this section as an eligible alter-
 19 native payment entity as described in clauses (i)
 20 and (ii)(I) of section 1833(z)(3)(D).

21 “(c) PROGRAM OPERATION AND SCOPE.—

22 “(1) IN GENERAL.—The Secretary shall develop
 23 a process such that an Organization can apply to
 24 offer one or more ESRD Fee-For-Service Integrated

1 Care Models. Such application shall include informa-
2 tion on at least the following:

3 “(A) The estimated average revenue
4 amount described in subsection (b)(2)(A)(ii)(II)
5 for the Organization to cover benefits described
6 in subsection (b)(2)(A)(i)(I).

7 “(B) Any benefits offered by the Organiza-
8 tion beyond those described in such subsection.

9 “(C) A description of the Organization’s
10 ESRD Fee-For-Service integrated care strategy
11 specified in subsection (b)(2)(D), including a
12 detailed explanation of the Organization’s ap-
13 proach to fulfill the requirement to coordinate
14 the delivery of multidisciplinary health and so-
15 cial services that, pursuant to a mutual agree-
16 ment between a State and Organization, inte-
17 grates acute and long-term care services and
18 supports.

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

23 “(3) INITIAL AGREEMENT PERIOD.—The Sec-
24 retary shall enter into agreements for an initial pe-
25 riod of not less than 5 years with all Organizations

1 that meet all Program requirements established
2 under this section, as determined by the Secretary
3 through the application process described in para-
4 graph (1).

5 “(4) ALLOWANCE FOR SERVICE AREA EXPAN-
6 SIONS.—During each year of the Program’s oper-
7 ation, the Secretary shall allow an Organization with
8 an agreement under this section to expand its serv-
9 ice area during the initial agreement period upon the
10 Secretary’s determination, through the application
11 process described in paragraph (1), that the Organi-
12 zation meets all Program requirements established
13 under this section.

14 “(5) CONTRACT SUSPENSION AND TERMI-
15 NATION PROCESS.—

16 “(A) IN GENERAL.—Subject to subpara-
17 graph (B)(ii), the Secretary may suspend as-
18 signment to or an election of an ESRD Fee-
19 For-Service Integrated Care Model offered by
20 an Organization if the Organization fails to
21 comply with any Program requirements speci-
22 fied in an agreement under this section. An Or-
23 ganization also shall be considered not in com-
24 pliance if, for any calendar month during an
25 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

1 compliance by the date specified in correc-
2 tive action plan, subject to clause (iii) and
3 depending on the severity of a compliance
4 deficiency, the Secretary in a manner con-
5 sistent with processes established under
6 part C of this title may—

7 “(I) suspend Program-eligible
8 beneficiaries’ assignments to or an
9 election of an ESRD Fee-For-Service
10 Integrated Care Model offered by an
11 Organization; or

12 “(II) terminate an agreement
13 with an Organization under this sec-
14 tion.

15 “(iii) IMMEDIATE AGREEMENT TERMI-
16 NATION FOR VIOLATING THE PROHIBITION
17 ON DISCRIMINATION.—Notwithstanding
18 the corrective action plan process estab-
19 lished under clause (i), the Secretary may,
20 in addition to the circumstances under
21 which a contract under part C may be im-
22 mediately terminated, immediately termi-
23 nate an agreement under this section with
24 an Organization if the Secretary—

1 “(I) notifies the Organization of
2 the intent to investigate allegations of
3 systematic activities with the intent of
4 violating the prohibition on discrimi-
5 nation established under subsection
6 (b)(3)(B)(ii);

7 “(II) determines, after con-
8 ducting a rigorous analysis of all
9 available data based on a sufficient
10 sample size, that the Organization en-
11 gaged in systematic activities with the
12 intent of violating the prohibition on
13 discrimination established in sub-
14 section (b)(3)(B)(ii); and

15 “(III) discloses credible evidence
16 to the Organization regarding a deter-
17 mination made under subclause (II).

18 “(iv) RECOVERY OF MONTHLY PRO-
19 SPECTIVE PAYMENTS.—The Secretary may
20 recover the prorated share of any monthly
21 prospective payments described in sub-
22 section (e) covering the period of the
23 month following an agreement termination
24 if such agreement termination is effective
25 in the middle of a calendar month.

1 “(v) NOTIFICATION OF PROGRAM-ELI-
 2 GIBLE BENEFICIARY UPON AGREEMENT
 3 TERMINATION.—Each agreement under
 4 this section between the Secretary and an
 5 Organization shall require the Organiza-
 6 tion to provide and pay for written notice
 7 in advance of an agreement’s termination,
 8 as well as a description of alternatives for
 9 obtaining benefits under this title, in a
 10 manner consistent with beneficiary notifi-
 11 cation requirements in the event of a con-
 12 tract termination under part C.

13 “(6) PROGRAM EVALUATION.—The Secretary
 14 shall conduct an evaluation of the Program under
 15 this section to inform a determination regarding a
 16 Program expansion under paragraph (7). Such eval-
 17 uation shall include an analysis of—

18 “(A) the quality of care furnished under
 19 the Program, including the measurement of pa-
 20 tient-level outcomes and patient experience and
 21 patient-reported outcome measures determined
 22 appropriate by the Secretary; and

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

25 “(7) PROGRAM EXPANSION.—

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

6 “(i) the Secretary determines that
 7 such expansion is expected to—

8 “(I) reduce spending under this
 9 title without reducing the quality of
 10 patient care; or

11 “(II) improve the quality of pa-
 12 tient care without increasing spending
 13 under this title;

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

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

23 “(B) ENSURING PROGRAM CONTINUITY.—
 24 The Secretary shall implement any Program ex-
 25 pansion made in accordance with this para-

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

5 “(8) PART D DATA SHARING ARRANGEMENT.—

6 The Secretary on a monthly basis shall, in accord-
 7 ance with the regulations promulgated under section
 8 264(c) of the Health Insurance Portability and Ac-
 9 countability Act of 1996, provide access to Organiza-
 10 tions to part D data claims that include part D data
 11 on Program-eligible beneficiaries assigned to or an
 12 election of an ESRD Fee-For-Service Integrated
 13 Care Model offered by an Organization unless a Pro-
 14 gram-eligible beneficiary opts out of such data shar-
 15 ing.

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

20 “(d) IDENTIFICATION AND ASSIGNMENT OF PRO-
 21 GRAM-ELIGIBLE BENEFICIARIES.—

22 “(1) IN GENERAL.—The Secretary shall estab-
 23 lish a process for the initial and ongoing identifica-
 24 tion of Program-eligible beneficiaries.

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

4 “(A) IN GENERAL.—Under the Program,
5 the Secretary shall assign all Program-eligible
6 beneficiaries to an ESRD Fee-For-Service Inte-
7 grated Care Model offered by an Organization
8 that includes the dialysis facility at which the
9 Program-eligible beneficiary primarily receives
10 renal dialysis services.

11 “(B) OPT-OUT PERIOD AND CHANGES
12 UPON INITIAL ASSIGNMENT OR ELECTION.—
13 The Secretary shall provide for a 90-day period
14 beginning on the date on which the assignment
15 of or election made by a Program-eligible bene-
16 ficiary into an ESRD Fee-For-Service Inte-
17 grated Care Model offered by an Organization
18 becomes effective during which a Program-eli-
19 ble beneficiary may—

20 “(i) opt out of the Program; or

21 “(ii) make a one-time change of as-
22 signment or election into an ESRD Fee-
23 For-Service Integrated Care Model offered
24 by a different Organization.

1 “(C) DEEMED RE-ASSIGNMENT AND RE-
 2 ELECTION.—The Secretary shall establish a
 3 process through which a Program-eligible bene-
 4 ficiary assigned to or who elects an ESRD Fee-
 5 For-Service Integrated Care Model offered by
 6 an Organization with respect to a year is
 7 deemed, unless the Program-eligible beneficiary
 8 otherwise changes such assignment or election
 9 under this paragraph, to have elected to con-
 10 tinue such assignment or election with respect
 11 to the subsequent year.

12 “(D) ANNUAL OPPORTUNITY TO OPT OUT
 13 OR ELECT AN ESRD FEE-FOR-SERVICE INTE-
 14 GRATED CARE MODEL OFFERED BY A DIF-
 15 FERENT ORGANIZATION.—

16 “(i) IN GENERAL.—Annually, a Pro-
 17 gram-eligible beneficiary shall be given a
 18 90-day period to—

19 “(I) opt out of the Program; or

20 “(II) make a one-time change of
 21 assignment or election into an ESRD
 22 Fee-For-Service Integrated Care
 23 Model offered by a different Organiza-
 24 tion.

1 “(ii) ALIGNMENT WITH MEDICARE AD-
2 VANTAGE OPEN ENROLLMENT PERIOD.—

3 To the extent practicable, the Secretary
4 shall align the annual 90-day period de-
5 scribed in clause (i) with the Medicare Ad-
6 vantage open enrollment period.

7 “(E) OPT OUT FOR CHANGE IN PRINCIPAL
8 DIAGNOSIS OR ENTERING HOME DIALYSIS
9 TREATMENT.—In addition to any other period
10 during which a Program-eligible beneficiary
11 may, pursuant to this paragraph, opt out of the
12 Program, in the case of a Program-eligible ben-
13 eficiary who, after assignment under this para-
14 graph, is diagnosed with a principal diagnosis
15 (as defined by the Secretary) other than end-
16 stage renal disease or enters into home dialysis
17 treatment, such individual shall be given the op-
18 portunity to opt out of the Program during
19 such period as specified by the Secretary.

20 “(3) PROGRAM-ELIGIBLE BENEFICIARY NOTIFI-
21 CATION.—

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

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

3 “(i) information about receiving bene-
 4 fits under this title through such Organiza-
 5 tion; and

6 “(ii) an explanation that they retain
 7 the right to receive care from any Medicare
 8 provider.

9 “(B) TIMING OF NOTIFICATION.—Upon as-
 10 signment to or election of an ESRD Fee-For-
 11 Service Integrated Care Model offered by an
 12 Organization, the Secretary shall provide the
 13 Organization written notification confirming the
 14 beneficiary’s assignment or election and not
 15 later than 15 business days after the date of re-
 16 ceipt of such notification, the Organization shall
 17 provide written notice to the Program-eligible
 18 beneficiary of such assignment or election.

19 “(C) CONTENT OF WRITTEN NOTICE.—
 20 Subject to subparagraph (D), such notification
 21 shall—

22 “(i) inform Program-eligible bene-
 23 ficiaries about the Program using an infor-
 24 mation guide developed by the Organiza-
 25 tion and approved by the Secretary;

1 “(ii) include the distribution of other
 2 Program materials developed by the Orga-
 3 nization and approved by the Secretary;

4 “(iii) inform Program-eligible bene-
 5 ficiaries about the importance of transplan-
 6 tation as the best outcome, as well as min-
 7 imum requirements for transplant eligi-
 8 bility before and during dialysis treatment;
 9 and

10 “(iv) provide contact information for
 11 representatives of the Organization to re-
 12 spond to Program-eligible beneficiaries’
 13 questions.

14 “(D) LIMITATION ON UNSOLICITED NOTI-
 15 FICATION.—

16 “(i) IN GENERAL.—Under the Pro-
 17 gram, no person or entity (other than the
 18 Secretary, an employee of the Secretary, or
 19 an employee or volunteer of a federally au-
 20 thorized State Health Insurance Assistance
 21 Program (SHIP)), subject to clause (ii),
 22 may provide any information about the
 23 Program, including information, materials,
 24 and assistance described in subparagraph
 25 (B), to a Program-eligible beneficiary un-

1 less such Program-eligible beneficiary re-
2 quests such information, materials, or as-
3 sistance.

4 “(ii) EXCEPTION FOR PROVIDERS
5 TREATING BENEFICIARIES.—An eligible
6 participating provider that is part of an
7 Organization may provide information, ma-
8 terials, and assistance described in sub-
9 paragraph (B) to a Program-eligible bene-
10 ficiary, without prior request of such bene-
11 ficiary, if such beneficiary is receiving
12 renal dialysis services from a facility that
13 participates in such Organization.

14 “(iii) PARITY IN NOTIFICATION.—In
15 the case that an eligible participating pro-
16 vider that is part of an Organization par-
17 ticipates in notifying Program-eligible
18 beneficiaries about the Program under this
19 subparagraph, such notification shall be
20 provided in the same manner to all Pro-
21 gram-eligible beneficiaries to which, pursu-
22 ant to clause (ii), such eligible partici-
23 pating provider may provide information,
24 materials, and assistance described in such
25 clause.

1 “(E) PROGRAM-ELIGIBLE BENEFICIARY
 2 GRIEVANCE AND APPEAL RIGHTS.—Program-el-
 3 igible beneficiaries participating in the Program
 4 under this section shall have grievance and ap-
 5 peal rights and procedures consistent with those
 6 rights and procedures established under sub-
 7 sections (f) and (g) of section 1852.

8 “(e) ESRD FEE-FOR-SERVICE INTEGRATED CARE
 9 PROGRAM MONTHLY PAYMENT AND CLAIMS PROCESSING
 10 MECHANISM.—

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

16 “(2) APPLICATION OF HEALTH STATUS RISK
 17 ADJUSTMENT METHODOLOGY.—The Secretary shall
 18 adjust the monthly prospective payment to an Orga-
 19 nization under this subsection in the same manner
 20 in which the payment amount to a Medicare Advan-
 21 tage plan is adjusted under section 1853(a)(1)(C).

22 “(3) TREATMENT OF AND PAYMENT FOR KID-
 23 NEY ACQUISITION COSTS.—

24 “(A) EXCLUDING COSTS FOR KIDNEY AC-
 25 QUISITIONS 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—

1 “(i) a hospice program participating
2 under this title is located within the Orga-
3 nization’s service area; or

4 “(ii) it is common practice to refer pa-
5 tients to hospice programs outside such
6 service area.

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

14 “(i) payment for the care furnished to
15 the Program-eligible beneficiary shall be
16 made by the Secretary to the hospice pro-
17 gram elected by the Program-eligible bene-
18 ficiary;

19 “(ii) payment for other services for
20 which the Program-eligible beneficiary in-
21 dividual is eligible notwithstanding the
22 Program-eligible beneficiary’s election of
23 hospice care under section 1812(d)(1), in-
24 cluding services not related to the Pro-
25 gram-eligible beneficiary’s terminal illness,

1 shall be made by the Secretary to the Or-
 2 ganization or the provider or supplier of
 3 the service instead of the monthly prospec-
 4 tive payment determined under subsection
 5 (f); and

6 “(iii) the Secretary shall continue to
 7 make monthly payments to the Organiza-
 8 tion in an amount equal to the value of
 9 benefits and services determined under
 10 subsection (b)(2)(A)(ii)(IV).

11 “(5) APPLICATION OF CMI CLAIMS PROCESSING
 12 FRAMEWORK.—

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

19 “(i) providers of services and suppliers
 20 serving Program-eligible beneficiaries con-
 21 tinue to submit claims to a Medicare ad-
 22 ministrative contractor;

23 “(ii) the Secretary forwards claims to
 24 the Organization for payment; and

1 “(iii) the Organization pays providers
 2 of services and suppliers an amount equal
 3 to the amount that they would otherwise
 4 receive under the original Medicare Fee-
 5 For-Service program plus any additional
 6 amount to which the provider may be eligi-
 7 ble under subsection (b)(2)(A)(v) of this
 8 section.

9 “(B) APPLICATION OF BALANCE BILLING
 10 LIMITATIONS.—Section 1852(a)(2)(A) (relating
 11 to payments made by an MA organization to a
 12 non-contract provider of services), section
 13 1852(k)(1) (relating to limitations on balance
 14 billing), and section 1866(a)(1)(o) (relating to
 15 payments made by an MA organization to a
 16 non-contract supplier) shall apply to the Pro-
 17 gram.

18 “(C) PAYMENTS FOR GRADUATE MEDICAL
 19 EDUCATION.—Section 1886(d)(11) and section
 20 1886(h)(3)(D) (relating to payments for grad-
 21 uate medical education) shall apply to Organi-
 22 zations and providers of services under the Pro-
 23 gram.

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

1 integrity of the Medicare Advantage end-stage renal
2 disease rate setting process and risk adjustment fac-
3 tors applied to Medicare Advantage end-stage renal
4 disease rates, claims paid on behalf of Program-eligible
5 beneficiaries shall not be included in neither the
6 determination of such rates nor the development of
7 such risk adjustment factors.

8 “(7) AGREEMENT BETWEEN A STATE AND OR-
9 GANIZATION FOR MEDICAID BENEFITS.—In the case
10 that a State and Organization enter into a mutual
11 agreement under which the Organization coordinates
12 benefits under title XIX for Program-eligible bene-
13 ficiaries eligible for benefits under this title and title
14 XIX such mutual agreement shall specify the pay-
15 ment from the State for providing or arranging for
16 the provision of such benefits.

17 “(8) AFFIRMATION OF STATE OBLIGATIONS TO
18 PAY PREMIUM AND COST-SHARING AMOUNTS.—A
19 State shall continue to make medical assistance
20 under the State plan under title XIX available for
21 the duration of the Program for Medicare cost-shar-
22 ing (as defined in section 1905(p)(3)) under this
23 title for qualified Medicare beneficiaries described in
24 section 1905(p)(1) and other individuals who are
25 Program-eligible beneficiaries assigned to or who

1 elect an Organization and entitled to medical assist-
2 ance for premiums and such cost-sharing under the
3 State plan under title XIX in an amount equal to
4 the amount of medical assistance that would be
5 made available by such State if such Program-eligible
6 beneficiaries were not participating in the Pro-
7 gram under this section.

8 “(f) WAIVER AUTHORITY.—

9 “(1) IN GENERAL.—The Secretary shall waive
10 those requirements waived under section 1899 deter-
11 mined by the Secretary to be relevant and necessary
12 for the operation of the Program under this section
13 and may waive, as necessary, such additional re-
14 quirements that have been or may be waived based
15 on authority established under section 1115A for
16 purposes of models tested by the Centers for Medi-
17 care and Medicaid Innovation in order to carry out
18 the Program under this section.

19 “(2) NOTICE OF WAIVERS.—Not later than 3
20 months after the date of enactment of this section,
21 the Secretary shall publish a notice of waivers that
22 will apply in connection with the Program. The no-
23 tice shall include the specific conditions that an Or-
24 ganization must meet to qualify for each waiver, and
25 commentary explaining the waiver requirements.

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

4 (b) RULES OF CONSTRUCTION.—

5 (1) USE OF MEDICARE SUPPLEMENTAL POLICY
 6 UNDER AN ESRD FEE-FOR-SERVICE INTEGRATED
 7 CARE MODEL.—Nothing in the provisions of, or
 8 amendments made by, this Act shall be construed to
 9 prevent a Program-eligible beneficiary assigned to,
 10 or who elects, an ESRD Fee-For-Service Integrated
 11 Care Model offered by an Organization with an
 12 agreement under this section from enrolling in or
 13 continuing enrollment in a Medicare supplemental
 14 policy available to such Program-eligible beneficiary
 15 or receiving benefits under such Medicare supple-
 16 mental policy throughout the duration of the Pro-
 17 gram-eligible beneficiary’s participation in an ESRD
 18 Fee-For-Service Integrated Care model offered by an
 19 Organizations with an agreement under this section.

20 (2) APPLICATION OF STATE RULES REGARDING
 21 ISSUANCE OF MEDICARE SUPPLEMENTAL POLICIES
 22 TO INDIVIDUAL UNDER AGE 65.—Nothing in the pro-
 23 visions of, or amendments made by, this Act shall be
 24 construed to establish a Federal requirement on an
 25 issuer of a Medicare supplemental policy to offer

1 such Medicare supplemental policy to individuals
 2 under age 65.

3 (3) CONTINUED AVAILABILITY OF MEDICARE
 4 SUPPLEMENTAL POLICIES TO INDIVIDUALS UNDER
 5 AGE 65.—Nothing in the provisions of, or amend-
 6 ments made by, this Act shall be construed to affect
 7 a State’s authority to require an issuer of a Medi-
 8 care supplemental policy to offer such Medicare sup-
 9 plemental policy to individual.

10 (c) GAO STUDY AND REPORT ON PAYMENT ADE-
 11 QUACY FOR PEDIATRIC ESRD SERVICES.—

12 (1) STUDY ON PAYMENT FOR PEDIATRIC ESRD
 13 SERVICES.—The Comptroller General of the United
 14 States shall conduct a study to examine the accuracy
 15 of pediatric data reported to the Centers for Medi-
 16 care & Medicaid Services as part of the ESRD pro-
 17 spective payment system. The study shall evaluate
 18 whether the organizations described in section
 19 1866G of the Social Security Act, as added by sub-
 20 section (a), and the existing prospective payment
 21 system accurately capture and reimburse costs of pe-
 22 diatric dialysis care and include an analysis of the
 23 following factors that influence such costs:

24 (A) Increased acuity of nursing care com-
 25 pared to adult dialysis patients, especially for

1 smaller and younger pediatric hemodialysis pa-
2 tients.

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

5 (C) Need for more frequent assessment by
6 pediatric dieticians to adjust formulas and diet
7 for the specialized growth and nutrition require-
8 ments of children treated with dialysis.

9 (D) Need for social workers, school liai-
10 sons, and other trained individuals designated
11 to help families navigate challenging psycho-
12 social situations and to coordinate with schools
13 to ensure school attendance and optimize school
14 performance among pediatric dialysis patients.

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

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

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

4 (1) STUDY ON IMPACT OF RACE-BASED COR-
5 RECTION OF EGFR ON REFERRAL OF ESRD PA-
6 TIENTS FOR TRANSPLANT EVALUATION.—The
7 Comptroller General of the United States shall con-
8 duct a study to examine the impact of race-based
9 correction of the estimated glomerular filtration rate
10 (referred to in this subsection as “eGFR”) on the
11 referral of ESRD patients for transplant evaluation.

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

○